Statistical Analysis Plan

Sponsor: Cocrystal Pharma Australia Pty Ltd.

Protocol Number: CDI-988-P1-001

A Phase 1, Randomized, Double-Blinded, Placebo-Controlled, First-in-Human Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single-Ascending and Multiple-Ascending Doses of Oral CDI-988 in Healthy Adult Participants

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1. Introduction

The purpose of this statistical analysis plan (SAP) is to describe the methodology that will be followed in the analysis of the data that were collected for the Cocrystal Pharma Australia Pty Ltd., CDI-988-P1-001 study.

This SAP is based on assessments and methods described in the study Protocol Version 6.0 dated 03 April 2025. The SAP contains a complete and detailed specification of the statistical analyses that will be performed.

All analyses described in this document will be conducted in accordance with Resolutum Global's standard operating procedures (SOPs).

1.1 Rationale

Cocrystal Pharma is developing CDI-988 for the oral treatment of nonhospitalized patients with symptomatic mild to moderate COVID-19. SARS-CoV-2 is a member of the family Coronaviridae, the largest of the positive sense, single-stranded RNA viruses. The coronavirus3C-like protease (3CL pro) is a chymotrypsin-like cysteine protease that cleaves two SARS-CoV-2 polyproteins at 11 sites to produce 16 functional non-structural proteins essential for viral replication, such as the viral 3CL pro, papain-like protease, helicase, and RNA-dependent RNA polymerase. The 3CL pro gene is highly conserved among coronaviruses, including pandemic SARS-CoV-2 variants of concern. Humans do not produce a homologous 3CL pro. The inhibition of 3CL pro can effectively block viral RNA replication and transcription and further block viral proliferation. Therefore, the 3CL pro is considered an important therapeutic target for diseases caused by coronaviruses, including COVID-19.

CDI-988 is a peptidomimetic 3CL pro inhibitor with high affinity for binding to the highly conserved SARS-CoV-2 3CL pro catalytic site. Accelerated SARS-CoV-2 clearance with CDI-988 treatment administered orally to symptomatic persons not requiring hospitalization has the potential to lessen pulmonary involvement, reduce symptom duration and hospital admissions, and lower disease severity.

CDI-988 is a peptidomimetic covalent inhibitor of SARS-CoV-2 3CL pro. Peptidomimetic inhibitors typically have a two-step process where they initially mimic the natural peptide substrate and form a non-covalent complex that is spatially close to the catalytic residue (Cys-145), it then undergoes a nucleophilic interaction to catalyze the formation of cysteine- participating covalent bonds. The binding of CDI-988 to SARS-CoV-2 3CL protease active site prevents the cleavage of the viral polyproteins, thus impairing viral replication and infectious virus production.CDI-988 has a higher affinity for SARS-CoV-2 3CL pro's catalytic residues than nimatrelvir, which is a component of Paxlovid used to treat SARS-CoV-2 infection in defined populations.

In vitro studies evaluated the antiviral activity of CDI-988 against a broad-spectrum panel of coronaviruses that cause human disease, including pandemic SARS-CoV-2 variants of concern (Beta, Delta, and Omicron variants), SARS-CoV, Middle Eastern respiratory syndrome-CoV, and those related to milder infections human CoV strains (hCoV)229E, OC43, and NL63. CDI-988 had good broad-spectrum anti-coronavirus activity as measured by a reduction in virus cytopathic effect, viral nucleocapsid, genomic RNA, or infectious virus in appropriate cell lines and primary 3-dimensional human bronchial epithelial cells Furthermore, CDI-988 significantly reduced SARS-CoV-2 genome copies in that model by as much as 4 orders of magnitude (99.99%) at 48 and 72 hours post-virus challenge in a dose-dependent manner in primary human bronchial epithelial cells. Antiviral efficacy was demonstrated for hCoV infections in multiple cell lines with EC50 values ranging between <0.32 to

4.8 µM and a selectivity index of 5.2 to >53. CDI-988 had synergistic antiviral activity when used in combination with inhibitors of coronavirus RNA-dependent RNA polymerase that have been FDA-approved to treat SARS-CoV-2 infections (remdesivir and molnupiravir) and GS-441524.

Secondary pharmacology testing, conducted in vitro, comprised cytotoxicity and off-target binding characterization. Short-term cytotoxicity testing demonstrated no significant cytotoxicity at concentrations up to 10 µM. Off-target inhibitory effects were found at 10 µM against agonist radioligands for cannabinoid CB1, kappa-opioid, mu-opioid, glucocorticoid, and vasopressin V1A receptors with 92%, 89%, 66%, 90%, and 96% inhibition, respectively, and antagonist radioligands for calcium L channel (dihydropyridine site) and dopamine transporter with 93% and 55% inhibition, respectively. These off-target interactions of CDI-988 have a safety margin to in vitro efficacy of 2 to >31-fold. No effects were observed in the acute toxicity studies at high oral doses to suggest these interactions would have clinical implications.

GLP safety pharmacology studies confirmed that CDI-988, when administered at single oral doses up to 1000 mg/kg, had no effect on CNS or respiratory function in rats and was not associated with any cardiovascular changes in dogs at peak plasma concentrations established in toxicokinetic (TK) work of 6.35 to 6.78 µg/mL. Dose concentrations approaching those did exhibit inhibitory potential against hERG potassium currents in vitro with an IC50 ≥ 8.8 µM (5.34 µg/mL).

In a single oral dose GLP toxicity study with a 14-day extended recovery period conducted in SD rats with CDI-988, there were no test article-related clinical signs, or effects on body weight, food consumption, ophthalmologic, serum chemistry, urinalysis, gross (necropsy) evaluation, organ weight, and histopathological parameters. Test article-related hematology changes were noted at the end of the recovery phase, including decreased monocyte counts in male animals at≥100 mg/kg and females at 300 mg/kg, and coagulation parameter changes at 1000 mg/kg in male and female animals on Day 3 comprising decreased fibrinogen. None of these changes were considered adverse. The maximum tolerated dose (MTD) and NOAEL in this study was 1000 mg/kg, corresponding to an AUC0-24h and C_{max} of 7390 h*ng/mL and 874 ng/mL for males and18300 h*ng/mL and 1050 ng/mL for females.

In a single oral dose GLP toxicity study with a 14-day extended recovery period conducted in Beagle dogs with CDI-988, there was no mortality nor changes in body weight, food consumption, ophthalmologic examination, body temperature, clinical pathology, gross pathology, and histopathology. Clinical signs at 300 and 1000 mg/kg were limited to small/medium amounts of food-like vomitus and abnormal stool (mucoid/watery stool) on the day of dosing (Day 1) with the degree of incidence being dose related. All of the changes were completely reversible on the following days. The NOAEL was assigned as 1000 mg/kg. The corresponding AUC0-24h and C_{max} of CDI-988 at the NOAEL were 46500 ± 13300 h*ng/mL and 6780 ± 2700 ng/mL for males, and 54300 ± 22900 h*ng/mL and 6350 ± 1600 ng/mL for females, respectively.

The completed in vitro GLP genotoxicity studies demonstrated no mutagenic potential (bacterial reverse mutation test and chromosomal aberration assay in CHO cells).

The NOAELs from the rat and dog acute toxicology studies provided human equivalent doses (HED), calculated according to FDA guidance Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers, of 9,680 and 33,300 mg to a 60-kg person for the rat and dog, respectively, and 7260 and 25000 mg to a 45-kg person for the rat and dog, respectively.

Repeat oral dose toxicity testing in rats and dogs was assessed using 7-day dose range finding and 14-day GLP studies at doses up to 1000 mg/kg/day (HD). In the rat 7-day study, there were no

mortalities or any moribund animals. CDI-988-related clinical signs were limited to salivation and piloerection at the HD. Macroscopic changes were confined to white solid material in the stomach at the HD. Microscopic changes comprised minimal to mild, non-adverse, diffuse follicular atrophy in bilateral thyroid glands of males at ≥100 mg/kg/day and females at ≥300 mg/kg/day. Focal erosion in the pyloric mucosa of the stomach was noted in two males at the HD, but the relationship with test article treatment was uncertain. The microscopic findings in the stomach and thyroid can be non-specific observations consistent with stress. In rats, stress/glucocorticoids are associated with focal erosions/ulcers in the stomach glandular mucosa and decreases in thyroid stimulatory hormone function, which subsequently results in follicular epithelial atrophy.

In the 14-day rat GLP study, there was one death in an HD male on Day 12; the cause of death was undetermined and given the isolated occurrence a relationship to CDI-988 is uncertain. At 1000 mg/kg/day,clinical signs of hunched posture, salivation, unkempt, and abnormal respiratory sounds were found chiefly at the HD that reversed in a 7-day recovery. Raised platelets and white blood cell counts, and serum total bilirubin were noted at the HD; all reversed in recovery. Microscopic findings occurred in the thyroids comprising minimal colloid vacuolation and minimal follicular epithelial atrophy in dosing phase animals at ≥30 mg/kg/day and minimally to mildly decreased thyroid weights in males at ≥200 mg/kg/day. Microscopic thyroid findings reversed, but minimally decreased thyroid weights persisted in the HD recovery males. Females at the HD had mildly decreased uterine weights which persisted at the end of the recovery phase but were without macroscopic or microscopic findings. The NOAEL assigned by the Contract Research Laboratory that conducted the study was 200 mg/kg/day on the basis of the one death at 1000 mg/kg/day that was of uncertain relationship to CDI-988. Given this uncertainty and no findings judged to be adverse in other animals at any dose level, including 1000 mg/kg/day, the HD is considered a better representation of the NOAEL. At the HD, the with corresponding mean $AUC_{0\text{-}24h}$ and C_{max} on Day 14 of 19,200 h*ng/mL and 1230 ng/mL for males, 27,200 h*ng/mL and 1880 ng/mL for females, respectively.

In the dog 7-day study, there was no mortality, and clinical signs were limited to soft/watery stool observed in males at ≥100 mg/kg/day and females at the HD, and small amounts of food-like vomit observed in both sexes at the HD. Decreased food consumption was observed in some animals at the HD. The 14-day GLP study also had no mortality. Clinical signs at ≥100 mg/kg/day included sporadic food-like/white frothy or cloudy vomitus, and abnormal stool (soft/mucoid/watery stool) with dose-related incidence. Transient light to moderate salivation at ≥300 mg/kg/day and white material in pans/bedding was noted at the HD. A slight body weight decrease was noted at the HD in females. Hematology changes were limited to slight to mildly decreased absolute reticulocyte count across all the test article dose groups that lacked any consistent dose response. Serum chemistry changes at ≥100 mg/kg/day included slight to moderate increases in alanine aminotransferase, alkaline phosphatase, gamma-glutamyltransferase and minimal to mild decreases in total protein, albumin, total cholesterol, triglycerides, and globulin. Those changes correlated with the non-adverse microscopic finding of moderate diffuse hepatocellular cytoplasmic vacuolation. Organ weight changes consisted of increased mean absolute and relative liver weights for males and females at ≥100 mg/kg/day. All findings reversed in recovery. The NOAEL was set at 1000 mg/kg/day with corresponding mean $AUC_{0\text{-}24h}$ and C_{max} on Day 14 of 105000 ± 47800 h*ng/mL and 11000 ± 5770 ng/mL for males, and 77200 ± 37100 h*ng/mL and 9080 ± 3220 ng/mL for females, respectively.

More detailed information about nonclinical studies with CDI-988 can be found in the Investigator's Brochure.

2. Summary of the Protocol

2.1 Study Objectives

2.1.1 Primary Objective

The primary objective of the study is to the safety and tolerability of increasing doses of CDI-988 when given as a single or multiple-ascending oral doses to cohorts of healthy subjects.

2.1.2 Secondary Objectives

The secondary objectives of the study are to

- Assess the pharmacokinetics (PK) of CDI-988 following a single oral dose.
- Explore the effect of food on the single oral dose PK of CDI-988.
- Assess the PK of CDI-988 when given as multiple oral doses.

2.2 Study Endpoints

2.2.1 Primary Endpoints

The following primary endpoints will be evaluated during this study:

- The incidence of treatment-emergent adverse events (TEAEs).
- The incidence of clinically significant laboratory abnormalities.
- The incidence of clinically significant changes from baseline in vital signs.
- The incidence of clinically significant changes from baseline in Electrocardiograms (ECGs).

2.2.2 Secondary Endpoints

The following secondary PK endpoints will be evaluated during this study including (but not limited to) the following PK parameters for CDI-988:

- The maximum observed concentration (C_{max}) for Single-Ascending Dose (SAD) Day 1 and Day 1 and last dose (Day 5 or 10) for Multiple-Ascending Dose (MAD).
- The time to reach C_{max} (T_{max}) for SAD Day 1 and last dose (Day 5 or 10) for MAD.
- Elimination rate constant (λ_z) for SAD and MAD Day 1 and after the last dose for MAD (Day 5 or 10).
- The terminal elimination half-life ($t_{½}$) for SAD and MAD Day 1 and after the last dose for MAD(Day 5 or 10).
- Area under the curve (AUC) from time zero to 24 hours ($AUC_{(0\text{-}24hr)}$) on Day 1 last dose (Day 5 or 10) for MAD.
- AUC from time zero to time t of the last measured concentration above the limit of quantification ($AUC_{(0\text{-}t)}$) for SAD.
- AUC from time zero to infinity ($AUC_{(0\text{-}inf)}$) for SAD.
- Trough concentrations on intermediate dosing days for MAD.
- The difference between fasted and fed conditions in systemic exposure to CDI-988: C_{max}, T_{max}, $AUC_{(0\text{-}t)}$ and $AUC_{(0\text{-}inf)}$ for SAD.

The PK analysis for this study falls outside the scope of the statistical analysis plan.

2.3 Study Design

This is a single-center, randomized, double-blind, placebo-controlled phase 1 study of the SARS- CoV-2 replication and protease inhibitor CDI-988 given orally to healthy subjects at a single site in Australia. Subjects will be recruited from the Nucleus Network panel or by direct advertising to the public. Screening assessments must be done within 28 days prior to randomization to determine subject eligibility. Written consent must be obtained before conducting any study procedures.

Part 1: Single-Ascending Dose

In Cohorts 1A–1D and 1F, subjects will be randomly assigned within each cohort to receive a single dose of CDI-988 or placebo. Doses will escalate in sequential dose cohorts. It is planned that 5 cohorts will be dosed with 8 healthy subjects per cohort (6 active and 2 placebo). In addition, 6 healthy subjects will be enrolled and dosed with CDI-988 in an open-label (“standard non-high fat meal”) food-effect cohort.

Cohorts 1A–1D and 1F will include the initial dosing of a sentinel group (1 CDI-988 and 1 placebo) at least 24 hours before dosing the remaining 6 subjects in the cohort (5 CDI-988 and 1 placebo). The remainder of the cohort will only be dosed if, in the opinion of the investigator and sponsor’s medical representative, there is no significant safety concern identified in the sentinel subjects within the first 24 hours after administration of the dose (CDI-988 or placebo). The following regimens are planned:

- Cohort 1A (N=8): 100 mg CDI-988 or placebo.
- Cohort 1B (N=8): 200 mg CDI-988 or placebo.
- Cohort 1C (N=8): 400 mg CDI-988 or placebo on Days 1 and 9 (high-fat food-effect cohort).
- Cohort 1D (N=8): 600 mg CDI-988 or placebo.
- Cohort 1E (N=6): 100 mg CDI-988 on Days 1 and 9 (standard non-high fat food-effect cohort).
- Cohort 1F (N=8): 1200 mg CDI-988 or placebo on Days 1 and 9 (standard non-high fat food effect cohort).

Cohorts 1C, 1E, and 1Fwill be two-period sequential food-effect cohorts in which subjects will receive a single dose of study drug under fasted conditions on Day 1 and a single dose of study drug under fed conditions on Day 9.

Part 2: Multiple-Ascending Dose

Part 2 of the study may be opened after satisfactory review of the safety and PK data from the cohorts in Part 1, as well as preclinical data to support the duration of multiple ascending dose cohorts. Cohort 2A may be started in parallel with the highest dose cohort in Part 1.

Subjects will be randomly assigned to receive once-daily oral doses of CDI-988 or placebo for 10 days (Cohorts 2A-2C), once-daily doses of CDI-988 or placebo for 5 days (Cohort 2D), and twice-daily (q12h) doses of CDI-988 or placebo for 5 days (Cohorts 2E-2F). It is planned that up to 6 cohorts will be dosed with 8 healthy subjects per cohort (6 active and 2 placebo). A minimum of 6 subjects must be dosed in a given cohort to allow dose escalation to proceed.

The following regimens are planned:

- Cohort 2A (N=8): 200 mg CDI-988 or placebo once daily for 10 days.
- Cohort 2B (N=8): 400 mg CDI-988 or placebo once daily for 10 days.
- Cohort 2C (N=8): 800 mg CDI-988 or placebo once daily for 10 days.
- Cohort 2D (N=8): 1200 mg CDI-988 or placebo once daily for 10 days.

- Cohort 2E (N=8): 1200 mg CDI-988 or placebo given twice daily (q12h) for 5 days (9 doses).
- Cohort 2F (N=8): 1200 mg CDI-988 or placebo given twice daily (q12h) for 5 days (9 doses) with a standard meal.

The randomized, double-blind, placebo-controlled design provides the optimal opportunity to differentiate potential adverse events associated with CDI-988 from background events in healthy volunteers. Dose escalation in sequential cohorts with interim review by a Safety monitoring committee (SMC) mitigates risk to study subjects in this first-in-human study.

The NOAELs from the rat and dog acute toxicology studies provided human equivalent doses (HED), calculated according to FDA guidance Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers, of 7260 and 25000 mg to a 45-kg person for the rat and dog study, respectively. Using the lowest HED (7260 mg) and the normal safety factor of 10, the maximum recommended starting dose for this first-in-human clinical trial would be a 726-mg dose to a 45-kg human (the lower limit of the allowable weight range for the study). The lowest HED at the NOAEL in acute rat and dog studies thus provides a safety margin that is >70-fold over the 100-mg starting dose for the first SAD cohort.

Subjects will be healthy adults and receive standard assessments to determine eligibility.
The safety assessments of physical examination, vital signs, clinical laboratories, ECG, and adverse event collection used in this trial are standard assessments for phase 1 studies evaluating the safety of single and repeated dosing.

2.4 Sample Size Determination

No formal sample size calculation was done. Based on experience from similar studies, the target number of subjects to be enrolled is appropriate for the assessment of safety and tolerability.

In Part 1, 46 healthy subjects will be enrolled: 5 randomized cohorts of 8 subjects and 1 open-label cohort of 6 subjects. In Part 2, 48 healthy subjects will be enrolled into 6 cohorts, each with 8 subjects.

In both Parts 1 and 2, up to 2 replacement subjects may be enrolled per cohort. Subjects withdrawn due to an adverse event related to CDI-988 will be considered evaluable and will not be replaced.

2.5 Schedule of Events

Table 1 presents the schedule of study events.

Table 1 Schedule of Study Events: Part 1 - Single-Ascending Dose Schedule of Events

	Screening	Clinical Unit						EOS Visit [1]
	Day -28 to -2	Day -1	Day 1			Day 2	Day 3	Day 8
Assessments			Pre-dose	Dosing	Post-dose			(+1 d)
Unit Check-in		X						
Informed consent	X							
Inclusion/exclusion criteria	X	X						
Demographic data	X							
Medical history	X	X	X					
Prior medication history	X	X						
Vein assessment	X							
Height	X							
Weight	X	X						
Pregnancy screen [2]	X	X						X
FSH [3]	X							
Serology [4]	X							
Drugs of abuse screen [5]	X	X						
Alcohol breath test	X	X						
Physical examination [6]	X	X			X (abbrev)		X (abbrev)	X (abbrev)
Clinical safety labs [7]	X	X			X	X		X
Lipid panel (fasted)		X				X		X
Vital signs [8]	X	X	X		X	X	X	X
12-lead ECG [9]	X	X	X		X	X	X	X
Randomization [10]			X					
Study Drug				X				
Adverse event reporting [11]				X	X	X	X	X
Concomitant medications			X			X	X	X
PK samples [12]			X		X	X	X	
Discharge from Unit							X	

Footnotes

1. End of study (EOS) visit for all cohorts except for the food-effect cohorts, Cohorts 1C, 1E and 1F
2. Females of childbearing potential will be tested for pregnancy by detecting the presence of β-HCG (serum test at Screening and urine test at other time points).
3. Only for women of postmenopausal status.
4. Serology screening will include tests for hepatitis B surface antigen, hepatitis C virus, and human immunodeficiency virus.
5. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylene-dioxy-methamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
6. Physical examination will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. Abbreviated exam will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. The physical exam will take place after the ECG and vital signs (4-hr ECG on Day 1).
7. Standard clinical safety labs may be collected fasted or non-fasted. Post-dose samples will be collected 6 hours ±1 hour after dosing.
8. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured once prior to dosing (within 2 hours) and 2 and 4 hours ±15 minutes post-dosing on Day 1 and before blood draw on Days 2, 3 and 8.
9. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG once during screening, on Day 1 pre- dose (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, and once on Days 2, 3, and 8. ECGs will be measured prior to vital sign measurements with subjects in a supine position after a minimum 5-minute rest.
10. Randomization not required for Cohort 1E (open-label food-effect cohort)
11. Adverse event reporting will be continuous through end of study on Day 8.
12. PK samples to be collected before dosing and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 36, and 48 h after dosing. Sampling windows are within 1 hour pre- dose, ±5 minutes for samples through 4 h post-dose and ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hour and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw.

Table 1 Schedule of Study Events: Part 1 - Cohort 1C Schedule of Events – Period 2

	Clinical Unit						EOS Visit [1]
	Day 8	Day 9			Day 10	Day 11	Day 16
Assessments		Pre-dose	Dosing	Post-dose			(+/-1 d)
Unit Check-in	X						
Inclusion/exclusion criteria [2]	X	X (abbrev)					
Weight	X						
Pregnancy screen [3]	X						X
Drugs of abuse screen [4]	X						
Alcohol breath test	X						
Physical examination [5]	X			X (abbrev)		X (abbrev)	X (abbrev)
Clinical safety labs [6]	X			X	X		X
Lipid panel (fasted)	X				X		X
Vital signs [7]	X	X		X	X	X	X
12-lead ECG [8]	X	X		X	X	X	X
High-fat breakfast [9]		X					
Study Drug			X				
Adverse event reporting [10]	X	X	X	X	X	X	X
Concomitant medications	X	X			X	X	X
PK samples [11]		X		X	X	X	
Discharge from Unit						X	

Footnotes

Note: The washout window between Period 1 and Period 2 may be optionally extended for up to 3 days, with other Period 2 visits adjusted accordingly. Thus, dosing for Period 2 may occur between Day 9 and Day 12.

1. End of study visit.
2. Full eligibility review on Day 8 and abbreviated review on Day 9.
3 Pregnancy will be determined by urine dipstick.
4. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylene-dioxy-methamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
5. Physical examination will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. Abbreviated exam will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. The physical exam will take place after the ECG and vital signs (4-hr ECG on Day 9).
6. Standard clinical safety labs may be collected fasted or non-fasted. Post-dose samples will be collected 6 hours ±1 hour after dosing.
7. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured on Day 8, on Day 9 prior to dosing (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, and on Days 10, 11, and 16.
8. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG on Day 8, on Day 9 pre-dose (within 2 hours) and 2 and 4 hours after dosing ±15 minutes, and on Days 10, 11, and 16. ECGs will be measured prior to vital sign measurements with subjects in a supine position after a minimum 5-minute rest.
9. High-fat breakfast started and finished within 30 minutes prior to dosing. Breakfast is considered completed if ≥75% is consumed.
10. Adverse event reporting will be continuous to end of study on Day 16.
11. PK samples to be collected before dosing (within 1 hour) and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 36, and 48 h after dosing. Sampling windows are within 1 hour pre-dose, ±5 minutes for samples through 4 h post-dose, ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hours and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw.

Table 1 Schedule of Study Events: Part 1 - Cohort 1E and Cohort 1F Schedule of Events – Period 2

	Clinical Unit						EOS Visit [1]
	Day 8	Day 9			Day 10	Day 11	Day 16
Assessments		Pre-dose	Dosing	Post-dose			(+/-1 d)
Unit Check-in	X						
Inclusion/exclusion criteria	X	X					
Weight	X						
Pregnancy screen [2]	X						X
Drugs of abuse screen [3]	X						
Alcohol breath test	X						
Physical examination [4]	X			X (abbrev)		X (abbrev)	X (abbrev)
Clinical safety labs [5]	X			X	X		X
Lipid panel (fasted)	X				X		X
Vital signs [6]	X	X		X	X	X	X
12-lead ECG [7]	X	X		X	X	X	X
Standard non-high fat breakfast [8]		X					
CDI-988			X				
Adverse event reporting [9]	X	X	X	X	X	X	X
Concomitant medications	X	X			X	X	X
PK samples [10]		X		X	X	X	
Discharge from Unit						X	

Footnotes

Note: The washout window between Period 1 and Period 2 may be optionally extended for up to 3 days, with other Period 2 visits adjusted accordingly. Thus, dosing for Period 2 may occur between Day 9 and Day 12.

1. End of study visit.
2. Pregnancy will be determined by urine dipstick.
3. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylene-dioxy-methamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
4. Physical examination will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. Abbreviated exam will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. The physical exam will take place after the ECG and vital signs (4-hr ECG on Day 9).
5. Standard clinical safety labs may be collected fasted or non-fasted. Post-dose samples will be collected 6 hours ±1 hour after dosing
6. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured on Day 8, on Day 9 prior to dosing (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, and on Days 10, 11, and 16.
7. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG on Day 8, on Day 9 pre-dose (within 2 hours) and 2 and 4 hours after dosing ±15 minutes, and on Days 10, 11, and 16. ECGs will be measured prior to vital sign measurements with subjects in a supine position after a minimum 5-minute rest.
8. Standard non-high fat breakfast started and finished within 30 minutes prior to dosing. Breakfast is considered completed if ≥75% is consumed.
9. Adverse event reporting will be continuous to end of study on Day 16.
10. PK samples to be collected before dosing (within 1 hour) and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 36, and 48 h after dosing. Sampling windows are within 1 hour pre-dose, ±5 minutes for samples through 4 h post-dose, ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hour and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw.

Table 1 Schedule of Study Events: Part 2 - Multiple-Ascending Dose Schedule of Events (Cohorts 2A - 2C)

	SCRN Day -28 to -2	Clinical Unit														EOS[1] visit Day 17
		Day -1	Day 1			Day 2-4			Day 5-9			Day 10			Day 12	
Assessments			Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-		(+ 1 d)
Check-in		X														
Informed consent	X															
Eligibility[2] criteria	X	X														
Demographic data	X															
Medical history	X	X	X													
Prior medication History	X	X														
Vein assessment	X															
Height	X															
Weight	X	X														
Pregnancy screen[3]	X	X														X
FSH [4]	X															
Serology [5]	X															
Drugs of abuse screen [6]	X	X														
Alcohol breath test	X	X														
Physical examination [7]	X	X			X(Ab)			X(Ab)						X(Ab)		X(Ab)
Clinical safety labs [8]	X	X			X	X (D3)								X		X
Lipid panel (fasted)		X										X				X
Vital signs [9]	X	X	X		X			X			X			X	X	X
12-lead ECG [10]	X	X	X		X			X						X		
Randomization			X													
Study Drug				X			X			X			X			
AE reporting [11]				X	X	X	X	X	X	X	X	X	X	X	X	X
Con. Medications			X	X	X	X	X	X	X	X	X	X	X	X	X	X
PK samples [12]					X	X			X			X		X	X	
Discharge															X	

Footnotes

1. End of study visit.
2. Eligibility does not need to be re-reviewed between doses.
3. Females of childbearing potential will be tested for pregnancy by detecting the presence of β-HCG (serum test at Screening and urine test at other time points).
4. Only for women of postmenopausal status.
5. Serology screening will include tests for tests hepatitis B surface antigen, hepatitis C virus, and human immunodeficiency virus.
6. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylene-dioxy-methamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
7. Physical examination will be performed at screening and Day -1 and will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. Abbreviated exam (Ab) will be performed at other timepoints and will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. The physical exam will take place after the ECG and vital signs (4-hr ECG on Day 1).
8. Standard clinical safety labs may be collected fasted or nonfasted. Post-dose samples will be collected 8 hours ±1 hour after dosing.
9. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured at screening, on Day -1, on Day 1 prior to dosing (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, on Days 2-12 and Day 17.
10. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG once during screening, on Day 1 pre- dose (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, and after blood draw on Days 2-4 post-dose, and once post-dosing on Day 10. ECGs will be measured prior to vital sign measurements with subjects in a supine position after a minimum 5-minute rest.
11. Adverse event reporting will be continuous to end of study on Day 17.
12. Dense PK sampling done on Days 1 and 10, with pre-dose trough sampling (within 1 hour pre-dose) on Days 3, 6, and 9. On Day 1, samples taken pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, 12, and 24 hours postdose (pre-dose on Day 2). On Day 10, samples taken pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, 12, 24 hours post-dose (pre-dose on Day 11), 36 hours (Day 11), and 48 hours (Day 12). Sampling windows for Days 1 and 10 are ±5 minutes for samples through 4 hours post-dose, ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hours and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw.

Table 1 Schedule of Study Events: Part 2 - Multiple-Ascending Dose Schedule of Events (Cohorts 2D)

	Clinical Unit												EOS[1] visit
	SCRN Day -28 to -2	Day -1	Day 1			Day 2-4			Day 5			Day 7	Day 12
Assessments			Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-Dose		(+ 1 d)
Check-in		X											
Informed consent	X												
Eligibility[2] criteria	X	X											
Demographic data	X												
Medical history	X	X	X										
Prior medication history	X	X											
Vein assessment	X												
Height	X												
Weight	X	X											
Pregnancy screen[3]	X	X											X
FSH[4]	X												
Serology[5]	X												
Drugs of abuse screen[6]	X	X											
Alcohol breath test	X	X											
Physical examination[7]	X	X		X(Ab)			X(Ab)			X(Ab)			X(Ab)
Clinical safety labs[8]	X	X			X	X (D3)					X		X
Lipid panel (fasted)		X							X				X
Vital signs[9]	X	X	X		X			X			X	X	X
12-lead ECG[10]	X	X	X		X			X			X		X
Randomization[11]		X	X										
Study Drug				X			X			X			
AE reporting[12]				X	X	X	X	X	X	X	X	X	X
Con. medications			X	X	X	X	X	X	X	X	X	X	X

		Clinical Unit										EOS[1] visit
	SCRN Day -28 to -2	Day -1	Day 1			Day 2-4			Day 5			Day 7	Day 12
Assessments			Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-Dose	Pre-dose	Dosing	Post-Dose		(+ 1 d)
PK samples[13]			X		X	X (D3, D4)			X		X	X	
Discharge												X	

1. End of study visit.
2. Eligibility does not need to be re-reviewed between doses.
3. Females of childbearing potential will be tested for pregnancy by detecting the presence of β-HCG (serum test at Screening and urine test at other time points).
4. Only for women of postmenopausal status.
5. Serology screening will include tests for tests hepatitis B surface antigen, hepatitis C virus, and human immunodeficiency virus.
6. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylenedioxymethamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
7. Physical examination will be performed at screening and Day -1 and will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. An abbreviated exam (Ab) will be performed at other timepoints and will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. On Day 1 the abbreviated exam will be done at 4 hours post dose ±1 hour. On Days 2-5 the abbreviated exam will be done at 4 hours post dose ±1 hour. The Day 1 physical exam will take place after the ECG and vital signs (4-hr ECG on Day 1). Operational discretion can be used to define the order of assessments at all other visits.
8. Standard clinical safety labs may be collected fasted or nonfasted. Post-dose samples on Day 1 and Day 5 will be collected 8 hours ±1 hour after dosing. A predose sample will be collected on Day 3 within 2 hours prior to dosing.
9. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured at screening, on Day -1, on Day 1 prior to dosing (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, on Days 2-5 at 2 and 4 hours ±15 minutes after dosing, on Day 7 prior to discharge and on Day 12.
10. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG at screening, on Day -1, on Day 1 pre-dose (within 2 hours) and 2 and 4 hours ±15 minutes after dosing, on Days 2-5 at 2 and 4 hours ±15 minutes after dosing, and on Day 12. ECGs will be measured prior to vital sign measurements with subjects in a supine position after a minimum 5-minute rest.
11. Randomization can be performed either on Day -1 or pre-dose on Day 1
12. Adverse event reporting will be continuous to end of study on Day 12.
13. Dense PK sampling done on Days 1 and 5, with pre-dose trough sampling (within 1 hour pre-dose) on Days 3 and 4. On Day 1, samples taken pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, 12, and 24 hours postdose (pre-dose on Day 2). On Day 5, samples taken pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, 12, 24 hours post-dose (Day 6), 36 hours (Day 6), and 48 hours (Day 7). Sampling windows for Days 1 and 5 are ±5 minutes for samples through 4 hours post-dose, ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hours and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw. All pre-dose PK samples should be collected prior to the meal.

Table 1 Schedule of Study Events: Part 2 - Multiple-Ascending Dose Schedule of Events (Cohorts 2E)

		Clinical Unit											EOS[1] visit
	SCRN Day -28 to -2	Day -1	Day 1			Day 2-4			Day 5			Day 7	Day 12
Assessments			Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-Dose		(+ 1 d)
Check-in		X											
Informed consent	X												
Eligibility[2] criteria	X	X											
Demographic data	X												
Medical history	X	X	X										
Prior medication history	X	X											
Vein assessment	X												
Height	X												
Weight	X	X											
Pregnancy screen[3]	X	X											X
FSH[4]	X												
Serology[5]	X												
Drugs of abuse screen[6]	X	X											
Alcohol breath test	X	X											
Physical examination[7]	X	X		X(Ab)			X(Ab)			X(Ab)			X(Ab)
Clinical safety labs[8]	X	X			X	X (D3)					X		X
Lipid panel (fasted)		X							X				X
Vital signs[9]	X	X	X		X			X			X	X	X
12-lead ECG[10]	X	X	X		X			X			X		X
Randomization[11]		X	X										
Study Drug[12]				X			X			X			
AE reporting[13]				X	X	X	X	X	X	X	X	X	X
Con. medications			X	X	X	X	X	X	X	X	X	X	X

		Clinical Unit											EOS[1] visit
	SCRN Day -28 to -2	Day -1	Day 1			Day 2-4			Day 5			Day 7	Day 12
Assessments			Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-Dose		(+ 1 d)
PK samples[14]			X		X	X			X		X	X	
Discharge												X	

1. End of study visit.
2. Eligibility does not need to be re-reviewed between doses.
3. Females of childbearing potential will be tested for pregnancy by detecting the presence of β-HCG (serum test at Screening and urine test at other time points).
4. Only for women of postmenopausal status.
5. Serology screening will include tests for tests hepatitis B surface antigen, hepatitis C virus, and human immunodeficiency virus.
6. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylenedioxymethamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
7. Physical examination will be performed at screening and Day -1 and will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. Abbreviated exam (Ab) will be performed at other timepoints and will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. On Day 1 the abbreviated exam will be done at 4 hours post first dose ±1 hour. On Days 2-5 the abbreviated exam will be done at 4 hours post first dose ±1 hour.The Day 1 physical exam will take place after the ECG and vital signs (4-hr ECG on Day 1). Operational discretion can be used to define the order of assessments at all other visits.
8. Standard clinical safety labs may be collected fasted or nonfasted. Samples on Day 1 and Day 5 will be collected 8 hours ±1 hour after the first dose of study drug. A predose sample will be collected on Day 3 within 2 hours prior to the first dose of study drug.
9. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured at screening, on Day -1, on Day 1 prior to the first dose of study drug (within 2 hours) and 2 and 4 hours ±15 minutes after the first dose, on Days 2-5 at 2 and 4 hours ±15 minutes after the first dose, on Day 7 prior to discharge and on Day 12.
10. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG at screening, on Day -1, on Day 1 prior to the first dose (within 2 hours) and 2 and 4 hours ±15 minutes after the first dose, on Days 2-5 at 2 and 4 hours ±15 minutes after the first dose, and on Day 12. ECGs will be measured prior to vital sign measurements with subjects in a supine position after a minimum 5-minute rest.
11. Randomization can be performed either on Day -1 or pre-dose on Day 1
12. Study drug will be administered for 5 days (9 doses); q12h dosing on Days 1 through 4 and a single last dose given on Day 5. The q12h times (± 30 minutes) for study drug dosing are to be set on Day 1 and reverted back to each day. Subjects will be required to fast for one hour prior and two hours after each dose of study drug.
13. Adverse event reporting will be continuous to end of study on Day 12.
14. Dense PK sampling done on Days 1 and 5, with pre-dose trough sampling (within 1 hour pre-dose) on Days 2, 3 and 4. On Day 1, samples taken prior to the first dose of study drug and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, and 12 hours after the first dose of study drug. The 12-hour PK sample should be collected prior to administering the second dose of study drug. On Day 5, samples taken pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, 12, 24 hours post-dose (Day 6), 36 hours (Day 6), and 48 hours (Day 7). Sampling windows for Days 1 and 5 are ±5 minutes for samples through 4 hours post-dose, ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hours and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw.

Table 1 Schedule of Study Events: Part 2 - Multiple-Ascending Dose Schedule of Events (Cohorts 2F)

	SCRN Day -28 to -2	Clinical Unit											EOS[1] visit
		Day -1	Day 1			Day 2-4			Day 5			Day 7	Day 12
Assessments			Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-Dose		(+ 1 d)
Check-in		X											
Informed consent	X												
Eligibility[2] criteria	X	X											
Demographic data	X												
Medical history	X	X	X										
Prior medication history	X	X											
Vein assessment	X												
Height	X												
Weight	X	X											
Pregnancy screen[3]	X	X											X
FSH[4]	X												
Serology[5]	X												
Drugs of abuse screen[6]	X	X											
Alcohol breath test	X	X											
Physical examination[7]	X	X			X(Ab)			X(Ab)			X(Ab)		X(Ab)
Clinical safety labs[8]	X	X			X	X (D3)					X		X
Lipid panel (fasted)		X							X				X
Vital signs[9]	X	X	X		X			X			X	X	X
12-lead ECG[10]	X	X	X		X			X			X		X
Randomization[11]		X	X										
Study Drug[12]				X			X			X			
AE reporting[13]				X	X	X	X	X	X	X	X	X	X
Con. medications			X	X	X	X	X	X	X	X	X	X	X

	SCRN Day -28 to -2	Clinical Unit										EOS[1] visit
		Day -1	Day 1			Day 2-4			Day 5			Day 7	Day 12
Assessments			Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-First Dose	Pre-dose	Dosing	Post-Dose		(+ 1 d)
PK samples[14]			X		X	X			X		X	X	
Discharge												X	

1. End of study visit.
2. Eligibility does not need to be re-reviewed between doses.
3. Females of childbearing potential will be tested for pregnancy by detecting the presence of β-HCG (serum test at Screening and urine test at other time points).
4. Only for women of postmenopausal status.
5. Serology screening will include tests for tests hepatitis B surface antigen, hepatitis C virus, and human immunodeficiency virus.
6. Includes amphetamines (AMP), methamphetamines (MET), methadone (MTD), barbiturates (BAR), benzodiazepines (BZO), cocaine (COC), opiates (OPI), methylenedioxymethamphetamine (MDMA), phencyclidine (PCP), and tetrahydrocannabinol (THC).
7. Physical examination will be performed at screening and Day -1 and will include examination of general appearance, head, ears, eyes, nose, throat, neck (including thyroid), skin, cardiovascular system, respiratory system, gastrointestinal system, musculoskeletal system, lymph nodes, and nervous system. Abbreviated exam (Ab) will be performed at other timepoints and will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system. On Day 1 the abbreviated exam will be done at 4 hours post first dose ±1 hour. On Days 2-5 the abbreviated exam will be done at 4 hours post first dose ±1 hour. The Day 1 physical exam will take place after the ECG and vital signs (4-hr ECG on Day 1). Operational discretion can be used to define the order of assessments at all other visits.
8. Standard clinical safety labs may be collected fasted or nonfasted. Samples on Day 1 and Day 5 will be collected 8 hours ±1 hour after the first dose of study drug. A predose sample will be collected on Day 3 within 2 hours prior to the first dose of study drug.
9. Vital signs include blood pressure, heart rate, respiratory rate, and body temperature and will be collected prior to blood draws following a minimum 5-minute rest in a seated position. Vital signs will be measured at screening, on Day -1, on Day 1 prior to the first dose of study drug (within 2 hours) and 2 and 4 hours ±15 minutes after the first dose, on Days 2-5 at 2 and 4 hours ±15 minutes after the first dose, on Day 7 prior to discharge and on Day 12.
10. Electrocardiogram will be taken in triplicate (at least 1 minute apart and with all 3 completed within 5 minutes) with 12-lead ECG at screening, on Day -1, on Day 1 prior to the first dose (within 2 hours) and 2 and 4 hours ±15 minutes after the first dose, on Days 2-5 at 2 and 4 hours ±15 minutes after the first dose, and on Day 12. ECGs will be measured prior to vital sign measurements with participants in a supine position after a minimum 5-minute rest.
11. Randomization can be performed either on Day -1 or pre-dose on Day 1
12. Study drug will be administered for 5 days (9 doses); q12h dosing on Days 1 through 4 and a single last dose given on Day 5. The q12h times (± 30 minutes) for study drug dosing are to be set on Day 1 and reverted back to each day. Study drug will be administered within 30 minutes after ingesting a standard non-high fat meal. Participants will be required to fast for 2 hours and be restricted from having any fluids after each dose of study drug.
13. Adverse event reporting will be continuous to end of study on Day 12.
14. Dense PK sampling done on Days 1 and 5, with pre-dose trough sampling (within 1 hour pre-dose) on Days 2, 3 and 4. On Day 1, samples taken prior to the first dose of study drug and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, and 12 hours after the first dose of study drug. The 12-hour PK sample should be collected prior to administering the second dose of study drug. On Day 5, samples taken pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4. 6, 8, 12, 24 hours post-dose (Day 6), 36 hours (Day 6), and 48 hours (Day 7). Sampling windows for Days 1 and 5 are ±5 minutes for samples through 4 hours post-dose, ±10 minutes for samples at 6 and 8 hours, and ±30 minutes for samples at 12 hours and beyond. When ECGs and vital signs are scheduled at the same time as PK samples, the sample will be taken at the scheduled time point, with the ECGs and vital signs obtained as close as possible prior to the blood draw.

3. Analysis Sets

Two (2) different analysis populations will be defined:

- Intention-to-Treat (ITT) Analysis Set.
- Safety Analysis Set (SAS).

The criteria for exclusion from each analysis set will be described in the following sections.

Screen failure data will not be included in any output.

3.1 Intent to Treat Analysis Set

The ITT analysis set is defined as the set of all randomized/enrolled subjects.

The following are reasons for exclusion from the all-treated analysis set:

- Subject did not provide informed consent.
- Subject was not randomized/enrolled.

The ITT analysis set will be used as the analysis set for all baseline characteristics, disposition, and all by-subject listings and will be based on randomized/enrolled treatment if different from the actual treatment received.

3.2 Safety Analysis Set

This safety analysis set will include all subjects from the ITT analysis set who received at least one dose of the study drug (CDI-988 or Placebo).

The following are reasons for exclusion from the safety analysis set:

- The subject is not included in the ITT analysis set.
- The subject has not received at least one dose of CDI-988 or Placebo.

The safety analysis set will be used for the analysis of tolerability and safety parameters and will be based on actual treatment received if different from the randomized treatment.

3.3 Analysis of Subgroups

No subgroup analyses are planned for this study.

4. Study Measures

This section describes the measures that were collected and/or derived during the study at the time points specified in the Schedule of Events (Section 2.5). This includes safety and tolerability and subjects characteristics data.

4.1 Safety Measures

The safety endpoints described in this section will be analyzed according to the analysis methods described in Section 6.8.

4.1.1 Exposure to Study Medication

Study drug administration information will be reported on the 'Study Drug Administration' eCRF. For Cohort 1C, 1E and 1F and Part 2, the date and time of the last meal and the amount of (high fat or non-high fat meal) breakfast consumed (%) will be reported on the eCRF.

For Part 2 (MAD), duration of exposure (treatment) and the total dose of CDI-988 administered (mg) per dosing day and overall will be presented.

4.1.2 Adverse Events

For purposes of this trial, an adverse event (AE) will be defined as any new unfavorable or unintended sign, symptom, or disease, or change of an existing condition, which occurs during or after treatment, whether or not considered treatment-related. If clinically significant laboratory value lead to or are associated with clinical symptoms(s), the diagnosis should be reported as an adverse events.

Missing and partial AE dates will be handled according to the rules specified in Sections 5.1.4 and 5.6.2.2.

4.1.2.1 Adverse Event Definitions

TEAEs are defined as AEs occurring or worsening after the first dose of study drug through Day 8 in Part 1 (Day 16 in cohort 1C), and Day 17 in Part 2 Cohorts 2A-2C, and Day 12 in Part 2 Cohorts 2D-2F. If only partial information is available, the rules specified in Section 5.6.2.2 will be applied to determine treatment emergence.

TEAEs are assigned to the last treatment/ food effect that was administered prior to the start of the event. For subjects in Cohorts 1C, 1E and 1F, TEAEs will be assigned to the fasted state if the event occurred post the study drug dosing on Day 1, and to the fed state if the event occurred post the study drug administration on Day 9.

Treatment-related AEs are defined as AEs where the relationship to study drug was reported as 'Related', 'Possibly Related', 'Probably Related' or is missing. An AE will be classified as not related to study drug if the relationship to study drug was recorded as 'Unrelated'.

Serious AEs (SAEs) are defined as AEs where the events are reported as serious.

Grade 3/Severe/ Grade 4/Life-threatening adverse events are defined as adverse events where the event severity is reported as 'Grade 3/Severe' or 'Grade 4/Life-threatening'.

Adverse events leading to study drug withdrawal (MAD) are defined as AEs where the action taken is reported as 'Drug Withdrawn'.

Adverse events leading to study withdrawal are defined as AEs where other action taken is reported as 'Withdrawn from study'.

4.1.2.2 Coding of Adverse Event Terms

Adverse event terms (Investigator terms) will be coded to a lowest level term (LLT), preferred term (PT), high level term (HLT), high level group term (HLGT) and a system organ class (SOC) according to the Medical Dictionary for Regulatory Activities (MedDRA) dictionary, Version 26.0 or higher, depending on the latest version available during the study. Although there can be multiple SOCs for a PT, each PT will be linked with one SOC, namely the primary SOC which is automatically assigned by MedDRA via a single HLT, HLGT route.

If no coding information is available for a specific AE, the AE will be presented as an 'Uncodable Event' in all summary tables.

Adverse events will be reported on a per-subject basis and per-event. On a per-subject basis this means that even if a subject reported the same event repeatedly (i.e., events mapped to the same PT) during the study period, the event will be counted only once. In the latter case the event will be assigned the worst severity and the strongest relationship to the study medication.

4.1.3 Laboratory Evaluations

Laboratory evaluations were performed in accordance with the Schedule of Study Events (Section 2.5). The blood and urine samples that were collected were sent to the central laboratory for analysis, and the results were provided in electronic format. Serology, pregnancy test, urine drug test and alcohol breath test results were reported on the CRF.

If the results for a specific laboratory test were not required by the study protocol (for example, only one subject has data for a specific test that was performed in error) or for urine microscopy tests that were only required in the presence of abnormal urinalysis results, the results will not be included in the summary tables, but the data will be listed. The following test panels and parameters are required based on Section 9.2.4 of the study protocol:

- **Hematology:** Hemoglobin, Hematocrit, Mean Cell Volume (MCV), Erythrocyte Count (RBC), Reticulocytes, Leukocytes (WBC), Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils and Platelets.
- **Coagulation:** International Normalized Ratio (INR), Activated Partial Thromboplastin Time (APTT), Prothrombin Time (PT).
- **Clinical Chemistry:** Albumin, ALP (Alkaline phosphatase), ALT (Alanine-aminotransferase), AST (Aspartate-aminotransferase), Direct Bilirubin, Indirect Bilirubin, Total Bilirubin, Calcium, Chloride. Cholesterol, Creatine Clearance, Creatinine, Creatinine Kinase, Glucose, Phosphorus, Potassium, Total Protein, Sodium, Urea, Uric Acid and Follicle-Stimulating Hormone (FSH).
- **Lipid Panel:** Total Cholesterol, High-density lipoprotein (HDL) cholesterol, Non-high-density lipoprotein (Non-HDL) cholesterol, Low-density lipoprotein (LDL) cholesterol, Triglycerides, Cholesterol/HDL ratio, LDL/HDL ratio.
- **Urinalysis:** Specific gravity, pH, Protein, Glucose, Blood, Nitrites, Leucocyte esterase.
- **Urine Microscopy:** Erythrocytes, Leukocytes, Epithelial Cells, Crystals, Bacteria.
- **Serology:** Hepatitis B surface antigen, Hepatitis C virus, and Human Immunodeficiency Virus.
- **Pregnancy Test:** β-HCG.
- **Urine Drug Test:** Amphetamines (AMP), Methamphetamines (MET), Methadone (MTD), barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC),

Opiates (OPI), Methylene dioxy Methamphetamine (MDMA), Phencyclidine (PCP), and Tetrahydrocannabinol (THC).

- **Alcohol Breath Test**

Parameter names will be based on the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) Controlled Terminology terms. The mapping of the reported parameter names to the standardized names will be presented in the SDTM specifications.

If the results for a parameter were reported in different units, the results (including the actual measurement and the normal range limits) will be converted to the Système International (S.I.) unit for the specific parameter and the standardized results/units will be reported. The specific conversion rules will be documented in the SDTM/derived dataset specifications.

If a result for a parameter that is normally considered continuous is reported as a range (i.e., the result for basophils is reported as '<0.01' for a single time point), the result may be converted to a numeric value that is equal to the lower or upper bound than the reported result to contribute to the derivations and the summary statistics. Any conversion rules that are applied will be highlighted in the footnotes of the affected tables and listings. The original reported result value will however be included in the listing.

If a re-test was performed at any visit, the results from the repeat test will be used in all analyses for the specific visit. The repeat test result will be flagged in the data listing.

For all test panels except for urinalysis and urine microscopy, the parameter names that will be used in the outputs will comprise of the test name and the standardized unit of measure (if applicable), for example, 'Albumin (g/L)'. For the urinalysis and urine microscopy tests, the parameter name will be the reported test name only.

For all parameters where a normal range limit value was reported, the normal range will be derived based on the available lower and upper limit values and any reported mathematical symbols. If both a lower and upper limit value is available, the normal range will be presented as '(Lower, Upper)'. If only one of the limit values exist, 'N/A' will be used to replace the 'missing' limit value (for example, '(N/A, Upper)'), unless a direction has been specified, in which case the normal range will be displayed as '(< or > Limit)'.

Quantitative parameter results will be classified as 'Normal' (within the normal range) or 'Abnormal' (outside the normal range) according to the subjects' individual normal ranges that were provided by the analyzing laboratory. Abnormal results will further be classified as being 'Low' or 'High' depending on whether the result is below or above the normal range limits.

Baseline and change from baseline values will be derived for each parameter (as appropriate) in accordance with the methods defined in Section 5.1.2.

4.1.4 Vital Signs Evaluations

Vital signs will be performed in accordance with the Schedule of Study Events (Section 2.5).

The following parameters are required based on Section 9.2.2 of the study protocol and will be recorded on the '12-Lead ECG' eCRF:

- **Vital Sign Parameters:** Systolic blood pressure (SBP) (mmHg), Diastolic blood pressure (DBP) (mmHg), Heart rate (beats/min), Respiratory Rate (breaths/min). Temperature (°C), Height (cm), Body Weight (kg).

Baseline and change from baseline will be derived for each parameter (as appropriate) in accordance with the methods defined in Section 5.1.2.

4.1.5 ECG Evaluations

Triplicate ECG evaluations will be performed in accordance with the Schedule of Study Events (Section 2.5), at least 1 minute apart and with all 3 completed within 5 minutes.

The following parameters are required based on Section 9.2.3 of the study protocol and will be recorded on the '12-Lead ECG' eCRF:

- **ECG Parameters:** Heart Rate (beats per minute [bpm]), QRS Duration (msec), PR (msec), QT (msec), QTcF (msec) Intervals and Overall ECG Assessment ('Normal', 'Abnormal Not Clinically Significant [NCS]' or 'Abnormal Clinically Significant [CS]').

For the qualitative ECG overall assessment, it will be recorded whether the parameter at the specific visit was 'Normal' or 'Abnormal'. For all abnormal values, clinical significance (as determined by the Investigator) and any ECG findings should be indicated.

Baseline (for quantitative and qualitative parameters) and change from baseline values (for quantitative parameters) will be derived for each parameter (as appropriate) in accordance with the methods defined in Section 5.1.2.

4.1.6 Physical Examination

Full and abbreviated physical examinations will be performed in accordance with the Schedule of Study Events (Section 2.5).

The following parameters are required based on Section 9.2.1 of the study protocol and will be recorded on the 'Physical Examination' eCRF:

- **Physical Examination Parameters:** General Appearance, Head, Ears, Eyes, Nose and Throat, Neck (including Thyroid), Skin, Cardiovascular System, Respiratory System, Gastrointestinal System, Musculoskeletal System, Lymph Nodes, and Nervous System.

Abbreviated exam will include at a minimum assessment of general appearance, head, nose, throat, respiratory system, and cardiovascular system.

The qualitative parameters will record whether at the specific visit was 'Normal' or 'Abnormal'. Each collected quantitative ECG parameter will be classified as 'Normal' or 'Abnormal' at each visit. For all abnormal values, clinical significance (as determined by the Investigator) and any ECG findings should be indicated.

4.2 Pharmacokinetic Analysis

The PK analysis for this study fall outside the scope of the statistical analysis plan.

4.3 Other Measures

4.3.1 Subject Disposition

Subject disposition data will be collected on the 'Study Completion' eCRF when a subject completed or early terminates the study.

The following data will also be presented in the disposition listing:

- Date and version of informed consent ('Informed Consent' eCRF),
- Date/time of the first study drug administrations ('Study Drug Administration' eCRF.)
- Date/time of the last study drug administrations ('Study Drug Administration' eCRF.)

The analysis sets defined in Section 3 will be summarized and presented as part of the subject disposition data.

For the food effect cohorts, disposition and analysis set data will be assigned to the fasted effect at the trial initiation. At Day 8 (eligibility) and Day 9 (eligibility and dosing) the subjects will be reevaluated for all analysis sets for the fed group. Subject that discontinue without evaluation of eligibility Day 8, will be terminated as part of the fasted group. If a subject underwent eligibility assessments on Day 8/9, it will be assumed the subject completed the fasted period as planned.

4.3.2 Protocol Violations and Eligibility

Protocol deviations will be reported on the 'Protocol Deviations' eCRF.

Major protocol deviations are defined as violations that might affect the safety or pharmacokinetics of a subject. Minor deviations are protocol deviation that, in the Investigator's judgment, do not adversely affect the risk/benefit ratio of the study, the rights, safety, or welfare of the subjects or others, or the integrity of the study.

Eligibility will be reported on the 'Eligibility Criteria' eCRF.

The eligibility of all subjects for entry into the study will be assessed at Screening and Day -1 and pre-dose Day 9 (Cohort 1C, 1E and 1F Fed) of each study part. A subject should have met all the inclusion, and none of the exclusion criteria before entry into the study.

Protocol deviations are assigned to the last treatment/ food effect that was administered prior to the start of the event. For subjects in Cohorts 1C, 1E and 1F, protocol deviations will be assigned to the fasted state if the event occurred post the study drug dosing on Day 1, and to the fed state if the event occurred post the study drug administration on Day 9.

4.3.3 Demography

Demographic information provides data regarding the subjects and is necessary for the determination of whether the individuals in the study are a representative sample of the target population.

The following demography data will be collected on the 'Demographics' eCRF at Screening.

- Year of birth and Age (Years)
- Sex ('Male', 'Female')
- Childbearing potential ('Yes', 'No')
- Ethnicity ('Hispanic or Latino', 'Not Hispanic or Latino')

- Race:
    - 'Asian'
    - 'Black or African American'
    - 'White'
    - 'Native Hawaiian or Other Pacific Islander'
    - 'Not Reported'
    - Unknown'
    - 'American Indian or Alaska Native'
    - 'Other

For subjects in Cohorts 1C, 1E and 1F, the demography and baseline characteristics at Screening and Day 1 will be included for the fed groups if the subject is included in the fed ITT analysis set.

4.3.4 Baseline Subject Characteristics

Baseline subject characteristics include characteristics that subjects presented with prior to the administration of study drug.

The following subject characteristics will be collected on the 'Vital Signs' eCRF at Screening:

- Height (cm)
- Body Weight (kg)

The following other baseline data will also be collected (see Section 4.1.3 for more detail):

- Alcohol breath test results ('Alcohol Breath Test' eCRF).
- Serology ('Serology' eCRF).
- Urine drug test results ('Urine Drug Test' eCRF).

For subjects in Cohorts 1C, 1E and 1F, the demography and baseline characteristics at Screening and Day 1 will be included for the fed groups if the subject is included in the fed ITT analysis set

4.3.5 Medical History

Medical history is information about conditions that a subject might have suffered from prior to the administration of study drug, or conditions that were ongoing at the time of the administration of study drug.

Medical and surgical history data will be collected at Screening on the 'Medical History' eCRF page.

For subjects in Cohorts 1C, 1E and 1F, medical history will be included for the fed groups if the subject is included in the fed ITT analysis set.

4.3.5.1 Coding of Medical History Terms

Medical and surgical history terms (Investigator terms) will be coded to a LLT, PT, HLT, HLGT and SOC according to the MedDRA dictionary, Version 26.0, depending on the latest version available during the study. Although there can be multiple SOCs for a PT, each PT will be linked with one SOC, namely the primary SOC which is automatically assigned by MedDRA via a single HLT, HLGT route.

Medical history and surgical history will be reported on a per-subject basis. This means that even if a subject suffered the same clinical event repeatedly (i.e., events mapped to the same PT) the event will be counted only once.

4.3.6 Prior and Concomitant Medications

Prior and concomitant medications data will be collected throughout the study on the 'Prior Medications' and 'Concomitant Medications' eCRF.

Missing and partial concomitant medications dates will be handled according to the rules specified in Sections 5.1.4 and 5.6.2.3.

The food effect cohorts will be summarized separately from the SAD fasted cohorts.

4.3.6.1 Medication Definitions

Prior medications are defined as any medication where the use was stopped prior to the first administration of study drug.

Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of study drug. Medications stopping on the same day as the first study drug administration will be considered as concomitant medications.

4.3.6.2 Coding of Medication Terms

Prior and concomitant medication terms will be coded to an anatomical therapeutic chemical (ATC) class term (Level 2) and a preferred drug name based on the active drug substance using the World Health Organization-Drug Dictionary (WHO-DD), Version Global C3 March 1, 2023.

4.3.7 Assignment to Treatment

Subjects will be randomized to a treatment group prior to the study drug administration and the randomization number will be reported on the 'Randomization Number' eCRF.

5. Statistical Methodology

5.1 General Statistical Methods

5.1.1 Software

All analysis data sets and outputs will be produced by the Biostatistics Department of Resolutum Global using the SAS® Version 9.4 (SAS Institute, Cary, North Carolina, USA) or higher.

5.1.2 Definitions

The following definitions will be used:

- Date of the First Study Medication Administration: The date of the first study medication administration is defined as the earliest date on which study medication was administered as reported on the 'Study Drug Administration' CRF page.
- Date of the Last Study Medication Administration: The date of the last study medication administration is defined as the latest known date on which study medication was administered as reported on the 'Study Drug Administration' CRF page.

The date of the last study medication administration will be derived based on the available information for all subjects who did not complete the study, or who reported having missed administrations during the study.

- Baseline: The baseline value is defined as the last available valid, non-missing observation for each subject prior to first study medication administration. Repeat and unscheduled assessments will be included in the derivation of the baseline values. Results including, but not limited to, 'Not done', 'Not applicable', 'Unknown' will not be included in the baseline derivation.

  For the food effect parts of the study, baseline will be derived for each food effect. The baseline value for the specific treatment period is defined as the last available valid, non-missing observation prior to the first study drug administration in that period.

- Change from Baseline: The change from baseline value is defined as the difference between the result collected/derived at a post-baseline visit and the baseline value.

  The change from baseline value at each post-baseline visit will be calculated for all continuous parameters using the following formula:

  Change from Baseline Value = Result at post-Baseline visit – Baseline Value

  The change from baseline value will only be calculated if the specific post-baseline visit result and the baseline value for the parameter are both available and will be treated as missing otherwise. In the data listings, the change values will be set to 'N/A' (not applicable) for pre-baseline assessments.

- Event Duration:

  The duration of an event will be calculated for events with complete start and end date information using the following formula:

  Duration of Event (days) = (Event Stop Date – Event Start Date) + 1

  The duration of an event will be calculated for events with complete start and end time information using the following formula:

  Duration of Event (minutes) = (Event Stop Time – Event Start Time)

- Study Day: The study day of an event is defined as the relative day of the event starting with the date of the first study medication administration (reference date) as Day 1 (there will be no Day 0).

  The study day of events occurring before the first study medication administration will be calculated as:

  Study Day = (Date of Event - Date of First Study Medication Administration)

  For events occurring on or after Day 1, study day will be calculated as:

  Study Day = (Date of Event - Date of First Study Medication Administration) + 1

  Study days will only be calculated for events with complete dates and will be undefined for events that are 'Ongoing' at the end of the study.

5.1.3 Default Descriptive Statistics and Data Presentation Rules

Unless otherwise stated, summary statistics including the number of subjects, mean, standard deviation, median, minimum, and maximum, will be presented for all continuous variables. Minimum and maximum values will be presented to the same decimal precision as the raw values, the mean, median and standard deviation values will be presented to one more decimal than the raw values. Derived values (including descriptive statistics) will be presented to a maximum of 3 significant decimals.

For categorical variables, per category, the absolute counts (n) and percentages (%) of subjects with data, and if appropriate, the number of subjects with missing data will be presented. Unless specifically stated otherwise, denominator for all percentage calculations will be the number of subjects in the specific treatment group and analysis set. All percentages will be presented as integers.

5.1.4 Date and Time Display Conventions

The following display conventions will be applied in all outputs where dates and/or times are displayed:

- Date only: YYYY-MM-DD
- Date and time: YYYY-MM-DD/HH:MM

If only partial information is available, unknown components of the date or time will be presented as 'NK' (not known), i.e., '2016-NK-NK'. Times will be reported in military time.

5.1.5 General Display Conventions

All data collected during the study (data originating from the CRFs or electronic transfers), except for screen failure data, will be presented in the data listings. Event-based listings will be sorted by treatment

group, subject number and event start and end dates. Assessment-based listings will be sorted by treatment group, patient number, parameter name (alphabetically unless specifically stated otherwise), visit and time point (if applicable).

Fields that are missing because they are not applicable for the subject/time point (for example change from baseline results at the baseline visit) will be presented as “N/A”, unless otherwise specified. Missing data points will be presented as blank fields in the data listings.

All summary tables will present the results by study part and treatment group. Assessment-based tables will be sorted alphabetically by parameter (unless specifically stated otherwise) and chronologically by visits/time point within parameter. Only values collected at scheduled study visits/time points will be presented in summary tables. Event-based tables will be ordered as specified in Section 6.

Treatment groups will be presented based on increasing dose levels of the study drug, followed by any active comparators and lastly, placebo in all tables, listings, and figures. The All-Subjects group will be presented on all tables where indicated in the mock shells.

Tables 2 and 3 present the treatment group, visit and time point labels that will be used in the tables, listings, and figures (TLFs).

Table 2 Study Treatments

SAD and Food Effect		
Actual Treatment	**Summary Table Treatment Label**	**By-subject Listing Treatment Label**
Cohort 1A: CDI-988 100 mg Fasted	CDI-988 100 mg Fasted	Cohort 1A: CDI-988 100 mg Fasted
Cohort 1E: CDI-988 100 mg Fasted	CDI-988 100 mg CDI-988 100 mg Fasted CDI-988 100 mg Fasted/Fed	Cohort 1E: CDI-988 100 mg Fasted/ Fed • Fasted • Fed
Cohort 1E: CDI-988 100 mg Fed	CDI-988 100 mg Fed	
	CDI-988 100 mg Fasted/Fed	
Cohort 1B: CDI-988 200 mg Fasted	CDI-988 200 mg Fasted	Cohort 1B: CDI-988 200 mg Fasted
Cohort 1C: CDI-988 400 mg Fasted	CDI-988 400 mg CDI-988 400 mg Fasted	Cohort 1C: CDI-988 400 mg Fasted/ Fed • Fasted • Fed
Cohort 1C: CDI-988 400 mg Fed	CDI-988 400 mg Fed	
	CDI-988 400 mg Fasted/Fed	
Cohort 1D: CDI-988 600 mg Fasted	CDI-988 600 mg Fasted	Cohort 1D: CDI-988 600 mg Fasted
Cohort 1F: CDI-988 1200 mg Fasted	CDI-988 1200 mg CDI-988 1200 mg Fasted	Cohort 1F: CDI-988 1200 mg Fasted/ Fed • Fasted • Fed
Cohort 1F: CDI-988 1200 mg Fed	CDI-988 1200 mg Fed	
	CDI-988 1200 mg Fasted/Fed	
Cohorts 1A – 1F Fasted: CDI-988	Pooled CDI-988	
Cohorts 1A – 1F Fasted: Placebo	Pooled Placebo	
Cohorts 1A, 1B and 1D: Placebo		Pooled Placebo
Cohorts 1C, 1E and 1F: Placebo	Pooled Placebo Fasted	Pooled Placebo Fasted/ Fed • Fasted • Fed
	Pooled Placebo Fed	
	All Subjects (Where indicated)	

MAD		
Actual Treatment	**Summary Table Treatment Label**	**By-subject Listing Treatment Label**
Cohort 2A: CDI-988 200 mg Fed	CDI-988 200 mg Fed	Cohort 2A: CDI-988 200 mg Fed
Cohort 2B: CDI-988 400 mg Fed	CDI-988 400 mg Fed	Cohort 2B: CDI-988 400 mg Fed
Cohort 2C: CDI-988 800 mg Fed	CDI-988 800 mg Fed	Cohort 2C: CDI-988 800 mg Fed
Cohort 2D: CDI-988 1200 mg Fed	CDI-988 1200 mg Fed	Cohort 2D: CDI-988 1200 mg Fed
Cohort 2E: CDI-988 1200 mg BID Fasted	CDI-988 1200 mg BID Fasted	Cohort 2E: CDI-988 1200 mg BID Fasted
Cohort 2F: CDI-988 1200 mg BID Fed	CDI-988 1200 mg BID Fed	Cohort 2F: CDI-988 1200 mg BID Fed
	Pooled CDI-988	
Cohort 2A – 2F: Placebo	Pooled Placebo	Pooled Placebo
	All Subjects	

Table 4 Study Visits

SAD and Food Effect		
Actual Visit	**Summary Table Treatment Label**	**By-subject Listing Treatment Label**
Screening (Day -28 to -1)		Screening
Day -1/ Day 8		Day -1
		Day 8
Day 1/ Day 9: Pre-dose		Day 1: Pre-dose
		Day 9: Pre-dose
Day 1/ Day 9: Post-dose	Day 1	Day 1
	Day 9	Day 9
	Baseline	
Day 1/ Day 9: 2 hours	Day 1: 2 hours	Day 1: 2 hours
	Day 9: 2 hours	Day 9: 2 hours
Day 1/ Day 9: 4 hours	Day 1: 4 hours	Day 1: 4 hours
	Day 9: 4 hours	Day 9: 4 hours
Day 2/ Day 10	Day 2	Day 2
	Day 10	Day 10
Day 3/ Day 11	Day 3	Day 3
	Day 11	Day 11
	Day 8/ Early Termination (Safety)	Day 8
End of Study/ Day 8/ Day 16	Day 16/ Early Termination (Safety)	Day 16
		Early Termination
Unscheduled		Unscheduled

MAD Cohorts 2A-2C		
Actual Visit	**Summary Table Treatment Label**	**By-subject Listing Treatment Label**
Screening (Day -28 to -1)		Screening
Day -1		Day -1
Day 1: Pre-dose	Day 1: Pre-dose	Day 1: Pre-dose
Day 1: Post-dose	Day 1	Day 1
	Baseline	
Day 1-12: 2 hours	Day 1-12: 2 hours	Day 1-12: 2 hours
Day 1-12: 4 hours	Day 1-12: 4 hours	Day 1-12: 4 hours
Day 3: Pre-dose	Day 3: Pre-dose	Day 3: Pre-dose
Days 2 – 10, Day 12	Day 2 – Day 10, Day 12	Day 2 – Day 10 , Day 12
End of Study/ Day 17	Day 17/ Early Termination (Safety)	Day 17
		Early Termination
Unscheduled		Unscheduled

MAD Cohorts 2D-2F		
Actual Visit	**Summary Table Treatment Label**	**By-subject Listing Treatment Label**
Screening (Day -28 to -1)		Screening
Day -1		Day -1
Day 1: Pre-dose	Day 1: Pre-dose	Day 1: Pre-dose
Day 1: Post-dose	Day 1	Day 1
	Baseline	
Day 1-5: 2 hours	Day 1-5: 2 hours	Day 1-5: 2 hours
Day 1-5: 4 hours	Day 1-5: 4 hours	Day 1-5: 4 hours
Day 3: Pre-dose	Day 3: Pre-dose	Day 3: Pre-dose
Days 2 – 5, Day 7	Day 2 – Day 5, Day 7	Day 2 – Day 5 , Day 7
End of Study/ Day 12	Day 12/ Early Termination (Safety)	Day 12
		Early Termination
Unscheduled		Unscheduled

5.2 Hypotheses and Decision Rules

Not applicable for this study.

5.3 Multiple Comparisons and Adjustments for Multiplicity

Not applicable for this study.

5.4 Covariates

Not applicable for this study.

5.5 Multi-Centre Data

Not applicable for this study.

5.6 Handling of Missing Data

5.6.1 Efficacy Endpoint

Not applicable for this study.

5.6.2 Other Endpoints

5.6.2.1 Exposure

If the start of treatment date is missing, the latest possible time of all the pre-dose assessments, up to and including Randomization will be imputed as the start of treatment date.

If the end of treatment date is missing, the latest possible time of all the post-dose assessments will be imputed as the end of treatment date.

5.6.2.2 Adverse Events

Missing start dates/times will be imputed to one minute after the study drug administration.

Partial start dates will be imputed to the last day of the month/year considering that the start date should not be after the stop date/time. Missing start times will be imputed to '23:59'. If the imputation results in the start date/time being after the stop date/time, the start date/time will be set to the stop/date time.

The imputation method will only be used to determine treatment emergence and to determine the time of the event relative to the first administration of study drug. If no clear determination can be made, the event will be deemed to have started at the same time as the study drug, i.e., the event will be analyzed as being treatment emergent.

Stop dates/times will not be imputed if the AE is ongoing.

A worst-case approach will be followed in the event of missing severity or causality data. If the severity is missing, 'Severe' will be imputed. If causality data are missing, 'Related' will be imputed.

Missing/partial concomitant medication dates will be handled in a similar fashion as described for the adverse event dates.

5.6.2.3 Concomitant Medications

Missing concomitant medication dates will be handled in a similar fashion as described for Adverse Events in Section 5.6.2.2.

5.7 Windowing Conventions

Not applicable for this study.

5.8 Interim Analyses

Not applicable for this study.

5.9 Clinical Data Interchange Standards Consortium (CDISC) Specifications

The study data will be converted into CDISC-compliant datasets based on the Study Data Tabulation Model Implementation Guide (SDTMIG) Version 3.3 and the Analysis Data Model Implementation Guide (ADaMIG) Version 1.3.

The SDTM data package will be based on raw data (clinical database and external data) and will include SAS® datasets and transport files (.XPT format) for each required SDTM domain, as well as the SDTM Case Report Tabulation Data Definition Specifications (CRT-DD) (define.xml Version 2.1) that describes the origin of the data and all of the derivations and imputations that were applied, and includes an SDTM-annotated CRF and the Study Data Reviewer's Guide (SDRG).

The ADaM datasets will be based on the SDTM datasets and will be used for the analysis. The ADaM data package will include SAS® datasets and transport files (.XPT format) for each analysis dataset, as well as the ADaM CRT-DD (define.xml Version 2.1) and the Analysis Data Reviewer's Guide (ADRG).

The SDTM and ADaM data packages will be validated using Pinnacle 21 Community (531 Plymouth Road, Suite 508, Plymouth Meeting, PA 19462) and the validation reports will be included with the respective data packages.

All data conversions will be performed using SAS® Version 9.4 or higher (SAS Institute, Cary, North Carolina, USA) with program code prepared specifically for the study.

The output SAS® programs will generate rich-text-formatted (RTF) output with the '.RTF' extension using the SAS® Output Delivery System (ODS). Each output display will show the name of the SAS® program which was used to produce it.

6. Statistical Analyses

Continuous and categorical variables will be summarized using the methods described in Section 5.1.3.

6.1 Subject Disposition and Analysis Sets

Summary tables will be based on the ITT analysis set.

The number and percentage of enrolled subjects, subjects completing or withdrawing from treatment/ the study as well as the primary reason for withdrawal will be presented by study part, treatment group, food effect (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis). The denominator for the reason for withdrawal from treatment/ the study percentage calculations will be the number of subjects that withdrew from treatment/ the study.

All subject disposition information (as described in Section 4.4.1) collected on the 'Study Completion' eCRF will be listed together with the date/time that the subject provided informed consent and the date/time of the first and last (MAD) study drug administration.

The number of subjects included in the analysis sets (safety) defined in Section 3 will be summarized along with the reasons for exclusion from any analysis set by study part, treatment group, food effect (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis) using frequencies and percentages.

In addition, the inclusion/exclusion of each subject into/from each of the defined analysis set will be listed.

The randomization information including the assigned treatment group will be listed.

6.2 Protocol Violations and Eligibility

Summary tables will be based on the ITT analysis set.

The number and percentage of subjects with at least one protocol deviation (as described in section 4.4.2), as well as the number and percentage of subjects with a deviation in each of the deviation categories will be presented by study part, treatment group, food effect (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis) in the protocol deviation table. Subjects will be counted once per category, but all deviation will be counted.

All protocol deviation information and all eligibility data will be listed.

6.3 Demography

Summary tables will be based on the ITT analysis set.

Demography data (as described in Section 4.3.3) will be summarized and presented study part, treatment group, food effect (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis). The homogeneity between treatment groups will be assessed based on the descriptive statistics only.

All collected and derived demography data will be listed.

6.4 Baseline Subject Characteristics

Summary tables will be based on the ITT analysis set.

Baseline subject characteristics data (as described in Section 4.3.4) will be summarized and presented study part, treatment group, food effect (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis).

The vital signs parameters will be listed as part of the vital signs listing.

The listings of serology, alcohol breath test and urine drug test results will include all available results (collected at scheduled and unscheduled visits) in the clinical database.

6.5 Medical History

Summary tables will be based on the ITT analysis set.

Medical and surgical history conditions will be summarized by SOC and by PT within SOC study part, treatment group, food effect (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis). Within each category, the number of subjects who experienced a condition (frequency and percentage) and the actual number of events (frequency only) will be presented by study part, treatment and for all subjects overall. Subjects who experienced the same condition on more than one

occasion (based on the specific category) will only be counted once in each relevant category (SOC and PT), but all conditions will be included in the event frequencies. System organ class terms will be sorted alphabetically, and preferred terms will be sorted alphabetically within SOCs in the table. In addition to the coded terms, the number of subjects with at least one medical history condition and the total number of events will be presented.

All information that was collected on the 'Medical and Surgical History' eCRF as well as the coded MedDRA terms, and the start and end study days (relative to the study drug administration) will be included in the listing. Partial dates will not be imputed.

6.6 Prior and Concomitant Medication

Summary tables will be based on the safety analysis set.

Concomitant mediations will be summarized by WHO-DD ATC Level 2 term and preferred medication name. Within each ATC term and preferred name, the number of subjects who used the medication (frequency and percentage) will be presented by study part, treatment group/ food effect and all subjects overall. Subjects who used the same medication on multiple occasions will only be counted once. ATC terms and preferred names with ATC term will be sorted alphabetically. In addition to the summaries by the WHO-DD terms, the number of subjects who used at least one concomitant medication during the study will be presented.

All information that was collected will be included in the prior and concomitant medication listing. Furthermore, the relative medication starts, and end days (relative to the first study drug administration) will be presented where complete medication start and end dates are available.

6.7 Efficacy Analyses

Not applicable for this study.

6.8 Safety Analyses

Statistical methods for the safety analyses will be descriptive in nature and no formal statistical comparisons will be made. Endpoints will be summarized by study part, treatment group and food effect (Cohorts 1C, 1E and 1F) based on the methods described in Section 5.1.

Safety endpoints will be analyzed based on the Safety Analysis Set according to the actual treatment received.

6.8.1 Exposure to Study Medication

For Part 1, 'Was study drug administered yes/no' will be summarized by treatment group, (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis).

For Part 2 (MAD) the total dose of CDI-988 administered and the duration of treatment will be summarized by treatment group and for all subjects overall.

All collected study drug administration and breakfast data (high fat meal/ standard non-high fat meal as described in section 4.1.1) will be listed.

6.8.2 Adverse Events

All tables will present the number of subjects who experienced an AE (count and percentage) and the actual number of AEs (count only) within each specific category by study part, treatment group, (Cohorts

1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis). Subjects who experienced multiple AEs will only be counted once in each relevant category (high-level summary, SOC, PT, severity rating or relationship to study drug category), but all events will be included in the event counts. Percentages will be based on the number of subjects in the Safety Analysis Set. Tables will only include treatment-emergent events and will be presented by study part and treatment group .

The overall summary of TEAEs table will present the total number of subjects who experienced a TEAE and the total number of TEAEs in each of the following categories:

- At least one TEAE.
- At least one serious TEAE.
- At least one Grade 3/ Severe or Grade 4/ Life-threatening TEAE.
- At least one treatment related TEAE.
- At least one TEAE leading to study drug withdrawal (MAD).
- At least one TEAE leading to study withdrawal.

The incidence of TEAEs table will include the number and percentage of subjects who experienced at least one TEAE and the corresponding number of events, and furthermore summarize the TEAE data by SOC and preferred term (PT) within SOCs. SOC terms will be sorted by decreasing frequency overall as will the PTs within the SOC terms in the table. In addition, a separate table will be created to summarize the TEAE data by PT only. PT terms will be sorted by decreasing frequency overall.

The incidence of serious TEAE table will include the number and percentage of subjects who experienced at least one serious TEAE and the corresponding number of events, and furthermore summarize the serious TEAE data by SOC and preferred term within SOCs. SOC terms will be sorted by decreasing frequency overall as will the PTs within the SOC terms in the table.

The summary of TEAEs by severity table will include the number of subjects who experienced at least one TEAE, the number of subjects who experienced at least one TEAE within each severity rating (‘Grade 1/ Mild’, ‘Grade 2/ Moderate’, ‘Grade 3/ Severe’, ’ Grade 4/ Life-threatening’) and the corresponding number of events for each rating. In addition, the TEAE data will be summarized by SOC, preferred term within SOC, and severity rating within preferred term. SOC terms will be sorted by decreasing frequency overall, and PTs will be sorted by decreasing frequency overall within SOC. Severity ratings will be sorted in increasing order of severity within preferred terms in the table.

The incidence of treatment-related TEAEs table will include the number and percentage of subjects who experienced at least one treatment-related (‘Possibly Related’, ‘Probably Related’ and ‘Related’) TEAE and the corresponding number of events, and furthermore summarize the TEAE data by SOC and PT within SOCs. SOC terms will be sorted by decreasing frequency overall, and PTs will be sorted by decreasing frequency overall within SOC.

The summary of TEAEs by relationship to study drug (causality) table will include the number of subjects who experienced at least one TEAE, the number of subjects who experienced at least one TEAE within each relationship category (‘Unrelated’, ‘Possibly Related’, ‘Probably Related’ and ‘Related’) and the corresponding number of events for each category. In addition, the TEAE data will be summarized by SOC, preferred term within SOC, and relationship category within preferred term. SOC terms will be sorted by decreasing frequency overall, and PTs will be sorted by decreasing frequency overall within

SOC. Relationship category will be sorted from the least to the most likely relationship to study drug within preferred terms in the table.

The incidence of TEAEs leading to study drug withdrawal (MAD) will include the number of subjects who experienced at least one TEAE that lead to study drug withdrawal and the corresponding number of events, and furthermore summarize the TEAE data by SOC and preferred term within SOCs SOC terms will be sorted by decreasing frequency overall, and PTs will be sorted by decreasing frequency overall within SOC.

The incidence of TEAEs leading to study withdrawal will include the number of subjects who experienced at least one TEAE that lead to study withdrawal and the corresponding number of events, and furthermore summarize the TEAE data by SOC and preferred term within SOCs SOC terms will be sorted by decreasing frequency overall, and PTs will be sorted by decreasing frequency overall within SOC.

The listing of AEs will include all AE data in the clinical database. The listing will present all the information (fields) collected on the 'Adverse Event' eCRF, as well as the SOC and preferred terms obtained from the MedDRA dictionary. In addition, the AE (period) start and end days (relative to the study drug administration of the treatment group that the AE was assigned to) and a flag indicating whether the AE was treatment emergent will be presented. Non-TEAEs will not be assigned to any treatment. If the AE was ongoing at the end of the study, 'Ongoing' will be presented under the 'End Date Time/Study Day' heading. Partial dates/times will be presented as described in Section 5.1.4. The subsets of SAEs, treatment-related AEs, AEs leading to the withdrawal of study drug or withdrawal from the study will be listed separately and will include all the information presented in the main AE listing.

6.8.3 Laboratory Parameters

The laboratory parameters described in Section 4.1.3 will be summarized by study part, treatment group (Cohorts 1C, 1E and 1F) and for all subjects overall (excluding the food effect analysis)

The summary tables of hematology, coagulation, lipid profile and clinical chemistry results will present summary statistics for each laboratory parameter within the specific test panel. For each parameter, summaries will be presented for the baseline and each scheduled post-baseline visit. In addition, summaries will be presented for the change from baseline values at each scheduled post-baseline visit. Refer to Section 4.1.3 for the handling of character results.

The summary of hematology, coagulation, lipid profile and clinical chemistry shift tables will present summaries for the shifts in the result classifications ('Normal', ''Low', 'High') from the baseline to each of the scheduled post-baseline visit within each period for each parameter with a defined reference range, within the specific test panel.

The listings of hematology, coagulation, lipid profile and serum chemistry data will include all laboratory data (collected at scheduled and unscheduled visits) in the clinical database. The listings will present all the information (fields) that is available in the laboratory data set. In addition, the observation that was used as the baseline records (values) for each parameter will be flagged, the change from baseline value and the derived result classification (based on the normal ranges where applicable) at each post-baseline visit will be presented. A separate listing that includes only the subset of subjects that had at least one abnormal result will also be created for each test panel. All the subjects' results for every parameter where at least one abnormal classification was observed will be included.

The listing of urinalysis data will include all laboratory data (collected at scheduled and unscheduled visits) in the clinical database. The listings will present all the information (fields) that is available in the laboratory data set. In addition, the observation that was used as the baseline record (value) for each parameter will be flagged and the result classification (derived or based on the normal range where applicable) will be presented. The listing will include urine microscopy tests if performed.

The listings of serology, pregnancy results and FSH will include all available results (collected at scheduled and unscheduled visits) in the clinical database. The listing will present all the information (fields) that is available in the laboratory data set.

6.8.4 Vital Signs

The vital signs parameters described in Section 4.1.4 will be summarized and listed.

The summary table of vital signs results will present summary statistics for results at the baseline and each scheduled post-baseline visit for each parameter. In addition, summaries will be presented for the change from baseline values (baselines) at each scheduled post-baseline visit/time point.

The listings of vital signs results will include all data (collected at scheduled and unscheduled visits) in the clinical database. The observations that were used as the baseline records for each parameter will be flagged and the change from baseline values at each post-baseline visit will be presented.

6.8.5 12-lead ECG Evaluations

The 12-lead ECG parameters described in Section 4.1.5 will be summarized and listed.

The summary of ECG results tables will present summary statistics for results at the baseline and each scheduled post-baseline visit for each parameter. In addition, summaries will be presented for the change from baseline values (baselines) at each scheduled post-baseline visit/time point.

The summary of ECG overall assessment table will present summaries for the baseline and each scheduled post-baseline visit for the overall result (Normal, Abnormal not clinically significant and Abnormal clinically significant).

If multiple tracings are done as part of one assessment, the mean of the three tracings per parameter and the worst clinical interpretation per timepoint will be summarized for each subject. All values will be listed including the mean value per parameter and the worst clinical interpretation. Changes from baseline will be calculated based on the mean values of the triplicates where appropriate.

The listings of ECG results will include all data (collected at scheduled and unscheduled visits) in the clinical database. The observations that were used as the baseline records for each parameter will be flagged and the change from baseline values at each post-baseline visit will be presented.

6.8.6 Physical Examination

The physical examination assessment data described in Section 4.1.6 will be listed.

6.9 Pharmacokinetic Analyses

The PK analysis for this study fall outside the scope of the statistical analysis plan.

7. Changes to the Planned Analyses

7.1 Changes to the Analyses Described in the Study Protocol and Protocol Amendments

No changes were made to the analyses described in the study protocol.

7.2 Changes from the Statistical Analysis Plan Version 1.0 to Version 2.0

The protocol was updated from version 4.2 (dated 24 July 2024) to version 5.0 (dated 17 December 2024) with the following:

- Cohort 2E was added receive a dose of up to 1200mg dose.
- The dose levels for cohorts 2C and 2D (800 mg 1200 mg BID) were added.
- Clarifications were added for the timing of vital sign assessments and the timing of randomization.
- Updates to the statistics on SARS-CoV-2 in the introduction section.
- Minor grammatical and typographical changes were made.

7.3 Changes from the Statistical Analysis Plan Version 2.0 to Version 3.0

The protocol was updated from version 5.0 (dated 17 December 2024) to version 6.0 (dated 03 April 2025) with the following:

- Cohort 2F was added to receive a 1200mg dose given with a standard meal twice daily for 5 days.
- The dose level for cohort 2E was added (1200 mg).
- Clarifications were added for the timing of ECG assessments for cohorts 2D and 2E.
- Minor grammatical and typographical changes were made.

7.4 Changes from the Statistical Analysis Plan Version 3.0 to Version 4.0

Administrative update of treatment labels to more clearly differentiate between fasted and fed treatment groups. Update/removal of concomitant medication coding details (not required in the SAP).

7.5 Changes from the Statistical Analysis Plan Version 4.0 to Version 5.0

The Intent to treat analysis set wording is updated to reflect the inclusion of enrolled subjects for Cohort 1E. These subjects were not randomized to treatment.

For vital sign assessments, the overall vital signs interpretation was not captured on the eCRF and was therefore removed from the proposed vital signs analysis.

8. Attachments and Appendices

Attachment 1 List of Tables, Listings and Figures

Attachment 1 of the Statistical Analysis Plan

Tables, Listings, and Figures

Sponsor: Cocrystal Pharma Australia Pty Ltd.

Protocol Number: CDI-988-P1-001

A Phase 1, Randomized, Double-Blinded, Placebo-Controlled, First-in-Human Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single-Ascending and Multiple-Ascending Doses of Oral CDI-988 in Healthy Adult Participants

Version: Final Version 5.0, Amendment 4.0
Date: 2025-06-25

List of Tables, Listings and Figures

1 General Statistical Methods

Courier New will be used as font for all output produced in SAS®. The font size for all output will be 8p.

Results presented in table columns will be positioned as follows:

- Alphanumeric values will be left aligned.
- Integer numbers (e.g., counts) will be right aligned.
- Numbers containing fractional portions will be decimal aligned.

In all titles and analysis population names, coordinating conjunctions (and, or), articles (a, an, the) or prepositions will not be capitalized. All other words will be capitalized as well as the first and last words of the title or name.

The footnotes must make provision for the name of the SAS® program used to produce the output and the date and time that the output was created.

Words followed by a designator will be capitalized, for example, Day 1, Subject 3046, Day 10 etc.

Page numbers will be indicated as “Page x of y” at the bottom of each page.

Individual subject listings will be produced for all raw data and a selection of the derived data.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.1.1.1 Part 1 SAD: Summary of Analysis Sets (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 200 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 600 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	Pooled CDI-988 Fasted (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Number of Subjects Randomized	xx	xx	xx	xx	xx	xx	xx	xx
Intention-to-Treat Analysis Set								
Number of Subjects Included	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects Excluded	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Reasons for Exclusion 1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Safety Analysis Set								
Number of Subjects Included	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

SAD: Single-Ascending Dose.
The Intention-to-Treat analysis set is defined as the set of all randomized/enrolled subjects.
This safety analysis set will include all subjects from the ITT analysis set who received at least one dose of the study drug (CDI-988 or Placebo).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Percentage (%) of subjects (n) for the reason for exclusion categories are calculated based on the number of subjects that were excluded from the specific analysis population.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.1.1.2 Part 1 Food Effect: Summary of Analysis Sets (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 100 mg Fed (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	Pooled Placebo Fasted (N=xx) n (%)	Pooled Placebo Fed (N=xx) n (%)
Number of Subjects Randomized	xx	xx	xx	xx	xx	xx	xx	xx
Intention-to-Treat Analysis Set								
Number of Subjects Included	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects Excluded	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Reasons for Exclusion 1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Safety Analysis Set								
Number of Subjects Included	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

The Intention-to-Treat analysis set is defined as the set of all randomized/enrolled subjects.
This safety analysis set will include all subjects from the ITT analysis set who received at least one dose of the study drug (CDI-988 or Placebo).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Percentage (%) of subjects (n) for the reason for exclusion categories are calculated based on the number of subjects that were excluded from the specific analysis population.

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.1.1.3 Part 2 MAD: Summary of Analysis Sets (Intention-to-Treat Analysis Set)

	CDI-988 200 mg Fed (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 800 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	CDI-988 1200 mg BID Fed (N=xx) n (%)	CDI-988 1200 mg BID Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Number of Subjects Randomized	xx	xx	xx	xx	xx	xx	xx	xx	xx
Intention-to-Treat Analysis Set									
Number of Subjects Included	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects Excluded	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Reasons for Exclusion 1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Safety Analysis Set									
Number of Subjects Included	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
The Intention-to-Treat analysis set is defined as the set of all randomized/enrolled subjects.
This safety analysis set will include all subjects from the ITT analysis set who received at least one dose of the study drug (CDI-988 or Placebo).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Percentage (%) of subjects (n) for the reason for exclusion categories are calculated based on the number of subjects that were excluded from the specific analysis population.

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.1.2.1 Part 1 SAD: Summary of Subject Disposition (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 200 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 600 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Number of Subjects who Completed the Study per Protocol	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects who did not Complete the Study per Protocol	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Primary Reason for Early Study Discontinuation								
Adverse Event	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Death	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Subject Receive Excluded Therapy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Physician Decision	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Withdrawal of Consent	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Subject Lost to Follow-up	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Pregnancy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

SAD: Single-Ascending Dose.
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Percentages (%) of subjects (n) for the reason of early study termination categories are based on the number of subjects who early terminated the study.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. If a subject underwent eligibility assessments on Day 8/9, it will be assumed the subject completed the fasted period as planned. 'Missing' category should only be presented in the event of missing data.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.1.2.2 Food Effect: Summary of Subject Disposition (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 100 mg Fed (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	Pooled Placebo Fasted (N=xx) n (%)	Pooled Placebo Fed (N=xx) n (%)
Number of Subjects who Completed the Study per Protocol	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects who did not Complete the Study per Protocol	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Primary Reason for Early Study Discontinuation								
Adverse Event	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Death	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Subject Receive Excluded Therapy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Physician Decision	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Withdrawal of Consent	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Subject Lost to Follow-up	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Pregnancy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Percentages (%) of subjects (n) for the reason of early study termination categories are based on the number of subjects who early terminated the study.

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Programming Note:
If a subject underwent eligibility assessments on Day 8/9, it will be assumed the subject completed the fasted period as planned.
'Missing' category should only be presented in the event of missing data.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.1.2.3 Part 2 MAD: Summary of Subject Disposition (Intention-to-Treat Analysis Set)

	CDI-988 200 mg Fed (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 800 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	CDI-988 1200 mg BID Fed (N=xx) n (%)	CDI-988 1200 mg BID Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Number of Subjects who Completed the Study per Protocol	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Number of Subjects who did not Complete the Study per Protocol	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Primary Reason for Early Study									
Adverse Event	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Death	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Subject Receive Excluded Therapy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Physician Decision	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Withdrawal of Consent	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Subject Lost to Follow-up	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Pregnancy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Missing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Percentages (%) of subjects (n) for the reason of early study termination categories are based on the number of subjects who early terminated the study.

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Programming Note:
'Missing' category should only be presented in the event of missing data.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.2.1 Part 1 SAD: Summary of Protocol Deviations (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 200 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 600 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Number of Subjects With at Least One Protocol Deviation	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Minor Protocol Category	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Major Protocol Category	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

SAD: Single-Ascending Dose.
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.2.2 Part 1 Food Effect: Summary of Protocol Deviations (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 100 mg Fed (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	Pooled Placebo Fasted (N=xx) n (%)	Pooled Placebo Fed (N=xx) n (%)
Number of Subjects With at Least One Protocol Deviation	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Minor Protocol Category	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Major Protocol Category	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.2.3 Part 2 MAD: Summary of Protocol Deviations (Intention-to-Treat Analysis Set)

	CDI-988 200 mg Fed (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 800 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	CDI-988 1200 mg BID Fed (N=xx) n (%)	CDI-988 1200 mg BID Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Number of Subjects With at Least One Protocol Deviation	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%) xx (xx%)	xx (xx%) xx (xx%)	xx (xx%)
Minor Protocol Category	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Major Protocol Category	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
XXXXXXXXXXXXXXXXXXXXXXXX	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.3.1 Part 1 SAD: Summary of Demography (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 200 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 600 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Age (Years)	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx
Sex	xx	xx	xx	xx	xx	xx	xx	xx
Female	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
*Childbearing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Male	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Ethnicity								
Hispanic or Latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Hispanic or Latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Race								
Asian	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Black or African	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
White	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Native Hawaiian or Other Pacific Islander	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Reported	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Unknown	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
American Indian or Alaska Native	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

SAD: Single-Ascending Dose. SD: Standard deviation.

*Based on the number of female subjects.
Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programming Note: Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
For subjects in Cohorts 1C, 1E and 1F, the demography and baseline characteristics at Screening and Day 1 will be included for the fed groups if the subject is included in the fed ITT analysis set.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.3.2 Part 1 Food Effect: Summary of Demography (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 100 mg Fed (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	Pooled Placebo Fasted (N=xx) n (%)	Pooled Placebo Fed (N=xx) n (%)
Age (Years)	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx
Sex	xx	xx	xx	xx	xx	xx	xx	xx
Female	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
*Childbearing	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Male	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Ethnicity								
Hispanic or Latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Hispanic or Latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Race								
Asian	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Black or African	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
White	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Native Hawaiian or Other Pacific Islander	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Reported	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Unknown	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
American Indian or Alaska Native	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

*Based on the number of female subjects.

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.3.3 Part 2 MAD: Summary of Demography (Intention-to-Treat Analysis Set)

	CDI-988 200 mg Fed (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 800 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	CDI-988 1200 mg BID Fed (N=xx) n (%)	CDI-988 1200 mg BID Fasted (N=xx) n (%)	Pooled CDI-988 (N=xx) n (%)	Pooled Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
Age (Years)	xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx	xx
Sex	xx	xx	xx	xx	xx	xx	xx	xx	xx
Female	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
*Childbearing Potential	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Male	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Ethnicity									
Hispanic or Latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Hispanic or Latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Race									
Asian	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Black or African	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
White	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Native Hawaiian or Other Pacific Islander	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Not Reported	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Unknown	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
American Indian or	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation.
*Based on the number of female subjects.

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.4.1 Part 1 SAD: Summary of Subject Baseline Characteristics (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx)	CDI-988 200 mg Fasted (N=xx)	CDI-988 400 mg Fasted (N=xx)	CDI-988 600 mg Fasted (N=xx)	CDI-988 1200 mg Fasted (N=xx)	Pooled CDI-988 (N=xx)	Pooled Placebo (N=xx)	All Subjects (N=xx)
Height (cm) at Screening	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx
Body Weight (kg) at Screening	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx

SAD: Single-Ascending Dose. SD: Standard deviation.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.4.2 Part 1 Food Effect: Summary of Subject Baseline Characteristics (Intention-to-Treat Analysis Set)

	CDI-988 100 mg Fasted (N=xx)	CDI-988 100 mg Fed (N=xx)	CDI-988 400 mg Fasted (N=xx)	CDI-988 400 mg Fed (N=xx)	CDI-988 1200 mg Fasted (N=xx)	CDI-988 1200 mg Fed (N=xx)	Pooled Placebo Fasted (N=xx)	Pooled Placebo Fed (N=xx)
Height (cm) at Screening	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx
Body Weight (kg) at Screening	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx

SD: Standard deviation.

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.4.3 Part 2 MAD: Summary of Subject Baseline Characteristics (Intention-to-Treat Analysis Set)

	CDI-988 200 mg Fed (N=xx)	CDI-988 400 mg Fed (N=xx)	CDI-988 800 mg Fed (N=xx)	CDI-988 1200 mg Fed (N=xx)	CDI-988 1200 mg BID Fed (N=xx)	CDI-988 1200 mg BID Fasted (N=xx)	Pooled CDI-988 (N=xx)	Pooled Placebo (N=xx)	All Subjects (N=xx)
Height (cm) at Screening									
	xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx	xx
Body Weight (kg) at Screening									
	xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	xx	xx	xx	xx	xx	xx	xx	xx	xx
	xx	xx	xx	xx	xx	xx	xx	xx	xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation.

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.5.1 Part 1 SAD: Summary of Medical History (Intention-to-Treat Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Medical history terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.5.2 Part 1 Food Effect: Summary of Medical History (Intention-to-Treat Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%)	CDI-988 100 mg Fed (N=xx) n (%)	CDI-988 400 mg Fasted (N=xx) n (%)	CDI-988 400 mg Fed (N=xx) n (%)	CDI-988 1200 mg Fasted (N=xx) n (%)	CDI-988 1200 mg Fed (N=xx) n (%)	Pooled Placebo Fasted (N=xx) n (%)	Pooled Placebo Fed (N=xx) n (%)
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Medical history terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.5.3 Part 2 MAD: Summary of Medical History (Intention-to-Treat Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Medical history terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

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Protocol: CDI-988-P1-001

Table 14.1.6.1 Part 1 SAD: Summary of Concomitant Medications (Safety Analysis Set)

ATC Class Level 2 Preferred Name	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One Concomitant Medication	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
ATC Class Level 2 Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
ATC Class Level 2 Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of events (Concomitant Medications).
Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of study drug. Medications stopping on the same day as the first study drug administration will be considered as concomitant medications.
Sujects who used the same medication on multiple occasions are counted only once in the specific category (n), however each instance of the medication is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programming Note:
Do not include fasted cohorts from the food effect analysis as part of the above noted SAD analysis
Sort by ATC Class Level 2 names and medication preferred names alphabetically.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.6.2 Part 1 Food Effect: Summary of Concomitant Medications (Safety Analysis Set)

ATC Class Level 2 Preferred Name	CDI-988 100 mg Fasted/ Fed (N=xx) n (%) E	CDI-988 400 mg Fasted/ Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted/ Fed (N=xx) n (%) E	Pooled Placebo Fasted/ Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One Concomitant Medication	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
ATC Class Level 2 Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
ATC Class Level 2 Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of events (Concomitant Medications).
Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of study drug. Medications stopping on the same day as the first study drug administration will be considered as concomitant medications.
Sujects who used the same medication on multiple occasions are counted only once in the specific category (n), however each instance of the medication is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programming Note:
Sort by ATC Class Level 2 names and medication preferred names alphabetically.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.1.6.2 Part 2 MAD: Summary of Concomitant Medications (Safety Analysis Set)

ATC Class Level 2 Preferred Name	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One Concomitant Medication	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
ATC Class Level 2 Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
ATC Class Level 2 Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Name 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of events (Concomitant Medications).
Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of study drug. Medications stopping on the same day as the first study drug administration will be considered as concomitant medications.
Sujects who used the same medication on multiple occasions are counted only once in the specific category (n), however each instance of the medication is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programming Note:
Sort by ATC Class Level 2 names and medication preferred names alphabetically.

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Table 14.1.7.1 Part 1 SAD: Summary of Treatment Exposure (Safety Population)

		Study Drug Administered	
Treatment Group	n	Yes	No
CDI-988 100 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 200 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 400 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 600 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 1200 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
Pooled CDI-988 (N=xx)	xx	xx (xx%)	xx (xx%)
Pooled Placebo (N=xx)	xx	xx (xx%)	xx (xx%)
All Subjects (N=xx)	xx	xx (xx%)	xx (xx%)

SAD: Single-Ascending Dose.
Percentage (%) are based on the number of subjects (n) with assessments available at the visit.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

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Table 14.1.7.2 Part 1 Food Effect: Summary of Treatment Exposure (Safety Population)

		Study Drug Administered	
Treatment Group	n	Yes	No
CDI-988 100 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 100 mg Fed (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 400 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 400 mg Fed (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 1200 mg Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
CDI-988 1200 mg Fed (N=xx)	xx	xx (xx%)	xx (xx%)
Pooled Placebo Fasted (N=xx)	xx	xx (xx%)	xx (xx%)
Pooled Placebo Fed (N=xx)	xx	xx (xx%)	xx (xx%)

Percentage (%) are based on the number of subjects (n) with assessments available at the visit.

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Table 14.1.7.3 Part 2 MAD: Summary of Treatment Exposure (Safety Population)

Parameter (Unit) Visit Treatment Group	Statistics					
	n	Mean	SD	Median	Minimum	Maximum
Duration of Exposure (Days)						
CDI-988 200 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 400 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 800 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg BID Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg BID Fasted (Fed N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Pooled CDI-988 (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Pooled Placebo (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
All Subjects (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Total Amount of CDI-988 Administered (mg)						
Overall						
CDI-988 200 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 400 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 800 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg BID Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg BID Fasted (Fed N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Pooled CDI-988 (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Pooled Placebo (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
All Subjects (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation.
Duration of Exposure (Days) is calculated as the difference between the date of the last study drug administration and the date of the first study drug administration + 1 day.
The CDI-988 dosing amount is zero for the Pooled Placebo group. The Overall Total Amount of CDI-988 Administered (mg) is the sum of the daily amounts.

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Table 14.1.7.2 Part 2 MAD: Summary of Treatment Exposure (Safety Population)

Parameter (Unit) Visit Treatment Group	Statistics					
	n	Mean	SD	Median	Minimum	Maximum
Day 1						
CDI-988 200 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 400 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 800 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg BID Fed (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
CDI-988 1200 mg BID Fasted (Fed N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Pooled CDI-988(N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
Pooled Placebo (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
All Subjects (N=xx)	xx	xx.x	xx.xx	xx.x	xx	xx
…						
Day 2						
…	xx	xx.x	xx.xx	xx.x	xx	xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation.
Duration of Exposure (Days) is calculated as the difference between the date of the last study drug administration and the date of the first study drug administration + 1 day.
The CDI-988 dosing amount is zero for the Pooled Placebo group. The Overall Total Amount of CDI-988 Administered (mg) is the sum of the daily amounts.

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Table 14.3.1.1.1 Part 1 SAD: Summary of Overall Summary of Adverse Events (Safety Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One								
TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Serious TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe/ Grade 4/ Life-threatening TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-Related TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
TEAE leading to Study Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Severe/ Life-threatening adverse events are defined as adverse events where the event severity is reported as 'Severe/ Life-threatening'.
Treatment-related adverse events are defined as adverse events where the relationship to study drug is reported as 'Possibly Related', 'Probably Related' and 'Related' or is missing.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentages (%) are calculated based on the number of subjects in the analysis set (N).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

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Table 14.3.1.1.2 Part 1 Food Effect: Summary of Overall Summary of Adverse Events (Safety Analysis Set)

	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One									
TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Serious TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe/ Grade 4/ Life-threatening TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-Related TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
TEAE leading to Study Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Severe/ Life-threatening adverse events are defined as adverse events where the event severity is reported as 'Severe/ Life-threatening'.
Treatment-related adverse events are defined as adverse events where the relationship to study drug is reported as 'Possibly Related', 'Probably Related' and 'Related' or is missing.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentages (%) are calculated based on the number of subjects in the analysis set (N).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.1.3 Part 2 MAD: Summary of Overall Summary of Adverse Events (Safety Analysis Set)

	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One									
TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Serious TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe/ Grade 4/ Life-threatening TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-Related TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
TEAE leading to Study Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
TEAE leading to Study Drug Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Grade 3/Severe/ Grade 4/Life-threatening adverse events are defined as adverse events where the event severity is reported as 'Severe/ Life-threatening'.
Treatment-related adverse events are defined as adverse events where the relationship to study drug is reported as 'Possibly Related', 'Probably Related' and 'Related' or is missing.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Treatment-emergent adverse events leading to study drug withdrawal are defined as adverse events where 'Action Taken' is reported as 'Drug withdrawn'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentages (%) are calculated based on the number of subjects in the analysis set (N).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

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Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.2.1 Part 1 SAD: Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.2.2 Part 1 Food Effect: Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.2.3 Part 2 MAD: Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.3.1 Part 1 SAD: Summary of Treatment-Emergent Adverse Events by Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.3.2 Part 1 Food Effect: Summary of Treatment-Emergent Adverse Events by Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.3.3 Part 2 MAD: Summary of Treatment-Emergent Adverse Events by Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.4.1 Part 1 SAD: Summary of Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One Serious TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.4.2 Part 2 Food Effect: Summary of Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One Serious TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.4.3 Part 2 MAD: Summary of Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One Serious TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.5.1 Part 1 SAD: Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity Rating
(Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 4/ Life-threatening	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 4/ Life-threatening	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 4/ Life-threatening	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose, n: Number of subjects, TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.5.2 Part 1 Food Effect: Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity Rating (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 4/ Life-	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 4/ Life-	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Grade 4/ Life-	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.5.3 Part 2 MAD: Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity Rating
(Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 4/ Life-threatening	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 4/ Life-threatening	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 1/ Mild	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 2/ Moderate	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 3/ Severe	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Grade 4/ Life-threatening	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.6.1 Part 1 SAD: Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship to Study Drug (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT) Relationship to Study Drug	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Possibly Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Probably Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Possibly Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Probably Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
…								

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-related adverse events are defined as adverse events where the relationship to study drug is reported as 'Possibly Related', 'Probably Related' and 'Related' or is missing.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.6.2 Part 1 Food Effect: Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship to Study Drug (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT) Relationship to Study Drug	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Possibly	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Probably	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Possibly	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Probably	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
…									

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-related adverse events are defined as adverse events where the relationship to study drug is reported as 'Possibly Related', 'Probably Related' and 'Related' or is missing.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.6.3 Part 2 MAD: Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship to Study Drug (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT) Relationship to Study Drug	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Possibly Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Probably Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
		xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx			
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Possibly Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Probably Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
		xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx			
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Unrelated	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Treatment-related	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
…									

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-related adverse events are defined as adverse events where the relationship to study drug is reported as 'Possibly Related', 'Probably Related' and 'Related' or is missing. Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E).
Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.

If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ‘ (Continued)’ appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.7.1 Part 1 SAD: Summary of Treatment-Emergent Adverse Events Leading to Study Withdrawal by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 200 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 600 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE Leading to Study Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

SAD: Single-Ascending Dose. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.7.2 Part 1 Food Effect: Summary of Treatment-Emergent Adverse Events Leading to Study Withdrawal by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 100 mg Fasted (N=xx) n (%) E	CDI-988 100 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fasted (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fasted (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	Pooled Placebo Fasted (N=xx) n (%) E	Pooled Placebo Fed (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE Leading to Study Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.7.3 Part 2 MAD: Summary of Treatment-Emergent Adverse Events Leading to Study Withdrawal by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg Fed (N=xx) n (%) E	CDI-988 400 mg Fed (N=xx) n (%) E	CDI-988 800 mg Fed (N=xx) n (%) E	CDI-988 1200 mg Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	CDI-988 1200 mg BID Fasted (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE Leading to Study Withdrawal	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse event.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).
Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.1.8.3 Part 2 MAD: Summary of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by System Organ Class and Preferred Term (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	CDI-988 200 mg (N=xx) n (%) E	CDI-988 400 mg (N=xx) n (%) E	CDI-988 800 mg (N=xx) n (%) E	CDI-988 1200 mg (N=xx) n (%) E	CDI-988 1200 mg BID (N=xx) n (%) E	CDI-988 1200 mg BID Fed (N=xx) n (%) E	Pooled CDI-988 (N=xx) n (%) E	Pooled Placebo (N=xx) n (%) E	All Subjects (N=xx) n (%) E
Subjects with at Least One TEAE Leading to	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx
System Organ Class 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
System Organ Class 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 1	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 2	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 3	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)
Preferred Term 4	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%) xx	xx (xx%)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. n: Number of subjects. E: Number of adverse events. TEAE: Treatment-emergent adverse
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study drug withdrawal are defined as adverse events where 'Action Taken' is reported as 'Drug withdrawn'.
Subjects who experienced multiple events within a category are counted only once in the specific category (n), however each instance of the event is counted (E). Percentage (%) of subjects (n) in each category are calculated based on the number of subjects in the analysis set (N).

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programming Note:
Results will be sorted by decreasing frequency of the SOC and PT terms for the overall group.
If PT terms within a SOC wraps onto a second page, the SOC term will be repeated on the second page with ' (Continued)' appended to the term.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.1.1 Part 1 SAD: Serious Adverse Events (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE Reason	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Life-threatening	Grade 1/ Mild	Unrelated/ Expected	-	None
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	Disability/ Incapacity	Grade 3/ Severe	Related/ Expected	Dose not Changed	None

SAD: Single-Ascending Dose, AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event.
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Only serious adverse events are presented.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Non-TEAEs will not be assigned to any treatment.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.1.2 Part 1 Food Effect: Serious Adverse Events (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Subject Number: xxx-xxx
Food Effect: Fasted (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE Reason	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Life-threatening	Grade 1/ Mild	Unrelated/ Expected	-	None
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	Disability/ Incapacity	Grade 3/ Severe	Related/ Expected	Dose not Changed	None

SAD: Single-Ascending Dose, AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event.
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Only serious adverse events are presented.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific treatment group and repeat for all treatment groups: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed, and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Non-TEAEs will not be assigned to any treatment.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.1.3 Part 2 MAD: Serious Adverse Events (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	One Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE Reason	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Life-threatening	Grade 1/ Mild	Unrelated/ Expected	-	None
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	Disability/ Incapacity	Grade 3/ Severe	Related/ Expected	Dose not Changed	None

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event. -: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Only serious adverse events are presented.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Non-TEAEs will not be assigned to any treatment.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.2.1 Part 1 SAD: Adverse Events Leading to Study Withdrawal (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

SAD: Single-Ascending Dose, AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event.
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.2.2 Part 1 Food Effect: Adverse Events Leading to Study Withdrawal (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Subject Number: xxx-xxx
Food Effect: Fasted (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

SAD: Single-Ascending Dose, AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event.
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific treatment group and repeat for all treatment groups: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed, and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Non-TEAEs will not be assigned to any treatment.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.2.3 Part 2 MAD: Adverse Events Leading to Study Withdrawal (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event. -: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent adverse events leading to study withdrawal are defined as adverse events where 'Other Action Taken' is reported as 'Withdrawn from study'.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.2.3.3 Part 2 MAD: Adverse Events Leading to Study Drug Withdrawal (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event. -: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Treatment-emergent Adverse events leading to study drug withdrawal (MAD) are defined as AEs where action taken is reported as 'Drug Withdrawn'.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.1.1.1 Part 1 SAD: Summary of Hematology Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 400 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SAD: Single-Ascending Dose. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters.
Start each new parameter on a new page.

Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.1.1.2 Part 1 Food Effect: Summary of Hematology Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[2]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 100 mg Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Pooled Placebo Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SD: Standard deviation. - : Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.1.1.3 Part 2 MAD: Summary of Hematology Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 200 mg Fed (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 5	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 12/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.1.2.1 Part 1 SAD: Summary of Shifts from Baseline in Hematology Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects(N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

SAD: Single-Ascending Dose.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note: Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters. Start each new parameter on a new page. Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.1.2.2 Part 1 Food Effect: Summary of Shifts from Baseline in Hematology Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[2] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pooled Placebo Fed(N=xx)					
Day 9	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.1.2.3 Part 2 MAD: Summary of Shifts from Baseline in Hematology Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 200 mg Fed (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 3: Pre-dose	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					
Day 17/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note: Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters. Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.1.3.1 Part 1 SAD: Individual Abnormal Hematology Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.1.3.2 Part 1 Food Effect: Individual Abnormal Hematology Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.1.3.3 Part 2 MAD: Individual Abnormal Hematology Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3: Pre-dose	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3: Pred-dose	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Present ‘Early Termination’ or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.2.1.1 Part 1 SAD: Summary of Coagulation Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 400 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SAD: Single-Ascending Dose. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters.
Start each new parameter on a new page.

Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.2.1.2 Part 1 Food Effect: Summary of Coagulation Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[2]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 100 mg Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Pooled Placebo Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SD: Standard deviation. - : Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.2.1.3 Part 2 MAD: Summary of Coagulation Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 200 mg Fed (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 5	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 12/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.2.2.1 Part 1 SAD: Summary of Shifts from Baseline in Coagulation Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects(N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

SAD: Single-Ascending Dose.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note: Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters. Start each new parameter on a new page. Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.2.2.2 Part 1 Food Effect: Summary of Shifts from Baseline in Coagulation Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[2] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pooled Placebo Fed(N=xx)					
Day 9	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.2.2.3 Part 2 MAD: Summary of Shifts from Baseline in Coagulation Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 200 mg Fed (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 3: Pre-dose	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					
Day 17/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note: Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.2.3.1 Part 1 SAD: Individual Abnormal Coagulation Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.2.3.2 Part 1 Food Effect: Individual Abnormal Coagulation Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.2.3.3 Part 2 MAD: Individual Abnormal Coagulation Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3: Pre-dose	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3: Pre-dose	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.3.1.1 Part 1 SAD: Summary of Clinical Chemistry Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 400 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SAD: Single-Ascending Dose. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters.
Start each new parameter on a new page.

Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.3.1.2 Part 1 Food Effect: Summary of Clinical Chemistry Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[2]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 100 mg Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Pooled Placebo Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SD: Standard deviation. - : Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.3.1.3 Part 2 MAD: Summary of Clinical Chemistry Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 200 mg Fed (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 5	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 12/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.3.2.1 Part 1 SAD: Summary of Shifts from Baseline in Clinical Chemistry Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects(N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

SAD: Single-Ascending Dose.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note: Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters). Start each new parameter on a new page. Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.3.2.2 Part 1 Food Effect: Summary of Shifts from Baseline in Clinical Chemistry Laboratory Range Indicator Categories
(Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[2] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pooled Placebo Fed(N=xx)					
Day 9	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters. Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.3.2.3 Part 2 MAD: Summary of Shifts from Baseline in Clinical Chemistry Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 200 mg Fed (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 3: Pre-dose	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…					
Day 17/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects (N=xx)					
Day 1	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note: Repeat for all treatment groups (CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects) and all parameters. Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.3.3.1 Part 1 SAD: Individual Abnormal Clinical Chemistry Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.3.3.2 Part 1 Food Effect: Individual Abnormal Clinical Chemistry Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.3.3.3 Part 2 MAD: Individual Abnormal Clinical Chemistry Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3: Pre-dose	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3: Pre-dose	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.4.1.1 Part 1 SAD: Summary of Lipid Profile Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 400 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SAD: Single-Ascending Dose. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters.
Start each new parameter on a new page.
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.4.1.2 Part 1 Food Effect: Summary of Lipid Profile Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[2]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
CDI-988 100 mg Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Pooled Placebo Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 16/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

SD: Standard deviation. - : Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.4.1.3 Part 2 MAD: Summary of Lipid Profile Results (Safety Analysis Set)

Parameter (Unit)

Treatment Group / Visit	Actual Values						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 200 mg Fed (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 10: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 5: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 10: Pre-dose	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 12/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page.
Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.4.2.1 Part 1 SAD: Summary of Shifts from Baseline in Lipid Profile Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects(N=xx)					
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

SAD: Single-Ascending Dose.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note: Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters. Start each new parameter on a new page. Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.4.2.2 Part 1 Food Effect: Summary of Shifts from Baseline in Lipid Profile Laboratory Range Indicator Categories
(Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[2] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 100 mg Fasted (N=xx)					
Day 2	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 8/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pooled Placebo Fed(N=xx)					
Day 10	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters. Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.4.4.2.3 Part 2 MAD: Summary of Shifts from Baseline in Lipid Profile Laboratory Range Indicator Categories (Safety Analysis Set)

Parameter (Unit)

Treatment Group Post-Baseline Visit	Post-Baseline Range Indicator	Baseline[1] Range Indicator Low n (%)	 Normal n (%)	 High n (%)	 Total n (%)
CDI-988 200 mg Fed (N=xx)					
Day 10: Pre-dose	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 17/ Early Termination	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
All Subjects (N=xx)					
Day 5: Pre-dose	Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Range Indicators (result classifications) are based on the laboratory defined normal ranges for the specific parameter.
Percentage (%) are based on the number of subjects (n) in the analysis set (N) with assessments available at baseline and the relevant post-baseline visit.
Only parameters with a defined reference range are included in the table.

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Programmer note: Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page. Present results in the order presented in Table 2 in the SAP.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.4.3.1 Part 1 SAD: Individual Abnormal Lipid Profile Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.4.3.2 Part 1 Food Effect: Individual Abnormal Lipid Profile Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 15	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 14.3.4.4.3.3 Part 2 MAD: Individual Abnormal Lipid Profile Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Include all records for each parameter where at least one abnormal result was observed for the specific parameter.
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.5.1.1 Part 1 SAD: Summary of Vital Signs Results (Safety Analysis Set)

Parameter (Unit)

	Actual Values						Change from Baseline[1]					
Treatment Group Visit: Time Point	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 1: 4 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												

SAD: Single-Ascending Dose. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters.
Start each new parameter on a new page.
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

Present the results in the following order:

- SBP.
- DBP.
- Heart Rate.
- Respiratory Rate.
- Body Temperature.
- Height.
- Body Weight.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.5.1.2 Part 1 Food Effect: Summary of Vital Signs Results (Safety Analysis Set)

Parameter (Unit)

	Actual Values						Change from Baseline[2]					
Treatment Group Visit: Time Point	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 1: 4 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Pooled Placebo Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												

SD: Standard deviation. - : Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page.

Present the results in the following order:

- SBP.
- DBP.
- Heart Rate.
- Respiratory Rate.
- Body Temperature.
- Height.
- Body Weight.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.5.1.3 Part 2 MAD: Summary of Vital Signs Results (Safety Analysis Set)

Parameter (Unit)

	Actual Values						Change from Baseline[1]					
Treatment Group Visit: Time Point	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 200 mg Fed (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 1: 4 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Day 17/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page.

Present the results in the following order:

- SBP.
- DBP.
- Heart Rate.
- Respiratory Rate.
- Temperature.
- Height.
- Body Weight.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.6.1.1 Part 1 SAD: Summary of 12-Lead ECG Overall Assessment (Safety Analysis Set)

Treatment Group Visit: Time Point		Overall Interpretation		
	n	Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)
CDI-988 100 mg Fasted (N=xx)				
Baseline[1]	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 2 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 4 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 2	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 3	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 8/ Early Termination	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…				
All Subjects (N=xx)				
Baseline[1]				
Day 1: 2 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 4 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…				

SAD: Single-Ascending Dose. CS: Clinically Significant. NCS: Not Clinically Significant.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Percentage (%) are based on the number of subjects (n) with assessments available at the relevant post-baseline visit.
Where triplicate measurements were taken, summaries were based on the worst overall interpretation of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters.
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.6.1.2 Part 1 Food Effect: Summary of 12-Lead ECG Overall Assessment (Safety Analysis Set)

Treatment Group Visit: Time Point		Overall Interpretation		
	n	Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)
CDI-988 100 mg Fasted (N=xx)				
Baseline[2]	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 2 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 4 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 2	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 3	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 8/ Early Termination	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…				
Pooled Placebo Fed (N=xx)				
Baseline[2]				
Day 9: 2 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…				

CS: Clinically Significant. NCS: Not Clinically Significant.
[2] The baseline value is defined as the last available valid assessment collected prior to study drug administration in that period.
Percentage (%) are based on the number of subjects (n) with assessments available at the relevant post-baseline visit.
Where triplicate measurements were taken, summaries were based on the worst overall interpretation of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.6.1.3 Part 2 MAD: Summary of 12-Lead ECG Overall Assessment (Safety Analysis Set)

		Overall Interpretation		
Treatment Group Visit: Time Point	n	Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)
CDI-988 200 mg Fed (N=xx)				
Baseline[1]	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 2 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 4 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 2	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 3	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 10	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…				
All Subjects (N=xx)				
Baseline[1]	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Day 1: 2 hours	xx	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
…				

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. CS: Clinically Significant. NCS: Not Clinically Significant.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Percentage (%) are based on the number of subjects (n) with assessments available at the relevant post-baseline visit.
Where triplicate measurements were taken, summaries were based on the worst overall interpretation of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.6.2.1 Part 1 SAD: Summary of 12-Lead ECG Results (Safety Analysis Set)

Parameter (Unit)

	Actual Values						Change from Baseline[1]					
Treatment Group Visit: Time Point	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 1: 4 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												

SAD: Single-Ascending Dose. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Where triplicate measurements were taken, summaries were based on the mean of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 200 mg Fasted, CDI-988 400 mg Fasted, CDI-988 600 mg Fasted, CDI-988 1200 mg Fasted, Pooled CDI-988, Pooled Placebo and All Subjects and all parameters).
Start each new parameter on a new page.
Include the fasted cohorts from the food effect analysis as part of the above noted SAD analysis.

Present the results in the following order:

- Heart Rate.
- PR Interval.
- QRS Duration.
- QT Interval.
- QTcF Interval.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.6.2.2 Part 1 Food Effect: Summary of 12-Lead ECG Results (Safety Analysis Set)

Parameter (Unit)

	Actual Values						Change from Baseline[2]					
Treatment Group Visit: Time Point	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 100 mg Fasted (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 1: 4 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 8/ Early Termination	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Pooled Placebo Fed (N=xx)												
Baseline[2]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 9: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												

SD: Standard deviation. - : Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to study drug administration in that period. Where triplicate measurements were taken, summaries were based on the mean of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups: CDI-988 100 mg Fasted, CDI-988 100 mg Fed, CDI-988 400 mg Fasted, CDI-988 400 mg Fed, CDI-988 1200 mg Fasted, CDI-988 1200 mg Fed, Pooled Placebo Fasted, Pooled Placebo Fed and all parameters.
Start each new parameter on a new page.

Present the results in the following order:

- Heart Rate.
- PR Interval.
- QRS Duration.
- QT Interval.
- QTcF Interval.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Table 14.3.6.2.3 Part 2 MAD: Summary of 12-Lead ECG Results (Safety Analysis Set)

Parameter (Unit)

	Actual Values						Change from Baseline[1]					
Treatment Group Visit: Time Point	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
CDI-988 200 mg Fed (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 1: 4 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
Day 3	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
Day 10	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												
All Subjects (N=xx)												
Baseline[1]	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	-					
Day 1: 2 hours	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xxx	xx.xx	xx.x	xx.x
…												

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. SD: Standard deviation. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Where triplicate measurements were taken, summaries were based on the mean of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups: CDI-988 200 mg Fed, CDI-988 400 mg Fed, CDI-988 800 mg Fed, CDI-988 1200 mg Fed, CDI-988 1200 mg BID Fasted, CDI-988 1200 mg BID Fed, Pooled CDI-988, Pooled Placebo, All Subjects and all parameters.
Start each new parameter on a new page.

Present the results in the following order:

- Heart Rate.
- PR Interval.
- QRS Duration.
- QT Interval.
- QTcB Interval.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.1.1.1 Part 1 SAD: Analysis Sets (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Analysis Set	Included in Analysis Set	Reason if Excluded from Analysis set
xxx-xxx	Intention-to-Treat Analysis Set	Yes	
	Safety Analysis Set	Yes	
xxx-xxx	Intention-to-Treat Analysis Set	Yes	
	Safety Analysis Set	Yes	
…			

SAD: Single-Ascending Dose.
The Intention-to-Treat analysis set is defined as the set of all randomized/enrolled subjects.
This safety analysis set will include all subjects from the Intention-to-Treat analysis set who received at least one dose of the study drug (CDI-988 or Placebo).

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.1.1.2 Part 1 Food Effect: Analysis Sets (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted

Subject Number	Food Effect	Analysis Set	Included in Analysis Set	Reason if Excluded from Analysis set
xxx-xxx	Fasted	Intention-to-Treat Analysis Set	Yes	
		Safety Analysis Set	Yes	
	Fed	Intention-to-Treat Analysis Set	Yes	
		Safety Analysis Set	Yes	

…

The Intention-to-Treat analysis set is defined as the set of all randomized/enrolled subjects.
This safety analysis set will include all subjects from the Intention-to-Treat analysis set who received at least one dose of the study drug (CDI-988 or Placebo).

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.1.1.3 Part 2 MAD: Analysis Sets (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Analysis Set	Included in Analysis Set	Reason if Excluded from Analysis set
xxx-xxx	Intention-to-Treat Analysis Set	Yes	
	Safety Analysis Set	Yes	
xxx-xxx	Intention-to-Treat Analysis Set	Yes	
	Safety Analysis Set	Yes	
…			

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
The Intention-to-Treat analysis set is defined as the set of all randomized/enrolled subjects.
This safety analysis set will include all subjects from the Intention-to-Treat analysis set who received at least one dose of the study drug (CDI-988 or Placebo).

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.1.2.1 Part 1 SAD: Subject Disposition (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Date Time of Informed Consent/ Reconsent	Date Time of Study Drug Administration	Date of Last Contact/ Study Day	Subject Completed the Study
xxx-xxx	YYYY-MM-DD HH:MM (version X dated YYYY-MM-DD)/ YYYY-MM-DD HH:MM (version x dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Yes
xxx-xxx	YYYY-MM-DD HH:MM (version X dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	No – Death
xxx-xxx	YYYY-MM-DD HH:MM (version X dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Other - *Description*
xxx-xxx	YYYY-MM-DD HH:MM (version X dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Yes

SAD: Single-Ascending Dose;
Study days are calculated relative to the date of the study drug administration.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
When referring to AEs, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.1.2.2 Part 1 Food Effect: Subject Disposition (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted

Subject Number	Food Effect	Date Time of Informed Consent/ Reconsent	Date Time of Study Drug Administration	Date of Last Contact/ Study Day	Subject Completed the Study
xxx-xxx	Fasted	YYYY-MM-DD HH:MM (version X dated YYYY-MM-DD)/ YYYY-MM-DD HH:MM (version x dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Yes
	Fed	YYYY-MM-DD HH:MM (version X dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	No – Death
xxx-xxx	Fasted	YYYY-MM-DD HH:MM (version x dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Yes
	Fed	YYYY-MM-DD HH:MM (version x dated YYYY-MM-DD)	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Other - *Description*

Study days are calculated relative to the date of the study drug administration.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
When referring to AEs, present the preferred term (PT) in the listing.
If a subject received the fed dosing, it will be assumed the subject completed the fasted period as planned.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.1.2.3 Part 2 MAD: Subject Disposition (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Date of Informed Consent/ Reconsent	Signature Date of Informed Consent	Date Time of First Study Drug Administration	Date Time of Last Study Drug Administration	Date of Last Contact/ Study Day	Subject Completed the Study
xxx-xxx	YYYY-MM-DD (version X dated YYYY-MM-DD)/ YYYY-MM-DD (version x dated YYYY-MM-DD)	YYYY-MM-DD	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Yes
xxx-xxx	YYYY-MM-DD (version X dated YYYY-MM-DD)/ YYYY-MM-DD (version x dated YYYY-MM-DD))	YYYY-MM-DD	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	No - Death
xxx-xxx	YYYY-MM-DD (version X dated YYYY-MM-DD)/ YYYY-MM-DD (version x dated YYYY-MM-DD)	YYYY-MM-DD	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Other - *Description*
xxx-xxx	YYYY-MM-DD (version X dated YYYY-MM-DD)/ YYYY-MM-DD (version x dated YYYY-MM-DD)	YYYY-MM-DD	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	YYYY-MM-DD/ XX	Yes

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.
Study days are calculated relative to the date of the study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
When referring to AEs, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.2.1.1 Part 1 SAD: Protocol Deviations (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted
Severity: Major

Subject Number	Date of Deviation	Visit	Deviation Number	Deviation Category	Assessment Reference	Deviation Description
xxx-xxx	YYYY-MM-DD	Day 2	x	Missed Procedures/ Assessments	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
		Day 3	x	Missed Visit	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
				XXXXXXXXXXXXXXXXXX	Informed Consent	XXXXXXXXXXXXXXXXXXXXXXXXXX

SAD: Single-Ascending Dose.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.2.1.2 Part 1 Food Effect: Protocol Deviations (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted
Severity: Major

Subject Number	Food Effect	Date of Deviation	Visit	Deviation Number	Deviation Category	Assessment Reference	Deviation Description
xxx-xxx	Fasted	YYYY-MM-DD	Day 2	x	Missed Procedures/ Assessments	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
			Day 3	x	Missed Visit	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
					XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
					XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXX
					XXXXXXXXXXXXXXXXXX	Informed Consent	XXXXXXXXXXXXXXXXXXXXXXXXXX

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.2.1.3 Part 2 MAD: Protocol Deviations (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Severity: Major

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.2.2.1 Part 1 SAD: Subject Eligibility (All Subjects Screened)

Screening Failures

Subject Number	Visit	Version Date and Number of Protocol used for Evaluation	Inclusion / Exclusion Evaluation Date	Did the Subject Meet All Eligibility Criteria	Category Failed (Inclusion/ Exclusion)	Inclusion Criterion not met/ Exclusion Criterion met
xxx-xxx	Screening	CDI-988-P1-001, 05-July-2023, V2.0	YYYY-MM-DD	No	Inclusion and Exclusion	Exclusion: xx, xx; Inclusion xx, xx
	Day -1	CDI-988-P1-001, 29-January-2024, V3.1	YYYY-MM-DD	No	Inclusion and Exclusion	Exclusion: xx, xx; Inclusion xx, xx

SAD: Single-Ascending Dose.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.2.2.2 Part 1 Food Effect: Subject Eligibility (All Subjects Screened)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Food Effect	Visit	Version Date and Number of Protocol used for Evaluation	Inclusion / Exclusion Evaluation Date	Did the Subject Meet All Eligibility Criteria	Category Failed (Inclusion/ Exclusion)	Inclusion Criterion not met/ Exclusion Criterion met
xxx-xxx	Fasted	Screening	CDI-988-P1-001, 05-July-2023, V2.0	YYYY-MM-DD	No	Inclusion and Exclusion	Exclusion: xx, xx; Inclusion xx, xx
		Day -1	CDI-988-P1-001, 05-July-2023, V2.0	YYYY-MM-DD	No	Inclusion and Exclusion	Exclusion: xx, xx; Inclusion xx, xx
	Fed	Day 8	CDI-988-P1-001, 05-July-2023, V2.0	YYYY-MM-DD	No	Inclusion and Exclusion	Exclusion: xx, xx; Inclusion xx, xx
		Day 9	CDI-988-P1-001, 05-July-2023, V2.0	YYYY-MM-DD	No	Inclusion and Exclusion	Exclusion: xx, xx; Inclusion xx, xx

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.2.2.2 Part 2 MAD: Subject Eligibility (All Subjects Screened)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.3.1 Part 1 SAD: Randomization (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Date of Randomization	Randomization Number	Replacement Subject	Replacement Randomization Number	Randomized/ Actual Treatment
xxx-xxx	YYYY-MM-DD	xxxxxxxx	No	-	CDI-988 100 mg/ CDI-988 100 mg
xxx-xxx	YYYY-MM-DD	xxxxxxxx	Yes	xxxxxxxx	CDI-988 100 mg/ CDI-988 100 mg

SAD: Single-Ascending Dose.
- : Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.3.2 Part 1 Food Effect: Randomization (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Date of Randomization	Randomization Number	Replacement Subject	Replacement Randomization Number	Randomized/ Actual Treatment
xxx-xxx	YYYY-MM-DD	xxxxxxxx	No	-	CDI-988 100 mg/ CDI-988 100 mg
xxx-xxx	YYYY-MM-DD	xxxxxxxx	Yes	xxxxxxxx	CDI-988 100 mg/ CDI-988 100 mg

- : Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.3.3 Part 2 MAD: Randomization (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.1.1 Part 1 SAD: Demography (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Date of Informed Consent/ Reconsent	Year of Birth	Age (Years)	Sex	Childbearing Potential	Ethnicity	Race
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY	xx	Female	Yes	Hispanic or Latino	White
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY	xx	Male	-	Hispanic or Latino	Other - XXXXXXXXXXXXXXXXXXX
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY	xx	Male	-	Non-Hispanic or Non-Latino	Asian

SAD: Single-Ascending Dose. -: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.1.2 Part 1 Food Effect: Demography (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Date of Informed Consent/ Reconsent	Year of Birth	Age (Years)	Sex	Childbearing Potential	Ethnicity	Race
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY	xx	Female	Yes	Hispanic or Latino	White
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY	xx	Male	-	Hispanic or Latino	Other - XXXXXXXXXXXXXXXXXXX
xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	YYYY	xx	Male	-	Non-Hispanic or Non-Latino	Asian

-: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.1.3 Part 2 MAD: Demography (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.2.1 Part 1 SAD: Medical and Surgical History (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	MH No.	Body System	System Organ Class/ Preferred Term/ Medical Condition or Surgery	Diagnosis Date/ Study Day	Resolution Date / Study Day	Ongoing
xxx-xxx	1	Cardiovascular	XXXXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD/ -XXX	YYYY-MM	No
	2	Gastrointestinal/ Hepatobiliary	XXXXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD/ -XXX	YYYY-MM-DD/ -XXX	No
	3	Musculoskeletal	XXXXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD/ -XXX		Yes

SAD: Single-Ascending Dose.
Study days are calculated relative to the date of the first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Sort terms by start and end date, then alphabetically within subject.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.2.2 Part 1 Food Effect: Medical and Surgical History (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	MH No.	Body System	System Organ Class/ Preferred Term/ Medical Condition or Surgery	Diagnosis Date/ Study Day	Resolution Date / Study Day	Ongoing
xxx-xxx	1	Cardiovascular	XXXXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD/ -XXX	YYYY-MM	No
	2	Gastrointestinal/ Hepatobiliary	XXXXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD/ -XXX	YYYY-MM-DD/ -XXX	No
	3	Musculoskeletal	XXXXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD/ -XXX		Yes

Study days are calculated relative to the date of the first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.
Sort terms by start and end date, then alphabetically within subject.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.2.3 Part 2 MAD: Medical and Surgical History (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed,
Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Sort terms by start and end date, then alphabetically within subject.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.3.1 Part 1 SAD: Alcohol Breath Test Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Test Performed	Sample Collection Date	Result
xxx-xxx	Screening	Yes	YYYY-MM-DD	Negative
	Day -1	Yes	YYYY-MM-DD	Negative
xxx-xxx	Screening	Yes	YYYY-MM-DD	Negative
	Day -1	Yes	YYYY-MM-DD	Negative

SAD: Single-Ascending Dose.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.3.2 Part 1 Food Effect: Alcohol Breath Test Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Food Effect	Visit	Test Performed	Sample Collection Date	Result
xxx-xxx	Fasted	Screening	Yes	YYYY-MM-DD	Negative
		Day -1	Yes	YYYY-MM-DD	Negative
	Fed	Day 8	Yes	YYYY-MM-DD	Negative

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.3.3 Part 2 MAD: Alcohol Breath Test Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.4.1 Part 1 SAD: Urine Drug Test Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Sample Collection Date Time	Urine Test Results	Drugs Tested Positive
xxx-xxx	Screening	YYYY-MM-DD	Positive	Amphetamines Barbiturates Benzodiazepines
	Day -1	YYYY-MM-DD	Negative	-

SAD: Single-Ascending Dose. -: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.4.2 Part 1 Food Effect: Urine Drug Test Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Food Effect	Visit	Sample Collection Date Time	Urine Test Results	Drugs Tested Positive
xxx-xxx	Fasted	Screening	YYYY-MM-DD	Positive	Amphetamines Barbiturates Benzodiazepines
		Day -1	YYYY-MM-DD	Negative	-
	Fed	Day 8	YYYY-MM-DD	Negative	-

-: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.4.3 Part 2 MAD: Urine Drug Test Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.5.1 Part 1 SAD: Serology Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Sample Collection Date	Parameter	Result
xxx-xxx	Screening	YYYY-MM-DD	HBsAg	Negative
			HCV antibody	Negative
			HIV	Negative

SAD: Single-Ascending Dose.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.5.2 Part 1 Food Effect: Serology Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Visit	Sample Collection Date	Parameter	Result
xxx-xxx	Screening	YYYY-MM-DD	HBsAg	Negative
			HCV antibody	Negative
			HIV	Negative

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.5.3 Part 2 MAD: Serology Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.6.1 Part 1 SAD: FSH Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Sample Collection Date Time	Result (unit)
xxx-xxx	Screening	YYYY-MM-DD HH:MM	xx.x
xxx-xxx	Screening	YYYY-MM-DD HH:MM	xx.x
	Screening	YYYY-MM-DD HH:MM	xx.x

SAD: Single-Ascending Dose.

Program Name: xxx.sas, Creation Date and Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.6.2 Part 1 Food Effect: FSH Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Visit	Sample Collection Date Time	Result (unit)
xxx-xxx	Screening	YYYY-MM-DD HH:MM	xx.x
xxx-xxx	Screening	YYYY-MM-DD HH:MM	xx.x
	Screening	YYYY-MM-DD HH:MM	xx.x

Program Name: xxx.sas, Creation Date and Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.6.3 Part 2 MAD: FSH Results (Intention-to-Treat Analysis Set)
Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.7.1 Part 1 SAD: Prior Medications (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted
Subject Number: xxx-xxx

CM No.	ATC Class Level 2 Term/ Preferred Term/ Verbatim Term	Indication Category	Dose	Unit	Frequency	Route	Start Date Time/ Study Day	Stop Date Time/ Study Day
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Medical History - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HHMM/ XX
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Medical History - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HH:MM/ XX

SAD: Single-Ascending Dose. CM No.: Medication Number.
Prior medications are defined as any medication where the use was stopped prior to the first administration of the study drug.
Only prior medications are presented.
Study days are calculated relative to the date of the first study drug administration.

Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
When referred to a MH or AE, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.7.2 Part 2 Food Effect: Prior Medications (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Subject Number: xxx-xxx

CM No.	ATC Class Level 2 Term/ Preferred Term/ Verbatim Term	Indication Category	Dose	Unit	Frequency	Route	Start Date Time/ Study Day	Stop Date Time/ Study Day
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Medical History - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HHMM/ XX
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Medical History - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HH:MM/ XX

CM No.: Medication Number.
Prior medications are defined as any medication where the use was stopped prior to the first administration of the study drug.
Only prior medications are presented.
Study days are calculated relative to the date of the first study drug administration.

Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.
When referred to a MH or AE, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.7.3 Part 2 MAD: Prior Medications (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Subject Number: xxx-xxx

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
When referred to a MH or AE, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.8.1 Part 1 SAD: Concomitant Medications (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted
Subject Number: xxx-xxx

CM No.	ATC Class Level 2 Term/ Preferred Term/ Verbatim Term	Indication Category	Dose	Unit	Frequency	Route	Start Date Time/ Study Day	Stop Date Time/ Study Day
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Adverse Event - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HHLMM/ XX
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Adverse Event - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HH:MM/ Ongoing

SAD: Single-Ascending Dose. CM No.: Medication Number.
Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of study drug. Medications stopping on the same day as the first study drug administration will be considered as concomitant medications.
Only concomitant medications are presented.
Study days are calculated relative to the date of the first study drug administration.

Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
When referred to a MH or AE, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.8.2 Part 1 Food Effect: Concomitant Medications (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Subject Number: xxx-xxx

CM No.	ATC Class Level 2 Term/ Preferred Term/ Verbatim Term	Indication Category	Dose	Unit	Frequency	Route	Start Date Time/ Study Day	Stop Date Time/ Study Day
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Adverse Event - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HHLMM/ XX
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	Adverse Event - XXXXXXXXX	xx.x	XXX	XXXXXXXX	XXXXXX	YYYY-MM-DD HH:MM/ XX	YYYY-MM-DD HH:MM/ Ongoing

CM No.: Medication Number.
Concomitant medications are defined as any medication (other than the study drug) that was used at least once after the first administration of study drug. Medications stopping on the same day as the first study drug administration will be considered as concomitant medications.
Only concomitant medications are presented.
Study days are calculated relative to the date of the first study drug administration.

Medication terms were coded using the World Health Organisation – Drug Dictionary Version Global (WHO-DD) C3, March 2023.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.
When referred to a MH or AE, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.4.8.3 Part 2 MAD: Concomitant Medications (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Subject Number: xxx-xxx

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
When referred to a MH or AE, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.5.1.1 Part 1 SAD: Study Drug Administration (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Drug Administered – Reason no Administered	Date Time of Last Meal Prior to Study Drug Administration	Date Time of Study Drug Administration	Study Drug Dose Administered (mg)	Suspension Volume Prepared (mL)	Complete Study Drug Ingested – If not Volume Ingested (mL)	Post Dosing Fasting for at least 4 hours – I not, Hours Fasted
xxx-xxx	Day 1	Yes	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	xx	xx	Yes	Yes
xxx-xxx	Day 1	Yes	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	xx	xx	No – xx.x	No – xx hours
xxx-xxx	Day 1	No – XXXXXXXXXX	YYYY-MM-DD HH:MM	-	-	-	-	-

SAD: Single-Ascending Dose. -: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.5.1.2 Part 1 Food Effect: Study Drug Administration (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Dosing

Subject Number/ Food Effect	Visit	Drug Administered – Reason not Administered	Date Time of Last Meal Prior to Study Drug Administration	Date Time of Study Drug Administration	Study Drug Dose Administered (mg)	Suspension Volume Prepared (mL)	Complete Study Drug Ingested – If not Volume Ingested (mL)	Post Dosing Fasting for at least 4 hours – I not, Hours Fasted
xxx-xxx			YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM				
Fasted	Day 1	Yes			xx	xx	Yes	Yes
			YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM				
Fed	Day 9	Yes			xx	xx	Yes	Yes
xxx-xxx			YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM				
Fasted	Day 1	Yes			xx	xx	No – xx.x	No – XX hours
			YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM				
Fed	Day 9	Yes			xx	xx	Yes	Yes
xxx-xxx		No – XXXXXXXXXX	YYYY-MM-DD HH:MM	-	-	-	-	-
Fasted	Day 1							
…								

-: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.5.1.2 Part 1 Food Effect: Study Drug Administration (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Meals

					Breakfast	
Subject Number	Food Effect	Visit	Drug Administered – Reason not Administered	Date Time of Last Meal Prior to Study Drug Admin	Type: High Fat/ Standard Non-High Fat Breakfast	Complete Breakfast Taken – If not Percentage Taken
xxx-xxx	Fed	Day 9	Yes	YYYY-MM-DD HH:MM	High Fat Meal	Yes
xxx-xxx	Fed	Day 9	Yes	YYYY-MM-DD HH:MM	Standard Non-High Fat Meal	No – XX%
xxx-xxx	Fed	Day 9	Yes	YYYY-MM-DD HH:MM	No	-
…						

-: Not Applicable.

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Programmer note:
This listing is wrapped to the following page with study dug admin information.
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.5.1.3 Part 2 MAD: Study Drug Administration (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Dosing

Subject Number	Duration of Exposure (days)	Total Dose Administered (mg) for the Duration of Exposure	Visit	Drug Administered - Reason no Administered	Date Time of Study Drug Administration	Study Drug Dose Administered (mg)	Suspension Volume Prepared (mL)	Complete Study Drug Ingested - If not Volume Ingested (mL)	Post Dosing Fasting for at least 4 hours - I not, Hours Fasted
xxx-xxx	xx	xx	Day 1	Yes	YYYY-MM-DD HH:MM	xx	xx	Yes	Yes
			Day 2	Yes	YYYY-MM-DD HH:MM	xx	xx	No - xx.x	No - xx hours
			Day 3	No - XXXXXXXXXX	-	-	-	-	-
			…						
xxx-xxx	xx	xx	Day 1	Yes	YYYY-MM-DD HH:MM	xx	xx	Yes	Yes

..

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. -: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.5.1.3 Part 2 MAD: Study Drug Administration (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Meals

						Breakfast	
Subject Number	Duration of Exposure (days)	Total Dose Administered (mg) for the Duration of Exposure	Visit	Drug Administered - Reason not Administered	Date Time of Last Meal Prior to Study Drug Admin	Type: High Fat/ Standard Non-High Fat Breakfast	Complete Breakfast Taken - If not Percentage Taken
xxx-xxx	xx	xx	Day 1	Yes	YYYY-MM-DD HH:MM	High Fat	Yes
			Day 2	Yes	YYYY-MM-DD HH:MM	Standard Non-High Fat Meal	No - XX%
			Day 3	Yes	YYYY-MM-DD HH:MM	No	-
			…				
xxx-xxx	xx	xx	Day 1	Yes	YYYY-MM-DD HH:MM	High Fat	Yes

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.-: Not Applicable.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
This listing is wrapped to the following page with study dug admin information.
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all treatment groups/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.7.1.1 Part 1 SAD: Adverse Events (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

SAD: Single-Ascending Dose, AE No.: Adverse Event Number. SAE: Serious adverse event. TEAE: Treatment-emergent adverse event.
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.7.1.2 Part 1 Food Effect: Adverse Events (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed
Subject Number: xxx-xxx
Food Effect: Fasted (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

AE No.: Adverse Event Number, SAE: Serious adverse event, TEAE: Treatment-emergent adverse event,
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific treatment group and repeat for all treatment groups: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed, and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Non-TEAEs will not be assigned to any treatment.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.7.1.3 Part 2 MAD: Adverse Events (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed
Subject Number: xxx-xxx (YYYY-MM-DD HH:MM)

AE No.	System Organ Class (SOC)/ Preferred Term (PT)/ Verbatim Term	Start Date Time/ Study Day/ TEAE	End Date Time/ Study Day/ Ongoing	Outcome	SAE	Severity	Relationship to Study Drug/ Expectedness	Action Taken	Other Action Taken
1	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM/ XX/ Yes	YYYY-MM-DD HH:MM /XX	Recovered/ Resolved	Yes	Grade 1/ Mild	Unrelated/ Expected	Drug Withdrawn	Withdrawn from Study
2	XXXXXXXXXXXXXXXXXX/ YYYYYYYYYYYYYYYYYY/ ZZZZZZZZZZZZZZZZZZ	YYYY-MM-DD HH:MM / XX/ Yes	YYYY-MM-DD Unknown/ Ongoing	Recovering/ Resolving	No	Grade 3/ Severe	Related/ Expected	Drug Withdrawn	Withdrawn from Study

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.AE No.: Adverse Event Number, SAE: Serious adverse event, TEAE: Treatment-emergent adverse event,
-: Not Applicable.
Treatment-emergent adverse events are defined as adverse events that commenced or worsened on or after the first study drug administration.
Study days are calculated relative to the date of the treatment group first study drug administration.

Adverse event terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.0.

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Programmer note:
Repeat for all AEs that a subject experienced that were assigned to the specific group and repeat for all treatment groups: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Add code list for Other Action Taken if results cannot be fitted onto a single page.
When referred to a CM or Prior medication, present the preferred term (PT) in the listing.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.1.1 Part 1 SAD: Individual Hematology Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.1.2 Part 1 Food Effect: Individual Hematology Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.1.3 Part 2 MAD: Individual Hematology Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Protocol: CDI-988-P1-001

Listing 16.2.8.2.1 Part 1 SAD: Individual Coagulation Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.2.2 Part 1 Food Effect: Individual Coagulation Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.2.3 Part 2 MAD: Individual Coagulation Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Protocol: CDI-988-P1-001

Listing 16.2.8.3.1 Part 1 SAD: Individual Clinical Chemistry Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present ‘Early Termination’ or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.3.2 Part 1 Food Effect: Individual Clinical Chemistry Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.3.3 Part 2 MAD: Individual Clinical Chemistry Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High
	…							

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.4.1 Part 1 SAD: Individual Lipid Profile Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
	…							
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present ‘Early Termination’ or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.4.2 Part 1 Food Effect: Individual Lipid Profile Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	-	(XXX, XXX)	Low
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low
		Day 15	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.4.3 Part 2 MAD: Individual Lipid Profile Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Result	Change from Baseline[1]	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Day -1[1]	YYYY-MM-DD HH:MM	XXX	-	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXX	XXX	(XXX, XXX)	Low
		Day 17	YYYY-MM-DD HH:MM	XXX	XXX	(XXX, XXX)	
	…						
xxx-xxx	XXXXXX (XX)	Day -1[1]	YYYY-MM-DD HH:MM	XXX	-	(XXX, XXX)	
		Day 10	YYYY-MM-DD HH:MM	XXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXX	XXX	(XXX, XXX)	High
	…						

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.-: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether the subject complete the study or not.

Protocol: CDI-988-P1-001

Listing 16.2.8.5.1 Part 1 SAD: Individual Urinalysis Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 8	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low
	…						
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	High

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present ‘Early Termination’ or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.5.2 Part 1 Food Effect: Individual Urinalysis Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Sample Collection Date Time	Lab Name	Result	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
	Fasted	Day -1[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
	Fed	Day 8[2]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low
		Day 9	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low
		Day 10	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 16	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.5.3 Part 2 MAD: Individual Urinalysis Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Sample Collection Date Time	Lab Name	Result	Reference Range (Low, High)	Reference Range Indicator
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	Low
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 2	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 3	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 4	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		…					
		Day 17	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
	…						
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day -1[1]	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		Day 1	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	
		…					
		Early Termination	YYYY-MM-DD HH:MM	XXXXXXXXX	XXX	(XXX, XXX)	High
	…						

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing. - : Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Reference range indicators (result classifications) are based on the laboratory defined reference ranges for the specific parameter.

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.6.1 Part 1 SAD: Pregnancy Test Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Sample	Sample Collection Date	Result
xxx-xxx	Screening	Serum	YYYY-MM-DD	Negative
	Day -1	Urine	YYYY-MM-DD	Negative
	Day 8	Urine	YYYY-MM-DD	Negative
xxx-xxx	Screening	Serum	YYYY-MM-DD	Negative
	Day -1	Urine	YYYY-MM-DD	Negative
	Early Termination	Urine	YYYY-MM-DD	Negative

SAD: Single-Ascending Dose;
Only female subjects of childbearing potential are included in this listing.

Program Name: xxx.sas, Creation Date and Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.6.2 Part 1 Food Effect: Pregnancy Test Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Visit	Sample	Sample Collection Date	Result
xxx-xxx	Screening	Serum	YYYY-MM-DD	Negative
	Day -1	Urine	YYYY-MM-DD	Negative
	Day 8	Urine	YYYY-MM-DD	Negative
	Day 16	Urine	YYYY-MM-DD	Negative
xxx-xxx	Screening	Serum	YYYY-MM-DD	Negative
	Day -1	Urine	YYYY-MM-DD	Negative
	Early Termination	Urine	YYYY-MM-DD	Negative

Only female subjects of childbearing potential are included in this listing.

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Programmer note:
Repeat for all treatment groups/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed.
Present 'Early Termination' or Day 8/16 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.8.6.3 Part 2 MAD: Pregnancy Test Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.1.1.1 Part 1 SAD: Vital Signs Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Assessment Date Time	Result	Change from Baseline[1]	Comment
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	xxx	-	
		Day -1	YYYY-MM-DD HH:MM	xxx	-	
		Day 1: Pre-dose[1]	YYYY-MM-DD HH:MM	xxx	-	
		Day 1: 2 hours	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 1: 4 hours	YYYY-MM-DD HH:MM	xxx	xxx	XXXXXXXXXXXXXXXXXX
		Day 2	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 3	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 8	YYYY-MM-DD HH:MM	xxx	xxx	
		…				
xxx-xxx	XXXXXX (XX)	Early Termination	YYYY-MM-DD HH:MM	xxx	xxx	

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to the first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo.
Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Present the results in the following order:

- SBP.
- DBP.
- Heart Rate.
- Respiratory Rate.
- Body Temperature.
- Height.
- Body Weight.
- BMI.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.1.1.2 Part 2 Food Effect: Vital Signs Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Assessment Date Time	Result	Change from Baseline[2]	Comment
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	xxx	-	
		Day -1	YYYY-MM-DD HH:MM	xxx	-	
	Fasted	Day 1: Pre-dose[2]	YYYY-MM-DD HH:MM	xxx	-	
		Day 1: 2 hours	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 1: 4 hours	YYYY-MM-DD HH:MM	xxx	xxx	XXXXXXXXXXXXXXXXXX
		Day 2	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 3	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 8	YYYY-MM-DD HH:MM	xxx	xxx	
	Fed	Day 9: Pre-dose[2]	YYYY-MM-DD HH:MM	xxx	-	
		Day 9: 2 hours	YYYY-MM-DD HH:MM	xxx	xxx	
		…				
xxx-xxx	XXXXXX (XX)	Early Termination	YYYY-MM-DD HH:MM	xxx	xxx	

-: Not Applicable.
[2] The baseline value is defined as the last available valid assessment collected prior to first study drug administration in that period.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Present the results in the following order:

- SBP.
- DBP.
- Heart Rate.
- Respiratory Rate.
- Body Temperature.
- Height.
- Body Weight.
- BMI.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.1.1.3 Part 2 MAD: Vital Signs Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Assessment Date Time	Result	Change from Baseline[1]	Comment
xxx-xxx	XXXXXX (XX)	Screening	YYYY-MM-DD HH:MM	xxx	-	
		Day -1	YYYY-MM-DD HH:MM	xxx	-	
		Day 1: Pre-dose[1]	YYYY-MM-DD HH:MM	xxx	-	
		Day 1: 2 hours	YYYY-MM-DD HH:MM	xxx	xxx	
		Day 1: 4 hours	YYYY-MM-DD HH:MM	xxx	xxx	XXXXXXXXXXXXXXXXXX
		Day 2	YYYY-MM-DD HH:MM	xxx	xxx	
		…				
		Day 17	YYYY-MM-DD HH:MM	xxx	xxx	
		…				
xxx-xxx	XXXXXX (XX)	Early Termination	YYYY-MM-DD HH:MM	xxx	xxx	

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.-: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to the first study drug administration.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Present the results in the following order:

- SBP.
- DBP.
- Heart Rate.
- Respiratory Rate.
- Body Temperature.
- Height.
- Body Weight.
- BMI.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.2.1.1 Part 1 SAD: 12-Lead ECG Overall Interpretations (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Trace Reading	Assessment Date Time	Result
xxx-xxx	Screening	1	YYYY-MM-DD HH:MM	Normal
		2	YYYY-MM-DD HH:MM	Normal
		3	YYYY-MM-DD HH:MM	Abnormal Not Clinically Significant
		Worst	YYYY-MM-DD HH:MM	Abnormal Not Clinically Significant
	Day -1	1	YYYY-MM-DD HH:MM	Normal
		2	YYYY-MM-DD HH:MM	Normal
		3	YYYY-MM-DD HH:MM	Normal
		Worst	YYYY-MM-DD HH:MM	Normal
	Day 1: Pre-dose	1	YYYY-MM-DD HH:MM	Normal
	…	..	…	…
		Worst[1]	YYYY-MM-DD HH:MM	Normal
	Day 8	1	YYYY-MM-DD HH:MM	Normal
xxx-xxx	Early Termination		YYYY-MM-DD HH:MM	Normal

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Where triplicate measurements were taken, overall interpretation was based on the worst overall interpretation of the triplicate measurements at each visit/time point.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo. Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.2.1.2 Part 1 Food Effect: 12-Lead ECG Overall Interpretations (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Food Effect	Visit	Trace Reading	Assessment Date Time	Result
xxx-xxx		Screening	1	YYYY-MM-DD HH:MM	Normal
			2	YYYY-MM-DD HH:MM	Normal
			3	YYYY-MM-DD HH:MM	Abnormal Not Clinically Significant
			Worst		Abnormal Not Clinically Significant
		Day -1	1	YYYY-MM-DD HH:MM	Normal
			2	YYYY-MM-DD HH:MM	Normal
			3	YYYY-MM-DD HH:MM	Normal
			Worst		Normal
	Fasted	Day 1: Pre-dose	1	YYYY-MM-DD HH:MM	Normal
			…		
			Worst[2]		Normal
		Day 8	1	YYYY-MM-DD HH:MM	Normal
			…		
			Worst		Normal
…	…	…			
	Fed	Day 9: Pre-dose	1	YYYY-MM-DD HH:MM	Normal
			…		
			Worst[2]		Normal
…	…	…			

-: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to the first study drug administration in that period. Where triplicate measurements were taken, overall interpretation was based on the worst overall interpretation of the triplicate measurements at each visit/time point.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:

Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.2.1.3 Part 2 MAD: 12-Lead ECG Overall Interpretations (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Visit	Trace Reading	Assessment Date Time	Result
xxx-xxx	Screening	1	YYYY-MM-DD HH:MM	Normal
		2	YYYY-MM-DD HH:MM	Normal
		3	YYYY-MM-DD HH:MM	Abnormal Not Clinically Significant
		Worst	YYYY-MM-DD HH:MM	Abnormal Not Clinically Significant
	Day -1	1	YYYY-MM-DD HH:MM	Normal
		2	YYYY-MM-DD HH:MM	Normal
		3	YYYY-MM-DD HH:MM	Normal
		Worst	YYYY-MM-DD HH:MM	Normal
	Day 1: Pre-dose	1	YYYY-MM-DD HH:MM	Normal
	…	..	…	…
		Worst[1]	YYYY-MM-DD HH:MM	Normal
	Day 10	1	YYYY-MM-DD HH:MM	Normal
xxx-xxx	Day 10	Worst	YYYY-MM-DD HH:MM	XXX

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.-: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to the first study drug administration.
Range indicators (result classifications) are based on the defined normal range for the specific parameter.
Where triplicate measurements were taken, overall interpretation was based on the worst overall interpretation of the triplicate measurements at each visit/time point.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM Page 1 of x

Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.2.2.1 Part 1 SAD: 12-Lead ECG Results (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Parameter (Unit)	Visit	Trace Reading	Assessment Date Time	Result	Change from Baseline[1]
xxx-xxx	XXXXXX (XX)	Screening	1	YYYY-MM-DD HH:MM	xxx	
			2	YYYY-MM-DD HH:MM	xxx	
			3	YYYY-MM-DD HH:MM	xxx	
			Mean	YYYY-MM-DD HH:MM	xxx	-
		Day -1	1	YYYY-MM-DD HH:MM	xxx	
			2	YYYY-MM-DD HH:MM	xxx	
			3	YYYY-MM-DD HH:MM	xxx	
			Mean	YYYY-MM-DD HH:MM	xxx	-
		Day 1: Pre-dose	1	YYYY-MM-DD HH:MM		
		…	..	…		
			Mean[1]	YYYY-MM-DD HH:MM	xxx	-
		Day 8	1	YYYY-MM-DD HH:MM	xxx	
xxx-xxx		Early Termination		YYYY-MM-DD HH:MM	xxx	xxx

SAD: Single-Ascending Dose. -: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to first study drug administration.
Where triplicate measurements were taken, continuous results were based on the mean of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo. Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Present the results in the following order:

- Heart Rate.
- PR Interval.
- QRS Duration.
- QT Interval.
- QTcF Interval.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.2.2.2 Part 1 Food Effect: 12-Lead ECG Results (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Parameter (Unit)/ Food Effect	Visit	Trace Reading	Assessment Date Time	Result	Change from Baseline[1]
xxx-xxx	XXXXXX (XX)	Screening	1	YYYY-MM-DD HH:MM	xxx	
			2	YYYY-MM-DD HH:MM	xxx	
			3	YYYY-MM-DD HH:MM	xxx	
			Worst		xxx	-
		Day -1	1	YYYY-MM-DD HH:MM	xxx	
			2	YYYY-MM-DD HH:MM	xxx	
			3	YYYY-MM-DD HH:MM	xxx	
			Worst		xxx	-
	Fasted	Day 1: Pre-dose	1	YYYY-MM-DD HH:MM	xxx	
			…			
			Worst[2]		xxx	-
		Day 8	1	YYYY-MM-DD HH:MM	xxx	
			…			
			Worst		xxx	xxx
…	…	…				
	Fed	Day 9: Pre-dose	1	YYYY-MM-DD HH:MM	xxx	
			…			
			Worst[2]		xxx	-
…	…	…				

-: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to the first study drug administration in that period. Where triplicate measurements were taken, continuous results were based on the mean of the triplicate measurements at each visit/time point.

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1C: CDI-988 400 mg Fasted/ Fed, Cohort 1E: CDI-988 100 mg Fasted/ Fed, Cohort 1F: CDI-988 1200 mg Fasted/ Fed and Pooled Placebo Fasted/ Fed and food effects: Fasted and Fed.
Present 'Early Termination' or Day 8/ 16 depending on whether/when the subject complete the study or not.

Present the results in the following order:

- Heart Rate.
- PR Interval.
- QRS Duration.
- QT Interval.
- QTcF Interval.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.2.2.3 Part 2 MAD: 12-Lead ECG Results (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Subject Number	Parameter (Unit)	Visit	Trace Reading	Assessment Date Time		
xxx-xxx	XXXXXX (XX)	Screening	1	YYYY-MM-DD HH:MM	xxx	
			2	YYYY-MM-DD HH:MM	xxx	
			3	YYYY-MM-DD HH:MM	xxx	
			Mean	YYYY-MM-DD HH:MM	xxx	-
		Day -1	1	YYYY-MM-DD HH:MM	xxx	
			2	YYYY-MM-DD HH:MM	xxx	
			3	YYYY-MM-DD HH:MM	xxx	
			Mean	YYYY-MM-DD HH:MM	xxx	-
		Day 1: Pre-dose	1	YYYY-MM-DD HH:MM		
		…	..	…		
			Mean[1]	YYYY-MM-DD HH:MM	xxx	-
		Day 10	1	YYYY-MM-DD HH:MM	xxx	
		…				
xxx-xxx	XXXXXX (XX)	Early Termination	Mean	YYYY-MM-DD HH:MM	xxx	xxx

MAD: Multiple-Ascending Dose. BID: Twice-daily dosing.-: Not Applicable.
[1] The baseline value is defined as the last available valid assessment collected prior to the first study drug administration.
Where triplicate measurements were taken, continuous results were based on the mean of the triplicate measurements at each visit/time point.

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Programmer note:
Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

Present the results in the following order:

- Heart Rate.
- PR Interval.
- QRS Duration.
- QT Interval.
- QTcF Interval.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.3.1 Part 1 SAD: Physical Examination Findings (Intention-to-Treat Analysis Set)

Cohort 1A: CDI-988 100 mg Fasted

Subject Number	Visit	Assessment Date Time	Body System	Clinical Assessment	Description of Abnormality
xxx-xxx	Screening	YYYY-MM-DD HH:MM	General Appearance	Abnormal, Not Clinically Significant	XXXXXXX
			Head, Ears, Eyes, Nose and Throat	Normal	
			Neck (including Thyroid)	Normal	
			Skin	Normal	
			Cardiovascular System	Normal	
			Respiratory System	Normal	
			Gastrointestinal System	Normal	
			Musculoskeletal System	Normal	
			Lymph Nodes	Normal	
			Nervous System	Normal	
			Other: XXXXXXXX	Normal	
	Day -1	YYYY-MM-DD HH:MM	General appearance	Abnormal, Not Clinically Significant	XXXXXXX

SAD: Single-Ascending Dose

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and Pooled Placebo. Present 'Early Termination' or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.3.2 Part 1 Food Effect: Physical Examination Findings (Intention-to-Treat Analysis Set)

Cohort 1C: CDI-988 400 mg Fasted/ Fed

Subject Number	Food Effect	Visit	Assessment Date Time	Body System	Clinical Assessment	Description of Abnormality
xxx-xxx		Screening	YYYY-MM-DD HH:MM	General Appearance	Abnormal, Not Clinically Significant	XXXXXXX
				Head, Ears, Eyes, Nose and Throat	Normal	
				Neck (including Thyroid)	Normal	
				Skin	Normal	
				Cardiovascular System	Normal	
				Respiratory System	Normal	
				Gastrointestinal System	Normal	
				Musculoskeletal System	Normal	
				Lymph Nodes	Normal	
				Nervous System	Normal	
				Other: XXXXXXXX	Normal	
	Fasted	Day -1	YYYY-MM-DD HH:MM	General appearance	Abnormal, Not Clinically Significant	XXXXXXX
		…				
		Day 1	YYYY-MM-DD HH:MM	General appearance	Abnormal, Not Clinically Significant	XXXXXXX

Program Name: xxx.sas, Creation Date Time: YYYY-MM-DD HH:MM

Programmer note:
Repeat for all treatment groups. Repeat for all parameters/subjects within a treatment group: Cohort 1A: CDI-988 100 mg Fasted, Cohort 1B: CDI-988 200 mg Fasted, Cohort 1D: CDI-988 600 mg Fasted and
Pooled Placebo. Present ‘Early Termination’ or Day 8 depending on whether the subject complete the study or not.

Sponsor: Cocrystal Pharma Australia Pty Ltd.
Protocol: CDI-988-P1-001

Listing 16.2.9.3.3 Part 2 MAD: Physical Examination Findings (Intention-to-Treat Analysis Set)

Cohort 2A: CDI-988 200 mg Fed

Programmer note:
Repeat previous SAD listing for the MAD Cohorts.

Repeat for all parameters/subjects within a treatment group: Cohort 2A: CDI-988 200 mg Fed, Cohort 2B: CDI-988 400 mg Fed, Cohort 2C: CDI-988 800 mg Fed, Cohort 2D: CDI-988 1200 mg Fed, Cohort 2E: CDI-988 1200 mg BID Fasted, Cohort 2F: CDI-988 1200 mg BID Fed and Pooled Placebo.
Present 'Early Termination' or Day 12/17 depending on whether/when the subject complete the study or not.

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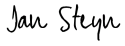
Jan Steyn jan.steyn@rgcro.com Director of Biostatistics Security Level: Email, Account Authentication (Required), Logged in	 Signature Adoption: Pre-selected Style Signature ID: 4D30EF5A-81E0-498A-8EF8-8F3A825BED7C Using IP Address: 27.131.74.15 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I am the author of this document	Sent: 2025-06-26 | 08:58 Viewed: 2025-06-26 | 08:59 Signed: 2025-06-26 | 08:59
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