STATISTICAL ANALYSIS PLAN
Protocol FX006-2019-017

A Single-arm, Open-label Study to Evaluate a Procedure for Intra-articular (IA) Injection of FX006 in Patients with Osteoarthritis (OA) of the Hip

Protocol Number: (Version Date)	FX006-2019-017 Version 1.0 (28 June 2019)
Name of Test Drug:	FX006
Phase:	2
Methodology:	Single-arm, open-label study
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SIGNATURE PAGE

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Cytel, Inc. Author:	
Laurel Bastone Associate Director, Biostatistics	Signature:_____ Date:_____

Sponsor Approval

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidances and guidelines.

I have discussed any questions I have regarding the contents of this document with the biostatistical author.

I also understand that any subsequent changes to the planned statistical analyses, as described herein, may have a regulatory impact and/or result in timeline adjustments. All changes to the planned analyses will be described in the clinical study report (CSR).

Sponsor Signatories:

Amy Cinar, PhD
Director, Biostatistics

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Date:_____

Scott Kelley, MD
Chief Medical Officer

Signature:_____

Date:_____

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ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
ACR	American College of Rheumatology
BMI	Body Mass Index
CI	Confidence Interval
cm	Centimeter
CM	Concomitant Medications
CMC	Carboxymethylcellulose Sodium
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
eCRF	Electronic Case Report Form
EOS	End of Study
EULAR	European League Against Rheumatism
HDL	High Density Lipoprotein
HIV	Human Immunodeficiency Virus
IA	Intra-articular
ICF	Informed Consent Form
ICH	International Conference on Harmonization
JSN	Joint Space Narrowing
KL	Kellgren-Lawrence
kg	Kilogram
LDL	Low Density Lipoprotein
LLN	Lower Limit of Normal
m	Meter
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
NaCl	Sodium Chloride
OA	Osteoarthritis
OARSI	Osteoarthritis Research Society International
PDF	Portable Document Format
Ph. Eur/USP	Pharmacopoeia Europaea/ United States Pharmacopeia
PLGA	Poly (Lactic-co-Glycolic Acid)
PT	Preferred Term
SAE	Serious Adverse Event

Abbreviation	Definition
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
SP	Safety Population
TA[1]	Triamcinolone Acetonide
TEAE	Treatment Emergent AE
ULN	Upper Limit of Normal
US	United States
WHO	World Health Organization

[1] Abbreviated in past protocols and documents as TCA

1. INTRODUCTION AND OBJECTIVES OF ANALYSIS

1.1. Introduction

Osteoarthritis (OA) is a painful and debilitating musculoskeletal disease that is characterized by intra-articular (IA) inflammation, deterioration of articular cartilage, and degenerative changes to peri-articular and subchondral bone (Creamer and Hochberg, 1997; Goldring and Goldring, 2006). Arthritis is the most common cause of disability in the United States of America (USA), and OA is the most common joint disease, affecting 31 million Americans, with numbers expected to grow as a result of aging, obesity and sports injuries (Cisternas et al., 2016). Recent data suggest that OA accounts for over $185 billion of annual healthcare expenditures in the US, which does not include loss of productivity costs. It is estimated that by 2030, 45 million people will have OA. OA commonly affect large weight-bearing joints like the knees and hips, but also occurs in the shoulders, hands, feet and spine. Patients with OA suffer from joint pain, tenderness, stiffness and limited movement. As the disease progresses, it becomes increasingly painful and debilitating, culminating, in many cases, in the need for total joint arthroplasty.

Current Guidelines from the American College of Rheumatology (ACR), Osteoarthritis Research Society International (OARSI) and the European League against Rheumatism (EULAR) recommend the use of IA corticosteroids for short-term acute pain relief (Hochberg et al, 2012; Jordan et al, 2003; Menge et al, 2014).

The prevalence of hip osteoarthritis is estimated to range from 6.7% to 9.2% among adults ≥45 years of age and increases with age (Lawrence et al, 2008; Murphy et al, 2012). It is recognized that chronic inflammation occurs in all stages of OA (Benito et al, 2005; Sellam and Berenbaum, 2010; Wenham and Conaghan, 2010). As inflammation is correlated with clinical symptoms and joint degeneration, it should be an important target for corticosteroid intervention.

FX006 is an extended-release formulation of triamcinolone acetonide (TA) for IA administration. It is approved in the US under the trade name ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) for the management of pain of osteoarthritis of the knee. FX006 is intended to deliver TA to the synovial and peri-synovial tissues for a period of approximately 3 months (Bodick et al, 2013). FX006 contains TA, United States Pharmacopeia (Ph. Eur/USP), formulated in 75:25 poly (lactic-co-glycolic acid) (PLGA) microspheres with a nominal drug load of 25% (weight by weight [w/w]) and is provided as a sterile white to off-white powder for reconstitution. The drug product is reconstituted with diluent containing an isotonic, sterile aqueous solution of sodium chloride (NaCl; 0.9% w/w), carboxymethylcellulose sodium (CMC; 0.5% w/w) and polysorbate-80 (0.1% w/w) to form a suspension prior to IA injection.

Similar as in knee OA, hip OA patients are confronted with insufficient management of their symptoms (Zhang et al, 2008). Conventional corticosteroids have demonstrated clinical benefits in patients with hip OA (Lambert et al, 2007; Qvistgaard et al, 2006; Atchia et al, 2011), but with short duration of effect (approximately 4-8 weeks) and side effects from burst release of steroids into systemic circulation (Habib et al, 2011). Due to its slow release formulation, FX006 has the potential to offer longer duration of efficacy and minimized systemic exposure, thus, an improved benefit/risk profile for hip OA patients.

Intra-articular administration of FX006, an extended-release microsphere formulation of triamcinolone acetonide, demonstrated safety and efficacy in the relief of pain in patients with pain associated with OA of the knee. Given the insufficient symptomatic management of hip OA patients and similar pathogenesis between knee and hip OA, it is anticipated that FX006 will provide similar benefit to these

patients. However, to fully assess the safety, efficacy and determine a benefit/risk profile for administration of FX006 to patients with hip OA, the procedure for IA administration of FX006 into the hip joint needs to be addressed. Thus, the sponsor is proposing a specific study to evaluate the ability of injection procedures to achieve successful IA injection of FX006 into the hip joints of patients with OA of the hip.

1.2. Objectives of Statistical Analysis

Primary:

• To evaluate the ability of injection procedures to achieve successful IA injection of FX006 into the hip joints of patients with OA of the hip.

Secondary:

• The secondary objective of this study is to assess the safety of FX006 administered by IA injection in patients with hip OA.

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analysis of study data in order to answer the study objective(s). Populations for analysis, data handling rules, statistical methods, and formats for data presentation are provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial, as well as be used for regulatory filings and manuscripts and presentations.

This SAP will also outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

2. STUDY DESIGN

2.1. Synopsis of Study Design

This is a prospective, multicenter, single-arm, open-label study to evaluate and confirm feasibility of an IA injection procedure of 32 mg FX006 under image guidance in patients with hip OA. The study will be conducted at up to 6 sites with approximately 22 patients. If one (1) unsuccessful IA administration is observed, 7 additional patients may be enrolled. Eligible patients will be administered a single IA injection of FX006 on Day 1 and then followed for safety for 8 weeks.

2.2. Study Procedures

Patients participating in this study will complete visit schedules and procedures as detailed in the Schedule of Study Assessments (Table 1).

Table 1 Schedule of Study Assessments

List of Assessments	Screening[1]	Day 1	Week 1	Week 4	Week 8
Window	-14 to -1	–	±2 days	±5 days	±5 days
Informed consent	X				
Inclusion/Exclusion Review	X	X[2]			
Medical History/Update	X	X[2]			
Patient Demographics	X				
OA Medical History	X				
Prior Treatments and Medications	X	X[2]			
Physical examination	X				
Vital signs	X	X[2]	X		X
Height	X				
Weight and BMI	X				
Index Hip Assessment	X	X[2]	X		X
Index Hip X-ray [3]	X				
Hematology, Chemistry[4]	X				
HIV, Hep B/C[4]	X				
Pregnancy Test[5]	X[5]	X[2,5]			
Index Hip Aspiration[6]		X			
IP administration[7]		X			
AE/SAE & ConMeds[8]	X	X	X	X[9]	X

1 Screening period is up to 14 days.
2 To be completed on Day 1 prior to injection procedure
3 A weight-bearing anterior-posterior view for index hip is recommended. Screening X-ray will be read locally for radiologic findings of OA meeting criteria for Kellgren-Lawrence Grade 2-3.
4 To be performed via local laboratory.
5 Pregnancy test will be done in women of childbearing potential. Serum Pregnancy Test to be performed at Screening visit by local lab; Urine Pregnancy Test to be performed on Day 1 by study site or local lab with result available prior to injection of study medication.
6 Aspiration must be attempted prior to IP administration. Synovial fluid volume aspirated will be recorded prior to discard.
7 To be performed under image guidance in compliance with protocol specified procedure.
8 AE/SAE's and concomitant medications will be captured from signing of informed consent through EOS visit.
9 To be conducted via telephone

2.3. Efficacy Endpoints

2.3.1. Primary Efficacy Endpoint

The primary endpoint for this study is successful study drug administration, defined as the Injector reporting the complete administration of study drug.

3. PATIENT POPULATIONS

3.1. Population Definitions

The following patient populations will be used for presentation and analysis of the data:

- Safety Population: All patients who received an attempted administration of study drug.

4. STATISTICAL METHODS

4.1. Sample Size Justification

Approximately 22 patients will be treated in this study. If there are no incomplete IA administrations, the study may be considered complete. Observing 0 incomplete injections (0%) in 22 patients gives 90% confidence that the true incomplete IA injection rate is between 0 and 10%. If one (1) unsuccessful IA administration of study drug is observed, 7 additional patients may be enrolled. Observing 1 incomplete IA injection in 29 patients (3%) gives 80% confidence that the true incomplete IA injection rate is between 0 and 10%.

4.2. General Statistical Methods and Data Handling

4.2.1. General Methods

All outputs will be incorporated into Portable Document Format (PDF) or Word files, sorted and labeled according to the International Conference on Harmonization (ICH) recommendations, and formatted to the appropriate page size(s).

Tables will be presented by a single treatment arm. For categorical variables, summary tabulations of the number and percentage within each category (with a category for missing data) of the parameter will be presented. For continuous variables, the number of non-missing values (n), the mean, median, standard deviation (SD), minimum and maximum values will be presented. 95% confidence intervals (CI) may be provided. Additional statistics may be presented for certain endpoints as described below.

All collected data for enrolled patients will be presented in by-patient listings sorted by patient number. All data listings that contain an evaluation date will contain a relative study day (Rel Day Dose 1). Pre-treatment and post-treatment study days are numbered relative to the day of the first dose of study treatment, which is designated as Day 1. The preceding day is Day -1, the day before that is Day -2, etc.

The sections below describe the intended analysis of the endpoints. Additional sensitivity analyses may be employed in the event of any unforeseen data anomalies or data issues not known at the time of writing this analysis plan.

4.2.2. Computing Environment

All descriptive statistical analyses will be performed using SAS® statistical software (Version 9.4 or higher), unless otherwise noted.

Adverse Events (AEs) will be coding using Medical Dictionary for Regulatory Activities (MedDRA) Version 22.0 (or higher).

Concomitant medications will be coded using World Health Organization (WHO) Drug Dictionary (DD) (Version March 1, 2019 or Higher).

4.2.3. Methods of Pooling Data

Not applicable to the present study.

4.2.4. Adjustments for Covariates

Not applicable to the present study.

4.2.5. Multiple Comparisons/Multiplicity

As all analyses are exploratory in nature, there will be no controls for multiplicity.

4.2.6. Subpopulations

Analysis of the primary endpoint would be carried out for subgroups defined by aspiration status, KL grade at baseline, and gender.

4.2.7. Discontinuations and Loss to Follow-up

Each treated patient from this study receives study medication as a single IA injection. Therefore, discontinuation from treatment is not applicable.

Each patient may only discontinue from the study for further assessments and study visits. Data collected from discontinued patients will be included in the CSR. Patients who discontinue from the study may be replaced at the discretion of the sponsor.

4.2.8. Missing, Unused, and Spurious Data

Missing values will not be imputed and data will be analyzed “as observed”.

4.2.9. Visit Windows

Data collected at unscheduled visits will be mapped to the closest scheduled visit, but only if that data is not already available in that visit. Otherwise data will be summarized and presented according to the nominal visit as recorded on the Electronic Case Report Form (eCRF).

4.2.10. Baseline definitions

Baseline is the Baseline/Day 1 assessment prior to administration of the first dose of study treatment. If the Baseline result is missing, the last non-missing result prior to administration of study treatment may be used from the screening period.

4.3. Interim Analyses

There will be no interim analyses for this study.

4.4. Final Analyses

The analyses of study data will be performed in an unblinded manner when all patients have completed, withdrawn or discontinued from the study. Final analyses specified in the protocol and SAP will be completed and reported in the CSR.

Post-hoc, exploratory analyses, may be completed to further understand and elucidate study results. Any post-hoc, exploratory analyses completed will be clearly identified as such in the final CSR.

4.5. Patient Disposition

Patient disposition will be tabulated and include the total number of patients enrolled, treated, completed and early terminated, reason for early termination and the number in each patient population.

The following by-patient data listings will be presented:

- Study completion information including the reason for premature study discontinuation, if applicable.
- Inclusion/exclusion criteria not met.
- Patient inclusion in the Safety Population.

4.6. Protocol Deviations

The number and percentage of patients with at least one protocol deviation will be summarized for the Safety Population. Additionally, incidence by type of deviation will be presented in the following categories: inclusion criteria not met, exclusion criteria met, informed consent form (ICF) related, visit out of window, study drug administration, missed visit, missed assessment / procedure, assessment out of window, prohibited medication taken, incorrect assessment sequence / timing, incorrect delegation, documentation issue, and other. In these tabulations, patients could be counted in more than one category if they have a deviation attributed to multiple categories. All protocol deviations will be presented in a data listing.

4.7. Demographic and Baseline Characteristics

Demographic and baseline characteristics will be listed by study site and patient and will be summarized. Frequencies and proportions will be presented for the categorical variables and descriptive statistics will be presented for continuous variables.

4.7.1. Demographic Characteristics

The following Baseline parameters will be summarized for the Safety Population:

- Age (year) at consent - Age will be calculated as the years between date of birth and date of informed consent, and will be rounded down to the nearest year.
- Weight (kilogram (kg));
- Height (centimeter (cm));
- Gender (Male/Female);
- Body mass index (BMI) (kg/meter $(m)^2$);
- BMI category:
    - Underweight: <18.5 kg/m^2
    - Normal: 18.5 to <25.0 kg/m^2
    - Overweight: 25.0 to <30.0 kg/m^2
    - Obesity Class I: 30.0 to <35.0 kg/m^2
    - Obesity Class II: 35.0 to <40.0 kg/m^2
    - Obesity Class III: >=40.0 kg/m^2
- Ethnicity (Hispanic or Latino / Not Hispanic or Latino);
- Race (White / Asian / Black or African American / American Indian or Alaska Native / Native Hawaiian or Other Pacific Islander);
- Age, height, weight, and BMI will be summarized using descriptive statistics (number of patients, mean, SD, median, minimum, and maximum). The number and percentage of patients in each gender, ethnicity, race and BMI category will also be presented.

4.7.2. OA Medical History

OA history and index hip characteristics as collected on the eCRF will be summarized for the SP.

Time from primary diagnosis of OA in the index hip to Day 1 of the study in days (first dose date – date of diagnosis + 1), will be computed and presented descriptively. If only month and year of initial diagnosis is available, day will be imputed as 1 for calculations. If month and day are missing, the time from primary diagnosis will be computed as year of first dose minus year of diagnosis. If year is missing, time from diagnosis will not be computed.

4.7.3. Prior medication

All prior medications will be presented in the concomitant medication data listing with a flag identifying which medications are prior medications (refer to Section 4.10.6 for details on defining prior and concomitant medications).

4.8. Study Drug Exposure

Details of study drug administration will be summarized for the SP.

Descriptive statistics summarizing the index hip injected, approach for injection, needle size used, numbing agent used, use of fluoroscopy guidance, use of contrast dye or air used to confirm IA placement, total prepared volume, volume injected in the hip joint, air volume injected into hip joint, positioning of patient and index leg/hip, index leg rotation, degrees of rotation, use of connector for FX006 injection, and horizontal positioning of syringe during injection with FX006 will be presented in a summary table.

All study drug exposure data will be presented in a data listing.

4.9. Efficacy Evaluation

All efficacy analyses will be conducted using the SP. The rate and 90% CI of successful FX006 administration will calculated using all patients dosed, using methodology for estimation of a binomial proportion. Confidence intervals will be calculated via the score method, including a continuity correction.

Exploratory analyses may be conducted to aid in determination of root causes of unsuccessful injections, should any occur.

In addition to the analyses described above, subgroup analyses will be performed for subgroups defined by aspiration status, KL grade at baseline, and gender.

4.10. Safety Analyses

Safety analyses will be conducted using the SP.

4.10.1. Adverse Events

AEs will be coded using MedDRA and displayed in tables and listings using System Organ Class (SOC) and Preferred Term (PT).

Analyses of AEs will be performed for those events that are considered treatment emergent, where treatment emergent is defined as any AE with onset after the administration of study treatment, or any event that was present at Baseline but worsened in intensity through the end of the study.

- If the start date/time of an AE is partially or completely missing, the date/time will be compared as far as possible with the date/time of the start of administration of study drug. The AE will be assumed to be treatment emergent if it cannot be definitively shown that the AE did not occur or worsen during the treatment-emergent period (worst case approach). The following general rules will be used:

- If the start time of an AE is missing but the start date is complete, an AE will only be excluded as being treatment emergent if the start date is before the date of study drug administration or if the stop date/time is before study drug administration.
- If the start time and day are missing but the start month and year are complete, an AE will only be excluded as being treatment emergent if the start month/year is before the month/year of study drug administration or if the stop date/time is before study drug administration.
- If the start day and month are missing but the start year is complete, an AE will only be excluded as being treatment emergent if start year is before the year of study drug administration or if the stop date/time is before study drug administration.
- If the start date is completely missing, an AE will be considered treatment-emergent unless the stop date/time is before study drug administration.

AEs will be summarized by patient incidence rates; therefore, in any tabulation, a patient contributes only once to the count for a given SOC or PT.

Summary tables will display the number and percentage of patients who experienced at least one treatment emergent AE (TEAE) in each of the following categories:

- Any TEAE
- Any Serious AE (SAE)
- Any TEAE leading to study discontinuation
- Any TEAE by severity (Mild/Moderate/Severe)
- Any TEAE by relationship
- Any index hip related TEAE
- Any index hip related SAE
- Any index hip related TEAE leading to study discontinuation
- Any index hip related TEAE by severity (Mild/Moderate/Severe)
- Any index hip related TEAE by relationship
- Any TEAE related to injection procedure

Separate tabulations will be produced for each of following categories:

- All TEAEs by SOC and PT
- All TEAEs by PT (decreasing frequency)
- All SAEs by SOC and PT
- All TEAEs related to study drug by SOC and PT
- All TEAEs related to injection procedure by SOC and PT
- All TEAEs by maximum severity by SOC and PT
- All TEAEs leading to study discontinuation by SOC and PT
- All TEAEs leading to death by SOC and PT
- All index hip related TEAEs by SOC and PT
- All index hip related TEAEs related to study drug by SOC and PT
- All index hip related TEAEs by maximum severity by SOC and PT

In the summary table for "Any TEAE by SOC and PT", an additional row with the number of events observed will be presented. A patient will be counted once for the number of patients if they have multiple events. The total number of events will be the absolute number of events observed, and a patient will be counted more than once for the event totals if they have multiple events.

In these tabulations, related is defined as any TEAE deemed related to study drug by the investigator. If relationship is missing, it will be imputed as related.

If an event has a TEAE start date that, after imputation rules are applied, is not complete enough to determine the time period in which the TEAE occurred, that event will not be included in the tabulations by study day.

Formal hypothesis-testing of AE incidence rates will not be performed.

By-patient listings of all AEs occurring on-study will be provided as well as for the following, for all patients: patient deaths, SAEs and AEs leading to discontinuation.

4.10.2. Laboratory Data

The Baseline (Screening) values will be summarized for each hematology and clinical chemistry laboratory parameter. All laboratory data, including Common Terminology Criteria for Adverse Events (CTCAE) 4.03 grade, will be provided in data listings. See Section 7.3 for CTCAE grade definitions.

4.10.3. Vital Signs and Physical Examinations

The observed value and change from Baseline at Week 1 and Week 8 for vital sign data will be summarized in a summary table. Vital sign measurements include blood pressure, heart rate, oral temperature, and weight, and BMI. Vital sign measurements will be presented for each patient in a data listing.

All physical examination results will be presented in a data listing.

4.10.4. Index Hip Assessment and Aspiration

The index hip will be assessed for evidence of inflammation, including tenderness, warmth, redness, swelling, and effusion, limitation on range of motion (directions: flexion, extension, abduction, adduction, internal rotation or external rotation; severity: mild, moderate or severe). Clinically significant findings will be summarized. Index hip assessment data will be presented in a data listing.

Aspiration of the index hip joint must be attempted prior to injection of contrast and study medication at Day 1. The synovial fluid volume, if any, will be measured. Data regarding protocol-required aspiration that is performed at the time of injection in will be included in the summary table and listing for Study Drug Exposure. Additional aspirations, not required per protocol, will be presented in a separate aspiration listing.

4.10.5. Index Hip X-Ray

Index hip X-rays are performed at Screening. The Screening X-ray will be read locally for Kellgren-Lawrence (KL) grading. KL grading at baseline will be summarized, based on the following grades:

- Grade 0: Normal appearance.
- Grade 1: Possible osteophytes, possible Joint Space Narrowing (JSN) medially.
- Grade 2: Definite osteophytes, definite JSN, slight sclerosis.
- Grade 3: Mild osteophytes, marked JSN, moderate sclerosis, cysts and deformity
- Grade 4: Large osteophytes, severe JSN, cysts sclerosis and deformity

A patient listing of index hip X-ray will also be presented.

4.10.6. Concomitant Medications

Concomitant medications (CM) will be defined as those medications that were initiated after study drug administration or those that were ongoing at the time of study drug administration. If the start date or stop date of a medication is partially missing, the date will be compared as far as possible with the date of the start of administration of study drug. The medication will be assumed to be prior medication if it cannot be definitively shown that the medication did not start or continue after study drug administration and was not ongoing at the time of study drug administration. The following approach will be taken:

- If the start date of medication is complete and occurs on or after the day of administration of study treatment, the medication will be assumed concomitant. If the start date occurs prior to administration of study treatment but the end date is on or after the administration of study treatment date or the medication is recorded as ongoing, the medication will be considered concomitant.
- If the start day is missing but the start month and year are complete, a medication will only be excluded as being concomitant if the start month/year is before the month/year of study drug administration and if the stop date (either full date, month and year if missing day, or year if missing month and day) is before study drug administration.
- If the start day and month are missing but the start year is complete, a medication will only be excluded as concomitant if the start year is before the year of study drug administration and if the stop date (either full date, month and year if missing day, or year if missing month and day) is before study drug administration.
- If the start date is completely missing and the stop date is prior to administration of study treatment or completely missing, the medication will be assumed to be a prior medication.

All prior and CMs will be presented in a data listing with flags indicating whether each medication was prior and/or concomitant. The listings will include type of medication (general or restrictive) and whether the CM was used for treatment of an AE.

4.10.7. Surgical Procedures

Surgical procedures that occurred during the study will be provided in a data listing.

5. CHANGES TO PLANNED ANALYSES

There are no major changes to the planned analyses.

6. REFERENCES

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7. CLINICAL STUDY REPORT APPENDICES

7.1. Statistical Tables and Figures to be Generated

Table 14.1.1	Patient Enrollment and Disposition (All Patients)
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7.3. Laboratory Unit Conversion Factors

Laboratory Parameter	Original Unit	Conversion Factor	SI Units
Alanine Aminotransferase	IU/L	x 1	U/l
Albumin	g/dl	x 10	g/l
Albumin	mg/dl	x 1/100	g/l
Albumin	umol/l	x 0.069	g/l
Alkaline Phosphatase	mcKat/l	x 1/0.01667	U/l
Alkaline Phosphatase	umol/l	x 1/0.01668	U/l
Alkaline Phosphatase	mU/ml	x 1	U/l
Alkaline Phosphatase	nKat/l	x 1/16.67	U/l
Alkaline Phosphatase	nmol/dl	x 1/1.667	U/l
Alkaline Phosphatase	IU/l	x 1	U/l
Alkaline Phosphatase	UI/l	x 1	U/l
Alpha-foetoprotein	ng/ml	x 1	mcg/l
Arginine test	mg/dl	x 57.4	umol/l
Aspartate Aminotransferase	IU/L	x 1	U/l
Basophils	/mm^3	x 1/1000	10^9/l
Basophils	10^3/micrl	x 1	10^9/l
Basophils	10^3/ml	x 1/1000	10^9/l
Basophils	10^3/mmc	x 1	10^9/l
Basophils	10^3/mm^3	x 1	10^9/l
Basophils	10^6/ml	x 1	10^9/l
Bicarbonate	mEq/l	x 1	mmol/l
Bilirubin (total)	mg/dl	x 1/0.0584671	umol/l
Bilirubin (total)	mg/l	x 1/0.584671	umol/l
Bilirubin (total)	umol/l	x 1	umol/l
BUN	mg/dl	x 0.357	mmol/l
Calcium (II)	meq/l	x 0.5	mmol/l
Calcium (II)	mg/dl	x 1/4.008	mmol/l
Calcium (II)	mg/l	x 1/40.08	mmol/l
CEA	ng/ml	x 1	mcg/l
Ceruloplasmin	mg/dl	x 10	mg/l
Chloride	mEq/l	x 1	mmol/l
Cholesterol (total)	mg/dl	x 1/38.67	mmol/l
Chorionic Gonadotrophin	mIU/ml	x 1	IU/l
Copper (serum)	mcg/dl	x 0.1574	umol/l
Creatine kinase	mcKat/l	x 1/0.017	U/l
Creatinine	mg/dl	x 1/0.0113119	umol/l
Creatinine	mg/l	x 1/0.113119	umol/l
Creatinine	micrmol/l	x 1	umol/l
DHEA	mcg/l	x 3.467	nmol/l
DHEA-S	mcg/dl	x 0.027	umol/l
DHEA-S	umol/l	x 1/0.027	umol/l
Eosinophils	/mm^3	x 1/1000	10^9/l
Eosinophils	10^3/micrl	x 1	10^9/l
Eosinophils	10^3/ml	x 1/1000	10^9/l
Eosinophils	10^3/mmc	x 1	10^9/l
Eosinophils	10^3/mm^3	x 1	10^9/l
Eosinophils	10^6/ml	x 1	10^9/l
Estradiol (female)	pg/ml	x 1/0.2724	pmol/l
Ferritin	ng/ml	x 1	mcg/l
Fibrinogen	g/dl	x 29.41	umol/l
FSH (female)	mIU/ml	x 1	IU/l
GGT	U/l	x 1	IU/l
GGT	UI/l	x 1	IU/l
GGT	mckat/l	x 1/0.017	IU/l
GH	ng/ML	x 1	mcg/l
Glucose	mg/%	x 1/18.0157	mmol/l
Glucose	g/l	x 1/0.180157	mmol/l

Glucose	mg/dl	x 1/18.0157	mmol/l
HBA1C	% total HB	x 100	%
HBA1C	%	x 1/100	fract of 1
HDL	mg/dl	x 0.0259	mmol/l
Haematocrit	%	x 0.01	Vol. Fract.
Haemoglobin	g/100 ml	x 10	g/l
Haemoglobin	g/dl	x 10	g/l
Haemoglobin	mmol/l	x 16.1145	g/l
IGF-I	ng/ml	x 1	mcg/l
Insulin	mcg/l	x 1/0.00580765	pmol/l
Insulin	mU/l	x 7.175	pmol/l
Insulin	mcU/ml	x 7.175	pmol/l
Iron (III)	mcg/dl	x 1/5.5847	umol/l
LDH	mckat/l	x 1/0.01666	IU/l
LDH	umol/l*s	x 1/0.01667	IU/l
LDH	mmol/l	x 1/16.67	IU/l
LDH	mmol/l*s	x 1/16.67	IU/l
LDH	mymol/l*s	x 1/0.01667	IU/l
LDH	nkat/l	x 1/16.67	IU/l
LDL	mg/dl	x 0.0259	mmol/l
LH (female)	mIU/ml	x 1	IU/l
Lymphocytes	/mm^3	x 1/1000	10^9/l
Lymphocytes	10^3/micrl	x 1	10^9/l
Lymphocytes	10^3/ml	x 1/1000	10^9/l
Lymphocytes	10^3/mmc	x 1	10^9/l
Lymphocytes	10^3/mm^3	x 1	10^9/l
Lymphocytes	10^6/ml	x 1	10^9/l
Magnesium (II)	mEq/l	x 0.5	mmol/l
Magnesium (II)	mg/dl	x 1/2.4305	mmol/l
Mean cell volume	mcm^3	x 1	fL
Mean cell volume	micrmc	x 1	fL
Mean cell volume	micrm^3	x 1	fL
Mean cell volume	10^-15/l	x 1	fL
Mean cell Hb	pg/cell	x 1	pg/cell
Mean cell Hb conc.	%	x 10	g/l
Mean cell Hb conc.	g/100 ml	x 10	g/l
Mean cell Hb conc.	g/dl	x 10	g/l
Monocytes	/mm^3	x 1/1000	10^9/l
Monocytes	10^3/micrl	x 1	10^9/l
Monocytes	10^3/ml	x 1/1000	10^9/l
Monocytes	10^3/mmc	x 1	10^9/l
Monocytes	10^3/mm^3	x 1	10^9/l
Monocytes	10^6/ml	x 1	10^9/l
Neutrophils	/mm^3	x 1/1000	10^9/l
Neutrophils	10^3/micrl	x 1	10^9/l
Neutrophils	10^3/ml	x 1/1000	10^9/l
Neutrophils	10^3/mmc	x 1	10^9/l
Neutrophils	10^3/mm^3	x 1	10^9/l
Neutrophils	10^6/ml	x 1	10^9/l
Packed cell volume	l/l	x 100	%
Phosphate	mg/dl	x 1/3.09737	mmol/l
Phosphate	mg/l	x 1/30.9737	mmol/l
Phosphate	mEq/dl	x 5	mmol/l
Phosphate	mEq/l	x 0.5	mmol/l
Platelets	/mcl	x 1/1000	10^9/l
Platelets	/mm^3	x 1/1000	10^9/l
Platelets	/nl	x 1	10^9/l
Platelets	/pl	x 1000	10^9/l
Platelets	10^12/l	x 1/1000	10^9/l
Platelets	10^3/mcl	x 1	10^9/l

Platelets	10^3/ml	x 1/1000	10^9/l
Platelets	10^3/mm^3	x 1	10^9/l
Platelets	10^3/ul	x 1	10^9/l
Platelets	k/mcl	x 1	10^9/l
Platelets	10^3/micrl	x 1	10^9/l
Platelets	10^3/mmc	x 1	10^9/l
Platelets	10^6/ml	x 1	10^9/l
Potassium ion (K)	mEq/l	x 1	mmol/l
Potassium ion (K)	mg/l	x 1/39.098	mmol/l
Prolactin	ng/ml	x 1	mcg/l
Protein (Total)	g/dl	x 10	g/l
Protein (Total)	mg/dl	x 0.01	g/l
Prothrombin	%	x 1/100	Fract of 1
PT	seconds	x 1	seconds
PTT	seconds	x 1	seconds
RBC	/mcl	x 1/1000	10^12/l
RBC	/pl	x 1	10^12/l
RBC	10^6/mcl	x 1	10^12/l
RBC	/nl	x 1000	10^12/l
RBC	10^6/mm3	x 1	10^12/l
RBC	10^9/l	x 1000	10^12/l
RBC	T/L	x 1	10^12/l
RBC	10^6/micrl	x 1	10^12/l
RBC	10^3/ml	x 1000000	10^12/l
RBC	10^6/mmc	x 1	10^12/l
RBC	10^6/mm^3	x 1	10^12/l
SGOT (AST)	mckat/l	x 1/0.01667	IU/l
SGOT (AST)	umol/l*s	x 1/0.01668	IU/l
SGOT (AST)	mmol/l	x 1/16.67	IU/l
SGOT (AST)	mmol/l*s	x 1/16.67	IU/l
SGOT (AST)	nkat/l	x 1/16.67	IU/l
SGOT (AST)	U/l	x 1	IU/l
SGOT (AST)	UI/l	x 1	IU/l
SGPT (ALT)	U/l	x 1	IU/l
SGPT (ALT)	UI/l	x 1	IU/l
Sodium ion (Na)	mEq/l	x 1	mmol/l
Sodium ion (Na)	mg/dl	x 1/2.29898	mmol/l
Sodium ion (Na)	g/l	x 1/0.0229898	mmol/l
TBG	mcg/dl	x 12.87	nmol/l
Thyroxin (T4)	mcg/dl	x 1/0.0776874	nmol/l
Thyroxin (T4)	mcg/l	x 1/0.776874	nmol/l
Thyroxin free (fT4)	ng/dl	x 1/0.0776874	pmol/l
Transferrin	mg/dl	x 1/100	g/l
Triglycerides	mg/dl	x 1/88.5445	mmol/l
Triglycerides	g/l	x 1/0.885445	mmol/l
Triiodothyronine (T3)	ng/dl	x 1/65.0976	nmol/l
Triiodothyronine free (fT3)	pg/dl	'x 1/65.0976	pmol/l
Triiodothyronine Uptake	%	x 1/100	fract of 1
TSH (thyrotropin)	mcU/ml	1	mU/l
TT	seconds	x 1	seconds
Urea	mg/dl	x 1/6.00554	mmol/l
Urea	mg/l	x 1/60.0554	mmol/l
Urea	g/l	x 1/0.0600554	mmol/l
Uric acid	mg/dl	x 59.4800	umol/l
Uric acid	mg/l	x 5.9480	umol/l
Uric acid	umol/l	x 1	umol/l
WBC	10^3/micrl	x 1/1000	10^9/l
WBC	/mm^3	x 1/1000	10^9/l
WBC	/pl	x 1000	10^9/l
WBC	10^3/ml	x 1/1000	10^9/l

WBC	10^3/mcl	x 1	10^9/l
WBC	x 10^3/mm^3	x 1	10^9/l
WBC	/mcl	x 1/1000	10^9/l
WBC	10^3/mmc	x 1	10^9/l
WBC	10^6/ml	x 1	10^9/l

7.4. Laboratory Normal Ranges

Site 033:

Lab Panel	Analyte	Male - LO	Male - HI	Female - LO	Female - HI	Units
Chemistry	Sodium	133	145	133	145	mmol/L
Chemistry	Potassium	3.6	5.5	3.6	5.5	mmol/L
Chemistry	Bicarbonate	21	31	21	31	meq/mL
Chemistry	Chloride	96	110	96	110	mmol/L
Chemistry	Calcium	8.5	10.4	8.5	10.4	mg/dL
Chemistry	Total Bilirubin	0.1	1.5	0.1	1.5	mg/dL
Chemistry	Alkaline Phosphatase	39	117	39	117	U/L
Chemistry	Alanine Aminotransferase	0	40	0	40	U/L
Chemistry	Aspartate Aminotransferase	0	37	0	37	U/L
Chemistry	Blood Urea Nitrogen	6	19	6	19	mg/dL
Chemistry	Creatinine	0.5	1.2	0.5	1.2	mg/dL
Chemistry	Uric Acid	3.4	7	3.4	7	mg/dL
Chemistry	Glucose	65	99	65	99	mg/dL
Chemistry	Total Protein	5.9	8.4	5.9	8.4	g/dL
Chemistry	Albumin	3.2	5.1	3.2	5.1	g/dL
Hematology	Hemoglobin	14	18	12	16	g/dL
Hematology	Hematocrit	42	52	37	47	%
Hematology	Erythrocytes count	4.7	6.1	4.2	5.4	x 10^6 / µl
Hematology	Mean Cell Volume	80	94	81	99	fL
Hematology	Leukocytes	4.8	10.8	4.8	10.8	x 10^3 / µl
Hematology	Neutrophils	40	70	40	70	%
Hematology	Lymphocytes	17	45	17	45	%
Hematology	Monocytes	0	12	0	12	%
Hematology	Eosinophils	0	9	0	9	%
Hematology	Basophils	0	3	0	3	
Hematology	Platelets	150	400	150	400	x 10^3 / µl

Site 053:

Lab Panel	Analyte	Male - LO	Male - HI	Female - LO	Female - HI	Units
Chemistry	Sodium	136	145	136	145	mmol/L
Chemistry	Potassium	3.5	5.2	3.5	5.2	mmol/L
Chemistry	Bicarbonate	21	32	21	32	mmol/L
Chemistry	Chloride	98	109	98	109	mmol/L
Chemistry	Calcium	8.8	10.6	8.8	10.6	mg/dL
Chemistry	Total Bilirubin	0.3	1	0.3	1	mg/dL
Chemistry	Alkaline Phosphatase	33	125	33	125	U/L
Chemistry	Alanine Aminotransferase	7	52	7	52	U/L
Chemistry	Aspartate Aminotransferase	13	39	13	39	U/L
Chemistry	Blood Urea Nitrogen	7	25	7	25	mg/dL
Chemistry	Creatinine	0.6	1.3	0.6	1.3	mg/dL
Chemistry	Uric Acid	4.4	7.6	2.3	6.6	mg/dL
Chemistry	Glucose	65	99	65	99	mg/dL
Chemistry	Total Protein	6.4	8.9	6.4	8.9	g/dL
Chemistry	Albumin	3.5	5.7	3.5	5.7	g/dL
Hematology	Hemoglobin	13.7	17.5	11.2	15.7	g/dL
Hematology	Hematocrit	40.1	51	34.1	44.9	%
Hematology	Erythrocytes count	4.63	6.08	3.93	5.22	x 10^6 / µl
Hematology	Mean Cell Volume	79	92.2	79.4	94.8	fL
Hematology	Leukocytes	4.23	9.07	3.98	10.04	x 10^3 / µl
Hematology	Neutrophils	1780	5380	1560	6130	Cell/Cmm
Hematology	Lymphocytes	1.32	3.57	1.18	3.74	x 10^3 / µl
Hematology	Monocytes	0.3	0.82	0.24	0.86	x 10^3 / µl
Hematology	Eosinophils	0.04	0.54	0.04	0.36	x 10^3 / µl
Hematology	Basophils	0.01	0.08	0.01	0.08	x 10^3 / µl
Hematology	Platelets	163	337	182	369	x 10^3 / µl

Site 309:

Lab Panel	Analyte	Male - LO	Male - HI	Female - LO	Female - HI	Units
Chemistry	Sodium	136	145	136	145	mmol/L
Chemistry	Potassium	3.4	5	3.4	5	mmol/L
Chemistry	Bicarbonate	20	31	20	31	mmol/L
Chemistry	Chloride	98	108	98	108	mmol/L
Chemistry	Calcium	8.4	10.2	8.4	10.2	mg/dL
Chemistry	Total Bilirubin	0	1.2	0	1.2	mg/dL
Chemistry	Alkaline Phosphatase	35	129	35	129	U/L
Chemistry	Alanine Aminotransferase	21	72	9	52	U/L
Chemistry	Aspartate Aminotransferase	0	40	0	34	U/L
Chemistry	Blood Urea Nitrogen (17-60 years)	5	22	5	22	mg/dL
Chemistry	Blood Urea Nitrogen (>60 years)	5	25	5	25	mg/dL
Chemistry	Creatinine	0.5	1.3	0.5	1.3	mg/dL
Chemistry	Uric Acid	3.4	8	2.4	7	mg/dL
Chemistry	Glucose	70	109	70	109	mg/dL
Chemistry	Total Protein	6.6	8.7	6.6	8.7	g/dL
Chemistry	Albumin	3.5	5.7	3.5	5.7	g/dL
Hematology	Hemoglobin	14	17.5	13	16	g/dL
Hematology	Hematocrit	38	52	35	47	%
Hematology	Erythrocytes count	4.5	6	4	5.2	x 10^6 / µl
Hematology	Mean Cell Volume	80	100	80	100	fL
Hematology	Leukocytes	4.5	11	4.5	11	x 10^3 / µl
Hematology	Neutrophils	44	77	44	77	%
Hematology	Lymphocytes	16	44	16	44	%
Hematology	Monocytes	5	13	5	13	%
Hematology	Eosinophils	0	8	0	8	%
Hematology	Basophils	0	3	0	3	%
Hematology	Platelets	140	400	140	400	x 10^3 / mcl

Site 326:

Lab Panel	Analyte	Male - LO	Male - HI	Female - LO	Female - HI	Units
Chemistry	Sodium	135	145	135	145	mmol/L
Chemistry	Potassium	3.5	5.3	3.5	5.3	mmol/L
Chemistry	Bicarbonate	22	31	22	31	mmol/L
Chemistry	Chloride	96	108	96	108	mmol/L
Chemistry	Calcium	8.5	10.5	8.5	10.5	mg/dL
Chemistry	Total Bilirubin	0.2	1	0.2	1	mg/dL
Chemistry	Alkaline Phosphatase	45	117	45	117	U/L
Chemistry	Alanine Aminotransferase	12	42	12	42	U/L
Chemistry	Aspartate Aminotransferase	15	37	15	37	U/L
Chemistry	Blood Urea Nitrogen	7	23	7	23	mg/dL
Chemistry	Creatinine	0.5	1.3	0.5	1.3	mg/dL
Chemistry	Uric Acid	3.5	7.2	2.6	6	mg/dL
Chemistry	Glucose	70	99	70	99	mg/dL
Chemistry	Total Protein	6.4	8.2	6.4	8.2	g/dL
Chemistry	Albumin	3.4	5	3.4	5	g/dL
Hematology	Hemoglobin	13	17	11.5	15.5	g/dL
Hematology	Hematocrit	39	50	34.5	45	%
Hematology	Erythrocytes count	4.2	5.8	3.8	5.2	M/uL
Hematology	Mean Cell Volume	80	100	80	100	fL
Hematology	Leukocytes	3.8	10.5	3.8	10.5	K/uL
Hematology	Neutrophils	43	77	43	77	%
Hematology	Lymphocytes	13	44	13	44	%
Hematology	Monocytes	2	14	2	14	%
Hematology	Eosinophils	0	6	0	6	%
Hematology	Basophils	0	2	0	2	%
Hematology	Platelets	150	400	150	400	K/uL

Site 330:

Lab Panel	Analyte	Male - LO	Male - HI	Female - LO	Female - HI	Units
Chemistry	Sodium	134	147	134	147	mmol/L
Chemistry	Potassium	3.6	5.3	3.6	5.3	mmol/L
Chemistry	Bicarbonate	19	31	19	31	mmol/L
Chemistry	Chloride	95	108	95	108	mmol/L
Chemistry	Calcium	8.8	10.4	8.8	10.4	mg/dL
Chemistry	Total Bilirubin	0.2	1.3	0.2	1.3	mg/dL
Chemistry	Alkaline Phosphatase	40	140	37	127	U/L
Chemistry	Alkaline Phosphatase (>50 years)	40	140	42	146	U/L
Chemistry	Alanine Aminotransferase	5	46	5	46	IU/L
Chemistry	Aspartate Aminotransferase	10	50	10	41	IU/L
Chemistry	Blood Urea Nitrogen	8	25	8	25	mg/dL
Chemistry	Creatinine	0.6	1.5	0.6	1.4	mg/dL
Chemistry	Uric Acid (13-60)	3.5	8	2.2	6.5	mg/dL
Chemistry	Uric Acid (>60 years)	3.5	8	2.2	7	mg/dL
Chemistry	Glucose	65	99	65	99	mg/dL
Chemistry	Total Protein	6	8	6	8	g/dL
Chemistry	Albumin (1-50 years)	3.6	5.1	3.6	5.1	g/dL
Chemistry	Albumin (>50 years)	3.4	4.9	3.4	3.9	g/dL
Hematology	Hemoglobin	13	18	11.5	16	g/dL
Hematology	Hematocrit	35	48	35	48	%
Hematology	Erythrocytes count	4.3	6	3.7	5.4	m/mm3
Hematology	Mean Cell Volume	78	100	78	100	fL
Hematology	Leukocytes	4	11	4	11	k/mm3
Hematology	Neutrophils	1.6	9.3	1.6	9.3	k/uL
Hematology	Lymphocytes	0.6	5.5	0.6	5.5	k/uL
Hematology	Monocytes	0.1	1.6	0.1	1.6	k/uL
Hematology	Eosinophils	0	0.7	0	0.7	k/uL
Hematology	Basophils	0	0.2	0	0.2	k/uL
Hematology	Platelets	130	450	130	450	k/mm3

7.5. Laboratory Grade Definitions - CTCAE 4.03

Lab Parameter	Hypo/Hyper	CTCAE Definition	SI Unit	Grade 1	Grade 2	Grade 3	Grade 4
Alanine Aminotransferase	Hyper	Alanine Aminotransferase increased	IU/L	>ULN-3xULN	>3-5xULN	>5-20xULN	>20xULN
Albumin	Hypo	Hypoalbuminemia	g/L	<LLN-30	<30-20	<20	-
Alkaline Phosphatase	Hyper	Alkaline Phosphatase increased	IU/L	>ULN-2.5xULN	>2.5-5xULN	>5-20xULN	>20xULN
Aspartate Aminotransferase	Hyper	Aspartate Aminotransferase increased	IU/L	>ULN-3xULN	>3-5xULN	>5-20xULN	>20xULN
Bilirubin	Hyper	Blood bilirubin increased	umol/L	>ULN-1.5xULN	>1.5-3xULN	>3-10xULN	>10xULN
Calcium	Hypo	Hypocalcemia	mmol/L	<LLN-2	<2-1.75	<1.75-1.5	<1.5
Calcium	Hyper	Hypercalcemia	mmol/L	>ULN-2.9	>2.9-3.1	>3.1-3.4	>3.4
Cholesterol	Hyper	Hypercholesterolemia	mmol/L	>ULN-7.75	>7.75-10.34	>10.34-12.92	>12.92
Creatinine	Hyper	Creatinine increased	umol/L	>1-1.5x Baseline;	>1.5-3x Baseline; >1.5-3x ULN	>3x Baseline; >3-6xULN	>6xULN

Lab Parameter	Hypo/Hyper	CTCAE Definition	SI Unit	Grade 1	Grade 2	Grade 3	Grade 4
				>ULN-1.5xULN			
Glucose	Hyper	Hyperglycemia	mmol/L	>ULN-8.9	>8.9-13.9	>13.9-27.8	>27.8
Phosphate	Hypo	Hypophosphatemia	mmol/L	<LLN-0.8	<0.8-0.6	<0.6-0.3	<0.3
Potassium	Hypo	Hypokalemia	mmol/L	<LLN-3	<LLN-3	<3-2.5	<2.5
Potassium	Hyper	Hyperkalemia	mmol/L	>ULN-5.5	>5.5-6	>6-7	>7
Sodium	Hypo	Hyponatremia	mmol/L	<LLN-130	-	<130-120	<120
Sodium	Hyper	Hypernatremia	mmol/L	ULN-150	>150-155	>155-160	>160
Triglycerides	Hyper	Hypertriglyceridemia	mg/dL	150-300	>300-500	>500-1000	>1000
Hemoglobin	Hypo	Anemia	g/L	<LLN-100	<100-80	<80	-
Hemoglobin	Hyper	Hemoglobin increased	g/L	Increase in>0-20 above ULN or above Baseline if Baseline is above ULN	Increase in >20-40 above ULN or above Baseline if Baseline is above ULN	Increase in >40 above ULN or above Baseline if Baseline is above ULN	-
Leukocytes	Hypo	White blood cells decreased	10^9/L	<LLN-3.0	<3.0-2.0	<2.0-1.0	<1.0

Lab Parameter	Hypo/Hyper	CTCAE Definition	SI Unit	Grade 1	Grade 2	Grade 3	Grade 4
Leukocytes	Hyper	Leukocytosis	10^9/L	-	-	>100	-
Lymphocytes	Hypo	Lymphocyte count decreased	10^9/L	<LLN-0.8	<0.8-0.5	<0.5-0.2	<0.2
Lymphocytes	Hyper	Lymphocyte count increased	10^9/L	-	>4-20	>20	-
Neutrophils	Hypo	Neutrophils count decreased	10^9/L	<LLN-1.5	<1.5-1	<1-0.5	<0.5
Platelets	Hypo	Platelet count decreased	10^9/L	<LLN-75	<75-50	<50-25	<25

The following hematology and chemistry parameters collected in the study are not gradable with CTCAE v4.03:

- Blood Urea Nitrogen
- Bicarbonate (removed from version 4.x; it was available in version 3)
- Chloride
- Erythrocyte Mean Corpuscular Volume
- HDL Cholesterol
- LDL Cholesterol
- Urate
- Basophils
- Eosinophils
- Erythrocytes
- Hematocrit
- Monocytes