Statistical Analysis Plan	
Study Code	C2661002
Edition Number	2.7
Date	22 March 2018

Open-label, Multicentre Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Ceftaroline in Neonates and Young Infants with Late-Onset Sepsis

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Study Statistician PPD

PPD, PRA Health Sciences

PPD

Date

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SIGNATURE OF GLOBAL PRODUCT STATISTICIAN

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LIST OF ABBREVIATIONS

Abbreviation or special term	Explanation
AE	Adverse event
AESI	Adverse event of special interest
BE	Base excess
BLQ	Below limit of quantification
CBC	Complete blood count
CI	Confidence interval
CRF	Case report form
CRP	C-reactive protein
CSF	Cerebrospinal fluid
CT	Computed tomography
CTMS	Clinical Trials Management System
CV	Coefficient of variation
CXR	Chest radiograph
DSMB	Data Safety Monitoring Board
EOT	End-of-therapy
ICF	Informed consent form
ITT	Intent-to-treat
IV	Intravenous
LLN	Lower limit of normal
LOS	Late-onset sepsis
LOQ	Limit of quantification
MedDRA	Medical Dictionary for Regulatory Activities
MIC	Minimum Inhibitory Concentration
MITT	Modified intent-to-treat
MRI	Magnetic resonance imaging
NC	Not calculable
NQ	Non quantifiable
OAE	Other significant AE
PCS	Potentially clinically significant
PD	Protocol deviation
PK	Pharmacokinetic
q8h	Every 8 hours

Abbreviation or special term	Explanation
SAE	Serious adverse event
SAP	Statistical analysis plan
SD	Standard deviation
SFU	Safety follow-up
SMQ	Standard MedDRA Query
SOC	System organ class
TFL	Tables, Figures and Listings
TOC	Test-of-cure
ULN	Upper limit of normal
WBC	White blood cell
WHODDE	World Health Organization Drug Dictionary Enhanced

AMENDMENT HISTORY

Date	Brief description of change
9 Dec 2014	V0.1 Initial Statistical Analysis Plan (SAP) for client review.
7 Jan 2015	V0.2 Version incorporating client review comments on V0.1.
21 Jan 2015	V1.0 Signed version approved for programming commencement incorporating client review comments on V0.2.
8 June 2016	V2.0 Updated version of the SAP incorporating Protocol Amendment changes as outlined below: Change in definition of study day from "Study Day 1 is defined as the first day of study therapy administration." to "Study Day 1 will start at the onset of study therapy and will end 24 hours later.". Change in definition of cohort 2 from "Cohort 2: term neonates (defined as gestational age **≥38 weeks**) aged 7 to ≤28 days". to "Cohort 2: term neonates (defined as gestational age **≥37 weeks**) aged 7 to ≤28 days". Change in definition of cohort 3 from "Cohort 3: preterm neonates (defined as gestational age ≥34 to **<38 weeks**) aged 7 to ≤28 days" to "Cohort 3: preterm neonates (defined as gestational age ≥34 to **<37 weeks**) aged 7 to ≤28 days". Change in dose from "Ceftaroline fosamil will be given at a dose of 4 mg/kg IV over 60 (± 10) minutes every 8 hours (q8h) (± 1 hour)." to "Ceftaroline fosamil will be given at a dose of 6 mg/kg IV over 60 (± 10) minutes every 8 hours (q8h) (± 1 hour).".]. Change in requirements for administration of IV ampicillin and optional aminoglycoside from "IV ampicillin and optional aminoglycoside will be given as per standard of care." to "IV ampicillin and optional aminoglycoside will be given as per standard of care. If the presence of an organism that requires treatment with ampicillin cannot be excluded, then the use of IV ampicillin for the first 48 hours is mandatory. If the result of additional microbiology, polymerase chain reaction or other investigations, indicate that ampicillin during the first 48 hours of treatment is not required, then its use is at the discretion of the investigator.". In addition to the changes in relation to protocol amendments, additional tables were added for the duration of different Investigational Products (IP) [Ceftaroline, Ampicillin and Aminoglycoside]. Some additional programming notes were added to the shells to assist with the definition of variables within the derived/analysis datasets. An additional appendix was added to the SAP to list the criteria for potentially clinically significant laboratory tests. An additional appendix was added to the SAP to indicate the TFLs required for the Data Safety Monitoring Board (DSMB).

Date	Brief description of change
12 July 2016	V2.1 Updated to incorporate client review comments on V2.0. Updated to incorporate protocol amendment 2 changes: study medication dose changed from 4mg/kg to 6mg/kg.
23 August 2016	V2.2 Updated to incorporate client review comments on V2.1: In section 3.1.1.1, if the intensity of an Adverse Event (AE) is missing, the AE will be regarded as having missing rather than severe intensity; If the relationship of an AE to IMP is missing, the AE will be regarded as having a missing relationship to IMP rather than being related to IMP; and an additional table for the duration of prior medication was added. Updated to incorporate protocol amendment 3 changes: inclusion criteria 3, 4 and 5 were revised so that patients must meet at least 1 of the listed laboratory criteria, rather than 2 of the criteria and justification provided for the dose increase to 6mg/kg in the previous protocol amendment.
5 September 2016	V2.3 Additional details added to the amendment history for V2.2 of the SAP. The text of SAP Appendix A was clarified. Listing was replaced with Appendix in the "Source: …" footnote of Tables. Listing xx.x.xx was removed from the footnotes of the TFL appendix shells, as not required.
6 December 2017	V2.4 Updated to incorporate protocol amendment 4. Version of protocol and CRF updated. Additional Tables and Listings added further to receipt of Pfizer review comments. Unnecessary appendices removed and cross-references within the SAP updated. Details in relation to the DSMB modified and DSMB Tables and Listings removed as no further DSMBs to occur.
12 January 2018	V2.5 Updated to incorporate final Pfizer review comments on V2.4 SAP and TFL shells. Additional Tables and Listings added. Further TFL numbering changes incorporated. Additional Microbiological ITT population added. Further clarification of non-eligible organisms provided in Appendix A.
16 March 2018	V2.6 Incorporate final changes to the SAP ahead of database lock. Update to include list of AESIs. Update to Micro-ITT population definition. Post Data Review Meeting changes incorporated.

Date	Brief description of change
22 March 2018	V2.7 Appendix A updated to move Enterococcus species from never to sometimes a pathogen based on investigator determination.

1. STUDY DETAILS

This statistical analysis plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under Pfizer Protocol C2661002. This version of the plan has been developed using the protocol dated 25 May 2017 and case report form (CRF) dated 17 November 2017. Any further changes to the protocol or CRF may necessitate updates to the SAP and will be captured in an amendment.

1.1 Study objectives

1.1.1 Primary objective

The primary objective is to evaluate the safety and tolerability of ceftaroline for the treatment of late-onset sepsis (LOS) in neonates and young infants aged 7 to <60 days.

1.1.2 Secondary objectives

The secondary objectives are:

- To evaluate the pharmacokinetic (PK) profile of ceftaroline in neonates and young infants aged 7 to <60 days with LOS
- To evaluate the efficacy of ceftaroline for the treatment of LOS in neonates and young infants aged 7 to <60 days.

1.1.3 Exploratory objectives (Not applicable)

1.2 Study design

This open label, multicentre, multinational, single treatment arm study will evaluate the safety, tolerability, PK, and efficacy of ceftaroline fosamil and ampicillin, plus an optional aminoglycoside of choice, in hospitalized neonates and young infants with LOS. The study will be conducted in approximately 30 centres worldwide. Eligible pediatric patients (7 to <60 days) with suspected or confirmed LOS will be enrolled in this study. At least 24 patients with LOS will be enrolled and treated within three age cohorts of 8 patients:

- Cohort 1: young infants aged >28 days to <60 days (n=8)
- Cohort 2: term neonates (defined as gestational age ≥37 weeks) aged 7 to ≤28 days (n=8)
- Cohort 3: preterm neonates (defined as gestational age ≥34 to <37 weeks) aged 7 to ≤28 days (n=8).

This study is not randomized, but patients will be stratified by age cohort and randomly assigned (1:1) at the time of enrolment to 1 of the PK sample collection schedules:

- PK Schedule 1: at the end of the ceftaroline fosamil infusion (± 5 minutes, i.e. within 5 minutes of the end of the ceftaroline infusion) and 3 to 4 hours after the end of the infusion
- PK Schedule 2: 15 minutes to 2 hours after the end of the ceftaroline fosamil infusion and 5 to 7 hours after the end of the infusion (before the start of the next infusion).

Study therapy will consist of standard of care ampicillin plus an optional aminoglycoside of choice, with the addition of intravenous (IV) ceftaroline fosamil, and will be given to all patients. Ceftaroline fosamil will be given at a dose of 6 mg/kg IV over 60 (± 10) minutes every 8 hours (q8h) (± 1 hour). If the presence of an organism that requires treatment with ampicillin cannot be excluded, then the use of IV ampicillin for the first 48 hours is mandatory. If the result of additional microbiology, polymerase chain reaction or other investigations, indicate that ampicillin during the first 48 hours of treatment is not required, then its use is at the discretion of the investigator.

The study design is described in the Study Diagram (Figure 1). Patient participation will require up to 49 days (up to 14 days of treatment plus up to 35 days of safety follow-up). The total duration of study therapy is 48 hours (minimum) to 14 days (maximum). Hospitalization is required during IV study therapy. Baseline assessments for study eligibility will occur within 36 hours before the first dose of study therapy.

Procedures will be performed according to the Study Plan in Table 1. Safety assessments will be done throughout the study. Between Day 2 and Day 14, 2 blood samples will be collected for PK analysis. The efficacy of ceftaroline fosamil will be evaluated based on the clinical outcome (clinical cure, clinical failure or indeterminate) at end of therapy (EOT; within 24 hours after completion of last infusion) and test-of-cure (TOC; 8 to 15 days after the last dose of study therapy) assessments. The Safety Follow-up (SFU) assessments will occur 28 to 35 days after the last dose of study therapy. Adverse events (AEs) will be followed up in the study until SFU.

A patient who is prematurely discontinued from study therapy administration for any reason will have EOT assessments conducted and undergo subsequent safety assessments at TOC and SFU per protocol.

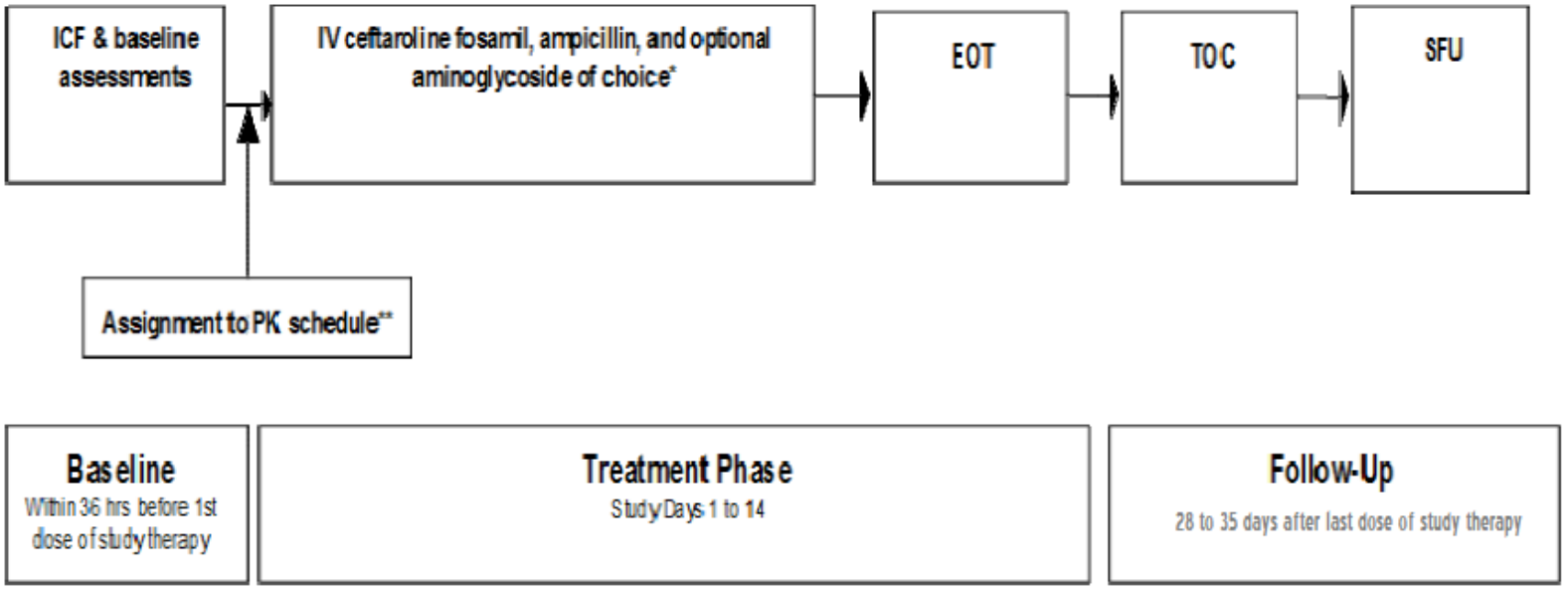
- If a patient is prematurely discontinued from study therapy due to an adverse event and the clinical signs and symptoms of sepsis have resolved completely or improved such that no further antibacterial therapy is necessary, the patient will be assessed as a clinical cure at EOT and reassessed at TOC.
- If a patient is prematurely discontinued from study therapy due to a study therapy-related AE and requires alternative non-study antibacterial for treatment for LOS, the patient will be assessed as a clinical failure (or indeterminate, if the patient discontinued before minimum treatment duration) at EOT and TOC.
- If a patient is prematurely discontinued from study therapy administration (at any time after the required minimum treatment duration of 48 hours) due to insufficient therapeutic effect, the patient will be assessed as a clinical failure on the day of discontinuation (ie, EOT) and at all subsequent evaluation time points.

A patient who is withdrawn completely from this study will undergo, if possible, EOT assessments per protocol on the day of withdrawal. Patients withdrawn from the study will not undergo subsequent TOC efficacy assessments. Patients who are withdrawn from the study and have not been assessed as clinical failure will be assessed as indeterminate for all remaining scheduled clinical assessments. Patients withdrawn from therapy and assessed as a clinical cure at EOT will undergo subsequent TOC efficacy assessments, if possible.

An external Data Safety Monitoring Board (DSMB) will review data on a regular basis to assess the safety of all patients enrolled in this and other ongoing pediatric studies of

ceftaoline fosamil. The scope of the DSMB and the data to be provided to them is documented in a separate DSMB charter.

Figure 1 Study Diagram



Abbreviations: EOT=end of therapy. ICF=informed consent. IV=intravenous. PK=pharmacokinetic. SFU=safety follow-up. TOC=test of cure.

An external Data and Safety Monitoring Board (DSMB) will be established to review safety data from this study and other ongoing pediatric studies of ceftaroline fosamil on a regular basis to ensure safety of all subjects enrolled

* IV ampicillin and optional aminoglycoside will be given as per standard of care. If the presence of an organism that requires treatment with ampicillin cannot be excluded, then the use of IV ampicillin for the first 48 hours is mandatory. If the result of additional microbiology, polymerase chain reaction or other investigations, indicate that ampicillin during the first 48 hours of treatment is not required, then its use is at the discretion of the investigator

** Patients will be randomly assigned to PK schedule using IXRS

Table 1 Study Plan

Assessment or Procedure		Baseline	Treatment period					Follow-up	
			Study Days*						
			1	2	3	4-14	EOT [b]	TOC[c]	SFU[d]
	Written informed consent	X							
	Inclusion/exclusion criteria[e]	X							
Clinical	Medical history (including antepartum/peripartum period)	X							
	Adverse event review (AEs and SAEs)	X	X	X	X	X	X	X	X
	Prior and concomitant medications[f]	X	X	X	X	X	X	X	X
	Length	X							
	Weight	X	X	X	X	X	X	X	X
	Physical examination	X	X	X	X	X	X	X	
	Vital signs and oxygen saturation[g]	X	X	X	X	X	X	X	X
	Clinical outcome						X	X	
	Record adjunctive therapeutic procedures (if performed)		X	X	X	X	X	X	
	CXR, CT scan, or other imaging tests[h]	X[j]							
Laboratory	CBC with differential[i]	X	X[j]				X	X[j]	X[j]
	Chemistry panel[i]	X	X[j]				X	X[j]	X[j]
	Base excess	X[j]							
	CRP and Procalcitonin[i]	X[j]							
	Urinalysis	X	X[j]				X	X[j]	
	Urine output	X[k]	X	X	X	X[j]			
	CSF	X[j]							
PK	Assignment to PK schedule[l]	X							
	PK blood sample[m]			X					
	CSF sample (if collected per standard of care) & matching blood sample[n]		X						
Micro	Blood culture	X[j]							
	Urine culture	X[j]							
	CSF culture	X[j]							
	Other specimen or tissue cultures	X[j]							
	Administration of study therapy		X	X	X	X	X		

Abbreviations: AEs=adverse events; CBC=complete blood count; CRP=C-reactive protein; CSF=cerebrospinal fluid; CT=computed tomography; CXR=chest radiograph; EOT=End-of-Therapy; MRI=magnetic resonance imaging; PK=pharmacokinetic; SAEs=serious adverse events; SFU=Safety Follow-up; TOC=Test-of-Cure.

a. Conduct Baseline assessments within 36 hours before first dose of study therapy.
b. Conduct EOT assessments within 24 hours after the last dose of study therapy. Study therapy may or may not be given on the same calendar day as EOT assessments; administration should be as for days 4-14.
c. Conduct TOC assessments 8 to 15 days after the last dose of study therapy.
d. Conduct SFU assessments, preferably in person, 28 to 35 days after the last dose of study therapy. The SFU may be conducted via telephone for any patient who has not experienced clinical relapse, did not have ongoing AEs or SAEs at TOC, or did not develop AEs or SAEs since TOC. If symptoms of relapse or new AEs or SAEs are noted, or at the discretion of the investigator, the patient should be immediately scheduled for an in-person visit. If the visit is in-person, weight, vital signs and oxygen saturation should be recorded. If a patient was previously assessed as a clinical failure, only safety assessments will be performed.
e. Refer to the inclusion criteria (Section 3.1 of the study protocol) for the recommended definitions of clinical and laboratory inclusion criteria.
f. For patients who are being breast fed, record all medications taken by the lactating mother for 3 days before first dose of study therapy through SFU.
g. Postbaseline, record highest and lowest postdose temperature measurements.
h. At baseline, record results of CXR, CT scan, or other imaging tests (eg, echocardiogram, CT, MRI, sonography) if performed within 72 hours before first dose of study therapy.
i. Refer to the inclusion criteria (Section 3.1 of the study protocol) for list of tests. Recommended to repeat at least every 7 days. If immature neutrophils are available, calculate I/T neutrophil ratio using the formula: I/T ratio=Immature cells/Total (mature+immature).
j. If clinically indicated.
k. For patients who have been hospitalized for ≥8 hours, calculate urine output over the last 8 hour period.
l. Patients will be randomly assigned (1:1) to one of the following PK sample collection schedules collected after any dose between the end of the 4th infusion of ceftaroline fosamil and before EOT or Study Day 14 (whichever is earlier):
   PK Schedule 1: at the end of the ceftaroline fosamil infusion (± 5 minutes) and 3 to 4 hours after the end of the infusion
   PK Schedule 2: 15 minutes to 2 hours after the end of the ceftaroline fosamil infusion and 5 to 7 hours after the end of the infusion (before the start of the next infusion).
m. PK blood samples are NOT to be drawn if the patient received a blood or blood component transfusion within the past 24 hours. For patients who are at risk from additional blood loss, collection of PK samples will require assessment by the investigator.
n. Matching blood sample to be collected only if 2 PK blood samples have not been collected already. The matching blood sample replaces one of the PK samples, so that the total number of PK samples does not exceed 2.

1.3 Number of patients

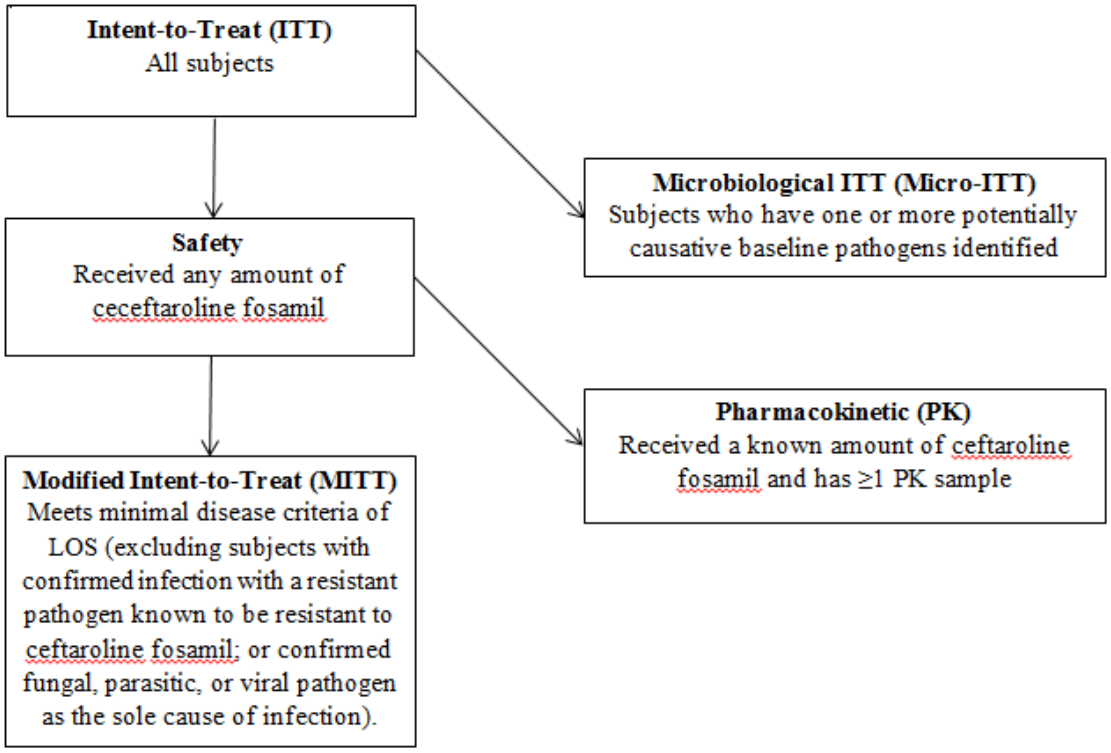
The primary objective of this study is to evaluate safety and tolerability of ceftaroline fosamil in neonates and young infants aged 7 to <60 days with LOS and the study is not powered for inferential statistical analysis. The sample size (24 patients; 3 cohorts of 8 patients) is considered adequate to evaluate the safety of ceftaroline fosamil in neonates and young infants with LOS.

2. ANALYSIS SETS

2.1 Definition of analysis sets

Figure 2 shows the relationship among different analysis sets graphically. The analysis of data will be based on different analysis sets according to the purpose of analysis, ie, for safety, efficacy, etc.

Figure 2 Study Analysis Sets



2.1.1 Intent-to-treat Analysis Set

The Intent-to-treat (ITT) Analysis Set will consist of all enrolled patients for whom informed consent form (ICF) was signed.

2.1.2 Safety Analysis Set

The Safety Analysis Set will be a subset of the ITT Analysis Set and will include all patients who received any amount of ceftaroline fosamil.

2.1.3 Modified Intent-to-Treat Analysis Set

The Modified Intent-to-treat (MITT) Analysis Set will include all patients who received any amount of ceftaroline fosamil and who met minimal disease criteria of LOS as described in the protocol inclusion criteria (diagnosis of sepsis within 36 hours before enrolment, defined as the presence of at least 2 clinical criteria and at least 1 laboratory criteria in the presence of or as a result of suspected or proven bacterial infection that requires IV antibiotic therapy). Patients with confirmed infection at baseline with a pathogen known to be resistant by CLSI methodologies and interpretive criteria (M100-S-28) to the study therapy received will be excluded. Patients with a confirmed fungal, parasitic, or viral pathogen as the sole cause of infection will also be excluded (Appendix A).

2.1.4 Microbiological Intent-to-Treat Analysis Set

The Microbiological Intent-to-treat (Micro-ITT) Analysis Set will include all ITT subjects who have one or more potentially causative baseline pathogens identified.

2.1.5 Pharmacokinetic (PK) Analysis Set

The PK Analysis Set will include all patients who received a known amount of ceftaroline fosamil, were randomized to a PK sample collection schedule, and had at least 1 PK sample collected.

2.2 Protocol deviations

Per PRA processes all important protocol deviations (PDs) as identified in the protocol deviation guidance document will be tracked and entered into the Clinical Trials Management System (CTMS). The study team will conduct ongoing reviews of PD data from CTMS throughout the study. Protocol deviations that the study team considers not to be important will not be tabulated or listed. Important protocol deviations will be verified as part of the final data review before database lock.

3. PRIMARY AND SECONDARY VARIABLES

For the calculation or derivations of the variables in this section, baseline will be defined as the last non-missing value before the start of study therapy. Change from baseline variables will be calculated for clinical laboratory tests and vital signs parameters as the post-treatment value minus the value at baseline. The visit windows for EOT, TOC, and SFU are defined in Table 2 for efficacy analyses.

Study days are to be calculated starting from the onset of the first dose of study therapy, in 24-hour increments. If a date is prior to the first study therapy dose date (eg, date of LOS diagnosis, prior medication start date) then the study day will be calculated as (past date – first

study therapy dose date); if the assessment date is on or after the first study therapy dose date then the study day will be calculated as (assessment date – first study therapy dose date + 1). Durations in days will be calculated as (end date – start date +1).

Table 2 Visit Windows for EOT, TOC, and SFU

Visit	Protocol-defined Window
End of IV therapy (EOT)	Within 24 hours of completion of the last infusion of study drug
Test of cure (TOC)	8 to 15 days after the last dose of study drug
Safety follow-up (SFU)	28 to 35 days after the last dose of study drug

NB. Since there is no per protocol population defined for this study, scheduled visits will be used for MITT analyses and derived analysis windows will not be evaluated.

For analyses purposes, nominal visit data was used.

3.1 Primary outcome variables

3.1.1 Safety variables

The safety analysis will be performed using the Safety Analysis Set. Safety parameters include AEs, serious adverse events (SAEs), deaths, clinical laboratory parameters (eg, complete blood count [CBC] with differential, chemistry panel), and vital signs.

No imputation on missing data will be undertaken for safety parameters.

3.1.1.1 Adverse events (AE) variables

An AE is the development of any new undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. An undesirable medical condition can be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver), or the abnormal results of an investigation (eg, laboratory findings). In clinical studies, an AE can include an undesirable medical condition occurring at any time, even if no study therapy has been administered. All AEs will be classified using the Medical Dictionary for Regulatory Activities (MedDRA) version 12.0 or higher.

The term AE is used to include both serious and nonserious AEs. Each AE will be graded for intensity (mild, moderate, severe). If intensity is missing it will be presented as such in the corresponding Tables. Each AE will be assessed for relationship to the study therapy (yes, no) as well. If relationship to study therapy is missing it will be presented as such in the corresponding Tables.

Adverse events will be collected from the time the parent(s)/legal guardian/legally acceptable representative provides informed consent throughout the treatment period up to and including the SFU visit in the study. AEs occurring after the start of administration of the first dose of study therapy or AEs that started prior to treatment and worsened on treatment up to and including the SFU visit will be summarised.

Adverse events of special interest (AESI) will be selected by subsetting MedDRA preferred terms from Pseudomembranous colitis Standard MedDRA Query (SMQ narrow) , Anaphylactic reaction (SMQ narrow), Angioedema (SMQ narrow), and Malignancies (SMQ

narrow). The MedDRA preferred terms identifying the AESI were provided by Pfizer, see Appendix C.

Serious adverse events variables

A SAE is an AE occurring during any study phase (ie, treatment, follow-up), that fulfils one or more of the following criteria:

- Results in death
- Is immediately life threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability or incapacity
- Is a congenital abnormality or birth defect
- Is an important medical event that may jeopardize the patient or may require medical intervention to prevent one of the outcomes listed above
- Is any suspected transmission via a medicinal product of an infectious agent.

SAEs will be collected from baseline throughout the treatment period up to and including the SFU visit in the study. SAEs occurring in a subject after the active collection period has ended are reported to Pfizer Safety if the investigator becomes aware of them; at a minimum, all SAEs that the investigator believes have at least a reasonable possibility of being related to investigational product must be reported to Pfizer Safety. SAEs reported after the active collection period will be reported in the Pfizer Safety database only, not in the clinical database.

Analysis of SAEs will focus on treatment-emergent SAEs which will be those occurring after the start of administration of the first dose of study therapy or SAEs that started prior to treatment and worsened on treatment.

3.1.1.2 Death

For any patients who die during the study, date and time of death, autopsy yes/no, and primary and secondary cause of death will be collected.

3.1.1.3 Clinical laboratory variables

The safety laboratory parameters presented in Table 3 will be measured.

Table 3 Laboratory safety variables

Chemistry panel	CBC and differential	Urinalysis
Albumin	Haematocrit	Bilirubin
Alkaline phosphatase	Haemoglobin	Blood
Alanine aminotransferase	Red Blood Cell count	Glucose
Aspartate aminotransferase	White Blood Cell count	Protein
Bilirubin, total and direct	Eosinophils[c]	pH
Blood urea nitrogen	Lymphocytes[c]	Specific Gravity
Urea	Monocytes[c]	Colour
Calcium	Neutrophils[c]	Appearance
Chloride	Platelets	Nitrite
Creatinine[a]	Immature granulocytes[c]	Urobilinogen
Glucose, nonfasting[a]	Metamyelocytes[c]	Leukocyte esterase
Potassium	Myelocytes[c]	
Sodium	Promyelocytes[c]	
Bicarbonate (HCO_3)[b]	Blasts[c]	
Lactate Dehydrogenase[b]		
pH[b]		
C-reactive protein[b]		
Procalcitonin[b]		

[a] Required for eligibility.
[b] Test not mandatory for eligibility if other eligibility criteria are met.
[c] Absolute count and/or %.

Hematology and chemistry will be performed at every visit or as clinically indicated. Urinalysis, 8-hour urine output if available, and CSF samples will be collected through the TOC visit. If available, base excess (BE) will be calculated from blood gases, and C-reactive protein (CRP) and procalcitonin will be assessed during the treatment period only.

Système International units will be reported for all analytes. Local laboratory upper limit of the normal range (ULN) and lower limit of the normal range (LLN) values for laboratory parameters will be applied for safety data in this study. No ULN or LLN are defined for vital signs parameters in the pediatric setting. Selected potentially clinically significant (PCS) laboratory results will be defined; see Appendix B for a list of PCS laboratory results.

3.1.1.4 Vital signs variables

Vital signs variables include weight, heart rate, blood pressure (systolic and diastolic), respiratory rate, and temperature will be assessed at every scheduled clinical visit. Highest and lowest daily temperature will be monitored as well. In addition, length will be collected at baseline only.

For heart rate and blood pressure measurements at baseline, at least 2 measurements will be taken during a 30 minute period; the mean of all measurements will be utilized for analysis.

3.1.1.5 Other safety variables

Other safety variables include:

- Physical exam by body system (general appearance, skin, head and neck, lymph nodes, musculoskeletal/extremities, cardiovascular, respiratory, abdomen, and neurological) through TOC, with specification of baseline and new/aggravated abnormalities

- Imaging study results (chest radiograph [CXR], computed tomography [CT] scan, or other radiology) through TOC including location, type of examination, result normal/abnormal, and description of abnormal findings

- Adjunctive therapeutic procedures related to infections variables through TOC including procedure, procedure type, other (specify), start date and time, stop date and time, and reason for procedure.

3.2 Secondary outcome variables

3.2.1 Efficacy variables

3.2.1.1 Clinical response variable at EOT and TOC

Efficacy outcome measures will include clinical response at EOT and TOC. The clinical outcome categories at EOT are defined in Table 4 below and the clinical outcome categories at TOC as defined in Table 5 below. A favourable outcome is clinical cure.

Table 4 Clinical outcome categories at End-of-Therapy

Outcome	Definition
Clinical Cure	Resolution of all acute signs and symptoms of LOS or improvement to such an extent that no further antibacterial therapy is required
Clinical Failure	Subjects who received ≥48 hours of study treatment and meet any of the following: • Discontinuation of study therapy due to insufficient therapeutic effect, including persistence, incomplete clinical resolution, worsening in signs and symptoms of LOS, or isolation of a resistant pathogen that requires alternative nonstudy antibacterial therapy • Discontinuation of study therapy due to a study therapy-related AE and requirement for alternative nonstudy antibacterial therapy for LOS • Death in which LOS is contributory
Indeterminate	Study data are not available for evaluation of efficacy for any reason, including: • Death in which LOS is clearly noncontributory • Lost to follow-up • Extenuating circumstances precluding classification as a cure or failure • Diagnosis of CNS infection, osteomyelitis, endocarditis, or NEC at any time after enrolment • Received <48 hours of study therapy

Abbreviations: AE=adverse event; CNS=central nervous system; LOS=late-onset sepsis; NEC=necrotizing enterocolitis.

Table 5 Clinical outcome categories at Test-of-Cure

Outcome	Definition
Clinical Cure	Resolution of all acute signs and symptoms of LOS or improvement to such an extent that no further antibacterial therapy is required
Clinical Failure	Subjects who received ≥48 hours of study treatment and meet either of the following criteria: • Incomplete resolution or worsening of LOS signs or symptoms or development of new signs or symptoms, or isolation of a resistant pathogen requiring alternative nonstudy antibacterial therapy • Death in which LOS is contributory
Indeterminate	Study data are not available for evaluation of efficacy for any reason, including: • Death in which LOS is clearly noncontributory • Lost to follow-up • Extenuating circumstances precluding classification as a cure or failure • Diagnosis of CNS infection, osteomyelitis, endocarditis, or NEC at any time after enrolment • Received <48 hours of study therapy

Abbreviations: CNS=central nervous system; LOS=late-onset sepsis; NEC=necrotizing enterocolitis.

Per-patient clinical response at TOC will be derived from clinical outcome (ie, investigator assessment) of clinical cure, clinical failure, or indeterminate at EOT and TOC as shown in Table 6 below.

Missing values may occur due to failure to record a response at TOC due to earlier clinical failure. An outcome of clinical failure at EOT will be carried forward to TOC. Missing values may occur due to premature discontinuation from study therapy administration. Patients who were prematurely discontinued from study therapy administration for any reason will have EOT assessments conducted (see Section 1.2) and will have per-patient clinical response at TOC derived according to the rules in Table 6. Unrelated deaths will be assessed as indeterminate for all remaining scheduled clinical assessments. Deaths occurring after TOC will not retrospectively change the TOC outcome (ie, if a patient was a clinical cure at TOC but died after TOC their clinical response at TOC remains clinical cure).

Table 6 Derivation of clinical response at TOC

EOT Outcome	TOC Outcome	Clinical Response at TOC
Clinical Cure	Clinical Cure	Clinical Cure
	Clinical Failure	Clinical Failure
	Indeterminate	Indeterminate
	Missing	Indeterminate
Clinical Failure	Clinical Cure	Clinical Failure
	Clinical Failure	Clinical Failure
	Indeterminate	Clinical Failure
	Missing	Clinical Failure
Indeterminate	Clinical Cure	Clinical Cure
	Clinical Failure	Clinical Failure
	Indeterminate	Indeterminate
	Missing	Indeterminate

The proportion of MITT Analysis Set patients with a clinical cure will be defined using the following formula:

$$\frac{\textit{Number of patients with clinical response at TOC=clinical cure}}{\textit{(Number of patients with clinical cure + Number of patients with clinical failure + Number of patients with indeterminate)}}$$

The proportion of MITT Analysis Set patients with clinical failure and with indeterminate clinical response will be calculated analogously. For proportion of patients with clinical cure, clinical failure, and indeterminate, indeterminate or missing assessments will be included in the denominator for calculation of the proportions for the MITT Analysis Set.

3.2.1.2 Per-pathogen and per-patient microbiological response variables at EOT and TOC

The per-pathogen microbiological outcome categories for pathogens identified at baseline are defined in Table 7. Local microbiology data will only be used when central data is not available, for example, samples were not sent to the central laboratory for processing. Please see section 3.3.1.3 for further details.

Table 7 Per-pathogen microbiological response categories

Microbiological Response[a]	Definition	Response Category
Eradication	Source specimen demonstrated absence of the original baseline pathogen	Favorable
Presumed eradication	Source specimen was not available to culture and the patient was assessed as a clinical cure	Favorable
Persistence	Source specimen demonstrates continued presence of the original baseline pathogen	Unfavorable
Presumed persistence	Source specimen was not available to culture and the patient was assessed as a clinical failure	Unfavorable
Indeterminate	Source specimen was not available to culture and the patient's clinical outcome was assessed as indeterminate	Indeterminate

[a] For patients who were clinical failures before TOC, the microbiological outcome will be carried forward to TOC and will be determined based on the cultures and/or clinical outcome at the time of the early clinical failure determination.

Similarly, per-patient microbiological response will be categorized as favorable, unfavorable, or indeterminate as follows. Per-patient microbiological response at EOT and TOC will be derived programmatically based on individual outcomes for each baseline pathogen. In order for a patient to have a favorable per-patient microbiological response, the outcome for each baseline pathogen must be favorable (eradicated or presumed eradicated) at that time point. This includes results of blood cultures, urine cultures, CSF cultures or other specimen cultures at the time point. If the outcome for any baseline pathogen from any culture is unfavorable (persistence or presumed persistence) at that time point, the patient will be considered to have an unfavorable per-patient microbiological response. If there is an indeterminate per-pathogen microbiological response at the time point (ie, no culture result available and patient's clinical outcome was indeterminate), the patient will be considered to have an indeterminate per-patient microbiological response. For per-patient microbiological response at TOC visit, the above definition is only applicable to patients who are not clinical failures at EOT. Patients who are clinical failures at EOT will have the corresponding per-patient microbiological outcome determined from EOT cultures and carried forward to TOC. If no EOT culture is available for patients who are clinical failures at EOT, then the microbiological outcome at TOC will be presumed persistence. Otherwise, the microbiological outcome at TOC will be determined from cultures obtained within the TOC visit window. If no culture is available in the TOC window, then the microbiological outcome at TOC will be presumed from the clinical response at TOC (if clinical cure, the microbiological outcome will be presumed eradication; if clinical failure, the microbiological outcome will be presumed persistence; if clinically indeterminate, the microbiological outcome will be indeterminate).

3.2.2 Pharmacokinetic variables

Two PK samples will be obtained at steady state from at least 20 patients to determine the population pharmacokinetics of ceftaroline fosamil, ceftaroline, and ceftaroline M-1 in this patient population. If CSF sample collection is expected per standard of care, PK blood samples should be collected at the time of CSF collection as a matching sample (see section

5.4.1 of the protocol). The total number of PK blood samples will not exceed 2. After the 2 PK blood samples have been collected, any portion of a CSF sample (collected as part of standard of care) not required for the patient's medical care should be retained for PK analysis.

Pharmacokinetic variables include actual sample collection times and plasma concentrations of ceftaroline fosamil, ceftaroline, and ceftaroline M-1 at each time point. If available, concentrations of ceftaroline and ceftaroline M-1 in cerebrospinal fluid (CSF) will be reported.

Plasma concentrations of ceftaroline fosamil, ceftaroline and ceftaroline M-1 will be listed by age cohort.

Covance Laboratories, using appropriate bioanalytical methods will determine plasma concentrations of ceftaroline fosamil, ceftaroline, and ceftaroline M-1.

3.3.1 Demographic and baseline characteristic variables

3.3.1.1 Demographic variables

Demographic variables include age (days), sex, race, and ethnicity. Age (days) will be calculated as (date of informed consent - date of birth + 1).

3.3.1.2 Surgical and medical history variables including antepartum/ peripartum period

Surgical history variables include procedures, study day of procedure start date, and current medication yes/no. Medical history variables include diagnosis, study day of condition start date and duration of condition (see Section 3 for calculation of study day and duration), status (past or current), and any current medication yes/no. Surgical and medical histories will be coded using MedDRA Version 12.0 or higher.

3.3.1.3 Baseline microbiological assessment variables for blood, CSF, urine, and other specimens

Identification of pathogens and susceptibility results will be recorded by both the local microbiology laboratory and the central reference laboratory. The identification and susceptibility results of the central microbiology reference laboratory will be regarded as definitive, if after re-testing, any discrepancies noted are not resolved. In the circumstance that the central lab could not isolate any organism from the submitted specimen, the local lab result will be used for organism identification (not including a result of "No Growth" at the central laboratory, which should be reported).

Microbiological assessments at baseline include collection data, culture data, antibiotic susceptibility data, and gram stain data:

- Collection data: specimen collected yes/no, type of specimen, reason for no specimen, specify if attempt made but unable to obtain, collection date and time and specimen acquisition method

- Culture data: specimen work up performed by, culture outcome, culture source location, laboratory name and identifier, pathogen type, isolate identification, isolate classification, isolate quantitation for 1 µL, 5 µL, 10 µL plates (for urine specimens only), isolate sent to central lab yes/no, reason if no specimen sent to central laboratory, accession identifier primary and secondary

- Antibiotic susceptibility data: local susceptibility tested yes/no, isolate identification, antibiotics tested, susceptibility, susceptibility criteria and susceptibility method

- Gram stain data: gram stain done yes/no, specify if no gram stain done and gram stain results, for example, epithelial cell results, etc.

3.3.2 Definition of prior and concomitant medication

Any medications (non-antimicrobial, antimicrobial, parenteral nutrition and blood/blood-component transfusions) taken by the patient between 7 days prior to study entry (or taken by the lactating mother of breast fed patients within 3 days prior to study entry) and prior to the first dose date of study therapy received will be considered prior medication. Any medication taken by the patient (or by the lactating mother of breast fed patients) at any time between dates of the first dose (including the date of the first dose) of study therapy through the TOC visit, inclusive, will be considered concomitant medication. Any medication started prior to the study entry and ended/ongoing up to the TOC will be considered as both prior and concomitant medication.

If any medications reported are not able to be determined as prior medications or concomitant medications due to missing or partial start dates and/or stop dates, the following imputation rules will be implemented:

- If the year is present but the month and day are missing, then 01JAN will be imputed for the start date and 31DEC for the stop date.
- If the year and month are present but the day is missing, then 01 will be imputed for the start date and the last day of the month for the stop date.

If both stop/start years are missing or both stop/start dates otherwise cannot be imputed, then the date will be treated as missing and the medication will be treated as both prior and concomitant medications.

3.3.3 Exposure and Compliance variable

Exposure to the study therapy will be calculated as the difference between the last study therapy date and the first study therapy date converted to days plus 1 day. Any partial infusion will be considered as a complete infusion for the purpose of exposure, and the relevant details will be listed.

Compliance will be calculated as the sum of the actual infusions over all doses/expected infusions over all doses)*100.

4. ANALYSIS METHODS

4.1 General principles

All analyses will use SAS® version 9.1.3 or higher. Summary tables will be organized by age cohort and overall. All available data for each analysis set will be used in the analyses, and a subset of key safety, efficacy, and PK data will be included in listings. No statistical hypothesis testing will be performed. Confidence intervals (CI) will be two-sided 95% CIs.

Unless otherwise noted, categorical data will be presented using counts and percentages with the denominator for percentages being the number of patients in the analysis set by age cohort. Percentages will be rounded to one decimal place; except 0% and 100% will be displayed without any decimal places and percentages will not be displayed for zero counts. Continuous variables will be summarized using the number of observations (n), mean, SD, median, minimum, and maximum. The minimum and maximum values will be displayed to the same level of precision as the raw data, the mean and median to a further decimal place and the SD to two additional decimal places.

Imputation of missing data will be performed as described within this document (see Section 3.2.1 for imputation of efficacy data at EOT and TOC and Section 3.3.2 for imputation of partial dates for prior and concomitant medication). Visit windowing will be performed as described in Section 3.

Baseline summaries will utilize the ITT and MITT Analysis Sets. Study therapy exposure, concomitant medication, and safety analyses will utilize the Safety Analysis Set. Efficacy analyses of clinical outcome and microbiological response will utilize the MITT and Micro-ITT Analysis Sets. PK analyses will utilize the PK Analysis Set. All data will be listed.

4.1.1 Data quality

The clinical database will be cleaned prior to analysis; see PRA Clinical Informatics Plan for details. Beyond the data screening built into the PRA Clinical Informatics Plan, the PRA programming of analysis datasets, tables, figures, and listings (TFLs) will provide additional data screening.

Review of a pre-freeze TFL run on clean patients and a post-freeze TFL run on the frozen database will allow for further data screening prior to lock. The post-freeze TFL will be discussed with Pfizer in a data review meeting to identify any final data issues and seek corrections prior to database lock. The PRA statistician and Pfizer must approve database lock.

PRA's goal is to ensure that each TFL delivery is submitted to the highest level of quality. Our quality control procedures will be documented separately in the study-specific clinical programming quality control plan.

4.2 Analysis methods

4.2.1 Patient disposition

The number and percentage of patients enrolled and treated with study therapy, along with the number and percentage of treatment completers, premature discontinuations from study

therapy administration, and withdrawals from the study will be provided overall and within each age cohort based for all patients, ie, all subjects who signed informed consent.

Disposition details for subjects who discontinued from the study and from study therapy; and those who completed the study will be listed for all patients.

The number of patients in each analysis set and the reasons for exclusion from analysis sets will be listed and summarized for the ITT Analysis Set.

4.2.2 Protocol deviations

A table of important PDs will be presented overall and by age cohort for the ITT Analysis Set. See Section 2.2 for details, including determination of importance.

Important PDs will be displayed in a data listing by age cohort and patient.

4.2.3 Demographics and baseline characteristics

Demographics data defined in Section 3.3.1 will be summarized for the ITT, MITT and Micro-ITT Analysis Set by age cohort and overall. Baseline length (cm) and weight (kg) will be tabulated.

Relevant surgical and medical history (past and current) including antepartum/ peripartum period will be summarized by MedDRA System Organ Class and preferred term, both by age cohort and overall for the ITT Analysis Set.

The number and percentage of patients with baseline pathogens (Genus and species) by specimen type (blood, CSF, urine, and other specimens) will be summarized by age cohort and overall for the ITT, MITT and Micro-ITT Analysis Set.

Demographics and baseline characteristics, and relevant medical and surgical history data will be listed by age cohort and patient. Baseline culture data including susceptibility (susceptible, intermediate, resistant) and gram stain testing results will be listed by age cohort and patient for the ITT Analysis Set.

4.2.4 Prior and concomitant medications

See Section 3.3.3 for definitions of prior and concomitant medications.

Medications received concomitantly with study therapy, categorized by anatomical therapeutic chemical classification and generic name according to the World Health Organization Drug Dictionary Enhanced (WHODDE, Version 20.0), will be summarized. The number and percentage of patients using at least one medication within each ATC Group and Generic Term will be displayed by age cohort and overall for the Safety Analysis Set. Prior medications will be summarized in an identical fashion. For lactating mothers, maternal prior and concomitant medications will be included in these summaries.

The duration of prior medications defined as the end date – start date +1, will also be summarized for each ATC Group and Generic Term and displayed by age cohort and overall for the ITT Analysis Set. In the event that prior medications had partial dates no imputation will be undertaken and consequently the duration of prior medication will be missing for any such records.

Prior and concomitant medication data will be listed for the ITT Analysis Set by age cohort and patient.

4.2.5 Study therapy exposure and compliance

Duration of study therapy exposure in days for ceftaroline fosamil, optional ampicillin and optional aminoglycoside will be tabulated by age cohort and overall for the Safety Analysis Set and MITT population. In addition to standard summary statistics, quartiles for each patient and total treatment days for all patients will be shown.

Following protocol amendment 2 the dose of ceftaroline fosamil was changed from 4mg/kg to 6mg/kg. No summaries will be provided by the different ceftaroline fosamil doses, under the different versions of the protocol to which patients were enrolled.

Treatment compliance will be summarized as continuous data and categorically (<80%, 80-120%, >120% compliance) by age cohort and overall for the Safety Analysis Set and MITT population.

Ceftaroline fosamil exposure data, compliance data and administration details will be listed by age cohort and patient for the Safety Analysis Set.

4.2.6 Safety analysis

4.2.6.1 Analysis of adverse events, serious adverse events, and deaths

The number and percentage of patients with AEs occurring after the start of administration of the first dose of study therapy, or AEs that started prior to treatment and worsened on treatment, up to the SFU visit will be summarized, i.e. treatment emergent(TE) AEs. The following summaries will be presented for the Safety Analysis Set:

- Overall summary of TEAEs by category (overall and by age cohort)
- Incidence of TEAEs by system organ class (SOC) and preferred term
- Incidence of TEAEs by SOC, preferred term, and maximum intensity
- Incidence of TEAEs by SOC, preferred term, and relationship to ceftaroline
- Incidence of TEAEs of special interest by SOC and preferred term
- Incidence of non-serious TEAEs by SOC and preferred term
- Incidence of TEAEs with fatal outcome by SOC and preferred term
- Incidence of all deaths
- Incidence of Serious TEAEs by SOC and preferred term
- Incidence of TEAEs leading to discontinuation of investigational product by SOC and preferred term

All AEs occurring prior to the first intake of ceftaroline will be listed for the Safety Analysis Set.

4.2.6.2 Clinical laboratory safety assessment

Clinical laboratory data include hematology, chemistry, CRP, CSF, blood gas and base excess, urinalysis, and urine output. Descriptive statistics (including n, mean, SD, minimum, median, and maximum) of observed results and change from baseline will be presented for continuous clinical laboratory results by age cohort and overall for the Safety Analysis Set.

In addition, the following summaries at each applicable visit will also be provided by age cohort and overall:

- Shift tables showing the number of patients with changes from low, normal, or high values from baseline
- Shift tables showing the number of patients with urinalysis changes from baseline to each category (negative, trace, positive)
- The number and percentage of patients with abnormal values using the PCS criteria in Appendix B

Listings of values for each patient will be presented by age cohort with abnormal or out-of-range values flagged. All laboratory results for each patient will be listed for the Safety Analysis Set.

4.2.6.3 Weight, vital signs, and oxygen saturation results

Weight, vital signs (heart rate, blood pressure, respiratory rate, temperature) and oxygen saturation (measured by oximeter) will be summarized. Descriptive statistics (including n, mean, SD, minimum, median, and maximum) of observed results and change from baseline will be presented for continuous results by age cohort and overall for the Safety Analysis Set.

Listings of values for each patient will be presented by age cohort for the Safety Analysis Set.

4.2.6.4 Other safety results

Data for physical examination by body system, imaging study results, and adjunctive therapeutic procedures related to infections will be included in ADaM datasets and presented in listings for the Safety Analysis Set.

4.2.7 Efficacy analysis

4.2.7.1 Clinical response

The number and percentage of patients with a clinical cure, clinical failure, and indeterminate clinical response at EOT and TOC will be tabulated overall and by baseline pathogen, overall and within each age cohort for the ITT, MITT and Micro-ITT Analysis Sets. A two-sided 95% CI for the observed clinical cure rate overall, within each cohort and overall will be constructed using the Jeffreys method. Sensitivity analyses will be conducted on the overall response excluding indeterminate responses.

Clinical outcome and derived response data will be listed by age cohort and patient for the ITT Analysis Set.

4.2.7.2 Microbiological response

The number and percentage of patients with a favourable, unfavourable and indeterminate microbiological response at EOT and TOC will be tabulated overall, and by baseline pathogen (overall and within each age cohort) for the MITT and Micro-ITT Analysis Sets. A two-sided 95% CI for the observed microbiological favourable rate overall within each cohort and overall will be constructed using the Jeffreys method.

The number and percentage of pathogens with a favorable microbiological response (eradication, presumed eradication) at TOC will be tabulated by baseline pathogen and baseline ceftaroline MIC (overall and within each age cohort) for the MITT and Micro-ITT Analysis Sets.

All other microbiological data including microbiological responses by pathogen and by patient, susceptibility testing and gram staining will be listed by age cohort and patient for the ITT Analysis Set.

4.2.8 Pharmacokinetics analysis

Ceftaroline plasma concentration data, along with other information including demographic data, will be combined with appropriate data from other clinical studies and analyzed using a population PK approach and reported separately.

PK schedule assignment data, sample collection data and plasma concentration data will be listed by age cohort and patient for the PK Analysis Set.

5. APPENDICES

APPENDIX A	Non-eligible pathogens
APPENDIX B	Criteria for potentially clinically significant laboratory results
APPENDIX C	Adverse Events of Special Interest

Appendix A
Non-eligible pathogens

Table 2 Pathogen Classifications for Study

Always	Never	Sometimes
Enterobacteriaceae	ESBL phenotype positive *Enterobacteriacea*e	*Enterococcus spp.**
Staphylococcus aureus	Other *Enterobacteriaceae* not susceptible to study drug received	
Streptococcus spp.	Other non-*Enterobacteriaceae* Gram negative bacteria	
Coagulase-negative *staphylococci*	Non-fermentative Gram-negative bacteria including *Pseudomonas* spp.	
Streptococcus spp. (except *viridans Streptococci)*	*viridans Streptococci*	
	Anaerobes	
	Fungal pathogens (including yeast)	
	Parasitic pathogens	
	Viral pathogens	

Table 1 represents the latest known list for pathogens susceptible to ceftaroline. If more data become available during the course of this study, then this list will be updated appropriately.

* Based on investigator determination.

Appendix B
Criteria for Potentially Clinically Significant Laboratory Tests

Category	Category Parameter	Lower Limit	Upper Limit	Percent decrease from baseline	Percent increase from baseline
Haematology	Haematocrit	< 0.6 x LLN	> 1.3 x ULN	> 25%	> 30%
	Haemoglobin	< 0.6 x LLN	> 1.3 x ULN	> 25%	> 30%
	Red Blood Cell count	< 0.8 x LLN	> 1.3 x ULN	> 20%	> 30%
	White Blood Cell count	< 0.5 x LLN	> 2.0 x ULN	> 60%	> 100%
	Eosinophils	N/A	> 4.0 x ULN	N/A	> 400%
	Lymphocytes (absolute count)	< 0.2 x LLN	> 2.2 x ULN	> 70%	> 100%
	Neutrophils (absolute count)	< 0.5 x LLN	> 2.2 x ULN	> 70%	> 100%
	Platelets	< 0.4 x LLN	> 2.0 x ULN	> 40%	> 100%
Haematology/ Coagulation	International normalized ratio	< 0.5 x LLN	> 2.0 x ULN	> 50%	> 100%
	Partial thromboplastin time	< 0.5 x LLN	> 2.0 x ULN	> 50%	> 100%
	Prothrombin Time	< 0.5 x LLN	> 2.0 x ULN	> 50%	> 100%
Chemistry	Albumin	< 0.6 x LLN	N/A	> 60%	N/A
	Alkaline phosphatase	< 0.5 x LLN	> 3.0 x ULN	> 80%	> 300%
	Alanine aminotransferase	N/A	> 3.0 x ULN	N/A	> 300%
	Aspartate aminotransferase	N/A	> 3.0 x ULN	N/A	> 300%
	Bilirubin, direct	N/A	> 2.5 x ULN	N/A	> 150%
	Bilirubin, total	N/A	> 2.5 x ULN	N/A	> 300%
	Bilirubin, indirect	N/A	> 2.5 x ULN	N/A	> 150%
	Blood urea nitrogen*	N/A	> 3 x ULN	N/A	> 300%
	Calcium	< 0.7 x LLN	> 1.3 x ULN	> 30%	> 30%
	Chloride	< 0.8 x LLN	> 1.2 x ULN	> 20%	> 20%
	Creatinine	N/A	> 2.0 x ULN	N/A	> 100%
	Glucose, nonfasting	< 0.6 x LLN	> 4.0 x ULN	> 40%	> 200%
	Potassium	< 0.8 x LLN	> 1.2 x ULN	> 15%	> 20%
	Sodium	< 0.85 x LLN	> 1.1 x ULN	> 10%	> 10%
	Lactate Dehydrogenase	< 0.4 x LLN	> 4.0 x ULN	> 60%	> 300%

PCS are based on P903-21 Study and consistent with Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.0, November 2014 with grade 2 or greater laboratory abnormalities being considered PCS and Harriet Lane Handbook Version 19.

* For sites that collect Urea instead of BUN, Urea will be converted to BUN using the following formula: Urea [mg/dL]/2.14 = BUN [mg/dL].

Appendix C
Adverse Events of Special Interest

SMQ PTs taken from Anaphylactic reaction (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Anaphylactic reaction	Anaphylactoid shock	Shock
Anaphylactic shock	Circulatory collapse	Shock symptom
Anaphylactic transfusion reaction	Dialysis membrane reaction	Type I hypersensitivity
Anaphylactoid reaction	Kounis syndrome	

SMQ PTs taken from Angioedema (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Allergic oedema	Idiopathic angioedema	Palatal oedema
Angioedema	Idiopathic urticaria	Palatal swelling
Circumoral oedema	Intestinal angioedema	Periorbital oedema
Conjunctival oedema	Laryngeal oedema	Pharyngeal oedema
Corneal oedema	Laryngotracheal oedema	Scleral oedema
Epiglottic oedema	Limbal swelling	Swelling face
Eye oedema	Lip oedema	Swollen tongue
Eye swelling	Lip swelling	Tongue oedema
Eyelid oedema	Mouth swelling	Tracheal oedema
Face oedema	Oculorespiratory syndrome	Urticaria
Gingival oedema	Oedema mouth	Urticaria cholinergic
Gingival swelling	Oropharyngeal oedema	Urticaria chronic
Gleich's syndrome	Oropharyngeal swelling	Urticaria papular
Hereditary angioedema		

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
5q minus syndrome	Gestational trophoblastic tumour	Ostectomy
Abdominal neoplasm	Gingival cancer	Osteosarcoma
Abdominal wall neoplasm	Glioblastoma	Osteosarcoma metastatic
Abdominal wall neoplasm malignant	Glioblastoma multiforme	Osteosarcoma recurrent
Acanthosis nigricans	Glioma	Otic cancer metastatic
Acinar cell carcinoma of pancreas	Gliomatosis cerebri	Ovarian cancer
Acinic cell carcinoma of salivary gland	Glioneuronal tumour	Ovarian cancer metastatic
Acquired thalassaemia	Gliosarcoma	Ovarian cancer recurrent
Acral lentiginous melanoma	Glossectomy	Ovarian cancer stage I
Acral lentiginous melanoma stage I	Glottis carcinoma	Ovarian cancer stage II
Acral lentiginous melanoma stage II	Glucagonoma	Ovarian cancer stage III
Acral lentiginous melanoma stage III	Good syndrome	Ovarian cancer stage IV
Acral lentiginous melanoma stage IV	Granular cell tumour	Ovarian clear cell carcinoma
Acrokeratosis paraneoplastica	Granulosa cell tumour of the testis	Ovarian dysgerminoma stage I
ACTH-producing pituitary tumour	Growth hormone-producing pituitary	Ovarian dysgerminoma stage II
Acute biphenotypic leukaemia	tumour	Ovarian dysgerminoma stage III

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Acute leukaemia	Haemangiopericytoma	Ovarian dysgerminoma stage IV
Acute leukaemia in remission	Haemangiopericytoma of meninges	Ovarian dysgerminoma stage unspecified
Acute lymphocytic leukaemia	Haematological malignancy	Ovarian embryonal carcinoma
Acute lymphocytic leukaemia (in remission)	Haematopoietic neoplasm	Ovarian endometrioid carcinoma
Acute lymphocytic leukaemia recurrent	Haemorrhagic tumour necrosis	Ovarian epithelial cancer
Acute lymphocytic leukaemia refractory	Hairy cell leukaemia	Ovarian epithelial cancer metastatic
Acute megakaryocytic leukaemia	Hairy cell leukaemia recurrent	Ovarian epithelial cancer recurrent
Acute megakaryocytic leukaemia (in remission)	Head and neck cancer	Ovarian epithelial cancer stage I
Acute monocytic leukaemia	Head and neck cancer metastatic	Ovarian epithelial cancer stage II
Acute monocytic leukaemia (in remission)	Head and neck cancer stage I	Ovarian epithelial cancer stage III
Acute myeloid leukaemia	Head and neck cancer stage II	Ovarian epithelial cancer stage IV
Acute myeloid leukaemia (in remission)	Head and neck cancer stage III	Ovarian germ cell cancer
Acute myeloid leukaemia recurrent	Head and neck cancer stage IV	Ovarian germ cell cancer stage I
Acute myelomonocytic leukaemia	Hemicorporectomy	Ovarian germ cell cancer stage II
Acute promyelocytic leukaemia	Hemilaryngectomy	Ovarian germ cell cancer stage III
Acute promyelocytic leukaemia differentiation syndrome	Hemipelvectomy	Ovarian germ cell cancer stage IV
Acute undifferentiated leukaemia	Hepatectomy	Ovarian germ cell choriocarcinoma
Adenocarcinoma	Hepatic angiosarcoma	Ovarian germ cell choriocarcinoma stage I
Adenocarcinoma gastric	Hepatic cancer	Ovarian germ cell choriocarcinoma stage II
Adenocarcinoma of appendix	Hepatic cancer metastatic	Ovarian germ cell choriocarcinoma stage III
Adenocarcinoma of colon	Hepatic cancer recurrent	Ovarian germ cell choriocarcinoma stage IV
Adenocarcinoma of salivary gland	Hepatic cancer stage I	Ovarian germ cell embryonal carcinoma stage I
Adenocarcinoma of the cervix	Hepatic cancer stage II	Ovarian germ cell embryonal carcinoma stage II
Adenocarcinoma pancreas	Hepatic cancer stage III	Ovarian germ cell embryonal carcinoma stage III
Adenoid cystic carcinoma	Hepatic cancer stage IV	Ovarian germ cell embryonal carcinoma stage IV
Adenoid cystic carcinoma of external auditory canal	Hepatic neoplasm	Ovarian germ cell endodermal sinus tumour
Adenoid cystic carcinoma of salivary gland	Hepatobiliary cancer	Ovarian germ cell endodermal sinus tumour stage I
Adenosquamous carcinoma of the cervix	Hepatobiliary cancer in situ	Ovarian germ cell endodermal sinus tumour stage II
Adenosquamous carcinoma of vagina	Hepatobiliary neoplasm	Ovarian germ cell endodermal sinus tumour stage III
Adenosquamous cell carcinoma	Hepatoblastoma	Ovarian germ cell endodermal sinus tumour stage IV
Adenosquamous cell lung cancer	Hepatoblastoma recurrent	Ovarian germ cell polyembryoma
Adenosquamous cell lung cancer recurrent	Hepatocellular carcinoma	Ovarian germ cell polyembryoma stage I
Adenosquamous cell lung cancer stage 0	Hepatosplenic T-cell lymphoma	Ovarian germ cell polyembryoma stage II
Adenosquamous cell lung cancer stage I	HER-2 positive breast cancer	Ovarian germ cell polyembryoma stage III
Adenosquamous cell lung cancer stage II	HER-2 positive gastric cancer	Ovarian germ cell polyembryoma stage IV
Adenosquamous cell lung cancer stage III	Hereditary leiomyomatosis renal cell carcinoma	Ovarian germ cell teratoma
Adenosquamous cell lung cancer stage IV	Hereditary papillary renal carcinoma	Ovarian germ cell teratoma stage I
Adrenal gland cancer	Hidradenocarcinoma	Ovarian germ cell teratoma stage II
Adrenal gland cancer metastatic	High frequency ablation	
Adrenal neoplasm	High grade B-cell lymphoma Burkitt-like lymphoma	
Adrenocortical carcinoma	High grade B-cell lymphoma Burkitt-like lymphoma recurrent	
Adult T-cell lymphoma/leukaemia	High grade B-cell lymphoma Burkitt-like lymphoma refractory	
Adult T-cell lymphoma/leukaemia recurrent	High grade B-cell lymphoma Burkitt-like lymphoma stage I	
Adult T-cell lymphoma/leukaemia refractory	High grade B-cell lymphoma Burkitt-like lymphoma stage II	
	High grade B-cell lymphoma Burkitt-like lymphoma stage III	
	High grade B-cell lymphoma Burkitt-like lymphoma stage IV	
	High intensity focused ultrasound	
	High-grade B-cell lymphoma	

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Adult T-cell lymphoma/leukaemia stage I	Histiocytic medullary reticulosis	Ovarian germ cell teratoma stage III
Adult T-cell lymphoma/leukaemia stage II	Histiocytic sarcoma	Ovarian germ cell teratoma stage IV
Adult T-cell lymphoma/leukaemia stage III	Hodgkin's disease	Ovarian germ cell tumour
Adult T-cell lymphoma/leukaemia stage IV	Hodgkin's disease lymphocyte depletion stage I site unspecified	Ovarian germ cell tumour mixed
Aesthesioneuroblastoma	Hodgkin's disease lymphocyte depletion stage I subdiaphragm	Ovarian granulosa cell tumour
Alcoholisation procedure	Hodgkin's disease lymphocyte depletion stage I supradiaphragm	Ovarian granulosa-theca cell tumour
Aleukaemic leukaemia	Hodgkin's disease lymphocyte depletion stage II site unspecified	Ovarian low malignant potential tumour
Alpha 1 foetoprotein abnormal	Hodgkin's disease lymphocyte depletion stage II subdiaphragm	Ovarian neoplasm
Alpha 1 foetoprotein increased	Hodgkin's disease lymphocyte depletion stage II supradiaphragm	Ovarian Sertoli-Leydig cell tumour
Alpha interferon therapy	Hodgkin's disease lymphocyte depletion type recurrent	Ovarian stromal cancer
Alpha-L-fucosidase increased	Hodgkin's disease lymphocyte depletion type refractory	Ovarian theca cell tumour
Alveolar rhabdomyosarcoma	Hodgkin's disease lymphocyte depletion type stage III	
Alveolar soft part sarcoma	Hodgkin's disease lymphocyte depletion type stage IV	Paget's disease of nipple
Alveolar soft part sarcoma metastatic	Hodgkin's disease lymphocyte depletion type stage unspecified	Paget's disease of penis
Alveolar soft part sarcoma recurrent	Hodgkin's disease lymphocyte predominance stage I site unspec	Paget's disease of the vulva
Anal cancer	Hodgkin's disease lymphocyte predominance stage I subdiaphragm	Palliative care
Anal cancer metastatic	Hodgkin's disease lymphocyte predominance stage I supradiaphragm	Pancoast's tumour
Anal cancer recurrent	Hodgkin's disease lymphocyte predominance stage II site unspec	Pancreastatin abnormal
Anal cancer stage 0	Hodgkin's disease lymphocyte predominance stage II subdiaphragm	Pancreastatin increased
Anal cancer stage I	Hodgkin's disease lymphocyte predominance stage II supradiaphragm	Pancreatectomy
Anal cancer stage II	Hodgkin's disease lymphocyte predominance type recurrent	Pancreatic carcinoma
Anal cancer stage III	Hodgkin's disease lymphocyte predominance type refractory	Pancreatic carcinoma metastatic
Anal cancer stage IV	Hodgkin's disease lymphocyte predominance type stage III	Pancreatic carcinoma recurrent
Anal neoplasm	Hodgkin's disease lymphocyte predominance type stage IV	Pancreatic carcinoma stage 0
Anal squamous cell carcinoma	Hodgkin's disease lymphocyte predominance type stage unspecified	Pancreatic carcinoma stage I
Anaplastic astrocytoma	Hodgkin's disease mixed cellularity recurrent	Pancreatic carcinoma stage II
Anaplastic large cell lymphoma T- and null-cell types	Hodgkin's disease mixed cellularity refractory	Pancreatic carcinoma stage III
Anaplastic large cell lymphoma T- and null-cell types recurrent	Hodgkin's disease mixed cellularity stage I site unspecified	Pancreatic carcinoma stage IV
Anaplastic large cell lymphoma T- and null-cell types refractory	Hodgkin's disease mixed cellularity stage I subdiaphragmatic	Pancreatic neoplasm
Anaplastic large cell lymphoma T- and null-cell types stage I	Hodgkin's disease mixed cellularity	Pancreatic neuroendocrine tumour
Anaplastic large cell lymphoma T- and null-cell types stage II		Pancreatic neuroendocrine tumour metastatic
Anaplastic large cell lymphoma T- and null-cell types stage III		Pancreatic sarcoma
Anaplastic large cell lymphoma T- and null-cell types stage IV		Pancreaticoduodenectomy
Anaplastic large-cell lymphoma		Pancreaticosplenectomy
Anaplastic meningioma		Pancreatoblastoma
Anaplastic oligodendroglioma		Papillary renal cell carcinoma
Anaplastic thyroid cancer		Papillary serous endometrial carcinoma
Androgen therapy		Papillary thyroid cancer
Angiocentric glioma		Paraganglion neoplasm
Angiocentric lymphoma		Paraganglion neoplasm malignant
Angiocentric lymphoma recurrent		Paranasal biopsy abnormal
Angiocentric lymphoma refractory		Paranasal sinus and nasal cavity malignant neoplasm
Angiocentric lymphoma stage I		Paranasal sinus and nasal cavity malignant neoplasm recurrent
Angiocentric lymphoma stage II		Paranasal sinus and nasal cavity malignant neoplasm stage 0
Angiocentric lymphoma stage III		Paranasal sinus and nasal cavity malignant neoplasm stage I
		Paranasal sinus and nasal cavity malignant neoplasm stage II
		Paranasal sinus and nasal cavity malignant neoplasm stage III
		Paranasal sinus and nasal cavity

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Angiocentric lymphoma stage IV	stage I supradiaphragmatic	malignant neoplasm stage IV
Angiogenesis biomarker increased	Hodgkin's disease mixed cellularity stage II subdiaphragmatic	Paranasal sinus neoplasm
Angioimmunoblastic T-cell lymphoma	Hodgkin's disease mixed cellularity stage II supradiaphragmatic	Paraneoplastic arthritis
Angioimmunoblastic T-cell lymphoma recurrent	Hodgkin's disease mixed cellularity stage III	Paraneoplastic dermatomyositis
Angioimmunoblastic T-cell lymphoma refractory	Hodgkin's disease mixed cellularity stage IV	Paraneoplastic dermatosis
Angioimmunoblastic T-cell lymphoma stage I	Hodgkin's disease mixed cellularity stage unspecified	Paraneoplastic encephalomyelitis
Angioimmunoblastic T-cell lymphoma stage II	Hodgkin's disease nodular sclerosis	Paraneoplastic glomerulonephritis
Angioimmunoblastic T-cell lymphoma stage III	Hodgkin's disease nodular sclerosis recurrent	Paraneoplastic nephrotic syndrome
Angioimmunoblastic T-cell lymphoma stage IV	Hodgkin's disease nodular sclerosis refractory	Paraneoplastic neurological syndrome
Angiosarcoma	Hodgkin's disease nodular sclerosis stage I	Paraneoplastic pemphigus
Angiosarcoma metastatic	Hodgkin's disease nodular sclerosis stage II	Paraneoplastic pleural effusion
Angiosarcoma non-metastatic	Hodgkin's disease nodular sclerosis stage III	Paraneoplastic rash
Angiosarcoma recurrent	Hodgkin's disease nodular sclerosis stage IV	Paraneoplastic syndrome
Antiandrogen therapy	Hodgkin's disease recurrent	Parathyroid scan abnormal
Anti-NMDA antibody positive	Hodgkin's disease refractory	Parathyroid tumour
Antioestrogen therapy	Hodgkin's disease stage I	Parathyroid tumour malignant
Anti-VGCC antibody positive	Hodgkin's disease stage II	Parathyroidectomy
Apocrine breast carcinoma	Hodgkin's disease stage III	Parotidectomy
Appendix cancer	Hodgkin's disease stage IV	Pelvic neoplasm
APUDoma	Hodgkin's disease unclassifiable	Penile cancer
Astroblastoma	Hormone refractory breast cancer	Penile neoplasm
Astrocytoma	Hormone suppression therapy	Penile squamous cell carcinoma
Astrocytoma malignant	Hormone therapy	Penis carcinoma metastatic
Atypical fibroxanthoma	Hormone-dependent prostate cancer	Penis carcinoma recurrent
Atypical teratoid/rhabdoid tumour of CNS	Hormone-refractory prostate cancer	Penis carcinoma stage I
Autologous bone marrow transplantation therapy	Hormone-secreting ovarian tumour	Penis carcinoma stage II
Axillary lymphadenectomy	Huerthle cell carcinoma	Penis carcinoma stage III
B precursor type acute leukaemia	Human chorionic gonadotropin increased	Penis carcinoma stage IV
Basal cell carcinoma	Human chorionic gonadotropin positive	Pepsinogen test positive
Basosquamous carcinoma	Human epidermal growth factor receptor increased	Percutaneous ethanol injection therapy
Basosquamous carcinoma of skin	Hypercalcaemia of malignancy	Pericardial effusion malignant
B-cell depletion therapy	Hyperleukocytosis	Pericardial mesothelioma malignant
B-cell lymphoma	Hyperthermia therapy	Pericardial mesothelioma malignant recurrent
B-cell lymphoma recurrent	Hypopharyngeal cancer	Pericardial neoplasm
B-cell lymphoma refractory	Hypopharyngeal cancer recurrent	Pericarditis malignant
B-cell lymphoma stage I	Hypopharyngeal cancer stage 0	Peripheral nerve sheath tumour malignant
B-cell lymphoma stage II	Hypopharyngeal cancer stage I	Peripheral nervous system neoplasm
B-cell lymphoma stage III	Hypopharyngeal cancer stage II	Peripheral neuroepithelioma of bone
B-cell lymphoma stage IV	Hypopharyngeal cancer stage III	Peripheral neuroepithelioma of bone metastatic
B-cell prolymphocytic leukaemia	Hypopharyngeal cancer stage IV	Peripheral neuroepithelioma of bone recurrent
B-cell small lymphocytic lymphoma	Hypopharyngeal neoplasm	Peripheral neuroepithelioma of soft tissue
B-cell small lymphocytic lymphoma recurrent	Hypophysectomy	Peripheral primitive neuroectodermal bone tumour
B-cell small lymphocytic lymphoma refractory		Peripheral primitive neuroectodermal tumour of soft tissue
B-cell small lymphocytic lymphoma stage I		Peripheral T-cell lymphoma unspecified
B-cell small lymphocytic lymphoma		Peripheral T-cell lymphoma unspecified recurrent
		Peripheral T-cell lymphoma unspecified refractory

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
stage II	Hysterectomy	Peripheral T-cell lymphoma
B-cell small lymphocytic lymphoma	Hysterosalpingectomy	unspecified stage I
stage III	Hysterosalpingo-oophorectomy	Peripheral T-cell lymphoma
B-cell small lymphocytic lymphoma	IDH differentiation syndrome	unspecified stage II
stage IV	Ileectomy	Peripheral T-cell lymphoma
B-cell type acute leukaemia	Ileocolectomy	unspecified stage III
B-cell unclassifiable lymphoma high	Imaging procedure abnormal	Peripheral T-cell lymphoma
grade	Immune enhancement therapy	unspecified stage IV
B-cell unclassifiable lymphoma low	Immune reconstitution inflammatory	Peritoneal carcinoma metastatic
grade	syndrome associated Kaposi's sarcoma	Peritoneal fluid protein increased
Beta interferon therapy	Immunoblastic lymphoma	Peritoneal mesothelioma malignant
Bile duct adenocarcinoma	Immunochemotherapy	Peritoneal mesothelioma malignant
Bile duct adenosquamous carcinoma	In vivo gene therapy	recurrent
Bile duct cancer	Infected neoplasm	Peritoneal neoplasm
Bile duct cancer recurrent	Inferior vena cava syndrome	Peritoneal sarcoma
Bile duct cancer stage 0	Inflammatory carcinoma of breast	Peritonectomy
Bile duct cancer stage I	recurrent	Peritumoural oedema
Bile duct cancer stage II	Inflammatory carcinoma of breast	Phaeochromocytoma
Bile duct cancer stage III	stage III	Phaeochromocytoma crisis
Bile duct cancer stage IV	Inflammatory carcinoma of breast	Phaeochromocytoma excision
Bile duct squamous cell carcinoma	stage IV	Phaeochromocytoma malignant
Biliary cancer metastatic	Inflammatory carcinoma of the breast	Pharyngeal cancer
Biliary neoplasm	Inflammatory malignant fibrous	Pharyngeal cancer metastatic
Biopsy abdominal wall abnormal	histiocytoma	Pharyngeal cancer recurrent
Biopsy adrenal gland abnormal	Inflammatory myofibroblastic tumour	Pharyngeal cancer stage 0
Biopsy anus abnormal	Insulinoma	Pharyngeal cancer stage I
Biopsy artery abnormal	Interleukin therapy	Pharyngeal cancer stage II
Biopsy bile duct abnormal	Intestinal adenocarcinoma	Pharyngeal cancer stage III
Biopsy bladder abnormal	Intestinal metastasis	Pharyngeal cancer stage IV
Biopsy blood vessel abnormal	Intestinal resection	Pharyngeal neoplasm
Biopsy bone abnormal	Intestinal T-cell lymphoma recurrent	Pharyngectomy
Biopsy bone marrow abnormal	Intestinal T-cell lymphoma refractory	Philadelphia chromosome positive
Biopsy brain abnormal	Intestinal T-cell lymphoma stage I	Photodynamic diagnostic procedure
Biopsy breast abnormal	Intestinal T-cell lymphoma stage II	Photon radiation therapy
Biopsy bronchus abnormal	Intestinal T-cell lymphoma stage III	Photon radiation therapy to bladder
Biopsy cartilage abnormal	Intestinal T-cell lymphoma stage IV	Photon radiation therapy to blood
Biopsy cervix abnormal	Intracranial germ cell tumour	Photon radiation therapy to bone
Biopsy chest wall abnormal	Intracranial meningioma malignant	Photon radiation therapy to brain
Biopsy chorionic villous abnormal	Intracranial tumour haemorrhage	Photon radiation therapy to breast
Biopsy colon abnormal	Intraductal papillary breast neoplasm	Photon radiation therapy to colon
Biopsy conjunctiva abnormal	Intraductal papillary-mucinous	Photon radiation therapy to ear, nose,
Biopsy cornea abnormal	carcinoma of pancreas	or throat
Biopsy diaphragm abnormal	Intraductal proliferative breast lesion	Photon radiation therapy to liver
Biopsy ear abnormal	Intraocular melanoma	Photon radiation therapy to lung
Biopsy endometrium abnormal	Intraperitoneal hyperthermic	Photon radiation therapy to pancreas
Biopsy epididymis abnormal	chemotherapy	Photon radiation therapy to pleura
Biopsy eyelid abnormal	Intratumoural aneurysm	Photon radiation therapy to prostate
Biopsy fallopian tube abnormal	Invasive breast carcinoma	Photon radiation therapy to skin
Biopsy foetal abnormal	Invasive ductal breast carcinoma	Photon radiation therapy to soft tissue
Biopsy gallbladder abnormal	Invasive lobular breast carcinoma	Photon radiation therapy to thyroid
Biopsy heart abnormal	Invasive papillary breast carcinoma	Photon radiation therapy to uterus
Biopsy intestine abnormal	Iris melanoma	Phyllodes tumour
Biopsy kidney abnormal	Iris neoplasm	Pilomatrix carcinoma
Biopsy larynx abnormal	Jejunectomy	Pineal germinoma
Biopsy ligament abnormal	Joint neoplasm	Pineal neoplasm
Biopsy lip abnormal	Juvenile chronic myelomonocytic	Pineal parenchymal neoplasm

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Biopsy liver abnormal	leukaemia	malignant
Biopsy lung abnormal	Kaposi's sarcoma	Pinealoblastoma
Biopsy lymph gland abnormal	Kaposi's sarcoma AIDS related	Pinealoma
Biopsy mucosa abnormal	Kaposi's sarcoma classical type	Pituitary cancer metastatic
Biopsy muscle abnormal	Keratinising squamous cell carcinoma	Pituitary gland radiotherapy
Biopsy oesophagus abnormal	of nasopharynx	Pituitary neoplasm malignant recurrent
Biopsy ovary abnormal	Keratoacanthoma	Pituitary tumour
Biopsy palate abnormal	Lacrimal duct neoplasm	Pituitary tumour recurrent
Biopsy pancreas abnormal	Langerhans' cell histiocytosis	Placental neoplasm
Biopsy parathyroid gland abnormal	Langerhans cell sarcoma	Plasma cell leukaemia
Biopsy penis abnormal	Large cell lung cancer	Plasma cell leukaemia in remission
Biopsy pericardium abnormal	Large cell lung cancer metastatic	Plasma cell myeloma
Biopsy peripheral nerve abnormal	Large cell lung cancer recurrent	Plasma cell myeloma in remission
Biopsy peritoneum abnormal	Large cell lung cancer stage 0	Plasma cell myeloma recurrent
Biopsy pharynx abnormal	Large cell lung cancer stage I	Plasmablastic lymphoma
Biopsy pleura abnormal	Large cell lung cancer stage II	Plasmacytoma
Biopsy prostate abnormal	Large cell lung cancer stage III	Pleomorphic adenoma
Biopsy rectum abnormal	Large cell lung cancer stage IV	Pleomorphic liposarcoma
Biopsy retina abnormal	Large granular lymphocytosis	Pleomorphic malignant fibrous
Biopsy salivary gland abnormal	Large intestinal polypectomy	histiocytoma
Biopsy sclera abnormal	Laryngeal cancer	Pleural mesothelioma
Biopsy seminal vesicle abnormal	Laryngeal cancer metastatic	Pleural mesothelioma malignant
Biopsy site unspecified abnormal	Laryngeal cancer recurrent	Pleural mesothelioma malignant
Biopsy skin abnormal	Laryngeal cancer stage 0	recurrent
Biopsy small intestine abnormal	Laryngeal cancer stage I	Pleural neoplasm
Biopsy spinal cord abnormal	Laryngeal cancer stage II	Pleural sarcoma
Biopsy spleen abnormal	Laryngeal cancer stage III	Pleurectomy
Biopsy stomach abnormal	Laryngeal cancer stage IV	PML/RAR alpha expression
Biopsy tendon abnormal	Laryngeal neoplasm	Pneumonectomy
Biopsy testes abnormal	Laryngeal squamous cell carcinoma	POEMS syndrome
Biopsy thymus gland abnormal	Laryngopharyngectomy	Polyneuropathy in malignant disease
Biopsy thyroid gland abnormal	Laser brain ablation	Poorly differentiated thyroid carcinoma
Biopsy tongue abnormal	Leiomyosarcoma	Porocarcinoma
Biopsy trachea abnormal	Leiomyosarcoma metastatic	Portal vein embolisation
Biopsy urethra abnormal	Leiomyosarcoma recurrent	Post breast therapy pain syndrome
Biopsy uterus abnormal	Lentigo maligna	Post transplant lymphoproliferative
Biopsy vagina abnormal	Lentigo maligna recurrent	disorder
Biopsy vocal cord abnormal	Lentigo maligna stage I	Postcricoid cancer
Biopsy vulva abnormal	Lentigo maligna stage II	Posterior fossa syndrome
Biotherapy	Lentigo maligna stage III	Precursor B-lymphoblastic lymphoma
Biphasic mesothelioma	Lentigo maligna stage IV	Precursor B-lymphoblastic lymphoma
Bladder adenocarcinoma recurrent	Leptomeningeal myelomatosis	recurrent
Bladder adenocarcinoma stage 0	Leukaemia	Precursor B-lymphoblastic lymphoma
Bladder adenocarcinoma stage I	Leukaemia basophilic	refractory
Bladder adenocarcinoma stage II	Leukaemia cutis	Precursor B-lymphoblastic lymphoma
Bladder adenocarcinoma stage III	Leukaemia granulocytic	stage I
Bladder adenocarcinoma stage IV	Leukaemia in remission	Precursor B-lymphoblastic lymphoma
Bladder adenocarcinoma stage	Leukaemia monocytic	stage II
unspecified	Leukaemia recurrent	Precursor B-lymphoblastic lymphoma
Bladder cancer	Leukaemic cardiac infiltration	stage III
Bladder cancer recurrent	Leukaemic infiltration	Precursor B-lymphoblastic lymphoma
Bladder cancer stage 0, with cancer in	Leukaemic infiltration extramedullary	stage IV
situ	Leukaemic infiltration gingiva	Precursor T-lymphoblastic
Bladder cancer stage 0, without cancer	Leukaemic infiltration hepatic	lymphoma/leukaemia
in situ	Leukaemic infiltration ovary	Precursor T-lymphoblastic
Bladder cancer stage I, with cancer in	Leukaemic infiltration pulmonary	lymphoma/leukaemia recurrent

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
situ	Leukaemic infiltration renal	Precursor T-lymphoblastic
Bladder cancer stage I, without cancer in situ	Leukaemic lymphoma	lymphoma/leukaemia refractory
	Leukaemic retinopathy	Precursor T-lymphoblastic
Bladder cancer stage II	Leukostasis syndrome	lymphoma/leukaemia stage I
Bladder cancer stage III	Leydig cell tumour of the testis	Precursor T-lymphoblastic
Bladder cancer stage IV	Linitis plastica	lymphoma/leukaemia stage II
Bladder neck resection	Lip and/or oral cavity cancer	Precursor T-lymphoblastic
Bladder neoplasm	Lip and/or oral cavity cancer recurrent	lymphoma/leukaemia stage III
Bladder neoplasm surgery	Lip and/or oral cavity cancer stage 0	Precursor T-lymphoblastic
Bladder squamous cell carcinoma recurrent	Lip and/or oral cavity cancer stage I	lymphoma/leukaemia stage IV
	Lip and/or oral cavity cancer stage II	Primary cardiac lymphoma
Bladder squamous cell carcinoma stage 0	Lip and/or oral cavity cancer stage III	Primary effusion lymphoma
	Lip and/or oral cavity cancer stage IV	Primary gastrointestinal follicular
Bladder squamous cell carcinoma stage I	Lip neoplasm	lymphoma
	Lip neoplasm malignant stage unspecified	Primary mediastinal large B-cell
Bladder squamous cell carcinoma stage II		lymphoma
	Lip squamous cell carcinoma	Primary mediastinal large B-cell
Bladder squamous cell carcinoma stage III	Liposarcoma	lymphoma recurrent
	Liposarcoma metastatic	Primary mediastinal large B-cell
Bladder squamous cell carcinoma stage IV	Liposarcoma recurrent	lymphoma refractory
	Liver ablation	Primary mediastinal large B-cell
Bladder squamous cell carcinoma stage unspecified	Liver carcinoma ruptured	lymphoma stage I
	Liver scan abnormal	Primary mediastinal large B-cell
Bladder transitional cell carcinoma	Lobular breast carcinoma in situ	lymphoma stage II
Bladder transitional cell carcinoma metastatic	Lung adenocarcinoma	Primary mediastinal large B-cell
	Lung adenocarcinoma recurrent	lymphoma stage III
Bladder transitional cell carcinoma recurrent	Lung adenocarcinoma stage 0	Primary mediastinal large B-cell
	Lung adenocarcinoma stage I	lymphoma stage IV
Bladder transitional cell carcinoma stage 0	Lung adenocarcinoma stage II	Primitive neuroectodermal tumour
	Lung adenocarcinoma stage III	Primitive neuroectodermal tumour
Bladder transitional cell carcinoma stage I	Lung adenocarcinoma stage IV	metastatic
	Lung cancer metastatic	Proctectomy
Bladder transitional cell carcinoma stage II	Lung carcinoma cell type unspecified recurrent	Proctocolectomy
		Progesterone receptor assay positive
Bladder transitional cell carcinoma stage III	Lung carcinoma cell type unspecified stage 0	Prolactin-producing pituitary tumour
		Prolymphocytic leukaemia
Bladder transitional cell carcinoma stage IV	Lung carcinoma cell type unspecified stage I	Prophylactic chemotherapy
		Prostate ablation
Blast cell crisis	Lung carcinoma cell type unspecified stage II	Prostate cancer
Blast crisis in myelogenous leukaemia		Prostate cancer metastatic
Blastic plasmacytoid dendritic cell neoplasia	Lung carcinoma cell type unspecified stage III	Prostate cancer recurrent
		Prostate cancer stage 0
Blood chromogranin A increased	Lung carcinoma cell type unspecified stage IV	Prostate cancer stage I
		Prostate cancer stage II
Bone cancer	Lung infiltration malignant	Prostate cancer stage III
Bone cancer metastatic	Lung lobectomy	Prostate cancer stage IV
Bone giant cell tumour	Lung neoplasm	Prostate cryoablation
Bone giant cell tumour malignant	Lung neoplasm malignant	Prostate interstitial hyperthermia
Bone marrow infiltration	Lung neoplasm surgery	therapy
Bone marrow leukaemic cell infiltration	Lung squamous cell carcinoma	Prostatectomy
Bone marrow reticulin fibrosis	metastatic	Prostatic specific antigen abnormal
Bone marrow tumour cell infiltration	Lung squamous cell carcinoma	Prostatic specific antigen increased
Bone neoplasm	recurrent	Pseudoachalasia
Bone sarcoma	Lung squamous cell carcinoma stage 0	Pseudomyxoma peritonei
Bone scan abnormal	Lung squamous cell carcinoma stage I	Pseudosarcoma
Borderline mucinous tumour of ovary	Lung squamous cell carcinoma stage II	Pulmonary resection
Borderline ovarian tumour		

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Borderline serous tumour of ovary	Lung squamous cell carcinoma stage III	Pulmonary tumour thrombotic microangiopathy
Bowen's disease	Lung squamous cell carcinoma stage IV	Pylorectomy
Brachytherapy	Lymph nodes scan abnormal	Pyoderma gangrenosum
Brachytherapy to eye	Lymphadenectomy	Queyrat erythroplasia
Brachytherapy to penis	Lymphangiosarcoma	Radiation therapy to ear, nose, or throat
Brachytherapy to tongue	Lymphangiosis carcinomatosa	Radical cystectomy
Brachytherapy to tonsil	Lymphatic mapping	Radical hysterectomy
Brain cancer metastatic	Lymphatic system neoplasm	Radical mastectomy
Brain neoplasm	Lymphocyte adoptive therapy	Radical neck dissection
Brain neoplasm malignant	Lymphocytic leukaemia	Radical prostatectomy
Brain sarcoma	Lymphocytic lymphoma	Radioactive iodine therapy
Brain scan abnormal	Lymphoid leukaemia (in remission)	Radioembolisation
Brain stem glioma	Lymphoma	Radioisotope scan abnormal
Brain teratoma	Lymphoma AIDS related	Radiosensitisation therapy
Brain tumour operation	Lymphoma cutis	Radiotherapy
Breast angiosarcoma	Lymphoma operation	Radiotherapy to abdomen
Breast angiosarcoma metastatic	Lymphoma transformation	Radiotherapy to adrenal gland
Breast cancer	Lymphoplasmacytoid lymphoma/immunocytoma	Radiotherapy to blood
Breast cancer female	Lymphoplasmacytoid lymphoma/immunocytoma recurrent	Radiotherapy to bone
Breast cancer in situ	Lymphoplasmacytoid lymphoma/immunocytoma refractory	Radiotherapy to brain
Breast cancer male	Lymphoplasmacytoid lymphoma/immunocytoma stage I	Radiotherapy to breast
Breast cancer metastatic	Lymphoplasmacytoid lymphoma/immunocytoma stage II	Radiotherapy to colon
Breast cancer recurrent	Lymphoplasmacytoid lymphoma/immunocytoma stage III	Radiotherapy to ear
Breast cancer stage I	Lymphoplasmacytoid lymphoma/immunocytoma stage IV	Radiotherapy to eye
Breast cancer stage II	Lymphoproliferative disorder	Radiotherapy to gallbladder
Breast cancer stage III	Lymphoproliferative disorder in remission	Radiotherapy to gastrointestinal tract
Breast cancer stage IV	Male reproductive tract neoplasm	Radiotherapy to head and neck
Breast capsulotomy	Malignant anorectal neoplasm	Radiotherapy to joint
Breast conserving surgery	Malignant ascites	Radiotherapy to kidney
Breast neoplasm	Malignant blue naevus	Radiotherapy to liver
Breast prosthesis implantation	Malignant bowel obstruction	Radiotherapy to lung
Breast reconstruction	Malignant connective tissue neoplasm	Radiotherapy to lymph nodes
Breast sarcoma	Malignant cranial nerve neoplasm	Radiotherapy to mediastinum
Breast sarcoma metastatic	Malignant dysphagia	Radiotherapy to nose
Breast sarcoma recurrent	Malignant exophthalmos	Radiotherapy to oesophagus
Breast tumour excision	Malignant fibrous histiocytoma	Radiotherapy to oral cavity
Brenner tumour	Malignant fibrous histiocytoma metastatic	Radiotherapy to ovary
Bronchial carcinoma	Malignant fibrous histiocytoma of bone	Radiotherapy to pancreas
Bronchial neoplasm	Malignant fibrous histiocytoma recurrent	Radiotherapy to pleura
Bronchioloalveolar carcinoma	Malignant genitourinary tract neoplasm	Radiotherapy to prostate
Burkitt's leukaemia	Malignant giant cell fibrous histiocytoma	Radiotherapy to rectum
Burkitt's lymphoma		Radiotherapy to skin
Burkitt's lymphoma recurrent		Radiotherapy to soft tissue
Burkitt's lymphoma refractory		Radiotherapy to spleen
Burkitt's lymphoma stage I		Radiotherapy to stomach
Burkitt's lymphoma stage II		Radiotherapy to throat
Burkitt's lymphoma stage III		Radiotherapy to thymus
Burkitt's lymphoma stage IV		Radiotherapy to thyroid
Buschke-Lowenstein's tumour		Radiotherapy to urinary bladder
Cancer hormonal therapy		Radiotherapy to uterus
Cancer in remission		Radiotherapy to vagina
Cancer pain		Rectal adenocarcinoma
Cancer staging		Rectal cancer
Cancer surgery		Rectal cancer metastatic
Carbohydrate antigen 125 increased		Rectal cancer recurrent
Carbohydrate antigen 15-3 increased		

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Carbohydrate antigen 19-9 increased	Malignant glioma	Rectal cancer stage 0
Carbohydrate antigen 27.29 increased	Malignant haemangiopericytoma	Rectal cancer stage I
Carbohydrate antigen 549 increased	Malignant haemangiopericytoma metastatic	Rectal cancer stage II
Carcinoembryonic antigen decreased	Malignant haemangiopericytoma recurrent	Rectal cancer stage III
Carcinoembryonic antigen increased	Malignant histiocytosis	Rectal cancer stage IV
Carcinoid crisis	Malignant hydatidiform mole	Rectal neoplasm
Carcinoid heart disease	Malignant joint neoplasm	Rectosigmoid cancer
Carcinoid syndrome	Malignant lymphoid neoplasm	Rectosigmoid cancer metastatic
Carcinoid tumour	Malignant lymphoma unclassifiable high grade	Rectosigmoid cancer recurrent
Carcinoid tumour of the appendix	Malignant lymphoma unclassifiable low grade	Rectosigmoid cancer stage 0
Carcinoid tumour of the caecum	Malignant mast cell neoplasm	Rectosigmoid cancer stage I
Carcinoid tumour of the duodenum	Malignant mediastinal neoplasm	Rectosigmoid cancer stage II
Carcinoid tumour of the gastrointestinal tract	Malignant melanoma	Rectosigmoid cancer stage III
Carcinoid tumour of the pancreas	Malignant melanoma in situ	Rectosigmoid cancer stage IV
Carcinoid tumour of the prostate	Malignant melanoma of eyelid	Recurrent cancer
Carcinoid tumour of the small bowel	Malignant melanoma of sites other than skin	Refractory cancer
Carcinoid tumour of the stomach	Malignant melanoma stage I	Regional chemotherapy
Carcinoid tumour pulmonary	Malignant melanoma stage II	Renal cancer
Carcinoma ex-pleomorphic adenoma	Malignant melanoma stage III	Renal cancer metastatic
Carcinoma in situ	Malignant melanoma stage IV	Renal cancer recurrent
Carcinoma in situ of eye	Malignant meningioma metastatic	Renal cancer stage I
Carcinoma in situ of penis	Malignant mesenchymoma	Renal cancer stage II
Carcinoma in situ of skin	Malignant mesenchymoma metastatic	Renal cancer stage III
Carcinoma in situ of trachea	Malignant mesenchymoma recurrent	Renal cancer stage IV
Carcinomatous polyarthritis	Malignant mesenteric neoplasm	Renal cell carcinoma
Cardiac neoplasm malignant	Malignant middle ear neoplasm	Renal cell carcinoma recurrent
Cardiac neoplasm unspecified	Malignant muscle neoplasm	Renal cell carcinoma stage I
Cardiac teratoma	Malignant neoplasm of ampulla of Vater	Renal cell carcinoma stage II
Carotid body tumour	Malignant neoplasm of auricular cartilage	Renal cell carcinoma stage III
Cartilage neoplasm	Malignant neoplasm of choroid	Renal cell carcinoma stage IV
CD20 antigen positive	Malignant neoplasm of conjunctiva	Renal neoplasm
CD25 antigen positive	Malignant neoplasm of cornea	Renal scan abnormal
CD30 expression	Malignant neoplasm of eye	Renal tumour excision
Cell marker increased	Malignant neoplasm of eyelid	Respiratory tract carcinoma in situ
Cell-free and concentrated ascites reinfusion therapy	Malignant neoplasm of islets of Langerhans	Respiratory tract neoplasm
Cementoplasty	Malignant neoplasm of lacrimal duct	Retinal melanoma
Central nervous system leukaemia	Malignant neoplasm of lacrimal gland	Retinal neoplasm
Central nervous system lymphoma	Malignant neoplasm of orbit	Retinal tumour excision
Central nervous system melanoma	Malignant neoplasm of paraurethral glands	Retinoblastoma
Central nervous system neoplasm	Malignant neoplasm of placenta	Retro-orbital neoplasm
Central nervous system neuroblastoma	Malignant neoplasm of pleura	Retroperitoneal cancer
Cerebellar tumour	Malignant neoplasm of pleura metastatic	Retroperitoneal neoplasm
Cerebellopontine angle tumour	Malignant neoplasm of renal pelvis	Retroperitoneal neoplasm metastatic
Cervical tumour excision	Malignant neoplasm of retina	Retro-pubic prostatectomy
Cervix cancer metastatic	Malignant neoplasm of seminal vesicle	Rhabdoid tumour
Cervix carcinoma	Malignant neoplasm of spermatic cord	Rhabdoid tumour of the kidney
Cervix carcinoma recurrent		Rhabdomyosarcoma
Cervix carcinoma stage 0		Rhabdomyosarcoma recurrent
Cervix carcinoma stage I		Richter's syndrome
Cervix carcinoma stage II		Round cell liposarcoma
Cervix carcinoma stage III		Salivary bypass tube insertion
Cervix carcinoma stage IV		Salivary gland cancer
Cervix neoplasm		Salivary gland cancer recurrent
Chemotherapy		Salivary gland cancer stage 0
		Salivary gland cancer stage I
		Salivary gland cancer stage II

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Chemotherapy cardiotoxicity attenuation	Malignant neoplasm of spinal cord	Salivary gland cancer stage III
Chemotherapy cytokine prophylaxis	Malignant neoplasm of thorax	Salivary gland cancer stage IV
Chemotherapy extravasation management	Malignant neoplasm of thymus	Salivary gland neoplasm
Chemotherapy multiple agents systemic	Malignant neoplasm of unknown primary site	Salivary gland resection
Chemotherapy neurotoxicity attenuation	Malignant neoplasm of uterine adnexa	Salivary gland scan abnormal
Chemotherapy sensitivity and resistance assay	Malignant neoplasm papilla of Vater	Salpingectomy
Chemotherapy single agent systemic	Malignant neoplasm progression	Salpingo-oophorectomy
Chemotherapy urothelial toxicity attenuation	Malignant nervous system neoplasm	Salpingo-oophorectomy bilateral
Chest wall tumour	Malignant nipple neoplasm	Salpingo-oophorectomy unilateral
Chloroma	Malignant nipple neoplasm female	Sarcoma
Chloroma (in remission)	Malignant nipple neoplasm male	Sarcoma excision
Cholangiocarcinoma	Malignant oligodendroglioma	Sarcoma metastatic
Cholangiosarcoma	Malignant ovarian cyst	Sarcoma of skin
Chondrosarcoma	Malignant palate neoplasm	Sarcoma uterus
Chondrosarcoma metastatic	Malignant pericardial neoplasm	Sarcomatoid mesothelioma
Chondrosarcoma recurrent	Malignant peritoneal neoplasm	Sarcomatosis
Chordoma	Malignant pituitary tumour	Scan abdomen abnormal
Choriocarcinoma	Malignant pleural effusion	Scan abnormal
Choroid melanoma	Malignant polyp	Scan adrenal gland abnormal
Choroid neoplasm	Malignant psoas syndrome	Scan bone marrow abnormal
Choroid plexus carcinoma	Malignant respiratory tract neoplasm	Scan gallium abnormal
Choroid tumour excision	Malignant splenic neoplasm	Scan myocardial perfusion abnormal
Chronic eosinophilic leukaemia	Malignant sweat gland neoplasm	Scan with contrast abnormal
Chronic leukaemia	Malignant transformation	Scrotal cancer
Chronic leukaemia in remission	Malignant urinary tract neoplasm	Sebaceous carcinoma
Chronic lymphocytic leukaemia	Mantle cell lymphoma	Second primary malignancy
Chronic lymphocytic leukaemia (in remission)	Mantle cell lymphoma recurrent	Secondary cerebellar degeneration
Chronic lymphocytic leukaemia recurrent	Mantle cell lymphoma refractory	Secretory adenoma of pituitary
Chronic lymphocytic leukaemia refractory	Mantle cell lymphoma stage I	Seminoma
Chronic lymphocytic leukaemia stage 0	Mantle cell lymphoma stage II	Serous cystadenocarcinoma of pancreas
Chronic lymphocytic leukaemia stage 1	Mantle cell lymphoma stage III	Serous cystadenocarcinoma ovary
Chronic lymphocytic leukaemia stage 2	Mantle cell lymphoma stage IV	Sertoli cell testicular tumour
Chronic lymphocytic leukaemia stage 3	Marginal zone lymphoma	Sigmoidectomy
Chronic lymphocytic leukaemia stage 4	Marginal zone lymphoma recurrent	Signet-ring cell carcinoma
Chronic lymphocytic leukaemia transformation	Marginal zone lymphoma refractory	Simple mastectomy
Chronic myeloid leukaemia	Marginal zone lymphoma stage I	Sinus cancer metastatic
Chronic myeloid leukaemia (in remission)	Marginal zone lymphoma stage II	Skin angiosarcoma
Chronic myeloid leukaemia recurrent	Marginal zone lymphoma stage III	Skin cancer
Chronic myeloid leukaemia transformation	Marginal zone lymphoma stage IV	Skin cancer metastatic
Chronic myelomonocytic leukaemia	Marjolin's ulcer	Skin cryotherapy
Chronic myelomonocytic leukaemia (in remission)	Mastectomy	Skin neoplasm bleeding
C-kit gene negative	Mastocytic leukaemia	Skin neoplasm bleeding
Clear cell carcinoma of cervix	Mastoidectomy	Skin neoplasm excision
Clear cell endometrial carcinoma	Maternal cancer in pregnancy	Skin squamous cell carcinoma metastatic
Clear cell renal cell carcinoma	Mature B-cell type acute leukaemia	Small cell carcinoma
Clear cell sarcoma of soft tissue	Maxillofacial sinus neoplasm	Small cell carcinoma of the cervix
	Mediastinal biopsy abnormal	Small cell lung cancer
	Mediastinum neoplasm	Small cell lung cancer extensive stage
	Medullary carcinoma of breast	Small cell lung cancer limited stage
	Medullary thyroid cancer	Small cell lung cancer metastatic
	Medulloblastoma	Small cell lung cancer recurrent
	Medulloblastoma recurrent	Small intestinal resection
	Meigs' syndrome	Small intestine adenocarcinoma
	Melanoma recurrent	Small intestine carcinoma
	Meningeal neoplasm	

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Clear cell sarcoma of the kidney	Meningioma malignant	Small intestine carcinoma metastatic
Clonal evolution	Mesenteric neoplasm	Small intestine carcinoma recurrent
CNS germinoma	Mesothelioma	Small intestine carcinoma stage 0
Colectomy	Mesothelioma malignant	Small intestine carcinoma stage I
Colectomy total	Mesothelioma malignant recurrent	Small intestine carcinoma stage II
Colon cancer	Metaplastic breast carcinoma	Small intestine carcinoma stage III
Colon cancer metastatic	Metastases to abdominal cavity	Small intestine carcinoma stage IV
Colon cancer recurrent	Metastases to abdominal wall	Small intestine leiomyosarcoma
Colon cancer stage 0	Metastases to adrenals	Smooth muscle cell neoplasm
Colon cancer stage I	Metastases to biliary tract	Soft tissue neoplasm
Colon cancer stage II	Metastases to bladder	Soft tissue sarcoma
Colon cancer stage III	Metastases to bone	Solid pseudopapillary tumour of the pancreas
Colon cancer stage IV	Metastases to bone marrow	Somatostatin receptor scan abnormal
Colon neoplasm	Metastases to breast	Somatostatinoma
Colony stimulating factor therapy	Metastases to central nervous system	Spermatocytic seminoma
Colorectal adenocarcinoma	Metastases to chest wall	Spinal cord neoplasm
Colorectal cancer	Metastases to diaphragm	Spinal meningioma malignant
Colorectal cancer metastatic	Metastases to Eustachian tube	Spindle cell sarcoma
Colorectal cancer recurrent	Metastases to eye	Spleen scan abnormal
Colorectal cancer stage I	Metastases to fallopian tube	Splenectomy
Colorectal cancer stage II	Metastases to gallbladder	Splenic marginal zone lymphoma
Colorectal cancer stage III	Metastases to gastrointestinal tract	Splenic marginal zone lymphoma recurrent
Colorectal cancer stage IV	Metastases to heart	Splenic marginal zone lymphoma refractory
Colorectal carcinoma stage 0	Metastases to kidney	Splenic marginal zone lymphoma stage I
Composite lymphoma	Metastases to larynx	Splenic marginal zone lymphoma stage II
Computerised tomogram breast abnormal	Metastases to liver	Splenic marginal zone lymphoma stage III
Computerised tomogram liver abnormal	Metastases to lung	Splenic marginal zone lymphoma stage IV
Congenital fibrosarcoma	Metastases to lymph nodes	Splenic neoplasm malignancy unspecified
Congenital malignant neoplasm	Metastases to meninges	Squamous cell breast carcinoma
Congenital neoplasm	Metastases to mouth	Squamous cell carcinoma
Congenital retinoblastoma	Metastases to muscle	Squamous cell carcinoma of head and neck
Congenital teratoma	Metastases to nasal sinuses	Squamous cell carcinoma of lung
Conjunctival melanoma	Metastases to neck	Squamous cell carcinoma of pharynx
Conjunctival neoplasm	Metastases to nervous system	Squamous cell carcinoma of skin
Conjunctival primary acquired melanosis	Metastases to oesophagus	Squamous cell carcinoma of the cervix
Connective tissue neoplasm	Metastases to ovary	Squamous cell carcinoma of the hypopharynx
Cutaneous lymphoma	Metastases to pancreas	Squamous cell carcinoma of the oral cavity
Cyclotron therapy	Metastases to pelvis	Squamous cell carcinoma of the tongue
Cystadenocarcinoma ovary	Metastases to penis	Squamous cell carcinoma of the vagina
Cystoprostatectomy	Metastases to perineum	Squamous cell carcinoma of the vulva
Cytokeratin 18 increased	Metastases to peripheral nervous system	Squamous endometrial carcinoma
Dedifferentiated liposarcoma	Metastases to peripheral vascular system	Stauffer's syndrome
Dermatofibrosarcoma protuberans	Metastases to peritoneum	Stem cell transplant
Dermatofibrosarcoma protuberans metastatic	Metastases to pharynx	Stewart-Treves syndrome
Desmoplastic melanoma	Metastases to pituitary gland	Stomach scan abnormal
Desmoplastic mesothelioma	Metastases to placenta	
Desmoplastic small round cell tumour	Metastases to pleura	
Diaphragm neoplasm	Metastases to prostate	
Diffuse large B-cell lymphoma	Metastases to rectum	
Diffuse large B-cell lymphoma recurrent	Metastases to reproductive organ	
Diffuse large B-cell lymphoma refractory	Metastases to retroperitoneum	
Diffuse large B-cell lymphoma stage I	Metastases to salivary gland	
	Metastases to skin	
	Metastases to soft tissue	

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Diffuse large B-cell lymphoma stage II	Metastases to spinal cord	Superficial spreading melanoma stage I
Diffuse large B-cell lymphoma stage III	Metastases to spine	Superficial spreading melanoma stage II
Diffuse large B-cell lymphoma stage IV	Metastases to spleen	Superficial spreading melanoma stage III
Diffuse uveal melanocytic proliferation	Metastases to stomach	Superficial spreading melanoma stage IV
Disseminated large cell lymphoma	Metastases to testicle	Superficial spreading melanoma stage unspecified
Double hit lymphoma	Metastases to the mediastinum	Superior vena cava occlusion
Ductal adenocarcinoma of pancreas	Metastases to the respiratory system	Superior vena cava syndrome
Duodenal neoplasm	Metastases to thorax	Suprapubic prostatectomy
Duodenectomy	Metastases to thyroid	Synovial sarcoma
Dysplastic naevus syndrome	Metastases to tonsils	Synovial sarcoma metastatic
Ear neoplasm	Metastases to trachea	Synovial sarcoma recurrent
Ear neoplasm malignant	Metastases to urinary tract	Targeted cancer therapy
Eastern Cooperative Oncology Group performance status improved	Metastases to uterus	T-cell chronic lymphocytic leukaemia
Eastern Cooperative Oncology Group performance status worsened	Metastases to vagina	T-cell lymphoma
Eccrine carcinoma	Metastasis	T-cell lymphoma recurrent
Ectopic ACTH syndrome	Metastatic bronchial carcinoma	T-cell lymphoma refractory
Ectopic aldosterone secretion	Metastatic carcinoid tumour	T-cell lymphoma stage I
Ectopic antidiuretic hormone secretion	Metastatic carcinoma of the bladder	T-cell lymphoma stage II
Ectopic calcitonin production	Metastatic choriocarcinoma	T-cell lymphoma stage III
Ectopic chorionic gonadotrophin secretion	Metastatic gastric cancer	T-cell lymphoma stage IV
Ectopic growth hormone secretion	Metastatic glioma	T-cell prolymphocytic leukaemia
Ectopic hormone secretion	Metastatic glucagonoma	T-cell type acute leukaemia
Ectopic parathyroid hormone production	Metastatic lymphoma	T-cell unclassifiable lymphoma high grade
Ectopic prolactin secretion	Metastatic malignant melanoma	T-cell unclassifiable lymphoma low grade
Ectopic renin secretion	Metastatic neoplasm	Tendon neoplasm
Electron radiation therapy	Metastatic nervous system neoplasm	Teratoma
Electron radiation therapy to bladder	Metastatic ocular melanoma	Testicular cancer metastatic
Electron radiation therapy to blood	Metastatic pulmonary embolism	Testicular choriocarcinoma
Electron radiation therapy to bone	Metastatic renal cell carcinoma	Testicular choriocarcinoma recurrent
Electron radiation therapy to brain	Metastatic salivary gland cancer	Testicular choriocarcinoma stage I
Electron radiation therapy to breast	Metastatic squamous cell carcinoma	Testicular choriocarcinoma stage II
Electron radiation therapy to colon	Metastatic uterine cancer	Testicular choriocarcinoma stage III
Electron radiation therapy to ear, nose, or throat	Microsatellite instability cancer	Testicular embryonal carcinoma
Electron radiation therapy to liver	Minimal residual disease	Testicular embryonal carcinoma stage I
Electron radiation therapy to lung	Mismatch repair cancer syndrome	Testicular embryonal carcinoma stage II
Electron radiation therapy to pancreas	Mixed adenoneuroendocrine carcinoma	Testicular embryonal carcinoma stage III
Electron radiation therapy to prostate	Mixed hepatocellular cholangiocarcinoma	Testicular germ cell cancer
Electron radiation therapy to skin	Mixed-type liposarcoma	Testicular germ cell cancer metastatic
Electron radiation therapy to soft tissue	Modified radical mastectomy	Testicular germ cell tumour
Electron radiation therapy to uterus	Monoclonal gammopathy	Testicular germ cell tumour mixed
Elephantiasis nostras verrucosa	Monocytic leukaemia in remission	Testicular germ cell tumour mixed stage I
Embryonal rhabdomyosarcoma	Mucinous adenocarcinoma of appendix	Testicular germ cell tumour mixed stage II
Endocrine neoplasm	Mucinous breast carcinoma	Testicular germ cell tumour mixed stage III
Endocrine neoplasm malignant	Mucinous cystadenocarcinoma of pancreas	Testicular leiomyosarcoma
Endometrial adenocarcinoma	Mucinous cystadenocarcinoma ovary	Testicular malignant teratoma
Endometrial cancer	Mucinous endometrial carcinoma	
Endometrial cancer metastatic	Mucoepidermoid carcinoma	
Endometrial cancer recurrent	Mucoepidermoid carcinoma of salivary gland	
Endometrial cancer stage 0	Mueller's mixed tumour	
Endometrial cancer stage I	Multiple gated acquisition scan abnormal	
Endometrial cancer stage II		
Endometrial cancer stage III		

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Endometrial cancer stage IV	Muscle neoplasm	Testicular malignant teratoma stage I
Endometrial neoplasm	Musculoskeletal cancer	Testicular malignant teratoma stage II
Endometrial sarcoma	Myasthenic syndrome	Testicular malignant teratoma stage III
Endometrial sarcoma metastatic	Mycosis fungoides	Testicular neoplasm
Endometrial sarcoma recurrent	Mycosis fungoides recurrent	Testicular scan abnormal
Endometrial stromal sarcoma	Mycosis fungoides refractory	Testicular seminoma (pure)
Endotheliomatosis	Mycosis fungoides stage I	Testicular seminoma (pure) stage I
Enteropathy-associated T-cell lymphoma	Mycosis fungoides stage II	Testicular seminoma (pure) stage II
Eosinophilic leukaemia	Mycosis fungoides stage III	Testicular seminoma (pure) stage III
Ependymoma	Mycosis fungoides stage IV	Testicular yolk sac tumour
Ependymoma malignant	Myectomy	Testicular yolk sac tumour stage I
Epididymal cancer	Myeloblastoma	Testicular yolk sac tumour stage II
Epididymal neoplasm	Myeloid leukaemia	Testicular yolk sac tumour stage III
Epiglottic carcinoma	Myeloid leukaemia in remission	Testis cancer
Epiglottidectomy	Myeloid metaplasia	Testis cancer recurrent
Epithelioid mesothelioma	Myeloma cast nephropathy	Throat cancer
Epithelioid sarcoma	Myeloproliferative neoplasm	Thymic cancer metastatic
Epithelioid sarcoma metastatic	Myxofibrosarcoma	Thymoma
Epithelioid sarcoma recurrent	Myxoid liposarcoma	Thymoma malignant
Epstein Barr virus positive mucocutaneous ulcer	Naevoid melanoma	Thymoma malignant recurrent
Epstein-Barr virus associated lymphoma	Nasal cavity cancer	Thyroid B-cell lymphoma
Epstein-Barr virus associated lymphoproliferative disorder	Nasal neoplasm	Thyroid cancer
Erythraemic myelosis (in remission)	Nasal sinus cancer	Thyroid cancer metastatic
Erythroleukaemia	Nasopharyngeal cancer	Thyroid cancer recurrent
Ewing's sarcoma	Nasopharyngeal cancer metastatic	Thyroid cancer stage 0
Ewing's sarcoma metastatic	Nasopharyngeal cancer recurrent	Thyroid cancer stage I
Ewing's sarcoma recurrent	Nasopharyngeal cancer stage 0	Thyroid cancer stage II
Ex vivo gene therapy	Nasopharyngeal cancer stage I	Thyroid cancer stage III
Exploratory operation	Nasopharyngeal cancer stage II	Thyroid cancer stage IV
Extended radical mastectomy	Nasopharyngeal cancer stage III	Thyroid electron radiation therapy
Extradural neoplasm	Nasopharyngeal cancer stage IV	Thyroid gland scan abnormal
Extragonadal primary embryonal carcinoma	Natural killer-cell leukaemia	Thyroid neoplasm
Extragonadal primary germ cell tumour	Natural killer-cell lymphoblastic lymphoma	Thyroid stimulating hormone-producing pituitary tumour
Extragonadal primary germ cell tumour mixed	Necrolytic migratory erythema	Thyroidectomy
Extragonadal primary germ cell tumour mixed stage I	Needle biopsy site unspecified abnormal	Tissue polypeptide antigen increased
Extragonadal primary germ cell tumour mixed stage II	Neoadjuvant therapy	Tongue cancer metastatic
Extragonadal primary germ cell tumour mixed stage III	Neobladder surgery	Tongue cancer recurrent
Extragonadal primary malignant teratoma	Neonatal leukaemia	Tongue carcinoma stage 0
Extragonadal primary non-seminoma	Neonatal neuroblastoma	Tongue carcinoma stage I
Extragonadal primary non-seminoma stage I	Neoplasm	Tongue carcinoma stage II
Extragonadal primary non-seminoma stage II	Neoplasm malignant	Tongue carcinoma stage III
Extragonadal primary non-seminoma stage III	Neoplasm of appendix	Tongue carcinoma stage IV
Extragonadal primary non-seminoma stage IV	Neoplasm of cornea unspecified malignancy	Tongue neoplasm
	Neoplasm of orbit	Tongue neoplasm malignant stage unspecified
	Neoplasm of thymus	Tonsil cancer
	Neoplasm progression	Tonsil cancer metastatic
	Neoplasm prostate	Tonsillar neoplasm
	Neoplasm recurrence	Total adrenalectomy
	Neoplasm skin	Tracheal cancer
	Neoplasm swelling	Tracheal neoplasm
	Nephrectomy	Tracheal resection
	Nephroblastoma	Transcatheter arterial chemoembolisation
	Nephroureterectomy	Transcranial electrical motor evoked

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Extragonadal primary seminoma (pure)	Nervous system neoplasm	potential monitoring abnormal
Extragonadal primary seminoma (pure) stage I	Nervous system neoplasm surgery	Transformation to acute myeloid leukaemia
Extragonadal primary seminoma (pure) stage II	Neuroblastoma	Transitional cell cancer of renal pelvis and ureter metastatic
Extragonadal primary seminoma (pure) stage III	Neuroblastoma recurrent	Transitional cell cancer of the renal pelvis and ureter
Extragonadal primary seminoma (pure) stage IV	Neuroectodermal neoplasm	Transitional cell cancer of the renal pelvis and ureter localised
Extramammary Paget's disease	Neuroendocrine breast tumour	Transitional cell cancer of the renal pelvis and ureter recurrent
Extranodal marginal zone B-cell lymphoma (MALT type)	Neuroendocrine carcinoma	Transitional cell cancer of the renal pelvis and ureter regional
Extranodal marginal zone B-cell lymphoma (MALT type) recurrent	Neuroendocrine carcinoma metastatic	Transitional cell carcinoma
Extranodal marginal zone B-cell lymphoma (MALT type) refractory	Neuroendocrine carcinoma of the bladder	Transitional cell carcinoma metastatic
Extranodal marginal zone B-cell lymphoma (MALT type) stage I	Neuroendocrine carcinoma of the skin	Transitional cell carcinoma recurrent
Extranodal marginal zone B-cell lymphoma (MALT type) stage II	Neuroendocrine tumour	Transitional cell carcinoma urethra
Extranodal marginal zone B-cell lymphoma (MALT type) stage III	Neuroendocrine tumour of the lung	Transurethral bladder resection
Extranodal marginal zone B-cell lymphoma (MALT type) stage IV	Neuroendocrine tumour of the lung metastatic	Transurethral prostatectomy
Extraocular retinoblastoma	Neuroendoscopy	Triple hit lymphoma
Extra-osseous Ewing's sarcoma	Neurofibrosarcoma	Triple negative breast cancer
Extra-osseous Ewing's sarcoma metastatic	Neurofibrosarcoma metastatic	Trousseau's syndrome
Extra-osseous Ewing's sarcoma recurrent	Neurofibrosarcoma recurrent	Tubular breast carcinoma
Extraskeletal chondrosarcoma metastatic	Neuromyotonia	Tumour associated fever
Extraskeletal chondrosarcoma recurrent	Neurotensinoma	Tumour budding
Extraskeletal myxoid chondrosarcoma	Nipple neoplasm	Tumour cavitation
Extraskeletal osteosarcoma	Nipple resection	Tumour cell mobilisation
Extraskeletal osteosarcoma metastatic	NMP22 test abnormal	Tumour compression
Extraskeletal osteosarcoma recurrent	Nodal marginal zone B-cell lymphoma	Tumour embolism
Eyelid tumour	Nodal marginal zone B-cell lymphoma refractory	Tumour excision
Fallopian tube cancer	Nodal marginal zone B-cell lymphoma stage I	Tumour exudation
Fallopian tube cancer metastatic	Nodal marginal zone B-cell lymphoma stage II	Tumour fistulisation
Fallopian tube cancer stage I	Nodal marginal zone B-cell lymphoma stage III	Tumour flare
Fallopian tube cancer stage II	Nodal marginal zone B-cell lymphoma stage IV	Tumour haemorrhage
Fallopian tube cancer stage III	Nodular lymphocyte predominant Hodgkin lymphoma	Tumour inflammation
Fallopian tube cancer stage IV	Nodular melanoma	Tumour invasion
Fallopian tube neoplasm	Nongerminomatous germ cell tumour of the CNS	Tumour lysis syndrome
Familial medullary thyroid cancer	Non-Hodgkin's lymphoma	Tumour marker abnormal
Female reproductive neoplasm	Non-Hodgkin's lymphoma metastatic	Tumour marker decreased
Female reproductive tract carcinoma in situ	Non-Hodgkin's lymphoma recurrent	Tumour marker increased
Fibrosarcoma	Non-Hodgkin's lymphoma refractory	Tumour necrosis
Fibrosarcoma excision	Non-Hodgkin's lymphoma stage I	Tumour obstruction
Fibrosarcoma metastatic	Non-Hodgkin's lymphoma stage II	Tumour of ampulla of Vater
Fiducial marker placement	Non-Hodgkin's lymphoma stage III	Tumour pain
Fms-like tyrosine kinase 3 positive	Non-Hodgkin's lymphoma stage IV	Tumour perforation
Follicle centre lymphoma diffuse small cell lymphoma	Non-Hodgkin's lymphoma transformed recurrent	Tumour pruritus
Follicle centre lymphoma diffuse small	Non-Hodgkin's lymphoma unspecified histology aggressive	Tumour pseudoprogression
	Non-Hodgkin's lymphoma unspecified histology aggressive recurrent	Tumour rupture
		Tumour thrombosis
		Tumour treating fields therapy
		Tumour ulceration
		Tumour vaccine therapy
		Ultrasound pancreas abnormal
		Ultrasound scan abnormal
		Ultrasound scan vagina abnormal
		Undifferentiated carcinoma of colon

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
cell lymphoma recurrent	Non-Hodgkin's lymphoma unspecified histology aggressive refractory	Undifferentiated nasopharyngeal carcinoma
Follicle centre lymphoma diffuse small cell lymphoma refractory	Non-Hodgkin's lymphoma unspecified histology aggressive stage I	Undifferentiated sarcoma
Follicle centre lymphoma diffuse small cell lymphoma stage I	Non-Hodgkin's lymphoma unspecified histology aggressive stage II	Ureteral neoplasm
Follicle centre lymphoma diffuse small cell lymphoma stage II	Non-Hodgkin's lymphoma unspecified histology aggressive stage III	Ureteric cancer
Follicle centre lymphoma diffuse small cell lymphoma stage III	Non-Hodgkin's lymphoma unspecified histology aggressive stage IV	Ureteric cancer local
Follicle centre lymphoma diffuse small cell lymphoma stage IV	Non-Hodgkin's lymphoma unspecified histology indolent	Ureteric cancer metastatic
Follicle centre lymphoma, follicular grade I, II, III	Non-Hodgkin's lymphoma unspecified histology indolent stage I	Ureteric cancer recurrent
Follicle centre lymphoma, follicular grade I, II, III recurrent	Non-Hodgkin's lymphoma unspecified histology indolent stage II	Ureteric cancer regional
Follicle centre lymphoma, follicular grade I, II, III refractory	Non-Hodgkin's lymphoma unspecified histology indolent stage III	Urethral cancer
Follicle centre lymphoma, follicular grade I, II, III stage I	Non-Hodgkin's lymphoma unspecified histology indolent stage IV	Urethral cancer metastatic
Follicle centre lymphoma, follicular grade I, II, III stage II	Nonkeratinising carcinoma of nasopharynx	Urethral cancer recurrent
Follicle centre lymphoma, follicular grade I, II, III stage III	Non-renal cell carcinoma of kidney	Urethral melanoma metastatic
Follicle centre lymphoma, follicular grade I, II, III stage IV	Non-secretory adenoma of pituitary	Urethral neoplasm
Follicular dendritic cell sarcoma	Non-small cell lung cancer	Urethrectomy
Follicular thyroid cancer	Non-small cell lung cancer metastatic	Urinary bladder sarcoma
Free prostate-specific antigen increased	Non-small cell lung cancer recurrent	Urinary cystectomy
Free prostate-specific antigen positive	Non-small cell lung cancer stage 0	Urinary tract carcinoma in situ
Fungating wound	Non-small cell lung cancer stage I	Urinary tract neoplasm
Gallbladder adenocarcinoma	Non-small cell lung cancer stage II	Uterine cancer
Gallbladder adenosquamous carcinoma	Non-small cell lung cancer stage III	Uterine carcinoma in situ
Gallbladder cancer	Non-small cell lung cancer stage IIIA	Uterine leiomyosarcoma
Gallbladder cancer metastatic	Non-small cell lung cancer stage IIIB	Uterine neoplasm
Gallbladder cancer recurrent	Non-small cell lung cancer stage IV	Uterine tumour excision
Gallbladder cancer stage 0	NUT midline carcinoma	Uvulectomy
Gallbladder cancer stage I	Ocular cancer metastatic	Vaginal adenocarcinoma
Gallbladder cancer stage II	Ocular haemangiopericytoma	Vaginal cancer
Gallbladder cancer stage III	Ocular lymphoma	Vaginal cancer metastatic
Gallbladder cancer stage IV	Ocular neoplasm	Vaginal cancer recurrent
Gallbladder neoplasm	Oesophageal adenocarcinoma	Vaginal cancer stage 0
Gallbladder squamous cell carcinoma	Oesophageal adenocarcinoma recurrent	Vaginal cancer stage I
Gamma interferon therapy	Oesophageal adenocarcinoma stage 0	Vaginal cancer stage II
Gamma radiation therapy	Oesophageal adenocarcinoma stage I	Vaginal cancer stage III
Gamma radiation therapy to bladder	Oesophageal adenocarcinoma stage II	Vaginal cancer stage IVA
Gamma radiation therapy to blood	Oesophageal adenocarcinoma stage III	Vaginal cancer stage IVB
Gamma radiation therapy to bone	Oesophageal adenocarcinoma stage IV	Vaginal neoplasm
Gamma radiation therapy to brain	Oesophageal cancer metastatic	Vaginectomy
Gamma radiation therapy to breast	Oesophageal carcinoma	Vascular neoplasm
Gamma radiation therapy to colon	Oesophageal carcinoma recurrent	Vipoma
Gamma radiation therapy to ear, nose, or throat	Oesophageal carcinoma stage 0	Vocal cord neoplasm
Gamma radiation therapy to liver	Oesophageal neoplasm	Vocal cordectomy
Gamma radiation therapy to lung	Oesophageal prosthesis insertion	Vulval cancer
Gamma radiation therapy to pancreas	Oesophageal squamous cell carcinoma	Vulval cancer metastatic
Gamma radiation therapy to pleura	Oesophageal squamous cell carcinoma metastatic	Vulval cancer recurrent
		Vulval cancer stage 0
		Vulval cancer stage I
		Vulval cancer stage II
		Vulval cancer stage III
		Vulval cancer stage IV
		Vulval neoplasm
		Vulvar adenocarcinoma
		Vulvectomy
		Waldenstrom's macroglobulinaemia
		Waldenstrom's macroglobulinaemia recurrent
		Waldenstrom's macroglobulinaemia

SMQ PTs taken from Malignancies (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Gamma radiation therapy to prostate	Oesophageal squamous cell carcinoma recurrent	refractory
Gamma radiation therapy to skin	Oesophageal squamous cell carcinoma stage 0	Waldenstrom's macroglobulinaemia stage I
Gamma radiation therapy to soft tissue	Oesophageal squamous cell carcinoma stage I	Waldenstrom's macroglobulinaemia stage II
Gamma radiation therapy to thyroid	Oesophageal squamous cell carcinoma stage II	Waldenstrom's macroglobulinaemia stage III
Gamma radiation therapy to uterus	Oesophageal squamous cell carcinoma stage III	Waldenstrom's macroglobulinaemia stage IV
Gammopathy	Oesophageal squamous cell carcinoma stage IV	X-ray therapy to bladder
Ganglioglioma	Oesophagectomy	X-ray therapy to blood
Ganglioneuroblastoma	Oesophagogastrectomy	X-ray therapy to bone
Garcin syndrome	Oestrogen receptor assay positive	X-ray therapy to brain
Gastrectomy	Oestrogen receptor positive breast cancer	X-ray therapy to breast
Gastric cancer	Oligoastrocytoma	X-ray therapy to colon
Gastric cancer recurrent	Oligodendroglioma	X-ray therapy to ear, nose, or throat
Gastric cancer stage 0	Omentectomy	X-ray therapy to joint
Gastric cancer stage I	Oncogenic osteomalacia	X-ray therapy to liver
Gastric cancer stage II	Oncologic complication	X-ray therapy to lung
Gastric cancer stage III	Oophorectomy	X-ray therapy to pancreas
Gastric cancer stage IV	Oophorectomy bilateral	X-ray therapy to pleura
Gastric neoplasm	Optic glioma	X-ray therapy to prostate
Gastric sarcoma	Optic nerve neoplasm	X-ray therapy to skin
Gastric stent insertion	Oral cavity cancer metastatic	X-ray therapy to soft tissue
Gastrinoma	Oral cavity neoplasm surgery	X-ray therapy to thyroid
Gastrinoma malignant	Oral neoplasm	X-ray therapy to uterus
Gastroenteropancreatic neuroendocrine tumour disease	Orchidectomy	X-ray treatment
Gastrointestinal cancer metastatic	Orchidotomy	Yolk sac tumour site unspecified
Gastrointestinal carcinoma	Oropharyngeal cancer	
Gastrointestinal carcinoma in situ	Oropharyngeal cancer recurrent	
Gastrointestinal lymphoma	Oropharyngeal cancer stage 0	
Gastrointestinal melanoma	Oropharyngeal cancer stage I	
Gastrointestinal neoplasm	Oropharyngeal cancer stage II	
Gastrointestinal stromal cancer	Oropharyngeal cancer stage III	
Gastrointestinal stromal tumour	Oropharyngeal cancer stage IV	
Gastrointestinal submucosal tumour	Oropharyngeal lymphoepithelioma	
Gastrooesophageal cancer	Oropharyngeal neoplasm	
Genital cancer male	Oropharyngeal squamous cell carcinoma	
Genital cancer male in situ		
Genital neoplasm malignant female		
Genitourinary melanoma		
Genitourinary tract neoplasm		
Germ cell cancer		
Germ cell cancer metastatic		
Germ cell neoplasm		

SMQ PTs taken from Pseudomembranous colitis (SMQ) narrow		
MedDRA v20.1 Preferred Term (PT)		
Clostridial infection	Clostridium colitis	Clostridium test positive
Clostridial sepsis	Clostridium difficile colitis	Gastroenteritis clostridial
Clostridium bacteraemia	Clostridium difficile infection	Pseudomembranous colitis