Study Number: KIN-1901-2001

Study Title: A Multi-Center, Adaptive, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Gimsilumab in Subjects With Lung Injury or Acute Respiratory Distress Syndrome (ARDS) Secondary to Coronavirus Disease 2019 (COVID-19)

Statistical Analysis Plan

Version 4, 17-November-2020

NCT04351243

PAREXEL International

Kinevant

KIN-1901-2001

A Multi-Center, Adaptive, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of Gimsilumab in Subjects With Lung Injury or Acute Respiratory Distress Syndrome (ARDS) Secondary to Coronavirus Disease 2019 (COVID-19)

Statistical Analysis Plan

Version: 4.0

PAREXEL Project Number: 250621

SPONSOR SIGNATURE PAGE

Approved by:

_____ _____
[redacted] **Date**
[redacted]
On Behalf of Kinevant Sciences Inc

_____ _____
[redacted] **Date**
[redacted]
On Behalf of Kinevant Sciences Inc

_____ _____
[redacted] **Date**
[redacted]
Kinevant Sciences Inc

PAREXEL SIGNATURE PAGE

Signature(s) below confom that the Statistical Analysis Plan was developed in accordance with SOP-GDO-WW-019 and that it is approved for release.

This document has been approved and signed electronically on the final page by the following:

	Signatory
Author	[redacted]

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REVISION HISTORY

Version No.	Effective Date	Summary of Change(s)
0.1	06Apr2020	New document
0.2	15Apr2020	Incorporate Parexel internal review comments
0.3	19Apr2020	Incorporate Sponsor statistical review comments
0.4	24Apr2020	Incorporate Sponsor review comments
0.5	01May2020	Incorporate Sponsor review comments
1.0	06May2020	Final version for signature
1.1	19Jun2020	Update to align with Protocol v4.0 (12Jun2020) and to address FDA comments on SAP v1.0. Major updates: - Updates to key secondary endpoints. - Change missing data imputation method from LOCF to tipping point method. - Use estimand framework to describe primary and key secondary efficacy analyses.
1.2	21Jun2020	Incorporate Sponsor statistical review comments
1.3	22Jun2020	Additional details for interim analysis and missing data analyses added.
2.0	26Jun2020	Incorporate final Sponsor review comments. Final version for signature
2.1	20Jul2020	Incorporate FDA comments on SAP v2. and editorial changes to fix minor typographical errors and add clarity.
2.2	11Aug2020	Add superiority boundary for IA2, incorporate Parexel internal review comments
3.0	12Aug2020	Incorporate final comments. Final version for signature.
3.1	19Oct2020	Update per IA2 decisions: - Section 4.7 – Add summaries of any steroid use, any dexamethasone use, any other COVID-19 therapies. - Section 4.8.1.5 – Add new subgroup 'Baseline invasive ventilator use or severe ARDS at baseline' - Section 4.8.4 – Amend proposed analyses for 7-point ordinal scale to include shift tables and remove odds ratios and CMH tests. - Add section 5.2.6: Interim analysis 2 outcome
3.2	30Oct2020	Incorporate sponsor comments. Add multi-state competing risks analysis as supplementary analysis for time to hospital discharge and time to clinical improvement (section 4.8.1.13).
4.0	13Nov2020	Incorporate final comments. Final version for signature.

LIST OF ABBREVIATIONS

Abbreviation / Acronym	Definition / Expansion
ADA	Anti-drng antibodies
AE	Adverse event
AESI	Adverse events of special interest
ALP	Alkaline phosphatase
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
aPTT	Activated partial thromboplastin time
ARDS	Acute respiratory distress syndrome
AST	Aspartate aminotransferase
BILI	Total bilirnbin
BMI	Body Mass Index
BP	Blood pressure
CI	Confidence interval
CMH	Cochran-Mantel-Haenszel
CMQ	Company MedDRA que1y
COVID-19	Coronavims disease 2019
CPAP	Continuous positive aiiway pressure
CRP	C-reactive protein;
DBP	Diastolic blood pressure
DMC	Data monitoring committee
DoD	Day-of-discharge
DRM	Data Review Meeting
EAIR	Exposure-adjusted incidence rate
ECMO	Extraco1poreal membrane oxygenation
eCRF	Electronic Case Repo1i Fo1m
eGFR	Estimated glomernlar filtration rate
EoS	End-of-study
ET	Early te1mination
FAS	Full analysis set
FiO2	Fraction of inspii·ed oxygen

Abbreviation / Acronym	Definition / Expansion
GM-CSF	Granulocyte macrophage-colony stimulating factor
HR	Heart rate
IA	Interim analysis
ICU	Intensive care unit
ITT	Intent-to-ti·eat
IV	Inti·avenous
LDH	Lactate dehydrogenase
LIS	Lung injmy score
LOCF	Last observation calTied fo1ward
LVEF	Left venti·icular ejection fraction
MDRD	Modification of Diet in Renal Disease
MMRP	Mixed model with repeated measures
MedDRA	Medical Dictionaiy for Regulato1y Activities
NA	Not available
NEWS	National Early Warning Score
02	Oxygen
PEEP	Positive end-expiratory pressure
PIF	PaOi/Fi02 ratio
Pa02	Paiiial pressure of oxygen
PCR	Polymerase chain reaction
P-D	Patient days
PK	Phannacokinetics
pp	Per-protocol
PT	Prefe1Ted Tenn
SAE	Serious adverse event
SAP	Statistical analysis plan
SARS-CoV-2	Severe acute respiratory syndrome corona vims 2
SBP	Systolic blood pressure
SD	Standard deviation
SMQ	Standard MedDRA que1y
SOC	System Organ Class

Abbreviation / Acronym	Definition / Expansion
SOFA	Sequential Organ Failure Assessment
SP-D	Surfactant protein D
SpO2	Peripheral capillary oxygen saturation
TEAE	Treatment-emergent adverse event
TLF	Tables, Listings, Figures
WHODDE	Wodd Health Organization - Dmg Dictionary Enhanced

1 INTRODUCTION

In December 2019, the city of Wuhan, China experienced an outbreak of coronavirus disease 2019 (COVID-19), caused by a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As of March 2020, COVID-19 has become a global pandemic, and there are currently no approved agents available to treat coronaviruses. SARS-CoV-2 infection often induces an overactive immune response that causes significant lung damage, leading to acute respiratory distress syndrome (ARDS) and ultimately death. Granulocyte macrophage-colony stimulating factor (GM-CSF), a hematopoietic growth factor and immunomodulatory cytokine, is believed to have a key driver of cytokine storm and lung hyper-inflammation. Targeting GM-CSF using an anti-GM-CSF antibody, gimsilumab (KIN-1901), represents a promising strategy to treat patients who have developed lung injury or ARDS secondary to COVID-19.

KIN-1901-2001 is a randomized, double-blind, placebo-controlled study of gimsilumab for the treatment of lung injury or ARDS secondary to COVID-19. A total of 270 subjects are planned to be treated with IV gimsilumab on day 1 (400mg) and day 8 (200mg) or matching IV placebo (saline solution on days 1 and 8). This study consists of a 2-week Treatment Period and a 22-week Follow-up Period.

This study will have two database locks, the first when all subjects have completed through Day 43 or withdraw from the study early or meet the primary mortality endpoint. The second database lock will be when the last subject completes the Day 169/End-of-study (EoS) visit.

This statistical analysis plan (SAP) provides a detailed description of the statistical methods and analyses to be carried out in support for study KIN-1901-2001.

The following will be collected and not entered into the clinical study database until the database is locked:

- Pharmacokinetic data
- Immunogenicity data
- Exploratory biomarkers

The analyses described in this SAP are based upon the following study documents:

- Study Protocol, Version 2.0 (April 5, 2020)
- Study Protocol, Version 5.0 (August17, 2020)
- KIN-1901-2001 DMC Charter Version 3.1 (July 11, 2020)
- eCRF (September 29, 2020)

2 STUDY OBJECTIVES

2.1 Primary Objective(s)

The primary objective is to evaluate the impact of intravenous (IV) treatment with gimsilumab on mortality in subjects with lung injury or ARDS secondary to COVID-19.

2.2 Secondary Objective(s)

Key Secondary Objectives:

- To assess the effect of gimsilumab on ventilation requirements
- To assess the effect of gimsilumab on overall duration of hospitalization

Additional Secondary Objectives:

- To assess the effect of gimsilumab on the need for Intensive Care Unit (ICU) level of care
- To assess the effect of gimsilumab as measured by the National Early Warning Score (NEWS)
- To assess the effect of gimsilumab as assessed by the Sequential Organ Failure Assessment (SOFA) score
- To assess the effect of gimsilumab as measured by the 7-point ordinal scale
- To assess the effect of gimsilumab on peripheral capillary oxygen saturation / fraction of inspired oxygen (SpO_2/FiO_2)
- To assess the effect of gimsilumab on oxygenation requirements
- To assess changes in on-treatment viral load
- To assess the effect of gimsilumab on biomarkers of inflammation
- To determine the pharmacokinetic (PK) properties of gimsilumab
- To assess the immunogenicity of gimsilumab
- To determine the safety and tolerability of gimsilumab

2.3 Exploratory Objective(s)

- To explore the effect of gimsilumab on serum cytokine concentrations and surfactant protein D (SP-D)
- To explore the effect of gimsilumab on other measurements of lung injury that may be performed during standard care (e.g., Lung Injury Score [LIS], chest radiography, PaO_2/FiO_2 [P/F ratio], need for extracorporeal membrane oxygenation [ECMO])
- To explore the effect of gimsilumab on cardiac function (if measured)
- To assess the effect of gimsilumab on renal function

3 INVESTIGATIONAL PLAN

3.1 Overall Study Design and Plan

This is a randomized, adaptive, double-blind, placebo-controlled study in male and/or female subjects who are at risk of developing, or have developed, ARDS consequent to moderate to severe COVID-19. This study will include subjects with moderate-to-severe disease. There will be 2 treatment aims, one receiving blinded gimsilumab, and one receiving blinded placebo.
Efficacy, safety, tolerability, phannacokinetics, and phaimacodynamics of gimsilumab will be assessed in hospitalized adult subjects diagnosed with COVID-19. Randomization will bestratified by:

- Subject's clinical status at Baseline
  - Lung injmy/mild ARDS
  - Moderate/severe ARDS

Lung injmy is defined as (1) requiring supplemental oxygen >4L 02 to maintain >92% SpO2, or (2) PaOi/FiO2:S 300 rmnHg (can be imputed).

ARDS is defined (ARDS Definition Task Force 2012) as:

- Bilateral opacities - not fully explained by effusions, lobai·/lung collapse, or nodules;
- Respirato1y failme not fully explained by cai·diac failw-e or fluid overload;
- Need objective assessment (e.g., echocai·diography) to exclude hydrostatic edema if no risk factor present.
- ARDS severity categories are defined as:
  - Mild: 200 m1nHg, < PaOi/FiO2, :S300 rmnHg with PEEP or CPAP::::5 cm H2O.
  - Moderate: 100 mmHg, < PaOi/FiO2, :S 200 rmnHg with PEEP::::5 cm H2O.
  - Severe: PaOi/FiO2:Sl00 rmnHg with PEEP::::5 cm H2O.

A schematic of the study design is presented in Figure 3-1. Subjects will be assessed daily while hospitalized. Follow-up assessments are planned through Week 24, for a total study duration post-randomization of approximately 169 days (24 weeks). Follow-up visits at Days 15, 22, 29, 36, 43, 85 and 169 will be perfonned by phone if the subject has been discharged from the hospital. All subjects will undergo a series of efficacy, safety, and laborato1y assessments as detailed in the Schedule of Assessments (Appendix 7.1).

Each subject will pa1ticipate for approximately 24 weeks, with a 2-week Treatment Period (last dose on Day 8) and a 22-week Follow-up Period. Treatment Anns for KIN-1901-2001:

Arm 1: Gimsilumab (400 mg) as a single IV infusion on Day 1 followed by a single 200 mg IV infusion on Day 8* (N=135)

Arm 2: Placebo (0.9% saline solution) IV infusion on Day 1 and Day 8* (N=135)

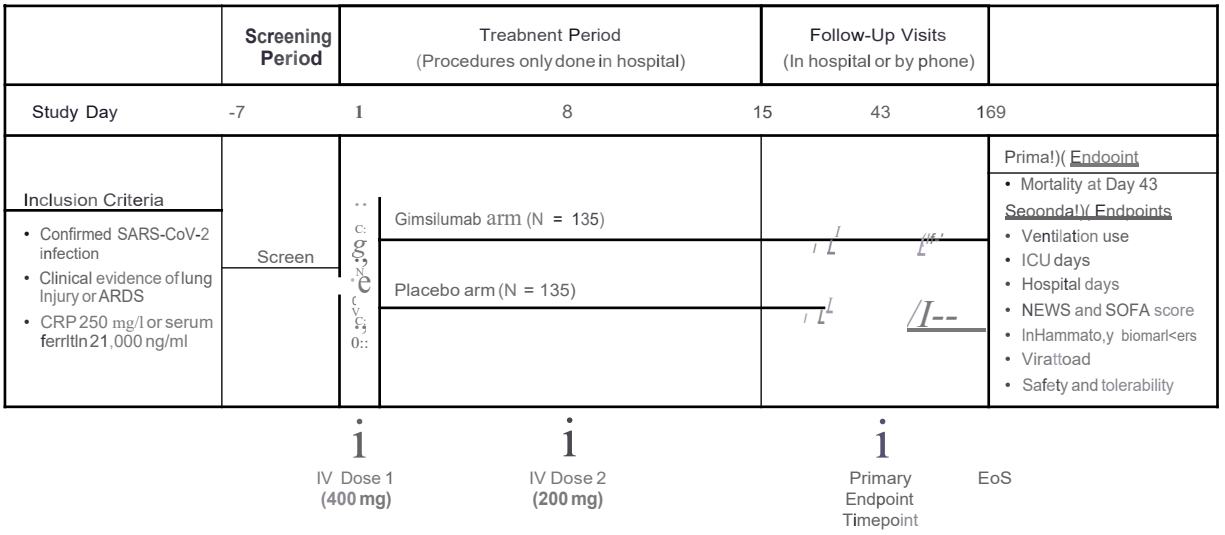
*The Day 8 dose will be omitted if the subject is discharged from the hospital or is no longer in need ofsupplemental oxygen or ventilatory suppo1t for >48 hours.

Asufficient number ofsubjects will be emolled to achieve approximately 270 evaluable subjects total, with 135 subjects per treatment aim. There will be two inte1im analyses (IA):

1st IA: For safety and futility when 60 subjects have completed treatment and completed through study Day 15

2nd IA: For safety, superiority, and futility when 100 subjects have completed the study Day 29 Visit (for non-mo1tality endpoints) or have died (mo1tality data) by Day 43 (see Section 5.2.1 for details). The sample size re-estimation will be perfo1med to maintain the conditional power of 80% the primary analysis ofM01tality by Day 43.

Figure 3-1: Study Schematic



ARDS = acute respirato1y distress syndrnme; CRP = C-reactive prntein; EoS = End of Study; IV = intravenous; ICU = Intensive Care Unit; NEWS= National Early Waming Score; SOFA= Sequential Organ Failure Assessment

3.2 Database locks

The database will be locked first when all subjects complete the Day 43 Visit, discontinue from the study eai·ly, or meet the primary m01tality endpoint. The second lock will occm when the last subject completes the Day 169/ EoS visit, discontinue from the study eai·ly, or died up to Day 169. Study unblinding will occm at the first database lock.

All analyses described in this SAP will be perfo1med at the 1st database lock. For the 2nd lock, all safety analyses will be perfo1med but efficacy analyses without new data (*e.g.* assessments only collected dming hospitalization if all subjects have been discharged by 1st database lock) may not be perfo1med again.

3.3 Determination of Sample Size

There will be 270 subjects (135 subjects per treatment aim) with 1:1 randomization.

The comparisons between the treatment anns will have approximately 83% power and overall two-sided alpha level 0.05 (the equivalent one-sided overall significance level 0.025 will be used in the remainder of this SAP) to demonstrate a statistically significant reduction in mo1tality by Day 43 for

gimsilumab compared to placebo when assuming tme propo1tions of 15% and 30%, respectively and a superiolity / futility inte1im analysis as described in Section 5.2.

The study will emoll at least 40%, but no more than 60%, of total patients in each of the 2 categories of clinical status: ([lung injmy/mild ARDS] or [moderate/severe ARDS]) at Baseline, which will be used as the stratified factor in the randomization.

3.4 Endpoints

3.4.1 Efficacy Variables

Primary:

- Mo1tality by Day 43

Key Secondary:

- Propo1tion of subjects who survived and not requiring mechanical ventilation on Day 29
- Mechanical ventilation-free days by Day 29
- Time to hospital discharge

Additional Secondary:

- Mortality by Days 15, 22, 29, 85, and 169 (EoS)
- Proportion ofsubjects who survived and were not requiring mechanical ventilation on Days 15, 22, and 43
- Mechanical ventilation-free days for all subjects by Days 15, 22, and 43.
- ICU-free days for all subjects by Days 15, 22, 29, and 43
- Incidence of mechanical ventilation use for all subjects Days 15, 22, 29, and 43.
- Incidence ofICU use for all subjects Days 15, 22, 29, 43
- Time to death by Day 43 and Day 169 (EoS)
- NEWS assessed daily while hospitalized
- SOFA score and each of the components assessed daily while in the ICU
- Status on the 7-point ordinal scale daily while hospitalized and on Days 15, 22, 29, 36, 43, 85, and 169 if discharged
- Time to clinical improvement
- Change from Baseline in SpOi/Fi02 assessed daily while hospitalized
- Incidence and duration of oxygen use during the study
- Change from Baseline in viral load as measured by quantitative polymerase chain reaction (PCR) test on Days 2, 9, and Day-of-discharge (DoD)
- Change from Baseline in D-dimer, cardiac troponin I, lactate dehydrogenase (LDH), fen-itin, procalcitonin, and C-reactive protein (CRP) on Days 4, 8, and DoD (and Days 15, 22, 29, 36, and 43 if hospitalized)
- Se1um gimsilumab concentrations on Days 1, 8, and DoD
- Anti-gimsilumab antibodies (ADAs) on Day 1 and DoD (and Days 15, 29, and 43 if hospitalized)

3.4.2 Safety Variables

- Physical examinations
- Vital signs (supine blood pressure [BP] and pulse, oral body temperature, respirato1y rate)

- Clinical laboratory tests (hematology, clinical chemistry, and urinalysis parameters)
- Adverse event (AE) assessments
- Concomitant medication assessments

The above safety variables will be summarized by Day 43 and Day 169/EoS.

3.5 Exploratory Variables

- Change from Baseline in the cytokine panel on Days 4, 8, and DoD (and Days 15 and 29 if hospitalized)
- Change from Baseline in LIS (if performed) daily while hospitalized
- Change from Baseline in chest radiographic assessment (if performed)
- Change from Baseline in P/F ratio (if performed) daily while hospitalized
- Incidence and duration of ECMO use
- Change from Baseline in left ventricular ejection fraction (LVEF) (when measured)
- Change from Baseline in eGFR [Modification of Diet in Renal Disease (MDRD) equation], assessed when central clinical safety laboratory measurements are collected during hospitalization

4 STATISTICAL METHODS

4.1 Data Quality Assurance

All tables, figures and data listings to be included in the report will be independently checked for consistency, integrity and in accordance with standard Parexel procedures.

4.2 General Presentation Considerations

4.2.1 Study Periods

This study has two periods, the treatment period and the follow-up period (Figure 3-1). The follow-up period will be divided into two for analysis purposes, the first for follow-up through Day 43 and the second for Day 44 through the end-of study. Some assessments will only be done while subjects are hospitalized as detailed in the schedule of assessment (Appendix 7.1), because of this some endpoints during each period will not be available for all subjects. The hospitalization period will contain all assessments during either the treatment period or follow-up period that occur before the subject is discharged. The discharge period will cover the time starting the day after hospital discharge through the end-of-study. Differences in time at risk will also be taken to account at the endpoint level and each endpoint be analyzed using methods appropriate to its planned collection pattern. Medical events and medications will be classified into study periods using their start dates.

The following definitions will be applied:

Treatment period (Day 1 – Day 15): Starts on *first dose date* and ends at the earliest of *first dose date* + 14 and *end of study date*.

Follow-up period 1 (Day 16 through Day 43): Starts on *first dose date* + 15 and ends at the *Day 43 Visit date*.

Follow-up period 2 (Day 44+): Starts on *first dose date* + 43 and ends at the *end of study date*.

Overall: Treatment period, follow-up period 1 and follow-up period 2 combined.

Overall - Hospitalized: Study Day 1 to *date of discharge.* This period will include all assessments that were taken while the subject was hospitalized.

Overall – After Discharge: Day of discharge through end of study. This period starts at *date of discharge + 1 and ends at the end of study date.*

Where,

First dose date: Day 1, date first dose of study drug received.

End of study date: date of End-of-Study visit (Day 169/ EoS) if subject completes the study or date of early withdrawal if subject discontinues early or date of death.

Date of discharge: date subject is discharged from the hospital.

Study Day: <Assessment Date> - *first dose date* + 1 if <Assessment Date> is on or after *first dose date*. <Assessment Date> - *first dose date*, if <Assessment Date> is before *first dose date*.

Study drug: gimsilumab or placebo

Study treatment: administration of study drug on Day 1 and Day 8 (as required per protocol).

4.2.2 Study Visits and Windowing

Baseline: the last available pre-ti·eatment assessment. All assessments should have time collected. If time is not collected and date of assessment is the same as the *first dose date,* then assessment will be assumed to be collected prior to ti·eatment unless schedule of assessments and protocol indicate planned collection is always after dosing.

Day-of-Discharge (DoD): day when subject is discharged from the hospital.

Early Termination (ET): day when subject withdraws from the study before completion.

End-of-Study (EoS): the end of study visit is at Day 169 (24 weeks after first dose) for subjects who complete the study.

Study Visits:

Planned study visits are detailed in Table 4-1 and in the Schedule of Assessments (Appendix 7.1). Planned study visits that occur outside of their protocol defined window will be analyzed as repo1ied and there will no attempt to coITect visits that fall outside their planned time frame by applying analysis visit windows. Unscheduled visits will be assigned to a study visit if they fall into the study windows. Unscheduled visits that do not fall into scheduled study visit window will be included when classifying endpoints across a period (e.g. maximum value during study period) but will not be repo1ied in by visit summaries.

fu the case of multiple assessments on the same visit the following rnles will apply:

- If more than one assessment occurs during the same nominal visit time window of the planned visit, select the record closest to the nominal day for that paiiicular visit day.
- If there ai·e two assessments that are equidistant from the nominal planned visit day, the data of the assessment after the scheduled study day will be used.
- If multiple measurements are all taken on the same day the earliest measurement of this day will be used.

Table 4-1: Study Visit Windowing

Visit	Study Day/Week	Window
Screening	-7 to 1/0	None
Baseline	1/0	None
Day2	2/1	+/- 1 day*
Dav3	3/1	+/- 1 day*
Dav4	4/1	+/- 1 day*
Day5	5/1	+/- 1 day*
Day6	6/1	+/- 1 day*
Dav7	7/1	+/- 1 day*
Dav8	8/2	+/- 1 dav*
Day9	9/2	+/- 1 day*
Dav 10	10/2	+/- 1 day*
Dav 11	11/2	+/- 1 dav*
Day 12	12/2	+/- 1 day*
Dav 13	13/2	+/- 1 day*
Dav 14	14/2	+/- 1 day*
Day 15	15/2	+/- 2 day

Visit	Study Dav/Week	Window
Dav22	22/3	+/- 2 dav
Day29	29/4	+/- 2 day
Dav36	36/5	+/- 2 day
Dav43	43/6	+/- 2 day
Day85	85/12	+/- 2 day
Dav 169/EoS	169/24	+/- 2 day
*no window will be applied for assessments collected daily during hospitalization per Schedule of Assessments (Aooendix 7.1)		

4.2.3 Missing dates

Every effo1t will be made to collect complete dates for all study assessments. The following date imputation rnles will be applied for missing or pa1tial dates:

- If month and year available, set start date to latest of (1st of the *month,first dose date),* if end date is complete and imputed strut date > end date, set imputed strut date to end date - 1.
- If year available: Set strut date to Janua1y 1st of year recorded, if end date is complete and imputed strut date > end date, set imputed strut date to end date - 1.
- If strut date is completely missing, set to *first dose date,* if end date is complete and imputed strut date > end date, set imputed strut date to end date- 1.
- If any imputed date results in an improbable date (e.g. date occurs in the future, date occurs after subject died), set to *first dose date.*

4.2.4 Conventions

Continuous data will be summarized in tenns of the mean, standai·d deviation (SD), median, minimum, maximum, and number of observations, unless othe1wise stated. Continuous data that are expected to be skewed will be presented in tenns of the maximum, upper quaitile, median, lower qurutile, minimum, and number of observations. The minimum and maximum will be repo1ted to the same number of decimal places as the raw data recorded in the database. The mean, median, lower qurutile, and upper quaitile will be repo1ted to one more decimal place than the raw data recorded in the database. The SD will be repo1ted to two more decimal places than the raw data recorded in the database. In general, the maximum number of decimal places repo1ted shall be four for any summary statistic.

Categorical data will be smnmru·ized in tenns of the number of subjects providing data at the relevant time point (n), frequency counts and percentages. Any planned collapsing of categories will be detailed in the SAP text and the data displays.

Percenta ges will be presented to one decimal place. Percenta ges will not be presented for zero counts. Percenta ges will be calculated using n as the denominator. If sample sizes ai·e small, the data displays will show the percentages, but any textual report will describe frequencies only.

Changes from baseline in categorical data will be summarized using shift tables where appropriate.

P-values greater than or equal to 0.001, in general, will be presented to three decimal places. P-values less than 0.001 will be presented as "<0.001".

Confidence intervals will be presented to one more decimal place than the raw data.

4.3 Software

All report outputs will be produced using SAS® version 9.4 or a later version in a secure and validated environment.

4.4 Study Subjects

4.4.1 Disposition of Subjects

A clear accounting of the disposition of all subjects who enter the study will be provided, from screening to study completion.

Summaries will include:

- the number of subjects randomized (full analysis set)
- the number and percentage of subjects treated (with any amount of study drug)
- the number and percentage of subjects entering, withdrawing from study treatment, withdrawing from the study and completing each phase of the study by treatment group and overall. Withdrawals from the study and from study treatment will also be summarized by major reason. (Analysis set: Full Analysis Set)

By-subject listings of eligibility details, randomization details, visit dates and withdrawal/study completion details (including reason for discontinuation and duration of treatment prior to discontinuation) will be provided.

4.4.2 Protocol Deviations

Major protocol deviations are defined as those deviations from the protocol likely to have an impact on the perceived efficacy and/or safety of study treatments. The impact of major protocol deviations on the efficacy and/or safety results will be investigated by assessing the robustness of the study results and conclusions to the choice of analysis set, both including and excluding data potentially affected by major protocol deviations.

Major protocol deviations and any action to be taken regarding the exclusion of subjects or affected data from specific analyses are defined in the Protocol Deviation Specification. A summary of the number and percentage of subjects with major protocol deviation by treatment group and overall and by type of deviation (full analysis set and intent-to-treat analysis set). A by-subject listing of major protocol deviations will be provided.

4.5 Analysis Sets

The **Full Analysis Set** (FAS) consists of all subjects randomized regardless of whether they received study treatment. Subjects will be summarized and analyzed ‘as randomized’ i.e. by randomized treatment group. If a subject is stratified incorrectly, ‘randomized stratum’ will be used rather than ‘actual stratum’. Summaries of study disposition, protocol deviations and by-subject listings (unless otherwise specified) will be based on the FAS. Efficacy summaries and analyses will be based on the FAS.

The efficacy summaries and analyses will be based on the **intent-to-treat (ITT) analysis set,** which is defined as all randomized subjects who received any amount of study drug. Subjects will be summarized and analyzed ‘as randomized’ i.e. by randomized treatment group. If a subject is stratified incorrectly, ‘randomized stratum’ will be used rather than ‘actual stratum’.

For the primary and key secondary efficacy endpoints, a sensitivity analysis will be performed on the **per-protocol analysis set** to assess the robustness of the study conclusions to the choice of analysis set. The per-protocol population is defined as all subjects in the ITT **analysis set** who complete the study with no major protocol deviations. A blinded data review will occur prior to the first database lock to decide the subjects being excluded from the per-protocol **analysis set**.

The safety summaries and analyses will be based on the **safety analysis set**. The safety analysis set is defined as all randomized subjects who received any amount of study drug. Subjects will be summarized and analyzed 'as treated' i.e. by actual treatment group.

PK analyses will be based on the **PK analysis set** defined as subjects that receive at least one dose of gimsilumab and have at least 1 evaluable post-dose pharmacokinetic sample.

Upon database release, protocol deviation and analysis set outputs will be produced and will be sent to Kinevant for review. An analysis set classification meeting will be arranged to discuss the outputs and to decide which subjects and/or subject data will be included in the different analysis sets. Such decisions will be made prior to unblinding and will be documented and approved by Kinevant.

A summary of the number and percentage of subjects entering and completing each phase of the study by treatment group and overall for each analysis set (Analysis set: FAS).

A by-subject listing of analysis set details including center, subject identifier, inclusion/exclusion flag for each analysis set and reason for exclusion from an analysis set.

4.6 Demographic and Other Baseline Characteristics

Demographic and other baseline characteristics will be summarized by treatment group and for both treatment groups combined (Total) using the ITT analysis set. The summaries provided will include the following.

- Demographic variables:
  - Age (continuous and categorical (<65 years; ≥65years))
  - Sex
  - Race (American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; Other; Multiple)
  - Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
  - Baseline Height
  - Baseline Weight
  - Baseline Body Mass Index (BMI)
- Baseline disease characteristics:
  - Randomization strata (Lung injury/mild ARDS; moderate severe/ARDS)
  - Ventilation status
  - Ventilation type
  - ICU status
  - Oxygenation status
  - Oxygenation type
  - SpO_2, FiO_2, PaO_2, P/F ratio, S/F ratio
  - Baseline ferritin, CRP, d-dimer, cardiac troponin I, LDH
  - Baseline Lung Injury Score

- Baseline NEWS Total Score
- Baseline 7-point Ordinal Scale
- Baseline SOFA Total Score
- Baseline anti-GM-CSF autoantibody concentration (continuous and by categories of <5 µg/mL, ≥5 µg/mL)
- Days since onset of symptoms

Medical history will be reported by system organ class and preferred term as coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 23.0 or higher.

Age will be reported as calculated in the study database at day of informed consent. BMI will be calculated from baseline height and weight as weight (kg) / height^2 (m^2).

By-subject listings of demographic data and other baseline characteristics (as summarized above) will be provided.

4.7 Prior, Concomitant, and Prohibited Medications and Procedures

Prior and concomitant medications will be summarized by drug class and preferred medication name by treatment group and for both treatment groups combined (Total) using the ITT analysis set . Prior and concomitant medications will be summarized separately, concomitant medications will also be summarized overall and by study period. WHO DDE March 2020 will be used to classify medications.

Medication start and stop dates will be compared to the date of first dose of study drug to allow medications to be classified as either Prior only, both Prior and Concomitant, or Concomitant only. Missing or partial start dates will be imputed as described in Section 4.2.3. Medications starting after the completion/withdrawal date will be listed but will not be classified or summarized.

Medications that start and stop prior to the date of first dose of study drug will be classified as Prior only. If a medication starts before the date of first dose of study drug and stops on or after the date of first dose of study drug, then the medication will be classified as both Prior and Concomitant. Medications will be classified as Concomitant only if they have a start date on or after the date of first dose of study drug.

Use of tocilizumab or any other immunomodulatory biologic (e.g., anti-IL-1, anti-IL-6R, anti-TNF), cell therapies (e.g., mesenchymal stem cells), or small molecules (e.g., JAK inhibitors) is prohibited during the study. Additional prohibited medications may also be defined during blinded data review prior to general study unblinding. The number and percentages of the subjects using such medications will be summarized by treatment groups, and the impact on efficacy and safety will be analyzed by subgroup analyses.

In addition, separate summaries of prior and concomitant steroid use (including the categories ‘Any Steroid Use’ and ‘Any Dexamethasone Use’) and other COVID-19 therapies will be provided. Lists of drugs to include in each of these categories will be provided by a medical monitor and the final list will be reviewed and approved prior to general study unblinding.

By-subject listings of prior, concomitant and prohibited medications will be provided. Listings will also be provided for any concomitant procedures reported.

4.8 Efficacy Evaluation

4.8.1 Analysis and Data Conventions

4.8.1.1 Multi-center Study

The statistical analysis for this multi-center study (with centers quite different in tenns of number of subjects per center) will use the pooled set of subjects across all centers. Center will not be used as a stratification factor or covariate in the statistical analysis models.

4.8.1.2 Adjustments for Covariates

The primary efficacy analysis will be adjusted by baseline clinical status (lung injmy/mild ARDS vs moderate/severe ARDS). Baseline clinical status is a randomization factor and the status as repo1ied from the randomization system will be used for all efficacy analyses.

4.8.1.3 Handling of Dropouts or Missing Data

The reason of early study treatment / study discontinuation will be identified, and the percentage of these subjects will be smnmarized by treatment group.

Methodology for multiple imputation and tipping point approaches is described in Section 4.8.1.6 and Section 4.8.1.7, respectively.

4.8.1.4 Multiple Comparisons/Multiplicity

The one-sided type-I-enor rate (0.025) for the primaiy efficacy endpoint will be adjusted following the Haybittle-Peto approach with 0.0005 allocated to the interim analysis and 0.0248 allocated to the final analysis.

For the key secondaiy efficacy endpoints, there is the following serial gate-keeping procedme (also known as sequential conditional testing) addressing the multiplicity and controlling the family-wise one-sided type-I-enor probability to 0.025 (equivalent to two-sided 0.05) for the fainily of primaiy and key secondary efficacy endpoints:

- Analysis of the primary efficacy endpoint
  Its null hypothesis is tested on one-sided significance level 0.0248
  - if the null hypothesis cannot be rejected, the entire testing procedme stops here, i.e., null hypotheses for any of the key secondary efficacy endpoints cannot be rejected
  - if the null hypothesis can be rejected, the testing procedure continues with the testing of key secondaiy efficacy endpoint as described below.
- Analysis of the key secondary efficacy endpoints:
  A. Survival and no mechanical ventilation on Day 29
     Its null hypothesis is tested on one-sided significance level 0.025
     - if the null hypothesis is not rejected, the entire testing procedme stops here, i.e., null hypotheses for remaining key secondaiy efficacy endpoints cannot be rejected
     - if the null hypothesis is rejected, the testing procedme continues with the testing of key seconda1y efficacy endpoint as described below.

  B. Mechanical ventilation-free days by Day 29

Its null hypothesis is tested on one-sided significance level 0.025

- if the null hypothesis is not rejected, the entire testing procedme stops here, i.e., null hypotheses for the remaining key secondary efficacy endpoint cannot be rejected
- if the null hypothesis is rejected, the testing procedme continues with the testing of key seconda1y efficacy endpoint as described below.

C. Time to hospital discharge by Day 43

Its null hypothesis is tested on one-sided significance level 0.025

- if the null hypothesis is not rejected, the entire testing procedme stops here, i.e., null hypotheses for remaining key secondaiy efficacy endpoints cannot be rejected
- if the null hypothesis can be rejected, the testing procedme continues with the testing of key secondaiy efficacy endpoint as described below.

4.8.1.5 Exainination of Subgroups

The treatment effect for the primaiy, key seconda1y efficacy endpoints, and the 7-point ordinary scale will be examined for the following subgroups:

- Site
- Clinical status (lung injmy/mild ARDS vs. moderate/severe ARDS)
- Age (<65 yeai·s,≥65 yeai·s)
- Sex (Male, Female)
- Body weight (by quaiiiles)
- Race (White, African American, additional groups must represent at least 25% of the population if not, will group as 'All Other')
- Ethnicity (Hispanic or Latino, Not Hispanic Latino)
- Invasive ventilator use at baseline (yes, no)
- Baseline invasive ventilator use or severe ARDS at baseline (yes, no)
- Presence of anti-GM-CSF auto antibodies at Screening (<5 µg/mL,≥5µg/mL)
- 7-point ordinal scale status at baseline
- Received Day 8 study dmg (yes, no)
- Prohibited medications use (yes, no) (see Section 4.7)

Prohibited medication use will be aligned to time period of endpoint being summai·ized as follows:

- Prohibited medication from Day 1 - Day 43 (Mo1iality by Day 43)
- Prohibited medication from Day 1 - Day 29 (Smvival and no mechanical ventilation by Day 29, Mechanical ventilation-free days by Day 29)
- Prohibited medication dming the study (Time to hospital discharge, 7-point ordinal scale)

Summaries of the primaiy, key secondaiy efficacy vai·iables and the WHO 7-point ordinal scale by treatment group and subgroups will be produced.

Homogeneity of the treatment effect across subgroups may be investigated using graphical and analytical methods. An appropriate summa1y of the treatment effect (e.g., risk difference, mean difference, hazai·d ratio) and 95% confidence inte1vals will be estimated within each subgroup

using the methods described for the main analysis for each endpoint. A forest plot showing these estimates and 95% confidence interval within each subgroup and overall will be provided.

4.8.1.6 Analysis Methods – Multiple imputation

General approach

Multiple imputation methods replace each missing primary efficacy endpoint value with a set of m=10 plausible values based on a model predicting values for a missing data point based on available data, i.e., assuming a Missing at Random (MAR) missingness mechanism.

This set of values represents the uncertainty about the correct value to be imputed. These complete datasets (generated by SAS PROC MI) are then analyzed by relevant statistical procedure (e.g., SAS PROC FREQ, SAS PROC LOGISTIC, etc) generating parameter estimates and their standard errors, followed by combining those results from these analyses (by using SAS PROC MIANALYZE).

Prediction model

The prediction model attempts to predict a missing endpoint values (e.g, "death by Day 43" or "alive at Day 43" for the binary primary efficacy endpoint) based on available data (variables) that may have an influence on that endpoint.

The proposed prediction model for the binary primary efficacy endpoint is a logistic regression model with the following covariates:

- randomized study treatment: Gimsilumab or placebo
- baseline clinical status: lung injury/mild ARDS or moderate/severe ARDS
- country: USA, etc
- sex: male or female
- age at baseline (continuous covariate)
- body weight at baseline (continuous covariate)
- race (White, African American, additional groups must represent at least 25% of the population if not, will group as 'All Other')
- invasive ventilator use at baseline: no or yes
- anti-GM-CSF auto antibodies at screening: <5 µg/mL or ≥5 µg/mL
- WHO 7-point ordinal scale status at baseline
- National Early Warning Score (NEWS) at baseline
- SpO2 at baseline
- WHO 7-point ordinal scale status at hospital discharge
- NEWS at hospital discharge
- SpO2 at hospital discharge
- second administration of study treatment: yes or no
- administration of prohibited treatments (see Section 4.7) during the study: yes or no

Algorithm for the multiple imputation of missing values

Within the Bayesian framework, the task of imputing missing values is achieved by drawing random values from the posterior predictive disti·ibution of the missing primaiy efficacy endpoint data (predicted by the logistic regression prediction model specified above). This posterior predictive disti·ibution is a function of the observed data and regression parameters (or function of regression parameters).

As non-monotone missing pattern may be observed, the fully conditional specification (FCS) method will be used for dealing with arbiti·aiy non-monotone missing data patterns. The FCS is based on an iterative algorithm; at each iteration and for each vai·iable of the prediction model, there is a

- prediction step (P-step): the cmTent (iteration) values of the observed and imputed values are used to derive the predictive disti·ibution of the missing values
- and an imputation step (I-step): updated imputations ai·e generated by draws from the predictive disti·ibution defined by the updated regression model.

When the last vai·iable in the sequence (e.g., the primaiy efficacy endpoint) has been imputed, the algorithm cycles again through each variable, repeating the chain of regression estimation and imputation draw steps. These cycles are repeated and finally there will *m=IO* draws from the predictive disti-ibution for each missing primaiy efficacy endpoint value.

Analyzing multiply imputed datasets

Individual statistical analysis (as described in Section 4.8.2 and Section 4.8.3) will be perfo1med for each of the *m=IO* imputed complete datasets and the results (point estimates and associated standard enors for the study u-eatment effect) will be stored in a single output file.

Estimation and inference for multiply imputed datasets

As a final step, the *m=IO* estimates and associated standai·d enors will be combined as described below for making statistical inference.

Let *Qi* and *Wi* denote the point and vai·iance estimates for the study ti·eatment effect from the i-th imputed complete data set, *i=l,* 2,...,*m.* Then the point estimate for the study ti·eatment effect from multiple imputations, $\bar{Q}$, is the average of them imputed complete datasets estimates:

$$\bar{Q} = \frac{1}{m}\sum_{i=1}^{m} \hat{Q}_i .$$

Let W denote the average of the *m* ("within-imputation") variance estimates

$$W = \frac{1}{m}\lim_{i=1} W_1$$

and B the estimated ("between-imputation") variance of the point estimates

$$B = \frac{1}{m-1}\lim_{i=1} (Q_i - \bar{Q})^2 .$$

Then the total variance V of the multiple imputation estimate Q for the study treatment effect is estimated as

$$V = W + (1 + m^{-1}) \cdot B.$$

Q and Vwill be used for testing null hypotheses stated in Section 4.8.2 and Section 4.8.3 and constructing two-sided 95% Cis for the study ti·eatment effects:

- test statistic

$$t = \frac{Q}{\sqrt{V}}$$

is approximately disti-ibuted as a I-distribution with degrees of :freedom equal to

$$DFMI = (m-1)\left(1 + \frac{(1+:1)\cdot B}{W}\right)^2$$

- and the two-sided 95% CI for the study ti·eatment effect is calculated as

$$(Q - \sqrt{V}'_{to.975,DFMI},\ Q + \sqrt{V}'_{to.975,DFMI}).$$

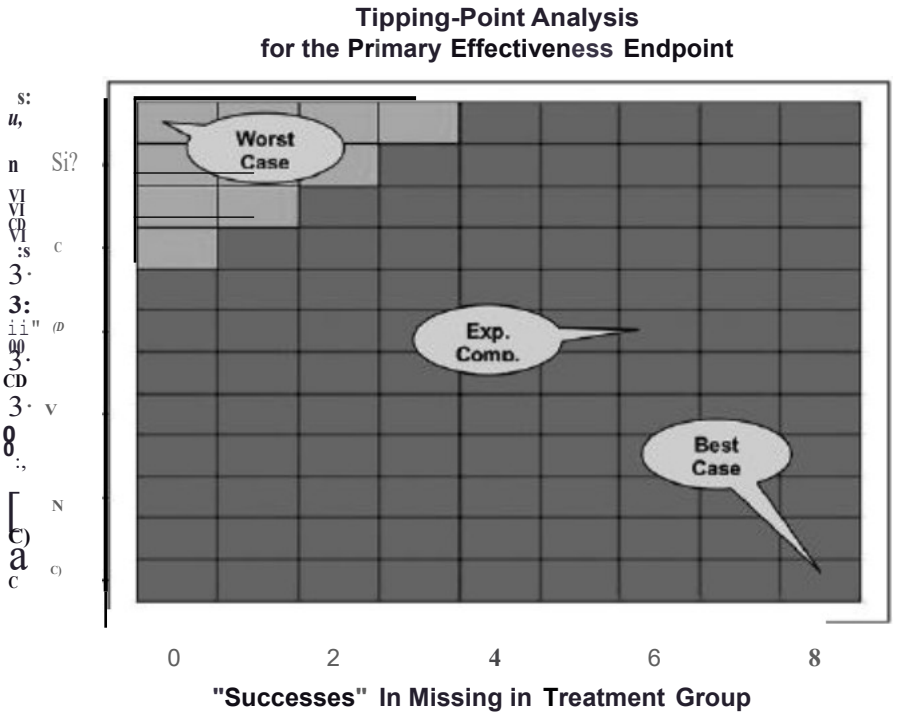
Where relevant, the exponential function will be used for ti·ansfonning point estimates and CI limits from the log scale to the original scale.

4.8.1.7 Analysis Methods - Tipping point analysis

Graphical displays, based on the "tipping-point" analysis inti·oduced by Yan 2009 and not requiring the MAR assumption, will be used to visualize the results of a two-dimensional set of sensitivity analyses using different imputations for missing binaiy endpoint values (e.g., either "death by Day 43" or "alive at Day 43" for the primaiy efficacy endpoint) for compai·ison of the two study t:I'eatments. All possible combinations of imputations of missing binaiy endpoint values in the gimsilumab and placebo group will be evaluated by the statistical method described in Section 4.8.2 and Section 4.8.3, with study ti·eatment as the only factor.

Figure 4-1 below is an example graphic taken from Campbell 2011 with 8 missing endpoint values in the "Treatment Group" (one can impute Oto 8 successes) and 11 missing endpoint values in the "Cont:I'ol group" (one can impute O to 11 successes), leading to a mati·ix of 108 (= 9 times 12) combinations to be tested. For the example displayed in Figure 4-1, 10 combinations close to the upper left upper comer "worst case" (all missing values in the "Cont:I'ol Group" were imputed as successes and all missing value in the "Treatment Group" were imputed as failures) did not lead to a significant test result (rejection of the null hypothesis).

Figure 4-1 Example for a tipping point analysis summary display



"Enhanced tipping-point displays" (Liublinska 2014) will be provided as compact summaries of conclusions drawn from different alternative assumptions.

4.8.1.8 Analysis Methods - Final analysis following adaptive sample size increase

If the sample size has been increased at interim analysis 2 (see Section 5.2.5), then the final analysis of the primaiy efficacy endpoint (mo1iality by Day 43) and key secondaiy endpoints will be perfo1med by using a weighted average of the two one-sided test statistics Z1 and Z2 based on data from subjects in stage 1 and stage 2 sepai·ately, respectively.

The test statistic *ZcHw* (maintaining the type-l-eITor probability restricted to one-sided 0.0248 (primaiy endpoint) or 0.025 (key seconda1y endpoints) per Cui/Hung/Wang 1999) for the final analysis will be

$ZcHw = w_1 \cdot Z1 + w_2 \cdot Z2$

and the pre-specified weights are

$w_1 = \sqrt{n_1/270}$ with n_1 denoting the number of subjects in the FAS for stage 1

$w_2 = \sqrt{(270 - n_1)/270}$ where 270 - n_1 represents the number of subjects in the FAS for stage 2.

4.8.1.9 Analysis Methods - Continuous vai·iables

All continuous outcomes will be sUffilnai·ized using descriptive statistics by treatment group and visit. For each outcome only planned visits as detailed in the schedule of assessments (Appendix 7.1) will be summarized.

4.8.1.10 Analysis methods - Count variables

For number of event-free days (mechanical ventilation free days, ICU-free days) the median, 1st quaiiile and 3rd qua1iile will be presented by treatment. A Wilcoxon rank sum test will be used to evaluate the difference between treatment groups.

4.8.1.11 Analysis methods - Categorical vai·iables

For bina1y endpoints the number and propo1iion in each treatment group will be presented along with the common risk difference with 95% CI (gimsilumab - placebo) as estimated using the Mantel-Haenszel method. Baseline clinical status will be used as stratification factor. A Cochran-Mantel-Haenszel (CMH) test may be used to test for a treatment effect.

Binaiy primaiy and key secondaiy endpoints will also be evaluated with common risk difference obtained from logistic regression (following Ge et al 2011) with covariates study treatment and baseline clinical status

Other categorical outcomes will be evaluated using CMH tests stratified for baseline clinical status.

4.8.1.12 Analysis Methods - Time to event variables

Time to event analyses will be perfonned using Kaplan-Meier method and a log-rank test stratified by baseline clinical status will be used to evaluate the treatment effect (gimsilumab vs. placebo). The total number of subjects with an event, the total number censored, reasons for censoring, and Kaplan-Meier estimates with associated 95% Cis for survival probabilities at Days 15, 29, 43, 85, 169 as well as 25th percentile, median, and 75% percentile (if available) survival time and 95% Cis will be presented bytreatment group. Survival plots or cumulative incidence plots as specified for each time to event endpoint will be presented by treatment and by randomization strata (baseline clinical sta.tus) and treatment. If one of the baseline clinical sta.tus categories have fewer than 10 events overall, Kaplan-Meier estimates will only be presented overall.

A propo1iional hazard model stratified by baseline clinical sta.tus (if there are sufficient events in each stratum) will be used to estimate the hazai·d ratio and associated 95% CI of gimsilumab vs. placebo.

4.8.1.13 Analysis Methods - Multi-state competing risks models

For time to hospital discharge and time to clinical improvement a supplementaiy analysis using a multi-stat competing risks model will be perfo1med (Beyersmann, Allignol, Schumacher 2012).

Multi-state competing risks model

For each subject, a multi-state stochastic process *(Xd)tkO* is considered where *Xd* denotes the state a subject is in at the end of day *d,* 1 :S *d* '.S 43 (43 is the final day of the planned observation period Three states are defined as follows:

[Baseline] baseline state

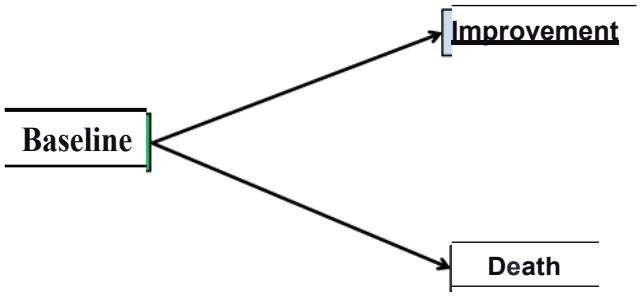
[Improvement] improvement state (assumed as an absorbing state as further transitions ai·e not considered here)

[Death] death state (absorbing state)

All subjects staii in the initial state [Baseline] at time of randomization, $_{d=0,}$ i.e., x_0 =[Baseline]. If subject recovers but dies (afte1wai·ds) on the same day d, then that subject's state x_d will be set to x_d =[Death].

States and possible transitions between states are illustrated by Figure 1 below.

Figure 1 Competing risks model



A transition probability from state [Baseline] at day $_d$ (0 $_d$ 42) to state $_{[m]}$ at day $_{e,\ d}$ $_e$ 43, is defined as:

P[Baseline)[m](d, e) = $P(Xe$ = [m]IXd = [Baseline])

Subjects stay in state [Baseline] as long as none of the competing events have occuned; the competing risks process moves out of the [Baseline] state at day TD, defined as

TD= min{d > $OIXd^*$ [Baseline]}

and is called the transition day; state Xm is the type of transition.

The competing risks process is subject to right-censoring (assumed to be independent of the transition processes) when a subject's follow-up was terminated while the subject was still in state [Baseline]:

- either prematurely prior to the end of Day 43
- or when reaching the planned end of observation period at end of Day 43.

The hazai·d functions for transitions from state [Baseline] to state [Improvement] or to state [Death], respectively, ai·e assumed to detennine the stochastic behavior of the competing risks process; these hazai·d functions differ bystudy treatment group.

The transition-specific cumulative incidence functions over the 43 days observation period are defined as $Pk,c(D$ :::; d,Xv = [m]), where [m] can be state [Improvement] or state [Death], k denotes the stratum and c the study treatment (gimsilumab or placebo) will be derived from non-parametric Nelson-Aalen estimators for cumulative hazai·d functions.

Stratified transition-specific proportional hazards models

The transition-specific proportional hazards model stratified for factors used in the randomization and its assumptions are illustrated by:

$h_{[\text{Baseline}],[m]}\ (d, x_{jk}, \beta_{[\text{Baseline}],[m]}) = h_{[\text{Baseline}],[m];0k}(d) \cdot \exp\ (x_{jk} \cdot \beta_{[\text{Baseline}],[m]})$

$h_{[\text{Baseline}],[m]}(.)$ transition-specific hazard functions as a function of days (relative to date of randomization), the subject's stratum and study treatment (gimsilumab or placebo), and unknown hazard ratio

$h_{[\text{Baseline}],[m];0k}(d)$ unspecified transition-specific hazard function for placebo subjects in stratum k at day d; transition-specific hazard functions for placebo are allowed to vary across strata without any restrictions

x_{jk} study treatment indicator for subject j in stratum k, coded as 0 for placebo, 1 for gimsilumab

$h_{[\text{Baseline}],[m]}$: vector of unknown transition-specific log hazard ratios for study treatment; assumed to be common across strata, allowed to differ by transition.

Estimation of transition-specific hazard ratios will be performed by maximizing partial likelihood functions; two-sided 95% confidence intervals will be provided.

4.8.1.14 By-subject listings

All derived efficacy endpoints and the raw data points used to derive them will be listed by subject.

4.8.2 Analysis of the Primary Efficacy Endpoint

Clinical question of interest: Does gimsilumab reduce mortality (up to Day 43) in subjects with lung injury or ARDS secondary to COVID-19 in comparison to placebo?

Intercurrent events (may occur between randomization and Day 43), not mutually exclusive:

- IE1: subject's withdrawal from the study prior to Day 43
- IE2: subject lost to follow-up prior to Day 43
- IE3: subject did not receive any dose of study treatment

Attributes of Estimand 1 (following a treatment policy strategy)

A. Patient population: as defined by protocol eligibility criteria and treated
B. Treatment conditions:
   - condition of interest: randomized to gimsilumab and treated
   - alternative/control condition: randomized to placebo and treated
C. Endpoint: subject's death by Day 43
D. Population-level summary: estimated incidence probability for death up to Day 43 (in each treatment group separately)

Main estimator for Estimand 1: common mortality risk difference (for death up to Day 43) across both strata defined by baseline clinical status used in the stratified randomization

- Intercurrent events IE1 and IE2 will be disregarded for the inclusion of subjects in the statistical analysis, IE3 restricts the inclusion of subjects to those who received at least one dose of study treatment. Hence, the main estimator for Estimand 1 will be based on the ITT analysis set.

- For subjects with missing primaiy endpoint data resulting from !El and IE2, a multiple imputation approach (details see Section 4.8.1.6) assuming MAR will be used. The set of complete (imputed) datasets will be analyzed as 2x2 frequency tables strntified by baseline clinical status obtaining Mantel-Haenszel common risk difference estimates and respective standard enors for those datasets. These results will then appropriately combined (see Section 4.8.1.6) to obtain point estimate and CI for the common risk difference as well as for a one-sided p-value for testing the null hypothesis of a common mo1iality risk difference 0.

Sensitivity estimators for Estimand 1 (also based on the ITT analysis set):

- Two-dimensional tipping point analysis vaiying the missing primaiy endpoint data in the two study treatment aims (see Section 4.8.1.7) not assuming MAR
- Common mo1iality risk difference (for death up to Day 43) obtained from logistic regression (following Ge et al 2011) with covai·iates study treatment and baseline clinical status (and multiple imputation approach described in Section 4.8.1.6 assuming MAR).

Supplementaiy analysis: Overall smvival will be analyzed using time to event methods as described in Section 4.8.1.12. Time to death is defined as the time from randomization to death in days *(date of death - randomization date* + 1). Subjects without a recorded death will be censored at their last date known alive (completion date if they were followed through Day 169 or at their early discontinuation date if they withdrew early or at their date of last assessment if they ai·e alive and ongoing in study at time of analysis; *last date known alive - randomization date* +J).

Eugpl fuantluly5 Secondaiy) analysis: Main estimator analysis will be repeated for mo1iality by

Attributes of Estimand 2 (following a composite policy strategy)

A. Patient population: as defined by protocol eligibility criteria and treated
B. Treatment conditions:
   - condition of interest: randomized to gimsilumab and treated
   - alternative/control condition: randomized to placebo and treated
C. Endpoint: subject's death by Day 43 or subject withdrawn from the study prior to Day 43 or subject got lost to follow-up prior to Day 43
D. Population-level summaiy: estimated incidence probability for death by Day 43 or study withdrawal prior to Day 43 or lost to follow-up prior to Day 43 (in each treatment group sepai·ately)

Main estimator for Estimand 2: common risk difference across both strata defined by baseline clinical status used in the stratified randomization

- !El and IE2 are pait of the composite endpoint, so these two!Es will be disregarded for the inclusion ofsubjects in the statistical analysis, IE3 restricts the inclusion ofsubjects to those who received at least one dose of study treatment. Hence, the main estimator for Estimand 2 will be based on the ITT analysis set and none of the subjects have a missing composite endpoint value.

Sensitivity estimators for Estimand 2 (also based on the ITT analysis set):

- Common risk difference obtained from logistic regression (following Ge et al 2011) with covariates study treatment and baseline clinical status

Supplementaiy analysis: time to death or withdrawal or lost to follow-up will be analyzed using time to event methods as described in Section 4.8.1.12. Time to death or withdrawal is defined as the time from randomization to death or withdrawal in days *(date of death/withdrawal - randomization date + 1)*. Subjects without a recorded death or withdrawal will be censored at their last date known alive in the study (completion date if they were followed through Day 169 or othe1wise at their date of last assessment; *last date known alive in the study - randomization date +1)*.

4.8.3 Key Secondary Efficacy Analysis

4.8.3.1 Survival and no mechanical ventilation on Day 29

Clinical question of interest: Does gimsilumab reduce mechanical ventilation on Day 29 and m01iality up to Day 29 in subjects with lung injury or ARDS secondary to COVID-19 m comparison to placebo?

futercmTent events (may occur between randomization and Day 29), not mutually exclusive:

- IEl: subject's discharge from the hospital prior to Day 29
- IE2: subject's withdrawal from the study prior to Day 29
- IE3: subject lost to follow-up prior to Day 29
- IE4: subject did not receive any dose of study treatment

Attributes of Estimand 2-1 (following a composite policy strategy)

A. Patient population: as defmed by protocol eligibility criteria and treated
B. Treatment conditions:
   - condition of interest: randomized to gimsilumab and treated
   - alternative/control condition: randomized to placebo and treated
C. Endpoint: subject is alive and not on mechanical ventilation on Day 29 or discharged prior to Day29
D. Population-level summaiy: estimated probability of being alive and not on mechanical ventilation on Day 29 (in each treatment group separately)

Main estimator for Estimand 2-1: common risk difference across both strata defmed by baseline clinical status used in the stratified randomization

- futercmTent events IEl is included in the endpoint definition: subjects dischai·ged alive prior to Day 29 (IEl) are considered successes for this endpoint as it is assumed that mechanical ventilation is no longer necessaiy for subjects who have been discharged from the hospital.
- futercmTent events IE2 and IE3 will be disregarded for the inclusion of subjects in the statistical analysis; IE4 restricts the inclusion of subjects to those who received at least one dose of study treatment. Hence, the main estimator for Estimand 2-1 will be based on the ITT analysis set.

- For subjects with missing primaiy endpoint data resulting from IE2 and IE3, a multiple imputation approach (details see Section 4.8.1.6) assuming MAR will be used. The set of complete (imputed) datasets will be analyzed as 2x2 frequency tables strntified by baseline clinical status obtaining Mantel-Haenszel common risk difference estimates and respective standard enors for those datasets. These results will then appropriately combined (see Section 4.8.1.6) to obtain point estimate and confidence interval (CI) for the common risk difference as well as for a one-sided p-value for testing the null hypothesis of a common risk difference 0.

Sensitivity estimators for Estimand 2-1:

- Two-dimensional tipping point analysis vaiying the missing primaiy endpoint data in the two study treatment aims (see Section 4.8.1.7)
- Common response probability difference obtained from logistic regression (following Ge et al 2011) with covai·iates study ti·eatment and baseline clinical status (and multiple imputation approach described in Section 4.8.1.6).

Supplementaiy (Secondaiy) analysis: Main estimator analysis will be repeated for probability of being alive and not on mechanical ventilation on Days 15, 22, and 43.

4.8.3.2 Mechanical ventilation-free days by Day 29

Clinical question of interest: Does gimsilumab increase the number of mechanical ventilation-free days up to Day 29 in subjects with lung injmy or ARDS secondaiy to COVID-19 in comparison to placebo?

Intercmrent events (may occm between randomization and Day 29), not mutually exclusive:

- !El: subject's death prior to Day 29
- IE2: subject discharge (alive) from the hospital prior to Day 29
- IE3: subject's withdrawal from the study prior to Day 29 and prior to hospital discharge
- IE4: subject did not receive any dose of study ti·eatment

Attributes of Estimand 2-2 (following a composite policy strategy)

A. Patient population: as defined by protocol eligibility criteria and ti·eated
B. Treatment conditions:
   - condition of interest: randomized to gimsilumab and ti·eated
   - altemative/conti·ol condition: randomized to placebo and ti·eated
C. Endpoint: subject's number of mechanical ventilation-free days by Day 29
D. Population-level summaiy: median number of days not on mechanical ventilation by Day 29 (in each ti·eatment group separately)

Main estimator for Estimand 2-2: difference of medians for number of days not on mechanical ventilation by Day 29.

- Mechanical ventilation status (yes/no) will be assessed daily while subjects remain hospitalized up to and including their date of dischai·ge.
- For a subject who died prior to Day 29 (IEl), the number of mechanical ventilation-free days up to Day 29 will be set to 0.

- For a subject alive at Day 29 and hospitalized at least up to Day 29, the number of mechanical ventilation-free days up to Day 29 is the sum of days with mechanical ventilation status of 'no' from Day 1 through Day 29.
- For a subject discharged from hospital alive prior to study day 29 (IE2), the number of mechanical ventilation-free days up to Day 29 is the sum of
  (1) the number of days with mechanical ventilation status of 'no' from Day 1 to date of hospital discharge and
  (2) the number of days from their date of discharge through their Day 29 visit (Day 29 visit date – date of discharge), assuming that a subject is not mechanically ventilated after hospital discharge.
- For a subject who withdrew from the study prior to Day 29 and prior hospital discharge (IE3), the number for mechanical ventilation-free days will be the sum of days with mechanical ventilation status of 'no' from Day 1 through the day of study withdrawal.
- Intercurrent event IE3 will be disregarded for the inclusion of subjects in the statistical analysis; IE4 restricts the inclusion of subjects to those who received at least one dose of study treatment. Hence, the main estimator for Estimand 2-2 will be based on the ITT analysis set.

The number of mechanical ventilation-free days will be analyzed by a Wilcoxon rank sum test stratified by baseline clinical status to obtain a one-sided p-value for testing the null hypothesis of equal or more favorable distribution for placebo compared to gimsilumab.

Supplementary (Secondary) analyses: Main estimator analysis will be repeated for mechanical ventilation-free days by Days 15, 22, and 43.

4.8.3.3 Time to hospital discharge

Clinical question of interest: Does treatment with gimsilumab result in a shorter overall duration of hospitalization in subjects with lung injury or ARDS secondary to COVID-19 in comparison to placebo?

Intercurrent events :

- IE1: subject's death prior to hospital discharge
- IE2: subject's withdrawal from the study prior to hospital discharge
- IE3: subject did not receive any dose of study treatment

Attributes of Estimand 2-3 (following a composite policy strategy)

A. Patient population: as defined by protocol eligibility criteria and treated
B. Treatment conditions:
   - condition of interest: randomized to gimsilumab and treated
   - alternative/control condition: randomized to placebo and treated
C. Endpoint: subject's time to hospital discharge
D. Population-level summary: median time to hospital discharge (in each treatment group separately)

Main estimator for Estimand 2-3: hazard ratio across combined strnta defined by baseline clinical status used in the stratified randomization (see Section 4.8.1.12 for details)

- Time to hospital discharge is the time in the hospital after randomization in days (Table 4-
- i Ihd case that a subject is still hospitalized at time of analysis they will be censored at their date of last assessment in the data cut.
- Subjects who die before leaving the hospital (IEl) will be considered failures (did not achieve hospital discharge) and will continue to contribute to the risk pool through the end of the analysis period, that is they will be censored at the date of data cut.
- ill the case that a subject withdraws from the study before leaving the hospital (IE3), they will be censored at their discontinuation date, respectively.
- IE3 restricts the inclusion of subjects to those who received at least one dose of study treatment. Hence, the main estimator for Estimand 2-3will be based on the ITT analysis set.

Sensitivity estimator: Analyses for main estimator will be repeated using a modified definition of time to hospital discharge where subjects who died (IEl) are censored at time of death. Table 4-2 provides endpoint derivation details.

Table 4-2: Time to hospital discharge definitions

Subjects status at time of analysis:	Main estimator *		Sensitivity estimator*	
	Event date	Censored (yes/no)	Event date	Censored (yes/no)
Alive, discharged from hospital	Date of discharge	No	Date of discharge	No
Alive, still hospitalized	Date oflast assessment	Yes	Date oflast assessment	Yes
Early withdrawal from study before discharged from hospital (IE2)	Date of early withdrawal	Yes	Date of early withdrawal	Yes
Lost to follow-up before discharged from hospital (IE3)	Date oflast assessment	Yes	Date oflast assessment	Yes
Died (IEl)	Date of data cut	Yes	Date of death	Yes
*Time to hospital dischar e will be repo1ted in davs and defined as event date - randomization date + 1.				

Supplementa1y analysis: A multi-state competing risks model will be perfo1med as described in Section 4.8.1.13 replacing the improvement state by hospital discharge.

4.8.4 Other Secondary and Exploratory Efficacy Analyses

Other secondary and explorato1y endpoints will be analyzed according to the type of endpoint as described below. If data are sparse for any of the exploratory endpoints, summaries may be limited to descriptive statistics of available data or listings only as appropriate.

ICU-free days by Days 15, 22, 29 and 43

This endpoint will be defined and analyzed similarly to mechanical ventilation-free days (Section 4.8.3.2). ICU status (yes/no) will be assessed daily while subjects remain hospitalized up to and

including their date of discharge. For subjects who are alive at the time of analysis and remain hospitalized the number of days with ICU status of 'no' from day of first dose through their Day 15 (22/29/43) visit will be summed. For subjects who are alive at time of analysis visit but have been discharged prior to study Day 15 (22/29/43), the total number of ICU-free days will be the sum of (1) the number of days with ICU status of 'no' will be summed through their date of discharge and (2) the number of days from their date of discharge through their Day 15 (22/29/43) visit (Day 15 (22/29/43) visit date – date of discharge). For subjects who died at time of analysis the number of ICU-free days will be set to 0. For subjects with missing data due to early study withdrawal prior to hospital discharge, the number for ICU-free days will be the sum of days with ICU status of 'no' from Day 1 through the day of study withdrawal. The median, 1st quartile, and 3rd quartile of the number of ICU-free days will be presented for each treatment group. A Wilcoxon rank sum test will be used to test the null hypothesis that there is no difference in number of ICU-free days between gimsilumab and placebo (Section 4.8.1.10).

Incidence of mechanical ventilation use Overall and by Days 15, 22, 29 and 43

This endpoint will be evaluated for all subjects, no matter if the subject was on or not on a mechanical ventilator at the time of the randomization. Mechanical ventilation use by Day 15 (22/29/43) will be defined as 'Yes' if subject is alive and was on mechanical ventilation on or prior to Day 15 (22/29/43). As ventilation status is only collected while subject remains in the hospital, subjects who were discharged before Day 15 (22/29/43) and are still alive will be considered not be on mechanical ventilation. Subjects missing data due to death, early study withdrawal, or lost to follow-up prior to Day 15 (22/29/43) will be considered 'on mechanical ventilation'.

The number and percentage of subjects achieving this endpoint will be summarized by treatment group. In addition, the common mechanical ventilation use risk difference across both strata defined by baseline clinical status used in the stratified randomization with 95% CI will be reported.

Among subjects with mechanical ventilation, median, 25th percentile and 75th percentile (with 95% confidence intervals) estimated using Kaplan-Meier method will be used to summarize duration of mechanical ventilation and time to first mechanical ventilation. Duration of mechanical ventilation will be summarized for subjects on mechanical ventilation separately for ventilation starting at baseline and ventilation starting post-baseline. Duration of mechanical ventilation will only be derived for subjects who are removed from ventilation (end date of ventilation – start date of ventilation + 1) or who died while still on ventilation (date of death – start date of ventilation + 1).

Time to first mechanical ventilation will be summarized only for subjects starting mechanical ventilation post-baseline and is defined as time from randomization to first date of mechanical ventilation for subjects who started ventilation post-baseline.

Incidence of ICU use by Days 15, 22, 29 and 43

Incidence of ICU use will be defined and analyzed similarly to incidence of mechanical ventilation use using the daily assessments of ICU status taken while subjects are hospitalized.

NEWS and SOFA scores

Standard descriptive statistics (mean, standard deviation, median, minimum, maximum) will be used to summarize each of these scores by treatment group and visit. NEWS and SOFA (total and component scores) scores will be assessed daily while subject is hospitalized. Plots of mean score

(with standard error bars) by treatment group over time may be produced. SOFA component scores are respiratory score, cardiovascular score, liver score, renal score, coagulation score, and neurologic score.

Figure 4-2: National Early Warning Score (NEWS)

PHYSIOLOGICAL PARAMETERS	3	2	1	0	1	2	3
Respiration Rate	≤8		9 - 11	12 - 20		21 - 24	≥25
Oxygen Saturations	≤91	92 - 93	94 - 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35.0		35.1 - 36.0	36.1 - 38.0	38.1 - 39.0	≥39.1	
Systolic BP	≤90	91 - 100	101 - 110	111 - 219			≥220
Heart Rate	≤40		41 - 50	51 - 90	91 - 110	111 - 130	≥131
Level of Consciousness				A			V, P, or U

7-point ordinal scale

The 7-point ordinal scale is as follows:

1. Not hospitalized, no limitations on activities;
2. Not hospitalized, limitation on activities;
3. Hospitalized, not requiring supplemental oxygen;
4. Hospitalized, requiring supplemental oxygen;
5. Hospitalized, on non-invasive ventilation or high-flow oxygen devices;
6. Hospitalized, on invasive mechanical ventilation or ECMO;
7. Death.

The 7-point ordinal scale represents the worst status on the day prior to the visit, that is, assessment collected on Day 2 is reported for Baseline (Day 1), assessment collected on Day 3 is reported for Day 2, etc. As data is not expected to be reported the day after a subject's death, hence a score of 7/"Death" will be imputed on the date of death for analysis purposes. No visit windowing will be applied. For example, for subjects who were discharged from the hospital prior to Day 15 their results from follow-up visit Day 15 are reported on Day 14 regardless of actual study day result was recorded for.

The percentage of subjects reporting each severity rating (1-7) of the 7-point ordinal scale and shift from baseline category will be reported for all study days (Daily while hospitalized and then on Days 15, 22, 29, 35, 43, 85, and 169/EoS). The percentage of subjects with change in ordinal scale at these time points will also be summarized for each of the following:

- 1-point improvement from baseline
- 2-point improvement from baseline

- 3-point improvement from baseline
- ≥4-point improvement from baseline
- No change from baseline
- 1-point worsening from baseline
- 2-point worsening from baseline
- 3-point worsening from baseline
- 4-point worsening from baseline

Shift tables comparing score at baseline to last assessment available for each subject will be created overall and by subgroup.

Stacked bar plots by treatment group and visit (Baseline, Days 7, 14, 21, 28, 35, 42, 84 and 168) will be produced for 7-point scale results and change from baseline (excluding baseline visit).

Time to first clinical improvement

Time to first clinical improvement is defined as the earliest of (1) first time the 7-point ordinal scale shows a 2-point decrease from the baseline score or (2) discharge from the hospital (*date of first clinical improvement - first dose date* + 1) for subjects who achieved clinical improvement and are still alive at time of analysis. Subjects who did not achieve a 2-point reduction and are still alive at time of analysis will be censored at their date of last assessment. Subjects who died will be treated as failures (did not achieve clinical improvement) and will continue to contribute to the risk pool through the end of the analysis period, that is they will be censored at the date of data cut. Kaplan-Meier method will be used to estimate the median time to clinical improvement (Section 4.8.1.12) and a cumulative incidence plot will be provided.

Supplementary analysis: A multi-state competing risks model will be performed as described in Section 4.8.1.13 replacing the improvement state by first clinical improvement (earliest of 2-point decrease from baseline in 7-point ordinal scale score or hospital discharge).

Oxygen-free days during hospitalization

Oxygen use status (yes/no) will be assessed daily while subjects remain hospitalized up to and including their date of discharge. For subjects who are alive at the time of analysis and remain hospitalized the number of days with oxygen status of 'no' from day of randomization through their Day 15 (22/29/43) visit will be summed. For subjects who died at time of analysis the number of Oxygen-free days during the hospitalization will be set to 0. Descriptive statistics by treatment group and a treatment group comparison of number of days not oxygen by Day 15 (22/29/43) using a Wilcoxon rank sum test as described in Section 4.8.1.10.

Incidence of ECMO use and duration

The number and percentage of subjects using ECMO while on study will be summarized by treatment. For subjects who used ECMO the duration in days will be summarized using descriptive statistics.

Change from baseline in respiratory outcomes, select laboratory test results, COVID-19 viral load, and LVEF

Respiratory outcomes include the secondary endpoint SpO_2/FiO_2 and the exploratory endpoints lung injury score (LIS), and PaO_2/FiO_2. Laboratory test endpoints include D-dimer, cardiac troponin I, lactate dehydrogenase (LDH), ferritin, procalcitonin, and C-reactive protein (CRP) as

seconda1y endpoints. COVID-19 viral load as measured by quantitative PCR is a secondaiy endpoint. and LVEF is an optional cardiovascular assessment and explorato1y endpoint.

Standard descriptive statistics (mean, standai·d deviation, median, minimum, maximum) will be used to summarize each outcome and it's change from baseline bytreatment group and visit. Only scheduled visits as described in the schedule of assessments (Appendix 7.1) will be included for each endpoint.

For select endpoints, mean (with standard enor bars) results and change from baseline may be plotted over time by treatment group.

Explorato1y endpoints (LIS, PaO2/FiO2, LVEF) will only be summarized by visit if at least 20% of subjects have at least one non-missing assessment, othe1wise only by-subject listings will be provided for these endpoints. Chest radiographic results will be provided in a by-subject listing.

4.9 Safety Evaluation

All safety summaries and analyses will be based upon the safety analysis set as defined in Section 4.5. Safety analyses summarized by study period will be analyzed separately for each of the following periods as defined in Section 4.2.1:

- Overall
- Treatment Period (Day 1 -Day 15)
- Follow-up Period 1 (Day 16-Day 43)
- Follow-up Period 2 (Day 44 +)
- Overall-Hospitalized (Day 1 through DoD)
- Overall - After Discharge (DoD +)

Note: only subjects who were on study in a given period will be included in the analysis for that period *(e.g.* if a subject withdraws from study or dies before Day 43 they will contribute to the denominator for summaries in the Overall, Treatment Period, and Follow-up Period 1 periods, but not in summaries of Follow-up Period 2).

4.9.1 Extent of Exposure

The number and percent of subjects that were dosed at each planned dose (Day 1 and Day 8) will be presented by treatment group. The number and percent of dose inte1n1ptions will also be summarized by treatment group. The daily dose at days 1 and 8 and cumulative dose will be presented by treatment group using descriptive statistics. A by-subject listing of exposure data will be provided.

4.9.2 Adverse Events

Adverse events will be coded using the Medical Dictionaiy for Regulatory Activities (MedDRA) Version 23.0 or higher.

Treatment-emergent adverse events will be tabulated and are defined as those adverse events that either staii or worsen in severity on or after the date/time of first dose of study treatment and through the end of safety follow-up period.

Where dates are missing or paiiially missing, adverse events will be classified as treatment emergent and into study periods using imputed dates as described in Section 4.2.3.

An overall summaiy table of treatment-emergent AEs (TEAEs) will be provided with the number and percentage of patients (incidence) repo1iing an event along with the total number of events presented for the following categories:

- All TEAEs (all grades and grades 3-5)
- Study dmg-related TEAEs (all grades and grades 3-5)
- Serious TEAEs
- Study dmg-related SAEs
- Fatal TEAEs
- TEAEs leading to study diug discontinuation
- Each AESI (see Section 4.9.2.2)

4.9.2.1 AE Summaries bysystem organ class (SOC) and prefened te1m (PT)

The incidence and total number of events for the following will be sUillllllai·ized by SOC and PT:

- All TEAEs
- Study dmg-related TEAEs
- TEAEs by maximum severity
- Study dmg-related TEAEs by maximum severity
- Grade 3 or higher TEAEs
- Study dmg-related grade 3 or higher TEAEs
- Serious TEAEs
- Dmg-related SAEs
- Fatal Serious TEAEs
- TEAEs leading to study diug discontinuation
- Each AESI (see Section 4.9.2.2)

Adverse events will be summarized by treatment overall and by study period. Adverse event summaries will be ordered by decreasing frequency for SOC, and PT within SOC, in the gimsilumab treatment group, and then similai·ly by decreasing frequency in the placebo treatment group, and then alphabetically for SOC, and PT within SOC.

For each subject and each adverse event, the worst severity recorded will be attributed and used in the by-severity summaries. Similarly, the worst causality (most related to treatment) will be attributed and used in the by-causality summaries. If severity or causality is missing, the worst case will be assumed.

4.9.2.2 AE of Special Interest (AESI)

AESI will be defined using standard MedDRA queries (SMQ). See Appendix 7.3 for a complete list of terms. The following TEAEs are of special interest:

Adverse Event of Special Interest	**Include all terms (Narrow and Broad) from SMQs**
Clinically severe or life-threatening onset of new infections (besides COVID-19)	Infective Pneumonia Opportunistic Infections *Note: include only events with severity of 'Severe' or 'Life-threatening', exclude PTs 'Coronavirus infection' 'Coronavirus test positive'*
Neutropenia, Thrombocytopenia, and Leukopenia	Hematopoietic Cytopenia
Injection related reactions	Hypersensitivity Reaction Drug Reaction Anaphylactic reaction
Transaminitis	Hepatic Disorders- Drug related hepatic disorder
Pulmonary alveolar proteinosis	Interstitial Lung Disease

4.9.2.3 Adverse event listings

By-subject listings of all adverse events (including non-treatment-emergent events) will be provided. This listing will be presented by treatment group and will include center, subject identifier, age, sex, race, adverse event (SOC, PT, and verbatim term), date of onset, date of resolution, study period, hospitalization status, duration, severity, seriousness, action taken, outcome and causality. The following listings will be provided:

- All adverse events
- All drug-related adverse events
- All grade 3-5 adverse events
- All serious adverse events
- All fatal adverse events
- All adverse events leading to discontinuation of study treatment
- All adverse events of special interest

4.9.3 Clinical Laboratory Evaluation

The following laboratory parameters will be summarized by treatment group and visit for each study period using appropriate descriptive statistics.

Hematology	**Chemistry**	**Coagulation**
Hemoglobin	BUN	Prothrombin time

Hematocrit	Creatinine	Activated pa1iial thromboplastin time (aPTT)
Platelets	Glucose	Fibrinogen
Red blood cells	Sodium	**Urinalysis**
White bloods cells	Potassium	Glucose
Neutrophils	Chloride	Protein
Lymphocytes	Total CO2	Ketones
Monocytes	Calcium	Specific gravity
Eosinophils	Alanine aminotransferase (ALT	pH
Basophils	Aspaiiate aminotransferase (AST)	Blood
Reticulocyte Count	Albumin	Nitrite
MCV	Alkaline phosphatase (ALP)	Leukocytes
MCH	Total bilirnbin (BILI)	Clai·ity
MCHC	Total protein	Color
	Creatine Kinase	Urobilinogen
	NT-proBNP	Bilirnbin

For by-visit summai·ies, visit windows as described in Section 4.2.2 will be used. In the case more than one result is collected for the same visit date the eai·liest result will be presented. For summaries across visits (e.g. maximum post-baseline value), scheduled, unscheduled and repeat assessments will be considered.

Abnonnal laborato1y results ai·e defined as any result outside the nonnal range (either below the lower limit of the nonnal range or above the upper limit of the nonnal range) at any visit

The following will be summai·ized:

- A summa1y of each laboratory pai·ameter result and change from baseline by treatment group and visit
- A summa1y of the number and percentage of subjects experiencing low, nonnal or high values at baseline and worst post-baseline result, by laborato1y paraineter and treatment group (shift table). Worst will be defined for both low and high abnonnalities for each pai·ameter *(i.e.* each paraineter will be presented twice, once where low abno1malities ai·e worst and once where high abno1malities ai·e worst).
- A summary of the number and percentage of subjects experiencing at least one post-baseline laboratory abno1malities, by laboratory paraineter and treatment group. Both low and high abnonnalities will be repo1ied for each parameter.
- A summaiy of the number and percentage of subjects experiencing clinically significant laboratory abno1malities, by laborato1y pai·ameter, treatment group and visit and at any post-baseline visit

Clinically significant laboratory abno1malities include laborato1y results of special interest and markers of potential liver injmy.

Laboratory results of special interest:

- Hemoglobin < 8 g/dL or decrease > 2 g/dL from baseline
- Leukocytes < 4 x $10^3/\mu L$
- Neutrophils < 1.0 x $10^3/\mu L$
- Platelets < 30 x $10^3/\mu L$

Assessment of Liver Injury:

- ALT > 3x upper limit of normal (ULN)
- ALT > 5x ULN
- ALT > 10x ULN
- AST > 3x ULN
- AST > 5x ULN
- AST> 10x ULN
- ALP > 1.5x ULN
- BILI > 2x ULN
- ALT > 3x ULN and BILI > 2x ULN at the same visit
- AST > 3x ULN and BILI > 2x ULN at the same visit
- ALT or AST >3x ULN and BILI > 2x ULN at the same visit
- ALT > 3x ULN and BILI > 2x ULN and ALP < 2x ULN at the same visit
- AST > 3x ULN and BILI > 2x ULN and ALP < 2x ULN at the same visit
- ALT or AST >3x ULN and BILI > 2x ULN and ALP < 2x ULN at the same visit

By-subject listings of all laboratory data will be provided by treatment group, with abnormal values highlighted, and including center, subject identifier, age, sex, race, weight and visit. Laboratory reference ranges will also be listed.

Laboratory values (hematology, chemistry, coagulation/cardiac, and urinalysis) will be listed by subject and study time point including changes from baseline (with the exception of urinalysis).

All values outside the clinical reference ranges will be flagged in the data listings. The abnormal values will be flagged with 'L' for values below the lower limit of the clinical reference range and 'H' for values above the upper limit of the clinical reference range and included in the listings. Listings of abnormal or clinically significant results may be provided.

4.9.4 Vital Signs, Physical Findings and Other Observations Related to Safety

The following vital sign parameters including change from baseline will be summarized by treatment group and visit for each study period.:

- Heart rate (HR: bpm)
- Respiratory rate (breaths per minute)
- Diastolic blood pressure (DBP; mmHg)
- Systolic blood pressure (SBP; mmHg)

- Body temperature (C)

fu addition, a summary of the number and percentage of patients meeting the following abno1mal vital sign criteria by visit and at any time during each study period:

- HR > 110 beats per minute
- HR > 20 beats per minute change from baseline
- DBP 90 mmHg
- DBP < 60 mmHg
- DBP >20 mmHg change from baseline
- SBP 160 mmHg
- SBP < 90 mmHg
- SBP > 30 mmHg change from baseline

By-subject listings of vital sign parameters and physical examination results will be provided.

4.9.5 Independent Data Monitoring Committee

An independent Data Monitoring Committee (DMC) will meet regularly while the study is ongoing and will be responsible for inte1preting the results of both interim analyses.

Programs for analysis datasets and tables, listings, and figures (TLFs) for the DMC will be created by the blinded statistical team (biostatisticians and statistical programmers) using dummy randomization. These programs will be passed to the unblinded statistical team who will apply the trne randomization. Blinded and unblinded directories will be maintained and access to the unblinded directory will be restricted to the unblinded team member until general study unblinding.

All TLFs (planned and ad hoc) created for the DMC will be developed following the guidelines defined in this SAP as appropriate.

Further details can be found in section 2and in the DMC Charter.

Table 4-3: Scheduled DMC Meetings

Meetin!!:	Timin!!:	ReviewTvoe
1st Data Review Meeting	After 10% of planned subjects are randomized, after 6 days of follow up post-first dose day, DMC will review the unblinded data for safety and change from baseline in clinically meaningful parameters such as change from baseline in hypoxemia measurements and the 7-point ordinal scale.	Safety
futerim Analysis 1 Meeting	After 22% of planned subjects have been treated and have completed 7 days of follow-up (i.e., completed the Day 15 Visit), the DMC will review unblinded accumulated data for safety and futility, including an analysis of whether any changes in measures of hypoxemia or oxygen saturation (e.g., SpOi/FiO2, PaO2/FiO2,	Safety/ Futility/ Change in oxygenation

Meetine:	Timine:	Review Type
	or SpO2 on room air) are clinically meaningful. The DMC may recommend a pause in emolhnent at this time.	
futerim Analysis 2 Meeting	After 100 subjects completed the Day 29 Visit or died by Day 43 (Section 5.2.1), the DMC will review unblinded accumulated data.	Safety/ Superiority/Futility/ Sample Size Re-Estimation
2nd Data Review Meeting *(if needed)*	After 75% of planned subjects* are discharged from the hospital, complete the Day 43 Visit, discontinue the study early, or meet the primaiy mortality endpoint (by Day 43), the DMC will review unblinded accumulated data.	Safety

4.10 Other Analyses

4.10.1 Pharmacokinetics

Sernm gimsilumab concentrations will be summarized (including geometric mean, CV%, and 95% confidence interval for post-baseline timepoints) at Baseline (pre-dose), Day 8 (pre-dose) and DoD/ET using descriptive statistics for the PK population. A scatter plot of individual concentrations (overlaid) versus actual time of sampling (relative to Day 1 dose) will be provided (conditioned on subjects receiving Day 1 or Day 1 and Day 8 dosesofstudy chug). Phannacokinetic data analysis will not be perfonned until after database lock as it is potentially unblinding.

Population PK analysis, if conducted, will be described in a separate analysis plan and report.

4.10.2 Immunogenicity

Sernm anti-chug antibody (ADA) data will be summarized by visit and treatment for the safety analysis set (note, this analysis is distinct from the anti-GM-CSF auto-antibody test at Screening).

The following will be summai·ized:

- ADA positive at baseline
- ADA negative post baseline
- ADA positive post baseline (regai·dless of baseline; hnmunogenicity rate)
- ADA positive post baseline (but negative at baseline)

Assessment of ADA incidence and Day 8 pre-dose sernm gimsilumab concentrntion will be descriptively summarized by:

- ADA positive on any day
- ADA positive on Day 15

4.10.3 Biomarker

Actual and change from baseline senun cytokines and safety biomarker SP-D results will be summarized by ti·eatment at Baseline (pre-dose), Day 4, Day 8, and DoD/ET using descriptive statistics for the safety analysis set. Summary plots of actual and change from baseline sernm cytokines will be provided, where time=0 will be:

- Study Day 1
- Day of onset of symptoms

By-subject listings of biomarker results will be provided. Biomarker data analysis will not be performed until after database lock as it is potentially unblinding. Additional exploratory analyses may be performed.

4.11 Changes in the Conduct of the Study or Planned Analysis

SAP v3.0 incorporates changes to Interim Analysis 2 to include stopping criteria for superiority (Section 5.2.3) and to amend the stopping criteria for inferiority to use Mortality by Day 43 instead of Mortality by Day 29 (Section 5.2.4). SAP was updated before planned amendments to include these changes in the protocol and DMC Charter were finalized.

5 INTERIM ANALYSES

See also Section 4.9.5 for infonnation on the DMC interim analyses. Please note the distinction between "DMC data review" and "DMC interim analysis".

5.1 Interim Analysis 1

Objectives of interim analysis 1 (!Al) are for the DMC to

- review unblinded safety data
- check efficacy for futility

5.1.1 Subjects to be included in interim analysis 1

Trigger date for !Al: 60 subjects ti-eated completed the Day 15 Visit or died

Subjects to be included in !Al: All subjects in the ITT analysis set randomized and treated at least 15 days prior to the !Al trigger date

5.1.2 Analysis of efficacy endpoints at interim analysis 1

- Mortality up to Day 15: treatment effect estimated using CMH test strntified by baseline clinical status, odds ratio and 95% CI estimated using logistic regression model with treatment and baseline clinical status and independent variables.
- Overall survival: treatment effect estimated using logrank test, median, 25th percentile, 75th percentile smvival times in days, and by ti·eatment surivival cmve as estimated using Kaplan-Meier methods.
- Alive and no mechanical ventilation on Day 15: ti·eatment effect estimated using CMH test sti·atified by baseline clinical status, odds ratio and 95% CI estimated using logistic regression model with ti·eatment and baseline clinical status and independent variables.
- Time to hospital discharge: ti·eatment effect estimated using logrank test, median, 25th percentile, 75th percentile smvival times in days, and by ti·eatment surivival cmve as estimated using Kaplan-Meier methods.
- Time to first 2-point improvement on 7-point ordinal scale: ti·eatment effect estimated using logrank test, median, 25th percentile, 75th percentile smvival times in days, and by ti·eatment surivival cmve as estimated using Kaplan-Meier methods.

5.1.3 Futility criteria at interim analysis 1

No fonnal futility criteria were set. DMC met on June 19, 2020 and agreed that the study could continue without modification.

5.2 Interim Analysis 2

Objectives of interim analysis 2 (IA2) are for the DMC to

- review unblinded safety data
- check efficacy superiority stopping criteria
- check efficacy futility stopping criteria
- assess, if applicable, a sample size re-estimation based on the primary efficacy endpoint.

5.2.1 Subjects to be included in interim analysis 2

Trigger date for IA2: 100 subjects completed at least the Day 29 Visit (non-mortality data by Day 29) or died (mo1iality data by Day 43).

All subjects in the ITT analysis set randomized (and treated) at least 29 days prior to the IA2 trigger date and safety and efficacy data collected through the IA2 trigger date for these subjects will be included in the interim analysis.

Superiority analysis, futility analysis, and sample size re-estimation on the primaiy endpoint, Mo1iality by Day 43, will be based on subjects randomized (and treated) at least 43 days prior to the IA2 trigger date. Confnmation of survival status by Day 43 will consist of review of death date and eai·ly study withdrawal date by a clinical research associate and dates confmned by source data verification. If no death date is available site personnel should confinn whether or not the subject was still alive on Day 43.

5.2.2 Analysis of efficacy endpoints at interim analysis 2

The following efficacy endpoints will be analyzed at IA2:

- Mortality up to Day 43 as Estimand 1 described in Section 4.8.2
- Composite key secondaiy endpoint "Survival and no mechanical ventilation on Day 29" as described in Section 4.8.3.1.

5.2.3 Superiority stopping criteria at interim analysis 2

The DMC may recommend stopping the study for superiority if the following condition is met:

D. Robust and compelling benefit of gimsilumab compai·ed to placebo on mo1iality up to Day 43, i.e., one-sided p-value < 0.0005.

5.2.4 Futility stopping criteria at interim analysis 2

The DMC may recommend stopping the study for futility, if at least one of the following conditions ai·e met (relevant analysis specifications follow Section 5.2.1 and Section 5.2.2):

- No benefit of gimsilumab compared to placebo on m01iality up to Day 43, i.e., estimated treatment risk difference 0 and one-sided p-value 0.5.
- No benefit of gimsilumab compared to placebo on composite "survival and no mechnical ventilation on Day 29", i.e., estimated treatment response difference:::;0 and one-sided p-value 0.5.

5.2.5 Sample size re-estimation at interim analysis 2

If the study is neither stopped for superiority nor futility at IA2, the sample size will be re-assed by the following procedure for the primaiy efficacy endpoint mo1iality by Day 43:

(A) The conditional power given the estimated common risk difference at IA2 will be calculated by

- using the estimated common risk difference and its standai·d enor at IA2 (Estimand 1 described in Section 4.8.2)
- assuming the cunent trend observed up to IA2 (stage 1) as hue disti·ibution pai·ameters for the remaining paii of the study (stage 2)
- keeping the total sample size as 270 subjects.

(B) If the conditional power is ≥ 0.8 (80%), then the initial sample size can be kept.

(C) If the conditional power is < 0.8 (80%), then the sample size may be increased, so that

- the conditional power calculated with the increased sample size is 0.8 (80%) for the final analysis combining the test statistics from first and second stage with pre-specified weights (Cui/Hung/Wang 1999) to maintain the type-I-error probability restricted to 0.025 one-sided; the two pre-specified weights are

  $w_1 = \sqrt{\frac{n_1}{270}}$ with n_1 denoting the number of subjects in the FAS for stage 1, i.e., subjects randomized at least 43 days prior to the IA2 trigger date

  $w_2 = \sqrt{\frac{270-n_1}{270}}$ where $270 - n_1$ represents the number of subjects in the FAS for stage 2, i.e., subjects randomized 42 days prior to the IA2 trigger date or later
- but not increasing the maximum allowed total sample size of 400 subjects.

(D) In order not disclosing too much information to sponsor and investigators, only the following categories for the total sample size can be recommended:

- 270 subjects (i.e., no increase of the initial sample size)
- 300 subjects
- 330 subjects
- 360 subjects
- 400 subjects (i.e., the maximum allowed total sample size).

5.2.6 Interim analysis 2 outcome

The DMC met on Aug 26th, 2020 to review results from interim analysis 2. After the meeting ad hoc analyses were requested to review efficacy endpoints by select subgroups and to perform some additional analyses on mechanical ventilation-free days. These analyses are documented in *KIN-1901-2001 PXL250621 Additional Statistical Analysis V1.0.docx.* Per sponsor decision, enrollment was stopped early with the intention of completing the study as planned for the 227 (84%) of subjects randomized on or before October 12, 2020. For planning purposes the ad hoc analyses were repeated using a data cut-off date of September 28, 2020 including all subjects randomized as of the cut-off date.

6 REFERENCES

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7 APPENDICES

7.1 Schedule of Assessments

Schedule of Assessments: Screening and Treatment Period				
	Screen	Baseline[a]	On-Treatment Assessments (only done if in hospital)	DoD / ET
Study Day (± Window)	**-7 to 1**	**1**	**Days 2 – 14, inclusive (All ± 1 day)**	**—**
Week	**0**	**0**	**1 to 2**	**—**
Informed consent and randomization	X			
Inclusion/Exclusion criteria	X	X[b]		
Demographic information, medical history, prior medications[c]	X			
Local QuantiFERON® test[d]	X			
Local Viral Screen (HBsAG, HCV RNA/Ag, HIV)[d]	X			
Height and Weight[e]	X			
Local Urine pregnancy test β-hCG and follicle-stimulating hormone (women only)[f]	X			
Central sample for anti-GM-CSF autoAb[d] (result not required for determination of eligibility)	X			
Chest X-ray or chest CT scan (within 3 days of Day 1)	X			
Local qualitative sample (e.g., nasopharyngeal swab) for PCR SARS-CoV-2 (if not already documented)	X			
Central quantitative sample (e.g., nasopharyngeal swab) for PCR SARS-CoV-2[g]		X	Days 2 and 9	X
Physical examination[h] and vital signs (blood pressure, heart rate, respiration rate, and body temperature)[i]	X	X	Daily, only while hospitalized	X
Central clinical laboratory measurements (hematology, blood chemistry [including CRP, ferritin, LDH, procalcitonin, troponin I], coagulation [including D-dimer], and urinalysis)[j]	X	X	Days 4 and 8	X
Administration of IV study drug[k]		X	Day 8	
Central PK samples for quantification of gimsilumab serum concentration		Predose	Predose on Day 8	X
Central samples for cytokine panel		X	Days 4 and 8	X

Schedule of Assessments: Screening and Treatment Period				
	Screen	Baseline[a]	On-Treatment Assessments (only done if in hospital)	DoD / ET
Study Day (± Window)	**-7 to 1**	**1**	**Days 2 – 14, inclusive (All ± 1 day)**	**—**
Week	**0**	**0**	**1 to 2**	**—**
Central samples for SP-D measurement		X	Day 8	X
Central sample for immunogenicity (antibodies to gimsilumab)		X		X
7-point Ordinal Scale		X	Daily, only while hospitalized	X
National Early Warning Score (NEWS)		X	Daily, only while hospitalized	X
SOFA score		X	Daily, only while in ICU	X
SpO_2/FiO_2, and if performed, PaO_2/FiO_2 (can be imputed)	X	X	Daily, only while hospitalized	X
Oxygenation requirements	X	X	Daily, only while hospitalized	X
Ventilation requirements[l]	X	X	Daily, only while hospitalized	X
ECMO requirements		X	Daily, only while hospitalized	X
Concomitant medications/concurrent procedures[m]		X	Daily, only while hospitalized	X
Adverse event monitoring[n]		X	Daily, only while hospitalized	X

β-hCG = beta human chorionic gonadotropin; anti-GM-CSF autoAb = anti-granulocyte macrophage colony- stimulating factor auto-antibody; DoD = Day of Discharge from hospital; ECMO = extracorporeal membrane oxygenation; EoS = End-of-Study; ET = early termination; FiO_2 = fraction of inspired oxygen; HBsAg = hepatitis B surface antigen; HCVAb = hepatitis C virus antibodies; HIV = human immunodeficiency virus; ICU = Intensive Care Unit; IGRA = interferon gamma release assay; IV = intravenous; PCR = polymerase chain reaction; PK = pharmacokinetics; SOFA = sequential organ failure assessment; SP-D = serum surfactant protein D; SpO_2 = peripheral capillary oxygen saturation

a. Baseline assessments should be performed prior to study drug administration. Assessments performed within 48 hours of Baseline do not need to be repeated at Baseline.
b. Verification that no changes affecting eligibility have occurred since Screening will be performed at the Baseline/Day 1 Visit.
c. Collect medication history from the 30 days leading up to, and including, the time of the Screening Visit, including date of onset of COVID-19 symptoms, prescription medications, over-the-counter medications, and herbal supplements/vitamins.
d. Sample will be collected, but enrollment can continue without receiving results first. HCV testing can be RNA or Ag, only to confirm suspected infection. If a subject is diagnosed with latent TB (positive QuantiFERON Gold or purified protein derivative [PPD]), hepatitis B or C, or HIV during the study, the Investigator must discuss this with the medical monitor and a decision will then be made concerning the second dose of gimsilumab, if applicable. In the event the QuantiFERONn Gold assay is not available, and the site performs a different IGRA such as T Spot, then the alternative IGRA will be acceptable for patient screening and enrollment. Enrollment should not be delayed to obtain the QuantiFERONn Gold assay in lieu of the IGRA available at the site. If no IGRA test is available, PPD can be used.
e. Height will be assessed only once (at Screening). Estimated height and weight are acceptable if unable to be measured due to patient clinical condition.
f. The Screening sample can be assessed using local laboratory services for Screening/Eligibility purposes.

g. When at all possible, if only 1 nostril is swabbed for viral assessments, the same nostril should be used for all subsequent samples.
h. An abbreviated, targeted physical examination will be performed based on the subject's clinical status and what the clinic staff feel is appropriate.
i. Vital signs will be assessed at all timepoints specified above. On study drug administration days, vital signs will be assessed pre-dose (within 15 minutes) and ± 30 minutes post end of infusion.
j. ALT, AST, CRP, and Ferritin can be assessed using local laboratory services for Screening. For all on-study laboratory assessments, if central laboratory assessments cannot be collected for any reason, best efforts will be made to record local laboratory data.
k. Subjects will receive a single IV infusion of blinded study treatment on Day 1 and Day 8. The Day 8 dose will be omitted if the subject is discharged or is no longer in need of supplemental oxygen or ventilatory support for >48 hours.
l. If subject is receiving mechanical ventilation, the following parameters will be recorded: type of ventilation (CPAP, BiPAP, or intubation), FiO_2, SpO_2, ventilation rate, pulse, tidal volume, positive end-expiratory pressure (PEEP), and airway pressure.
m. Collect information on concomitant medications and concurrent procedures from the time of informed consent through the EoS Visit (or ET Visit if subject discontinues early), including prescription medications, over-the-counter medications, and herbal supplements/vitamins.
n. Adverse event monitoring will include assessment of treatment-emergent AEs (TEAEs), serious adverse events (SAEs), and severe AEs (Grade 3 or 4 events).

Note: SCREENING LABORATORY ASSESSMENTS: For all screening laboratory assessments, if more than one result is available during the screening period, the most recent value will be used as the screening value and for determination of eligibility.

Note: All subjects who are discharged from the hospital will undergo all Day-of-Discharge (DoD) Visit assessments; daily in-hospital assessments will only need to be performed once on DoD. All subjects who discontinue from the study prematurely will undergo all Early Termination (ET) Visit assessments, whenever possible. All subjects who discontinue treatment and/or the study early will be followed for Day 43 all-cause mortality.

Schedule of Assessments: Follow-up Period (Visits will be in-hospital or by phone, if subject has been discharged)								
Study Day (± Window)	**15 (± 2)**	**22 (± 2)**	**29 (± 2)**	**36 (± 2)**	**43[a] (± 2)**	**85 (± 2)**	**EoS 169 (± 2)**	**DoD / ET**
Week	**2**	**3**	**4**	**5**	**6**	**12**	**24**	**—**
Procedures/Assessments								
SOFA Score	Daily, only if in ICU, through Day 43							X
National Early Warning Score (NEWS)	Daily, only while hospitalized, through Day 43							X
Central samples for cytokine panel	Hosp		Hosp					
Central samples for SP-D measurement	Hosp		Hosp					
Central sample for immunogenicity (antibodies to gimsilumab)	Hosp		Hosp		Hosp			
Central clinical laboratory measurements (hematology, blood chemistry [including CRP, ferritin, LDH, procalcitonin, troponin I], coagulation [including D-dimer], and urinalysis)[b]	Hosp	Hosp	Hosp	Hosp	Hosp			X
SpO_2/FiO_2, and if performed, PaO_2/FiO_2 (can be imputed)	Daily, only while hospitalized, through Day 43							X
Oxygenation requirements	Daily, only while hospitalized, through Day 43[c]							X
Ventilation requirements	Daily, only while hospitalized, through Day 43							X
ECMO requirements	Daily, only while hospitalized, through Day 43							X
Concomitant medications/concurrent procedures	Daily, only while hospitalized[d]					X	X	X
Physical examination and vital signs (blood pressure, heart rate, respiration rate, and body temperature)	Hosp	Hosp	Hosp	Hosp	Hosp			X
7-point Ordinal Scale	Daily, only while hospitalized, through Day 43[d]					X	X	X
Adverse event monitoring[e]	Daily, only while hospitalized[d]					X	X	X

ECMO = extracorporeal membrane oxygenation; EoS = End-of-Study; FiO_2 = fraction of inspired oxygen; Hosp = Assessment to be performed only if subject has not been discharged; ICU = Intensive Care Unit; SOFA = sequential organ failure assessment; SP-D = serum surfactant protein D; SpO_2 = peripheral capillary oxygen saturation

a. Day 43 will be used for the primary all-cause mortality endpoint.
b. For all on-study laboratory assessments, if central laboratory assessments cannot be collected for any reason, best efforts will be made to record local laboratory data.
c. IF DISCHARGED, will be measured via phone follow-up on Day 15, 22, 29, 36, and 43.
d. IF DISCHARGED, will be measured via phone follow-up on Day 15, 22, 29, 36, 43, 85, and 169.
e. Adverse event monitoring will include assessment of treatment-emergent AEs (TEAEs), serious adverse events (SAEs), and severe AEs (Grade 3 or 4 events)

Note: Assessments at time points indicated with "Hosp" will only be conducted if the subject has not yet been discharged from the hospital. Assessments indicated with an 'X' will be performed in-hospital if the subject has not been discharged or via phone if subject has been discharged from the hospital.

Note: All subjects who are discharged from the hospital will undergo all Day-of-Discharge (DoD) Visit assessments; daily in-hospital assessments will only need to be performed once on DoD.
All subjects who discontinue from the study prematurely will undergo all Early Termination (ET) Visit assessments, whenever possible.
All subjects who discontinue treatment and/or the study early will be followed for Day 43 all-cause mortality.

7.2 Adverse Events of Special Interest

Infective pneumonia (SMQ)			
Scope	*Group*	*PT*	*PT Code*
NaITow	**A**	Actinomycotic pulmonary infection	10000628
NaITow	**A**	Acute pulmonary histoplasmosis	10001027
NaITow	**A**	Atypical mycobacterial pneumonia	10071075
NaITow	**A**	Atypical pneumonia	10003757
NaITow	**A**	Blastomycosis	10005098
NaITow	**A**	Bronchopulmonary aspergillosis	10006473
NaITow	**A**	Burkholderia cepacia complex infection	10069657
NaITow	**A**	Burkholderia pseudomallei infection	10069748
NaITow	**A**	Candida pneumonia	10053158
NaITow	**A**	Chlamydia! infection	10061041
NaITow	**A**	Chronic pulmonary histoplasmosis	10009115
NaITow	**A**	Coccidioidomycosis	10009825
NaITow	**A**	Embolic oneumonia	10065680
NaITow	**A**	Enterobacter pneumonia	10054218
NaITow	**A**	Haemophilus infection	10061190
NaITow	**A**	HaemoITha!lic pneumonia	10077933
NaITow	**A**	Hantavirns pulmonary infection	10019143
NaITow	**A**	Herpes simplex pneumonia	10065046
NaITow	**A**	Histoplasmosis	10020141
NaITow	**A**	fufectious pleural effusion	10071699
NaITow	**A**	Lung abscess	10025028
NaITow	**A**	Miliaiy pneumonia	10055088
NaITow	**A**	Pai·acancerouspneumonia	10080986
NaITow	**A**	Pai·asitic pneumonia	10078883
NaITow	**A**	Pleural infection	10061351
NaITow	**A**	Pleural infection bacterial	10067334
NaITow	**A**	Pleurisy viral	10052761
NaITow	**A**	Pneumocystis iirovecii pneumonia	10073755
NaITow	**A**	Pneumonia	10035664
NaITow	**A**	Pneumonia acinetobacter	10079866
NaITow	**A**	Pneumonia adenoviral	10035665
NaITow	**A**	Pneumonia anthrax	10035667
NaITow	**A**	Pneumonia bacterial	10060946
NaITow	**A**	Pneumonia blastomyces	10035671
NaITow	**A**	Pneumonia bordetella	10035672

Narrow	A	Pneumonia chlamydial	10035673
Narrow	A	Pneumonia cryptococcal	10067565
Narrow	A	Pneumonia cytomegaloviral	10035676
Narrow	A	Pneumonia escherichia	10035699
Narrow	A	Pneumonia fungal	10061354
Narrow	A	Pneumonia haemophilus	10035702
Narrow	A	Pneumonia helminthic	10065246
Narrow	A	Pneumonia herpes viral	10035703
Narrow	A	Pneumonia influenzal	10035714
Narrow	A	Pneumonia klebsiella	10035717
Narrow	A	Pneumonia legionella	10035718
Narrow	A	Pneumonia measles	10035722
Narrow	A	Pneumonia moraxella	10035723
Narrow	A	Pneumonia mycoplasmal	10035724
Narrow	A	Pneumonia necrotising	10055672
Narrow	A	Pneumonia parainfluenzae viral	10035727
Narrow	A	Pneumonia pneumococcal	10035728
Narrow	A	Pneumonia proteus	10079867
Narrow	A	Pneumonia pseudomonal	10035731
Narrow	A	Pneumonia respiratory syncytial viral	10035732
Narrow	A	Pneumonia salmonella	10035733
Narrow	A	Pneumonia serratia	10079868
Narrow	A	Pneumonia staphylococcal	10035734
Narrow	A	Pneumonia streptococcal	10035735
Narrow	A	Pneumonia toxoplasmal	10067566
Narrow	A	Pneumonia tularaemia	10035736
Narrow	A	Pneumonia viral	10035737
Narrow	A	Pneumonic plague	10053026
Narrow	A	Post procedural pneumonia	10066590
Narrow	A	Pulmonary echinococciasis	10037374
Narrow	A	Pulmonary mucormycosis	10078354
Narrow	A	Pulmonary mycosis	10037422
Narrow	A	Pulmonary nocardiosis	10080435
Narrow	A	Pulmonary paracoccidioidomycosis	10080468
Narrow	A	Pulmonary sepsis	10051739
Narrow	A	Pulmonary sporotrichosis	10080480
Narrow	A	Pulmonary syphilis	10037434
Narrow	A	Pulmonary trichosporonosis	10068184
Narrow	A	Pulmonary tuberculosis	10037440

Narrow	A	Pyopneumothorax	10057102
Narrow	A	Septic pulmonary embolism	10083093
Narrow	A	Tuberculosis	10044755
Narrow	A	Tuberculous pleurisy	10045104
Narrow	A	Varicella zoster pneumonia	10074254
Broad	A	Acinetobacter infection	10051894
Broad	A	Acinetobacter test positive	10069962
Broad	A	Adenovirus infection	10060931
Broad	A	Adenovirus test positive	10070369
Broad	A	Aspergillus infection	10074171
Broad	A	Aspergillus test positive	10070448
Broad	A	Aspiration tracheal abnormal	10003531
Broad	A	Atelectasis	10003598
Broad	A	Atypical mycobacterial infection	10061663
Broad	A	Atypical mycobacterial lower respiratory tract infection	10075026
Broad	A	Auscultation	10076270
Broad	A	Avian influenza	10064097
Broad	A	Bacterial test positive	10059421
Broad	A	Bronchopneumopathy	10053582
Broad	A	Burkholderia test positive	10069960
Broad	A	Carbon dioxide abnormal	10064156
Broad	A	Carbon dioxide increased	10007225
Broad	A	Chest X-ray abnormal	10008499
Broad	A	Chlamydia test positive	10070159
Broad	A	Coxiella test positive	10070194
Broad	A	Crepitations	10011376
Broad	A	Cryptococcosis	10011490
Broad	A	Culture throat positive	10011634
Broad	A	Disseminated aspergillosis	10080492
Broad	A	Disseminated blastomycosis	10080477
Broad	A	Disseminated coccidioidomycosis	10080474
Broad	A	Disseminated mucormycosis	10073239
Broad	A	Disseminated paracoccidioidomycosis	10080478
Broad	A	Disseminated sporotrichosis	10080491
Broad	A	Disseminated tuberculosis	10013453
Broad	A	Egobronchophony	10056744
Broad	A	Empyema	10014568
Broad	A	Enterobacter infection	10051910

Broad	A	Enterobacter test positive	10070023
Broad	A	Escherichia infection	10061126
Broad	A	Escherichia test positive	10070090
Broad	A	Francisella test positive	10070097
Broad	A	Fungal test positive	10059423
Broad	A	H1N1 influenza	10069767
Broad	A	H2N2 influenza	10077909
Broad	A	H3N2 influenza	10081286
Broad	A	Haemophilus test positive	10070100
Broad	A	Haemoptysis	10018964
Broad	A	Hantavirus test positive	10070212
Broad	A	Human metapneumovirus test positive	10072859
Broad	A	Hypoventilation	10021133
Broad	A	Hypoxia	10021143
Broad	A	Increased bronchial secretion	10062530
Broad	A	Influenza	10022000
Broad	A	Influenza A virus test positive	10070215
Broad	A	Influenza virus test positive	10070717
Broad	A	Klebsiella infection	10061259
Broad	A	Klebsiella test positive	10070091
Broad	A	Legionella infection	10061266
Broad	A	Legionella test positive	10070092
Broad	A	Lower respiratory tract congestion	10075565
Broad	A	Lower respiratory tract herpes infection	10077390
Broad	A	Lower respiratory tract infection	10024968
Broad	A	Lower respiratory tract infection bacterial	10063890
Broad	A	Lower respiratory tract infection fungal	10065187
Broad	A	Lower respiratory tract infection viral	10065188
Broad	A	Lung consolidation	10025080
Broad	A	Lung infiltration	10025102
Broad	A	Lung opacity	10081792
Broad	A	Metapneumovirus infection	10066226
Broad	A	Middle East respiratory syndrome	10075271
Broad	A	Moraxella infection	10062204
Broad	A	Moraxella test positive	10070095
Broad	A	Mucormycosis	10028098
Broad	A	Mycobacterial infection	10062207
Broad	A	Mycobacterium test positive	10070323
Broad	A	Mycoplasma infection	10061300

Broad	A	Mycoplasma test positive	10070160
Broad	A	Nocardiosis	10029444
Broad	A	Organising pneumonia	10067472
Broad	A	Oxygen saturation abnormal	10033317
Broad	A	Oxygen saturation decreased	10033318
Broad	A	Paracoccidioides infection	10061906
Broad	A	PCO2 abnormal	10058982
Broad	A	PCO2 decreased	10034181
Broad	A	Percussion test abnormal	10051721
Broad	A	Pleural effusion	10035598
Broad	A	Pleural rub	10035615
Broad	A	Pleuritic pain	10035623
Broad	A	Pneumococcal bacteraemia	10058859
Broad	A	Pneumococcal infection	10061353
Broad	A	Pneumococcal sepsis	10054047
Broad	A	Pneumocystis test positive	10070454
Broad	A	Pneumovirus test positive	10070345
Broad	A	PO2 abnormal	10062087
Broad	A	PO2 decreased	10035768
Broad	A	Productive cough	10036790
Broad	A	Proteus infection	10061470
Broad	A	Proteus test positive	10070134
Broad	A	Pseudomonas infection	10061471
Broad	A	Pseudomonas test positive	10070135
Broad	A	Psittacosis	10037151
Broad	A	Pulmonary congestion	10037368
Broad	A	Pulmonary imaging procedure abnormal	10082582
Broad	A	Pulmonary tuberculoma	10066927
Broad	A	Q fever	10037688
Broad	A	Rales	10037833
Broad	A	Respiratory tract infection	10062352
Broad	A	Respiratory tract infection bacterial	10060693
Broad	A	Respiratory tract infection fungal	10060692
Broad	A	Respiratory tract infection viral	10062106
Broad	A	Rhonchi	10039109
Broad	A	Serratia infection	10061512
Broad	A	Serratia test positive	10070128
Broad	A	Severe acute respiratory syndrome	10061982
Broad	A	Sporotrichosis	10041736

Broad	A	Sputum abnonnal	10060991
Broad	A	Sputum culture positive	10051612
Broad	A	Sputum discoloured	10041807
Broad	A	Sputum pmulent	10050090
Broad	A	Staphylococcal infection	10058080
Broad	A	Staphylococcus test positive	10070052
Broad	A	Sti·eptococcal infection	10061372
Broad	A	Sti·eptococcus test positive	10070055
Broad	A	Tachypnoea	10043089
Broad	A	Tularaemia	10045146
Broad	A	Use of accessory respirato1y muscles	10069555
Broad	A	Venous oxygen saturation abno1mal	10068428
Broad	A	Venous oxygen saturation decreased	10068427

Opportunistic infections (SMQ)			
Scope	*Group*	*PT*	*PT Code*
NaITow	A	Acid fast bacilli infection	10054204
NaITow	A	Acinetobacter sepsis	10083897
NaITow	A	Acute oulmonarv histoolasmosis	10001027
NaITow	A	Adenoviral haemonhagic cystitis	10057373
NaITow	A	Adrenal gland tuberculosis	10001358
NaITow	A	Altemaria infection	10054207
NaITow	A	Amoebic brain abscess	10001984
NaITow	A	Amoebic lung abscess	10001990
NaITow	A	Althritis fungal	10060966
NaITow	A	Aspergillosis oral	10003489
NaITow	A	Asoergillus infection	10074171
NaITow	A	Atypical mycobacterial infection	10061663
NaITow	A	Atypical mycobacterial lower respirato1y ti·act infection	10075026
NaITow	A	Atypical mycobacterial lvmphadenitis	10003755
NaITow	A	Atypical mycobacterial pneumonia	10071075
NaITow	A	Atypical mycobacterium pericarditis	10055036
NaITow	A	Bacillaiy angiomatosis	10003971
NaITow	A	Biliary ti-act infection cryptosporidial	10067319
NaITow	A	Biliary ti-act infection fungal	10065203
NaITow	A	BK vims infection	10055181
NaITow	A	Blastocystis infection	10005092
NaITow	A	Blastomycosis	10005098

Narrow	A	Bone tuberculosis	10056377
Narrow	A	Borderline leprosy	10006029
Narrow	A	Bovine tuberculosis	10006049
Narrow	A	Bronchitis fungal	10061737
Narrow	A	Bronchopulmonary aspergillosis	10006473
Narrow	A	Burkholderia cepacia complex sepsis	10069684
Narrow	A	Burkholderia gladioli infection	10073030
Narrow	A	Burkholderia pseudomallei infection	10069748
Narrow	A	Candida endophthalmitis	10059449
Narrow	A	Candida osteomyelitis	10064699
Narrow	A	Candida pneumonia	10053158
Narrow	A	Candida retinitis	10068612
Narrow	A	Candida sepsis	10053166
Narrow	A	Capnocytophaga infection	10061738
Narrow	A	Capnocytophaga sepsis	10081740
Narrow	A	Central nervous system fungal infection	10072805
Narrow	A	Central nervous system viral infection	10061037
Narrow	A	Cerebral aspergillosis	10051597
Narrow	A	Cerebral fungal infection	10049657
Narrow	A	Cerebral toxoplasmosis	10057854
Narrow	A	Chromoblastomycosis	10008803
Narrow	A	Chronic pulmonary histoplasmosis	10009115
Narrow	A	Coccidioides encephalitis	10054214
Narrow	A	Coccidioidomycosis	10009825
Narrow	A	Colitis herpes	10051782
Narrow	A	Conjunctivitis tuberculous	10010754
Narrow	A	Cryptococcal cutaneous infection	10054216
Narrow	A	Cryptococcal fungaemia	10067112
Narrow	A	Cryptococcosis	10011490
Narrow	A	Cryptosporidiosis infection	10011502
Narrow	A	Cutaneous coccidioidomycosis	10068747
Narrow	A	Cutaneous tuberculosis	10011684
Narrow	A	Cytomegalovirus chorioretinitis	10048843
Narrow	A	Cytomegalovirus colitis	10048983
Narrow	A	Cytomegalovirus duodenitis	10049014
Narrow	A	Cytomegalovirus enteritis	10049074
Narrow	A	Cytomegalovirus enterocolitis	10049015
Narrow	A	Cytomegalovirus gastritis	10049016
Narrow	A	Cytomegalovirus gastroenteritis	10051349

Narrow	A	Cytomegalovirus gastrointestinal infection	10052817
Narrow	A	Cytomegalovirus gastrointestinal ulcer	10075619
Narrow	A	Cytomegalovirus hepatitis	10011830
Narrow	A	Cytomegalovirus infection	10011831
Narrow	A	Cytomegalovirus infection reactivation	10058666
Narrow	A	Cytomegalovirus mononucleosis	10011834
Narrow	A	Cytomegalovirus mucocutaneous ulcer	10065036
Narrow	A	Cytomegalovirus myelomeningoradiculitis	10065621
Narrow	A	Cytomegalovirus myocarditis	10056261
Narrow	A	Cytomegalovirus oesophagitis	10049018
Narrow	A	Cytomegalovirus pancreatitis	10049566
Narrow	A	Cytomegalovirus pericarditis	10056721
Narrow	A	Cytomegalovirus syndrome	10056262
Narrow	A	Cytomegalovirus urinary tract infection	10051350
Narrow	A	Cytomegalovirus viraemia	10058854
Narrow	A	Disseminated aspergillosis	10080492
Narrow	A	Disseminated blastomycosis	10080477
Narrow	A	Disseminated coccidioidomycosis	10080474
Narrow	A	Disseminated cryptococcosis	10013439
Narrow	A	Disseminated cytomegaloviral infection	10049075
Narrow	A	Disseminated leishmaniasis	10013444
Narrow	A	Disseminated mucormycosis	10073239
Narrow	A	Disseminated mycobacterium avium complex infection	10069662
Narrow	A	Disseminated paracoccidioidomycosis	10080478
Narrow	A	Disseminated sporotrichosis	10080491
Narrow	A	Disseminated strongyloidiasis	10080496
Narrow	A	Disseminated toxoplasmosis	10083434
Narrow	A	Disseminated trichosporonosis	10068185
Narrow	A	Disseminated tuberculosis	10013453
Narrow	A	Disseminated varicella zoster vaccine virus infection	10076667
Narrow	A	Ear tuberculosis	10014027
Narrow	A	Encephalitis cytomegalovirus	10014586
Narrow	A	Encephalitis fungal	10065170
Narrow	A	Endocarditis candida	10014669
Narrow	A	Endocarditis histoplasma	10014676
Narrow	A	Endocarditis Q fever	10014682
Narrow	A	Enterocolitis fungal	10065205
Narrow	A	Epididymitis blastomyces	10015001

Narrow	A	Epididymitis tuberculous	10015004
Narrow	A	Epstein-Barr virus associated lymphoproliferative disorder	10068349
Narrow	A	Epstein-Barr virus infection reactivation	10015109
Narrow	A	Exserohilum infection	10073244
Narrow	A	Extrapulmonary tuberculosis	10064445
Narrow	A	Eye infection toxoplasmal	10015939
Narrow	A	Female genital tract tuberculosis	10061150
Narrow	A	Flavobacterium infection	10054222
Narrow	A	Fournier's gangrene	10017068
Narrow	A	Fungaemia	10017523
Narrow	A	Fungal abscess central nervous system	10017524
Narrow	A	Fungal cystitis	10017525
Narrow	A	Fungal endocarditis	10017529
Narrow	A	Fungal labyrinthitis	10065174
Narrow	A	Fungal oesophagitis	10049656
Narrow	A	Fungal peritonitis	10061138
Narrow	A	Fungal retinitis	10068613
Narrow	A	Fungal rhinitis	10065182
Narrow	A	Fungal sepsis	10058872
Narrow	A	Fungal tracheitis	10069508
Narrow	A	Fusarium infection	10051919
Narrow	A	Gastritis fungal	10061972
Narrow	A	Gastritis herpes	10051784
Narrow	A	Gastroenteritis cryptococcal	10011485
Narrow	A	Gastroenteritis cryptosporidial	10017899
Narrow	A	Gastrointestinal fungal infection	10049479
Narrow	A	Gastrointestinal mucormycosis	10082721
Narrow	A	Hepatic candidiasis	10049653
Narrow	A	Hepatic infection fungal	10065217
Narrow	A	Hepatosplenic candidiasis	10051590
Narrow	A	Herpes oesophagitis	10052330
Narrow	A	Herpes ophthalmic	10062004
Narrow	A	Herpes pharyngitis	10066888
Narrow	A	Herpes sepsis	10058876
Narrow	A	Herpes simplex colitis	10074239
Narrow	A	Herpes simplex encephalitis	10019953
Narrow	A	Herpes simplex gastritis	10074240
Narrow	A	Herpes simplex hepatitis	10067389

Narrow	A	Herpes simplex meningitis	10019956
Narrow	A	Herpes simplex meningoencephalitis	10074247
Narrow	A	Herpes simplex meningomyelitis	10074250
Narrow	A	Herpes simplex necrotising retinopathy	10074252
Narrow	A	Herpes simplex oesophagitis	10074242
Narrow	A	Herpes simplex otitis externa	10019959
Narrow	A	Herpes simplex pharyngitis	10074244
Narrow	A	Herpes simplex pneumonia	10065046
Narrow	A	Herpes simplex sepsis	10074246
Narrow	A	Herpes simplex visceral	10019963
Narrow	A	Herpes zoster cutaneous disseminated	10074297
Narrow	A	Herpes zoster disseminated	10065038
Narrow	A	Herpes zoster infection neurological	10061208
Narrow	A	Herpes zoster meningitis	10074259
Narrow	A	Herpes zoster meningoencephalitis	10074248
Narrow	A	Herpes zoster meningomyelitis	10074251
Narrow	A	Herpes zoster necrotising retinopathy	10074253
Narrow	A	Herpes zoster oticus	10063491
Narrow	A	Herpes zoster pharyngitis	10074245
Narrow	A	Histoplasmosis	10020141
Narrow	A	Histoplasmosis cutaneous	10049142
Narrow	A	Histoplasmosis disseminated	10020144
Narrow	A	Human herpesvirus 6 encephalitis	10081897
Narrow	A	Human herpesvirus 6 infection reactivation	10066845
Narrow	A	Human herpesvirus 8 infection	10066435
Narrow	A	Immune reconstitution inflammatory syndrome associated tuberculosis	10072797
Narrow	A	Indeterminate leprosy	10021700
Narrow	A	Infection in an immunocompromised host	10021818
Narrow	A	Infection susceptibility increased	10021866
Narrow	A	Intestinal tuberculosis	10075268
Narrow	A	Isosporiasis	10023076
Narrow	A	JC virus CSF test positive	10078957
Narrow	A	JC virus granule cell neuronopathy	10074361
Narrow	A	JC virus infection	10023163
Narrow	A	Joint tuberculosis	10056367
Narrow	A	Kaposi's sarcoma	10023284
Narrow	A	Kaposi's sarcoma AIDS related	10023286
Narrow	A	Kaposi's varicelliform eruption	10051891

Narrow	A	Laryngitis fungal	10067321
Narrow	A	Lepromatous leprosy	10024227
Narrow	A	Leprosy	10024229
Narrow	A	Listeria encephalitis	10054116
Narrow	A	Listeria sepsis	10063085
Narrow	A	Listeriosis	10024641
Narrow	A	Lower respiratory tract infection fungal	10065187
Narrow	A	Lupus vulgaris	10025143
Narrow	A	Lymph node tuberculosis	10025183
Narrow	A	Lymphadenitis fungal	10065208
Narrow	A	Male genital tract tuberculosis	10061234
Narrow	A	Mastitis fungal	10065211
Narrow	A	Meningitis aspergillus	10073245
Narrow	A	Meningitis candida	10027205
Narrow	A	Meningitis coccidioides	10027207
Narrow	A	Meningitis cryptococcal	10027209
Narrow	A	Meningitis exserohilum	10073246
Narrow	A	Meningitis fungal	10027236
Narrow	A	Meningitis herpes	10027242
Narrow	A	Meningitis histoplasma	10027243
Narrow	A	Meningitis listeria	10027248
Narrow	A	Meningitis toxoplasmal	10048848
Narrow	A	Meningitis tuberculous	10027259
Narrow	A	Meningoencephalitis herpetic	10027285
Narrow	A	Meningomyelitis herpes	10074249
Narrow	A	Methylobacterium infection	10070983
Narrow	A	Microsporidia infection	10053982
Narrow	A	Miliary pneumonia	10055088
Narrow	A	Mucormycosis	10028098
Narrow	A	Mycetoma mycotic	10028426
Narrow	A	Mycobacterial infection	10062207
Narrow	A	Mycobacterial peritonitis	10073514
Narrow	A	Mycobacterium abscessus infection	10064789
Narrow	A	Mycobacterium avium complex immune restoration disease	10058449
Narrow	A	Mycobacterium avium complex infection	10058806
Narrow	A	Mycobacterium chelonae infection	10071401
Narrow	A	Mycobacterium fortuitum infection	10049659
Narrow	A	Mycobacterium kansasii infection	10028447

Narrow	A	Mycobacterium marinum infection	10028452
Narrow	A	Mycobacterium ulcerans infection	10066289
Narrow	A	Mycotic endophthalmitis	10063202
Narrow	A	Myocarditis mycotic	10059026
Narrow	A	Myocarditis toxoplasmal	10028617
Narrow	A	Necrotising fasciitis fungal	10052892
Narrow	A	Necrotising herpetic retinopathy	10065119
Narrow	A	Neurocryptococcosis	10068368
Narrow	A	Nocardia sepsis	10064952
Narrow	A	Nocardiosis	10029444
Narrow	A	Oesophageal candidiasis	10030154
Narrow	A	Oesophageal tuberculosis	10030200
Narrow	A	Ophthalmic herpes simplex	10073938
Narrow	A	Ophthalmic herpes zoster	10030865
Narrow	A	Opportunistic infection	10030901
Narrow	A	Oral tuberculosis	10076879
Narrow	A	Oro-pharyngeal aspergillosis	10053029
Narrow	A	Osteomyelitis blastomyces	10031255
Narrow	A	Osteomyelitis fungal	10065239
Narrow	A	Otitis media fungal	10065175
Narrow	A	Pancreatitis fungal	10065190
Narrow	A	Paracoccidioides infection	10061906
Narrow	A	Parvovirus B19 infection reactivation	10076281
Narrow	A	Penicillium infection	10078580
Narrow	A	Pericarditis fungal	10065220
Narrow	A	Pericarditis histoplasma	10034489
Narrow	A	Pericarditis tuberculous	10055069
Narrow	A	Peritoneal candidiasis	10056562
Narrow	A	Peritoneal tuberculosis	10053583
Narrow	A	Phaeohyphomycosis	10080815
Narrow	A	Pneumocystis jirovecii infection	10073756
Narrow	A	Pneumocystis jirovecii pneumonia	10073755
Narrow	A	Pneumonia blastomyces	10035671
Narrow	A	Pneumonia cryptococcal	10067565
Narrow	A	Pneumonia cytomegaloviral	10035676
Narrow	A	Pneumonia fungal	10061354
Narrow	A	Pneumonia herpes viral	10035703
Narrow	A	Pneumonia legionella	10035718
Narrow	A	Pneumonia toxoplasmal	10067566

Narrow	A	Polyomavirus viraemia	10083628
Narrow	A	Polyomavirus-associated nephropathy	10065381
Narrow	A	Proctitis herpes	10036780
Narrow	A	Progressive multifocal leukoencephalopathy	10036807
Narrow	A	Progressive vaccinia	10069582
Narrow	A	Prostatitis tuberculous	10064743
Narrow	A	Protothecosis	10081250
Narrow	A	Pseudallescheria infection	10061919
Narrow	A	Pseudallescheria sepsis	10058973
Narrow	A	Pseudomonas aeruginosa meningitis	10074185
Narrow	A	Pulmonary mucormycosis	10078354
Narrow	A	Pulmonary mycosis	10037422
Narrow	A	Pulmonary trichosporonosis	10068184
Narrow	A	Pulmonary tuberculoma	10066927
Narrow	A	Pulmonary tuberculosis	10037440
Narrow	A	Pyelonephritis fungal	10065214
Narrow	A	Renal tuberculosis	10038534
Narrow	A	Respiratory tract infection fungal	10060692
Narrow	A	Retinitis histoplasma	10038912
Narrow	A	Retinitis viral	10038915
Narrow	A	Rhinocerebral mucormycosis	10076959
Narrow	A	Rhodococcus infection	10065041
Narrow	A	Salpingitis tuberculous	10039463
Narrow	A	Scedosporium infection	10059045
Narrow	A	Septic arthritis staphylococcal	10040063
Narrow	A	Sinusitis aspergillus	10051016
Narrow	A	Sinusitis fungal	10058678
Narrow	A	Sphingomonas paucimobilis bacteraemia	10081563
Narrow	A	Sphingomonas paucimobilis infection	10069639
Narrow	A	Spleen tuberculosis	10041640
Narrow	A	Splenic candidiasis	10051725
Narrow	A	Splenic infection fungal	10065194
Narrow	A	Stenotrophomonas infection	10054138
Narrow	A	Stenotrophomonas sepsis	10054137
Narrow	A	Superinfection fungal	10066984
Narrow	A	Superinfection mycobacterial	10075381
Narrow	A	Systemic candida	10042938
Narrow	A	Systemic mycosis	10052366
Narrow	A	Thyroid tuberculosis	10043774

Narrow	A	Tonsillitis fungal	10065236
Narrow	A	Toxoplasmosis	10044272
Narrow	A	Tuberculoid leprosy	10044729
Narrow	A	Tuberculoma of central nervous system	10052883
Narrow	A	Tuberculosis	10044755
Narrow	A	Tuberculosis bladder	10044758
Narrow	A	Tuberculosis gastrointestinal	10061390
Narrow	A	Tuberculosis liver	10058120
Narrow	A	Tuberculosis of central nervous system	10061391
Narrow	A	Tuberculosis of eye	10044819
Narrow	A	Tuberculosis of genitourinary system	10044828
Narrow	A	Tuberculosis of intrathoracic lymph nodes	10044846
Narrow	A	Tuberculosis of peripheral lymph nodes	10044965
Narrow	A	Tuberculosis ureter	10045026
Narrow	A	Tuberculous abscess central nervous system	10052884
Narrow	A	Tuberculous endometritis	10071559
Narrow	A	Tuberculous laryngitis	10045072
Narrow	A	Tuberculous pleurisy	10045104
Narrow	A	Tuberculous tenosynovitis	10059161
Narrow	A	Upper respiratory fungal infection	10062219
Narrow	A	Urinary tract infection fungal	10049059
Narrow	A	Varicella zoster gastritis	10074241
Narrow	A	Varicella zoster oesophagitis	10074243
Narrow	A	Varicella zoster pneumonia	10074254
Narrow	A	Varicella zoster sepsis	10074298
Broad	A	Abdominal sepsis	10058040
Broad	A	Abscess fungal	10065330
Broad	A	Acanthamoeba infection	10061618
Broad	A	Achromobacter infection	10082866
Broad	A	Acinetobacter bacteraemia	10064965
Broad	A	Acinetobacter infection	10051894
Broad	A	Actinomyces test positive	10069956
Broad	A	Actinomycosis	10000620
Broad	A	Actinomycotic abdominal infection	10000621
Broad	A	Actinomycotic pulmonary infection	10000628
Broad	A	Actinomycotic skin infection	10000629
Broad	A	Acute haemorrhagic conjunctivitis	10067817
Broad	A	Acute hepatitis B	10059193
Broad	A	Acute hepatitis C	10065051

Broad	A	Adenoviral conjunctivitis	10001257
Broad	A	Adenoviral encephalitis	10080441
Broad	A	Adenoviral hepatitis	10056885
Broad	A	Adenoviral upper respiratory infection	10001260
Broad	A	Adenovirus encephalomyeloradiculitis	10079668
Broad	A	Adenovirus infection	10060931
Broad	A	Adenovirus test positive	10070369
Broad	A	Aeromonas infection	10054205
Broad	A	Aeromonas test positive	10069957
Broad	A	African trypanosomiasis	10001461
Broad	A	Alcaligenes infection	10068911
Broad	A	Allergic bronchopulmonary mycosis	10082909
Broad	A	Allescheriosis	10001754
Broad	A	Alpha haemolytic streptococcal infection	10054265
Broad	A	Alphavirus test positive	10070370
Broad	A	American trypanosomiasis	10001935
Broad	A	Amoeba test positive	10072431
Broad	A	Amoebiasis	10001980
Broad	A	Amoebic colitis	10001985
Broad	A	Amoebic dysentery	10001986
Broad	A	Amoebic skin ulcer	10001992
Broad	A	Anal candidiasis	10002140
Broad	A	Anal fungal infection	10068556
Broad	A	Angina gangrenous	10002379
Broad	A	Angiostrongylus infection	10069517
Broad	A	Anogenital warts	10059313
Broad	A	Anorectal human papilloma virus infection	10073941
Broad	A	Anthrax sepsis	10058873
Broad	A	Anti-JC virus antibody index	10075613
Broad	A	Arbovirus test positive	10070371
Broad	A	Arenavirus test positive	10070376
Broad	A	Arthritis salmonella	10003271
Broad	A	Aspergilloma	10003487
Broad	A	Aspergillus test positive	10070448
Broad	A	Atypical mycobacterium test positive	10070326
Broad	A	Atypical pneumonia	10003757
Broad	A	Avian influenza	10064097
Broad	A	Babesiosis	10003965
Broad	A	Bacteraemia	10003997

Broad	A	Bacterial sepsis	10053840
Broad	A	Bacterial test positive	10059421
Broad	A	Balamuthia infection	10069523
Broad	A	Balanitis candida	10004074
Broad	A	Bartonella test positive	10070157
Broad	A	Bartonellosis	10004145
Broad	A	Beta haemolytic streptococcal infection	10052100
Broad	A	Biliary sepsis	10057847
Broad	A	BK polyomavirus test positive	10070355
Broad	A	Bladder candidiasis	10058523
Broad	A	Blood beta-D-glucan abnormal	10051795
Broad	A	Blood beta-D-glucan increased	10051793
Broad	A	Blood beta-D-glucan positive	10083491
Broad	A	Blood culture positive	10005488
Broad	A	Body tinea	10005913
Broad	A	Botryomycosis	10072055
Broad	A	Bronchitis haemophilus	10006460
Broad	A	Bronchopulmonary aspergillosis allergic	10006474
Broad	A	Brucella sepsis	10054210
Broad	A	Brucella test positive	10070021
Broad	A	Bullous impetigo	10006563
Broad	A	Burkholderia cepacia complex infection	10069657
Broad	A	Burkholderia infection	10073031
Broad	A	Burkholderia mallei infection	10069747
Broad	A	Burkholderia test positive	10069960
Broad	A	Bursitis infective staphylococcal	10048894
Broad	A	Buschke-Lowenstein's tumour	10059427
Broad	A	Campylobacter sepsis	10070681
Broad	A	Campylobacter test positive	10070025
Broad	A	Candida cervicitis	10071209
Broad	A	Candida infection	10074170
Broad	A	Candida test positive	10070451
Broad	A	Capnocytophaga test positive	10070026
Broad	A	Cat scratch disease	10007729
Broad	A	Catheter bacteraemia	10062957
Broad	A	Cellulitis enterococcal	10007904
Broad	A	Cellulitis pasteurella	10007919
Broad	A	Cellulitis staphylococcal	10007921
Broad	A	Cellulitis streptococcal	10007922

Broad	A	Cerebral malaria	10063094
Broad	A	Cervicitis human papilloma virus	10051800
Broad	A	Cervicitis streptococcal	10067236
Broad	A	Cervix warts	10063815
Broad	A	Chancroid	10008392
Broad	A	Chlamydia test positive	10070159
Broad	A	Choriomeningitis lymphocytic	10008761
Broad	A	Choroid tubercles	10008779
Broad	A	Chronic active Epstein-Barr virus infection	10082848
Broad	A	Chronic hepatitis B	10008910
Broad	A	Chronic hepatitis C	10008912
Broad	A	Citrobacter infection	10051904
Broad	A	Citrobacter sepsis	10054213
Broad	A	Citrobacter test positive	10069963
Broad	A	Clostridial sepsis	10078496
Broad	A	Clostridium bacteraemia	10058852
Broad	A	Clostridium colitis	10058305
Broad	A	Clostridium difficile colitis	10009657
Broad	A	Clostridium difficile infection	10054236
Broad	A	Clostridium test positive	10070027
~~Broad~~	~~A~~	~~Coronavirus infection~~	~~10051905~~
~~Broad~~	~~A~~	~~Coronavirus test positive~~	~~10070255~~
Broad	A	Corynebacterium infection	10061092
Broad	A	Corynebacterium sepsis	10057767
Broad	A	Corynebacterium test positive	10070028
Broad	A	Coxiella infection	10053187
Broad	A	Coxiella test positive	10070194
Broad	A	Coxsackie viral disease of the newborn	10011260
Broad	A	Creutzfeldt-Jakob disease	10011384
Broad	A	Cronobacter bacteraemia	10069854
Broad	A	Cronobacter infection	10069855
Broad	A	Cronobacter necrotising enterocolitis	10069939
Broad	A	Cryptococcus test positive	10070455
Broad	A	CSF measles antibody positive	10061795
Broad	A	Cutaneous anthrax	10011660
Broad	A	Cutaneous mucormycosis	10082722
Broad	A	Cutaneous sporotrichosis	10011676
Broad	A	Cyclosporidium infection	10061802
Broad	A	Cystitis escherichia	10011790

Broad	A	Cystitis klebsiella	10011797
Broad	A	Cystitis pseudomonal	10011799
Broad	A	Cytomegalovirus immunisation	10072247
Broad	A	Cytomegalovirus test positive	10051620
Broad	A	Delftia acidovorans infection	10081339
Broad	A	Deltaretrovirus test positive	10070346
Broad	A	Dengue fever	10012310
Broad	A	Device related sepsis	10069802
Broad	A	Ear infection fungal	10068630
Broad	A	Eczema herpeticum	10014197
Broad	A	Encephalitis australia	10014583
Broad	A	Encephalitis california	10014584
Broad	A	Encephalitis eastern equine	10014587
Broad	A	Encephalitis enteroviral	10063946
Broad	A	Encephalitis influenzal	10058094
Broad	A	Encephalitis Japanese B	10014596
Broad	A	Encephalitis meningococcal	10014597
Broad	A	Encephalitis mumps	10014598
Broad	A	Encephalitis post varicella	10014603
Broad	A	Encephalitis protozoal	10061118
Broad	A	Encephalitis rickettsial	10061119
Broad	A	Encephalitis venezuelan equine	10014611
Broad	A	Encephalitis viral	10014612
Broad	A	Encephalitis western equine	10014614
Broad	A	Encephalomyelitis rubella	10014622
Broad	A	Endocarditis enterococcal	10014671
Broad	A	Endocarditis haemophilus	10014675
Broad	A	Endocarditis pseudomonal	10067336
Broad	A	Endocarditis staphylococcal	10014684
Broad	A	Endocarditis viral	10061837
Broad	A	Enterobacter bacteraemia	10058857
Broad	A	Enterobacter infection	10051910
Broad	A	Enterobacter pneumonia	10054218
Broad	A	Enterobacter sepsis	10054219
Broad	A	Enterobacter test positive	10070023
Broad	A	Enterobacter tracheobronchitis	10054220
Broad	A	Enterococcal bacteraemia	10014885
Broad	A	Enterococcal infection	10061124
Broad	A	Enterococcal sepsis	10054221

Broad	A	Enterococcus test positive	10070024
Broad	A	Enterocolitis viral	10061841
Broad	A	Enterovirus test positive	10070386
Broad	A	Epiglottitis haemophilus	10015031
Broad	A	Epstein-Barr viraemia	10065110
Broad	A	Epstein-Barr virus antibody positive	10052324
Broad	A	Epstein-Barr virus antigen positive	10052363
Broad	A	Epstein-Barr virus associated lymphoma	10071441
Broad	A	Epstein-Barr virus infection	10015108
Broad	A	Epstein-Barr virus test positive	10064545
Broad	A	Erysipelas	10015145
Broad	A	Erythema induratum	10015213
Broad	A	Escherichia bacteraemia	10054258
Broad	A	Escherichia infection	10061126
Broad	A	Escherichia sepsis	10015296
Broad	A	Escherichia test positive	10070090
Broad	A	Escherichia urinary tract infection	10052238
Broad	A	Escherichia vaginitis	10054259
Broad	A	Exanthema subitum	10015586
Broad	A	Exserohilum test positive	10073243
Broad	A	Eye infection fungal	10015933
Broad	A	Eye infection staphylococcal	10015937
Broad	A	Eye infection viral	10015940
Broad	A	Flavivirus test positive	10070211
Broad	A	Flavobacterium test positive	10070007
Broad	A	Fungal infection	10017533
Broad	A	Fungal paronychia	10017540
Broad	A	Fungal test positive	10059423
Broad	A	Gastric ulcer helicobacter	10051348
Broad	A	Gastroenteritis adenovirus	10017889
Broad	A	Gastroenteritis aeromonas	10017891
Broad	A	Gastroenteritis Escherichia coli	10017903
Broad	A	Gastroenteritis pseudomonas	10017911
Broad	A	Gastroenteritis salmonella	10017914
Broad	A	Gastroenteritis staphylococcal	10017916
Broad	A	Gastroenteritis vibrio	10017917
Broad	A	Gastrointestinal anthrax	10017931
Broad	A	Gastrointestinal candidiasis	10017938
Broad	A	Genital candidiasis	10018143

Broad	A	Genital herpes	10018150
Broad	A	Genital herpes simplex	10073931
Broad	A	Genital herpes zoster	10072210
Broad	A	Genital infection fungal	10061180
Broad	A	Geotrichum infection	10056660
Broad	A	Group B streptococcus neonatal sepsis	10053588
Broad	A	H1N1 influenza	10069767
Broad	A	Haemophilus bacteraemia	10058922
Broad	A	Haemophilus infection	10061190
Broad	A	Haemophilus sepsis	10058875
Broad	A	Haemophilus test positive	10070100
Broad	A	Helicobacter gastritis	10054272
Broad	A	Helicobacter infection	10054263
Broad	A	Helicobacter sepsis	10054264
Broad	A	Helicobacter test positive	10070101
Broad	A	Hepatitis A antibody abnormal	10019722
Broad	A	Hepatitis A antibody positive	10019725
Broad	A	Hepatitis A antigen positive	10058751
Broad	A	Hepatitis A virus test positive	10070216
Broad	A	Hepatitis B	10019731
Broad	A	Hepatitis B antibody abnormal	10019733
Broad	A	Hepatitis B antibody positive	10019736
Broad	A	Hepatitis B antigen positive	10063411
Broad	A	Hepatitis B core antibody positive	10071344
Broad	A	Hepatitis B core antigen positive	10052328
Broad	A	Hepatitis B DNA assay positive	10060047
Broad	A	Hepatitis B DNA increased	10068379
Broad	A	Hepatitis B e antibody positive	10071348
Broad	A	Hepatitis B e antigen positive	10052329
Broad	A	Hepatitis B surface antibody positive	10071346
Broad	A	Hepatitis B surface antigen positive	10019742
Broad	A	Hepatitis B virus test positive	10070217
Broad	A	Hepatitis C	10019744
Broad	A	Hepatitis C antibody positive	10019747
Broad	A	Hepatitis C core antibody positive	10077052
Broad	A	Hepatitis C RNA increased	10068377
Broad	A	Hepatitis C RNA positive	10019750
Broad	A	Hepatitis C virus test positive	10070218
Broad	A	Hepatitis D	10019762

Broad	A	Hepatitis D antibody positive	10059528
Broad	A	Hepatitis D antigen positive	10058436
Broad	A	Hepatitis D RNA positive	10059540
Broad	A	Hepatitis D virus test positive	10070626
Broad	A	Hepatitis E antibody positive	10057985
Broad	A	Hepatitis E antigen positive	10060049
Broad	A	Hepatitis E virus test positive	10070220
Broad	A	Hepatitis infectious mononucleosis	10019781
Broad	A	Hepatitis non-A non-B	10019786
Broad	A	Hepatitis non-A non-B non-C	10019787
Broad	A	Hepatitis syphilitic	10019794
Broad	A	Hepatitis toxoplasmal	10019798
Broad	A	Hepatitis viral test positive	10072748
Broad	A	Herpes dermatitis	10062639
Broad	A	Herpes gestationis	10019939
Broad	A	Herpes simplex	10019948
Broad	A	Herpes simplex test positive	10077969
Broad	A	Herpes simplex virus conjunctivitis neonatal	10049458
Broad	A	Herpes virus infection	10019973
Broad	A	Herpes zoster	10019974
Broad	A	Human anaplasmosis	10071038
Broad	A	Human ehrlichiosis	10020429
Broad	A	Human herpes virus 6 serology positive	10060827
Broad	A	Human herpes virus 8 test positive	10071210
Broad	A	Human herpesvirus 6 infection	10020431
Broad	A	Human herpesvirus 7 infection	10063571
Broad	A	Human metapneumovirus test positive	10072859
Broad	A	Human papilloma virus test positive	10064328
Broad	A	Human polyomavirus infection	10057366
Broad	A	Immune reconstitution inflammatory syndrome	10065042
Broad	A	Infectious thyroiditis	10071250
Broad	A	Infective aneurysm	10058017
Broad	A	Influenza	10022000
Broad	A	Influenza A virus test positive	10070215
Broad	A	Influenza B virus test positive	10070208
Broad	A	Influenza C virus test positive	10070209
Broad	A	Influenza virus test positive	10070717
Broad	A	Interferon gamma release assay positive	10072866
Broad	A	JC polyomavirus test positive	10070356

Broad	A	Keratitis fungal	10062353
Broad	A	Keratitis viral	10062029
Broad	A	Klebsiella bacteraemia	10058856
Broad	A	Klebsiella infection	10061259
Broad	A	Klebsiella sepsis	10054160
Broad	A	Klebsiella test positive	10070091
Broad	A	Lactobacillus infection	10062031
Broad	A	Legionella infection	10061266
Broad	A	Legionella test positive	10070092
Broad	A	Leishmaniasis	10024198
Broad	A	Leptotrichia infection	10070981
Broad	A	Leuconostoc infection	10070982
Broad	A	Listeria test positive	10070094
Broad	A	Lower respiratory tract infection viral	10065188
Broad	A	Malaria	10025487
Broad	A	Malaria antibody test positive	10070881
Broad	A	Malarial myocarditis	10054123
Broad	A	Meningitis cronobacter	10069856
Broad	A	Meningitis enterococcal	10027232
Broad	A	Meningitis haemophilus	10027241
Broad	A	Meningitis meningococcal	10027249
Broad	A	Meningitis pneumococcal	10027253
Broad	A	Meningitis salmonella	10027254
Broad	A	Meningitis staphylococcal	10027255
Broad	A	Meningitis streptococcal	10027256
Broad	A	Meningitis trypanosomal	10027258
Broad	A	Meningoencephalitis herpes simplex neonatal	10053586
Broad	A	Meningoencephalitis viral	10074672
Broad	A	Metapneumovirus infection	10066226
Broad	A	Micrococcal sepsis	10054162
Broad	A	Micrococcus infection	10054120
Broad	A	Micrococcus test positive	10070001
Broad	A	Microsporum infection	10054121
Broad	A	Middle East respiratory syndrome	10075271
Broad	A	Morganella infection	10054876
Broad	A	Mucocutaneous candidiasis	10028080
Broad	A	Mumps antibody test positive	10059644
Broad	A	Murray Valley encephalitis	10053981
Broad	A	Mycobacterium leprae test positive	10070324

Broad	A	Mycobacterium test positive	10070323
Broad	A	Mycobacterium tuberculosis complex test positive	10070325
Broad	A	Mycotic corneal ulcer	10028518
Broad	A	Mycotoxicosis	10028520
Broad	A	Myocarditis septic	10028615
Broad	A	Nail candida	10028688
Broad	A	Nasal candidiasis	10050345
Broad	A	Nasal herpes	10074936
Broad	A	Necrotising fasciitis staphylococcal	10028887
Broad	A	Necrotising fasciitis streptococcal	10028888
Broad	A	Neisseria test positive	10070096
Broad	A	Neonatal candida infection	10028924
Broad	A	Neonatal infective mastitis	10028950
Broad	A	Neonatal mucocutaneous herpes simplex	10053587
Broad	A	Neutropenic infection	10059482
Broad	A	Neutropenic sepsis	10049151
Broad	A	Nocardia test positive	10070131
Broad	A	Onychomycosis	10030338
Broad	A	Oral candidiasis	10030963
Broad	A	Oral fungal infection	10061324
Broad	A	Oral hairy leukoplakia	10030979
Broad	A	Oral herpes	10067152
Broad	A	Organic dust toxic syndrome	10075078
Broad	A	Oropharyngeal candidiasis	10050346
Broad	A	Oropharyngitis fungal	10061891
Broad	A	Orthopox virus infection	10069586
Broad	A	Orthopoxvirus test positive	10070349
Broad	A	Osteomyelitis salmonella	10031262
Broad	A	Otitis externa candida	10033076
Broad	A	Otitis media haemophilus	10067322
Broad	A	Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	10072147
Broad	A	Pantoea agglomerans infection	10070020
Broad	A	Pantoea agglomerans test positive	10070019
Broad	A	Papilloma viral infection	10061331
Broad	A	Parainfluenzae viral laryngotracheobronchitis	10033797
Broad	A	Parainfluenzae virus infection	10061907
Broad	A	Parasitic encephalitis	10069588
Broad	A	Parechovirus infection	10071449

Broad	A	Pasteurella test positive	10070132
Broad	A	Peliosis hepatis	10034229
Broad	A	Pelvic sepsis	10059070
Broad	A	Penile wart	10034325
Broad	A	Peptostreptococcus infection	10054124
Broad	A	Peptostreptococcus test positive	10070003
Broad	A	Perianal streptococcal infection	10068921
Broad	A	Perinatal HBV infection	10075233
Broad	A	Periporitis staphylogenes	10064163
Broad	A	Peritonitis pneumococcal	10034681
Broad	A	Pharyngeal abscess	10067781
Broad	A	Pharyngoconjunctival fever of children	10034843
Broad	A	Plasmodium falciparum infection	10035500
Broad	A	Plasmodium malariae infection	10035501
Broad	A	Plasmodium ovale infection	10035502
Broad	A	Plasmodium vivax infection	10035503
Broad	A	Pneumococcal bacteraemia	10058859
Broad	A	Pneumococcal infection	10061353
Broad	A	Pneumococcal sepsis	10054047
Broad	A	Pneumocystis test positive	10070454
Broad	A	Pneumonia adenoviral	10035665
Broad	A	Pneumonia anthrax	10035667
Broad	A	Pneumonia escherichia	10035699
Broad	A	Pneumonia haemophilus	10035702
Broad	A	Pneumonia influenzal	10035714
Broad	A	Pneumonia klebsiella	10035717
Broad	A	Pneumonia parainfluenzae viral	10035727
Broad	A	Pneumonia pneumococcal	10035728
Broad	A	Pneumonia pseudomonal	10035731
Broad	A	Pneumonia respiratory syncytial viral	10035732
Broad	A	Pneumonia salmonella	10035733
Broad	A	Pneumonia staphylococcal	10035734
Broad	A	Pneumonia streptococcal	10035735
Broad	A	Polyomavirus test positive	10070342
Broad	A	Pontiac fever	10054161
Broad	A	Porphyromonas infection	10061914
Broad	A	Porphyromonas test positive	10070133
Broad	A	Post streptococcal glomerulonephritis	10036303
Broad	A	Post transplant lymphoproliferative disorder	10051358

Broad	A	Presumed ocular histoplasmosis syndrome	10063664
Broad	A	Prion agent test positive	10070343
Broad	A	Proctitis fungal	10063201
Broad	A	Proctitis monilial	10036781
Broad	A	Prostatitis Escherichia coli	10067320
Broad	A	Pseudomonal bacteraemia	10058923
Broad	A	Pseudomonal sepsis	10058877
Broad	A	Pseudomonas bronchitis	10067024
Broad	A	Pseudomonas infection	10061471
Broad	A	Pseudomonas peritonitis	10082669
Broad	A	Pseudomonas test positive	10070135
Broad	A	Pulmonary sepsis	10051739
Broad	A	Pyoderma streptococcal	10037637
Broad	A	Pythium insidiosum infection	10074264
Broad	A	Q fever	10037688
Broad	A	Raoultella ornithinolytica infection	10070087
Broad	A	Respiratory moniliasis	10038705
Broad	A	Respiratory syncytial virus bronchiolitis	10038718
Broad	A	Respiratory syncytial virus bronchitis	10069811
Broad	A	Respiratory syncytial virus infection	10061603
Broad	A	Respiratory syncytial virus test positive	10068563
Broad	A	Retroviral rebound syndrome	10065989
Broad	A	Rhodococcus test positive	10070005
Broad	A	Roseolovirus test positive	10070213
Broad	A	Rubella antibody positive	10039258
Broad	A	Salmonella bacteraemia	10058924
Broad	A	Salmonella sepsis	10058878
Broad	A	Salmonella test positive	10070127
Broad	A	Salmonellosis	10039447
Broad	A	Scarlet fever	10039587
Broad	A	Sepsis	10040047
Broad	A	Sepsis neonatal	10040049
Broad	A	Sepsis pasteurella	10040051
Broad	A	Sepsis syndrome	10053879
Broad	A	Septic arthritis haemophilus	10040059
Broad	A	Septic arthritis streptobacillus	10040064
Broad	A	Septic arthritis streptococcal	10067323
Broad	A	Septic coagulopathy	10083159
Broad	A	Septic embolus	10040067

Broad	A	Septic necrosis	10052762
Broad	A	Septic phlebitis	10056518
Broad	A	Septic pulmonary embolism	10083093
Broad	A	Septic shock	10040070
Broad	A	Serratia bacteraemia	10058921
Broad	A	Serratia infection	10061512
Broad	A	Serratia sepsis	10058879
Broad	A	Serratia test positive	10070128
Broad	A	Severe acute respiratory syndrome	10061982
Broad	A	Severe invasive streptococcal infection	10072839
Broad	A	Shewanella algae bacteraemia	10076437
Broad	A	Shigella infection	10054178
Broad	A	Shigella test positive	10070129
Broad	A	Silicotuberculosis	10068876
Broad	A	Skin candida	10054152
Broad	A	Sporotrichosis	10041736
Broad	A	Spotted fever rickettsia test positive	10070196
Broad	A	St. Louis encephalitis	10041896
Broad	A	Staphylococcal abscess	10041917
Broad	A	Staphylococcal bacteraemia	10051017
Broad	A	Staphylococcal impetigo	10041923
Broad	A	Staphylococcal infection	10058080
Broad	A	Staphylococcal mediastinitis	10066410
Broad	A	Staphylococcal osteomyelitis	10064250
Broad	A	Staphylococcal scalded skin syndrome	10041929
Broad	A	Staphylococcal sepsis	10056430
Broad	A	Staphylococcal skin infection	10066409
Broad	A	Staphylococcal toxaemia	10041932
Broad	A	Staphylococcus test positive	10070052
Broad	A	Stenotrophomonas test positive	10070006
Broad	A	Stoma site candida	10059052
Broad	A	Stomatococcal infection	10068385
Broad	A	Stomatococcus test positive	10070008
Broad	A	Streptobacillary fever	10042175
Broad	A	Streptobacillus infection	10062118
Broad	A	Streptobacillus test positive	10070054
Broad	A	Streptococcal abscess	10042176
Broad	A	Streptococcal bacteraemia	10051018
Broad	A	Streptococcal endocarditis	10073742

Broad	A	Streptococcal impetigo	10042178
Broad	A	Streptococcal infection	10061372
Broad	A	Streptococcal sepsis	10048960
Broad	A	Streptococcal urinary tract infection	10070300
Broad	A	Streptococcus test positive	10070055
Broad	A	Streptokinase antibody increased	10053797
Broad	A	Strongyloidiasis	10042254
Broad	A	Subacute sclerosing panencephalitis	10042297
Broad	A	Syphilis	10062120
Broad	A	Systemic inflammatory response syndrome	10051379
Broad	A	Thrombophlebitis septic	10043593
Broad	A	Tick-borne viral encephalitis	10043847
Broad	A	Torulopsis infection	10053188
Broad	A	Toxic shock syndrome staphylococcal	10044250
Broad	A	Toxic shock syndrome streptococcal	10044251
Broad	A	Toxoplasma serology positive	10056278
Broad	A	Toxoplasmosis prophylaxis	10066653
Broad	A	Treponema test positive	10070158
Broad	A	Trichophytic granuloma	10053419
Broad	A	Trichosporon infection	10053461
Broad	A	Trypanosoma serology positive	10063055
Broad	A	Trypanosomiasis	10044707
Broad	A	Tuberculid	10044725
Broad	A	Tuberculin test false negative	10074840
Broad	A	Tuberculin test false positive	10064057
Broad	A	Tuberculin test positive	10044728
Broad	A	Typhus rickettsia test positive	10070193
Broad	A	Urinary tract candidiasis	10083162
Broad	A	Urinary tract infection enterococcal	10046572
Broad	A	Urinary tract infection pseudomonal	10062279
Broad	A	Urinary tract infection staphylococcal	10062280
Broad	A	Urogenital infection fungal	10065582
Broad	A	Urosepsis	10048709
Broad	A	Variant Creutzfeldt-Jakob disease	10064199
Broad	A	Varicella	10046980
Broad	A	Varicella post vaccine	10063522
Broad	A	Varicella virus test positive	10070214
Broad	A	Varicella zoster virus infection	10075611
Broad	A	Vibrio test positive	10070161

Broad	A	Viraemia	10058874
Broad	A	Viral myelitis	10071763
Broad	A	Viral myocarditis	10047470
Broad	A	Viral oesophagi.tis	10060190
Broad	A	Viral pericarditis	10047472
Broad	A	Viral sepsis	10071362
Broad	A	Viral test positive	10059424
Broad	A	Viral uveitis	10071005
Broad	A	Vulvovaginal candidiasis	10047784
Broad	A	Vulvovaginal human papilloma vims infection	10066416
Broad	A	West Nile viral infection	10057293
Broad	A	West Nile vims test positive	10068812
Broad	A	Wound infection fungal	10065242
Broad	A	Wound infection pseudomonas	10059444
Broad	A	Wound infection staphylococcal	10059442
Broad	A	Wound sepsis	10058041
Broad	A	Yersinia sepsis	10072902
Broad	A	Yersinia test positive	10070162

Haematopoietic cytopenias (SMQ)			
Scope	*Group*	*PT*	*PT Code*
Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)			
NaITow	**A**	Aplastic anaemia	10002967
NaITow	**A**	Autoimmune aolastic anaemia	10071576
NaITow	**A**	Bicytopenia	10058956
NaITow	**A**	Bone maiTow failure	10065553
NaITow	**A**	Cytopenia	10066274
NaITow	**A**	Febrile bone mairnw aplasia	10053213
NaITow	**A**	Full blood count decreased	10017413
NaITow	**A**	Gelatinous transfonnation of the bone marrow	10078097
NaITow	**A**	Immune-mediated pancytopenia	10083004
NaITow	**A**	Pancytopenia	10033661
NaITow	**A**	Panmyelopathy	10050026
Broad	**A**	Aspiration bone maITow abnonnal	10003506
Broad	**A**	Biopsy bone maiTow abno1mal	10004738
Broad	**A**	Blood count abno1mal	10064198
Broad	**A**	Blood disorder	10061590
Broad	**A**	Bone maiTow disorder	10061729

Broad	A	Bone maiTow infiltrntion	10075173
Broad	A	Bone maiTow mvelo!Zram abnonnal	10057528
Broad	A	Bone maiTow necrosis	10058822
Broad	A	Bone maiTow toxicity	10051779
Broad	A	Congenital aplastic anaemia	10053138
Broad	A	Haematotoxicitv	10061188
Broad	A	Myelodysplastic syndrome	10028533
Broad	A	Myelodysplastic syndrome trnnsfonnation	10067387
Broad	A	Mvelofibrosis	10028537
Broad	A	Mveloid metaplasia	10028561
Broad	A	Plasmablast count decreased	10058774
Broad	A	Primary myelofibrosis	10077161
Broad	A	Scan bone maITow abnonnal	10053504
Haematopoietic erythropenia (SMQ)			
NaITow	A	Anaemia macrocytic	10002064
NaITow	A	Aplasia pure red cell	10002965
NaITow	A	Aplastic anaemia	10002967
NaITow	A	Ervthroblast count decreased	10058505
NaITow	A	Erythroid maturation aITest	10015279
NaITow	A	Erythropenia	10015287
NaITow	A	Hypoplastic anaemia	10021074
NaITow	A	Microcvtic anaemia	10027538
NaITow	A	Proerythroblast count decreased	10060229
NaITow	A	Red blood cell count decreased	10038153
NaITow	A	Reticulocvte count decreased	10038790
NaITow	A	Reticulocytopenia	10038795
Broad	A	Anaemia	10002034
Broad	A	Anaemia neonatal	10002068
Broad	A	Ervthroblast count abnormal	10058508
Broad	A	Ervthropoiesis abnonnal	10049467
Broad	A	Foetal anaemia	10077577
Broad	A	Haematocrit abnonnal	10049221
Broad	A	Haematocrit decreased	10018838
Broad	A	Haemo1Zlobin abnonnal	10018879
Broad	A	Haemoglobin decreased	10018884
Broad	A	Leukoerythroblastic anaemia	10053199
Broad	A	Nonnochromic anaemia	10029782
Broad	A	Nonnochromic n01mocvtic anaemia	10029783
Broad	A	Nonnocytic anaemia	10029784

Broad	A	Proervthroblast count abno1mal	10060227
Broad	A	Red blood cell count abno1mal	10038151
Broad	A	Reticulocyte count abnormal	10038788
Broad	A	Reticulocyte percentage decreased	10059921
Haematopoietic leukopenia (SMQ)			
NaITow	**A**	A1zranulocvtosis	10001507
NaITow	**A**	Band neutrophil count decreased	10057950
NaITow	**A**	Band neutrophil percentage decreased	10059130
NaITow	**A**	Basophil count decreased	10004167
NaITow	**A**	Basophilopenia	10075813
NaITow	**A**	B-lymphocyte count decreased	10051313
NaITow	**A**	Cyclic neutropenia	10053176
NaITow	**A**	Eosinopenia	10014940
NaITow	**A**	Eosinophil count decreased	10014943
NaITow	**A**	Febrile neutropenia	10016288
NaITow	**A**	Granulocyte count decreased	10018681
NaITow	**A**	Granulocvtes maturation anest	10050443
NaITow	**A**	Granulocytopenia	10018687
NaITow	**A**	Idiopathic neutropenia	10051645
NaITow	**A**	Leukopenia	10024384
NaITow	**A**	Lymphocvte count decreased	10025256
NaITow	**A**	Lvmohooenia	10025327
NaITow	**A**	Metamyelocyte count decreased	10050984
NaITow	**A**	Monoblast count decreased	10058772
NaITow	**A**	Monocvte count decreased	10027878
NaITow	**A**	Monocytopenia	10027905
NaITow	**A**	Myeloblast count decreased	10050961
NaITow	**A**	Myelocyte count decreased	10050986
NaITow	**A**	Neutropenia	10029354
NaITow	**A**	Neutropenic infection	10059482
NaITow	**A**	Neutropenic sepsis	**10049151**
NaITow	**A**	Neutrophil count decreased	10029366
NaITow	**A**	Promvelocvte count decreased	10050987
NaITow	**A**	Pure white cell aolasia	10068043
NaITow	**A**	Radiation leukopenia	10067354
NaITow	**A**	T-lymphocyte count decreased	10051318
NaITow	**A**	White blood cell count decreased	10047942
Broad	**A**	Basophil count abno1mal	10060978
Broad	**A**	Basophil percentage decreased	10052219

Broad	A	B-lvmphocvte abno1malities	10053775
Broad	A	B-lvmphocvte count abnonnal	10078589
Broad	A	Differential white blood cell count abnonnal	10012785
Broad	A	Eosinophil count abno1mal	10061125
Broad	A	Eosinophil percentage decreased	10052221
Broad	A	Full blood count abnonnal	10017412
Broad	A	Granulocytes abno1mal	10018685
Broad	A	Granulocytopenia neonatal	10018688
Broad	A	Leukopenia neonatal	10050504
Broad	A	Lymphocvte count abnormal	10025252
Broad	A	Lymphocyte percentage abno1mal	10063337
Broad	A	Lymphocyte percentage decreased	10052231
Broad	A	Lymphocytopenia neonatal	10025279
Broad	A	Monocvte count abno1mal	10061293
Broad	A	Monocyte percentage decreased	10052229
Broad	A	Mononuclear cell count decreased	10082036
Broad	A	Mveloblast percentage decreased	10052225
Broad	A	Mvelocvte percentage decreased	10052227
Broad	A	Myeloid maturation aiTest	10028560
Broad	A	Neutropenia neonatal	10029358
Broad	A	Neutrophil count abno1mal	10061313
Broad	A	Neutrophil percentage decreased	10052223
Broad	A	Plasma cell disorder	10062081
Broad	A	Plasma cells absent	10035230
Broad	A	T-lvmphocvte count abno1mal	10057284
Broad	A	White blood cell analysis abno1mal	10073323
Broad	A	White blood cell count abno1mal	10047940
Broad	A	White blood cell disorder	10061414
Haematopoietic thrombocytopenia (SMQ)			
NaITow	A	Acquired amegakarvocvtic thrombocytopenia	10076747
NaITow	A	Megakaryocytes decreased	10027119
NaITow	A	Platelet count decreased	10035528
NaITow	A	Platelet maturation aiTest	10035537
NaITow	A	Platelet production decreased	10035540
NaITow	A	Platelet toxicity	10059440
NaITow	A	Thrombocytopenia	10043554
Broad	A	Megakarvocvtes abnonnal	10027118
Broad	A	Platelet count abno1mal	10035526
Broad	A	Platelet disorder	10035532

Broad	A	Plateletcrit abnonnal	10064785
Broad	A	Plateletcrit decreased	10064784
Broad	A	Thrombocytopenia neonatal	10043557

Hypersensitivity (SMQ)			
Scope	*Group*	*PT*	*PT Code*
NaITow	A	Acquired Cl inhibitor deficiency	10081035
NaITow	A	Acute generalised exanthematous pustulosis	10048799
NaITow	A	Administrntion related reaction	10069773
NaITow	A	Administrntion site de1matitis	10075096
NaITow	A	Administration site eczema	10075099
NaITow	A	Administration site hypersensitivity	10075102
NaITow	A	Administration site rash	10071156
NaITow	A	Administration site recall reaction	10075964
NaITow	A	Administration site urticaria	10075109
NaITow	A	Administration site vasculitis	10075969
NaITow	A	Allergic bronchitis	10052613
NaITow	A	Allergic colitis	10059447
NaITow	A	Allergic cough	10053779
NaITow	A	Allergic cystitis	10051394
NaITow	A	Allergic eosinophilia	10075185
NaITow	A	Allergic gastroenteritis	10075308
NaITow	A	Allergic hepatitis	10071198
NaITow	A	Allergic keratitis	10057380
NaITow	A	Allergic oedema	10060934
NaITow	A	Allergic otitis extema	10075072
NaITow	A	Allergic otitis media	10061557
NaITow	A	Allergic pharyngitis	10050639
NaITow	A	Allergic reaction to excipient	10078853
NaITow	A	Allergic resoiratory disease	10063532
NaITow	A	Allergic respiratory symptom	10063527
NaITow	A	Allergic sinusitis	10049153
NaITow	A	Allergic stomatitis	10079554
NaITow	A	Allergic transfusion reaction	10066173
NaITow	A	Allergy aleit test positive	10075479
NaITow	A	Allenrv test positive	10056352
NaITow	A	Allernv to immunoglobulin therapy	10074079
NaITow	A	Allergy to sur!rical sutures	10077279
NaITow	A	Allergy to vaccine	10055048

Narrow	A	Anal eczema	10078682
Narrow	A	Anaphylactic reaction	10002198
Narrow	A	Anaphylactic shock	10002199
Narrow	A	Anaphylactic transfusion reaction	10067113
Narrow	A	Anaphylactoid reaction	10002216
Narrow	A	Anaphylactoid shock	10063119
Narrow	A	Anaphylaxis treatment	10002222
Narrow	A	Angioedema	10002424
Narrow	A	Antiallergic therapy	10064059
Narrow	A	Antiendomysial antibody positive	10065514
Narrow	A	Anti-neutrophil cytoplasmic antibody positive vasculitis	10050894
Narrow	A	Application site dermatitis	10003036
Narrow	A	Application site eczema	10050099
Narrow	A	Application site hypersensitivity	10063683
Narrow	A	Application site rash	10003054
Narrow	A	Application site recall reaction	10076024
Narrow	A	Application site urticaria	10050104
Narrow	A	Application site vasculitis	10076027
Narrow	A	Arthritis allergic	10061430
Narrow	A	Aspirin-exacerbated respiratory disease	10075084
Narrow	A	Atopic cough	10081492
Narrow	A	Atopy	10003645
Narrow	A	Blepharitis allergic	10005149
Narrow	A	Blood immunoglobulin E abnormal	10005589
Narrow	A	Blood immunoglobulin E increased	10005591
Narrow	A	Bromoderma	10006404
Narrow	A	Bronchospasm	10006482
Narrow	A	Bullous haemorrhagic dermatosis	10083809
Narrow	A	Catheter site dermatitis	10073992
Narrow	A	Catheter site eczema	10073995
Narrow	A	Catheter site hypersensitivity	10073998
Narrow	A	Catheter site rash	10052271
Narrow	A	Catheter site urticaria	10052272
Narrow	A	Catheter site vasculitis	10074014
Narrow	A	Chronic eosinophilic rhinosinusitis	10071399
Narrow	A	Chronic hyperplastic eosinophilic sinusitis	10071380
Narrow	A	Circulatory collapse	10009192
Narrow	A	Circumoral oedema	10052250

Narrow	A	Circumoral swelling	10081703
Narrow	A	Conjunctival oedema	10010726
Narrow	A	Conjunctivitis allergic	10010744
Narrow	A	Contact stomatitis	10067510
Narrow	A	Contrast media allergy	10066973
Narrow	A	Contrast media reaction	10010836
Narrow	A	Corneal oedema	10011033
Narrow	A	Cutaneous vasculitis	10011686
Narrow	A	Dennie-Morgan fold	10062918
Narrow	A	Dermatitis	10012431
Narrow	A	Dermatitis acneiform	10012432
Narrow	A	Dermatitis allergic	10012434
Narrow	A	Dermatitis atopic	10012438
Narrow	A	Dermatitis bullous	10012441
Narrow	A	Dermatitis contact	10012442
Narrow	A	Dermatitis exfoliative	10012455
Narrow	A	Dermatitis exfoliative generalised	10012456
Narrow	A	Dermatitis herpetiformis	10012468
Narrow	A	Dermatitis infected	10012470
Narrow	A	Dermatitis psoriasiform	10058675
Narrow	A	Device allergy	10072867
Narrow	A	Dialysis membrane reaction	10076665
Narrow	A	Distributive shock	10070559
Narrow	A	Documented hypersensitivity to administered product	10076470
Narrow	A	Drug eruption	10013687
Narrow	A	Drug hypersensitivity	10013700
Narrow	A	Drug provocation test	10074350
Narrow	A	Drug reaction with eosinophilia and systemic symptoms	10073508
Narrow	A	Eczema	10014184
Narrow	A	Eczema infantile	10014198
Narrow	A	Eczema nummular	10014201
Narrow	A	Eczema vaccinatum	10066042
Narrow	A	Eczema vesicular	10058681
Narrow	A	Eczema weeping	10055182
Narrow	A	Encephalitis allergic	10056387
Narrow	A	Encephalopathy allergic	10014627
Narrow	A	Eosinophilic granulomatosis with polyangiitis	10078117
Narrow	A	Epidermal necrosis	10059284

Narrow	A	Epidermolysis	10053177
Narrow	A	Epidermolysis bullosa	10014989
Narrow	A	Epiglottic oedema	10015029
Narrow	A	Erythema multiforme	10015218
Narrow	A	Erythema nodosum	10015226
Narrow	A	Exfoliative rash	10064579
Narrow	A	Eye allergy	10015907
Narrow	A	Eye oedema	10052139
Narrow	A	Eye swelling	10015967
Narrow	A	Eyelid oedema	10015993
Narrow	A	Face oedema	10016029
Narrow	A	Fixed eruption	10016741
Narrow	A	Giant papillary conjunctivitis	10018258
Narrow	A	Gingival oedema	10049305
Narrow	A	Gingival swelling	10018291
Narrow	A	Gleich's syndrome	10066837
Narrow	A	Haemorrhagic urticaria	10059499
Narrow	A	Hand dermatitis	10058898
Narrow	A	Henoch-Schonlein purpura	10019617
Narrow	A	Henoch-Schonlein purpura nephritis	10069440
Narrow	A	Heparin-induced thrombocytopenia	10062506
Narrow	A	Hereditary angioedema	10019860
Narrow	A	Hereditary angioedema with C1 esterase inhibitor deficiency	10080955
Narrow	A	Hypersensitivity	10020751
Narrow	A	Hypersensitivity myocarditis	10081004
Narrow	A	Hypersensitivity pneumonitis	10081988
Narrow	A	Hypersensitivity vasculitis	10020764
Narrow	A	Idiopathic urticaria	10021247
Narrow	A	Immediate post-injection reaction	10067142
Narrow	A	Immune thrombocytopenia	10083842
Narrow	A	Immune tolerance induction	10070581
Narrow	A	Implant site dermatitis	10063855
Narrow	A	Implant site hypersensitivity	10063858
Narrow	A	Implant site rash	10063786
Narrow	A	Implant site urticaria	10063787
Narrow	A	Incision site dermatitis	10073168
Narrow	A	Incision site rash	10073411
Narrow	A	Infusion related hypersensitivity reaction	10082742

Narrow	A	Infusion related reaction	10051792
Narrow	A	Infusion site dermatitis	10065458
Narrow	A	Infusion site eczema	10074850
Narrow	A	Infusion site hypersensitivity	10065471
Narrow	A	Infusion site rash	10059830
Narrow	A	Infusion site recall reaction	10076085
Narrow	A	Infusion site urticaria	10065490
Narrow	A	Infusion site vasculitis	10074851
Narrow	A	Injection related reaction	10071152
Narrow	A	Injection site dermatitis	10022056
Narrow	A	Injection site eczema	10066221
Narrow	A	Injection site hypersensitivity	10022071
Narrow	A	Injection site rash	10022094
Narrow	A	Injection site recall reaction	10066797
Narrow	A	Injection site urticaria	10022107
Narrow	A	Injection site vasculitis	10067995
Narrow	A	Instillation site hypersensitivity	10073612
Narrow	A	Instillation site rash	10073622
Narrow	A	Instillation site urticaria	10073627
Narrow	A	Interstitial granulomatous dermatitis	10067972
Narrow	A	Intestinal angioedema	10076229
Narrow	A	Iodine allergy	10052098
Narrow	A	Kaposi's varicelliform eruption	10051891
Narrow	A	Kounis syndrome	10069167
Narrow	A	Laryngeal oedema	10023845
Narrow	A	Laryngitis allergic	10064866
Narrow	A	Laryngospasm	10023891
Narrow	A	Laryngotracheal oedema	10023893
Narrow	A	Limbal swelling	10070492
Narrow	A	Lip oedema	10024558
Narrow	A	Lip swelling	10024570
Narrow	A	Mast cell degranulation present	10076606
Narrow	A	Medical device site dermatitis	10075572
Narrow	A	Medical device site eczema	10075575
Narrow	A	Medical device site hypersensitivity	10075579
Narrow	A	Medical device site rash	10075585
Narrow	A	Medical device site recall reaction	10076140
Narrow	A	Medical device site urticaria	10075588
Narrow	A	Mouth swelling	10075203

Narrow	A	Mucocutaneous rash	10056671
Narrow	A	Multiple allergies	10028164
Narrow	A	Nephritis allergic	10029120
Narrow	A	Nikolsky's sign	10029415
Narrow	A	Nodular rash	10075807
Narrow	A	Nutritional supplement allergy	10084049
Narrow	A	Oculomucocutaneous syndrome	10030081
Narrow	A	Oculorespiratory syndrome	10067317
Narrow	A	Oedema mouth	10030110
Narrow	A	Oral allergy syndrome	10068355
Narrow	A	Oropharyngeal blistering	10067950
Narrow	A	Oropharyngeal oedema	10078783
Narrow	A	Oropharyngeal spasm	10031111
Narrow	A	Oropharyngeal swelling	10031118
Narrow	A	Palatal oedema	10056998
Narrow	A	Palatal swelling	10074403
Narrow	A	Palisaded neutrophilic granulomatous dermatitis	10068809
Narrow	A	Palpable purpura	10056872
Narrow	A	Pathergy reaction	10074332
Narrow	A	Perioral dermatitis	10034541
Narrow	A	Periorbital oedema	10034545
Narrow	A	Periorbital swelling	10056647
Narrow	A	Pharyngeal oedema	10034829
Narrow	A	Pharyngeal swelling	10082270
Narrow	A	Procedural shock	10080894
Narrow	A	Pruritus allergic	10063438
Narrow	A	Radioallergosorbent test positive	10037789
Narrow	A	Rash	10037844
Narrow	A	Rash erythematous	10037855
Narrow	A	Rash follicular	10037857
Narrow	A	Rash macular	10037867
Narrow	A	Rash maculo-papular	10037868
Narrow	A	Rash maculovesicular	10050004
Narrow	A	Rash morbilliform	10037870
Narrow	A	Rash neonatal	10037871
Narrow	A	Rash papulosquamous	10037879
Narrow	A	Rash pruritic	10037884
Narrow	A	Rash pustular	10037888
Narrow	A	Rash rubelliform	10057984

Narrow	A	Rash scarlatiniform	10037890
Narrow	A	Rash vesicular	10037898
Narrow	A	Reaction to azo-dyes	10037973
Narrow	A	Reaction to colouring	10037974
Narrow	A	Reaction to excipient	10079925
Narrow	A	Reaction to food additive	10037977
Narrow	A	Reaction to preservatives	10064788
Narrow	A	Red man syndrome	10038192
Narrow	A	Rhinitis allergic	10039085
Narrow	A	Scleral oedema	10057431
Narrow	A	Scleritis allergic	10051126
Narrow	A	Scrotal dermatitis	10083260
Narrow	A	Scrotal oedema	10039755
Narrow	A	Serum sickness	10040400
Narrow	A	Serum sickness-like reaction	10040402
Narrow	A	Shock	10040560
Narrow	A	Shock symptom	10040581
Narrow	A	SJS-TEN overlap	10083164
Narrow	A	Skin necrosis	10040893
Narrow	A	Skin reaction	10040914
Narrow	A	Skin test positive	10040934
Narrow	A	Solar urticaria	10041307
Narrow	A	Solvent sensitivity	10041316
Narrow	A	Stevens-Johnson syndrome	10042033
Narrow	A	Stoma site hypersensitivity	10074509
Narrow	A	Stoma site rash	10059071
Narrow	A	Swelling face	10042682
Narrow	A	Swelling of eyelid	10042690
Narrow	A	Swollen tongue	10042727
Narrow	A	Symmetrical drug-related intertriginous and flexural exanthema	10078325
Narrow	A	Therapeutic product cross-reactivity	10079645
Narrow	A	Tongue oedema	10043967
Narrow	A	Toxic epidermal necrolysis	10044223
Narrow	A	Toxic skin eruption	10057970
Narrow	A	Tracheal oedema	10044296
Narrow	A	Type I hypersensitivity	10045240
Narrow	A	Type II hypersensitivity	10054000
Narrow	A	Type III immune complex mediated reaction	10053614

Narrow	A	Type IV hypersensitivity reaction	10053613
Narrow	A	Urticaria	10046735
Narrow	A	Urticaria cholinergic	10046740
Narrow	A	Urticaria chronic	10052568
Narrow	A	Urticaria contact	10046742
Narrow	A	Urticaria papular	10046750
Narrow	A	Urticaria physical	10046751
Narrow	A	Urticaria pigmentosa	10046752
Narrow	A	Urticaria vesiculosa	10046755
Narrow	A	Urticarial dermatitis	10082290
Narrow	A	Urticarial vasculitis	10048820
Narrow	A	Vaccination site dermatitis	10069477
Narrow	A	Vaccination site eczema	10076161
Narrow	A	Vaccination site exfoliation	10069489
Narrow	A	Vaccination site hypersensitivity	10068880
Narrow	A	Vaccination site rash	10069482
Narrow	A	Vaccination site recall reaction	10076188
Narrow	A	Vaccination site urticaria	10069622
Narrow	A	Vaccination site vasculitis	10076191
Narrow	A	Vaccination site vesicles	10069623
Narrow	A	Vaginal ulceration	10046943
Narrow	A	Vasculitic rash	10047111
Narrow	A	Vernal keratoconjunctivitis	10081000
Narrow	A	Vessel puncture site rash	10077117
Narrow	A	Vessel puncture site vesicles	10077813
Narrow	A	Vulval eczema	10066273
Narrow	A	Vulval ulceration	10047768
Narrow	A	Vulvovaginal rash	10071588
Narrow	A	Vulvovaginal ulceration	10050181
Narrow	A	Vulvovaginitis allergic	10080783
Broad	A	Acute respiratory failure	10001053
Broad	A	Administration site photosensitivity reaction	10075961
Broad	A	Airway remodelling	10075289
Broad	A	Allergy to chemicals	10061626
Broad	A	Allergy to fermented products	10054929
Broad	A	Alpha tumour necrosis factor increased	10059982
Broad	A	Alveolitis	10001889
Broad	A	Antibody test abnormal	10061425
Broad	A	Antibody test positive	10061427

Broad	A	Anti-insulin antibody increased	10053815
Broad	A	Anti-insulin antibody positive	10053814
Broad	A	Anti-insulin receptor antibody increased	10068226
Broad	A	Anti-insulin receptor antibody positive	10068225
Broad	A	Application site photosensitivity reaction	10058730
Broad	A	Asthma	10003553
Broad	A	Asthma late onset	10003559
Broad	A	Asthma-chronic obstructive pulmonary disease overlap syndrome	10077005
Broad	A	Asthmatic crisis	10064823
Broad	A	Auricular swelling	10003800
Broad	A	Blister	10005191
Broad	A	Blister rupture	10073385
Broad	A	Blood immunoglobulin A abnormal	10005584
Broad	A	Blood immunoglobulin A increased	10005586
Broad	A	Blood immunoglobulin D increased	10063244
Broad	A	Blood immunoglobulin G abnormal	10005594
Broad	A	Blood immunoglobulin G increased	10005596
Broad	A	Blood immunoglobulin M abnormal	10005599
Broad	A	Blood immunoglobulin M increased	10005601
Broad	A	Bronchial hyperreactivity	10066091
Broad	A	Bronchial oedema	10056695
Broad	A	Bullous impetigo	10006563
Broad	A	Caffeine allergy	10074895
Broad	A	Capillaritis	10068406
Broad	A	Charcot-Leyden crystals	10008413
Broad	A	Cheilitis	10008417
Broad	A	Childhood asthma	10081274
Broad	A	Choking	10008589
Broad	A	Choking sensation	10008590
Broad	A	Complement factor C1 decreased	10051552
Broad	A	Complement factor C2 decreased	10051555
Broad	A	Complement factor C3 decreased	10050981
Broad	A	Complement factor C4 decreased	10050983
Broad	A	Complement factor decreased	10061048
Broad	A	Conjunctivitis	10010741
Broad	A	Corneal exfoliation	10064489
Broad	A	Cough variant asthma	10063076
Broad	A	Cytokine release syndrome	10052015

Broad	A	Cytokine storm	10050685
Broad	A	Ear swelling	10014025
Broad	A	Eosinophil count abnormal	10061125
Broad	A	Eosinophil count increased	10014945
Broad	A	Eosinophil percentage abnormal	10058133
Broad	A	Eosinophil percentage increased	10052222
Broad	A	Eosinophilia	10014950
Broad	A	Eosinophilia myalgia syndrome	10014952
Broad	A	Eosinophilic bronchitis	10065563
Broad	A	Eosinophilic oesophagitis	10064212
Broad	A	Eosinophilic pneumonia	10014962
Broad	A	Eosinophilic pneumonia acute	10052832
Broad	A	Eosinophilic pneumonia chronic	10052833
Broad	A	Erythema	10015150
Broad	A	Flushing	10016825
Broad	A	Gastrointestinal oedema	10058061
Broad	A	Generalised oedema	10018092
Broad	A	Genital rash	10018175
Broad	A	Genital swelling	10067639
Broad	A	Haemolytic transfusion reaction	10067122
Broad	A	HLA marker study positive	10067937
Broad	A	Human anti-hamster antibody increased	10082107
Broad	A	Human anti-hamster antibody positive	10082109
Broad	A	Immune complex level increased	10064650
Broad	A	Immunoglobulins abnormal	10021497
Broad	A	Immunoglobulins increased	10021500
Broad	A	Immunology test abnormal	10061214
Broad	A	Implant site photosensitivity	10073415
Broad	A	Infusion site photosensitivity reaction	10065486
Broad	A	Injection site panniculitis	10083040
Broad	A	Injection site photosensitivity reaction	10053396
Broad	A	Interstitial lung disease	10022611
Broad	A	Laryngeal dyspnoea	10052390
Broad	A	Laryngeal obstruction	10059639
Broad	A	Leukotriene increased	10064663
Broad	A	Lip exfoliation	10064482
Broad	A	Localised oedema	10048961
Broad	A	Macrophage inflammatory protein-1 alpha increased	10083049
Broad	A	Mechanical urticaria	10068773

Broad	A	Medical device site photosensitivity reaction	10076137
Broad	A	Mesenteric panniculitis	10063031
Broad	A	Monocyte chemotactic protein-2 increased	10083043
Broad	A	Mouth ulceration	10028034
Broad	A	Mucocutaneous ulceration	10028084
Broad	A	Mucosa vesicle	10028103
Broad	A	Mucosal erosion	10061297
Broad	A	Mucosal exfoliation	10064486
Broad	A	Mucosal necrosis	10067993
Broad	A	Mucosal ulceration	10028124
Broad	A	Nasal crease	10078581
Broad	A	Necrotising panniculitis	10062579
Broad	A	Neurodermatitis	10029263
Broad	A	Neutralising antibodies positive	10064980
Broad	A	Noninfective conjunctivitis	10074701
Broad	A	Non-neutralising antibodies positive	10064982
Broad	A	Occupational asthma	10070836
Broad	A	Occupational dermatitis	10030012
Broad	A	Oedema mucosal	10030111
Broad	A	Oral mucosal exfoliation	10064487
Broad	A	Orbital oedema	10031051
Broad	A	Panniculitis	10033675
Broad	A	Penile exfoliation	10064485
Broad	A	Penile oedema	10066774
Broad	A	Penile rash	10082571
Broad	A	Penile swelling	10034319
Broad	A	Perineal rash	10075364
Broad	A	Perivascular dermatitis	10064986
Broad	A	Photosensitivity reaction	10034972
Broad	A	Pneumonitis	10035742
Broad	A	Prurigo	10037083
Broad	A	Pruritus	10037087
Broad	A	Pulmonary eosinophilia	10037382
Broad	A	Reactive airways dysfunction syndrome	10070832
Broad	A	Respiratory arrest	10038669
Broad	A	Respiratory distress	10038687
Broad	A	Respiratory failure	10038695
Broad	A	Respiratory tract oedema	10070774
Broad	A	Reversible airways obstruction	10062109

Broad	A	Rhinitis perennial	10039094
Broad	A	Scrotal exfoliation	10081178
Broad	A	Scrotal swelling	10039759
Broad	A	Seasonal allergy	10048908
Broad	A	Septal panniculitis	10056876
Broad	A	Skin erosion	10040840
Broad	A	Skin exfoliation	10040844
Broad	A	Skin oedema	10058679
Broad	A	Skin swelling	10053262
Broad	A	Sneezing	10041232
Broad	A	Status asthmaticus	10041961
Broad	A	Stomatitis	10042128
Broad	A	Streptokinase antibody increased	10053797
Broad	A	Stridor	10042241
Broad	A	Suffocation feeling	10042444
Broad	A	Sunscreen sensitivity	10083629
Broad	A	Throat tightness	10043528
Broad	A	Tongue exfoliation	10064488
Broad	A	Tracheal obstmction	10044291
Broad	A	Tracheostomy	10044320
Broad	A	Transplantation associated food allergy	10075008
Broad	A	Uooer ai1wav obstruction	10067775
Broad	A	Vaccination site photosensitivity reaction	10076186
Broad	A	Vaginal oedema	10063818
Broad	A	Visceral oedema	10065768
Broad	A	Vulval oedema	10047763
Broad	A	Vulvovaginal exfoliation	10083435
Broad	A	Vulvovaginal swelling	10071211
Broad	A	Wheezing	10047924

Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)			
Scope	*Group*	*PT*	*PT Code*
NaITow	A	Dmg reaction with eosinophilia and systemic symptoms	10073508
NaITow	A	Pseudolymphoma	10037127
Broad	B	Acute generalised exanthematous pustulosis	10048799
Broad	B	Acute hepatic failure	10000804
Broad	B	Acute interstitial pneumonitis	10066728
Broad	B	Acute kidney inimv	10069339

Broad	B	Acute respiratory distress syndrome	10001052
Broad	B	Adenovirus reactivation	10083326
Broad	B	Alanine aminotransferase abnormal	10001547
Broad	B	Alanine aminotransferase increased	10001551
Broad	B	Allergic hepatitis	10071198
Broad	B	Allergic oedema	10060934
Broad	B	Allergic pharyngitis	10050639
Broad	B	Allergic stomatitis	10079554
Broad	B	Alveolitis	10001889
Broad	B	Amylase increased	10002016
Broad	B	Anal blister	10082677
Broad	B	Angioedema	10002424
Broad	B	Anuria	10002847
Broad	B	Ascites	10003445
Broad	B	Aspartate aminotransferase abnormal	10003477
Broad	B	Aspartate aminotransferase increased	10003481
Broad	B	Autoimmune blistering disease	10083961
Broad	B	Autoimmune colitis	10075761
Broad	B	Autoimmune hepatitis	10003827
Broad	B	Autoimmune myocarditis	10064539
Broad	B	Autoimmune myositis	10082418
Broad	B	Autoimmune thyroiditis	10049046
Broad	B	Bilirubin conjugated abnormal	10067718
Broad	B	Bilirubin conjugated increased	10004685
Broad	B	Bilirubin urine	10053113
Broad	B	Bilirubinuria	10004710
Broad	B	Biopsy liver abnormal	10004792
Broad	B	Blood alkaline phosphatase abnormal	10059571
Broad	B	Blood alkaline phosphatase increased	10059570
Broad	B	Blood bilirubin abnormal	10058477
Broad	B	Blood bilirubin increased	10005364
Broad	B	Blood bilirubin unconjugated increased	10005370
Broad	B	Blood creatine abnormal	10005462
Broad	B	Blood creatine increased	10005464
Broad	B	Blood creatinine abnormal	10005481
Broad	B	Blood creatinine increased	10005483
Broad	B	Blood lactate dehydrogenase increased	10005630
Broad	B	Blood urea abnormal	10005846
Broad	B	Blood urea increased	10005851

Broad	B	Blood urea nitrogen/creatinine ratio increased	10050760
Broad	B	Bullous haemorrhagic dermatosis	10083809
Broad	B	Carditis	10062746
Broad	B	Cholestasis	10008635
Broad	B	Cholestatic liver injury	10067969
Broad	B	Cholestatic pruritus	10064190
Broad	B	Chromaturia	10008796
Broad	B	Chronic active Epstein-Barr virus infection	10082848
Broad	B	Chronic autoimmune glomerulonephritis	10073016
Broad	B	Circumoral oedema	10052250
Broad	B	Coma hepatic	10010075
Broad	B	Conjunctival hyperaemia	10051625
Broad	B	Conjunctival oedema	10010726
Broad	B	Creatinine renal clearance abnormal	10068447
Broad	B	Creatinine renal clearance decreased	10011372
Broad	B	Cutaneous vasculitis	10011686
Broad	B	Cytomegalovirus infection	10011831
Broad	B	Cytomegalovirus infection reactivation	10058666
Broad	B	Cytomegalovirus test positive	10051620
Broad	B	Dermatitis	10012431
Broad	B	Dermatitis allergic	10012434
Broad	B	Dermatitis bullous	10012441
Broad	B	Dermatitis exfoliative	10012455
Broad	B	Dermatitis exfoliative generalised	10012456
Broad	B	Dermatosis	10048768
Broad	B	Dialysis	10061105
Broad	B	Drug eruption	10013687
Broad	B	Drug hypersensitivity	10013700
Broad	B	Drug-induced liver injury	10072268
Broad	B	Encephalitis	10014581
Broad	B	Encephalitis allergic	10056387
Broad	B	Encephalopathy	10014625
Broad	B	Endocarditis	10014665
Broad	B	Eosinophilia myalgia syndrome	10014952
Broad	B	Eosinophilic bronchitis	10065563
Broad	B	Eosinophilic colitis	10057271
Broad	B	Eosinophilic cystitis	10056246
Broad	B	Eosinophilic fasciitis	10014954

Broad	B	Eosinophilic gastritis	10083619
Broad	B	Eosinophilic myocarditis	10014961
Broad	B	Eosinophilic oesophagitis	10064212
Broad	B	Eosinophilic otitis media	10081430
Broad	B	Eosinophilic pleural effusion	10080148
Broad	B	Eosinophilic pneumonia	10014962
Broad	B	Eosinophilic pneumonia acute	10052832
Broad	B	Eosinophilic pneumonia chronic	10052833
Broad	B	Eosinophilic pustulosis	10049172
Broad	B	Eosinophils urine present	10058363
Broad	B	Epidermal necrosis	10059284
Broad	B	Epidermolysis	10053177
Broad	B	Epidermolysis bullosa	10014989
Broad	B	Epstein-Barr virus antibody positive	10052324
Broad	B	Epstein-Barr virus infection	10015108
Broad	B	Epstein-Barr virus infection reactivation	10015109
Broad	B	Erythema	10015150
Broad	B	Erythema annulare	10015153
Broad	B	Erythema multiforme	10015218
Broad	B	Erythrodermic atopic dermatitis	10082985
Broad	B	Exfoliative rash	10064579
Broad	B	Eye oedema	10052139
Broad	B	Eye swelling	10015967
Broad	B	Eyelid exfoliation	10064580
Broad	B	Eyelid oedema	10015993
Broad	B	Face oedema	10016029
Broad	B	Fibrillary glomerulonephritis	10068279
Broad	B	Gamma-glutamyltransferase abnormal	10017688
Broad	B	Gamma-glutamyltransferase increased	10017693
Broad	B	Genital blister	10074995
Broad	B	Giant cell myocarditis	10083635
Broad	B	Glomerular filtration rate abnormal	10018356
Broad	B	Glomerular filtration rate decreased	10018358
Broad	B	Glomerulonephritis	10018364
Broad	B	Glomerulonephritis acute	10018366
Broad	B	Glomerulonephritis chronic	10018367
Broad	B	Glomerulonephritis membranoproliferative	10018370
Broad	B	Glomerulonephritis membranous	10018372

Broad	B	Glomerulonephritis minimal lesion	10018374
Broad	B	Glomerulonephritis proliferative	10018376
Broad	B	Glomerulonephritis rapidly progressive	10018378
Broad	B	Glossitis	10018386
Broad	B	Haematuria	10018867
Broad	B	Haemodialysis	10018875
Broad	B	Hepatic encephalopathy	10019660
Broad	B	Hepatic enzyme abnormal	10062685
Broad	B	Hepatic enzyme increased	10060795
Broad	B	Hepatic failure	10019663
Broad	B	Hepatic function abnormal	10019670
Broad	B	Hepatic infiltration eosinophilic	10064668
Broad	B	Hepatic necrosis	10019692
Broad	B	Hepatitis	10019717
Broad	B	Hepatitis acute	10019727
Broad	B	Hepatitis cholestatic	10019754
Broad	B	Hepatitis fulminant	10019772
Broad	B	Hepatitis toxic	10019795
Broad	B	Hepatocellular injury	10019837
Broad	B	Hepatomegaly	10019842
Broad	B	Hepatorenal failure	10019845
Broad	B	Hepatorenal syndrome	10019846
Broad	B	Hepatosplenomegaly	10019847
Broad	B	Hepatotoxicity	10019851
Broad	B	Herpes simplex reactivation	10080137
Broad	B	Herpes zoster reactivation	10080516
Broad	B	Human herpes virus 6 serology positive	10060827
Broad	B	Human herpesvirus 6 infection	10020431
Broad	B	Human herpesvirus 6 infection reactivation	10066845
Broad	B	Hyperammonaemia	10020575
Broad	B	Hyperamylasaemia	10062770
Broad	B	Hyperbilirubinaemia	10020578
Broad	B	Hypercholia	10051924
Broad	B	Hypercreatininaemia	10062747
Broad	B	Hyperlipasaemia	10067725
Broad	B	Hyperphosphatasaemia	10060851
Broad	B	Hypersensitivity	10020751
Broad	B	Hypersensitivity myocarditis	10081004

Broad	B	Hypersensitivity pneumonitis	10081988
Broad	B	Hypertransaminasaemia	10068237
Broad	B	Immune effector cell-associated neurotoxicity syndrome	10083347
Broad	B	Immune-mediated arthritis	10083155
Broad	B	Immune-mediated cholangitis	10083406
Broad	B	Immune-mediated dermatitis	10083156
Broad	B	Immune-mediated encephalitis	10083074
Broad	B	Immune-mediated enterocolitis	10078961
Broad	B	Immune-mediated hepatic disorder	10083521
Broad	B	Immune-mediated hepatitis	10078962
Broad	B	Immune-mediated hyperthyroidism	10083517
Broad	B	Immune-mediated hypothyroidism	10083075
Broad	B	Immune-mediated myocarditis	10082606
Broad	B	Immune-mediated myositis	10083073
Broad	B	Immune-mediated nephritis	10083070
Broad	B	Immune-mediated pancreatitis	10083072
Broad	B	Immune-mediated pneumonitis	10082452
Broad	B	Immune-mediated renal disorder	10083522
Broad	B	Immune-mediated thyroiditis	10083071
Broad	B	Immune-mediated uveitis	10083069
Broad	B	Immunotactoid glomerulonephritis	10067871
Broad	B	Interstitial lung disease	10022611
Broad	B	Intestinal angioedema	10076229
Broad	B	Ischaemic skin ulcer	10077408
Broad	B	Jaundice	10023126
Broad	B	Jaundice cholestatic	10023129
Broad	B	Jaundice hepatocellular	10023136
Broad	B	Lip erosion	10051992
Broad	B	Lip exfoliation	10064482
Broad	B	Lip oedema	10024558
Broad	B	Lip swelling	10024570
Broad	B	Lip ulceration	10024572
Broad	B	Lipase abnormal	10054821
Broad	B	Lipase increased	10024574
Broad	B	Liver disorder	10024670
Broad	B	Liver function test abnormal	10024690
Broad	B	Liver injury	10067125
Broad	B	Liver palpable	10075895

Broad	B	Liver scan abnormal	10061947
Broad	B	Liver transplant	10024714
Broad	B	Localised oedema	10048961
Broad	B	Lung infiltration	10025102
Broad	B	Macule	10025421
Broad	B	Membranous-like glomerulopathy with masked IgG-kappa deposits	10083098
Broad	B	Meningitis	10027199
Broad	B	Mixed liver injury	10066758
Broad	B	Mouth ulceration	10028034
Broad	B	Mucocutaneous rash	10056671
Broad	B	Mucocutaneous ulceration	10028084
Broad	B	Mucosal erosion	10061297
Broad	B	Mucosal exfoliation	10064486
Broad	B	Mucosal necrosis	10067993
Broad	B	Mucosal ulceration	10028124
Broad	B	Multi-organ disorder	10058092
Broad	B	Multiple organ dysfunction syndrome	10077361
Broad	B	Myocarditis	10028606
Broad	B	Myopathy	10028641
Broad	B	Myopathy toxic	10028648
Broad	B	Myositis	10028653
Broad	B	Nasal mucosal blistering	10082185
Broad	B	Nephritic syndrome	10065673
Broad	B	Nephritis	10029117
Broad	B	Nephritis allergic	10029120
Broad	B	Nephropathy toxic	10029155
Broad	B	Nephrotic syndrome	10029164
Broad	B	Nikolsky's sign	10029415
Broad	B	Ocular icterus	10058117
Broad	B	Oedema mouth	10030110
Broad	B	Oedema mucosal	10030111
Broad	B	Oliguria	10030302
Broad	B	Oral lichenoid reaction	10083833
Broad	B	Oral macule	10083314
Broad	B	Oral mucosa erosion	10064594
Broad	B	Oral mucosal blistering	10030995
Broad	B	Oral mucosal eruption	10030997
Broad	B	Oral mucosal erythema	10067418

Broad	B	Oral mucosal exfoliation	10064487
Broad	B	Oral papule	10031010
Broad	B	Oral purpura	10083533
Broad	B	Oral pustule	10056674
Broad	B	Orbital oedema	10031051
Broad	B	Oropharyngeal blistering	10067950
Broad	B	Oropharyngeal swelling	10031118
Broad	B	Palpable purpura	10056872
Broad	B	Pancreatic enzymes increased	10061900
Broad	B	Pancreatitis	10033645
Broad	B	Pancreatitis acute	10033647
Broad	B	Papule	10033733
Broad	B	Parvovirus B19 infection reactivation	10076281
Broad	B	Pemphigoid	10034277
Broad	B	Pemphigus	10034280
Broad	B	Penile blister	10052898
Broad	B	Pericardial effusion	10034474
Broad	B	Pericarditis	10034484
Broad	B	Perioral dermatitis	10034541
Broad	B	Periorbital oedema	10034545
Broad	B	Periorbital swelling	10056647
Broad	B	Peritoneal dialysis	10034660
Broad	B	Perivascular dermatitis	10064986
Broad	B	Pharyngeal oedema	10034829
Broad	B	Pharyngeal swelling	10082270
Broad	B	Pharyngeal ulceration	10034834
Broad	B	Pharyngitis	10034835
Broad	B	Pleural effusion	10035598
Broad	B	Pleuropericarditis	10059361
Broad	B	Pneumonia	10035664
Broad	B	Pneumonitis	10035742
Broad	B	Polymyositis	10036102
Broad	B	Polyserositis	10036141
Broad	B	Post streptococcal glomerulonephritis	10036303
Broad	B	PRIDE syndrome	10082958
Broad	B	Protein urine present	10053123
Broad	B	Proteinuria	10037032
Broad	B	Pruritus	10037087

Broad	B	Pruritus allergic	10063438
Broad	B	Pulmonary eosinophilia	10037382
Broad	B	Purpura	10037549
Broad	B	Pustule	10037578
Broad	B	Rash	10037844
Broad	B	Rash erythematous	10037855
Broad	B	Rash follicular	10037857
Broad	B	Rash macular	10037867
Broad	B	Rash maculo-papular	10037868
Broad	B	Rash maculovesicular	10050004
Broad	B	Rash morbilliform	10037870
Broad	B	Rash papular	10037876
Broad	B	Rash papulosquamous	10037879
Broad	B	Rash pruritic	10037884
Broad	B	Rash pustular	10037888
Broad	B	Rash rubelliform	10057984
Broad	B	Rash scarlatiniform	10037890
Broad	B	Rash vesicular	10037898
Broad	B	Red blood cells urine positive	10038182
Broad	B	Renal disorder	10038428
Broad	B	Renal failure	10038435
Broad	B	Renal function test abnormal	10061480
Broad	B	Renal impairment	10062237
Broad	B	Renal tubular disorder	10038537
Broad	B	Renal tubular dysfunction	10050335
Broad	B	Renal tubular necrosis	10038540
Broad	B	Respiratory distress	10038687
Broad	B	Scrotal dermatitis	10083260
Broad	B	Serum sickness-like reaction	10040402
Broad	B	SJS-TEN overlap	10083164
Broad	B	Skin erosion	10040840
Broad	B	Skin exfoliation	10040844
Broad	B	Skin lesion	10040882
Broad	B	Skin necrosis	10040893
Broad	B	Skin oedema	10058679
Broad	B	Skin reaction	10040914
Broad	B	Skin swelling	10053262
Broad	B	Skin ulcer	10040943

Broad	B	Stevens-Johnson syndrome	10042033
Broad	B	Stomatitis	10042128
Broad	B	Stomatitis necrotising	10042135
Broad	B	Subacute hepatic failure	10056956
Broad	B	Sunscreen sensitivity	10083629
Broad	B	Swelling face	10042682
Broad	B	Swelling of eyelid	10042690
Broad	B	Swollen tongue	10042727
Broad	B	Symmetrical drug-related intertriginous and flexural exanthema	10078325
Broad	B	Target skin lesion	10081998
Broad	B	Therapeutic product cross-reactivity	10079645
Broad	B	Thyroiditis	10043778
Broad	B	Thyroiditis acute	10043780
Broad	B	Tongue exfoliation	10064488
Broad	B	Tongue necrosis	10067360
Broad	B	Tongue oedema	10043967
Broad	B	Tongue ulceration	10043991
Broad	B	Tonsillitis	10044008
Broad	B	Toxic epidermal necrolysis	10044223
Broad	B	Toxic skin eruption	10057970
Broad	B	Transaminases abnormal	10062688
Broad	B	Transaminases increased	10054889
Broad	B	Tubulointerstitial nephritis	10048302
Broad	B	Type IV hypersensitivity reaction	10053613
Broad	B	Urea renal clearance decreased	10046358
Broad	B	Urine bilirubin increased	10050792
Broad	B	Urine output decreased	10059895
Broad	B	Urobilinogen urine increased	10070479
Broad	B	Urticaria	10046735
Broad	B	Urticaria papular	10046750
Broad	B	Urticaria vesiculosa	10046755
Broad	B	Urticarial dermatitis	10082290
Broad	B	Vaginal mucosal blistering	10048904
Broad	B	Vasculitic rash	10047111
Broad	B	Yellow skin	10048245
Broad	C	Body temperature increased	10005911
Broad	C	Hyperpyrexia	10020741
Broad	C	Hyperthermia	10020843

Broad	C	Masked fever	10079681
Broad	C	Pyrexia	10037660
Broad	D	Abdominal lymphadenopathy	10073485
Broad	D	Dermatopathic lymphadenopathy	10074339
Broad	D	Hilar lymphadenopathy	10020094
Broad	D	Lymph node pain	10025182
Broad	D	Lymph node palpable	10057470
Broad	D	Lymphadenitis	10025188
Broad	D	Lymphadenopathy	10025197
Broad	D	Lymphadenopathy mediastinal	10025205
Broad	D	Paratracheal lymphadenopathy	10033969
Broad	D	Persistent generalised lymphadenopathy	10049025
Broad	D	Retroperitoneal lymphadenopathy	10067015
Broad	E	Autoimmune heparin-induced thrombocytopenia	10083812
Broad	E	Blood immunoglobulin E increased	10005591
Broad	E	B-lymphocyte count decreased	10051313
Broad	E	Cytopenia	10066274
Broad	E	Eosinophil count abnormal	10061125
Broad	E	Eosinophil count increased	10014945
Broad	E	Eosinophil percentage abnormal	10058133
Broad	E	Eosinophil percentage increased	10052222
Broad	E	Eosinophilia	10014950
Broad	E	Hypereosinophilic syndrome	10048643
Broad	E	Hypogammaglobulinaemia	10020983
Broad	E	Immune thrombocytopenia	10083842
Broad	E	Immune-mediated pancytopenia	10083004
Broad	E	Leukocytosis	10024378
Broad	E	Leukopenia	10024384
Broad	E	Lymphocyte count abnormal	10025252
Broad	E	Lymphocyte count decreased	10025256
Broad	E	Lymphocyte count increased	10025258
Broad	E	Lymphocyte morphology abnormal	10062047
Broad	E	Lymphocyte percentage abnormal	10063337
Broad	E	Lymphocyte percentage decreased	10052231
Broad	E	Lymphocyte percentage increased	10052232
Broad	E	Lymphocyte stimulation test positive	10060760
Broad	E	Lymphocyte transformation test positive	10057771
Broad	E	Lymphocytic infiltration	10062049

Broad	E	Lymphocytosis	10025280
Broad	E	Lymphopenia	10025327
Broad	E	Monocyte count abnormal	10061293
Broad	E	Monocyte count increased	10027880
Broad	E	Monocyte percentage abnormal	10067238
Broad	E	Monocyte percentage increased	10052230
Broad	E	Monocytosis	10027906
Broad	E	Mononuclear cell count increased	10082032
Broad	E	Mononucleosis syndrome	10027924
Broad	E	Natural killer cell count decreased	10068497
Broad	E	Neutropenia	10029354
Broad	E	Neutrophil count abnormal	10061313
Broad	E	Neutrophil count decreased	10029366
Broad	E	Neutrophil count increased	10029368
Broad	E	Neutrophil percentage decreased	10052223
Broad	E	Neutrophil percentage increased	10052224
Broad	E	Neutrophilia	10029379
Broad	E	Pancytopenia	10033661
Broad	E	Platelet count decreased	10035528
Broad	E	Splenomegaly	10041660
Broad	E	Thrombocytopenia	10043554
Broad	E	White blood cell count abnormal	10047940
Broad	E	White blood cell count decreased	10047942
Broad	E	White blood cell count increased	10047943

Anaphylactic reaction (SMQ)			
Scope	*Group*	*PT*	*PT Code*
NarrowTow	**A**	Anaphylactic reaction	10002198
NarrowTow	**A**	Anaphylactic shock	10002199
NarrowTow	**A**	Anaphylactic transfusion reaction	10067113
NarrowTow	**A**	Anaphylactoid reaction	10002216
NarrowTow	**A**	Anaphylactoid shock	10063119
NarrowTow	**A**	Circulatory collapse	10009192
NarrowTow	**A**	Dialysis membrane reaction	10076665
NarrowTow	**A**	Kounis syndrome	10069167
NarrowTow	**A**	Procedural shock	10080894
NarrowTow	**A**	Shock	10040560
NarrowTow	**A**	Shock symptom	10040581
NarrowTow	**A**	Type I hypersensitivity	10045240

Broad	B	Acute respiratory failure	10001053
Broad	B	Asthma	10003553
Broad	B	Bronchial oedema	10056695
Broad	B	Bronchospasm	10006482
Broad	B	Cardio-respiratory distress	10049874
Broad	B	Chest discomfort	10008469
Broad	B	Choking	10008589
Broad	B	Choking sensation	10008590
Broad	B	Circumoral oedema	10052250
Broad	B	Cough	10011224
Broad	B	Cough variant asthma	10063076
Broad	B	Cyanosis	10011703
Broad	B	Dyspnoea	10013968
Broad	B	Hyperventilation	10020910
Broad	B	Irregular breathing	10076213
Broad	B	Laryngeal dyspnoea	10052390
Broad	B	Laryngeal oedema	10023845
Broad	B	Laryngospasm	10023891
Broad	B	Laryngotracheal oedema	10023893
Broad	B	Mouth swelling	10075203
Broad	B	Nasal obstruction	10028748
Broad	B	Oedema mouth	10030110
Broad	B	Oropharyngeal oedema	10078783
Broad	B	Oropharyngeal spasm	10031111
Broad	B	Oropharyngeal swelling	10031118
Broad	B	Pharyngeal oedema	10034829
Broad	B	Pharyngeal swelling	10082270
Broad	B	Respiratory arrest	10038669
Broad	B	Respiratory distress	10038687
Broad	B	Respiratory failure	10038695
Broad	B	Reversible airways obstruction	10062109
Broad	B	Sensation of foreign body	10061549
Broad	B	Sneezing	10041232
Broad	B	Stridor	10042241
Broad	B	Swollen tongue	10042727
Broad	B	Tachypnoea	10043089
Broad	B	Throat tightness	10043528
Broad	B	Tongue oedema	10043967

Broad	B	Tracheal obstruction	10044291
Broad	B	Tracheal oedema	10044296
Broad	B	Upper airway obstruction	10067775
Broad	B	Wheezing	10047924
Broad	C	Acquired C1 inhibitor deficiency	10081035
Broad	C	Allergic oedema	10060934
Broad	C	Angioedema	10002424
Broad	C	Circumoral swelling	10081703
Broad	C	Erythema	10015150
Broad	C	Eye oedema	10052139
Broad	C	Eye pruritus	10052140
Broad	C	Eye swelling	10015967
Broad	C	Eyelid oedema	10015993
Broad	C	Face oedema	10016029
Broad	C	Flushing	10016825
Broad	C	Hereditary angioedema with C1 esterase inhibitor deficiency	10080955
Broad	C	Injection site urticaria	10022107
Broad	C	Lip oedema	10024558
Broad	C	Lip swelling	10024570
Broad	C	Nodular rash	10075807
Broad	C	Ocular hyperaemia	10030041
Broad	C	Oedema	10030095
Broad	C	Oedema blister	10080039
Broad	C	Periorbital oedema	10034545
Broad	C	Periorbital swelling	10056647
Broad	C	Pruritus	10037087
Broad	C	Pruritus allergic	10063438
Broad	C	Rash	10037844
Broad	C	Rash erythematous	10037855
Broad	C	Rash pruritic	10037884
Broad	C	Skin swelling	10053262
Broad	C	Swelling	10042674
Broad	C	Swelling face	10042682
Broad	C	Swelling of eyelid	10042690
Broad	C	Urticaria	10046735
Broad	C	Urticaria papular	10046750
Broad	D	Blood pressure decreased	10005734
Broad	D	Blood pressure diastolic decreased	10005737

Broad	D	Blood pressure systolic decreased	10005758
Broad	D	Cardiacmest	10007515
Broad	D	Cardio-respiratory anest	10007617
Broad	D	Cardiovascular insufficiency	10065929
Broad	D	Diastolic hypotension	10066077
Broad	D	Hypotension	10021097
Broad	D	Hypotensive crisis	10083659
Broad	D	Post procedural hypotension	10084013

Drue related hepatic disorders - comprehensive search (SMQ)			
Scope	*Group*	*Pr ferred Term*	*PT Code*
Cholestasis and _jaundice of hepatic orhdn (SMQ)			
Nanow	A	Bilirnbin excretion disorder	10061009
Nanow	A	Cholaemia	10048611
Nanow	A	Cholestasis	10008635
Nanow	A	Cholestatic liver iniury	10067969
Nanow	A	Cholestatic prnritus	10064190
Nanow	A	Drng-induced liver iniurv	10072268
Nanow	A	Hepatitis cholestatic	10019754
Nanow	A	Hyperbilirnbinaemia	10020578
Nanow	A	Icterns index increased	10021209
Nanow	A	Jaundice	10023126
Nanow	A	Jaundice cholestatic	10023129
Nanow	A	Jaundice hepatocellular	10023136
Nanow	A	Mixed liver iniury	10066758
Nanow	A	Ocular icterns	10058117
Nanow	A	Parenteral nutrition associated liver disease	10074151
Broad	A	Deficiency of bile secretion	10071634
Broad	A	Yellow skin	10048245
Dru!!: related heoatic disorders - severe events onlv (SMO)			
Nanow	A	Acquired hepatocerebral degeneration	10080860
Nanow	A	Acute hepatic failure	10000804
Nanow	A	Acute on chronic liver failure	10077305
Nanow	A	Acute yellow liver atrophy	10070815
Nanow	A	Ascites	10003445
Nanow	A	Asterixis	10003547
Nanow	A	Bacterascites	10068547
Nanow	A	Biliarv cinhosis	10004659
Nanow	A	Biliary fibrosis	10004664

Narrow	A	Cardiohepatic syndrome	10082480
Narrow	A	Cholestatic liver injury	10067969
Narrow	A	Chronic hepatic failure	10057573
Narrow	A	Coma hepatic	10010075
Narrow	A	Cryptogenic cirrhosis	10063075
Narrow	A	Diabetic hepatopathy	10071265
Narrow	A	Drug-induced liver injury	10072268
Narrow	A	Duodenal varices	10051010
Narrow	A	Gallbladder varices	10072319
Narrow	A	Gastric variceal injection	10076237
Narrow	A	Gastric variceal ligation	10076238
Narrow	A	Gastric varices	10051012
Narrow	A	Gastric varices haemorrhage	10057572
Narrow	A	Gastrooesophageal variceal haemorrhage prophylaxis	10066597
Narrow	A	Hepatectomy	10061997
Narrow	A	Hepatic atrophy	10019637
Narrow	A	Hepatic calcification	10065274
Narrow	A	Hepatic cirrhosis	10019641
Narrow	A	Hepatic encephalopathy	10019660
Narrow	A	Hepatic encephalopathy prophylaxis	10066599
Narrow	A	Hepatic failure	10019663
Narrow	A	Hepatic fibrosis	10019668
Narrow	A	Hepatic hydrothorax	10067365
Narrow	A	Hepatic infiltration eosinophilic	10064668
Narrow	A	Hepatic lesion	10061998
Narrow	A	Hepatic necrosis	10019692
Narrow	A	Hepatic steato-fibrosis	10077215
Narrow	A	Hepatic steatosis	10019708
Narrow	A	Hepatitis fulminant	10019772
Narrow	A	Hepatobiliary disease	10062000
Narrow	A	Hepatocellular foamy cell syndrome	10053244
Narrow	A	Hepatocellular injury	10019837
Narrow	A	Hepatopulmonary syndrome	10052274
Narrow	A	Hepatorenal failure	10019845
Narrow	A	Hepatorenal syndrome	10019846
Narrow	A	Hepatotoxicity	10019851
Narrow	A	Immune-mediated cholangitis	10083406
Narrow	A	Immune-mediated hepatic disorder	10083521

Narrow	A	Intestinal varices	10071502
Narrow	A	Intestinal varices haemorrhage	10078058
Narrow	A	Liver dialysis	10076640
Narrow	A	Liver disorder	10024670
Narrow	A	Liver injury	10067125
Narrow	A	Liver operation	10062040
Narrow	A	Liver transplant	10024714
Narrow	A	Lupoid hepatic cirrhosis	10025129
Narrow	A	Minimal hepatic encephalopathy	10076204
Narrow	A	Mixed liver injury	10066758
Narrow	A	Nodular regenerative hyperplasia	10051081
Narrow	A	Nonalcoholic fatty liver disease	10082249
Narrow	A	Non-alcoholic steatohepatitis	10053219
Narrow	A	Non-cirrhotic portal hypertension	10077259
Narrow	A	Oedema due to hepatic disease	10049631
Narrow	A	Oesophageal varices haemorrhage	10030210
Narrow	A	Peripancreatic varices	10073215
Narrow	A	Portal fibrosis	10074726
Narrow	A	Portal hypertension	10036200
Narrow	A	Portal hypertensive colopathy	10079446
Narrow	A	Portal hypertensive enteropathy	10068923
Narrow	A	Portal hypertensive gastropathy	10050897
Narrow	A	Portal vein cavernous transformation	10073979
Narrow	A	Portal vein dilatation	10073209
Narrow	A	Portopulmonary hypertension	10067281
Narrow	A	Primary biliary cholangitis	10080429
Narrow	A	Regenerative siderotic hepatic nodule	10080679
Narrow	A	Renal and liver transplant	10052279
Narrow	A	Retrograde portal vein flow	10067338
Narrow	A	Reye's syndrome	10039012
Narrow	A	Reynold's syndrome	10070953
Narrow	A	Splenic varices	10067823
Narrow	A	Splenic varices haemorrhage	10068662
Narrow	A	Steatohepatitis	10076331
Narrow	A	Subacute hepatic failure	10056956
Narrow	A	Sugiura procedure	10083010
Narrow	A	Varices oesophageal	10056091
Narrow	A	Varicose veins of abdominal wall	10072284

NaITow	A	White nioole si!lll	10078438
Broad	A	Anorectal varices	10068924
Broad	A	Anorectal varices haemonhage	10068925
Broad	A	Complications of transplanted liver	10010186
Broad	A	Hepatic perfusion disorder	10083840
Broad	A	fucreased liver stiffness	10082444
Broad	A	futrahepatic portal hepatic venous fistula	10072629
Broad	A	Liver and pancreas ti·ansplant rejection	10051603
Broad	A	Liver transplant failure	10083175
Broad	A	Liver transplant reiection	10024715
Broad	A	Multivisceral transplantation	10082450
Broad	A	Peritoneovenous shunt	10052716
Broad	A	Po1tal shunt	10036204
Broad	A	Po1tal shunt procedure	10077479
Broad	A	Small-for-size liver syndrome	10069380
Broad	A	Spider naevus	10041519
Broad	A	Splenic aiterv embolisation	10083795
Broad	A	Splenorenal shunt	10041661
Broad	A	Splenorenal shunt procedure	10077281
Broad	A	Spontaneous inti·ahepatic po1tosysteinic venous shunt	10076239
Broad	A	Stomal varices	10075186
	Heoatitis. non-infectious (SMO)		
NaITow	A	Acute graft versus host disease in liver	10066263
NaITow	A	Allergic hepatitis	10071198
NaITow	A	Alloimmune hepatitis	10080576
NaITow	A	Autoimmune hepatitis	10003827
NaITow	A	Chronic graft versus host disease in liver	10072160
NaITow	A	Chronic hepatitis	10008909
NaITow	A	Graft versus host disease in liver	10064676
NaITow	A	Hepatitis	10019717
NaITow	A	Hepatitis acute	10019727
NaITow	A	Hepatitis cholestatic	10019754
NaITow	A	Hepatitis chronic active	10019755
NaITow	A	Hepatitis chronic persistent	10019759
NaITow	A	Hepatitis fulininant	10019772
NaITow	A	Hepatitis toxic	10019795
NaITow	A	Immune-mediated hepatitis	10078962
NaITow	A	Ischaeinic hepatitis	10023025

NaITow	A	Lupus hepatitis	10067737
NaITow	A	Non-alcoholic steatohepatitis	10053219
NaITow	A	Radiation hepatitis	10051015
NaITow	A	Steatohepatitis	10076331
Broad	A	Granulomatous liver disease	10018704
Broad	A	Liver sarcoidosis	10068664
Broad	A	Portal trnct inflammation	10075331
	Liver neoplasms, benie.n (incl cysts and polyps) (SMQ)		
NaITow	A	Beni!ffihepatic neoplasm	10004269
NaITow	A	Beni!ffihepatobiliarv neoplasm	10077922
NaITow	A	Focal nodular hyperplasia	10052285
NaITow	A	Haemangioma of liver	10018821
NaITow	A	HaemoITha!lic hepatic cyst	10067796
NaITow	A	Hepatic adenoma	10019629
NaITow	A	Hepatic cyst	10019646
NaITow	A	Hepatic cyst rnptured	10053973
NaITow	A	Hepatic haemangioma rnpture	10054885
NaITow	A	Hepatic hama1toma	10079685
NaITow	A	Hepatobiliaiy cyst	10079889
	Liver neoplasms, malie.nant and unspecified (SMQ)		
		Liver malie.nant tumours (SMQ)	
NaITow	A	Cholangiosai·coma	10077861
NaITow	A	Hepatic an!liosarcoma	10067388
NaITow	A	Hepatic cancer	10073069
NaITow	A	Hepatic cancer metastatic	10055110
NaITow	A	Hepatic cancer recuITent	10073070
NaITow	A	Hepatic cancer stage I	10059318
NaITow	A	Hepatic cancer stage II	10059319
NaITow	A	Hepatic cancer stage III	10059324
NaITow	A	Hepatic cancer stage IV	10059325
NaITow	A	Hepatobiliaiy cancer	10073073
NaITow	A	Hepatobiliarv cancer in situ	10073074
NaITow	A	Hepatoblastoma	10062001
NaITow	A	Heoatoblastoma recmTent	10019823
NaITow	A	Hepatocellulai·cai·cinoma	10073071
NaITow	A	Liver cai·cinoma rnptured	10050842
NaITow	A	Mixed hepatocellular cholangiocarcinoma	10027761
Broad	A	Liver ablation	10074766

		Liver tumours of unspecified malie:nancv (SMQ)	
NaITow	A	Hepatic neoplasm	10019695
NaITow	A	Hepatobiliaiy neoplasm	10061203
Liver related investieations, siens and symptoms (SMQ)			
NaITow	A	Alanine aminotransferase abno1mal	10001547
NaITow	A	Alanine aminotransferase increased	10001551
NaITow	A	Ammonia abnonnal	10001942
NaITow	A	Ammonia increased	10001946
NaITow	A	Ascites	10003445
NaITow	A	Aspartate aminotransferase abnonnal	10003477
NaITow	A	Aspartate aminotransferase increased	10003481
NaITow	A	AST/ALT ratio abno1mal	10082832
NaITow	A	Bacterascites	10068547
NaITow	A	Bile output abno1mal	10051344
NaITow	A	Bile output decreased	10051343
NaITow	A	Biliai·y ascites	10074150
NaITow	A	Bilirnbin conjugated abnonnal	10067718
NaITow	A	Bilirnbin conjugated increased	10004685
NaITow	A	Bilirnbin urine present	10077356
NaITow	A	Biopsy liver abnonnal	10004792
NaITow	A	Blood bilirnbin abno1mal	10058477
NaITow	A	Blood bilirnbin increased	10005364
NaITow	A	Blood bilirnbin unconjugated increased	10005370
NaITow	A	Bromosulphthalein test abno1mal	10006408
NaITow	A	Child-Pugh-Turcotte score abno1mal	10077020
NaITow	A	Child-Pugh-Turcotte score increased	10068287
NaITow	A	Computerised tomogram liver abno1mal	10078360
NaITow	A	Congestive hepatopathy	10084058
NaITow	A	Foetor hepaticus	10052554
NaITow	A	Galactose elimination capacity test abnonnal	10059710
NaITow	A	Galactose elimination capacity test decreased	10059712
NaITow	A	Gamma-glutamvltransferase abn01mal	10017688
NaITow	A	Gamma-glutamvltransferase increased	10017693
NaITow	A	Guanase increased	10051333
NaITow	A	Hepaplastin abno1mal	10019621
NaITow	A	Hepaplastin decreased	10019622
NaITow	A	Hepatic aiterv flow decreased	10068997
NaITow	A	Hepatic enzyme abno1mal	10062685

Narrow	A	Hepatic enzyme decreased	10060794
Narrow	A	Hepatic enzyme increased	10060795
Narrow	A	Hepatic function abnormal	10019670
Narrow	A	Hepatic hydrothorax	10067365
Narrow	A	Hepatic hypertrophy	10076254
Narrow	A	Hepatic mass	10057110
Narrow	A	Hepatic pain	10019705
Narrow	A	Hepatic sequestration	10066244
Narrow	A	Hepatic vascular resistance increased	10068358
Narrow	A	Hepatic venous pressure gradient abnormal	10083172
Narrow	A	Hepatic venous pressure gradient increased	10083171
Narrow	A	Hepatobiliary scan abnormal	10066195
Narrow	A	Hepatomegaly	10019842
Narrow	A	Hepatosplenomegaly	10019847
Narrow	A	Hyperammonaemia	10020575
Narrow	A	Hyperbilirubinaemia	10020578
Narrow	A	Hypercholia	10051924
Narrow	A	Hypertransaminasaemia	10068237
Narrow	A	Kayser-Fleischer ring	10023321
Narrow	A	Liver function test abnormal	10024690
Narrow	A	Liver function test decreased	10077677
Narrow	A	Liver function test increased	10077692
Narrow	A	Liver induration	10052550
Narrow	A	Liver palpable	10075895
Narrow	A	Liver scan abnormal	10061947
Narrow	A	Liver tenderness	10024712
Narrow	A	Magnetic resonance imaging liver abnormal	10083123
Narrow	A	Magnetic resonance proton density fat fraction measurement	10082443
Narrow	A	Mitochondrial aspartate aminotransferase increased	10064712
Narrow	A	Molar ratio of total branched-chain amino acid to tyrosine	10066869
Narrow	A	Oedema due to hepatic disease	10049631
Narrow	A	Perihepatic discomfort	10054125
Narrow	A	Retrograde portal vein flow	10067338
Narrow	A	Total bile acids increased	10064558
Narrow	A	Transaminases abnormal	10062688
Narrow	A	Transaminases increased	10054889
Narrow	A	Ultrasound liver abnormal	10045428

NaITow	A	Urine bilirnbin increased	10050792
NaITow	A	White nioole si!lll	10078438
NaITow	A	X-ray hepatobiliary abno1mal	10056536
Broad	A	5'nucleotidase increased	10000028
Broad	A	Blood alkaline phosphatase abnonnal	10059571
Broad	A	Blood alkaline phosphatase increased	10059570
Broad	A	Blood cholinesterase abno1mal	10005429
Broad	A	Blood cholinesterase decreased	10005430
Broad	A	Deficiency of bile secretion	10071634
Broad	A	Glutamate dehydrogenase increased	10049483
Broad	A	Glycocholic acid increased	10080824
Broad	A	HaemoIThamc ascites	10059766
Broad	A	Hepatic fibrosis marker abno1mal	10074084
Broad	A	Hepatic fibrosis marker increased	10074413
Broad	A	Hepatic lymphocytic infiltration	10079686
Broad	A	Hypoalbuminaeinia	10020942
Broad	A	Leucine aminopeptidase increased	10024275
Broad	A	Liver iron concentration abno1mal	10074352
Broad	A	Liver iron concentration increased	10074354
Broad	A	Liver opacity	10084071
Broad	A	Model for end stage liver disease score abno1mal	10077291
Broad	A	Model for end stage liver disease score increased	10077292
Broad	A	Peripoital oedema	10068821
Broad	A	Peritoneal fluid protein abno1mal	10069000
Broad	A	Peritoneal fluid protein decreased	10068999
Broad	A	Peritoneal fluid protein increased	10068998
Broad	A	Pneumobilia	10066004
Broad	A	Portal vein flow decreased	10067337
Broad	A	Po1tal vein pressme increased	10064936
Broad	A	Retinol binding protein decreased	10048473
Broad	A	Urobilinogen mine decreased	10070480
Broad	A	Urobilinogen mine increased	10070479
	Liver-related coae:ulation and bleedine: disturbances (SMQ)		
NaITow	A	Acauired antithrombin III deficiency	10074561
NaITow	A	Acquired factor IX deficiency	10082747
NaITow	A	Acquired factor VIII deficiency	10082745
NaITow	A	Acauired factor XI deficiency	10082746
NaITow	A	Acauired protein S deficiency	10068370

Narrow	A	Anti factor X activity abnormal	10077670
Narrow	A	Anti factor X activity decreased	10077674
Narrow	A	Anti factor X activity increased	10077671
Narrow	A	Antithrombin III decreased	10049547
Narrow	A	Blood fibrinogen abnormal	10005518
Narrow	A	Blood fibrinogen decreased	10005520
Narrow	A	Blood thrombin abnormal	10005818
Narrow	A	Blood thrombin decreased	10005820
Narrow	A	Blood thromboplastin abnormal	10005824
Narrow	A	Blood thromboplastin decreased	10005826
Narrow	A	Coagulation factor decreased	10009736
Narrow	A	Coagulation factor IX level abnormal	10061770
Narrow	A	Coagulation factor IX level decreased	10009746
Narrow	A	Coagulation factor V level abnormal	10061771
Narrow	A	Coagulation factor V level decreased	10009754
Narrow	A	Coagulation factor VII level abnormal	10061772
Narrow	A	Coagulation factor VII level decreased	10009761
Narrow	A	Coagulation factor X level abnormal	10061774
Narrow	A	Coagulation factor X level decreased	10009775
Narrow	A	Hyperfibrinolysis	10074737
Narrow	A	Hypocoagulable state	10020973
Narrow	A	Hypofibrinogenaemia	10051125
Narrow	A	Hypoprothrombinaemia	10021085
Narrow	A	Hypothrombinaemia	10058517
Narrow	A	Hypothromboplastinaemia	10058518
Narrow	A	International normalised ratio abnormal	10022592
Narrow	A	International normalised ratio increased	10022595
Narrow	A	Protein C decreased	10037005
Narrow	A	Protein S abnormal	10051736
Narrow	A	Protein S decreased	10051120
Narrow	A	Prothrombin level abnormal	10037048
Narrow	A	Prothrombin level decreased	10037050
Narrow	A	Prothrombin time abnormal	10037057
Narrow	A	Prothrombin time prolonged	10037063
Narrow	A	Prothrombin time ratio abnormal	10061918
Narrow	A	Prothrombin time ratio increased	10037068
Narrow	A	Thrombin time abnormal	10051319
Narrow	A	Thrombin time prolonged	10051390

Interstitial lung disease (SMQ)			
Scope	*Group*	*PT*	*PT Code*
NaITow	**A**	Acute interstitial pneumonitis	10066728
NaITow	**A**	Alveolar lung disease	10073344
NaITow	**A**	Alveolar proteinosis	10001881
NaITow	**A**	Alveolitis	10001889
NaITow	**A**	Alveolitis necrotising	10050343
NaITow	**A**	Autoimmune lung disease	10080701
NaITow	**A**	Bronchiolitis	10006448
NaITow	**A**	Combined pulmonary fibrosis and emphysema	10076515
NaITow	**A**	Diffuse alveolar damage	10060902
NaITow	**A**	Eosinophilia myalgia syndrome	10014952
NaITow	**A**	Eosinophilic izranulomatosis with polyan!Ziitis	10078117
NaITow	**A**	Eosinophilic pneumonia	10014962
NaITow	**A**	Eosinoohilic oneumonia acute	10052832
NaITow	**A**	Eosinophilic pneumonia chronic	10052833
NaITow	**A**	Hypersensitivity pneumonitis	10081988
NaITow	**A**	Idiopathic interstitial pneumonia	10078268
NaITow	**A**	Idiopathic pneumonia syndrome	10063725
NaITow	**A**	Idiopathic pulmonary fibrosis	10021240
NaITow	**A**	Immune-mediated pneumonitis	10082452
NaITow	**A**	Interstitial lung disease	10022611
NaITow	**A**	Lung infiltration	10025102
NaITow	**A**	Lung opacity	10081792
NaITow	**A**	Necrotising bronchiolitis	10070831
NaITow	**A**	Obliterative bronchiolitis	10029888
NaITow	**A**	Pneumonitis	10035742
NaITow	**A**	Progressive massive fibrosis	10036805
NaITow	**A**	Pulmonary fibrosis	10037383
NaITow	**A**	Pulmonary necrosis	10058824
NaITow	**A**	Pulmonary radiation injury	10061473
NaITow	**A**	Pulmonary toxicity	10061924
NaITow	**A**	Pulmonary vasculitis	10037457
NaITow	**A**	Radiation alveolitis	10037754
NaITow	**A**	Radiation fibrosis - lung	10037758
NaITow	**A**	Radiation pneumonitis	10037765
NaITow	**A**	Small aiiways disease	10080547
NaITow	**A**	Transfusion-related acute lung injury	10052235

Broad	A	Acute lung injury	10069351
Broad	A	Acute respiratory distress syndrome	10001052
Broad	A	Airway remodelling	10075289
Broad	A	Allergic eosinophilia	10075185
Broad	A	Antisynthetase syndrome	10068801
Broad	A	Biopsy lung abnormal	10004795
Broad	A	Complications of transplanted lung	10010187
Broad	A	Cystic lung disease	10078811
Broad	A	Goodpasture's syndrome	10018620
Broad	A	Granulomatosis with polyangiitis	10072579
Broad	A	Granulomatous pneumonitis	10069152
Broad	A	Langerhans' cell histiocytosis	10069698
Broad	A	Lung induration	10057261
Broad	A	Lung transplant rejection	10051604
Broad	A	Lupus pneumonitis	10057481
Broad	A	Lymphangioleiomyomatosis	10049459
Broad	A	Organising pneumonia	10067472
Broad	A	Pneumonitis chemical	10035745
Broad	A	Polyarteritis nodosa	10036024
Broad	A	Pulmonary alveolar haemorrhage	10037313
Broad	A	Pulmonary eosinophilia	10037382
Broad	A	Pulmonary granuloma	10037391
Broad	A	Pulmonary haemosiderosis	10037396
Broad	A	Pulmonary renal syndrome	10068513
Broad	A	Pulmonary sarcoidosis	10037430
Broad	A	Restrictive pulmonary disease	10048667
Broad	A	Rheumatoid lung	10039081
Broad	A	Sarcoidosis	10039486
Broad	A	Systemic sclerosis pulmonary	10042954
Broad	A	Toxic oil syndrome	10051222

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