STATISTICAL ANALYSIS PLAN

HyQvia/ HYQVIA [Immune Globulin Infusion 10% (Human) with rHuPH20] or Human normal immunoglobulin for intravenous or subcutaneous infusion/Alternative treatment

PHASE IV

Pregnancy Registry to Collect Long-Term Safety Data from Women treated with HyQvia

PROTOCOL IDENTIFIER: 161301

Study Sponsor(s): EU: Baxalta Innovations GmbH,
Industriestrasse 67,
A-1221 Vienna, Austria
USA: Baxalta US Inc., 300 Shire Way
Lexington, MA 02421, USA

Author: [redacted]
IQVIA

Protocol: 2015 OCT 22, Amendment 3

SAP Version #: 1.0

SAP Date: 20MAR2020

Status: Draft

REVISION HISTORY

Version	Issue Date	Summary of Changes
1.0 draft	15Jan2020	New Document
1.0 final V1	19Feb2020	Update based on sponsor and internal review comments
1.0 final V2	20Mar2020	Update based on sponsor/fda comments - Add retrospective vs prospective cohorts and infant growth/development compared with CDC/WHO standards
1.0 final V3	02Apr2020	Update required signatures based on sponsor request

TABLE OF CONTENTS

SIGNATURE PAGE

Shire

Director, Global Medical Affairs Group Lead
Data Science Institute

[redacted]

[redacted]

IQVIA

Statistical Scientist

[redacted]

[redacted]

ABBREVIATIONS

AE	Adverse Event
AESI	Adverse Event Of Special Interest
CI	Confidence Interval
CRF	Case Report Form
FAS	Full Analysis Set
GA	Gestational Age
HyQvia/HYQVIA	Immune Globulin Infusion 10% (Human) with rHuPH20
LBW	Low Birth Weight
LMP	Last Menstrual Period
MedDRA	Medical Dictionary for Regulatory Activities
PSUR	Periodic Safety Update Report
rHuPH20	Recombinant Human Hyalurinidase
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMQ	Standardized MedDRA® Query
SOC	System Organ Class
WHO	World Health Organization

1. INTRODUCTION

This statistical analysis plan (SAP) provides a technical and detailed elaboration of the statistical analyses of safety data as described in the final study protocol dated 22 OCT 2015 incorporating most recent amendment #3. Specifications for tables, figures, and listings are contained in a separate document.

2. OBJECTIVES, ESTIMAND(S), AND ENDPOINTS

2.1 Objectives

2.1.1 Primary Objective

To collect and assess clinical safety data regarding the possible effects of HyQvia (Immune Globulin Infusion 10% [Human] with recombinant human hyaluronidase [rHuPH20]) on the course and outcome of pregnancy, and on the growth and development of the fetus/infant.

2.1.2 Secondary Objective(s)

To collect any laboratory safety data and additional safety assessments obtained during the clinical management of the pregnancy or in the evaluation of the fetus in utero and the infant post partum.

2.1.3 Primary Endpoint(s)

The primary endpoint is the incidence of all serious adverse events (SAEs) (expectant mother and infant).

2.1.4 Secondary Endpoint(s)

1. Incidence of non-serious adverse events (AEs), related and not-related to HyQvia/Human normal immunoglobulin or alternative treatment (expectant mother and infant)
2. Incidence of local/immunologic AEs including skin changes (such as: local erythema, local pruritus, induration, nodules) (expectant mother)
3. Development of anti-rHuPH20 antibodies (rHuPH20 binding and neutralizing antibodies) (expectant mother)
4. Complications of pregnancy
5. Fetal growth/development
6. Outcome of pregnancy
7. Neonatal assessment
8. Status of the infant at birth
9. Growth measurement and charts for the infant, if available
10. Development milestones determined by standard test methods, for each region, if available

3. STUDY DESIGN

3.1 General Description

This study is a non-interventional, prospective, uncontrolled, two-arm, open-label, multicenter post-authorization pregnancy registry of women ever treated with HyQvia. The overall study design is illustrated in Figure 1.

Subjects who prior to the study received HyQvia and at enrollment receive a licensed human normal immunoglobulin other than HyQvia or an alternative treatment during the study will be assigned to Study Arm 1 (Alternative Product Arm); subjects in countries, where HyQvia treatment during pregnancy is not indicated, should be enrolled in this arm. Subjects who continue treatment with HyQvia during pregnancy will be followed in Study Arm 2 (HyQvia Arm).

The data for the registry will be derived from several medical specialists (such as immunologist, gynecologist, obstetrician, pediatrician). The specialist responsible for the pregnant woman's HyQvia treatment and/or the treatment of her underlying disease will be responsible for data collection and case report form (CRF) completion.

Data will be collected according to the standard of care in the region. After enrollment in the registry by signing the appropriate informed consent form, the pregnant subject (expectant mother) will return to her physicians as she normally would as part of routine medical practice. There will be no required predefined visits, medical tests, laboratory tests and procedures during the course of the registry, except for the assessment of antibodies to rHuPH20. Approximately every 3 months, the pregnant subject will be invited to have a blood sample taken for the measurement of anti-rHuPH20 antibodies. For subjects with an anti- rHuPH20 antibody titer ≥ 160 binding antibodies, also neutralizing antibodies, will be measured. In addition, characterization of antibodies will be performed in subjects who test positive for anti-rHuPH20 antibodies at a titer of ≥ 10,000. For subjects with occurrence of any AEs, complications of pregnancy and fetal growth and development will be recorded on the CRF, if data is available.

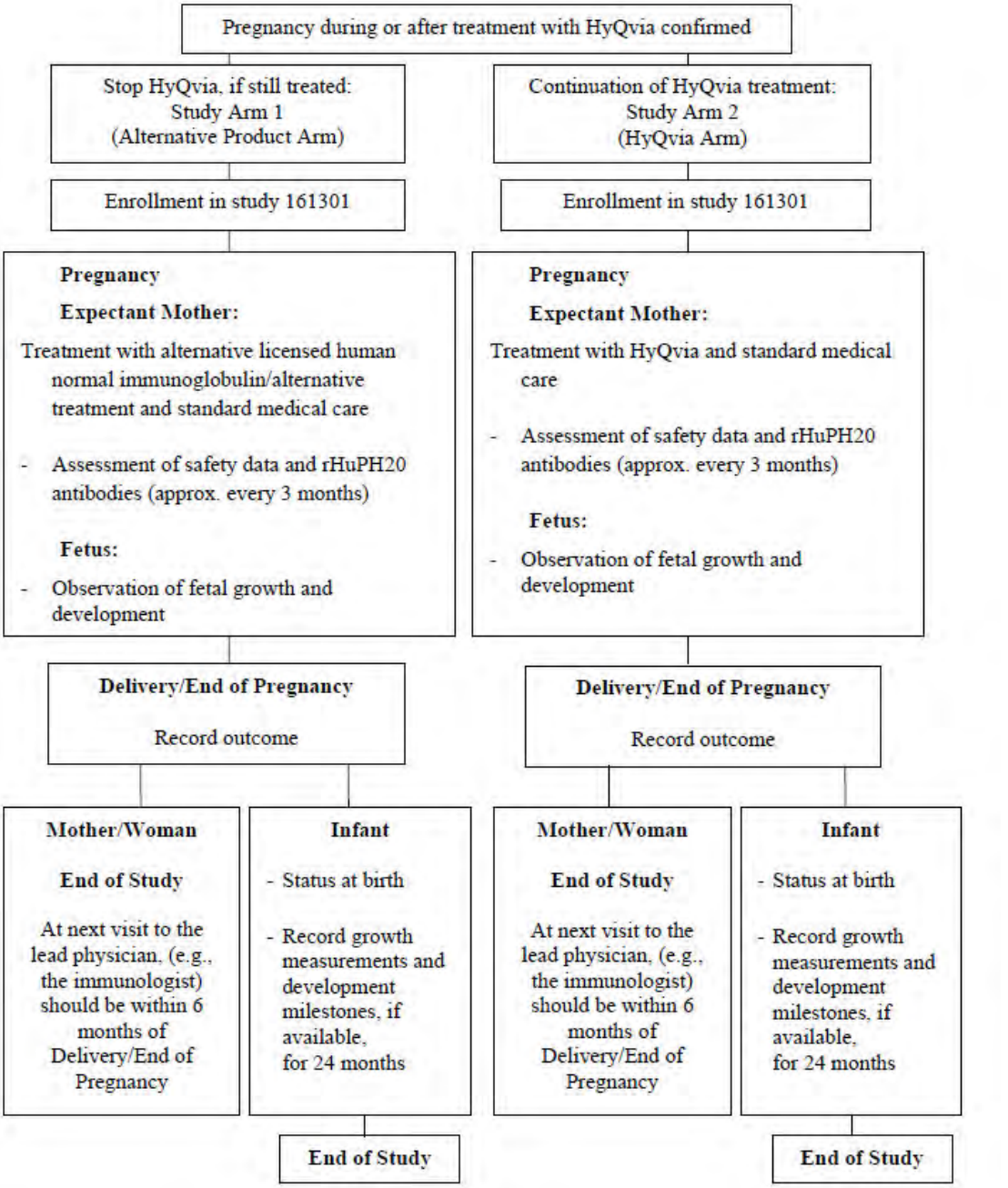
After delivery/end of pregnancy, data on the outcome of the pregnancy will be collected if available.

The infant will be followed up for two years to collect safety data. Approximately every 6 ±2 months (as part of routine medical practice) the infant and the legal representative(s) will be invited to return to the pediatrician/lead physician to record assessments. The pediatrician/lead physician will record data on the development and growth of the infant in the appropriate CRFs, if data is available.

Regular study progress information will be provided in Europe with each Periodic Safety Update Report (PSUR) at least annually. In the USA, this information will be made available with the annual status report.

Should a physician retrospectively (i.e., at a more advanced stage of the pregnancy) become aware of a patient who could have been included in this registry, then the physician should include this patient and the patient's data should be entered retrospectively (as available), if the patient provides informed consent.

Figure 1. Study Design for Clinical Study 161301
(copied from protocol)



Note: Procedures and assessments are performed according to the routine standard at the site, and are documented as available (with the exception of Informed Consent, Eligibility and anti-rHuPH20).

3.2 Sample Size and Power Considerations

There is no pre-specified minimum sample size for this registry. All women ever treated with HyQvia who become pregnant will be requested to participate in the registry by the marketing authorization holder. Every effort will be made to identify and include subjects in this registry. Furthermore, physicians treating patients with HyQvia will be informed of the possible enrollment in this registry. The purpose of the registry and the possibility of participation is included in the package insert/Summary of Product Characteristics of the respective country.

4. STATISTICAL ANALYSIS SETS

4.1 Enrolled Set

The Enrolled Set consists of all subjects who have signed informed consent and meet all inclusion/exclusion criteria at the time of enrollment.

All subjects will be analyzed according to the Study Arm 1 and 2, and together. If the treatment of the subject is changed in the course of the study, the subject will continue to be followed in the study arm assigned initially, for the remaining observation period. The infants will be assigned to the study arm of the respective mother.

All subjects will also be analyzed according to the type of enrollment – Retrospective or Prospective. The cases where the condition of the fetus has been assessed through prenatal testing such as targeted ultrasound, via the antenatal diagnostic CRF, prior to the time of enrollment or the outcome of the pregnancy is known, via the pregnancy outcome CRF, prior to the time of enrollment will be assigned to Retrospective. The cases where the condition of the fetus has not been assessed through prenatal testing such as targeted ultrasound prior to the time of enrollment and the outcome of the pregnancy is not known at the time of enrollment will be assigned to Prospective.

4.2 Safety Set

The Safety Set consists of all subjects on the Enrolled Set.

5. STUDY SUBJECTS

5.1 Disposition of Subjects

The following summaries will be presented for expectant mothers and infants for each study arm and overall for the Enrolled Set:

1. Number and percentage of subjects enrolled
2. Number and percentage of subjects who discontinued the study and the reason for discontinuation.

5.2 Demographics and Subjects Characteristics

Descriptive summaries of demographic and baseline characteristics will be presented for expectant mothers and infants by study arm and overall for the Enrolled Set.

The following demographic and subject characteristics will be summarized for expectant mothers: age at conception(years), ethnicity, race and pre-pregnancy weight (kg).

The following demographic characteristics will be summarized in the following order for infants: sex, ethnicity, and race.

5.3 Medical History

Medical history will be collected on "Medical History/Surgical History" case report form (CRF) and will be coded using MedDRA Version 19.0 or newer. The medical history with start date or surgery date for all conditions/procedures prior to the date of last menstrual period (LMP) will be summarized by system organ class (SOC) and preferred term for expectant mothers in the Enrolled Set.

5.4 Family, Pregnancy and Obstetrical History of the Mother

A summary will be provided for expectant mothers in the Enrolled Set (Overall, and for each study arm) on the following variables: family history of congenital abnormalities/birth defects, adverse fetal outcome, psychomotor retardation and consanguinity between parents; number of previous pregnancies and outcome, previous maternal pregnancy complications and previous fetal/neonatal abnormalities.

5.5 HyQvia Treatment History

Descriptive statistics will be presented to describe the exposure to HyQvia, for both study arms and overall, for expectant mothers in the Enrolled Set. Variables include regimen, immunoglobulin total monthly dose, weight, treatment interval and duration of each treatment regimen. The duration (in days) is defined as date of last infusion – date of first infusion + 1.

5.6 Planned HyQvia Treatment

Descriptive statistics will be presented to describe the planned HyQvia treatment for Arm 2 for expectant mothers in the Enrolled Set. Variables include planned immunoglobulin total monthly dose, planned HyQvia treatment interval, planned total volume of rHuPH20 per administration, body weight used for calculation, planned immunoglobulin dose per 4 weeks to be administered, planned number of infusion sites per administration, and planned maximum immunoglobulin infusion rate.

5.7 Changes in HyQvia Treatment

Descriptive statistics will be presented to describe the changes in HyQvia treatment regimen for both study arms for expectant mothers in the Enrolled Set. Variables include type of regimen change, gestational age at the time treatment was changed/stopped or restarted and reason for dose change.

5.8 Concomitant (Therapies), (Procedures and) Medications

Concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary dated 01MAR2016. Concomitant therapies and procedures will be coded using MedDRA Version 19.0 or newer.

For the expectant mothers, concomitant medication (therapy), including non-drug therapies, is defined as any medication (therapy) with a start date prior to the date of LMP and continuing after the date of LMP or with a start date on or after the date of the LMP but before the date of end of pregnancy, and also all the medication (therapy) that has an end date 6 months prior to enrollment. Concomitant procedure is defined as any procedure with a start date on or after the date of LMP and before the date of end of pregnancy. Any medication (therapy/procedure) with a start date on or after the date of the pregnancy outcome will not be considered a concomitant medication (therapy/procedure).

For the infants, concomitant medication (therapy) or procedure is defined as any concomitant medication (therapy) or procedure that starts on or after the date of birth.

For expectant mothers and infants separately, the concomitant therapies, procedure and medication usage will be summarized by the number and proportion of subjects in each study arm and in overall subjects receiving each medication within each preferred term for the Enrolled Set. Multiple medication usage by a subject in the same category will be counted only once.

All concomitant therapies, procedures and medication will be listed for the Enrolled Set.

5.9 Current Pregnancy

Summaries will be provided for expectant mothers in the Enrolled Set on the following variables:

1. Time from the date of LMP to enrollment date of the study
2. Weight gain during pregnancy (weight at the third interval study visit - pre-pregnancy weight)
3. Number of fetuses
4. History of subfertility/infertility
5. Treatment for subfertility/infertility for the current pregnancy
6. Any exposure for tobacco, alcohol and recreational drug use in each trimester (peri-LMP, 1st, 2nd or 3rd trimester). If exposure, number of days of exposures during pregnancy; for cigarettes, number of cigarettes per day.
7. Any complications during pregnancy (all included in Adverse Reactions)

5.10 Pregnancy Outcome

Summaries will be provided for expectant mothers in the Enrolled Set on the following variables:

1. Outcome of pregnancy (Live birth, Fetal death, Termination or Unknown)
2. Duration of gestation (date of delivery or date of end of pregnancy – date of LMP + 1)
3. Mode of delivery for live births (Vaginal delivery or Cesarean section)

5.11 Labor/delivery complications (None, Fetal distress, Amniotic fluid abnormal, Abnormal placenta or Other). Infants at Birth

Summaries will be provided for live birth infants in the Enrolled Set on the following variables:

1. Gestational age at birth in weeks: (date of delivery – date of LMP + 1)/7
2. Weight, length and head circumference at birth
3. Apgar scores at 1, 5 and 10 minutes, need for resuscitation, admission to intensive care unit
4. Presence of congenital malformation/anomalies
5. Other conditions noted at or around birth [pulse rate (bpm), systolic/diastolic blood pressure (mmHg), respiratory rate (breaths/min), body temperature (ºC), need for resuscitation of the infant, admission in intensive care unit]

5.12 Infants at Follow-up

Summaries will be provided for live birth infants in the Enrolled Set on the following variables:

1. Any congenital malformation diagnosis that was not reported at birth
2. Any conditions that were noted since birth
3. Any abnormal height/length, weight, head circumference, pulse rate, blood pressure, respiratory rate and body temperature
4. Total duration of breast feeding on study
5. Any illnesses (since birth)
6. Any drug therapy/non drug therapy/procedure
7. Any evidence of missed developmental milestones

In addition, Length-for-age, Weight-for-age, and Head Circumference-for-age percentiles will be calculated using the most recent version of WHO Growth Charts (https://www.cdc.gov/growthcharts/who_charts.htm#The%20WHO%20Growth%20Charts) as recommended by the CDC for ages 0-2 years old and provided in a listing.

5.13 Adverse Events

AE will be coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 19.0 or newer.

For expectant mothers, only AE's that occurred on or after the date of LMP and before the date of end of pregnancy will be analyzed. If an AE has a partial date that might be during this period then from a conservative perspective it will be analyzed as during pregnancy.

For infants, only AE's that occurred on or after the date of birth will be analyzed. If an AE has a partial date that could fall during this period then from a conservative perspective, it will be analyzed as in period.

An overall summary will be provided for the number and percentage of subjects with any AEs, any serious AEs, any severe AEs, any AEs related to HyQvia treatment, and any AEs causing dose reduction, interruptions or withdrawal, for expectant mothers and infants, by study arms and overall.

A point estimate and 95% confidence interval (by the Wilson score method) for the proportion of subjects with any AE will be provided for expectant mothers and infants, by study arms and overall. The analysis will be repeated for SAE.
The number and percentage of subjects reporting AEs in each study arm and overall will

be tabulated by SOC and preferred term. Presentation by SOC and PT will show SOC sorted alphabetically and PT within SOC by descending incidence.

AEs and related AEs will be summarized by preferred term by descending frequency. Serious AEs will be summarized by SOC, preferred term and study arm.

All AEs reported in the time period of interest will be listed for expectant mothers and infants.

5.13.1 Adverse Events of Special Interest

Separate summaries will be provided for the selected adverse events of special interest (AESI) based on standardized MedDRA queries. AESI's considered will be: local/immunologic AEs including skin changes (such as: local erythema, local pruritus, induration, nodules). See Appendix 1 for full list of SOCs/PTs.

5.14 rHuPH20 Antibodies

Assessment (negative or positive [titer ≥160]) of anti-rHuPH20 binding and neutralizing antibodies will be summarized on the expectant mother in the Enrolled Set.

5.15 Clinical Laboratory Data

All clinically significant clinical laboratory results (hematology, clinical chemistry, urinalysis and antenatal parameters where applicable) will be summarized for the expectant mothers and infants in the Enrolled Set. All clinical laboratory data will be provided in listings for the Enrolled Set.

5.16 Physical Examinations

Abnormal physical examinations will be summarized for the expectant mothers in the Enrolled Set. All physical examination data will be presented in listings for the Enrolled Set.

5.17 Vital Signs

No summaries will be done on vital signs data, instead data will be provided in listings for the Enrolled Set.

5.18 Protocol Violations/Deviations

Protocol violations/deviations will be recorded by the site separately from the clinical database. The initial review of the protocol violations/deviations and their classification will be done by the Contract Research Organization and subsequently Shire study team will provide review at regular intervals and before database lock.

Protocol violations/deviations will be summarized in a listing for all subjects, on an appendix file.

5.19 Handling of Missing or Spurious Data

Missing values, in general, will not be imputed unless mentioned below.

Statistical techniques will not be used to identify and exclude any observations as outliers from the analyses. If any data is considered spurious, e.g., for lack of biological plausibility, it will be documented to include the reason for exclusion and the analyses from which the data points were excluded.

5.19.1 Missing Severity Assessment for Adverse Events

If the severity is missing for an AE then a severity of "Severe" will be assigned. The imputed values for severity assessment will be used in the summary table, while both the actual and the imputed values will be used in data listings.

5.19.2 Missing Relationship to Investigational Product for Adverse Events

If the relationship to HyQvia/Human normal immunoglobulin or alternative treatment is missing for an AE, a causality of "Related" will be assigned. The imputed values for relationship will be used in the summary table, while both the actual and the imputed values will be presented in data listings.

6. ANALYSIS SOFTWARE

Statistical analyses will be performed using Version 9.4 (or newer) of SAS® on a suitably qualified environment.

7. CHANGES TO ANALYSIS SPECIFIED IN PROTOCOL

None.

8. REFERENCES

None.

9. APPENDIX 1

List of Immunologic SOCs/PTs:

Allergic conditions [10001708]
Allergic conditions NEC [10027654]
Administration site hypersensitivity [10075102]
Airway remodelling [10075289]
Allergic bronchitis [10052613]
Allergic bronchopulmonary mycosis [10082909]
Allergic cough [10053779]
Allergic cystitis [10051394]
Allergic eosinophilia [10075185]
Allergic hepatitis [10071198]
Allergic keratitis [10057380]
Allergic oedema [10060934]
Allergic otitis externa [10075072]
Allergic otitis media [10061557]
Allergic pharyngitis [10050639]
Allergic respiratory symptom [10063527]
Allergic sinusitis [10049153]
Allergic transfusion reaction [10066173]
Allergy to animal [10001742]
Allergy to arthropod bite [10058285]
Allergy to arthropod sting [10058284]
Allergy to immunoglobulin therapy [10074079]
Allergy to metals [10066414]
Allergy to plants [10054928]
Allergy to silk [10074789]
Allergy to sting [10001749]
Allergy to surgical sutures [10077279]
Allergy to venom [10001751]
Application site hypersensitivity [10063683]
Arthritis allergic [10061430]
Asthma [10003553]
Asthma late onset [10003559]
Asthma-chronic obstructive pulmonary disease overlap syndrome [10077005]
Bacterial allergy [10052748]
Blepharitis allergic [10005149]
Bronchopulmonary aspergillosis allergic [10006474]
Bronchospasm [10006482]
Catheter site hypersensitivity [10073998]
Chronic actinic dermatitis [10072578]
Chronic eosinophilic rhinosinusitis [10071399]
Chronic hyperplastic eosinophilic sinusitis [10071380]
Cockroach allergy [10057643]
Dermatitis allergic [10012434]
Device allergy [10072867]
Dust allergy [10077439]
Encephalopathy allergic [10014627]
Erythema induratum [10015213]
Erythema multiforme [10015218]
Eye allergy [10015907]
Giant papillary conjunctivitis [10018258]
Human seminal plasma hypersensitivity [10067432]
Hypersensitivity [10020751]
Hypersensitivity myocarditis [10081004]
Hypersensitivity pneumonitis [10081988]
Immediate post-injection reaction [10067142]

Implant site hypersensitivity [10063858]
Infusion related hypersensitivity reaction [10082742]
Infusion site hypersensitivity [10065471]
Injection site hypersensitivity [10022071]
Injection site panniculitis [10083040]
Instillation site hypersensitivity [10073612]
Kounis syndrome [10069167]
Laryngitis allergic [10064866]
Medical device site hypersensitivity [10075579]
Mesenteric panniculitis [10063031]
Mite allergy [10077290]
Multiple allergies [10028164]
Mycotic allergy [10052758]
Necrotising panniculitis [10062579]
Nephritis allergic [10029120]
Occupational asthma [10070836]
Panniculitis [10033675]
Parasite allergy [10062625]
Pruritus allergic [10063438]
Reactive airways dysfunction syndrome [10070832]
Scleritis allergic [10051126]
Sea bather's eruption [10075552]
Septal panniculitis [10056876]
Serum sickness [10040400]
Serum sickness-like reaction [10040402]
Severe asthma with fungal sensitisation [10078120]
Skin reaction [10040914]
Stevens-Johnson syndrome [10042033]
Stoma site hypersensitivity [10074509]
Type 1 lepra reaction [10070516]
Type 2 lepra reaction [10070517]
Type I hypersensitivity [10045240]
Type II hypersensitivity [10054000]
Type III immune complex mediated reaction [10053614]
Type IV hypersensitivity reaction [10053613]
Urticarial dermatitis [10082290]
Vaccination site hypersensitivity [10068880]

Allergies to foods, food additives, drugs and other chemicals [10001737]
Administration related reaction [10069773]
Allergic colitis [10059447]
Allergic gastroenteritis [10075308]
Allergic reaction to excipient [10078853]
Allergic stomatitis [10079554]
Allergy to chemicals [10061626]
Allergy to fermented products [10054929]
Allergy to synthetic fabric [10076764]
Allergy to vaccine [10055048]
Aspirin-exacerbated respiratory disease [10075084]
Caffeine allergy [10074895]
Contact stomatitis [10067510]
Contrast media allergy [10066973]
Contrast media reaction [10010836]
Dermatitis contact [10012442]
Dermatitis exfoliative [10012455]
Dermatitis exfoliative generalised [10012456]
Drug eruption [10013687]
Drug hypersensitivity [10013700]

Drug reaction with eosinophilia and systemic symptoms [10073508]
Eosinophilic oesophagitis [10064212]
Erythrodermic atopic dermatitis [10082985]
Fixed eruption [10016741]
Flagellate dermatitis [10075467]
Flour sensitivity [10016788]
Food allergy [10016946]
Gluten sensitivity [10076493]
Infusion related reaction [10051792]
Injection related reaction [10071152]
Iodine allergy [10052098]
Milk allergy [10027633]
Oral allergy syndrome [10068355]
Perfume sensitivity [10034434]
Reaction to azo-dyes [10037973]
Reaction to colouring [10037974]
Reaction to excipient [10079925]
Reaction to food additive [10037977]
Reaction to preservatives [10064788]
Red man syndrome [10038192]
Rubber sensitivity [10039251]
SJS-TEN overlap [10083164]
Smoke sensitivity [10069201]
Solvent sensitivity [10041316]
Symmetrical drug-related intertriginous and flexural exanthema [10078325]
Therapeutic product cross-reactivity [10079645]
Toxic epidermal necrolysis [10044223]
Toxic skin eruption [10057970]
Transplantation associated food allergy [10075008]
Vulvovaginitis allergic [10080783]

Anaphylactic and anaphylactoid responses [10077535]
Anaphylactic reaction [10002198]
Anaphylactic shock [10002199]
Anaphylactic transfusion reaction [10067113]
Anaphylactoid reaction [10002216]
Anaphylactoid shock [10063119]
Anaphylactoid syndrome of pregnancy [10067010]
Dialysis membrane reaction [10076665]

Angioedemas [10002425]
Acquired C1 inhibitor deficiency [10081035]
Angioedema [10002424]
Circumoral oedema [10052250]
Circumoral swelling [10081703]
Eyelid oedema [10015993]
Face oedema [10016029]
Gleich's syndrome [10066837]
Hereditary angioedema [10019860]
Hereditary angioedema with C1 esterase inhibitor deficiency [10080955]
Hereditary angioedema with normal C1 esterase inhibitor [10080953]
Idiopathic angioedema [10073257]
Intestinal angioedema [10076229]
Laryngeal oedema [10023845]
Laryngotracheal oedema [10023893]
Lip oedema [10024558]
Lip swelling [10024570]
Mouth swelling [10075203]

Oculorespiratory syndrome [10067317]
Oedema mouth [10030110]
Oropharyngeal oedema [10078783]
Oropharyngeal swelling [10031118]
Periorbital oedema [10034545]
Periorbital swelling [10056647]
Pharyngeal oedema [10034829]
Swelling face [10042682]
Swelling of eyelid [10042690]
Swollen tongue [10042727]
Tongue oedema [10043967]

Atopic disorders [10052737]
Atopic cataract [10069649]
Atopic cough [10081492]
Atopic keratoconjunctivitis [10069664]
Atopy [10003645]
Conjunctivitis allergic [10010744]
Dennie-Morgan fold [10062918]
Dermatitis atopic [10012438]
Eczema herpeticum [10014197]
Eczema vaccinatum [10066042]
Kaposi's varicelliform eruption [10051891]
Nasal crease [10078581]
Perennial allergy [10069493]
Rebound atopic dermatitis [10076881]
Rhinitis allergic [10039085]
Rhinitis perennial [10039094]
Seasonal allergy [10048908]
Vernal keratoconjunctivitis [10081000]

Urticarias [10046736]
Administration site urticaria [10075109]
Application site urticaria [10050104]
Catheter site urticaria [10052272]
Chronic spontaneous urticaria [10072757]
Cold urticaria [10009869]
Diffuse cutaneous mastocytosis [10012812]
Haemorrhagic urticaria [10059499]
Idiopathic urticaria [10021247]
Implant site urticaria [10063787]
Infusion site urticaria [10065490]
Injection site urticaria [10022107]
Instillation site urticaria [10073627]
Mechanical urticaria [10068773]
Medical device site urticaria [10075588]
Schnitzler's syndrome [10062908]
Solar urticaria [10041307]
Urticaria [10046735]
Urticaria aquagenic [10046739]
Urticaria cholinergic [10046740]
Urticaria chronic [10052568]
Urticaria contact [10046742]
Urticaria papular [10046750]
Urticaria physical [10046751]
Urticaria pigmentosa [10046752]
Urticaria pressure [10052572]

Urticaria thermal [10061399]
Urticaria vesiculosa [10046755]
Urticaria vibratory [10052571]
Urticarial vasculitis [10048820]
Vaccination site urticaria [10069622]