Severe Paediatric Asthma Collaborative in Europe (SPACE) Registry

Baseline form – at recruitment

BASIC CASE INFORMATION

Patient code number: _____
(Note: this will be automatically generated by the online database at data entry – please do not change this code as it is linked on your site)

Gender: Male/ Female

Ethnicity	√
Caucasian (Europe, Israel, Australia, USA, Canada, Mexican Americans, Brazil, Chile, Mexico, Uruguay, Venezuela, Algeria, Tunisia)	
Black/ African American/ Afro-Caribbean	
South East Asian (Thailand, Taiwan and China (including Hong Kong) south of the Huaihe River and Qinling Mountains)	
North East Asian (Korea and China north of the Huaihe River and Qinling Mountains)	
Other/ mixed: _____	

Centre: _____
(This will be automatically generated by the online database based on your login details)

Age of asthma diagnosis by a doctor: _____ years
(Enter the age in complete years. For example, if it is age 7 years and 8 months, please enter "7"; if it is under the age of 1 year, please enter "0".)

Date of birth: _____
(Date of birth will only be available to the local user and not to the wider group or when the data is downloaded)

Date of patient enrolment: _____

Written informed consent: yes/no
(Please obtain informed consent before collecting/ entering data)

Written informed assent (child): yes/no

CRITERIA FOR INCLUSION

	Yes	No
Fulfils age criteria (6-17 years old)		

Confirmation of asthma

Diagnosis confirmed, evaluated and managed at a specialised centre ≥ 6 months		
Symptoms: - Wheeze heard by trained healthcare professional - Self reported wheeze with documented evidence	☐ ☐	☐ ☐
Spirometry evidence: Bronchial obstruction with bronchodilator reversibility ≥12% *OR* *If spirometry normal or no reversibility demonstrated,* Bronchial provocation test ≥20% fall in FEV_1; or >10% for exercising provocation	☐ ☐	☐ ☐
Biologic use - Currently on a biologic treatment *OR* - Just before (within 1 month) starting on a biologic treatment *For patients about to start on a biologic, they should fulfil at least 1 of the following options, at recruitment:* - High dose inhaled corticosteroids for at least 6 months in the last year and at time of recruitment; AND - LABA or second controller for at least 6 months in the last year and at time of recruitment. OR - Systemic corticosteroids for ≥25% of last 12 months	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐

Inhaled corticosteroids	High dose definition (mcg): 12 years or older
Beclomethasone dipropionate (pMDI, standard particle, HFA)	>1000
Beclomethasone dipropionate (DPI, pMDI, extrafine particle, HFA)	>400
Budesonide (DPI or pMDI, standard particle, HFA)	>800
Ciclesonide (pMDI, extrafine particle, HFA)	>320
Fluticasone furoate (DPI)	200
Fluticasone propionate (DPI, pMDI, standard particle, HFA)	>500
Mometasone furoate (pMDI, standard particle, HFA)	>400

Inhaled corticosteroids	High dose definition (mcg): 6-11 years
Beclomethasone dipropionate (pMDI, standard particle, HFA)	>400
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	>200
Budesonide (DPI, pMDI, standard particle, HFA)	>400
Budesonide (nebules)	>1000
Ciclesonide (pMDI, extrafine particle, HFA)	>160
Fluticasone propionate (DPI, pMDI, standard particle, HFA)	>200
Mometasone furoate (pMDI, standard particle, HFA)	200

If not selected "yes" for all the above (except for options with "or"): The patient does not fulfil all the inclusion criteria for SPACE, and will therefore not be included in the database

Conditions that might mimic asthma:

Conditions	√
Allergic Bronchopulmonary Aspergillosis	
Bronchiolitis Obliterans	
Bronchopulmonary Dysplasia	
Cystic Fibrosis	
PCD	
Significant bronchiectasis (not related to asthma)	
Protracted bacterial bronchitis	
Hypersensitivity pneumonia	
Severe Immunodeficiency/ Immunosuppression	
Central airway obstruction, or compression	
Vocal cord dysfunction/ Hyperventilation	
Swallowing dysfunction	
Congenital airway malformation (e.g. vascular ring)	
Foreign body	
Tracheobronchomalacia	
Interstitial Lung Disease	
Lobectomy	
Other pulmonary surgery	
Carcinoid or other tumour	
Congenital Heart Disease	
Connective Tissue Disease	
Neuromuscular Diseases	

*This patient's symptoms are primarily due to asthma, rather than the above list of conditions.

Yes ☐ No ☐

If selected "no":
This patient does not fulfil all the inclusion criteria for SPACE, and will therefore not be included in the database.

CURRENT COMORBIDITIES AND RISK FACTORS

Conditions	Present	Not assessed	Not present
Nasal polyps (ENT endoscopy)			
Obstructed sleep apnoea (positive PSG)			
Eosinophilic Oesophagitis (oesophageal endoscopy + criteria on biopsies)			
Symptomatic gastro-oesophageal reflux (clinical diagnosis)			
Atopic dermatitis			
Allergic rhinitis or conjunctivitis			
Food allergy (current clinical symptoms with previous provocational evidence + IgE and/or skin prick test positivity)			
Other chronic diseases (please list with CDC code): _____			

Smoking history

	Yes	No	Unknown
Does the patient smoke cigarettes?			
Does the patient smoke e-cigarettes/vape?			
Does father smoke?			
Does mother smoke?			
Does anyone else smoke at home?			

BACKGROUND INFORMATION

Lung function at recruitment *(recruitment and lung function should be far from an exacerbation)*:

Date: _____

Weight (kg): _____ Height (cm): _____

Was LABA administered in the 12 hours (formoterol, salmeterol) or 24 hours (vilanterol) prior to lung function test? Yes ☐ No ☐

Pre-bronchodilator Please enter the raw spirometry values, the predicted values and z-scores can be automatically calculated on the SPACE website.		
	Value	**Z-score**
FEV1 (L)		
FEV1 (% predicted)		
FVC (L)		
FVC (% predicted)		
FEV1:FVC ratio		
FEF 25-75 (L/sec)		
FEF 25-75 ((% predicted)		

☐ ☐

Post-bronchodilator Please enter the raw spirometry values, the FEV1 change, predicted values and z-scores can be automatically calculated on the SPACE website.		
	Value	**Z-score**
FEV1 (L)		
FEV1 (% predicted)		
FVC (L)		
FVC (% predicted)		

FeNO (ppb) (not during exacerbations)
(Mandatory only for patients who are just (within 1 month) starting on a biologic treatment)

Not done ☐

	Date	Result
At recruitment or in the last 12 months		

Blood eosinophil count
(Mandatory only for patients who are just (within 1 month) starting on a biologic treatment)

Not done ☐

	Date	Absolute number of eosinophils
At recruitment or in the last 12 months		

Total IgE °
(Mandatory only for patients who are just (within 1 month) starting on a biologic treatment)

N/A because on Omalizumab ☐

	Date	Result	Units
At recruitment or in the last 12 months			kU/L *or* IU/ml *(please circle)*

° to be filled in only if the patient is/was NOT on Omalizumab

Please perform either specific IgE or skin prick test for aeroallergens if not done previously.

Specific IgE (latest, any time in the past) - please rate as positive if >0.35 Ku/L

Not done ☐
Date _____

House dust mite (any)	Positive / Negative/ Not done	Egg	Positive / Negative/ Not done
Cat	Positive / Negative/ Not done	Milk	Positive / Negative/ Not done
Dog	Positive / Negative/ Not done	Fish	Positive / Negative/ Not done
		Shellfish	Positive / Negative/ Not done
Ragweed / weeds (mix)	Positive / Negative/ Not done	Wheat	Positive / Negative/ Not done
Grass pollen (mix or individual)	Positive / Negative/ Not done	Peanut/ tree nuts	Positive / Negative/ Not done
Tree pollen (mix or individual)	Positive / Negative/ Not done		
Mould (mix or individual)	Positive / Negative/ Not done		
Aspergillus	Positive / Negative/ Not done		
Alternaria	Positive / Negative/ Not done		
Cladosporium	Positive / Negative/ Not done		

Skin prick test (latest, any time in the past) - please rate as positive if > 3mm

Not done ☐
Date: _____

House dust mite (any)	Positive / Negative/ Not done	Egg	Positive / Negative/ Not done
Cat	Positive / Negative/ Not done	Milk	Positive / Negative/ Not done
Dog	Positive / Negative/ Not done	Fish	Positive / Negative/ Not done
		Shellfish	Positive / Negative/ Not done
Ragweed / weeds (mix)	Positive / Negative/ Not done	Wheat	Positive / Negative/ Not done
Grass pollen (mix or individual)	Positive / Negative/ Not done	Peanut/ tree nuts	Positive / Negative/ Not done
Tree pollen (mix or individual)	Positive / Negative/ Not done		
Mould (mix or individual)	Positive / Negative/ Not done		
Aspergillus	Positive / Negative/ Not done		
Alternaria	Positive / Negative/ Not done		
Cladosporium	Positive / Negative/ Not done		

Lung imaging: CT - latest, not during exacerbations

Not done ☐

Date	Type	Findings	√
	CT	Normal	
		Air trapping	
		Bronchial wall thickening	
		Bronchiectasis	
		Atelectasis	
		Mucous plugging	
		Other_____	

Bronchoscopy (latest)

Not done ☐

Date: _____

Total number of cells/mm^3: _____

Eosinophils (%): _____

Neutrophils (%): _____

Macrophages (%)_____

Lipid Laden Macrophage (%): _____

Organisms	√	Organisms	√
Staphylococcus aureus		Mycoplasma pneumoniae	
Methicillin-resistant Staphylococcus aureus		Aspergillus	
Streptococcus pneumoniae		Haemophilus influenzae	
Acinetobacter baumanni		Chlamydia pneumoniae	
Pseudomonas aeruginosa		Other: _____	

ASTHMA CONTROL AT RECRUITMENT (not during an exacerbation)

- Composite Asthma Severity Index (**CASI** questionnaire)
  Daytime symptoms score: _____
  Night time symptoms score: _____
  Lung function score:_____
  Treatment score: _____
  Exacerbation score: _____

  Total composite asthma severity index *(automatically calculated on website)*: _____

- Test of adherence to inhalers (**TAI** questionnaire)
  Answered by patient/parents (total score from questions 1-5): _____
  Answered by patient/parents (total score from questions 6-10): _____

  Total TAI score *(automatically calculated on website)*: _____

- Paediatric asthma quality of life questionnaire (**PAQLQ**) score
  Domains:
  Activity Limitation (total score from questions 1,2,3,19,22): _____
  Symptoms (total score from questions 4,6,8,10,12,14,16,18,20,23): _____
  Emotional Function (total score from questions 5,7,9,11,13,15,17,21): _____

  Total PAQLQ score *(automatically calculated on website)*: _____

- Childhood Asthma Control Test (CACT) – Years 6 to <12
  Total score: _____

  OR

  Asthma Control Test (ACT)
  Total score: _____

- **GINA** assessment
  In the past 4 weeks before recruitment, has the patient had:

Daytime asthma symptoms more than twice/week?	
Any night waking due to asthma?	
Reliever needed for symptoms more than twice/week?	
Any activity limitation due to asthma?	

The following degree of control will be automatically calculated on the website:

Well controlled ☐ Partly controlled ☐ Uncontrolled ☐

In the last 12 months before enrolment, in relation to asthma:

Number of episodes requiring systemic steroid for ≥ 3 days	
Number of unscheduled medical attendances (GP/ emergency department)	
Number of episodes requiring non-invasive ventilatory support	
Number of episodes requiring intubation and ventilation	
Number of hospital admissions (>4 hours of hospital stay) for acute asthma	
Persistent chronic asthma symptoms *(most days for >3 months)*	Yes/No

Since diagnosis of asthma (including the last 12 months):

Number of ICU admission	
Number of episodes requiring intubation and ventilation	

TREATMENTS AT ENROLMENT

Anticholinergic	√
Ipratropium Bromide	
Tiotropium	

Combination inhaled treatment	√	**Total daily steroid dose (µg)**
Formoterol & Beclometasone		
Formoterol & Budesonide		
Formoterol & Fluticasone propionate		
Salmeterol & Fluticasone		
Vilanterol & Fluticasone furoate		
Other: _____		

Inhaled steroid (single inhaler)	√	**Total daily steroid dose (µg)**
Beclometasone		
Beclometasone extra fine		
Budesonide		
Ciclesonide		
Flunisonide		
Fluticasone Furoate		
Fluticasone Propionate		
Mometasone		
Triamcinolone		
Other: _____		

Systemic corticosteroid	√	**Frequency**	**Total daily steroid dose (on days the patient takes systemic corticosteroids), mg**
Prednisolone		Daily/ Every other day/ Other: _____	
Dexamethasone		Daily/ Every other day/ Other: _____	
Other: _____		Daily/ Every other day/ Other: _____	

Leukotriene receptor antagonist	√
Montelukast	
Zafirlukast	

Long acting beta agonist (single inhaler)	√
Formoterol	
Salmeterol	
Vilanterol	

Monoclonal antibody	Start date	Dose (mg)	Frequency
Mepolizumab			Bi-weekly / Monthly / Other: _____
Omalizumab			Bi-weekly / Monthly / Other: _____
Dupilumab			Bi-weekly / Monthly / Other: _____
Tezepelumab			Bi-weekly / Monthly / Other: _____
Other:			Bi-weekly / Monthly / Other: _____

Monoclonal antibody administered off-label? Yes ☐ No ☐

If YES: For age ☐
For indications (criteria for prescription) ☐
Other reasons ☐

Previous monoclonal antibody use

Tried (but stopped) another monoclonal antibody? Yes ☐ No ☐

If YES:

Biologic: Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other: _____
Start date:_____ End date: _____

Reason for discontinuation:

☐ Non-responder/ partial responder

☐ Uncontrolled comorbidity (e.g. dermatitis) – please specify _____

☐ Side effects – please specify _____

☐ Other – please specify _____

Biologic: Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other: _____
Start date:_____ End date: _____

Reason for discontinuation:

☐ Non-responder/ partial responder

☐ Uncontrolled comorbidity (e.g. dermatitis) – please specify _____

☐ Side effects – please specify _____

☐ Other – please specify _____

Biologic: Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other: _____
Start date:_____ End date: _____

Reason for discontinuation:

☐ Non-responder/ partial responder

☐ Uncontrolled comorbidity (e.g. dermatitis) – please specify _____

☐ Side effects – please specify _____

☐ Other – please specify _____

Biologic: Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other: _____
Start date:_____ End date: _____

Reason for discontinuation:

☐ Non-responder/ partial responder

☐ Uncontrolled comorbidity (e.g. dermatitis) – please specify _____

☐ Side effects – please specify _____

☐ Other – please specify _____

ADDITIONAL INFORMATION

Will the patient be happy to take part in future trials? Yes ☐ No ☐ Undecided ☐

Provide any additional required information

– **The End** –