Severe Paediatric Asthma Collaborative in Europe (SPACE) Registry

16 week follow up – for those who started a biologic when recruited into SPACE

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)

Date of 16-week follow-up: _____

Is the patient still under follow-up at your department? Yes ☐ No ☐

If no, reason:

Transitioned to adult care ☐
Not followed up by the centre anymore ☐
Other reasons ☐

BACKGROUND INFORMATION
Lung function at follow up:

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%		
FEF 25-75 (% predicted)		

FeNO (ppb) (while on biologics, not during exacerbations, latest result since recruitment)

	Date	Result
Latest since recruitment		

Blood eosinophil count (while on biologics, since recruitment, cells/µl)

	Date	Absolute number of eosinophils
Latest since recruitment		

Total IgE * (since recruitment)

	Date	Result	Units
Latest since recruitment			kUL / lUml

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

ASTHMA CONTROL at 16-week follow up (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 score (total score from questions 1-5): _____
  Answered by patient/parents score (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, 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 ☐

Since recruitment, 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
Number of ICU admission	

RESPIRATORY TREATMENTS at 16-week follow up

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: _____

Is the patient still on a monoclonal antibody? Yes ☐ No ☐

If YES:
Is the patient on the same monoclonal antibody as at recruitment? Yes ☐ No ☐
If NO, please ensure current monoclonal antibody is in the medication section above.

Is the current monoclonal antibody administered off-label? Yes ☐ No ☐

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

If NO:
Please provide information on all previously used but discontinued monoclonal antibody treatment(s) since recruitment.

Monoclonal antibody discontinued:

Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other _____
Start date (month/year): _____ Stop date (month/year): _____
Reason for discontinuation:
- ☐ Non-responder / partial responder
- ☐ Uncontrolled co-morbidity (e.g. atopic dermatitis)
  Please specify: _____
- ☐ Side effects
  Please specify: _____
- ☐ Other
  Please specify: _____

Monoclonal antibody discontinued:

Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other _____
Start date (month/year): _____ Stop date (month/year): _____
Reason for discontinuation:
- ☐ Non-responder / partial responder
- ☐ Uncontrolled co-morbidity (e.g. atopic dermatitis)
  Please specify: _____
- ☐ Side effects
  Please specify: _____
- ☐ Other
  Please specify: _____

Monoclonal antibody discontinued:

Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other ________
Start date (month/year): _________ Stop date (month/year): ________
Reason for discontinuation:
☐ Non-responder / partial responder
☐ Uncontrolled co-morbidity (e.g. atopic dermatitis)
Please specify: _________________
☐ Side effects
Please specify: __________________
☐ Other
Please specify: __________________

Monoclonal antibody discontinued:

Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other ________
Start date (month/year): _________ Stop date (month/year): ________
Reason for discontinuation:
☐ Non-responder / partial responder
☐ Uncontrolled co-morbidity (e.g. atopic dermatitis)
Please specify: _________________
☐ Side effects
Please specify: __________________
☐ Other
Please specify: __________________

Since recruitment/last follow up, did the patient experience side effects related/possibly related to biologic? Yes ☐ No ☐

If YES:
Which biologic?
Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other ________
Injection site side effects:
Erythema / Edema / Noduli / Other ________
Systemic side effects:
Anaphylaxis / Arthralgia / Parasitic Infection / Urticaria / Angioedema / Rash / Other ________

Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other ________
Injection site side effects:
Erythema / Edema / Noduli / Other ________
Systemic side effects:
Anaphylaxis / Arthralgia / Parasitic Infection / Urticaria / Angioedema / Rash / Other ________

Omalizumab / Mepolizumab / Dupilumab / Tezepelumab / Other ________
Injection site side effects:
Erythema / Edema / Noduli / Other ________
Systemic side effects:
Anaphylaxis / Arthralgia / Parasitic Infection / Urticaria / Angioedema / Rash / Other ________

ADDITIONAL INFORMATION

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

Provide any additional information

– **The End** –