



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?

Yes ☐

No ☐

If no, reason:

Transitioned to adult care ☐

Not followed up by the centre anymore ☐

Other reasons: _____

Since the last SPACE visit, was biologic use discontinued?

Yes ☐

No ☐

If Yes, please fill in only the biologic therapy section of this form, including relevant dates and the reason for stopping.

Is the most recently administered biologic the same as the one used at the last SPACE visit?

Yes ☐

No ☐

(Please consider omalizumab and omalizumab biosimilar to be the same drug.)

If Yes, please fill in the rest of the form.

If No, please fill in only the biologic therapy section of this form, including which biologic was discontinued, reason for discontinuation; which is the new biologic, its start date, dose and frequency.

*Note: If you manage to review the patient again just before (14 days) switching or at the time of switching to a new biologic → **Please complete the biologic section of this form and fill in the Switch Form.***

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/ μ l)

	Date	Absolute number of eosinophils
Latest since recruitment		

Total IgE * (since recruitment)

	Date	Result	Units
Latest since recruitment			kUL / IUml

****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 (<i>most days for >3 months</i>)	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
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Mepolizumab			Bi-weekly / Monthly / Other: _____
Omalizumab			Bi-weekly / Monthly / Other: _____
Omalizumab Biosimilar			Bi-weekly / Monthly / Other: _____
Autoinjector ☐			
Pre-filled syringe ☐			
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/ Omalizumab Biosimilar/ 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: _____

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- ☐ Non-responder / partial responder
- ☐ Uncontrolled co-morbidity (e.g. atopic dermatitis)
Please specify: _____
- ☐ Side effects
Please specify: _____
- ☐ Other
Please specify: _____

Monoclonal antibody discontinued:

Omalizumab/ Omalizumab Biosimilar/ 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/ Omalizumab Biosimilar/ Mepolizumab/ Dupilumab/ Tezepelumab/ Other ____

Injection site side effects:

Erythema / Edema / Noduli / Other _____

Systemic side effects:

Anaphylaxis / Arthralgia / Parasitic Infection / Urticaria /
Angioedema / Rash / Other _____

Omalizumab/ Omalizumab Biosimilar/ Mepolizumab/ Dupilumab/ Tezepelumab/ Other ____

Injection site side effects:

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Anaphylaxis / Arthralgia / Parasitic Infection / Urticaria /
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Omalizumab/ Omalizumab Biosimilar/ 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

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– The End –