



About SPACE

SPACE is an international online database which collects prospective (recruitment and follow ups) data on two groups of patients with severe asthma:

1. Patients who are **already on a biologic treatment**; or
2. Patients who are **starting a biologic treatment**.

At recruitment patients should be between 6 to <18 years old. If a patient is recruited when <18 years old and continues to be followed up by the centre after turning 18 years old, SPACE follow up will still be accepted.

Recruitment

1. Patients **already on a biologic**: can be recruited at any time.
2. Patients **starting on a new biologic**: can be recruited just before (within one month) the first injection.

For all patients, recruitment should take place when there is no recent asthma attack. In case of an asthma attack in the past month, recovery should be complete at recruitment.

For all patients, information (including lung function and asthma scores which are found under "Asthma Control at Recruitment" section – see below) must be collected at the time of recruitment.

Please note a date is recorded only for lung function.

For all patients, either specific IgE or skin prick test for aeroallergens are mandatory; please perform them if not done previously (we accept historical results).

For patients starting on a new biologic, FeNO, blood eosinophils, and total IgE are mandatory at recruitment or in the previous 12 months (and again within the 12 months before each subsequent follow up). If these tests are not conducted at the time of recruitment, we accept results from the 12 months prior to the new biologic injection.

Please note that the date of data entry is not necessarily the same as the date of recruitment or the date of follow up. We only take into consideration the date of recruitment or follow up. Be sure to fill this in.

Informed consent

Informed consent must be obtained from patients (for those who are of/over legal age of consent), or parents/guardians (for patients under the legal age of consent).

Obtaining assent is optional, depending on local guidance from your hospital or country.

Lung function at recruitment and at follow up:

Ideally lung function should be done at the same time as “Asthma control” questions, at recruitment and at follow-up “within the acceptable time frames” (see below).

For lung function, a date must be provided, and this will be checked against the recruitment or follow-up date. A difference of a few days is acceptable, but please write in the comments at the end of the form whether the clinical conditions at the time of lung function test were the same as at recruitment or follow-up. However, if the difference is several weeks, we cannot accept the lung function values.

“Asthma Control” at recruitment and at follow up

SPACE collects multiple asthma scores to enable comparison and evaluation of which ones are most effective in assessing asthma control. It is therefore important to have all scores completed at recruitment and at each follow-up. Some scores should be filled in by doctors and can be downloaded in English from the registry website (see below for instructions), others can be self-administered by patients, depending on the child’s age (e.g. ≥ 10 years). You may help the child or adolescent to read or understand the questions.

***TAI** (test of adherence to inhalers questionnaire) was developed for adult patients as self-administered. The questionnaire can be downloaded from the TAI website (see below for instructions) in different languages. TAI can be self-administered in children ≥ 10 years old; or administered by healthcare professionals for those < 10 years old. Please note we do not collect the final two questions of the questionnaire (Questions 11 and 12).*

***PAQLQ:** Due to copyright, please obtain the questionnaire in your language from <https://www.qoltech.co.uk/paqlq.html> (we have questionnaires in several languages, which we can send to you upon request). We have opted to use the Standardised Paediatric Asthma Quality of Life Questionnaire (Interviewer-administered) for children < 10 years old; the same questionnaire can be self-administered in children ≥ 10 years old.*

***Asthma Control Test (ACT):** Please use Childhood-ACT (cACT) for 6 to < 12 years old and ACT for ≥ 12 years. Please obtain the questionnaire in your language from <https://www.asthmacontroltest.com> and follow the instructions.*

Follow up:

For all patients, follow-up visit should take place when there is no recent asthma attack. In case of an asthma attack in the past month, recovery should be complete at follow up.

For all patients, information (including lung function and asthma scores which are found under “Asthma Control” section – see below) must be collected at the time of follow-up. Please note a date is recorded only for lung function.

- 1. For patients who are **already on a biologic**, they should be followed up annually.*
- 2. For patients who are **starting on a new biologic**, they should be followed up at 16 weeks after the first biologic injection (to assess for any response), then at 52 weeks after the first biologic injection, then annually.*

Acceptable time frames for follow up:

- **16 week follow up** (for patients who are starting a new biologic at recruitment):
Due day = 16 weeks from day of first injection
Acceptable time frame for follow up to occur: - **1 weeks to + 4 weeks of due date**
- **Annual follow up** (for all patients):
1st due day = 52 weeks from day of recruitment (for patients starting a new biologic: this will be from the day of first injection)
2nd due day = 2 years from day of recruitment (or day of first injection); etc...
Acceptable time frame for follow up to occur: - **4 weeks to + 13 weeks of due date**

If a patient cannot be seen within the acceptable timeframes, please skip that follow-up and proceed with the next one. We kindly ask you to plan follow-ups within the acceptable timeframes whenever possible.

Follow-up special scenarios

- ❖ If a patient is **no longer followed up** by your centre, please provide this information in the next follow-up form as soon as you become aware, even if this is before the acceptable follow-up timeframe.
For example:
 - If a patient is recruited as **already on biologic** (so will require annual follow-up), and is no longer followed up by your centre at 24 weeks after recruitment, please provide this information as soon as you become aware, using the 52-week follow-up form.
 - If a patient is recruited as starting a biologic (so will require 16-week follow-up, 52-week follow-up and then annual follow-up), and is no longer followed up by your centre at 13 weeks after recruitment, please provide this information as soon as you become aware, using the 16-week follow-up form. If he/she is no longer followed up at 50 weeks after recruitment, please provide this information as soon as you become aware, using the 52-week follow-up form. If he/she is no longer followed up at 66 weeks after recruitment, please provide this information as soon as you become aware, using the 2-year follow-up form.

When a follow-up form is created, there are options to choose whether the patient is still followed up; and if not, for what reason.

- ❖ If a patient **stops using biologic** between follow-ups, as above, please provide this information in the next follow-up form as soon as you become aware, even if this is before the acceptable follow-up timeframe.
- ❖ If a patient **switches to a different biologic**: the SPACE website is being updated to include a "Switching Biologic Form", while this feature is under construction, please collect the required switching information using a new baseline form on paper.

Paper version of the forms

If you are new to SPACE, please download the paper versions of the forms for details on inclusion criteria and required data, as these are not included in this document.

We recommend filling in the baseline (recruitment) and/or follow-up forms fully (or partly) on paper, before entering data online onto database website.

INSTRUCTIONS ON HOW TO FILL IN THE FORMS ON THE SPACE WEBSITE

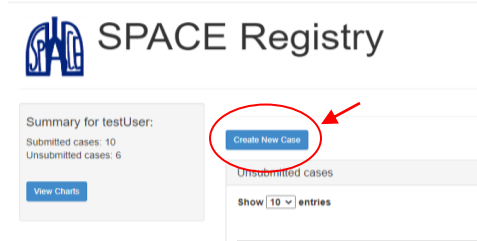
Paper versions of the forms

All forms can be downloaded from <https://asthmaregistry.hicservices.dundee.ac.uk/downloads>.

The screenshot shows the SPACE Registry website interface. At the top left is the SPACE Registry logo. Below it is a navigation bar with the following items: 'SPACE Registry', 'Home', 'Downloads' (circled in red), and 'nlIU'. Below the navigation bar, there is a 'Summary for nlIU:' section with the following text: 'Submitted cases: 874' and 'Unsubmitted cases: 21'. To the right of this summary is a 'Create New Case' button. Below the 'Create New Case' button is a section titled 'Unsubmitted cases' with a search icon. Underneath this section is a 'Show' dropdown menu with '10' selected and 'entries' below it. To the right of the dropdown is a search box labeled 'Search:'.

CREATING A NEW CASE ONLINE

Click "Create New Case":



SECTION 1: Basic Case Information section

Fill in all basic case information.

The patient code number will be automatically generated, this code links the patient ID to your centre so please do not change this automatically generated code.

Basic Case Information [back](#)

Automatically generated → Patient code number

Ethnicity

Automatically generated → Centre

Informed consent

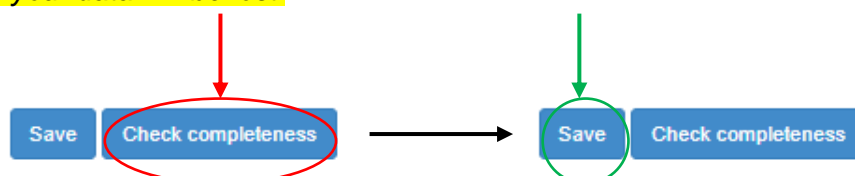
Please tick "yes" for informed assent even if you do not require to obtain assent, in order to move forward to the next section of the database form:

Written informed consent Yes No
(please obtain informed consent before collecting/ entering data)

Written informed assent (child) Yes No

At the end of each section, check the completeness and SAVE.

We recommend you click on "Check completeness" at the end of each section to make sure all the fields are filled in. Please click "Save" before moving on to the next section or signing out of the website, otherwise your data will be lost!



SECTION 2: Criteria For Inclusion

Please fill in the next section (“Criteria For Inclusion”) to ensure the patient is eligible to be included in the database.

Case Testing1 (Prospective)

[Back to list](#)

Basic Case Information

Complete

→ Criteria For Inclusion

Draft

Criteria for inclusion are detailed in the baseline form which is filled in at recruitment.

The two groups (already on a biologic; starting a new biologic) are differentiated in the “Criteria For Inclusion” section of the online database form:

Biologic use

Currently on a biologic treatment Yes No


OR

Just before (within 1 month) starting on a biologic treatment Yes No

For patients who are **starting on a new biologic**, they must fulfil the additional inclusion criteria of being treated with high dose inhaled corticosteroids as per GINA guidelines, or systemic steroids:

Just before (within 1 month) starting on a biologic treatment Yes No

Treatment (at least 1 of the options, at recruitment)

High dose inhaled corticosteroids  for at least 6 months in the last year and at time of recruitment Yes No

AND


LABA or second controller for at least 6 months in the last year and at time of recruitment Yes No

OR

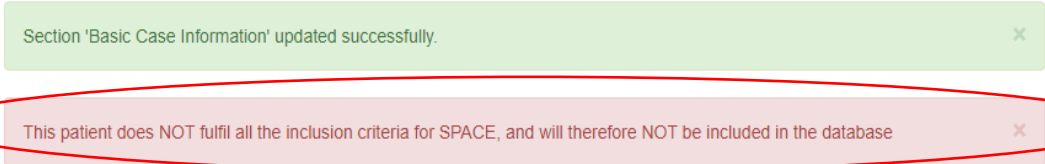
Systemic corticosteroids for \geq 25% of last 12 months Yes No

Hover your mouse over the “?” icon next to “high dose inhaled corticosteroids” to see the definitions which will popup on screen:

Treatment (at least 1 of the options, at recruitment)

High dose inhaled corticosteroids  for at least 6 months in the last year and at time of recruitment Yes No

If inclusion/exclusion criteria are not fulfilled, the patient will not be included.



Section 'Basic Case Information' updated successfully. ✕

This patient does NOT fulfil all the inclusion criteria for SPACE, and will therefore NOT be included in the database ✕

If the patient fulfils the inclusion criteria, the other sections will become available.

Basic Case Information	Complete
Criteria For Inclusion	Complete
Current Comorbidities and Risk Factors	Draft
Background	Draft
Asthma Control at recruitment	Draft
Treatment at enrolment	Draft
Additional Information	Draft

When all fields have been filled in, the section appears green (“COMPLETE”). If any fields are missing, the section appears red (“DRAFT”). If there is no way you can provide the missing data, please proceed and leave the section(s) as “DRAFT”. You can still submit the case with sections in “DRAFT”.



Basic Case Information	Complete	←
Criteria For Inclusion	Complete	
Comorbidities and Background	Draft	←

SECTION 3: Current Comorbidities and Risk Factors

Enter data within this section – remember to click “Save” before moving on.

SECTION 4: Background

For lung function, please enter raw spirometry values and click “calculate”, the z-scores and predicted values will be automatically calculated.

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 will be automatically calculated



	Value	Z-score		Value	Z-score
FEV ₁ L	<input type="text"/>	<input type="text"/>	FVC L	<input type="text"/>	<input type="text"/>
FEV ₁ L (% predicted)	<input type="text"/>		FVC L (% predicted)	<input type="text"/>	
FEV 25-75% (L/sec)	<input type="text"/>	<input type="text"/>	FEV ₁ :FVC ratio (%)	<input type="text"/>	
FEV 25-75 (% predicted)	<input type="text"/>				

Post-bronchodilator

Please enter the FEV₁-Post value. The FEV₁ change and FEV₁ % of change will be automatically calculated




	Value	Z-score		Value
FEV ₁ (L)	<input type="text"/>	<input type="text"/>	FVC (L)	<input type="text"/>
FEV ₁ (% predicted)	<input type="text"/>			
FEV ₁ (% of change)	<input type="text"/>			




Enter data within this section – remember to click “Save” before moving on to the next section.

SECTION 5: Asthma Control at recruitment

The **download buttons (red arrows below)** will take you directly to the English versions of CASI and TAI questionnaires.

The **total scores** for CASI, TAI, PAQLQ will be automatically calculated.

Composite Asthma Severity Index (CASI questionnaire)		
Daytime symptoms score	<input type="text"/>	
Night time symptoms score	<input type="text"/>	
Lung function score	<input type="text"/>	
Treatment score	<input type="text"/>	
Exacerbation score	<input type="text"/>	
Total composite asthma severity index	<input type="text"/>	 Automatically calculated


Test of adherence to inhalers (TAI questionnaire)		
Answered by patient/parents (total score from questions 1-5)	<input type="text" value="3"/>	
Answered by patient/parents (total score from questions 6-10)	<input type="text" value="4"/>	
Total TAI score	<input type="text" value="7"/>	 Automatically calculated

TAI questionnaire: Please download a version in your own language from the official website (<https://www.taitest.com>):

PAQLQ: Please obtain the questionnaire in your language from the SPACE team or from <https://www.qoltech.co.uk/paqlq.html> - please refer to above regarding which questionnaire to use and how to administer it.

Asthma Control Test (ACT): Please use Childhood-ACT (cACT) for 6 to < 12 years old and the ACT for 12 years and above. Please obtain the questionnaire in your language from <https://www.asthmacontroltest.com/> and follow Instructions.

GINA assessment: Please tick all the applicable boxes, the level of control will automatically be calculated.

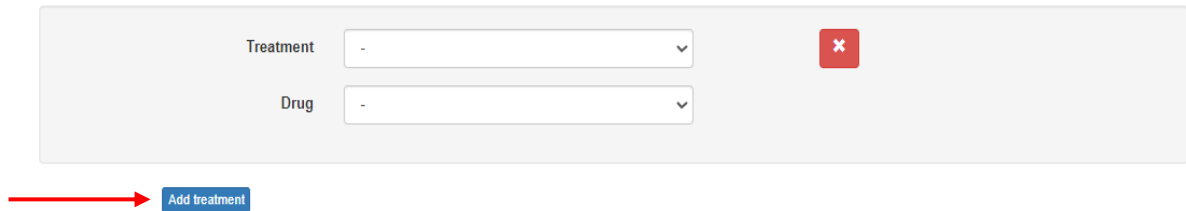
GINA assessment	In the past 4 weeks has the patient had:
	<input type="checkbox"/> Daytime asthma symptoms more than twice/week?
	<input type="checkbox"/> Any night waking due to asthma?
	<input type="checkbox"/> Reliever needed for symptoms more than twice/week?
	<input type="checkbox"/> Any activity limitation due to asthma?
Automatically generated	 Result: Well controlled.

Remember to click “Save” before moving on to the next section.

SECTION 6: Treatment at recruitment

Please input ALL respiratory treatments including the biologic that is patient is currently using or is about to start on.

Click “Add treatment” to add all other treatments.



Under “Previous monoclonal antibody use”, please include all previously used biologic treatments and provide start and end dates of each biologic, and reasons for discontinuation.

Please provide detailed responses in all free-text fields that appear throughout the form.

Remember to click “Save” before moving on to the next section.

SECTION 7: ADDITIONAL INFORMATION

Please include any relevant information in the free-text field.

Remember to click “Save” before closing the section.

SUBMITTING THE CASE

When all sections are completed, please **SUBMIT** the case.

If there is no way you can provide any missing data, please go on and leave the section(s) as “DRAFT” – you will still be able to submit the case but ideally, where possible, we would encourage you to submit forms with fully “COMPLETED” sections.

Once submitted, the case cannot be modified! If there is anything you would like to change to submitted cases, please contact the SPACE team.



CREATING FOLLOW UP

To follow up a patient, go to the main page of your account, under “submitted case”, select the correct patient and click “Create Follow Up” (red arrow below).

Please note, under “Biologic Treatment” (green circles below), the system automatically classifies cases into “On bio” for patients who are on biologic at recruitment, and “Start Bio” for patients who are starting biologic at recruitment. This helps us identify the two streams of patients and will remain the same throughout the patient’s journey, even though all patients will ultimately be on biologics during their time in SPACE.

Please do not be alarmed if the case status remains as “Awaiting approval” (red circle below) – we do not routinely approve cases but will check data entries regularly and get in touch with you if there are any missing or erroneous entries.

Patient	Case type	Biologic Treatment	Submitter	Date	Status	
13082024	Standard	On bio	frusconi (franca.rusconi@meyer.it)	13/08/2024	Awaiting approval	Create Followup
9991	Standard		admin (p.marshall001@dundee.ac.uk)	14/02/2023	Approved	Create Followup
FR 16/09/24	Standard	Start bio	frusconi (franca.rusconi@meyer.it)	17/09/2024	Awaiting approval	Create Followup

After clicking “Create Follow Up”, select the correct type of follow up, and fill in the form accordingly.

Follow up: Select...
Is the patient still under follow-up?
16 week
Annual follow up
Save

Please note that for patients who **started a biologic when recruited**: FeNO, blood eosinophils, and total IgE **at time of follow up** are mandatory.

SPECIAL SCENARIOS

- ❖ If a patient is **no longer followed up** by your centre, please provide this information in the next follow-up form.

Is the patient still under follow-up? Yes No

Transitioned to adult care

Not followed up by the center anymore

Other reasons

- ❖ If a patient **stops using biologic** between follow ups, as above, please provide this information in the next follow-up form.

Under “Respiratory Treatment” section of the follow-up form, please tick “No” for “Is the patient still on a monoclonal antibody?”; and provide information on why the last biologic was discontinued. If more than one biologic were tried and discontinued between now and recruitment (if this is the first follow-up form), or between now and last follow up (if there has been a previous follow-up form), please list out the biologics with discontinuation reasons:

Is the patient still on a monoclonal antibody? Yes No

Please provide information on all previously used but discontinued monoclonal antibody treatment(s) since last follow up

Discontinued monoclonal antibody	<input type="text" value="Other"/>	<input type="text"/>	<input type="button" value="x"/>
Start Date	<input type="text"/>		
End Date	<input type="text"/>		
Reason for discontinuation	<input type="text" value="-"/>		

Add another previously used but discontinued monoclonal antibody since last follow up