



SPACE registry user guide

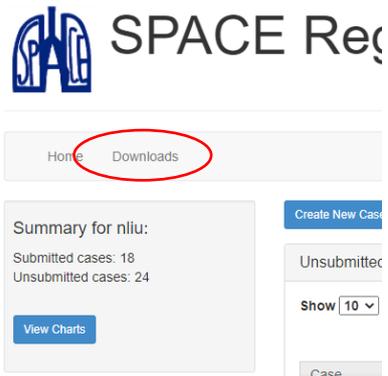
SPACE registry website:

<https://hicservices.dundee.ac.uk/Space/>

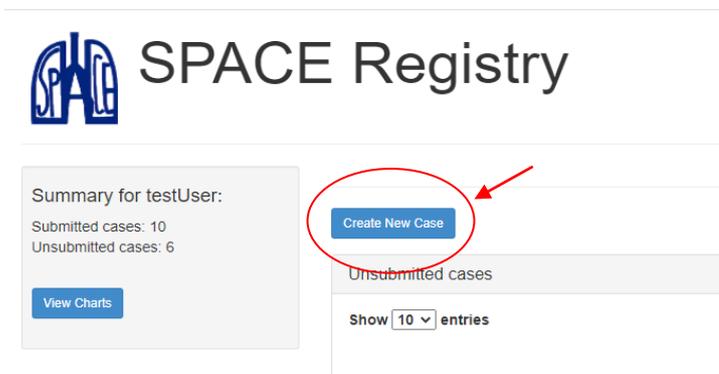
SPACE database 2024 update:

- Please note that SPACE no longer has “cross sectional” and “prospective” branches.
- SPACE now only has one stream – we will collect data on patients who are already on a biologic treatment, as well as those who are starting a new biologic treatment, along the same stream on the database website. The differentiation of the two groups is in the “Criteria For Inclusion” section of the online database form.
- For patients who are already on a biologic treatment, they should be followed up annually. (See point 6 below).
- For patients who are starting on a new biologic treatment, they must fulfil the inclusion criteria of being treated with high dose inhaled corticosteroids as per GINA guidelines, or systemic steroids. There is an additional 16-week follow up for these patients, as well as the annual follow ups. (See point 6 below). For patients starting on a new biologic, FeNO, blood eosinophils, and total IgE at recruitment or in the previous 12 months (and then at follow up or in the previous 12 months) are mandatory.
- All patients should be recruited at a distant time from any asthma exacerbation; this applies also for follow up visits and forms.
- If a patient is no longer followed up, please provide this information in the next follow up form – there are options to choose whether the patient is still followed up, and for what reasons, at the beginning of the follow up form.
- If a patient stops using biologic between follow ups, please provide this information in the next follow up form – there are questions and a free text box at the end of the form where you can list out any trialed and discontinued biologics, dates of discontinuation, and reasons why the drugs have been discontinued.
- Please follow up patients within the following acceptable timeframe:
 - 16 week follow up (for patients who are starting on a new biologic treatment at recruitment): **-1 weeks to + 4 weeks of due date**
 - Annual follow up (for all patients): **- 4 weeks to + 13 weeks of due date**

1. You can download the printable versions of the database CRF forms via the “download” tab.



2. To add a new patient, click “Create New Case”.



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

Caucasian



Automatically generated



Centre

3. Fill in the “Basic Case Information” section.

Please ensure you have obtained informed consent from the parent/guardian or you will not be allowed to continue. If your country/hospital allows young people (e.g. age 16 years or above) to provide their own consent, please tick “yes” for informed consent, and tick “yes” for informed assent even if you do not require assent as well as consent in such a case.

Written informed consent Yes No

(please obtain informed consent before collecting/ entering data)

Written informed assent (child) Yes No

Once you click “Save”, you will be directed back to the main page.

4. 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

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](#)

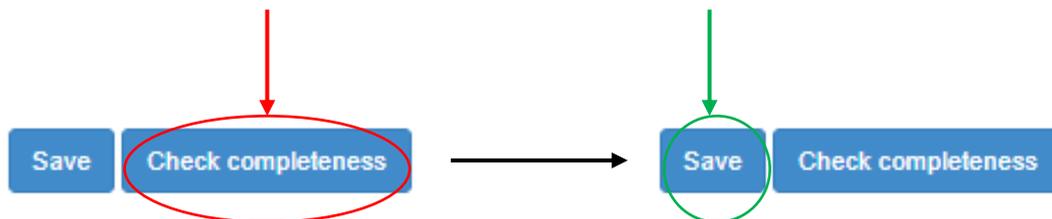
Draft

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 go on and leave the section(s) as “DRAFT”.



5. 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!



6. Under “Criteria For Inclusion” → “Confirmation of asthma” → please select the biologic use for the patient at the time of recruitment:

- “**Currently on a biologic treatment**” at the time of recruitment
 - The system will prompt you to follow these patients up every year
- “**Just before (within 1 month) starting on a biologic treatment**” at the time of recruitment
 - The system will prompt you to follow these patients up at 16 weeks, followed by yearly follow up – to capture response to the biologic treatment.
 - These patients have to fulfil the treatment criteria (high dose inhaled corticosteroids, LABA, etc):
 - Hover your mouse over the “?” icon next to “high dose inhaled corticosteroids” to see the definitions which will pop-up 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

SECTIONS

“Background Information”

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

“Asthma control”

The **download buttons** will take you directly to the CASI and TAI questionnaires.

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

Composite Asthma Severity Index (CASI questionnaire)	<input type="button" value="↓"/>	←
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)	<input type="button" value="↓"/>	←
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

For TAI questionnaire, the download button will take to the English version. You can download versions in your own language from the official website (<https://www.taitest.com>).

Home | **TAI Questionnaire** | Useful Documents | Request for Use

10-item TAI
12-item TAI
Download PDF Test
Ranges and Interpretation
Frequent asked questions

Spanish
English
German
French
Italian
Dutch
Russian
Greek
Polish
Bulgarian
Portuguese / Brazilian
Portuguese
Turkish
Árabe de Arabia Saudí
Árabe de Egipto

Why should it be used?
The TAI is a useful instrument in clinical decision making since the possibility of better understanding each patient's situation.

When should it be used?
The TAI may be used at the discretion of the healthcare professional, as it offers a reliable measure of patient adherence to inhalers.

Chiesi | TAI Test of Adherence to Inhalers® is a registered trademark of Chiesi, S.A.U.

For PAQLQ, due to copyright, please obtain the questionnaire in your language from <https://www.goltech.co.uk/paqlq.html> - please note that we have opted to use the Standardised Paediatric Asthma Quality of Life Questionnaire (Interviewer-administered) for all age groups.

For Asthma Control Test (ACT), which is a new addition in this version of SPACE, please use Childhood-ACT (CACT) for 6 to < 12 years old and the ACT for 12 years and above. Please follow the instructions on CACT regarding which part of the questionnaire should be filled in by child vs parent. (English version: <https://www.asthmacontroltest.com/en-gb/welcome/>)

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

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?

Automatically generated → **Result: Well controlled.**

“Treatment”

To add other respiratory medications, click “Add treatment”.

Treatment

Drug

→

We encourage you to fill in all free text boxes that pop up along the form in as much detail as possible.

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 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.

Summary:

Completed Sections: 3
Incomplete Sections: 4

Please ensure all information is correct as it cannot be modified once submitted.

[Submit](#)

Section 'Additional Information' updated successfully.

Case NL Test 30/7/24

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

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

Is the patient still under follow-up?

[Save](#)