



SPACE registry user guide

SPACE registry website:

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

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. To ensure sufficient longitudinal data, we recommend recruiting only patients who are expected to remain under follow-up at the centre for **at least 2 years after enrolment**.

If time or resource constraints limit recruitment, we recommend recruiting fewer patients (preferably those starting a new biologic) and ensuring that they are followed up appropriately at the scheduled time points, rather than recruiting more patients with incomplete or delayed follow-up.

Date of Enrolment

Patients already on a biologic. The date of enrolment (which corresponds to the clinical visit at which asthma control scores, lung function and other relevant clinical data are collected) can be at any time.

Patients starting on a new biologic: Patients should ideally be enrolled **on the day of their first biologic injection, or up to a maximum of 2 weeks before the first injection**. Baseline information, including asthma control scores, lung function and other relevant clinical data, should be collected on the day of enrolment. If enrolled up to 2 weeks before the first injection, patients must remain clinically stable between enrolment and treatment initiation.

The follow-up reminder emails are generated automatically based on the **date of enrolment**. However, the permitted follow-up windows are calculated from the **date of the first biologic injection**. Therefore, if a participant was enrolled up to two weeks before receiving their first injection, please use the **date of the first injection** when scheduling follow-up visits, particularly the **16-week follow-up**.

We appreciate the date of data entry may differ from the date of enrolment or follow-up. Please note that only the **date of enrolment** and **date of follow-up** are relevant, not the date on which the data are entered into the system.

For all patients, recruitment should only occur when patients have not experienced an asthma attack in the previous 2 weeks. If a patient has had an asthma attack within the past month, recruitment should be deferred until they have fully recovered and returned to their clinical baseline. Data should only be collected once the patient is back at their baseline clinical status.

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.

“Background information” and tests results at enrolment and follow up

Please fill in as much information as possible.

For **all patients**, lung function should be performed **at the time of enrolment (or subsequent follow-up)**. If this is not possible, lung function may be performed shortly before or after the visit, provided the patient's clinical condition has remained unchanged. In such cases, please confirm in the free text comments at the end of the form that the patient's clinical condition at the time of lung function testing was the same as at enrolment (or follow-up). Lung function performed several weeks before or after enrolment (or follow-up) will **not** be accepted.

For **all patients**, either specific IgE or skin prick test for aeroallergens is **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 enrolment or, if not available, in the previous 12 months** (and again within the 12 months before **each subsequent follow-up**).

For **all patients**, if any data are unavailable (e.g. lung function measurements, test results, asthma control questionnaire scores, medication doses, or other clinical values), leave the corresponding field **blank**. **Do NOT** enter a value of **0** to indicate missing data, as **0** is interpreted as a valid value in the database.

“Asthma Control” at enrolment and 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 enrolment** 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 their age (e.g. ≥ 10 years). You may help the child or adolescent to read or understand the questions.

CASI (Composite Asthma Severity Index) has a **maximum total score of 20**. Please pay close attention to the CASI scoring system explained within the CASI form:

To note:

- Score for section 1 is the highest point value from questions 1a and 1b, **NOT** the sum of these points (The same applies for section 2);
- If lung function was not performed around the time of assessment, please leave the section 3 score **blank**, do **NOT** assume good or poor lung function.
- Score for section 5 has a maximum of 6 points – which is calculated by assigning 2 points for each steroid burst, and 2 additional points for each associated hospitalisation).

Example 1:

SECTION 5: EXACERBATION ASSESSMENT	
5a. In the <u>last 2 months</u> , how many systemic corticosteroid bursts did the participant take for asthma symptoms? (See Table 3 in the appendix for a partial list of medications used for systemic corticosteroid bursts)	burst(s) [if 0, skip to 5c]
5b. How many of those systemic corticosteroid bursts were initiated during an overnight hospitalization for asthma?	burst(s)
5c. Score 2 points for each systemic corticosteroid burst recorded in 5a 2 and 2 additional points for each associated hospitalization in 5b 2	Exacerbation Score 4 Do not exceed 6 points.

Example 2:

SECTION 5: EXACERBATION ASSESSMENT	
5a. In the <u>last 2 months</u> , how many systemic corticosteroid bursts did the participant take for asthma symptoms? (See Table 3 in the appendix for a partial list of medications used for systemic corticosteroid bursts)	4 burst(s) [if 0, skip to 5c]
5b. How many of those systemic corticosteroid bursts were initiated during an overnight hospitalization for asthma?	2 burst(s)
5c. Score 2 points for each systemic corticosteroid burst recorded in 5a 8 and 2 additional points for each associated hospitalization in 5b 4	Exacerbation Score 6 Do not exceed 6 points.

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.goltech.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. Please ensure the version of PAQLQ that you are using, has a **maximum score of 7 for each question** – if your version allows scores of 8 or above for any question, it is NOT the correct version.

- What to do with missing values:
 - A maximum of 2 missing responses (1 from Symptom Domain, 1 from Emotional Function Domain) is accepted from all 23 questions. No missing responses from the Activity Limitation Domain are accepted.
 - Inputting the missing value: use the **mean** of the scores of the completed items with the **same domain** as the missing value

○ PAQLQ Domains:

Paediatric asthma quality of life questionnaire (PAQLQ)

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

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 their instructions.

“Respiratory Treatments” at enrolment and follow-up:

Please note that for single or combined **inhaled corticosteroids**, it is the **pre-dispense dose**, not delivered dose that you should enter on the system. Please record the total daily steroid dose.

- **For example:**
 - Indacaterol-Mometasone (Atectura Breezhaler)
 - 125 micrograms/62.5 micrograms (**80 micrograms pre-dispense**)
 - 125 micrograms/127.5 micrograms (**160 micrograms pre-dispense**)
 - Momet-Inda-Glycopyrronium (Enerzair Breezhaler)
 - 136 micrograms (**160 micrograms pre-dispense**)
 - Fluticasone with vilanterol (Relvar)
 - 92, 184 micrograms (**100 and 200 micrograms respectively pre-dispense**)

For patients on MART regime, please document the minimum (maintenance) dose that the patient is on, and write in the “Additional Information” free text box on last page of the form that the patient is on MART regime.

For patients **starting a biologic**, please ensure they fulfil the inclusion criteria of using “**high-dose**” inhaled corticosteroids – as listed on SPACE website, in accordance with GINA.

Follow up:

For **all patients**, follow-up visits should take place when there is no recent asthma attack (within 2 weeks). In case of an asthma attack in the past month, follow-up should only take place after full recovery.

For **all patients**, information (including lung function and asthma scores under “Asthma Control” section – see below) must be collected at the time of follow-up.

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 early response), then at 52 weeks after the first biologic injection, then annually.

Acceptable window 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 window for follow-up: **- 1 week 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 (for patients starting a new biologic: this will be from the day of first injection); etc...
Acceptable window for follow-up: **- 4 weeks to + 13 weeks of due date**

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

Please do **not** submit two follow ups within the same follow-up period, as one will be discarded

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 window.

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 window. Please answer the questions on the first page of the follow-up form to indicate patient is no longer using a biologic, the system will then prompt you to complete **only the Respiratory Treatment section**, where you can record the biologic name, stop date, and reason for discontinuation. This marks the end of the patient's journey in SPACE. No further follow-up data will be collected for this patient unless they start a new biologic and are re-enrolled in SPACE.
- ❖ If a patient **switches to a different biologic**:
 1. Please answer the questions on the first page of the follow-up form to indicate there has been a biologic switch, the system will then prompt you to complete **only the Respiratory Treatment section**, where you can record the new biologic name, start date and dose, and the old biologic name, stop date and reason for discontinuation.
 2. If the patient is **reviewed within 2 weeks before starting the new biologic**, please complete the **switch form** under the same patient ID. The automatic email reminders for 16-week and annual follow-up will restart from the **date of switch**. **If the patient is reviewed up to 2 weeks before starting the new biologic, please ensure that subsequent follow-ups are scheduled within the acceptable window based on the date of the new biologic injection.**
 - As for baseline, the **date of switch** is the date on which the clinical review takes place and lung function, asthma control scores and other relevant clinical data are collected. This should ideally be **on the day the new biologic** is started, but may be completed **up to a maximum of 2 weeks before starting the new biologic**, provided the patient remains clinically stable and is not experiencing an exacerbation.
 - FeNO, blood eosinophils, total IgE results should be **after stopping last biologic and ideally within 2 weeks of starting new biologic**, and far from exacerbations
 - Imaging and bronchoscopy results from only **after stopping last biologic**.
 3. If you are **unable to review the patient within 2 weeks of starting the new biologic**, complete Step 1 above to close the patient's journey for the discontinued biologic. You may then re-enrol the patient in SPACE with a new patient ID as a patient **already on a biologic**. The patient will subsequently be followed up annually while receiving the new biologic.

Example 1:

- First biologic = Omalizumab on 01/01/2026 (date of first injection = date of enrolment) → Baseline form to Starting Biologic
 - 16 week follow up: 23/04/2026 → 16 week follow up form
 - Decided to change to Mepolizumab on 01/06/2026 (21 weeks) (Last dose of Omalizumab 21/05/2026)
 - Patient seen on 01/06/2026 (lung function, asthma scores, etc)
 - Mepolizumab started 10/06/2026
- Close the Omalizumab journey by filling in annual follow up form NOW but only biologic section (stop date, reason for stopping).

Open the Mepolizumab journey: As patient seen within 2 weeks of starting new biologic
→ **Switch form** with fresh lung function, scores, etc
Clock restarts for 16 week follow up

Example 2:

- First biologic = Omalizumab on 01/01/2026 (date of first injection = date of enrolment) → Baseline form to Starting Biologic
 - 16 week follow up: 23/04/2026 → 16 week follow up form
 - Decided to change to Mepolizumab on 01/06/2026 (21 weeks) (Last dose of Omalizumab 21/05/2026)
 - Mepolizumab started 10/06/2026
 - Patient seen on 01/08/2026 (lung function, asthma scores, etc)
- Close the Omalizumab journey by filling in annual follow up form **NOW** but **only biologic section** (stop date, reason for stopping).

Option to re-enrol patient with new ID as a “already on biologic” case

Paper version of the forms

Paper versions of the forms are available on the SPACE website, for details on inclusion criteria and required data, as these are not included in this document.

We recommend completing the baseline (enrolment) and follow-up forms on paper before entering the data into the online database.

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>



SPACE Registry

SPACE Registry Home Downloads nliu v

Summary for nliu:
Submitted cases: 874
Unsubmitted cases: 21

[View Charts](#)

[Create New Case](#)

Unsubmitted cases

Show 10 entries

Search:

CREATING A NEW CASE ONLINE

Click “Create New Case”:

SPACE Registry

Summary for testUser:
Submitted cases: 10
Unsubmitted cases: 6

[View Charts](#)

[Create New Case](#)

Unsubmitted cases

Show 10 entries

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](#)

The screenshot shows the 'Basic Case Information' form. A red arrow points to the 'Patient code number' text label, and another red arrow points to the 'Centre' text label. The 'Patient code number' field is a text input box. The 'Ethnicity' field is a dropdown menu with 'Caucasian' selected. The 'Centre' field is a text input box.

Date of enrolment

Date of patient enrolment

A text input field for the date of patient enrolment.

For patients **already on a biologic** – this is when the patient is recruited (at **any time**).

For patients **starting a biologic** – this should be **on the day of, or up to 2 weeks before, the first injection**. Baseline information (e.g. lung function, asthma control scores, etc.) should be collected on the day of enrolment and should ideally be as close as possible to the date of the first biologic injection. If enrolled up to 2 weeks before the first injection, the patient should remain clinically stable during this period.

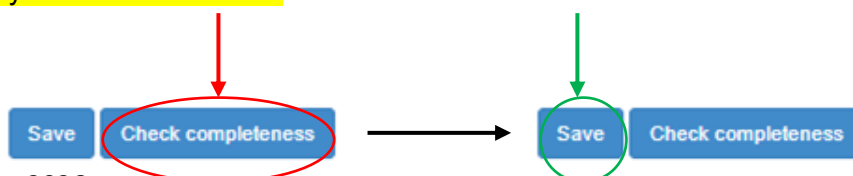
Informed consent

Please tick “yes” for informed assent even if you are not required to obtain assent, in order to move forward to the next section of the database form:

The form contains two sections. The first section is 'Written informed consent' with radio buttons for 'Yes' (selected) and 'No'. Below it is a red italicized note: '(please obtain informed consent before collecting/ entering data)'. The second section is 'Written informed assent (child)' with radio buttons for 'Yes' (selected) and '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 a maximum of 2 weeks) starting a biologic ☐ 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

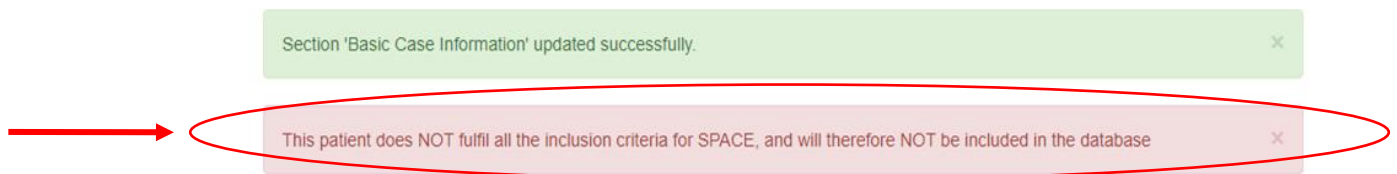
Systemic corticosteroids for $\geq$ 25% of last 12 months ☐ Yes ☐ No

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

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



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			FVC L		
FEV ₁ L (% predicted)			FVC L (% predicted)		
FEV 25-75% (L/sec)			FEV ₁ :FVC ratio (%)		
FEV 25-75 (% predicted)					

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)			FVC (L)	
FEV ₁ (% predicted)				
FEV ₁ (% of change)				

Enter data for 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.

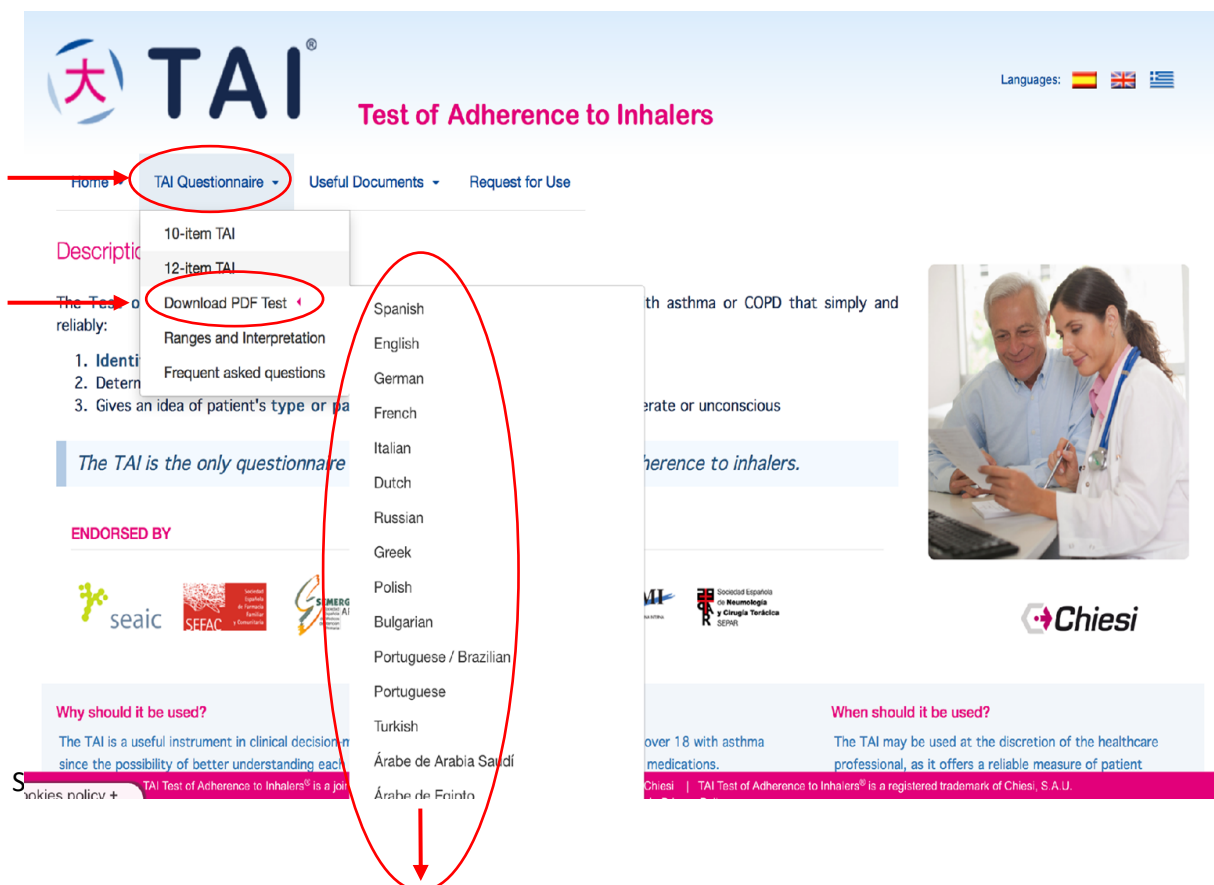
The **total scores** for CASI, TAI, PAQLQ will be automatically calculated.

Please pay attention to each questionnaires scoring system (see pages 2-4).

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		

Test of adherence to inhalers (TAI questionnaire)		
Answered by patient/parents (total score from questions 1-5)	3	
Answered by patient/parents (total score from questions 6-10)	4	
Total TAI score	7	

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



The screenshot shows the TAI Test of Adherence to Inhalers website. The page has a blue header with the TAI logo and the text 'Test of Adherence to Inhalers'. There are flags for Spanish, English, and Italian. Below the header, there is a navigation bar with 'Home', 'TAI Questionnaire', 'Useful Documents', and 'Request for Use'. The 'TAI Questionnaire' dropdown menu is open, showing options for '10-item TAI', '12-item TAI', and 'Download PDF Test'. The 'Download PDF Test' option is highlighted with a red circle. A red arrow points to the 'Download PDF Test' option. Another red arrow points to the 'Download PDF Test' option. A third red arrow points to the 'Download PDF Test' option. The page also features a section for 'ENDORSED BY' with logos for seaic, SEFAC, and S.M.E.R.G. There is a section for 'Why should it be used?' and a section for 'When should it be used?'. The Chiesi logo is visible in the bottom right corner.

PAQLQ: Please obtain the questionnaire in your language from the SPACE team or from <https://www.goltech.co.uk/paqlq.html> - please refer to above (page 3) 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. Please obtain the questionnaire in your language from <https://www.asthmacontroltest.com/> and follow their 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: ☐ 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.

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 the patient is currently using or is about to start on.

Click “Add treatment” to add all other treatments.



→ [Add treatment](#)

Please refer to page 4 for caution regarding inhaled corticosteroids.

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

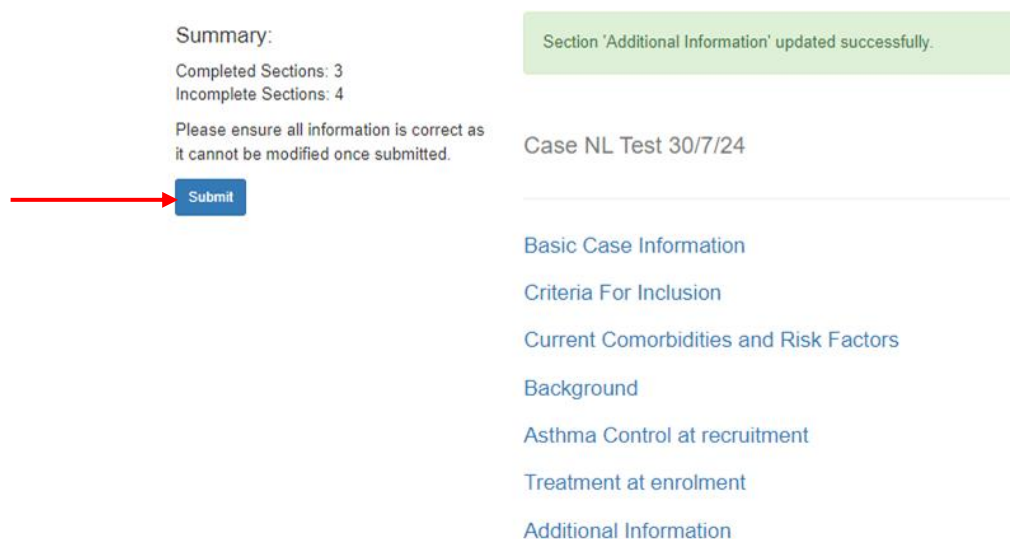
Please include any relevant information that will help us understand specific situations or decisions. Please do NOT provide detailed information that is outside the scope of the data requested. For example, we do not require a detailed clinical history of events that occurred before the patient entered SPACE. 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.

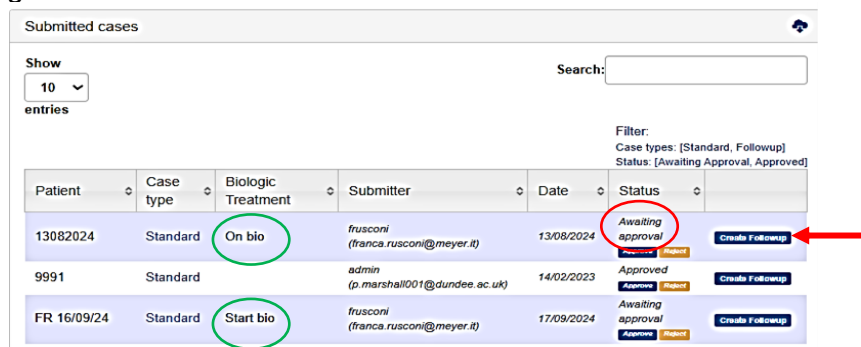


CREATING FOLLOW-UP

To follow-up a patient, go to the main page of your account, under “submitted case”, select the correct patient and click “Create FollowUp” (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.

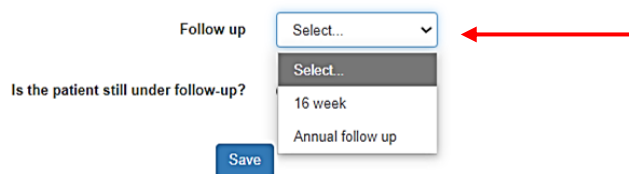
Please do not be alarmed if the case status remains as “Awaiting approval” (red circle below) – we do not routinely approve cases but will check data entries regularly and get in touch with you if there are any missing or erroneous entries.



The screenshot shows a table titled 'Submitted cases' with columns: Patient, Case type, Biologic Treatment, Submitter, Date, Status, and an action column. The first row has Patient ID 13082024, Case type 'Standard', Biologic Treatment 'On bio' (circled in green), Submitter 'frusconi (franca.rusconi@meyer.it)', Date '13/08/2024', and Status 'Awaiting approval' (circled in red). A red arrow points to the 'Create Followup' button in the action column. The second row has Patient ID 9991, Case type 'Standard', Biologic Treatment (empty), Submitter 'admin (p.marshall001@dundee.ac.uk)', Date '14/02/2023', and Status 'Approved'. The third row has Patient ID 'FR 16/09/24', Case type 'Standard', Biologic Treatment 'Start bio' (circled in green), Submitter 'frusconi (franca.rusconi@meyer.it)', Date '17/09/2024', and Status 'Awaiting approval'. A red arrow also points to the 'Create Followup' button in the action column of this row. Above the table, there is a 'Show' dropdown set to '10 entries' and a 'Search:' field. To the right of the table, there is a 'Filter:' section with 'Case types: [Standard, Followup]' and 'Status: [Awaiting Approval, Approved]'.

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

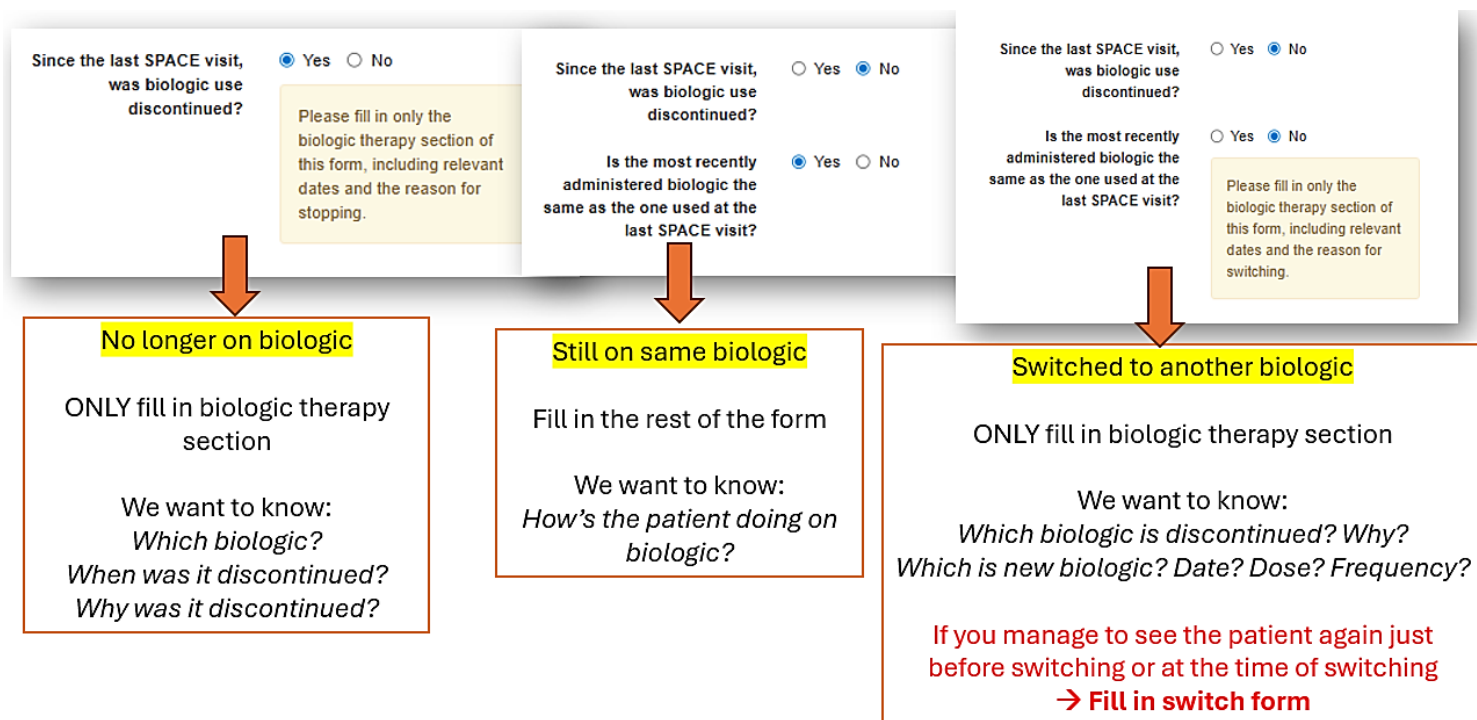
After clicking “Create FollowUp”, select the correct follow-up type, and fill in the form accordingly.



The screenshot shows a form with a 'Follow up' dropdown menu. The dropdown is open, showing options: 'Select...', 'Select...', '16 week', and 'Annual follow up'. A red arrow points to the dropdown menu. Below the dropdown is a checkbox labeled 'Is the patient still under follow-up?'. At the bottom left of the form is a 'Save' button.

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

Please answer the questions on the first page of the follow-up form to indicate if patient is no longer on biologic / still on same biologic / has switched to a new biologic:



Biosimilar

Please note that Omalizumab and Omalizumab Biosimilar are considered the same drug, and therefore **NOT** a “switch” of biologic. However, we are interested in capturing the use of biosimilars. Please document the change to Biosimilar:

- Record Biosimilar in the current medication section: Start date, dose, device
- Record Omalizumab as a discontinued drug: Stop date, reason for discontinuation (e.g. cost)
- Document any side effects for both drugs, if any.

Respiratory Medications at Annual follow up

The screenshot shows a digital form for recording respiratory medications. The 'Treatment' dropdown is set to 'Monoclonal antibody'. The 'Drug' dropdown is open, showing a list of biologics: Mepolizumab, Omalizumab, Omalizumab Biosimilar, Dupilumab, Tezepelumab, and Other. An 'Add treatment' button is located at the bottom left of the form area.

CREATING SWITCH FORM

To create a switch form, go to the main page of your account, under “submitted case”, select the correct patient and click “Switch Biologic” (red arrow below).

Submitted cases							
Show		Search:					
All v							
entries		Filter: Case types: [Standard, Followup, Switch] Status: [Awaiting Approval, Approved]					
Patient	Case type	Biologic Treatment	Submitter	Owner	Date	Status	
0021	Standard	Start bio	nliu (n.liu@qmul.ac.uk)	Florence	27/05/2025	Awaiting approval	Switch Biologic Approve Reject
0021	Followup		nliu (n.liu@qmul.ac.uk)	Florence	27/05/2025	Awaiting approval	Approve Reject
00210	Standard	Start bio	nliu (n.liu@qmul.ac.uk)	Florence	07/07/2026	Awaiting approval	Switch Biologic Approve Reject Create Followup

Please note: The clock will restart and automatic follow-up reminder emails will be generated based on the **date of switch**. As before, the permitted follow-up windows are calculated from the **date of new biologic injection**. Therefore, if a participant was reviewed up to two weeks before switching to new injection, please use the **date of the new biologic injection** when scheduling follow-up visits, particularly the **16-week follow-up**.

- As for baseline: Lung function and asthma control should be assessed **just before (max 2 weeks) starting the new biologic**, and far from exacerbations
- FeNO, blood eosinophils, total IgE results should be **after stopping last biologic and ideally within 2 weeks of starting new biologic**, and far from exacerbations
- Imaging and bronchoscopy results from only **after stopping last biologic**.

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

Since this patient is no longer followed up, please do not fill in the remainder of this form, unless the patient stopped or switched biologic therapy prior to transition or loss to follow-up, etc (see question below).

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

Since the last SPACE visit, was
biologic use discontinued?

☒ Yes ☐ No

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

- 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 was tried and discontinued between now and enrolment (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

Other



Start Date

End Date

Reason for discontinuation

-

Add another previously used but discontinued monoclonal antibody since last follow up [Add](#)

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

Since the last SPACE visit, was biologic use discontinued? ☐ Yes ☒ No

Is the most recently administered biologic the same as the one used at the last SPACE visit? ☐ Yes ☒ No

Please fill in only the biologic therapy section of this form, including relevant dates and the reason for switching.

- Under “Respiratory Treatment” section of the follow-up form, please add the new biologic under respiratory medications; tick “Yes” for “Is the patient still on a monoclonal antibody?”; tick “No” for “Is the patient on the same monoclonal antibody as at the last follow up”, then provide information on the last biologic (name, start and end dates, reason for discontinuation). Include any other biologics that were tried and discontinued since last SPACE visit.

Respiratory Medications at Annual follow up

Treatment	-	
Drug	-	

[Add treatment](#)

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

Is the patient on the same monoclonal antibody as at last follow up? ☐ 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

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

Discontinued monoclonal antibody	Select Monoclonal	
Start Date		
End Date		
Reason for discontinuation	-	

Add another previously used but discontinued monoclonal antibody since last follow up [Add](#)