EMBARC
The European Bronchiectasis Registry

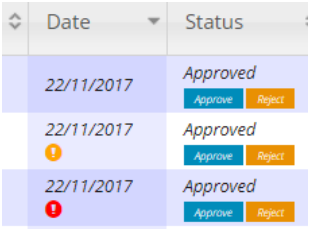
iABC
inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis

ERS EUROPEAN RESPIRATORY SOCIETY

In order to reduce the number of system queries and email traffic to the central office we have created an information sheet for the review CRF. Please ensure all staff members read this and a copy is filed in your site files.

Every patient consented to the registry should have a minimum of one annual review.
Completion of annual reviews are expected once each year until the end of study. The review period (12months +/- 3 months) is always calculated against the date of consent ie, if the patient consents on the 1st July, their reviews will always be due between 1st April and 30th September no matter which year of review is being completed.

For this example, the CRF system will send an automated email at the start of April to say the review window has started (this will also be indicated by an orange exclamation mark next to the case on your homepage), if the case is not submitted before 1st July, another automated email will be sent to say the case is due, and if a submission has still not been made a third reminder email will be sent at the end of September (orange exclamation mark on homepage will turn to red). Submitting a review will prevent further automated emails from being sent.



Cases can still be completed after the 15month window; however, the data being entered in the review should only include data relevant to the review period, this allows reviews to be completed retrospectively but keeps the annual information factually correct as per protocol request. Any data after the review period will be captured in the next years review.

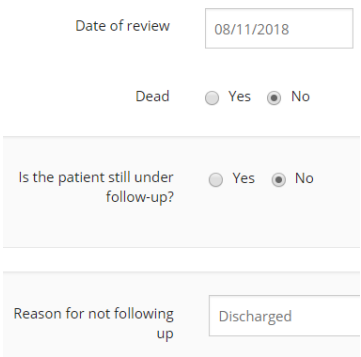
The eCRF will minimise the amount of data fields requiring an answer by first asking whether there have been any changes to that section, for example, f there have been no new aetiology tests and no new diagnoses listed on the pCRF, select “no”, SAVE the page and move on to the next section. All pages must be opened to confirm whether there are any relevant changes or not before the CRF can be submitted.

Helpful tip - if completing a review after the 15month window, please enter the review date as one which falls within the expected window. This will reduce the data queries regarding not being able to enter microbiology/CT data later in the CRF as these drop-down calendars are also calculated from consent date.

Note - the date displayed on the homepage is date of submission, not date of consent or date of review.

For patients who are discharged from secondary care, die or withdraw from ongoing consent.
A full review should still be created to capture any changes to care or condition since the previous data submission (every patient enrolled in the registry should have at least one review completed).

These reviews can be submitted at any time and do not require waiting until the expected review period. Please ensure the patient status on the first page of the CRF has been completed correctly. By selecting that the patient is no longer in follow-up or has died, the automated email reminders will be prevented. If you are still receiving notifications for patients no longer in follow-up, please contact the study coordinator who will be able to return the case for you to update the patient status. The study coordinator cannot make any amendments on your behalf. These situations do not require removal of the case from the system unless the patient withdraws full consent ie, all data backdated to the time of consent. Please contact the study coordinator for the removal of patient data belonging to those withdrawing full consent.



The intention of the registry is to follow only patients attending regular secondary care. In the event a patient is discharged on the same day as consent, please contact the patient for permission to complete a 12month review. At this review (providing they have not returned to secondary care) please complete to show they are no longer in follow-up. We do not expect GP’s to be contacted to obtain annual Review data.

Once a patient has been marked as no longer in follow-up no further reviews can be made and the review button will disappear.

Helpful tip – If MRC score has not been documented and the patient is not contactable in the above situations, please enter the same score as documented in the previous submission.

Note - You do not need to email us notification of patient discharges/withdraws (except full consent withdraw).

Note – If a review is submitted prior to the expected review period and the patient does not fit the above criteria ie patient remains in follow-up, the case will be rejected, and automated email reminders may still be sent as the system waits for the expected review submission.

Note to UK sites - EDGE is a separate system to EMBARC, the two will not "talk" to each other/share information. To notify us that the patient is no longer in the study the first page of the CRF must be completed to show the patient has died/been discharged. This is the only way to stop automated notifications.

To reduce data queries;

- Ensure that only data relevant to the review period is entered. This will also avoid duplicated data at the next review period.
- Spirometry and microbiology are essential data points requested in the study protocol, please ensure every attempt is made to collect this data annually.
- Only information relevant to bronchiectasis care/treatment should be entered in the additional information section. Please do not enter medical history or concomitant medications which are neither bronchiectasis related nor listed in the CRF.
- For assistance with respiratory medications please refer to the online supplementary document, https://www.bronchiectasis.eu/study-documents
- Short acting bronchodilators do not require documenting in the CRF.
- Every attempt should be made to collect a QOL-B annually (if relevant translation is available), we do not recommend posting, however this has been approved if necessary. Please note there is no funding to support the administration of this and EMBARC have not approved any letters for sending to patients.