

British Thoracic Society UK ILD Registry FAQs for Clinical Centres

This document provides information about the BTS ILD Registry to assist those who may be interested in participating. All enquiries should be sent to: registry@brit-thoracic.org.uk

All Registry documents – including those referred to in this FAQ – are available here:

<https://www.brit-thoracic.org.uk/quality-improvement/lung-disease-registries/bts-ild-registry/>

The most recent REC application is included here too, giving in-depth details of the Registry programme as well as its systems and security.

What is the purpose of the BTS Lung Disease Registry Programme?

The intention is to provide an easily accessed system for prospective (and retrospective) data collection in a large number of patients, so that the public health and epidemiological status of these conditions in the UK can be established. Through a secure online data collection system a clinical database has been developed containing information on demographics, method of diagnosis, markers of disease severity, and details of treatment and outcome. The intended outcomes of the Registry include:

- Refinement of the clinical characteristics, burden of disease (including its impact on health status and quality of life) and the course of the disease in the British population.
- Provision of information which will allow clinicians to reduce delays in diagnosis and to make more informed decisions on the best management strategies.
- Facilitating benchmarking and supporting analysis of changes in practice/outcomes over time.

What patients are eligible for inclusion in the Registry?

Patients may be included if they meet all three of the following criteria:

- First seen for the first time in clinic at the participating centre from 1st January 2013.
- Patients with a new or historic diagnosis of either:
 - o any ILD with evidence of fibrosis, including definite or strongly suspected IPF, OR
 - o any sarcoidosis with pulmonary involvement, with or without fibrosis.
- Informed, written consent has been obtained.

How can I/my centre participate in the Registry?

Institutions will require authorisation from their Trust's Information Governance office/Caldicott Guardian. Your R&D office do not need to provide authorisation, although they do need to be informed of your site's intended participation in the Registry. The information included in this document (and in the 2022 REC renewal application) may be helpful in completing the forms for the institution concerned.

In the first instance, contact registry@brit-thoracic.org.uk for further information.

What does the Registry involve?

Detailed instructions for using the Registry (covering everything from consent to recording mortality) are included in the *Quick Start Guide for Registry Users*.

Users may enter data into the Registry either manually (through typing data into the online system) or through populating and uploading a template Excel spreadsheet. Manual data entry takes 10 to 15 minutes for each new patient and 5 minutes for subsequent entries.

Each participating centre must have a named Registry Lead who will be a senior clinician with overall responsibility for entry of data to the Registry and who will act as the primary contact for that site. BTS will seek approval from this Registry Lead before other individuals within that centre are granted access to the online Registry. There can be a maximum of ten user accounts per hospital (including the Registry Lead) and these may be held by any relevant members of staff, including clinicians, nurses, data entry staff, etc.

Is submitting data to the Registry mandated?

That depends upon your centre's status and on which patients you are considering. The Registry is mandated in the NHSE ILD Service Specification for English specialist centres, meaning those centres are required to participate in the Registry and complete the demographics and clinical information records for their patients with IPF.

Does the Registry include recording of patient identifiable data?

Yes, items of personal identifiable data are collected and stored on the online data collection system. This includes name, date of birth, NHS number and post code.

Data are stored on a secure server with appropriate security safeguards, details of which are included in the 2022 REC renewal application form.

Does the British Thoracic Society have an Information Governance Policy document?

Yes. This document is updated annually and is available at <https://www.brit-thoracic.org.uk/about-us/governance-documents-and-policies/>

Does the Registry have Health Research Authority approval?

Yes. National research ethics approval was granted in October 2012 (REC ref: 12/EE/0381), renewed in October 2017 (17/EE/0346) and renewed again in October 2022 (22/EE/0235).

Is the Registry included on the NIHR Research Portfolio?

No, the Registry in itself does not meet the criteria for inclusion on the NIHR portfolio. Individual research projects which draw upon Registry data may be considered for inclusion on the portfolio.

Can the Registry be used to collate NHSE ILD Quality Dashboard returns?

Yes. Specialist centres in England are required to submit dashboard returns which cover specific items related to IPF (which is used as a surrogate marker for the wider ILD service). These items (with the exception of two) may be collated directly through the Registry site.

Entering details for patients with IPF into the Registry populates a user-downloadable report which provides a simple list of dashboard figures for submission to NHSE. Only two items are not collated directly through the Registry site: the proportion of patients with IPF included in the Registry, and whether the centre is recruiting patients to clinical trials.

Dashboard submission is only a requirement for English specialist centres. However, district general hospitals and sites from devolved nations may use this facility for benchmarking and service monitoring.

What information can I export/download from the BTS UK ILD Registry?

Individuals within an organisation are able to export their own patient data – so sites may use the Registry as a patient database. There are also a number of user-downloadable reports available through the Registry site, including patient-specific reports which may be printed and handed to individual patients in clinic.

Can other individuals or organisations request access to data stored on the Registry database?

Organisations (including centres which are participating in the Registry) are able to request access to data held on the Registry. For more information, including details of how to apply, please visit <https://www.brit-thoracic.org.uk/quality-improvement/bts-clinical-data-policy-and-data-access/>

If an application for data is approved, all records will be anonymised/pseudonymised before release. Information which could identify patients is never shown to anyone outside the care team (to researchers, individuals, organisations or even BTS staff) **unless** a numerical identifier is shared for the purpose of data linkage.