

Information for Patients

The IBD Registry collects and analyses data from patients with Inflammatory Bowel Disease (IBD) from around the UK. It brings all this data together for a unique view of IBD in the UK, which supports better understanding by people, hospitals and other health-related organisations in how IBD is treated, about medicines that are used and about IBD in general.

Most of the data comes from hospitals across the UK who are taking part in the Registry. It supports research into the causes of IBD and treatments that improve patients' lives; it also helps hospitals to deliver their services more effectively and seeks to improve society's understanding of how people's lives are affected by IBD.

This is an opportunity for all patients with these conditions to make a real and significant contribution to a leading Registry whose goal is to help everyone living with IBD.

How does the Registry help patients?

The Registry uses the information about your IBD and its treatment to contribute to improving patient care and research. This can be in several ways:

- The IBD Registry team will analyse information about IBD and use this to inform hospitals, medical and other organisations on how they can improve patient care, including better treatments and improved knowledge about medicines.
- Researchers working within IBD may request to undertake anonymous studies with the Registry; for example, to compare different treatments and outcomes, or to monitor the safety and effectiveness of medicines.
- The information collected and published by the Registry and other researchers will help in raising professional and public awareness by presenting a more accurate and complete picture of the number of people who have IBD and the impact on their lives.

Useful questions and answers overleaf ...

What does it mean for me if my hospital is part of the IBD Registry?

Your hospital will send (share) some information about you, your IBD and your IBD care with a central Registry database. This will be done several times each year to keep the information up to date. The way the information is sent means that every patient's confidentiality is protected. Only 'aggregated' statistics are used (so grouped together and cannot be tied back to an individual person). You can read more about this below.

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What information about me is shared with the Registry?

The information that is shared with the Registry may include demographic data, IBD diagnosis, additional clinical information including disease classification, details of surgery, admissions, cancer diagnosis and class of drugs. A complete listing of the data we collect can be found on our website.

Do I need to give consent for this information to be shared?

You will be asked to sign a consent form to give permission for your IBD team to

submit your data to the IBD Registry and to confirm how you wish your information to be used.

If the data submitted to a registry includes patient identifiable data, as in the case of the IBD Registry, then legislation requires that written consent is obtained from each individual patient. An exemption may be granted by the Government for public health benefit. The IBD Registry currently has such an exemption but is working towards a full 'consent-based' system where patients decide to consent. Our consent form has multiple options to give you detailed control of your data.

What if I don't want my information to be shared with the Registry ("opt out")

If you do not want your information to be sent to the IBD Registry, you can 'opt out' on the consent form. The IBD Registry will be most effective if it has information from as many patients as possible, but if you do not want your information to be used, please tell a member of your hospital team. They will make sure your information is not sent to the IBD Registry. This will not affect your treatment in any way.

How is the confidentiality of my personal information protected?

Information about you does not go directly to the Registry but is sent by your hospital to a 'data safe haven', an organisation which specialises in safe handling of data and is independent of the Registry. The data safe haven modifies the information before sending it to the IBD Registry so it is not patient identifiable. (This process is called pseudonymisation.) The data

safe haven keeps a master file so that future information about you can be added to your registry record. Your information is pseudonymised before being sent to the IBD Registry.

Does the Registry share my information with anyone?

The Registry does not share your personal information, even in pseudonymised form without your additional permission. As explained, any information issued by the Registry is in aggregated form (i.e. statistics and group results) so protecting patient confidentiality. The Registry has formal agreements with other organisations to 'process' the data. 'Processing' means that those organisations do not control the data in any way, they are simply doing work involving the data under instruction. They include expert analysts who perform much of the specialised biostatistical analysis, and the data hosting companies whose secure computer servers and equipment we license to hold the databases.

What does the Registry do with the information about me?

The IBD Registry will analyse the information and publish reports about IBD in the UK. These will tell us how many patients there are in each area and how the illness affects them, as well as describing the healthcare services and treatments they receive. All public reports will be available at our website. Reports (fully anonymised) may be made available to hospitals, medical and academic organisations and to health-related companies, such as pharmaceutical companies. All applications for access to the

anonymised data have to be approved by the Registry Oversight Committee.

How long will the IBD Registry keep information about me?

Crohn's Disease and Ulcerative Colitis are lifelong illnesses, so the Registry aims to keep information indefinitely. This will help us to understand the long-term pattern of disease and how different treatments work overtime.

What happens if I change my mind and want to opt out later

You can stop information about your IBD and your healthcare being held in the Registry at any time. Speak to your IBD doctor, nurse or contact the Registry.

Who is responsible for the information (data) about patients in the IBD Registry?

IBD Registry Ltd is the Data Controller for the information once it has been shared with the Registry and is responsible for ensuring that the IBD Registry complies with data protection and confidentiality laws.

How do I know that the Registry keeps my data secure?

Before any hospital can submit data to the Registry, a formal authorisation is required from the local Caldicott Guardian, who is the named 'guardian' of patient data at each hospital. Before the data safe haven releases any data, the IBD Registry formally must demonstrate that it has satisfied the formal NHS requirements for data security. The IBD Registry holds and processes all its data within the UK.

How can I access the information that the Registry holds about me?

You cannot be identified in the information that we hold in the IBD Registry database. You can be identified in the information that the safe haven holds about you, on behalf of the Registry. While we do not have access to it, we can help you obtain a copy.

What does 'linking my data' mean?

NHS data is typically held in completely separate secure databases. Linking these together provides new and valuable insights for healthcare professionals which supports them in your IBD care.

Does the Registry receive any money for my information?

The IBD Registry does not share or receive any money for your individual / personal information. However, running the IBD Registry involves costs, which we need to raise income to support. An appropriate charge may be made for anonymised aggregated information services to help support our running costs. The IBD Registry is a not-for-profit organisation and only seeks to cover ongoing running costs.

How does the Registry manage relationships with commercial entities?

We raise income from a variety of sources which may include pharmaceutical companies and other commercial entities. This support can be in the form of unrestricted sponsorship or educational grants, or commercial fees for services provided by the IBD Registry. The IBD Registry has

procedures that ensure that all relationships with industry are subject to clear guidelines for joint working, promote openness and transparency, and ensure that we maintain our independence and impartiality. More information is available on our website.

How can I contact the Registry?

You can find out more about us on our website or contact us as below. If you are unhappy about any aspect of the Registry or how your information is being used, you should, in the first instance, talk to your IBD doctor or nurse to try and resolve the problem. If you want to make a formal complaint about any aspect of the IBD Registry, then you can do so by emailing support@ibdregistry.org.uk

Thank you for your support!

We may need to make changes to this leaflet from time to time. We will publish the updated version on our website www.ibdregistry.org.uk with version date on it.

IBD Registry

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www.ibdregistry.org.uk

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