IBD Registry

Industry prospectus for long-term collaboration with the **IBD registry**

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Introduction

The IBD Registry provides the infrastructure to capture pseudonymised IBD patient data from every IBD team in the UK and combine it with routinely collected NHS hospital statistics (initially for England).

Bringing this data together for the first time will:

- Drive continuous improvement in patient care and access to care across the UK
- Inform commissioning and service design
- Improve our understanding of long term outcomes
- Provide local, regional and national data in order to better define the pattern of ulcerative colitis and Crohn's disease
- Support IBD research

To find out more about working with the **IBD Registry**, please contact support@ibdregistry.org.uk

As the national IBD audit run by the Royal College of Physicians is coming to an end, the IBD Registry 2016/17 goals are to move the biological therapies audit and quality improvement programme into the Registry and develop a near-complete UK Register of patients on biologics by the end of 2017.

This will give participating teams local data to manage their biologics patients and IBD service more effectively, while patients, clinicians and the NHS will all benefit from national audit of the safety and appropriate use of biologics and biosimilars. While the initial focus will be on biologics, in time the combined UK data will become a unique resource for real-world clinical effectiveness and health economic studies in IBD care.

The IBD Registry is owned and run by the British Society of Gastroenterology (BSG), and supported by: Crohn's and Colitis UK, CICRA – Crohn's In Childhood, Association of Coloproctology of Great Britain and Northern Ireland, British Dietetic Association, British Society for Paediatric Gastroenterology, Hepatology and Nutrition, Primary Care Society for Gastroenterology, Royal College of Nursing IBD Network and the Royal College of Physicians IBD Programme.

The Registry has been funded by the BSG, grants from industry and private donations. By the end of 2016, the BSG will have supported the development of the Registry with about £375,000, but is unable to maintain this level of funding into the future. The future annual running costs of the Registry are estimated to be in the region of £400,000 and the aim is to fund this from a mix of individual hospital or Trust subscriptions and revenue from providing information and research services to academic and commercial organisations. The purpose of this document is to outline the benefits of working with the IBD Registry to organisations seeking real world evidence.

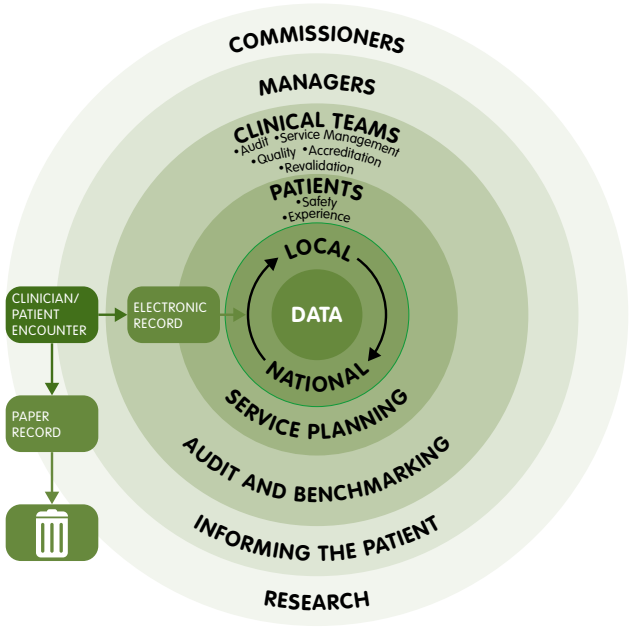
Principles

The Registry has been set up so that all IBD teams in the UK can take part. There are three data entry options to suit local conditions and resources: the IBD Registry patient management system (PMS) based on InfoFlex software, the IBD Registry web tool, and local systems using the IBD Registry Data Submission Framework.

The project is designed to facilitate data entry at the point of care and therefore the data is entered once but has multiple uses.

In England and Wales, data flows from sites to NHS Digital (previously known as the Health and Social Care Information Centre) where it is pseudonymised and sent to the IBD Registry. Information on patient consent and details on how data flows can be found in the appendices (Patient Information Leaflet and Consent forms, Information for Caldicott Guardians.) Similar arrangements will apply in Scotland and Northern Ireland via their preferred data safe havens.

The Registry will publish information based on the demographic and clinical data collected, including where possible information from related hospital activity data.



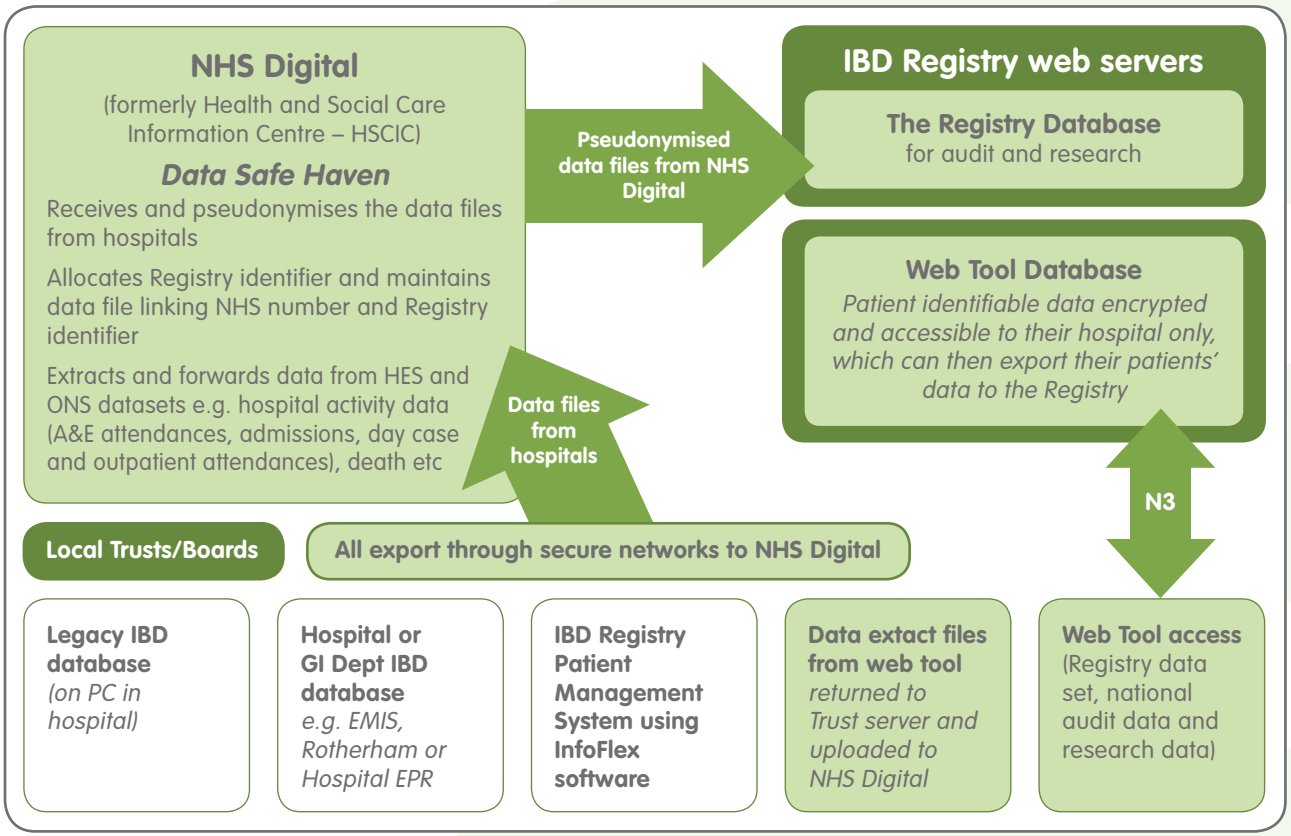
Aggregated, anonymised data from the Registry will be available to external researchers on approval of their application and this could potentially include information from English Hospital Episode Statistics (HES) assuming permission has been obtained from NHS Digital and subject to consent from patients for the secondary use of their clinical data. Metrics such as total emergency bed days, all-cause admissions, IBD-related admissions, length of stay, admissions for specific procedures (daycase, elective and emergency) may be reported and costed; this type of analysis will be more suited to retrospective studies, or those where the period of follow-up aligns with realistic timelines for HES becoming available. (Researchers should bear in mind there is a time delay in HES data becoming available – e.g. 2015/16 data only becomes available from March 2017.)

For pharmaceutical and medical devices companies, information on a drug, device or treatment may be made available (where patients have consented to Registry data sharing) to that company on application. This might include patient numbers, disease severity and change over time, patient outcomes and, if entered, previous treatment history and switch/ combination therapy use.

Baseline data reports (aggregated and anonymised) on non-biologics patients describing the clinical population characteristics of untreated populations may also be available.

The IBD Registry Web Tool allows questions to be added easily, providing anonymised data for studies. An example of this approach is the Anaemia Service Evaluation project. For sites using the PMS there will be annual reviews of the data set.

Overview of IBD Registry data-flow & pseudonymisation in England



For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

Confidentiality and Data Security

The BSG is registered with the Information Commissioner for the activities undertaken by the Registry and works to the standards required to pass the NHS Digital Information Governance (IG) Toolkit.

All patient-identifiable data is pseudonymised within an NHS-approved data safe haven before being forwarded to the Registry. The Registry servers are hosted by Redcentric, an NHS-accredited supplier. The Registry Web Tool operates within the NHS N3 Network and equivalents in the devolved nations. The Registry is progressing towards a fully-consented model, but at present operates on an 'opt-out' basis in England and Wales with the benefit of s251 approval. Unfortunately, legislation does not provide a s251 equivalent in Scotland and Northern Ireland. More details can be found in the appendices.

Registry Data

The Registry dataset (the data that can flow through to the Registry from hospitals via NHS Digital) is described in the Data Submission Framework (DSF) which can be accessed at http://ibdregistry.org.uk/data-submission-framework/.

It is intended that this dataset will be reviewed annually. The DSF determines the data items that can flow through to the Registry database from Registry-compliant systems. There is a minimum amount of data (6 items relating to demographics and diagnosis) that is mandatory for a patient to be centrally registered. All other data items will flow though the Data Submission process if they are present in the local IBD PMS or the Registry Web Tool. Additional data can be recorded within the PMS or Web Tool in the course of the management of the patient, and this will be available to the hospital team for their own analysis, but will not be routinely extracted and submitted to the Registry.

The focus for data collection in 2016/17 is to register patients receiving biological therapies and record certain data relating to the agreed biologics KPIs (see Appendix 4).

The data submitted includes patient identifiable information firstly to ensure that only one Registry record is created even where patients attend more than one hospital, and secondly to enable the Registry to import the relevant information for each patient from NHS Hospital Episode Statistics, mortality records and, in future we hope, national cancer audits.

The current Registry data collection strategy is as follows:

- To receive all eligible data collected by participating hospitals as part of their clinical management of patients. This will probably be biased to the patients who have greater interaction with their hospitals, but over time will provide a rich descriptive picture of an unselected cohort. It will be some years before this data enables critical analysis.
- To encourage all UK IBD teams to collect minimum data (selected KPIs) on the patients receiving biological therapy. We believe this offers the quickest path to achieving a near-complete subset of patients, making critical analysis possible and of high value. This also allows us to include the historical data from the RCP Biologics Audit in the analysis. The aim is to achieve this point by the end of 2017. The KPI dataset will record a disease score at the time of the decision to start biological therapy, post-induction and at 12-month review as a minimum, with information as to which treatment the patient is on at the time.

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

- Five hospitals are already committed to registering their complete secondary care population as part of a Crohn's and Colitis UK funded research project. We hope to encourage other hospitals to do the same, thus providing the denominator populations for comparison against the biologic cohort in those hospitals. (One of the incentives for completing registration of all their patients will be the availability of an annual report of current and historical hospital activity made possible by linking the Registry data to HES data.).
- The Registry hopes to reach agreement with BSPGHAN on using the Registry infrastructure to record basic demographics on all new paediatric IBD cases in 2017. This could develop into a valuable incidence cohort for future studies.
- Although there has been considerable analysis of HES data coded as IBD in the past, the Registry is collaborating with University of Liverpool to improve the analysis of HES by arranging for NHS Digital to link the Registry data to the HES data, thus improving the accuracy and completeness of the identification of activity related to IBD. As an example, adding the date of IBD diagnosis and date of initiation on biologic therapy (and dates of later switching) to the HES data will enable reporting of hospital utilisation before and after diagnosis, and before and after starting biologic therapy. The analytical methods are being developed and tested now; meaningful analysis will begin to become possible as soon as sufficient data on patients receiving biologic therapy is available, potentially from mid-2017 onwards.
- If a hospital has limited clinical data then they are encouraged at least to register the patient with minimal demographic data and an IBD diagnosis (6 data items only). Doing so provides the local IBD team with a basic register of their patients and enables the Registry to extract the full set of HES data for that patient via NHS Digital if the patient is resident in England.
- The Registry aims to encourage use of its data collection infrastructure to undertake specific data collections on various aspects of IBD care – initiated and coordinated by clinical teams, researchers or industry. Any such data collections will add to the value of the Registry as a whole (see page 9.)

Options for Working with the Registry

- Commissioning a prospective study using the IBD Registry infrastructure (e.g. VEST – a clinical observation study of vedolizumab using the Registry Web Tool for data collection. See more at: http://www.hra.nhs.uk/news/research-summaries/vest/#sthash.EAnb9ykt.dpuf).
- Commissioning a study using the IBD Registry data (e.g. Crohn's and Colitis UK project – developing the methodology for obtaining maximum value from HES data and from the combination of HES and data from any Registry site with registered cases).
- Service evaluation project using Registry infrastructure (e.g. Anaemia Service Evaluation – limited clinical audit on 100 patients across 5 sites to pilot data collection and analysis to evaluate the quality of anaemia management in IBD patients).
- Request a report of anonymised, aggregated data on a specific topic or drug or group of patients using whatever Registry data is available subject to appropriate patient consent for secondary usage.
- Investing in local data entry on a specific topic to increase completeness of Registry data, while providing logistical support to enable local consent for secondary uses of data to be obtained.

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

Data Quality

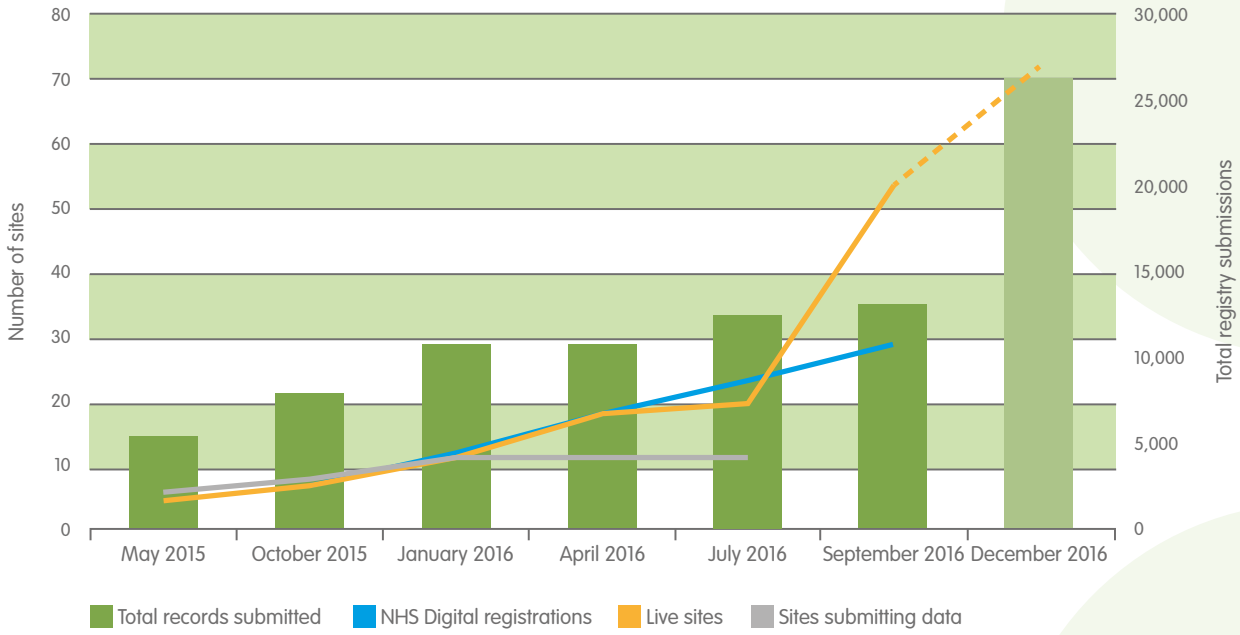
The first step in ensuring data quality is that the Registry promotes data entry to take place as part of the clinical interaction with and management of the patient and not as a separate, retrospective activity.

This facilitates continuous review of the data and correction where required. The Registry software uses coded values wherever possible and minimises the use of free text within the data collection tools. All data sent to the Registry is coded; no free text can be submitted.

Data is validated at the time of extraction in the Registry PMS and Web Tool and all data submissions are validated by NHS Digital and error logs are provided back to the user. Regular reporting back of the data and comparison with other sites also promotes assessment of face validity and critical review by clinical teams. The collaborative project between the IBD Registry and Liverpool University, funded by Crohn's and Colitis UK, includes the first formal validation of Registry data in a small number of selected hospitals. Data completeness will always be a question and the only way of assessing this will be to conduct reviews of data at local level, perhaps by comparing prescribing records with data recorded on the PMS or Web Tool. Where data completeness is essential to a study using the Registry infrastructure, funding for local validation will need to be costed into the project.

Registry Growth

IBD Registry growth



Data and site information August 2016:

- Hospitals submitting data to the IBD Registry: 11
- Patient records submitted: 13,034
- Patient contact events submitted: 29,000 (approx)
- Hospitals registered to participate: 165 (30 paediatric)
- Hospitals registered to use the Registry Web Tool: 82
- Hospitals with data collection system implemented: 48 (32 using Web Tool)
- Hospitals registered with NHS Digital for data submission: 27

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

Registry Aims 2016-18

Participation

- Build on the experience of the 10% of UK hospitals already in the Registry or in the pipeline.
- Encourage all IBD teams to enter data on all their biologics patients with the aim of a near-complete dataset on patients receiving biological therapy by the end of 2017, with continuing, prospective data collection.
- Encourage societies and organisations to use the Registry infrastructure for projects involving collection of patient data.

Transition and biologics KPIs

- Move all sites from the RCP Audit web tool to the Registry Web Tool or other Registry data collection system, maintaining existing patterns of data entry.
- Encourage Audit sites to transfer their historical biologics data into the Registry.
- Encourage all UK sites to collect data to fulfil the agreed key performance indicators (KPIs) on all their new biologics patients (in England using Quality Accounts status as a driver).
- Encourage all hospitals to extend the collection of KPI data to all their patients on biological therapies.

Develop reporting tools and processes at several levels

- Local (Trust/ hospital/ health board) reports giving a profile of patients in the database (early 2017).
- Pilot a continuous data reporting system for biologics KPIs using the Registry Web Tool and produce a standard set of benchmarking reports on biologics KPIs on a quarterly basis for all participating sites.
- Develop additional reporting tools and processes: e.g. routine quarterly reports profiling patients submitted to the Registry and highlighting (initially) the biologics KPIs. The reports will be developed in line with feedback.

- Provide hospitals with a profile of the healthcare utilisation (based on Hospital Episode Statistics (HES) data for 2005-2016) of all the biologics patients in England recorded in the Registry as at February 2017.
- Produce a national Registry Annual Report with a more detailed biologics section reporting on the KPIs, and updating the Biologics Audit Reporting so far as possible (June 2017 BSG Meeting).
- Produce an academic paper giving an overview of biologic/ biosimilar usage in the UK (2018).
- In collaboration with University of Liverpool team, produce an academic paper giving an up-to-date health economic analysis of biologic therapy for IBD (2018/19).
- Produce standardised aggregated reports for pharmaceutical companies on the usage of their medicines.

Research and service evaluation projects

- In a research project funded by Crohn's and Colitis UK and run by Dr Keith Bodger at the Department of Biostatistics at the University of Liverpool, encourage a sub-set of hospitals (Barking Havering and Redbridge, University College London Hospitals, Luton and Dunstable, Southampton, Aintree) to capture a minimal dataset (demographics, diagnosis and therapy split as on/not on biological therapy) on all their IBD patients to establish the denominator population for biologic therapy.
- Demonstrate the Registry data collection and processing systems as a cost-effective means of running a large-scale multi-centre research study (e.g. paediatric incidence study in collaboration with BSPGHAN).
- Deliver the Anaemia Service Evaluation demonstrating the potential of the Registry data collection and processing systems for small-scale multi-centre projects.

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

Industry & Academic Studies

Organisations will be able to use the IBD Registry to meet their real-world data needs. The VEST study has established that industry-supported investigator-initiated academic studies can be undertaken using Registry infrastructure.

However, industry partners will also want to sponsor their own studies. Applications to undertake a study should be submitted to the Registry via support@ibdregistry.org.uk

Key principles include:

- The IBD Registry is only used to support studies with robust methodology which answer reasonable and valid scientific questions.
- These are expected to be prospective, fully consented studies in the first few years, while data is being built up.
- We will provide a form for applications including criteria (academic credibility, robust methodology, clear patient or research benefit and commitment to publish results[1]).
- Data analysis is managed by the IBD Registry, such that investigators receive aggregated data sets in line with the relevant statistical analysis plan and do not have access to any patient level data.
- Sponsors (both academic and industry) and investigators are required to provide an appropriate undertaking regarding timely publication of study results.[1]
- A transparent fee structure will be established, enabling companies and researchers to estimate the likely cost of undertaking studies.
- Potential study concepts may be evaluated without the need for full protocol development.

1. In certain circumstances the Registry may allow studies to remain unpublished for an agreed period of time where these are commercially sensitive, on condition that the studies also provide clear patient and NHS benefits. An example might be a study to map patient pathways to understand the appropriate role of a new medicine and ensure that market access activities are properly aligned with NHS goals and prescribing guidelines.

Industry Working Group

In 2016, the IBD Registry set up an industry working group to facilitate collaboration with industry and allow for meaningful ongoing dialogue.

The aims of the group are to:

i. Support the Registry team with specific expertise.

ii. Work with the Registry to set up a transparent and compliant framework for industry involvement including processes and parameters for collaboration and access to anonymised data.

iii. Represent pharmaceutical companies working in IBD.

Applications were invited from pharmaceutical industry stakeholders with skills and experience in areas such as health outcomes, marketing, strategic planning, business development, regulatory, clinical research, clinical commissioning and market access. The group includes representation from a range of companies with different perspectives and interests (e.g. larger and smaller companies, and manufactures of drugs in different classes). Membership of this group is open to all companies, and will be on a rolling basis to ensure fairness.

The creation of this group does not in any way preclude the IBD Registry from consulting and collaborating with a broader range of industry stakeholders or any individual organisations.

Current members (2016) are:

- Mick Collins, Healthcare Strategy Manager, Janssen
- Glynn Owen, National Market Access Manager, Takeda
- Ella Salter, Medical Science Liaison, Biogen
- Jeremy Thorpe, General Manager, Tillotts Pharma UK Ltd
- Caroline Turnbull, Marketing Manager, Dr Falk

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

APPENDIX 1: Patient Information Leaflet 2016

(England & Wales)

IBD Registry – Information for Patients

The IBD Registry is a national project to collect information about Inflammatory Bowel Disease (IBD) from across the UK for the first time.

Why we're supporting the IBD Registry – a message from Crohn's and Colitis UK and CICRA (Crohn's in Childhood)

The IBD Team at your hospital want to join in the UK IBD Registry. This means sending information about patients and their treatment to a central database unless the patients state they do not wish their information to be shared.

We believe that the IBD Registry will benefit all IBD patients by:

- Helping hospitals to improve their IBD services.
- Supporting research into the causes of IBD and better IBD treatments.
- Improving society's understanding of how people's lives are affected by IBD.

No one in the Registry team will be able to identify any individual patient and all the Registry publications will be completely anonymous. We are confident that the Registry team have taken all the right steps to make sure that your information will be handled safely and confidentially.

We encourage you to say yes to the questions on the consent form so we can help to improve care for all IBD patients. If you have any questions, please speak to your IBD doctor or nurse, or call our helplines.

Thank you,

David Barker, CEO
Crohn's and Colitis UK
Helpline: 0300 222 5700

CROHN'S & COLITIS UK — FIGHTING INFLAMMATORY BOWEL DISEASE TOGETHER

Margaret Lee, Chair
Crohn's in Childhood (CICRA)
Helpline: 0208 949 6209

CICRA — children and young adults with crohns and colitis

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

Your hospital will send some information about you, your IBD and your IBD care to 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 fully protected and you can read more about this below.

If you do not want information about you submitted to the IBD Registry, section 8 tells you how to arrange this.

2 - How will the Registry help IBD patients?

Information about your IBD and its treatment can contribute to improving patient care and research in several ways:

- The IBD Registry team will analyse information about IBD and how it's treated across the UK and publish the results.
- Researchers from NHS or academic organisations, or from health-related companies may request anonymous information from the Registry to study IBD; for example to compare different treatments and outcomes or to monitor the safety and effectiveness of medicines.
- Researchers may ask the Registry to help find patients to take part in clinical studies. If a research project came up that might be relevant to you, your doctor would be contacted.

The information collected and published by the Registry and other researchers will all 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: for example the frequency of surgery, hospital attendances and admissions.

3 - How is the confidentiality of my personal information protected?

Information does not go direct to the Registry, but is sent by your hospital to NHS Digital (formerly the Health and Social Care Information Centre). NHS Digital changes any identifiable personal information into a different format so that no one at the IBD Registry can identify any individual patient. (This process is called pseudonymisation.) NHS Digital keeps a master file so that future information can be added to the right patient's registry record and to be able to contact hospitals about research studies.

4 - What is NHS Digital?

Previously known as the Health and Social Care Information Centre, NHS Digital is an organisation approved by the government for their standards of data security and confidentiality. It is authorised by the NHS to collect and process information about patients and the healthcare they receive. The information held by NHS Digital, including information from other NHS bodies, may be used to analyse the healthcare you receive, to help contact patients (e.g. about a research project) or to provide information to the IBD Registry about patients' health status.

5 - What identifiable personal information will be used?

Your NHS number, postcode, date of birth and gender are included in the information sent to NHS Digital. The NHS number means the IBD Registry can track the care a patient receives even if they attend different hospitals. The postcode means the IBD Registry can understand the care people receive in different parts of the country. This personal information is pseudonymised by NHS Digital before being passed to the IBD Registry.

6 - What happens to 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 published reports will be available at www.ibdregistry.org.uk. Some pseudonymised information may be shared with other UK NHS audits and research projects (e.g. the UK Bowel Cancer Audit). Reports with fully anonymised information may be made available to NHS and academic organisations and to health-related companies such as pharmaceutical companies, for example to monitor the safety and effectiveness of medicines. All applications for access to the anonymised Registry information will have to be approved by the Registry Research Committee.

7 - How long will the IBD Registry keep my data and can I opt out later?

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 over time. You can stop information about your IBD and your healthcare being held in the Registry at any time, by speaking to your IBD doctor or nurse, or by contacting the Registry Administrator at the address given below.

8 - If I do not want my information to be sent to the IBD Registry now, what should I do?

Talk to your IBD doctor or nurse about your concerns. 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 your doctor, nurse, or a member of the IBD clinic administration team. They will make sure your information is not sent to the IBD Registry. This will not affect your treatment in any way.

9 - Who is responsible for the information about patients in the IBD Registry?

The British Society of Gastroenterology is the Data Controller for the Registry information and is responsible for ensuring that the IBD Registry complies with the Data Protection Act 1998.

10 - How can I make a complaint?

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 writing direct to the Registry Administrator at the address given below.

11 - What will happen next?

Over the next year all patients will be asked to sign a consent form, to give permission for your IBD team to continue submitting your information to the IBD Registry and confirm how you wish your information to be used.

12 - Which organisations are involved in the IBD Registry?

The IBD Registry is run by the British Society of Gastroenterology and supported by:

- Crohn's and Colitis UK
- CICRA – Crohn's in Childhood
- Association of Coloproctology of Great Britain and Northern Ireland
- British Dietetic Association
- British Society of Gastroenterology
- British Society for Paediatric Gastroenterology, Hepatology and Nutrition
- Primary Care Society for Gastroenterology
- Royal College of Nursing - IBD Network
- Royal College of Physicians - IBD Programme

IBD Registry - British Society of Gastroenterology,
3 St Andrews Place,
Regent's Park, London
NW1 4LB
020 7935 3150
info@ibdregistry.org.uk
www.ibdregistry.org.uk

APPENDIX 2: Patient Consent Form 2016

(England & Wales)

IBD Registry

Patient sticker may be affixed here

IBD REGISTRY CONSENT FORM

Name of Trust.....

The purpose of the IBD Registry is to
- Help hospitals improve their IBD services
- Support research into the causes of IBD and better IBD treatments
- Improve society's understanding of how people's lives are affected by IBD

The IBD Registry Patient Information Leaflet explains how your information will be used and your identity protected. Please read the leaflet and then initial the boxes below as appropriate.

YES, I GIVE PERMISSION for relevant information from my health records to be submitted to the IBD Registry **If you agree to this, please also consider the following options and initial the boxes if you give permission for:**	☐
1. Information held by NHS Digital*, NHS Wales Informatics Service and other NHS bodies to be linked to my IBD Registry record.	☐
2. Information from my health records held by the IBD Registry to be: **(a)** used in studies run by approved researchers from non-commercial organisations	☐
(b) included in fully anonymised reports to companies developing healthcare products (e.g. drugs or medical devices) for research and safety monitoring purposes	☐
3. My information to be used so that my IBD Team can contact me about relevant research projects	☐

formerly known as the Health and Social Care Information Centre

OR

NO, I DO NOT GIVE PERMISSION for information from my records to be submitted to the IBD Registry	☐

Patient's name .....

Patient's signature ..... Date .....

Staff member's name and role .....

Staff member's signature ..... Date .....

For further information visit **www.ibdregistry.org.uk**

The IBD Registry is managed by the British Society of Gastroenterology which is a charity registered in England & Wales.
Charity number 114907

IBDR Consent Form for adults - England & Wales – July 2016

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

APPENDIX 3: Information for Caldicott Guardians 2016

(England & Wales)

IBD Registry – submitting data

Caldicott Guardian information sheet

NHS Trusts in England & NHS Boards in Wales (September 2016)

This is a request from the Gastroenterology Department for approval to participate in the Inflammatory Bowel Disease (IBD) Registry. Participation involves local collection of agreed data items and submission of these on a regular basis to the IBD Registry via the Clinical Audit Platform managed by NHS Digital (formerly the Health and Social Care Information Centre - HSCIC). This is the same platform used for several other national audits in England and Wales.

To meet information governance requirements, we ask that the Caldicott Guardian confirm approval for the IBD team to participate in the IBD Registry by submitting the required NHS Digital authorisation form, which will enable the IBD Team to be given access to the Clinical Audit Platform to upload patient data. Please note that the form must be sent to NHS Digital from the Caldicott Guardian's NHS email address and we ask that the form is copied to the IBD Registry at IBDProgramme@rcplondon.ac.uk.

Who owns the IBD Registry?

The IBD Registry is owned and managed by the British Society of Gastroenterology which is a Registered Charity (Number 1149074) located at 3 St Andrews Place, London NW1 4LB.

The objectives of the IBD Registry are to:

- drive continuous improvement in patient care and access to care across the UK
- inform commissioning and service design
- improve our understanding of long term outcomes
- provide local, regional & national data in order to better define the pattern of ulcerative colitis and Crohn's disease
- support IBD research

Participation in the Registry

This involves submitting demographic and clinical data on patients who have inflammatory bowel disease via NHS Digital to the central IBD Registry database. Submission of data to the IBD Registry for national clinical audit is listed as part of the NCAPOP programme and is a requirement for Quality Accounts in England in 2016/17. The IBD Audit and Quality Improvement Programme is being jointly run in 2016/17 by the British Society of Gastroenterology and the Royal College of Physicians.

The Registry dataset comprises a minimum of 12 data items for adult patients and 17 for paediatric patients, with additional data required for any surgery, medication, cancer diagnosis, hospital admission or death. Additional data is also required for the current focus of IBD Audit and quality improvement which relates to those patients receiving biologics therapy.

The data set includes patient-identifiable information and therefore the IBD Registry has contracted to use NHS Digital to act as data safe haven. When data is submitted to the Registry this is done by the hospital staff downloading an extract of data from their IBD database which they then upload to NHS Digital through a secure portal. This data is pseudonymised by NHS Digital before onward transmission to the IBD Registry. The IBD Registry does not have direct access to the patient identifiable records. A diagram of the data submission and processing system is included in this document as Appendix A.

Patient consent to processing of data

The patient identifiable data submitted to the IBD Registry enables record linkage by NHS Digital to other NHS datasets (currently HES data, but in future ONS mortality data and national audits such as the bowel cancer audit) and also ensures that where a patient attends more than one hospital either simultaneously or sequentially only one patient record is maintained in the Registry. (An application will be made to NWIS to undertake data linkage in Wales.)

The IBD Registry applied to the Confidentiality Advisory Group for exemption under s251 of the NHS Act 2006 from the requirement to obtain patient consent to the use of patient identifiable data. This was granted and has to be renewed annually. The application was to allow a period of time during which participating hospitals could submit data to the Registry without formal consent, whilst using that time to identify and seek written consent from their patients.

Once the s251 approval has expired, only data from consented patients will be submitted to and held by the Registry. The Registry has made available a pack of information materials for use by participating centres to inform and consent patients. (The NHS Digital system will ensure that only data from consenting patients is uploaded after expiry of the s251 approval.)

The s251 approval for the current period of exemption extends to May 2017 and can be verified by accessing the record of Approval decisions provided at http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions/. Open the file 'April 2013 onward approved non-research applications' - Row 19.

Requests for external and research access to Registry data

Requests for external and research access to the pseudonymised data held by the Registry will be overseen by the research sub-committee currently chaired by Dr Keith Bodger, Senior Lecturer in Medicine & Consultant Gastroenterologist, Department of Medicine, Aintree University Hospital.

Data Protection Compliance

The BSG is registered with the Information Commissioner and a copy of the registration can be accessed at http://ico.org.uk/ESDWebPages/DoSearch by entering reference Z5064566.

Statement on research ethics status from Health Research Authority

The Health Research Authority has confirmed that data collection for the Registry does not constitute research and does not require ethical approval. A copy of their email statement is attached to this document as Appendix B. Any additional data collection specifically to meet the needs of a research project will be submitted for national or local ethics approval in the usual way.

Information governance toolkit status of organisations involved in the Registry

Health and Social Care Information Centre – data safe haven, pseudonymisation and linkage
- Organisation Code x26 – Version 13: 91% (Satisfactory)

Chameleon Information Management Services Ltd – Registry software (InfoFlex)
- Organisation code 8HA87 – Version 13: 72% (Satisfactory)

Redcentric plc – N3 connection and Registry server hosting
- Organisation code YGMAP – Version 13: 100% (Satisfactory)

University of Liverpool – analysis of Registry data
- Organisation code 8HN20 – Version 13: 80% (Satisfactory)

British Society of Gastroenterology – ownership and management of IBD Registry
- Organisation code 8PF17 – Version 13: 61% (Satisfactory with improvement plan)

Royal College of Physicians of London – quality improvement programme
- Organisation code 8J008 – Version 13: 73% (Satisfactory)

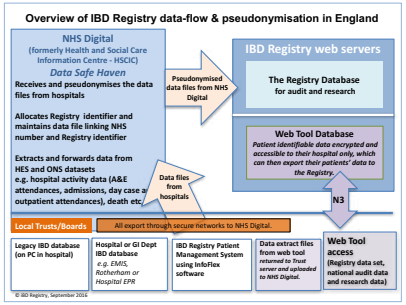
(The current IG toolkit status and scores for all the organisations can be confirmed by visiting https://www.igt.hscic.gov.uk and selecting the option to see organisations assessments.)

IBD Registry - further information

Further information is available at our website: www.ibdregistry.org.uk

Appendix A

IBD Registry data flow and pseudonymisation in England & Wales



Appendix B

Opinion by HRA on ethical status

From: Richard Driscoll
Subject: Re: Request for advice - Inflammatory Bowel Disease Registry
Date: 10 October 2013 15:14
To: Queries NRES (HEALTH RESEARCH AUTHORITY)

Many thanks for the prompts and helpful response
Richard

Richard Driscoll
Sent from my iPhone

On 10 Oct 2013, at 1407, "Queries NRES (HEALTH RESEARCH AUTHORITY)" wrote:

ENQUIRY TO QUERIES LINE

Dear Richard

RE: [Inflammatory Bowel Disease Registry]

Thank you for your email seeking additional clarity on whether your project should be classified as research requiring NHS Research Ethics Committee (REC) review.

Based on the information you have provided, our advice is that the project is not considered to be research and does not require review by an NHS Research Ethics Committee.

In giving this advice, our advisor states....

This is primarily a register and as such a tool for service evaluation. Hence it wouldn't need REC review.

This advice is in line with:

- The harmonised UK-wide edition of the Governance Arrangements for Research Ethics Committees (GAFREC), which came into effect on 01 September 2011;
- The Health Research Authority (HRA) decision tools for determining whether a project is research and whether NHS REC review is required;
- The National Research Ethics Service (NRES) leaflet, Defining Research and the algorithm Does my project require review by a Research Ethics Committee?

This response should not be interpreted as giving a form of ethical approval or any endorsement to your project. However, it may be provided to a journal or other body as evidence if required.

You should also be aware that:

- All types of study involving human participants should be conducted in accordance with basic ethical principles, such as informed consent and respect for the confidentiality of participants. Also, in processing identifiable data there are legal requirements under the Data Protection Act 2000. When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation.
- This response only covers whether your project is classified as research and whether it

APPENDIX 4: IBD Registry Biological Therapy Key Performance Indicators (KPI) 2016/17

The focus for the integrated RCP IBD Programme and IBD Registry in 2016/17 is to transition the RCP biological therapies audit and quality improvement into the Registry system and develop a near-complete UK register of patients on biologics by the end of 2017. This will give participating teams local data to manage their biologics patients and IBD Service more effectively, while patients, clinicians and the wider NHS will benefit from national audit of the safety and appropriate use of biologics and biosimilars. In time, the combined UK data will become a unique resource for real-world clinical effectiveness and health economic studies in IBD care.

The Biological Therapy Key Performance Indicators (KPIs) are as follows:

Pre-treatment checks

- Was the patient screened before starting on a biological therapy?
- Was a formal assessment of disease activity recorded at the point the decision was made to commence a biological therapy?
- Is there a record of Registry consent being discussed with the patient?

Post-induction review (approximately 3 months after the date of the initial treatment)

- Did a post-induction review take place?
- Was a formal assessment of disease activity recorded at this time?

12-month review (approximately 12 months after the date of the initial treatment)

- Did a 12-month review take place?
- Was a formal assessment of disease activity recorded at this time?

For more information, or to arrange a meeting with the Registry team, please contact support@ibdregistry.org.uk

The IBD Registry is owned and managed by the British Society of Gastroenterology,
3 St Andrews Place, London NW1 4LB (Charity no: 1149074, Company no: 8124892)

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