



Data Submission Specification 2019_J

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1 Version Control

Owner	Version	Date	Review date	Status
Richard Driscoll	2015_A	12 Feb 2015		First draft
Richard Driscoll	2015_B	13 Feb 2015		Second draft for comment
Richard Driscoll	2015_C	19 Feb 2015		With comments from SC and CM
Richard Driscoll	2015_D	17 Mar 2015		Minor typographical errors corrected, data items to be included in csv files clarified and missing data validation statements added to table on pp 9-14
Richard Driscoll	2015_E	19 May 2015		Addition of Contact Type as required data item and updates to submission process information
Richard Driscoll	2015_F	8 July 2015		Additional information requested by users of the document. Addition of the IBD Audit Biologics Dataset.
Richard Driscoll	2015_G	24 August 2015		Addition of the IBD Audit Biologics Dataset. Clearer specification of three levels of data submission. Extra codes for Contact Type
Richard Driscoll	2015_H	20 September 2015		Corrections to Biologics Dataset – removal of duplicate item (perianal disease) and submission filename corrected to BiologicsEvent.
Richard Driscoll	2015_H.1	12 November 2015		Wording changes to description of the levels of data that can be submitted. Updated data flow visual.
Stephen Grainger	2019_J.1	13 July 2019		Revised governance section. Additions to drug names/codes; additional consent field and ethnicity; other additions to modernise dataset; typographical errors corrected
Liz Dobson	2019_J.2.0	01 June 2021		Description updated to reference planned 2020-21 transition away from NHS Digital. Formatting and layout upgraded.
Liz Dobson	2019_J.2.0.1	11 June 2021		Minor formatting corrections

1.1 Version Control Numbering Rules

Any Version that has changes to the dataset that must be implemented will be labelled with the next letter in the alphabetical sequence (the letter I is omitted to avoid confusion with 1).

Any changes that are for clarification of the text will be labelled with a number after the appropriate letter. (e.g H.1)

2 Introduction

The IBD Registry is the curated database of IBD data collected in the UK, primarily from IBD clinical teams but also from patients.

The ethos of the Registry is to be open to the widest possible participation by clinical teams, and wherever possible to avoid or minimise additional data entry work by clinical teams. We describe this approach as 'system agnostic' and 're-using captured point of care data'

Data Submission into the Registry can be from any electronic clinical system (ranging from a Trust-wide eHR system to a basic local clinical spreadsheet) that can produce a Registry-compliant set of files for submission.

The **Dataset Definition** describes the standard for the Registry dataset. Any clinical system that can extract the identified data in a set of files in this format will be able to upload data into the Registry.

The detailed **Submission Framework** describes the standard for submitting data to the Registry. Any clinical system with data in a set of Registry submission-compliant extract files will be able to upload data into the Registry.

3 Audience

This document is designed for use by clinical teams and their supporting hospital IT teams.

4 Participating in the Registry Project

The IBD Registry encourages all hospitals in the UK to join the Project by collecting and submitting the Registry data on their IBD patients.

5 Joining the Registry

Information on the steps required to participate in the IBD Registry are set out in the Information Pack available by email from [our Support team](#). If you would like to be sent the detailed Submission Framework (2019_J), please email the same team.

6 Registry and IBD Audit

One of the missions of the IBD Registry is to facilitate the continued collection of data for national IBD Audits. The Royal College of Physicians' IBD Audit team and the Registry worked together in 2016-17 to transition the collection of the Biologics Audit data to ensure the IBD Registry's data framework, together with compliant data capture tools (such as the Registry WebTool, and the IBD PMS from Civica) were able to capture the data required for the Audit.

Users of these Registry-compliant data capture tools are able to submit their data for the Biologics Audit along with their Registry data. The specification for this is incorporated into the Data Submission Framework.

We suggest third-party software developers test their data submission files for accuracy before using them to submit real data; access can be arranged to a Test IBD

system by contacting support@ibdregistry.org.uk.

Any queries on this should be directed to support@ibdregistry.org.uk in the first instance.

7 The Data Submission Process

7.1 Submission schedule

The Registry works to a schedule of quarterly data submissions in the months of January, April, July and October each year. Submission dates are on [our website](#).

Hospitals wishing to submit live data to the Registry are encouraged to organise their registrations and approvals and then make a first submission some time before a quarterly update schedule to familiarise themselves with the process and test that their data can be successfully submitted. Please contact support@ibdregistry.org.uk if you wish to arrange this.

7.2 Data submission platform

Note: we are in the process of transition to a new submission platform, independent of NHS Digital. This is in progress in 2020-21. We would advise teams looking to participate in 2021 to join the new platform. The following is the existing NHS Digital registration route that will eventually be de-commissioned.

7.2.1 Registration with NHS Digital

The Registry currently uses NHS Digital as its data handling platform

Hospitals need to register with NHS Digital before submitting their data. The IBD Registration Form has to be completed with the names and NHS email addresses of the staff who will carry out the data submission, counter-signed and submitted to the NHS Digital Enquiries Desk by the Caldicott Guardian. The form can be obtained from the NHS Digital help desk (enquiries@hscic.gov.uk or 0300 303 5678) requesting access to IBD on the CAP system or is available direct from support@ibdregistry.org.uk.

7.2.2 Hospital Codes

NHS Digital uses the official NHSE Trust and Hospital Codes to identify the source of any data submission and the relevant code needs to be entered into Part B of the NHS Digital IBD Registration Form. The code will be 5 alphanumeric characters – the first three designating the Trust and the last two digits being ‘internal’ codes to identify different entities within the Trust. If only one IBD Registry data submission will be made for a Trust the top level Trust Code can be used and this will usually have 00 as the final two digits.

However, if there might be more than one submission – either because adult and paediatric data may be submitted separately or because there are several hospitals providing IBD care – then care should be taken to choose the appropriate sub-code for the last two digits.

7.2.3 Creating the NHS Digital account

The actual process for submitting data involves the relevant IBD Team member creating a Single Sign On (SSO) account at NHS Digital (www.clinicalaudit.hscic.gov.uk).

Once the NHS Digital IBD Registration Form has been authorised by the local Caldicott Guardian and sent to NHS Digital, then the SSO account is linked by NHS Digital Clinical Audit Team to the IBD system. Data can then be submitted by logging into NHS Digital clinical audit portal and uploading the set of data files in the format specified below.

NHS Digital will know from the Registration Form the Trust or hospital code for each authorised user and will automatically add the source code and date of submission to each of the data files. NHS Digital will verify the NHS numbers and validate the data in the files, accepting those records that meet the specification and rejecting those that do not. A report will be returned to the user stating which data has not been accepted. A presentation is available from support@ibdregistry.org.uk that illustrates the submission process.

8 The Data Submission Format

This section is primarily for the use of hospitals using third-party databases to submit data to the Registry. The IBD PMS and Registry Web Tool have this data submission format integrated into the software and the Registry Export Process.

Data must be submitted in csv format; no other format can be accepted by NHS Digital. Where data items have multi-select coding options, the codes must be separated by a semi-colon (;). All data fields must be provided, even when the value is unknown; when a data item is not available an empty value must be provided.

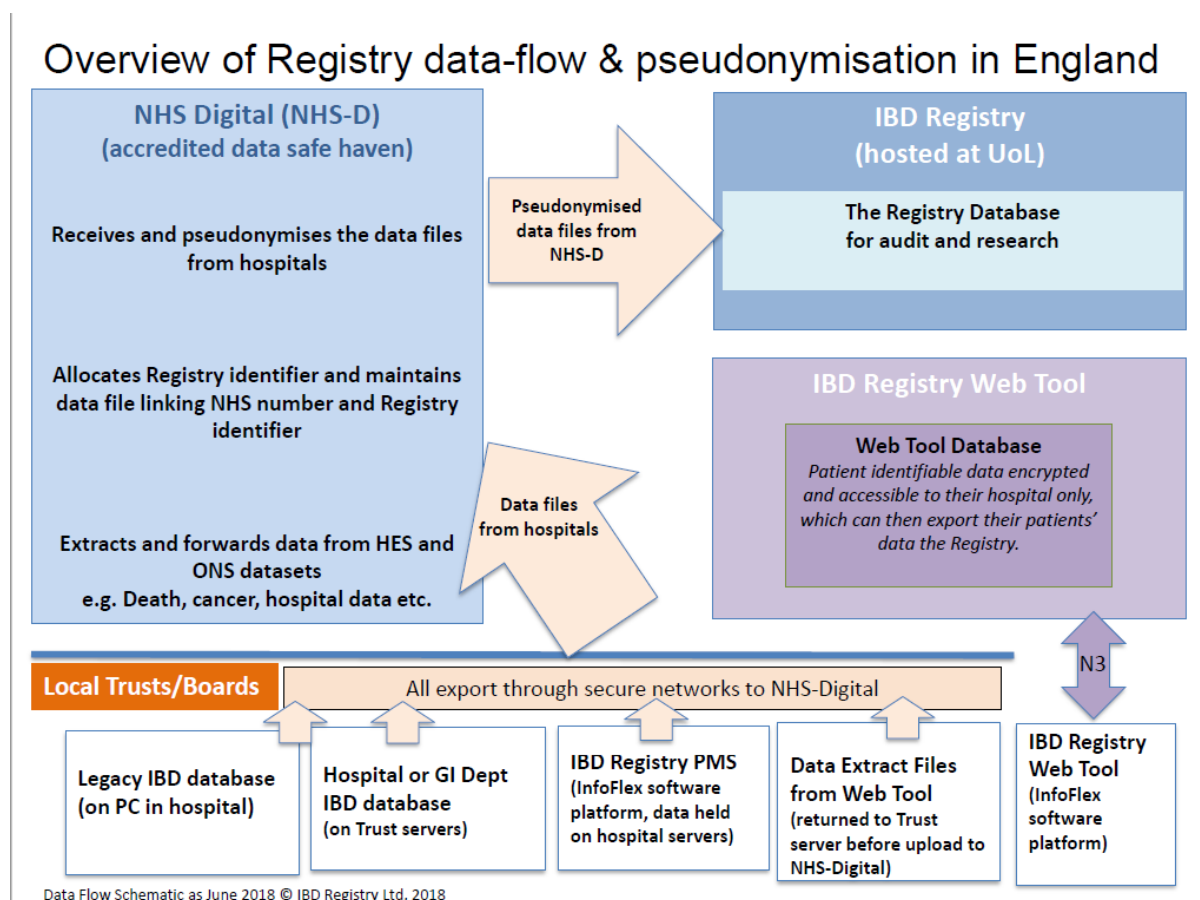
Each submission should contain all relevant Registry data including any data previously submitted.

The Registry has adopted this approach to minimise any local complications in tracking which data has previously been submitted and situations where previous data might subsequently have been corrected.

In selecting the patient records to submit, it is essential that any patient who has refused consent is excluded from the data submission. At present the Registry has been granted s251 approval under the NHS Act (2006) to collect patient data from hospitals without needing formal consent; however, patients have the right to 'opt-out'. At some point in the future, when the Registry's s251 approval expires, selection must be based on those who have positively consented. The Registry will notify all contributors when this change has to take place. The current s251 exemption runs until September 2021.

(NB. Third party software developers should ensure they notify support@ibdregistry.org.uk that they wish to be added to the list of developers to be notified of any changes to the Registry dataset or Data Submission Framework.)

8.1 Data Submission Flow



8.2 Data Submission Files

The data must be separated into the following individual files:

Data File	Status of file	Key Field(s)
Patient	Mandatory	NHS Number and Date of Birth (<i>must also be present in every row of data submitted in all following files</i>)
Diagnosis	Mandatory	Date of diagnosis
Consent	Mandatory	Date recorded
Contact (r)	Required if	Date of event and Contact Type
Admission (r)	Required if ...	Date of event
Surgery (r)	Required if ...	Date of event
Cancer (r)	Required if ...	Date of Cancer diagnosis
Growth (r)	Required if ... (paediatric)	Date recorded
IBDImpact (r)	Optional	Date recorded
PromControl (r)	Optional	Date recorded
Medication (r)	Required if ...	Start date
Biologics (r)	Required if ...	Date of Initiation or Review Event and Event Type

Mandatory = this file must be present in all submissions

Required if ... = file should be included if this event has occurred and data exists to be submitted

Optional = the Registry encourages this data to be collected and submitted

(r) = there can be more than one instance of these events per patient record, whereas there can only be one patient, one diagnosis, and one status for consent.

In the filename, abc can be replaced by any characters that are useful to you locally, but they must be preceded by the underscore character.

The Patient data file **must** contain each patient's NHS Number, Date of Birth, Gender and Postcode to be accepted. (All other data files must also contain the patient's NHS Number and Date of Birth in addition to any other required fields.)

Sites are encouraged to include their IBD Audit Site code plus the Local Unit Code if used. (The local unit code may be used to distinguish between hospitals, or between paediatric and adult IBD teams, where hospitals submit their data to the IBD Audit in a combined submission with one Audit Site code, but wish their Registry data to be capable of being analysed separately.)

The accompanying Data Submission excel file contains a worksheet with column headers for each of the required csv files.

9 Validation Rules

A record is registered by submission of the Patient data file and this must be submitted first in any batch of files.

Patient data file:

NHS Number AND Date of Birth AND Gender AND Postcode

Diagnosis data file:

NHS Number AND Date of Birth AND Date of Current Diagnosis AND Current Diagnosis are present

Consent data file:

NHS Number AND Date of Birth AND Informed consent for Registry DOES NOT = N

Contact data file:

NHS Number AND Date of Birth AND Date of Contact AND Contact Type are present

Admission data file:

NHS Number AND Date of Birth AND Date of Admission AND Type of Admission are present

Surgery data file:

NHS Number AND Date of Birth AND Date of surgery are present

Cancer data file:

NHS Number AND Date of Birth AND Date of diagnosis of cancer AND Site of Cancer are present

Growth data file:

NHS Number AND Date of Birth AND Date of measurement of growth are present

IBDImpact data file:

NHS Number AND Date of Birth AND Date Occupation Status recorded AND Year Type AND Relevant Year are present

ControlProm data file:

NHS Number AND Date of Birth AND Date of IBD Control Prom are present

Medication data file:

NHS Number AND Date of Birth AND Drug Code AND Drug Start Date are present

BiologicEvent data file:

NHS Number AND Date of Birth AND Date of Biologic Initiation or Review Event AND Biologic Event Type AND Biologic Treatment Type

9.1.1 Date Validation Rules

1. Date of birth is > 01/01/1900 and < today
2. Date of death cannot be before date of birth
3. Date of onset of symptoms cannot be before date of birth
4. Date of onset of symptoms must be before the date of diagnosis
5. Date of diagnosis cannot be before date of birth
6. Date consent last recorded must be before date of submission
7. Date of contact must be before date of submission
8. Date of admission must be before date of submission
9. Date of surgery must be before date of submission
10. Date of cancer diagnosis must be before date of submission
11. Date occupation status recorded must be before date of submission
12. Date of IBD Control Prom must be before date of submission
13. Date of starting a drug must be before the date of stopping a drug

Other validation rules for individual data items are shown in the table below.

9.1.2 Submission validation (via NHS Digital)

When data files are submitted to NHS Digital, the system will validate the files according to the following rules:

Records will be rejected if a required item is missing or has an invalid format or code.

Records which have an invalid format or code for a data item that is not a 'Required item' will be accepted but the invalid item will not be added to the Registry data.

The data submission report will clearly indicate rejected records and give warnings where data has been excluded.

10 Data Items

(NB. Those marked with an asterisk constitute the desirable Minimum Clinical Dataset; those marked with a double asterisk are the absolute minimum data to enable a patient to be registered - see page 4 above.)

Field	Item	Date File
**NHS Number	IBD01	Patient
**Date of birth	IBD02	Patient
**Gender	IBD03	Patient
**Postcode	IBD04	Patient
GP Practice code	IBD05	Patient
*Date of death	IBD06	Patient
*IBD involvement in death	IBD07	Patient
*Ethnicity	IBD07A	Patient
Field	Item	Date File
**Date of Current Diagnosis	IBD08	Diagnosis
**Current diagnosis	IBD09	Diagnosis
*Date of onset of symptoms	IBD10	Diagnosis
*Earliest Diagnosis	IBD11	Diagnosis
*Date of Earliest Diagnosis	IBD12	Diagnosis
Field	Item	Date File
*Date consent last recorded	IBD15	Consent
*Informed consent for registry	IBD16	Consent
*Informed consent for linkage	IBD17	Consent
*Informed consent for research	IBD18	Consent
*Consent to be contacted for future research	IBD19	Consent
*Consent for reporting to companies	IBD19A	Consent
Field	Item	Date File
*Date of contact	IBD20	Contact
Contact type	IBD21	Contact

Adult or paediatric service patient	IBD22	Contact
Postcode at time of contact	IBD23	Contact
AgeOfOnsetAdult (Montreal)	IBD24	Contact
*Extent of UC Adult (Montreal)	IBD25	Contact
*Behaviour Crohns Adult (Montreal)	IBD26	Contact
*LocationCrohnsAdult (Montreal)	IBD27	Contact
*Disease Proximal to terminal Ileum (Montreal L4)	IBD83	Contact
AgeOfOnsetPaediatric(Paris)	IBD28	Contact
*Extent of UC Paediatric(Paris)	IBD29	Contact
*Behaviour Crohns Paediatric(Paris)	IBD30	Contact
*LocationCDPaediatric(Paris)	IBD31	Contact
*Disease Proximal to terminal Ileum (Paris L4a L4b)	IBD84	Contact
Perianal Crohn's Disease	IBD32	Contact
HBI Total Score	IBD33	Contact
Modified UCDAI	IBD34	Contact
weightedPCDAI	IBD35	Contact
PUCAI	IBD36	Contact
SCCAI	IBD37	Contact
*Smoking status	IBD38	Contact
Local unit code	IBD13	Contact
IBD Audit code	IBD14	Contact

Field	Item	Date File
*Date of hospital admission for IBD management	IBD39	Admission
*Type of admission	IBD40	Admission
*Reason for admission	IBD41	Admission
*Date of discharge	IBD42	Admission
Local unit code	IBD13	Admission
IBD Audit code	IBD14	Admission
Field	Item	Date File
*Date of surgery	IBD43	Surgery
Hospital where surgery took place	IBD44	Surgery
*Main Surgical Procedure	IBD45	Surgery
*Other Surgical Procedure	IBD46	Surgery
*Surgery performed laparoscopically	IBD47	Surgery
Local unit code	IBD13	Surgery
IBD Audit code	IBD14	Surgery
Field	Item	Date File
*Date of diagnosis of cancer	IBD48	Cancer
*Site of cancer	IBD49	Cancer
Local unit code	IBD13	Cancer
IBD Audit code	IBD14	Cancer
Field	Item	Date File
*Date of measurement	IBD50	Growth
*Height (m)	IBD51	Growth
*Weight (kg)	IBD52	Growth
Local unit code	IBD13	Growth
IBD Audit code	IBD14	Growth
Field	Item	Date File
Date Occupation Status Recorded	IBD53	IbdImpact
Primary Occupation Status	IBD54	IbdImpact
Year Type	IBD55	IbdImpact
Relevant Year	IBD56	IbdImpact
Days lost - number	IBD57	IbdImpact
Days lost - range	IBD58	IbdImpact
Local unit code	IBD13	IbdImpact

IBD Audit code	IBD14	IbdImpact
Field	Item	Date File
Date of Control PROM	IBD59	PromControl
Question1a	IBD60	PromControl
Question1b	IBD61	PromControl
Question2	IBD62	PromControl
Question3a	IBD63	PromControl
Question3b	IBD64	PromControl
Question3c	IBD65	PromControl
Question3d	IBD66	PromControl
Question3e	IBD67	PromControl
Question 3f	IBD68	PromControl
Question4a	IBD69	PromControl
Question4b	IBD70	PromControl
Question4c	IBD71	PromControl
Question4d	IBD72	PromControl
Question5Vas	IBD73	PromControl
IBDCTRL-8SCORE	IBD74	PromControl
Local unit code	IBD13	PromControl
IBD Audit code	IBD14	PromControl
Field	Item	Date File
*Drug Code	IBD75	Medication
*Drug Start Date	IBD76	Medication
Drug End Date	IBD77	Medication
Dose	IBD78	Medication
Unit	IBD79	Medication
Frequency	IBD80	Medication
Route of Administration	IBD81	Medication
Biologics Drug End Reason	IBD82	Medication
Local unit code	IBD13	Medication
IBD Audit code	IBD14	Medication
IBD Biologics Audit site code	IBD200	Medication

IBD Biologics Audit Data Items (added July 2015)

Field	Item	Model
*Biologics - Date of Initiation or Review Event	IBD201	BiologicsEvent
*Biologics Event Type	IBD202	BiologicsEvent
*Biologic Treatment type	IBD210	BiologicsEvent
LocationCrohnsAdult (Montreal)	IBD203	BiologicsEvent

Disease Proximal to terminal Ileum (Montreal L4)	IBD243	BiologicsEvent
Extent of UC Adult (Montreal)	IBD204	BiologicsEvent
LocationCrohnsPaediatric (Paris)	IBD205	BiologicsEvent
Disease Proximal to terminal Ileum (Paris L4a L4b)	IBD255	BiologicsEvent
If Crohns perianal Involvement	IBD207	BiologicsEvent
Is the patient biologics naïve?	IBD208	BiologicsEvent
Reason for stopping previous biologic treatment	IBD209	BiologicsEvent
Date of initial treatment (first loading dose)	IBD211	BiologicsEvent
Biologics – Clinical indication (UC)	IBD212	BiologicsEvent
Biologics – Clinical indication (IBDU)	IBD213	BiologicsEvent
Biologics – Clinical indication (CD)	IBD214	BiologicsEvent
Biologics – Clinical indication Other	IBD215	BiologicsEvent
Biologics - Patient receiving concomitant immunosuppression	IBD216	BiologicsEvent
Concomitant immunosuppression therapies	IBD217	BiologicsEvent
Biologics - Has the patient previously failed to respond or is intolerant to IMM drugs/steroids?	IBD218	BiologicsEvent
Biologics - Specify drugs not tolerated/reacted to	IBD219	BiologicsEvent
Biologics initiation - any acute reaction recorded?	IBD220	BiologicsEvent
Immunity - CXR	IBD221	BiologicsEvent
Cdiff test	IBD222	BiologicsEvent
Immunity - HCV Serology	IBD223	BiologicsEvent
Immunity - HBV Serology	IBD224	BiologicsEvent
Immunity - HIV Serology	IBD225	BiologicsEvent
Immunity - TB Test	IBD226	BiologicsEvent
Stool culture/test	IBD227	BiologicsEvent
Immunity - VZV Serology	IBD228	BiologicsEvent
Biologics review - response to induction therapy	IBD229	BiologicsEvent

Biologics review - Current status	IBD230	BiologicsEvent
Biologics review - Treatment plan	IBD231	BiologicsEvent
Biologics Review - Reason for Treatment plan choice	IBD232	BiologicsEvent
Biologics Review - Adverse events recorded	IBD233	BiologicsEvent
Biologics review - Adverse reactions since last review - IBD Audit	IBD234	BiologicsEvent
Biologics review - Adverse reactions since last review – Registry	IBD235	BiologicsEvent
Physicians Global Assessment	IBD236	BiologicsEvent
HBI Total Score	IBD237	BiologicsEvent
weightedPCDAI	IBD238	BiologicsEvent
SCCAI	IBD239	BiologicsEvent
Modified UCDAI	IBD240	BiologicsEvent
PUCAI	IBD241	BiologicsEvent
Local unit code	IBD242	BiologicsEvent
IBD Audit Code	IBD014	BiologicsEvent
IBD Biologics Audit site code	IBD200	BiologicsEvent

Full Dataset Definition for Implementors

If you are a Trust or Health Board, and would like a copy for our full (detailed) Dataset Definition (2019_J) for implementing in your system, please contact us at support@ibdregistry.org.uk.