IBD Registry

IBD Biological Therapies Audit

Annual Report 2022

September 2022

1 Foreword

We are pleased to publish our 2022 annual report on the use of biological therapies in the treatment of inflammatory bowel disease (IBD).

New biological therapies continue to transform the options for treating IBD, just as the first agents did more than 20 years ago. The explosion of knowledge about the complex pathways that perpetuate inflammation in the intestine has led to many new drugs; the National Audit seeks to encourage their safe and effective administration by reporting benchmarked clinical aspects of biological treatment and care back to IBD teams.

After more than a decade of focus on delivering safe biological treatments, the national programme is expanding to include other vital aspects of care for people with IBD. Led by the British Society of Gastroenterology's IBD Section, new Key Performance Indicators have now been finalised. These include new indicators to assess the time from referral to diagnosis and treatment and the use of corticosteroid drugs, as well as retaining aspects of the current biologics audit. These KPIs will be embedded in the new Improving Quality in Crohn's and Colitis (IQICC) programme that seeks to examine and improve these areas from 2023 onwards.

The Registry is at the heart of delivering this important QI programme, working towards enabling national participation by minimising the task of collecting data for clinical teams. The sustained participation of IBD teams in the biologics audit despite continuing disruption from the pandemic attests to their interest in understanding the care they provide and developing their service. We thank them hugely on behalf of the ultimate beneficiary: the person living with IBD.

Prof Stuart Bloom
Medical Director, IBD Registry

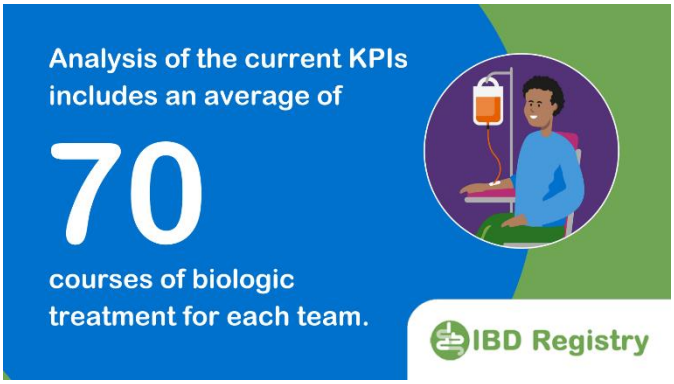
2 Summary

Participation in the national audit of biological therapies in inflammatory bowel disease has remained impressive despite the continuing impact of COVID-19 on healthcare delivery. The increase in records assessable in the cumulative audit has been maintained year-on-year at 2,000, and analysis of the current Key Performance Indicators includes an average of 70 courses of biologic treatment for each team.

Submission of new cases of IBD to the Registry has also been sustained, allowing the Registry to paint an ever-clearer picture of IBD in England and Wales, soon to be added to by records from Scotland and Northern Ireland with our new data submission portal, and complemented by patient-reported data as our new consent, direct with patients, is rolled out

Performance in the aspects of use of biologics reported here show a further improvement in safety assessments (pre-treatment screening) before a patient starts a biologic, whereas reporting of assessments of effectiveness of the treatment have plateaued. This is likely to be multifactorial. Fewer assessments might have been carried out in the difficult circumstances for patients and IBD teams brought on by the pandemic, but, perhaps as likely, reporting of this longitudinal data may have waned.

The refresh of the audit KPIs within the broader IQICC programme, new data collection mechanisms and the subsiding of the impact of COVID-19 should all serve to restore enthusiasm and momentum in quality improvement initiatives in the care of people with IBD.



IBD Registry

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3 Acknowledgements

This work is based on analysis of patient data held by the IBD Registry. We thank all the participating IBD hospital teams for their help and support for the Registry in collecting this important resource, together with everyone with IBD (Crohn's disease, ulcerative colitis or another form of inflammatory bowel disease) who has given permission for their data to be held by the Registry.

We gratefully acknowledge Prof Stuart Bloom, Dr Keith Bodger, Dr Fraser Cummings and Dr Nick Kennedy for the clinical oversight provided for these reports, together with Liz Dobson and Dr Stephen Grainger for the operational and clinical management of the production of the report.

We would also like to acknowledge and thank the IBD Registry team involved in the analysis, production and distribution of these reports: Fred Taylor, Judith Bunn, Rachel Hunter, Megan Harrison, Olivia Li and Sarah Miles.

Finally we would also like to thank the BSG IBD Section members who have provided input and liaison for the next stage of development of the clinical KPIs which will form the foundation for future quality improvement in IBD.

4 Reading this report

This report has been written primarily for a clinical readership, but to make it more informative for the general reader we have added endnotes to signpost explanations key terms. We hope in this way that the report will be accessible to patients and clinicians alike.

Biological agents are drugs used to treat Crohn's disease and ulcerative colitis (the two main forms of IBD). More information about these is available from the charity Crohn's & Colitis UK.

HQIP is an independent organisation led by the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. HQIP's purpose is to influence and improve healthcare at all levels.

5 Biological Therapies Clinical Audit

5.1 Definition

Participation in the audit by IBD teams is voluntary and data is collected from a variety of clinical systems used in the hospitals/Trusts who submit data to us.

The Registry has developed and maintains the Key Performance Indicators for the National Audit of Biological Therapies (now part of Quality Accounts). These clinical KPIs track changes in biologics treatment of patients and are presented as a cumulative audit of biological treatments since 2016.

The scope, purpose and guide to the KPI definitions are all available on our website. A diagrammatic summary is given below.

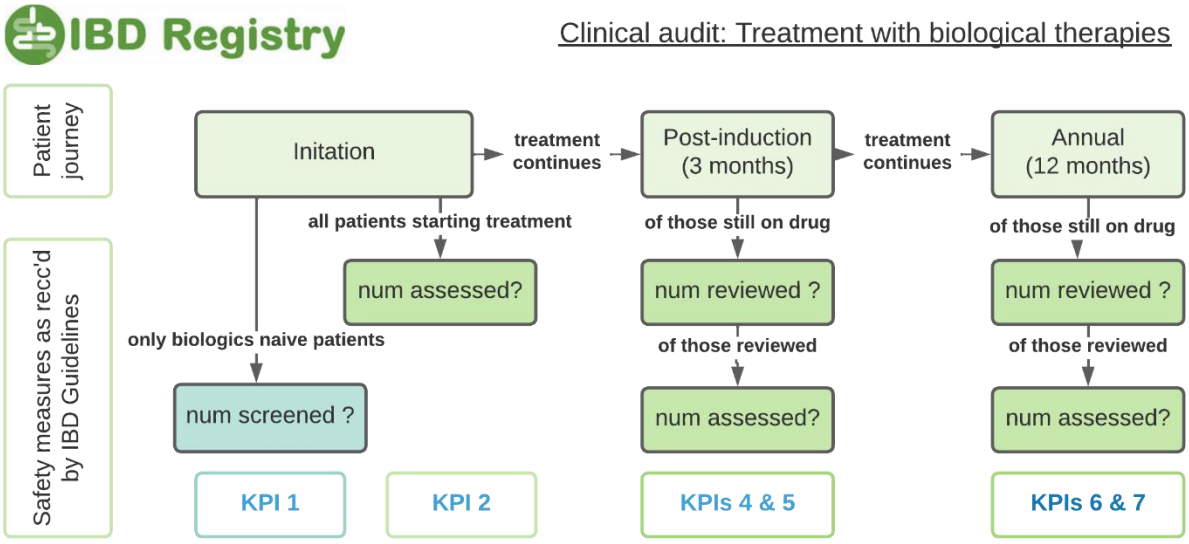


Diagram: the six clinical KPIs for monitoring quality of care in treatment using biological therapy (see Guide for details)

KPI 3 (not shown in this schematic) refers to the collection of Registry consent. This KPI has been suspended as the Registry moves from patient consent sought by clinical teams to engaging patients directly with the Registry's online consent process. In this way, the Registry has a direct relationship with the patients on whose data it depends, patients have greater control over how their data is used and clinical teams are relieved of the burden of seeking consent..

5.2 Local Reports to IBD teams

This report is the national summary of the clinical audit performance, published annually. It is a summary of the analysed data that we present back to IBD clinical teams.

Each participating team receives individual reports, presenting their cumulative performance against the national benchmark, to support them in their local quality of care monitoring and tracking.

Each year we publish reports for each team every quarter, with each report containing 1,250 datapoints. Participating teams are able to review their local statistics against the national figures.

5.3 Criteria for inclusion

NHS Trusts and Health Boards providing care for adult or paediatric patients in UK diagnosed with IBD: Crohn's disease, ulcerative colitis or IBD-Unspecified (ICD-10 Codes K50, K51 and K52 respectively)

5.4 KPI Performance

This is presented as cumulative performance, as at each year, for the past 3 years.

	Cumulative to Jan 2020	Cumulative to Jan 2021	Cumulative to Jan 2022	Trend
Cumulative total of adult patients eligible for audit	6,411	8,315	10,329	
KPI 1: Complete pre-treatment screening	71%	74%	76%	
KPI 2: Disease activity assessment at initiation (PGA included)	67%	64%	62%	
KPI 3: Registry consent	45%	46%	43%	
KPI 4: Review at 3 months	41%	41%	41%	
KPI 5: Disease activity assessment recorded of those reviewed at 3 months (PGA included)	64%	62%	62%	
KPI 6: Review at 12 months	36%	35%	35%	
KPI 7: Disease activity assessment recorded of those reviewed at 12 months (PGA included)	67%	61%	60%	

Number of records

There have been consistent annual increases of records assessable for reporting in the audit, with no discernible slowing of submission of records due to COVID-19. The median cumulative number of records submitted by IBD teams is now 70 (interquartile range 23-145), providing a sizeable dataset for analysis.

Individual KPIs

KPI-1 Pre-treatment screening

Pre-treatment screening of patients seeks to minimise the risk of aggravating possible pre-existing infections when a patient is exposed to a biologic agent.

The reporting of the completion of pre-treatment screening has been encouragingly rising year-on-year, but still falls short of the 100% benchmark.

KPI-4 and KPI-6 Reviews at three and twelve months

National and international guidelines recommend that each patient starting a biologic should have a review with their clinical team at these time points.

Performance of these KPIs has been stable – but is lower than desirable. The low percentages do not necessarily imply other patients were not reviewed, as under-reporting of clinical activity is likely also to be a factor.

KPI-2, KPI-5 and KPI-7 Disease assessments

When a patient starts a new treatment, it is good practice to record an assessment of how their disease is behaving, and to repeat these assessments at intervals to measure the effectiveness of the treatment.

Reporting of disease assessments has fallen slightly but has been robust when considered in the context of a pandemic that has had a disproportionate effect on the delivery of care for long term conditions.

Despite these mitigating factors, we urge IBD teams to address the shortfall in recording reviews and disease assessments at all points in the patient's biologics pathway.

5.5 Re-basing the audit to reflect more recent performance

We report performance in the audit by analysing cumulative records submitted from the start of the audit in April 2016. Because of this methodology, it is possible the weight of early records (when biological treatments were novel and less well established) obscurs more recent changes in performance. To investigate this we report below the KPIs in two periods representing the first three years and the latter three years. In each period, records are included where the start date of the biologic fell within the time period.

	Cumulative from Apr 2016 to Jan 2019	Cumulative from Jan 2019 to Jan 2022
Cumulative total of adult patients eligible for audit	4,174	6,216
KPI 1: Complete pre-treatment screening	69%	81%
KPI 2: Disease activity assessment at initiation (PGA included)	63%	58%
KPI 3: Registry consent	44%	43%
KPI 4: Review at 3 months	39%	41%
KPI 5: Disease activity assessment recorded of those reviewed at 3 months (PGA included)	62%	59%
KPI 6: Review at 12 months	33%	27%
KPI 7: Disease activity assessment recorded of those reviewed at 12 months (PGA included)	60%	54%

This analysis by period points to a small fall-off in the reporting of disease assessments similar to that in the analysis of all audit records submitted. We re-iterate our encouragement to IBD teams to carry out and to report disease assements, so that the effectiveness of these expensive treatments can be determined fully.

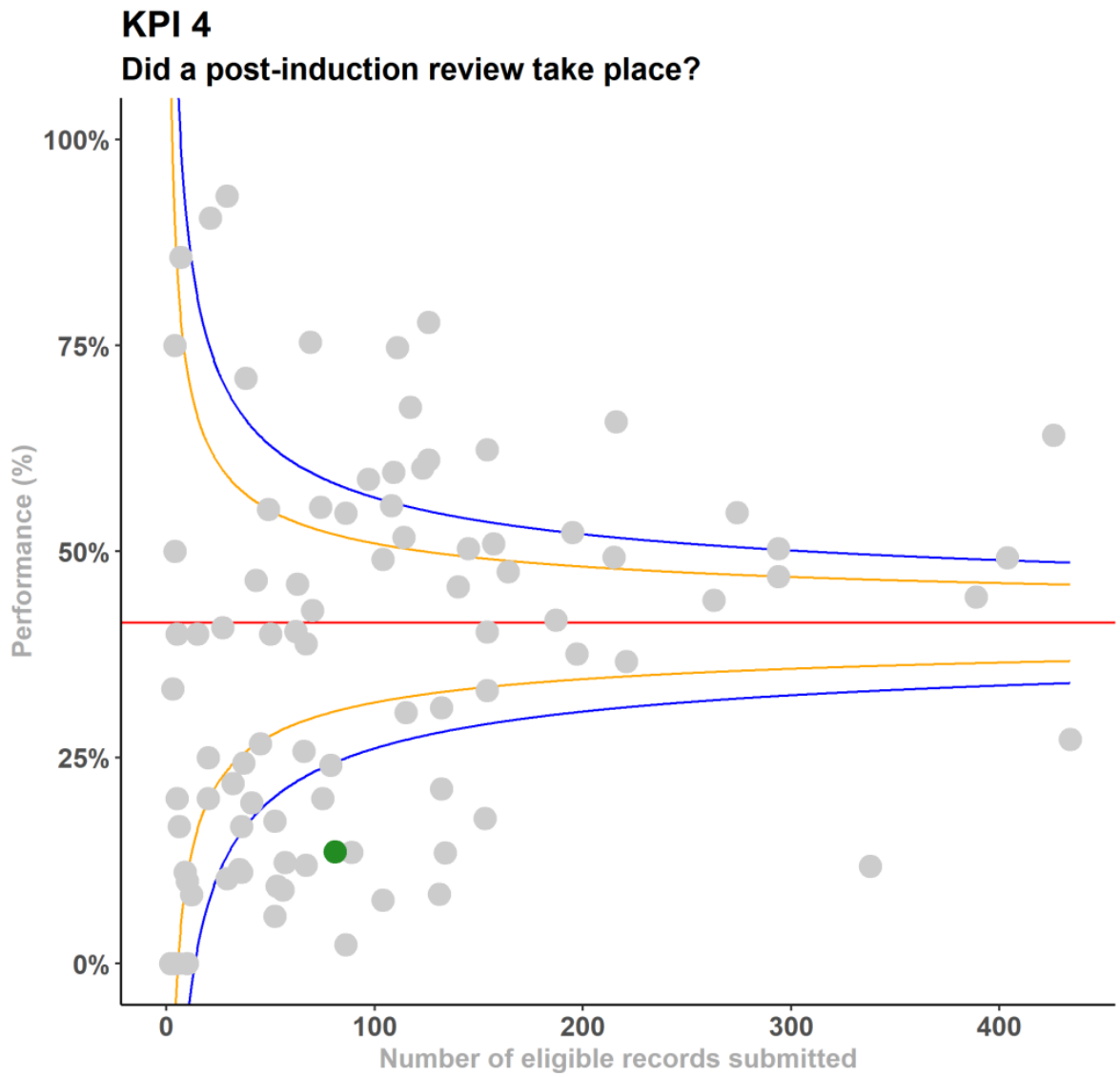
6 KPI reporting methods

Using the defined Key Performance Indicators (KPIs) of the annual biologics audit, we report to each participating IBD team on an ongoing basis (currently quarterly) their local performance.

To improve the information we provide to clinical teams, we are exploring better ways of displaying a site's key data.

We now produce for each team funnel plots identifying their site amongst all other (anonymised) participating sites. Yellow and blue lines represent upper and lower control limits (yellow 95%; blue 99.8% - roughly equating to ±2 and ±3 standard deviations from the mean) around a centre red line of average performance across all sites.

Sites located below the lower blue control limit are potential outliers and appear to have significantly lower performance than average (as indicated by the green dot below). Charted in this way makes it easy for an IBD team quickly to visualise and compare their performance and to identify areas that might warrant improvement.



The reporting of the KPIs is intended to influence and improve the quality of care patients receive, but there are other factors that affect a site's performance in the audit aside from the quality of care – such as: the ability of sites to submit complete records; the data collection tools in use; the number of clinical and administrative staff; and the differential impact on IBD services of external events such as COVID-19. When considering potentially poor performance all these facets of a service need to be taken into account.

Funnel plots also allow us to visualise trends in KPI performance over time and to investigate other factors that might affect performance, such as the way that an IBD team captures its data or the size of its population.

6.1 First biological agent

The table reports a patient level analysis of the first biologic initiation since April 2016 for all the adult records we hold. The data available is greater than that assessable for the audit KPIs, which require a clinical review also to have been reported at the time of the biologic initiation. Cumulative cases up to January 2022 are reported.

Patients who switched (stopped one biologic and started another) are included only once.

	Crohn's Disease		Ulcerative Colitis		IBDU	
Biologic Agent	**n**	**%**	**n**	**%**	**n**	**%**
Remicade	233	1.9%	129	1.8%	2	< 1%
Remsima	2040	16.9%	1349	19.1%	72	16.3%
Inflectra	1616	13.4%	1203	17.0%	115	26.0%
Flixabi	141	1.2%	128	1.8%	4	< 1%
Zessly	145	1.2%	113	1.6%	7	1.6%
Golimumab	25	< 1%	236	3.3%	4	< 1%
Humira	3450	28.5%	1310	18.5%	82	18.5%
Imraldi	1022	8.4%	468	6.6%	46	10.4%
Amgevita	544	4.5%	200	2.8%	14	3.2%
Hyrimoz	392	3.2%	211	3.0%	12	2.7%
Idacio	205	1.7%	103	1.5%	5	1.1%
Cyltezo	0	< 1%	0	< 1%	0	< 1%
Hulio	0	< 1%	0	< 1%	0	< 1%
Certolizumab	3	< 1%	0	< 1%	0	< 1%
Vedolizumab	1275	10.5%	1541	21.8%	72	16.3%
Ustekinumab	1009	8.3%	76	1.1%	8	1.8%
Total	**12100**	**(100%)**	**7067**	**(100%)**	**443**	**(100%)**

Key to the table:

Colours in the table above group the biological agents by their biologic originator (given at the top of each colour group).

Agents on a white background have no biosimilars.

As they have become available, unsurprisingly anti-TNF biosimilars and biologics acting on different aspects of the inflammatory pathway are being used increasingly.

7 Quality Improvement in IBD

7.1 Alignment of audit KPIs to UK IBD Standards

The audit KPIs originated from the RCP IBD Audit, and have been maintained with transition to the Registry. The Registry was closely involved in the development of the IBD Standards defined in 2019 and has ensured that the clinical KPIs remain aligned to these.

7.2 Revision and updating of audit KPIs

While the use of biological agents remains of major significance in the provision of good IBD care, the IBD section of the British Society of Gastroenterology have reviewed the audit questions and sought consensus from the members on additional areas of variation in patient care that should be included in the national audit going forward. The recent conclusion in October 2022 of this work is leading to the introduction of two new audit topics – the time from referral to the start of treatment for patients newly diagnosed with IBD, and a measure of the appropriate use of corticosteroids. Improvements in either of these aspects of patient care will improve the lived experience of people with IBD. The new KPIs are expected to launch in 2023.

7.3 Quality Accounts (NHS England)

The national IBD Audit has long been listed on Quality Account. For the coming year 2023-24, the change to the wider group of three focus areas is reflected in the change of the name from the IBD Audit to IQICC (Improving Quality in Crohn's and Colitis) name.

The value the UK IBD Registry adds is to enable ongoing data collection and provide analysis, which results in a growing picture of the longitudinal care of people with IBD. This information allows us to support IBD clinical teams in their continuing work to improve the quality of clinical care.

7.4 Benchmarking Surveys (IBD UK)

The current rolling IBD Biological Therapies Audit is the clinical audit element of the full IBD Audit and is complemented by an organisational audit of IBD services and a survey of patients' experience of their IBD service. These are conducted by the Registry on behalf of IBD UK, and are known as the Benchmarking Surveys. Trusts are encouraged to participate fully by submitting both clinical and organisational data to complete the two complementary workstreams. The next organisational audit of IBD services is scheduled for 2023

8 Site Participation

The table below shows, in alphabetical order, all the sites who have submitted records to the Registry at any time since 2016:

ADDENBROOKE'S HOSPITAL	QUEEN ELIZABETH HOSPITAL BIRMINGHAM
ALDER HEY CHILDREN'S NHS FOUNDATION TRUST	ROYAL ALBERT EDWARD INFIRMARY
ASHFORD & ST PETERS	ROYAL BERKSHIRE HOSPITAL
BASILDON HOSPITAL	ROYAL BOLTON HOSPITAL
BEDFORD HOSPITAL	ROYAL BOURNEMOUTH GENERAL HOSPITAL
BIRMINGHAM CHILDREN'S HOSPITAL	ROYAL CORNWALL HOSPITAL
BRADFORD ROYAL INFIRMARY	ROYAL DERBY HOSPITAL
BRISTOL ROYAL HOSPITAL FOR CHILDREN	ROYAL DEVON AND EXETER HOSPITAL
BUCKINGHAM HEALTHCARE TRUST	ROYAL FREE HOSPITAL
CALDERDALE & HUDDERSFIELD NHS FOUNDATION TRUST	ROYAL GLAMORGAN HOSPITAL
CHESTERFIELD ROYAL HOSPITAL	ROYAL LONDON HOSPITAL
DARENT VALLEY HOSPITAL	ROYAL MANCHESTER CHILDREN'S HOSPITAL
DARLINGTON MEMORIAL HOSPITAL	ROYAL SHREWSBURY HOSPITAL
DERRIFORD HOSPITAL	ROYAL STOKE UNIVERSITY HOSPITAL
DIANA, PRINCESS OF WALES HOSPITAL	ROYAL SURREY COUNTY HOSPITAL
DORSET COUNTY HOSPITAL	ROYAL SUSSEX COUNTY HOSPITAL
EAST KENT	ROYAL UNITED HOSPITAL
EAST SURREY HOSPITAL	SALISBURY HOSPITAL
EAST SUSSEX HEALTHCARE NHS TRUST HQ	SANDWELL & WEST BIRMINGHAM HOSPITAL
EPSOM HOSPITAL	SCUNTHORPE GENERAL HOSPITAL
FRIMLEY PARK HOSPITAL	SHEFFIELD CHILDREN'S HOSPITAL NHS TRUST
FURNESS GENERAL HOSPITAL	SHEFFIELD TEACHING HOSPITALS
GEORGE ELIOT HOSPITAL	SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST
GREAT ORMOND STREET HOSPITAL CENTRAL LONDON SITE	SOUTHAMPTON GENERAL HOSPITAL
GUY'S & ST THOMAS	SOUTHPORT GENERAL INFIRMARY
HAMPSHIRE HOSPITAL	ST GEORGE'S HOSPITAL
HARROGATE & DISTRICT NHS FOUNDATION TRUST	ST HELIER HOSPITAL
HEREFORD COUNTY HOSPITAL	ST MARY'S HOSPITAL (ISLE OF WIGHT)
HILLINGDON HOSPTIAL	STOCKPORT NHS FOUNDATION TRUST
HINCHINGBROOKE HOSPITAL	TAMESIDE GENERAL HOSPITAL
HOMERTON UNIVERSITY HOSPITAL	THE GREAT WESTERN HOSPITAL
IMPERIAL COLLEGE	THE PENNINE ACUTE HOSPITALS NHS TRUST
JAMES PAGET HOSPITAL	THE ROTHERHAM NHS FOUNDATION TRUST

KING GEORGE/QUEEN'S BHRUT	THE ROYAL LIVERPOOL UNIVERSITY HOSPITAL
KING'S COLLEGE LONDON	THE WHITTINGTON HOSPITAL
KINGSTON HOSPITAL	TORBAY HOSPITAL
LEIGHTON HOSPITAL	TUNBRIDGE WELLS HOSPITAL
LISTER HOSPITAL	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
LONDON NORTH WEST TRUST	UNIVERSITY HOSPITAL (COVENTRY)
LUTON AND DUNSTABLE HOSPITAL NHS FOUNDATION TRUST	UNIVERSITY HOSPITAL AINTREE
MANCHESTER ROYAL INFIRMARY	UNIVERSITY HOSPITAL LEWISHAM
MILTON KEYNES UNIVERSITY HOSPITAL	UNIVERSITY HOSPITAL OF WALES
MUSGROVE PARK HOSPITAL	WARRINGTON DISTRICT GENERAL HOSPITAL
NEW CROSS HOSPITAL (WOLVERHAMPTON)	WARWICK HOSPITAL
NORFOLK AND NORWICH UNIVERSITY HOSPITAL	WATFORD GENERAL HOSPITAL
NORTHAMPTON GENERAL HOSPITAL (ACUTE)	WEST SUFFOLK HOSPITAL
NOTTINGHAM UNIVERSITY HOSPITALS	WEXHAM PARK HOSPITAL
PETERBOROUGH CITY HOSPITAL	WHISTON HOSPITAL
POOLE GENERAL HOSPITAL	WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST
PRINCESS ALEXANDRA HOSPITAL NHS TRUST	WREXHAM MAELOR HOSPITAL
QUEEN ALEXANDRA HOSPITAL	YEOVIL DISTRICT HOSPITAL
QUEEN ELIZABETH HOSPITAL	

8.1 Cumulative Submission

The audit analyses cumulative data from April 2016. IBD teams are asked to submit new cases every quarter, but if a quarter is missed, the cumulative analysis means missing cases can be submitted in the next quarter without loss of data

	Cumulative to Jan 2020	Cumulative to Jan 2021	Cumulative to Jan 2022
Number of IBD teams participating in the IBD Registry	92	102	103

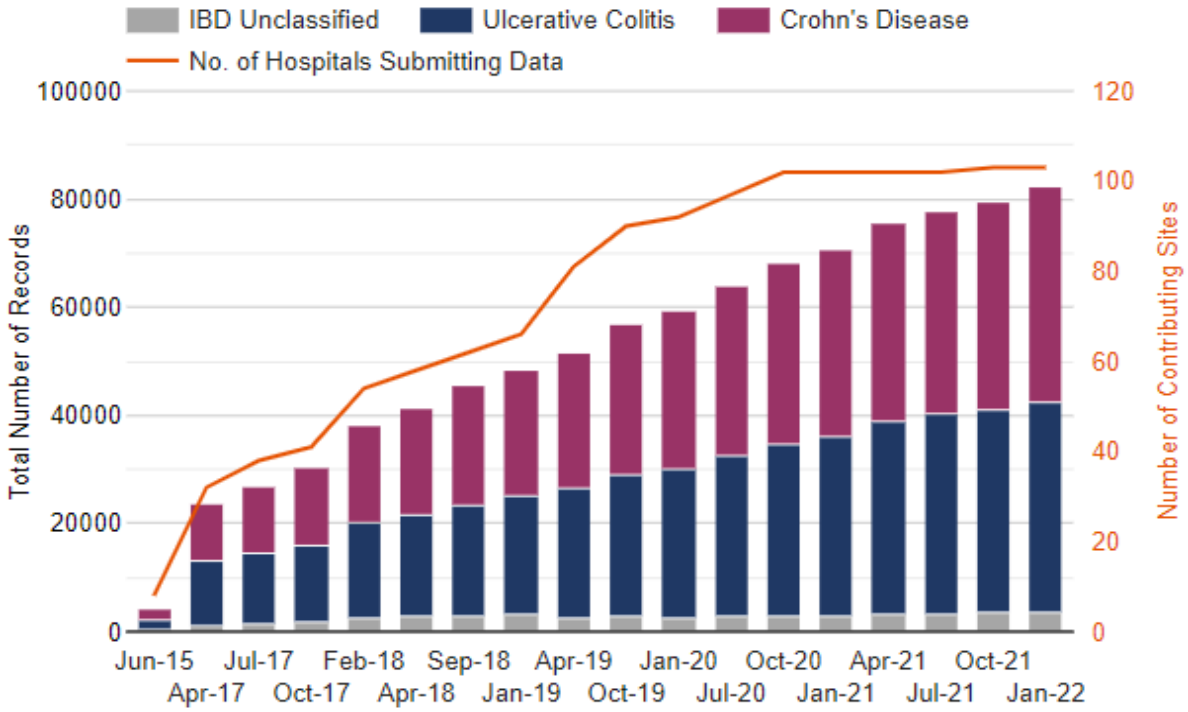
9 Growth and maturation of the UK IBD Registry

The IBD Registry as an organisation has matured and grown alongside our healthcare records, enabling us to fulfil our purpose more effectively:

- Retaining our clinician-facing activities while developing a patient-facing presence
- Seeking consent directly from patients, removing this task from over-burdened clinical teams
- Replacing NHS Digital as our data submission service with our own portal enabling us to receive data from Scotland and Northern Ireland
- Successfully being recognised by the Health Research Authority as an ethically approved research database, easing access to our data by approved researchers

9.1 Growth in records held

At Jan 2022, the number of patient level records held by the IBD Registry was 84,694. This is an increase of 9,522 records since Jan 2021, and 21,513 since 2020.



Despite the continuing impact of the pandemic on health services generally and the particularly disruptive effects on departments of gastroenterology in their provision of long term disease management and endoscopy, the unchanging steady rise in records submitted confirms the commitment of IBD services to the Registry's goal of improving care for people living with IBD. We congratulate teams on sustaining this effort.

10 About the IBD Registry

10.1 Purpose, Structure and Governance

The purpose of the IBD Registry is to improve the health of people living with inflammatory bowel disease in the UK by the collection and analysis of data in order to improve understanding of the care of people with IBD and their treatments and to facilitate research.

We are a not-for-profit organisation wholly owned by the British Society for Gastroenterology, the Royal College of Physicians and Crohn's & Colitis UK.

The IBD Registry is formed as a company limited by guarantee (i.e. without any shares). We are registered in England and Wales with company number 11197749 and registered address as 3 St Andrews Place, Regent's Park, London NW1 4LB (*note*: this is not our main office -please see below for our address).

11 Citation and Correspondence

11.1 Citation

If you wish to cite analysis from this report, please use the following citation

UK IBD Registry. Biological Therapies Annual Report (2022). London: UK IBD Registry Ltd, 2022.

11.2 Contact and Correspondence

Our website has further information on our work on quality improvement and in participation in the IBD Biological Therapies Clinical Audit. If you still have questions, please contact us as follows:

- If you are an IBD clinical team with an enquiry about participation in the biological therapies audit, please contact us on support@ibdregistry.org.uk
- If you have an enquiry about undertaking an IBD quality improvement study or research, please contact us on analysis@ibdregistry.org.uk

If you have a postal enquiry, our office address is: Suite 9, Epsom Workhub, Epsom Square, 6-7 Derby Square, Epsom KT19 8AG