IBD Registry DPIA

About this template
This template is intended for the standardised recording of our DPIA process and outcome. It follows the process set out in the ICO's DPIA guidance, and should be read alongside that guidance and the Criteria for an acceptable DPIA set out in European guidelines on DPIAs.

When to use this template
You should start to fill out the template at the start of any major project involving the use of personal data, or if you are making a significant change to an existing process. The final outcomes should be integrated back into your project plan.

Step 1: Identify the need for a DPIA

Explain broadly what project aims to achieve and what type of processing it involves. You may find it helpful to refer or link to other documents, such as a project proposal.

Summarise why you identified the need for a DPIA.

In response to the government's intention to shield high risk patients in response to the COVID-19 pandemic and their mandate to identify high-risk patients on immunosuppression, the British Society of Gastroenterology (BSG) and their COVID-19 Working Group (BSG COVID-19) have defined and published a grid on risk levels for people with IBD. The UK IBD Registry and the BSG via the COVID-19 Working Group intend to develop a web-based tool for people with Crohn's disease, ulcerative colitis or unspecified IBD so they can assess their level of risk relating to COVID-19 and communicate it to their IBD specialist team and the NHS.

https://www.gov.uk/government/news/major-new-measures-to-protect-people-at-highest-risk-from-coronavirus

The web-based tool is designed to:

1. Collect relevant information from respondents who are living with IBD across the UK to be able to quickly and easily determine the level of risk based on the risk assessment released by the BSG;
2. Allow respondents to enter their personal data and details of the hospitals, specialist doctors and the GPs that care for them so that the responses can be shared with:
    a. The specialist doctors that currently care for them within hospitals and NHS Trusts; and
    b. Their GP Practice.

    This will ensure that both sets of medical professionals have the most up to date information about their patients' condition and treatment which is relevant to their risk status during this COVID-19 response period;
3. Allow the specialist doctors and the GPs to be able to contact respondents to:
    a. Request additional information from them if this is considered necessary to more accurately inform their risk status or to better understand risk and outcomes;
    b. Inform them of any changes that may be made to advice contained within the risk grid or the tool;
    c. Provide any specific advice based on their risk status or specific needs; and

    d. Support their medical needs in any other way during the COVID-19 outbreak.
4. Allow information about those respondents living with IBD across the UK to be shared centrally with NHS England and equivalent bodies in the devolved nations to allow them to better respond to the COVID-19 pandemic;
5. Enable research and/or analysis of the data collected to improve care and treatment for IBD patients with respect in relation to COVID-19; and
6. For any other COVID-19 Purpose as defined within the 'COPI Notice' (see below).

The web-based tool will use the REDCap (Research Electronic Data Capture) software which is designed for use in clinical and translational research databases and is well-established. The Tool will be hosted at the IBD Registry's existing supplier of secure data hosting, AIMES, which is ISO27001 accredited and holds a Cyber Essentials certification plus an approved NHS Data Security and Protection Toolkit submission.

The ability for individuals to provide feedback on the Tool will also be provided via a feedback form hosted as part of the web-based tool. Those providing feedback will have the option of submitting their contact details alongside feedback to allow the IBD Registry to respond to their feedback where necessary and appropriate.

A need to conduct a Data Protection Impact Assessment has been identified as the project will involve:

- The use of personal data and special category data;
- Evaluation or scoring;
- Automated decision-making;
- The processing of sensitive data or data of a highly personal nature;
- Processing on a large scale;
- Processing of data concerning vulnerable data subjects; and
- Innovative technological solutions which have not previously been used by the IBDR.

Step 2: Describe the processing

Describe the nature of the processing:

- How will you collect, use, store and delete data?
- What is the source of the data?
- Will you be sharing data with anyone?

You might find it useful to refer to a flow diagram or other way of describing data flows.

What types of processing identified as likely high risk are involved?

The web-based IBD Tool will be publicised to individuals through a range of partner organisations and by using a range of communication methods to encourage those living with IBD in the UK to provide their relevant information. Crohn's & Colitis UK (CCUK) is a key organisation in this, and social media such as Twitter is a key communication method.

Individuals visiting the web-based IBD Tool will enter their information directly for submission to the IBD Tool's REDcap database. The IBD Registry will act as the data controller for the IBD Tool.

Respondents will enter their personal data and details of the hospitals, specialist doctors and the GPs that care for them so that the responses can be shared with:

- The specialist doctors that currently care for them within hospitals and NHS Trusts; and
- Their GP Practice.

The intention is to be able to share the data with both sets of medical professionals caring for a respondent so that these medical professionals have the most up to date information about their patients' condition and treatment which is relevant to their risk status during this COVID-19 response period, in order that they can support and assist in the delivery of health and care service to the respondent;

The intention is also that information about these respondents (who are living with IBD across the UK) will also be shared centrally with public health bodies such as Public Health England, NHS England and equivalent bodies in the devolved nations to allow them to better respond to the COVID-19 pandemic and address public health issues relating to this pandemic.

The intention is also that the data collected will be used in research and/or analysis of the data to improve care and treatment for IBD patients in relation to COVID-19, plus our understanding of IBD In the context of COVID-19. The data may be used for research in this way both as a standalone single dataset, or may be shared under an appropriate data sharing arrangement for the purposes of linking to other IBD and relevant datasets for approved research relating to IBD and COVID-19.

The intention is also to be able to re-contact respondents directly where required for purposes specifically related to the IBD Tool, and IBD and COVID-19. Respondents will not be contacted more generally for purposes outside the scope of IBD and COVID-19.

The data collected may also be used for any other COVID-19 Purpose as defined within the 'COPI Notice' issued on 20 March 2020 by the Secretary of State for Health and Social Care under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002 (COPI). This 'COPI Notice' requires organisations to process confidential patient information to support the Secretary of State's response to COVID-19.

A COVID-19 Purpose includes but is not limited to:

- understanding COVID-19 and risks to public health, trends in COVID-19 and such risks, and controlling and preventing the spread of COVID-19 and such risks;
- identifying and understanding information about patients or potential patients with or at risk of COVID-19, information about incidents of patient exposure to COVID-19 and the management of patients with or at risk of COVID-19 including: locating, contacting, screening, flagging and monitoring such patients and collecting information about and providing services in relation to testing, diagnosis, self-isolation, fitness to work, treatment, medical and social interventions and recovery from COVID-19;
- understanding information about patient access to health services and adult social care services and the need for wider care of patients and vulnerable groups as a direct or indirect result of COVID-19, and the availability and capacity of those services or that care;
- monitoring and managing the response to COVID-19 by health and social care bodies and the Government including providing information to the public about COVID-19 and its effectiveness and information about capacity, medicines, equipment, supplies, services and the workforce within the health services and adult social care services;
- delivering services to patients, clinicians, the health services and adult social care services, workforce and the public about and in connection with COVID-19, including the provision of information, fit notes and the provision of health care and adult social care services; and,
- research and planning in relation to COVID-19.

The data to be collected from respondents includes personal data, special categories of personal data and confidential information, and this will only be processed and shared for a COVID-19 Purpose. The processing of this data likely to result in a high-risk to data subjects. All use of the information will be limited to that which is necessary for the particular purpose and as far as is reasonably practical individual identifiers will be removed to the extent that they are not required for the purpose.

People of all ages have IBD and are exposed to risk of COVID-19, and so the expectation is that children, or the parents and guardians of children, will also want to use the IBD Tool. This is a higher risk form of processing, and appropriate forms of words will be put in place for this where required. We intend to work closely with IBD patient organisations that represent children (such as CICRA) and also with specialist paediatric gastroenterologists to develop appropriately written information, using clear and plain language to support children to submit data directly if they wish.

Individuals will also be able to provide feedback about the web-based IBD Tool via a feedback form hosted within the web-based tool itself. Those providing feedback will have the option of submitting their contact details alongside feedback to allow the IBD Registry to respond to their feedback where necessary and appropriate.

Describe the scope of the processing:

- What is the nature of the data?
- Does it include special category or criminal offence data?
- How much data will you be collecting and using?
- How often?
- How long will you keep it?
- How many individuals are affected?
- What geographical area does it cover?

The data to be collected and processed is personal and special category data relating to individuals living with IBD in the UK. It will be collected directly from individuals accessing the web-based tool and entering their data via that interface into the secure REDcap database behind it. Data may be entered by respondents completing a survey multiple times, with a new survey entry being created within the database each time, timestamped in order to identify the latest entry.. It is expected that the web-based tool will only be in use and personal data will only be retained for the duration of the COVID-19 pandemic as defined by the expiry of the COPI Notice.

The data collected will be that which is necessary to understand the level of risk faced by IBD patients. This is based on the risk factors as determined and governed by the BSG COVID-19 Working Group, the baseline for which has been captured as the BSG IBD COVID-19 Risk Grid. The specific questions which will initially be included within the web-based tool are based on this Risk Grid and are included at Appendix 1. With the emergence of new evidence, the risk factors for IBD and COVID-19 may change over the course of the pandemic, and the IBD Tool may be changed in response to those changing risk factors, as determined by the BSG COVID-19 Working Group. As most appropriate, respondents may be contacted directly; or a public notice Issued, using our website, social media and our links with patient organisations such as CCUK and CICRA; or contact via the clinical teams caring for the patient.

Where individuals provide feedback on the tool via the feedback form hosted within the web-based tool itself, this will be used for the purposes of investigating and responding to the feedback and communicating the outcome with the individual where necessary and appropriate.

Describe the context of the processing:

- What is the nature of your relationship with the individuals?
- How much control will they have?
- Would they expect you to use their data in this way?
- Do they include children or other vulnerable groups?
- Are there prior concerns over this type of processing or security flaws?
- Is it novel in any way?
- What is the current state of technology in this area?
- Are there any current issues of public concern that you should factor in?
- Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?

Individuals will be able to access the web-based IBD Tool freely and there is no requirement on individuals to complete it. Individuals may therefore choose to enter their data into the IBD Tool if

they wish. This applies both to the use of the web-based tool to submit personal data for the primary purposes, and to the submission of personal data within any feedback about the web-based tool which may be submitted.

Individuals will be provided with a privacy notice which will comply with the ICO's detailed guidance on the Right to be Informed. This will outline the identity of the IBD Registry as the Data Controller, the purposes for which data will be used, the intended recipients of the data and the lawful basis which will be relied upon to allow the data processing. This will be made available to all data subjects at the point they are asked to enter their personal data to ensure all usage of their personal data is in line with their reasonable expectations. Where possible, 'just-in-time' notices will also be used within the web-based IBD Tool at the point specific data items are requested to inform data subjects why specific data items are required.

Data about children will also be collected where children choose to enter this data directly, or if a parent or guardian chooses to enter data on behalf of a child for which they have parental responsibility. As consent will not be relied upon as the lawful basis, there is no legal requirement to restrict usage to those over the age of 13, or to implement age verification processes. Guidance will however be provided to support children to involve their parents or guardians in their decision to submit data via the web-based tool. To further support the processing of personal data relating to children, an appropriate provision of transparency materials will be identified and written in language which is accessible to children.

There are no known concerns relating to the type of processing being considered, or any security flaws in the technology selected to host the web-based IBD Tool. The IBD Registry will utilise its existing secure and accredited data centre hosted by AIMES who are ISO27001 certified and hold an NHS Data Security and Protection Toolkit submission and Cyber Essentials certification. The web-based tool will also be developed using the Research Electronic Data Capture (REDcap) application which is a secure web application for building and managing online surveys and databases for research studies, and is well-established with use at over 4,500 institutions worldwide. The data analysis platform where the data at-rest is stored is separated from the web-based front-end by a 'digital airlock' for additional data security. All this takes place within the secure environment at AIMES, I.e. the data is stored in the UK at AIMES. The IBD Registry also has an secure data platform (at AIMES) that allows the sharing of confidential data with medical professionals, and It Is envisaged that this will be used for the secure return of data to the pre-identified medical professionals. The IBD Registry and AIMES both hold approved NHS Digital DSP (Data Security Protection) Toolkit certificates This COVID-19 IBD Tool project is however a novel way of processing data by the IBD Registry which has previously only processed pseudonymised personal data and has not shared this for public health purposes as will be the case in responding to the COVID-19 pandemic.

Describe the purposes of the processing:

- What do you want to achieve?
- What is the intended effect on individuals?
- What are the benefits of the processing – for you, and more broadly?

The UK government has recommended measures for shielding and protecting people who are defined on medical grounds as extremely vulnerable from COVID-19.

- It is important that this group of people know which risk category they fall into, especially where that category is high risk
- It is also important that their hospital team and GP know who they are, what their risk status is and what data they provided that assigned them their risk category. It will also be important that relevant NHS bodies such as NHS England can have the same information. Sharing this information with hospital IBD teams and public health bodies such as NHS England will help them to make decisions about their IBD patients and their risk statii It also means that patients can be contacted quickly if the advice changes.
- Data collected will help the understanding how COVID-19 affects people with IBD across the UK, now and in the future.

The IBD Registry therefore intends to support the NHS and public health bodies in their ability to respond to the COVID-19 pandemic by ensuring these COVID-19 risk-related details of all patients living in the UK with IBD can be collected via a web-based tool and then shared with healthcare professionals to support direct care and elsewhere within the NHS to support the wider COVID-19 response.

Respondents who choose to submit their personal data via the web-based IBD Tool will benefit from:

- Ensuring accurate and up to date information about their condition and risk status are shared with:
    - The specialist doctors that currently care for them within hospitals and NHS Trusts; and
    - Their GP Practice.

  This will ensure that both sets of medical professionals have the most up to date information about their patients' condition and treatment which is relevant to their risk status during this COVID-19 response period;
- Allowing the specialist doctors and the GPs to be able to contact respondents to:
    - Request additional information from them if this is considered necessary to more accurately inform their risk status or to better understand risk and outcomes;
    - Inform them of any changes that may be made to advice contained within the risk grid or the tool;
    - Provide any specific advice based on their risk status or specific needs; and
    - Support their medical needs in any other way during the COVID-19 outbreak.

The IBD Registry will benefit from being able to further fulfill its primary purpose of improving care and treatments for people with IBD, improving their outcomes and widening knowledge about IBD, enabled through the collection and analysis of data relating to IBD on a national scale. The IBD Registry has a nationally scalable architecture and resources that it can draw on, and in providing this IBD Tool it can further demonstrate to both clinical teams and the wider public its ability to engage these resources In the national and public good, rapidly and flexibly, in support of patients, doctors and public health bodies. Further, the IBD Registry has historically been clinical-facing, with resulting lower awareness among the greater public; this activity will bring the IBD Registry more into the public view, which as healthcare shifts to be more patient-centric, is a desirable and positive direction to be moving in.

More broadly, those living with IBD and the general public will benefit from:

- Information about those respondents living with IBD across the UK being shared centrally with NHS England and equivalent bodies in the devolved nations to allow them to better respond to the COVID-19 pandemic;

- Research and/or analysis of the data collected to improve care and treatment for IBD patients with respect in relation to COVID-19; and
- The outcomes of other COVID-19 Purpose as defined within the 'COPI Notice' (see 'Step 4: Assess necessity and proportionality' for details).

Step 3: Consultation process

Consider how to consult with relevant stakeholders:

- Describe when and how you will seek individuals' views – or justify why it's not appropriate to do so.
- Who else do you need to involve within your organisation?
- Do you need to ask your processors to assist?
- Do you plan to consult information security experts, or any other experts?

In developing the risk assessment for individuals living with IBD, the British Society of Gastroenterology (BSG) have been working with the Royal College of Physicians (RCP), other societies and the Chief Medical Officer for England. The BSG has formed a working group to draw up the BSG's risk assessment to address the Government's mandate, known as the COVID-19 Working Group. This working group comprises highly recognised consultant gastroenterologists (the specialist senior doctors for IBD) from hospitals providing IBD treatment across the UK Our IBD Registry Clinical Technical Lead for this project is also a consultant gastroenterologist and a member of the COVID-19 Working Group. Our Caldicott Guardian is also a consultant gastroenterologist, and a member of the BSG. In this way we have enabled and ensured a close and effective working relationship between the IBD Registry and the BSG.

In developing the web-based tool to enable data collection, the following stakeholders have been consulted:

Stakeholder	**Area for Consultation**	**Outcome**
IBD Registry	Technical platform selection	REDcap solution selected to host web-based tool
	Hosting provider selection Data analysis platform selection	AIMES selected as hosting provider both for the web-based tool and the associated secure data analysis platform
	Data access security configuration	Access to web-based tool restricted to minimal possible range of allowable addresses (where possible: only UK IP addresses and to ensure only UK respondents can access and enter data, or blocked to foreign domains) Addition of CAPTCHA challenge–response test to confirm that users of the tool are human to protect against cyber attack Administration accounts protected by disabling default admin account and access

		specifically authorised and tracked
		Data sharing with healthcare professionals controlled by Identified access controls, login and password, with two-factor authentication implemented to secure backend
	Data storage security	The data analysis platform where the data at-rest is stored is separated from the web-based front-end by a 'digital airlock' for additional data security
	Data capture quality measures	NHS Number and postcode validation implemented to support key identifier data quality; lists of Trusts and hospitals provided to enable respondents to be able to easily Identify where they receive treatment
	Feedback and response mechanisms Operational support measures	Inclusion of feedback form and adaption of existing operational processes to ensure level of support required for this Tool In place
	Communications strategy	Website changes and oversight of strategic comms liaison with other stakeholders
	Senor project sponsor and director level governance	IBD Registry CEO as project sponsor; IBD Registry Board-level decision to go-ahead with this project
	Caldicott Guardian governance	IBD Registry Caldicott Guardian involvement and appropriate approvals
British Society of Gastroenterology (BSG)	Alignment with the BSG COVID-19 Risk Grid.	Point contact person identified to act as liaison point between the Registry and COVID-19 Group
	Changes to the COVID-19 Risk Grid	Feedback to this Group from the Tool to inform on learnings from the feedback and data

		collected, for the purpose of enabling improvements to the BSG guidance to the specialist gastroenterologists
	Specialist guidance of research requests	Joint oversight group to oversee development of both tool and purposes it will be used for, plus governance on research requests and forwards purposes
	Communications and dissemination	Specialist comms for the professional gastroenterology community
	Senor project sponsor	Endorsement from the BSG President; co-branding on the IBD Tool and in communications
Consultant Gastroenterologists	Implementation of data access methods	Approaches to take for data access and sharing of data back with clinical teams
Royal College of Physicians (RCP)	Interaction with greater medical community, especially other disease areas	Dissemination of IBD Tool to other disease areas
Crohn's & Colitis UK	Public audience	Guidance and feedback on wording to increase accessibility and understanding for a public (non-medical) audience
	Communications and dissemination	Public-facing comms for the public audience, especially of people with IBD
CICRA (Crohn's in Childhood Research Association)	Public audience (children)	Appropriateness for children
8foldGovernance (Information Governance consultancy)	Data Protection Compliance Common Law Duty of Confidentiality Compliance Data Security Compliance	Data Protection Impact Assessment (DPIA) Privacy Notice Data Processing contracts with data processors Data Protection by design and default approach to the development of web-based tool Data security arrangements Data disclosure approval process and log Data subject rights procedures
NHS Digital	Data provision for same purpose	Understanding of the detail level and coverage of relevant data held by NHS-D in order to

		confirm that this data cannot be provided nationally by another source
AIMES (hosting provider)	Data Security	Confirmation of data security accreditations Data Processing Agreement Access to web-based tool restrictions deployment Default admin account disabled, and two-factor authentication implemented to secure backend
Dovetail Strategies (communications)	Communications stakeholder engagement	Development of communications content Including for social media

Step 4: Assess necessity and proportionality

Describe compliance and proportionality measures, in particular: what is your lawful basis for processing? Does the processing actually achieve your purpose? Is there another way to achieve the same outcome? How will you prevent function creep? How will you ensure data quality and data minimisation? What information will you give individuals? How will you help to support their rights? What measures do you take to ensure processors comply? How do you safeguard any international transfers?

Lawful Basis – Common Law

On 20 March 2020 the Secretary of State for Health and Social Care issued a 'Notice' under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002 (COPI). This 'COPI Notice' requires organisations to process confidential patient information to support the Secretary of State's response to COVID-19.

A COVID-19 Purpose includes but is not limited to:

- understanding COVID-19 and risks to public health, trends in COVID-19 and such risks, and controlling and preventing the spread of COVID-19 and such risks;
- identifying and understanding information about patients or potential patients with or at risk of COVID-19, information about incidents of patient exposure to COVID-19 and the management of patients with or at risk of COVID-19 including: locating, contacting, screening, flagging and monitoring such patients and collecting information about and providing services in relation to testing, diagnosis, self-isolation, fitness to work, treatment, medical and social interventions and recovery from COVID-19;
- understanding information about patient access to health services and adult social care services and the need for wider care of patients and vulnerable groups as a direct or indirect result of COVID-19, and the availability and capacity of those services or that care;
- monitoring and managing the response to COVID-19 by health and social care bodies and the Government including providing information to the public about COVID-19 and its effectiveness and information about capacity, medicines, equipment, supplies, services and the workforce within the health services and adult social care services;

- delivering services to patients, clinicians, the health services and adult social care services, workforce and the public about and in connection with COVID-19, including the provision of information, fit notes and the provision of health care and adult social care services; and
- research and planning in relation to COVID-19.

This allows us to process and share confidential information about respondents for a COVID-19 Purpose. All use of information will be limited to that which is necessary for the particular purpose and as far as is reasonably practical individual identifiers will be removed to the extent that they are not required for the purpose.

Lawful Basis – Data Protection Law

As the Data Controller, the IBD Registry is still required to comply with relevant and appropriate data protection standards and to ensure within reason that we operate within statutory and regulatory boundaries. The General Data Protection Regulation (GDPR) allows health data to be used as long as one of the conditions under both Article 6 and Article 9 are met. There are conditions under both Articles that can be relied on for the sharing of health and care data:

For all processing:

Article 6(1)(e) – 'processing is necessary for the performance of a task carried out in the public interest…'

For sharing special categories of personal data with professionals involved in your care:

Article 9(2)(h) – 'processing is necessary for the purposes of…the provision of health or social care or treatment or the management of health or social care systems and services.

For sharing special categories of personal data with other recipients involved in the COVID-19 response:

Article 9(2)(i) – 'processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health…'

For research involving special categories of personal data as part of the COVID-19 response:

Article 9(2)(j) – 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes…'

For personal data submitted alongside any feedback provided about the web-based tool:

Article 6(1)(f) – 'processing is necessary for the purposes of the legitimate interests pursued by the controller…'

The legitimate interests pursued by the IBD Registry will be its ability to address any feedback provided about the web-tool, provide a written response to individuals that provide feedback regarding the web-based tool and maintain accurate records relating to any changes made to the web-based tool following feedback. This is considered a legitimate purpose on the basis that the provision of personal data will be entirely optional and that, where individuals choose to submit their personal data the purposes for which it will be used (to contact them regarding their feedback) will be clearly stated. It is also considered a proportionate approach given that the provision of personal data is entirely optional; and where this Is provided, the personal data processed will be extremely limited (email address or other contact method only required to return a response to feedback), the

fact that the use of the personal data will be within the reasonable expectations of the individual, and that no negative impacts on the individual as a result of this processing are foreseen.

Assessment of Necessity and Proportionality

The 'Necessity' Test

In line with the COPI Notice, where data collected is to be released, the necessity of any release shall be justified based on objective evidence. This does not mean that processing has to be absolutely essential. However, it must be more than just useful, and more than just standard practice. It must be a targeted and proportionate way of achieving a specific COVID-19 purpose. The lawful basis will not apply if the purpose can reasonably be achieved by some other less intrusive means, or by processing less data.

It is not enough to argue that processing is necessary because the organisation has chosen to operate in a particular way, or it may be helpful at some point in the future. The question is whether the processing is 'objectively necessary' for the stated COVID-19 purpose, not whether it is a necessary part of the organisation's chosen methods.

The 'Proportionality' Test

Proportionality is a general principle of law. It restricts organisations in the exercise of their powers by requiring them to strike a balance between the means used and the intended aim.
More specifically, proportionality in assessing the processing of personal data requires that only personal data which is adequate and relevant for the purposes of the processing are collected, processed, and shared.

The Necessity and Proportionality tests have been considered in relation to the use of the web-based tool to collect and process personal data.

Other ways to achieve the same outcome, namely of having the required details of data needed to assess the risk for each person with IBD from COVID-19 were explored (see the Stakeholders section, above). The primary sources for the data would be expected to be NHS Digital and the Trusts themselves. NHS Digital hold data on medications prescribed in the community, and inform us that the intention is to use this as the baseline for the Identification of high-risk patients across the UK. This is recognised as not an effective solution for IBD patients for a number of reasons: firstly, many of the drugs identified on the BSG Risk Grid are prescribed and often also delivered only in hospitals (I.e. many of the biologics medications); secondly, the interaction of certain conditions, certain demographic factors and certain drugs required to assess risk in IBD under COVID-19 conditions is not Identifiable from the NHS Digital datasets, leading to under identification of patients; and thirdly, there Is a risk of erroneous positive identification of patients from using just a drugs-based approach. For Trusts holding patient data, each Trust has a different system of patient record keeping with some having full electronic patient record systems, others having largely paper based records, with many variations in between those end points. Even where there was a good electronic clinical record, much of the high risk assessment comes from the presence of co-morbidities, which may not be identified within a focused gastroenterology record. The conclusion was that there was no other means to access this data consistently and at scale across the UK.

It is accepted that the proposed approach of collecting data via a web-based tool has a number of limitations in respect of the intended outcomes. Firstly, the use of a web-based tool to collect data directly from individuals which choose to complete it means that the dataset collected will not cover all individuals living with IBD in the UK. Secondly, as data is being collected directly from individuals, the accuracy and quality of the data may be limited if the respondents do not record accurate responses within the web-based tool. Linked to this is the potential issue of inaccurate information being provided by respondents in relation to the NHS Trust hospital, IBD professional or GP involved in their care, impacting the ability to accurately share the information submitted with the intended recipients. However, there are strong mitigations to these limitations, which we Intend to deploy. For the first, the target audience is less all people living with IBD In the UK but all people with IBD who may be at higher risk from COVID-19. We believe that this group correlates highly with patients receiving active clinical care (i.e. they are known to hospitals); plus those active as members of patient organisations (known to those organisations); and active in IBD research (known to IBD research groups). We Intend to work with all of the above groups to disseminate awareness of the IBD Tool through emails, social media and other appropriate contacts. For the second, we Intend to undertake a validation exercise on the quality of the data submitted, so that the potential for use of this data and data collected in similar circumstances for public health can be quantified and understood. For the third, we Intend to use the IBD Registry's existing site support operations to liaise with teams who believe patients have wrongly assigned their hospital in order to be able to re-contact those patients and request a data rectification.

Given the limitations around data already held and currently accessible within NHS Trusts and clinical teams, the web-based IBD Tool and the data collected through it is considered a necessary and proportionate mechanism for supplementing and complementing other activities being undertaken to support both direct care for individuals living with IBD and the wider COVID-19 response. The potential benefits of the data collection and the contribution to the wider purposes of supporting the COVID-19 response in the UK are considered to outweigh the risks relating to data completeness and data quality and therefore justify its implementation and operation. This assessment has been considered and agreed by the IBD Registry and the BSG.

Technical and Organisational Measures

The Necessity and Proportionality tests will be applied to all disclosures of personal data collected via the web-based tool. All disclosures will require approval by the IBD Registry's Senior Information Risk Owner (SIRO) and Caldicott Guardian with support from the Data Protection Officer (DPO) who will confirm that each disclosure is lawful and in line with the information provided to data subjects in the Privacy Notice.

Data quality is supported by ensuring the data is collected directly from the individual. This supports data quality with regards to data being up to date, however the accuracy of the data will not be subject to review or scrutiny by a healthcare professional as would be the case in a clinical setting. To address some of these data accuracy risks, a number of technical controls implemented within the web-based tool:

- Access to web-based tool restricted to UK audience for security and to ensure only UK respondents can access and enter data;
- NHS Number validation implemented to support data quality;
- Postcode validation Implemented to support data quality
- Trust lists and also hospital lists where patients may receive treatment Implemented to allow patients to select the hospital where they receive treatment

- Medication and condition response fields limited strictly to drop-down (no free text)
- Summary of data entered displayed prior to submission to allow respondents to confirm the accuracy of the responses provided.
- Re-submission of a new survey allowed, so that if the patient's circumstances change they can re-submit their entry.

Any changes to the web-based IBD Tool will be subject to a change control procedure whereby all proposed changes are assessed and approved before implementation (test and live), with the change documented as part of version control, and with all version changes maintained through the data audit trail.

Data minimisation has been achieved by ensuring the IBD Tool has been designed based on the BSG's COVID-19 risk assessment for individuals living with IBD in the UK. The data collected will therefore be the minimum required to accurately undertake the risk assessment, communicate this information to healthcare professionals involved in the person's care, and to support other COVID-19 purposes as defined within the COPI Notice. This together with any ongoing data changes will be reviewed and approved by the SIRO, plus the Caldicott Guardian where personal data is involved…

The 'COPI Notice' which supports the processing of confidential personal data is time limited and is currently due to be reviewed on or before 30 September 2020. It may be extended further by notice in writing by the Secretary of State for Health and Social Care. Personal data will be processed for the duration of the 'COPI Notice' at which point it will be securely destroyed by the IBD Registry and any recipients who have received this data on the basis of the 'COPI Notice', unless they can identify an alternative legal basis to support their continued retention or processing of the data. For example, the specialist or GP Practice may include the confidential data that has been supplied in the clinical records they hold about the respondent for the purposes of continuing to provide the respondent with direct care. Where a patient seeks information about how their specialist or GP Practice processes their personal confidential data, they will be referred to their GP's Privacy Notice.

Any data retained by the IBD Registry beyond the expiry of the 'COPI Notice', for example to support research into the impact of COVID-19 on patients with IBD, will be anonymised. This will ensure individuals can no longer be identified.

Data Subject Rights

Right to be informed

Individuals will be provided with a privacy notice which will comply with the ICO's detailed guidance on the Right to be Informed. This will outline the identity of the IBD Registry as the Data Controller, the purposes for which data will be used, the intended recipients of the data and the lawful basis which will be relied upon to allow the data processing. This will be made available to all data subjects at the point they are asked to enter their personal data to ensure all usage of their personal data is in line with their reasonable expectations. Where possible, 'just-in-time' notices will also be used within the web-based tool at the point specific data items are requested to inform data subjects why specific data items are required.

Data about children will also be collected where children choose to enter this data directly, or if a parent or guardian chooses to enter data on behalf of a child for which they have parental responsibility. As consent will not be relied upon as the lawful basis, there is no legal requirement to restrict usage to those over the age of 13, or to implement age verification processes. Guidance will however be provided to support children to involve their parents or guardians in their decision to submit data via the web-based tool. To further support the processing of personal data relating to children, transparency materials such as the Privacy Notice will be written in language which is accessible to children.

Right of access
Upon completion of the IBD Tool, data subjects will be presented with a summary of the data entered prior to submission to allow respondents to confirm the accuracy of the responses provided. Data subjects are also provided with the option of downloading a copy of the information entered to support their right of access.

A procedure will be developed to ensure any data subject access rights requests received by the IBD Registry can be responded to in line with legal requirements and timescales.

Right to rectification
Following completion of the IBD Tool, individuals can update any data that they previously submitted by submitting a new survey . Where the same name, date of birth, postcode and (ideally but not mandatory) NHS Number (England and Wales)/CHI Number (Scotland)/HSC Number (Northern Ireland) are used, previously submitted data will be superceded by a new version maintained within the system. This updated version will be made available to healthcare professionals caring for the respondent and Identified as an updated version.

A procedure will be developed to ensure any data subject rectification rights requests received by the IBD Registry can be responded to in line with legal requirements and timescales.

Right to erasure

Where personal data is processed on the basis of Article 6(1)(e) – 'processing is necessary for the performance of a task carried out in the public interest…' the right to erasure does not apply.

Furthermore, the GDPR specifies two additional circumstances in which the right to erasure does not apply:

- if the processing is necessary for public health purposes in the public interest (e.g. protecting against serious cross-border threats to health, or ensuring high standards of quality and safety of health care and of medicinal products or medical devices); or
- if the processing is necessary for the purposes of preventative or occupational medicine (eg where the processing is necessary for the working capacity of an employee; for medical diagnosis; for the provision of health or social care; or for the management of health or social care systems or services). This only applies where the data is being processed by or under the responsibility of a professional subject to a legal obligation of professional secrecy (e.g. a health professional).

As a result, the right to erasure will not apply to the data processed. It is anticipated that some people may want to complete the survey to understand their personal risk; if we receive a request to delete data at this early stage (when there has been no onwards processing or sharing) we will seek

to assist by complying with the request where it is possible. If we cannot comply, we will give the reason. Personal data will however be anonymised upon expiry of the COPI Notice which supports the lawful processing of confidential data by the IBD Registry to ensure that personal confidential data is no longer processed beyond that date.

A procedure will be developed to ensure any data subject erasure rights requests received by the IBD Registry can be responded to in line with legal requirements and timescales to explain why the right to erasure does not apply.

Right to restrict processing
The right to restrict the processing of data only applies in the following circumstances:

- the individual contests the accuracy of their personal data and the accuracy of the data is being verified;
- the data has been unlawfully processed (i.e. in breach of the lawfulness requirement of the first principle of the GDPR) and the individual opposes erasure and requests restriction instead;
- the personal data is no longer required but the individual needs it to be retained in order to establish, exercise or defend a legal claim; or
- the individual has objected to the processing their data and an assessment is being made regarding whether there are legitimate grounds to override those of the individual.

It is therefore anticipated that the right to restrict processing will only apply in the context of data collected and processed via the web-based tool where the IBD Registry receives a data subject rights request from a data subject relating to the accuracy of the data, or an objection. A procedure will be developed to ensure any data subject rights requests received by the IBD Registry relating to accuracy of objections will result in the processing of personal data being restricted whilst these are being considered and responded to.

In the unlikely event that the processing of personal data is deemed to be unlawful, the IBD Registry will cease all processing of personal data immediately which will also support the rights of data subjects to restrict the processing of their personal data.

Right to object

Individuals are free to choose whether or not to provide their personal data to the IBD Registry via the web-based tool. They can therefore exercise their right to object to the processing simply by choosing not to supply their personal data.

Where personal data has been provided via the web-based tool, it will be processed on the basis of Article 6(1)(e) – 'processing is necessary for the performance of a task carried out in the public interest…'. Where personal data is processed under this lawful basis, the right of data subjects to object is qualified. This means that any objections received by the IBD Registry relating to the processing of data submitted via the web-based tool may be overridden and the IBD Registry can refuse to comply if:

- it can demonstrate compelling legitimate grounds for the processing, which override the interests, rights and freedoms of the individual; or
- the processing is for the establishment, exercise or defence of legal claims.

In deciding whether there are compelling legitimate grounds which override the interests of an individual, the IBD Registry will consider the reasons why an individual has objected to the processing of their data. In particular, if an individual objects on the grounds that the processing is causing them substantial damage or distress (e.g. the processing is causing them financial loss), the grounds for their objection will have more weight. In making a decision on this, the IBD Registry will seek to balance the individual's interests, rights and freedoms with its own legitimate grounds. During this process the IBD Registry will ensure it is able to demonstrate that its legitimate grounds override those of the individual by documenting its decision and the reasons for this. It is anticipated that any objections received to the processing of data collected via the web-based tool will be overridden by the public interest being served by the continued processing. Each objection received will however be assessed on a case-by-case basis and the decision approved by the IBD Registry's SIRO and Caldicott Guardian supported by the DPO.

A procedure will be developed to ensure any objection to processing received from data subjects by the IBD Registry can be responded to in line with legal requirements and timescales. This will include informing the individual in writing the outcome of the decision reached and, in cases where the right to object is not upheld, of their right to make a complaint to the ICO or another supervisory authority and their ability to seek to enforce their rights through a judicial remedy.

Rights with respect to automated decision making and profiling

The data collected will be used to automatically generate a risk score based on the BSG's risk assessment. Where the level of risk identified is 'higher risk' details may be automatically shared centrally with NHS England and equivalent bodies in the devolved nations to allow them to better respond to the COVID-19 pandemic. This is considered to result in automated decisions being made via the web-based tool.

The IBD Registry are satisfied that there is an identified lawful basis to support the automated decision-making and this is documented within the Privacy Notice provided to data subjects. All data used to make the automated decision (to share data about individuals identified as 'higher risk' with NHS England and equivalent bodies in the devolved nations) is provided directly by the individuals. Data subjects are also presented with a summary of the information entered and used to support the automated decision before it is submitted, and have the ability to download a copy of the information and assessed risk level following submission. All of these measures support transparency.

The potential impact of the automated decision to share information about those identified as 'higher risk' centrally with NHS England and equivalent bodies in the devolved nations to allow them to better respond to the COVID-19 pandemic is considered to have the potential to result in a legal or similarly significant effect as defined by Article 22 of the GDPR. This is because any individuals whose data is shared may receive a letter or other correspondence from the central public health bodies identifying them as higher risk and outlining associated or required actions they may be required to take…

This activity is considered to be a COVID-19 Purpose as defined by the COPI Notice and so the processing is considered to be authorised by law (specifically Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002 (COPI)) and the processing of special category data

in support of this automated decision making is considered to be for reasons of substantial public interest. As such, the consent of the individual is not considered necessary to comply with the requirements of the GDPR.

Data Processors

The only data processor that will be engaged to support the processing of personal data on behalf of the IBD Registry is AIMES who will provide IT hosting services for the web-based tool and the resulting data storage and analysis platforms (known as the Trusted Research Environment). All other data processing will be undertaken directly by the IBD Registry and its staff.

To ensure the engagement of AIMES as a data processor is legally compliant, the following measures have been undertaken:

1. Due diligence has been completed to confirm that AIMES has the necessary data security accreditation in place including:
    a. Registration with the ICO (Registration Number: ZA499282)
    b. Data Security accreditations (https://www.aimes.uk/p-accreditation):
        i. ISO27001 Accreditation
        ii. Cyber Essentials Certification
        iii. NHS Data Security and Protection Toolkit submission – 19/20 Standards Exceeded (published 25/11/2019)
2. A Data Processing Contract has been put in place which covers:
    a. the subject matter of the processing;
    b. the duration of the processing;
    c. the nature and purpose of the processing;
    d. the type of personal data involved;
    e. the categories of data subject;
    f. the controller's obligations and rights;

    And requires that:
    g. the processor must only act on the controller's documented instructions, unless required by law to act without such instructions;
    h. the processor must ensure that people processing the data are subject to a duty of confidence;
    i. the processor must take appropriate measures to ensure the security of processing;
    j. the processor must only engage a sub-processor with the controller's prior authorisation and under a written contract;
    k. the processor must take appropriate measures to help the controller respond to requests from individuals to exercise their rights;
    l. taking into account the nature of processing and the information available, the processor must assist the controller in meeting its GDPR obligations in relation to the security of processing, the notification of personal data breaches and data protection impact assessments;
    m. the processor must delete or return all personal data to the controller (at the controller's choice) at the end of the contract, and the processor must also delete existing personal data unless the law requires its storage; and

n. the processor must submit to audits and inspections. The processor must also give the controller whatever information it needs to ensure they are both meeting their Article 28 obligations.

International Transfers

No international transfers of personal data are anticipated at the current time.

Step 5: Identify and assess risks			
Describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary.	**Likelihood of harm**	**Severity of harm**	**Overall risk**
Illegitimate Access (Confidentiality) Personal data processed via the web-based tool may be accessed illegitimately as a result of: • Data being intercepted in transit; • Data being sent to the wrong recipient; • Data being shared with an unauthorised recipient • Data at rest being illegitimately accessed; • Phishing/malware attacks; • Data being inadvertently accessed due to the application of inappropriate access controls; and • Data being illegitimately processed by a data processor. Personal data may be at risk of illegitimate access as it is being processed initially within a web-based system accessible via the internet which is hosted by a third party (data processor). Personal data may also be at risk as It needs to be shared, which means a data transfer needs to take place Illegitimate access to the personal data could result in a breach of confidentiality and an associated breach of privacy law resulting in embarrassment to data subject, reputational damage to project stakeholders and enforcement action from the ICO.	Probable	Severe	High
Undesired Modification (Integrity) Personal data processed via the web-based tool may be subject to undesired modification as a result of:	Possible	Significant	Medium

• Data being intercepted in transit; • Phishing/malware attacks; • Data being inaccurately recorded; • Data being overwritten; • Data being inadvertently accessed due to the application of inappropriate access controls; and • Data being illegitimately processed by a data processor. Personal data may be at risk of undesired modification as it is being processed initially within a web-based system accessible via the internet which is hosted by a third party (data processor), with data entry being undertaken directly by data subjects. Undesired modification of the personal data could result in inaccurate data being relied upon when providing advice or care to individuals, being entered into patient records and adversely impacting the wider response to the COVID-19 pandemic within the UK.			
Disappearance of Data (Availability) The disappearance of personal data processed via the web-based tool may occur as a result of: • Data being intercepted in transit; • Data at rest being illegitimately accessed; • Data being inadvertently deleted by authorised individuals; • Data being lost through disruption to services; • Phishing/malware attack; • Data being inadvertently deleted due to the application of inappropriate access controls; and • Data being illegitimately processed by a data processor. Personal data may be at risk of disappearance as it is being stored in a database hosted by a third party (data processor). Disappearance of the personal data could result in incomplete data being relied upon when providing advice or care to individuals, being entered into patient records and adversely impacting the wider response to the COVID-19 pandemic within the UK. It could also impact the providers' ability to comply with legal requirements around record retention and accountability, or to defend themselves against legal claims brought against them.	Possible	Significant	Medium

Compliance
A failure to comply with legal requirements relating to the processing of personal data via the web-based tool may occur as a result of:
• A failure to identify a lawful basis to process personal data;
• A failure to identify data subject rights requests submitted by data subjects;
• A failure to uphold data subject rights including:
  ○ Inadequate Privacy Notice arrangements which do not support the right to be informed;
  ○ An inability to respond to Data Subject Access Requests;
  ○ An inability to implement Data Subject Rights relating to Rectification, Erasure or Restriction of processing;
  ○ An inability to uphold Data Subject Rights relating to Objections to processing;
• A failure to implement effective technical and organisational measures to suitably protect personal data; and
• Data being illegitimately processed by a data processor.
Personal data may be processed in a manner which does not support the data controllers' ability to uphold data subject rights or comply with other legal requirements relating to the processing of personal data. This has the potential to result in a failure to uphold the rights and freedoms of data subjects.
An inability to fully comply with the law could result in an inability to uphold the fundamental rights and freedoms of data subjects leading to complaints from data subjects, reputational damage to project stakeholders and enforcement action from the ICO.
	Possible	Significant	Medium

Step 6: Identify measures to reduce risk				
Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5				
Risk	**Options to reduce or eliminate risk**	**Effect on risk**	**Residual risk**	**Measure approved**
Illegitimate Access (Confidentiality)	• The web-based tool will be hosted at a secure datacentre (ISO27001 certified) and will be accessible via an encrypted connection (https). • Data shared from the tool to other recipients (e.g. healthcare	Reduced and accepted	Low	Yes

	professionals and the wider NHS) will be subject to data minimisation to ensure that personal data is not shared unless necessary and proportionate, and that the minimum necessary personal data is shared. • Data will be encrypted in transit to ensure security and all data disclosures to other data controllers will be reviewed and authorised by the IBDR SIRO and Caldicott Guardian with support from the DPO and all data disclosures will be formally logged. • A Data Subject Access Request procedure will be established which includes a process for confirming the identity of requestors prior to confidential personal data being released. • All access for data sharing with healthcare professionals will be to pre-authorised individuals, to a login specific to the Trust / Heath Board that they are part of and using additional access security such as two-factor authentication • User access to the backend will be restricted to those IBDR administrators and staff members specifically authorised for administrative and data analysis purposes • Staff employed by AIMES will not have access to the backend database or personal data. • A CAPTCHA challenge–response test will be applied to the web-based tool to confirm that public users of the tool are human and to protect against cyber-attack. • Access to the web-based tool will also be restricted to the UK to limit access from other geographical locations. • A data processing agreement which complies with the requirements of the GDPR is in place with the data processor.			

Undesired Modification (Integrity)	• The data captured from the web-based IBD Tool will be hosted at a secure datacentre (ISO27001 certified) which Is separated from the web-based front-end used for access • Data in transit will be encrypted to ensure integrity. • User access to the backend will be restricted to those IBDR staff members with specified access permissions • Staff employed by the data processor will not have access to the backend database or personal data. • Where data is re-entered into the web-based tool this will not overwrite previously entered data held within the tool but will create an additional (updated) record within the database to ensure data integrity is maintained. Each record created will be given a unique identifier, and where possible, updated records will be linked back to the original record they have superceded so that the full change trail can be followed and audited • A data processing agreement which complies with the requirements of the GDPR is in place with the data processor.	Reduced and accepted	Low	Yes
Disappearance of Data (Availability)	• The data captured from the web-based IBD Tool will be hosted at a secure datacentre (ISO27001 certified) which Is separated from the web-based front-end used for access • Data stored at the data processor (AIMES) is part of an automated set of backup processes for all data help by IBD Registry. • AIMES (data processor) has business continuity arrangements in place to ensure the datacentre can continue to operate in circumstances such as the COVID-19 pandemic.	Reduced and accepted	Low	Yes

	• Data shared from the IBD Tool to other recipients (e.g. healthcare professionals and the wider NHS) will be subject to data minimisation to ensure that personal data is not shared unless necessary and proportionate, and that the minimum necessary personal data is shared. • Data will be encrypted in transit to ensure security and integrity of the data. • Staff employed by the data processor will not have access to the backend database or personal data. • A data processing agreement which complies with the requirements of the GDPR is in place with the data processor.			
Compliance	• A lawful basis under both confidentiality and data protection law have been identified within this DPIA. • Individuals will be provided with a privacy notice which will comply with the ICO's detailed guidance on the Right to be Informed. • A data subject rights request procedure will be established to support the IBD Registry's ability to effectively uphold data subject rights. • A range of technical and organisational measures have been identified and will be implemented to address risks relating to confidentiality, integrity and availability. • A data processing agreement which complies with the requirements of the GDPR is in place with the data processor.	Reduced and accepted	Low	Yes

Step 7: Sign off and record outcomes		
Item	**Name/date**	**Notes**
Measures approved by:		Integrate actions back into project plan, with date and responsibility for completion

Residual risks approved by:		If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:	Adam Spinks, Founder and IG Consultant, 8foldGovernance (on behalf of IBD Registry)	DPO should advise on compliance, step 6 measures and whether processing can proceed

Summary of DPO advice:

The approach being pursued goes some way to addressing the intended outcomes. The use of a web-based tool to collect data directly from individuals which choose to complete it means that the dataset collected will not cover all individuals living with IBD in the UK. The accuracy and quality of the data may also be limited if the respondents do not record accurate responses within the web-based tool. Linked to this is the potential issue of inaccurate information being provided by respondents in relation to the NHS Trust hospital, IBD professional or GP involved in their care, impacting the ability to accurately share the information submitted with the intended recipients.

The measures which will be adopted to mitigate and address the identified limitations and risks are considered to be both a reasonable and proportionate response. Many of the limitations cannot however be mitigated further meaning that some limited residual risk remains.

The professional opinion of the BSG and IBD Registry is that the contribution which will be made by the web-based tool and the benefits which will be derived from it, in conjunction with other activities being undertaken, will provide support to both the direct care of individuals living with IBD and the wider COVID-19 response. The potential benefits of the data collection and the contribution to the wider purposes of supporting the COVID-19 response in the UK are therefore considered to outweigh the residual limitations and risks relating to data completeness and data quality.

It is therefore accepted that, although imperfect, the proposed approach of collecting data via a web-based tool directly from individuals is a reasonable and proportionate response to the identified need and the identified risks have been mitigated as far as is reasonably practicable.

DPO advice accepted or overruled by:	Accepted	If overruled, you must explain your reasons
Comments:		
Consultation responses reviewed by:	Liz Dobson	If your decision departs from individuals' views, you must explain your reasons
Comments:		

This DPIA will kept under review by:	Liz Dobson (SIRO)	The DPO should also review ongoing compliance with DPIA

Record Management	
DPIA filed at:	IBD REGISTRY SHAREPOINT/ Information Governance/ DPIAs/ 2020 COVID-19 IBD Tool
Version Approved	V1.0 (FINAL)

Appendix 1: Web-based Tool Dataset/Questions

What type of inflammatory bowel disease do you have?

- Crohn's disease
- Ulcerative colitis
- Inflammatory bowel disease unclassified
- Other

Where do you live?

- England
- Northern Ireland
- Scotland
- Wales
- Other

Do you have another severe health condition that could mean you are high risk?
Including, but not limited to: Severe respiratory conditions, Solid organ transplants, Some types of cancer, Rare metabolic syndromes

- Yes
- No

What is your first name?

What is your surname?

What is your date of birth?

What is your gender?

- Female
- Male
- Other
- Prefer not to say

What is your NHS number?

What is your email address?

What is your UK mobile phone number?

What is your UK mobile phone number?

At which NHS hospital do you receive most of your IBD care?

What is the name of the main hospital consultant who treats your IBD?

Do you have a GP?

What is the name of your GP?

What is the name and address of your GP Practice?

Do you have hypertension (high blood pressure) requiring medication?

- Yes
- No

Do you have diabetes (e.g. type 1 or type 2 diabetes) for which you take insulin or tablets?

- Yes
- No

Do you have a respiratory or chest disease which has an impact on your day-to-day life (asthma where you take inhalers or tablets every day; emphysema or COPD which limits how much you can do)?

- Yes
- No

Have you ever been diagnosed with angina (chest pain caused by your heart), a heart attack or stroke?

- Yes
- No

Do you have a diagnosis of heart failure which limits how much you can do?

- Yes
- No

Have you been diagnosed with heart valve disease which limits how much you can do or has required valve surgery?

- Yes
- No

Are you currently taking oral steroids?

- Yes, prednisolone
- Yes, dexamethasone
- Yes, hydrocortisone
- None of the above

Please indicate which (if any) of the following biologic medications you are currently taking or have taken in the past three months:

- Ustekinumab (Stelara)
- Vedolizumab (Entyvio)
- Infliximab (Remicade, Inflectra, Remsima, Zessly, Inflxabi)
- Adalimumab (Humira, Amgevita, Hyrimoz, Imraldi, and Hulio)
- Golimumab (Simponi)

- Certolizumab (Cimzia)
- None of the above

Please indicate which (if any) of the following immunosuppressant medications you are currently taking or have taken in the past three months:

- Azathioprine (Imuran, Azapress)
- Mercaptopurine (6-MP, Hanixol, Xaluprine)
- Tioguanine (6-thioguanine)
- Methotrexate (Maxtrex, Methofill, Metoject, Ebetrex, Namaxir, Nordimet and Zlatal)
- Tacrolimus (Envarsus, Adoport,Prograf, Advagraf, Dalliport, Modigraf)
- Ciclosporin (Neoral, Vanquoral, Capimune, Capsorin, Deximune, Sandimmun)
- Tofacitinib (Xeljanz)
- Mycophenolate (MMF, Myfortic, Ceptava, CellCept)
- Thalidomide (Talidex)
- None of the above

Are you taking any immunosuppressant/biologic trial medication prescribed by your doctor as part of a clinical trial?

- Yes
- No

Do you believe that your Crohn's disease has been well controlled in the past two weeks?

- Yes
- No, mild symptoms
- No, moderate or severe symptoms (impacting on day-to-day life)
- Unsure

Do you currently receive intravenous feeding (parenteral nutrition)?

- Yes
- No

Do you have short gut syndrome requiring nutritional support?

- Yes
- No