ISRCTN96296121 https://doi.org/10.1186/ISRCTN96296121

IBD-RESPONSE – predicting treatment response in Crohn's disease and ulcerative colitis

Submission date
17/11/2021

Recruitment status
Recruiting

Registration date
29/12/2021

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Crohn's disease and ulcerative colitis (UC) are types of a bowel condition known as inflammatory bowel disease (IBD) and the symptoms (diarrhoea, pain, fatigue) have a major impact on daily life. IBD affects around 1 in 125 people in the UK and this is expected to rise to 1 in 100 by 2028. "Biologics" are powerful medications that are given to reduce inflammation in IBD. These treatments can be effective but up to 40% of patients don't respond, and in those that do, many don't respond well enough to stay on the drug after one year of treatment. Unfortunately, we have no way to predict which patients are most likely to benefit from treatment (known as responders), and we do not fully understand how medications work in responders. As these drugs may have serious side effects and are expensive to the NHS, this lack of understanding is a major obstacle in deciding which treatment is best to give to an individual patient, and when to give it to them in order to have the greatest benefit and the least risk. Recent data from small studies in people with IBD and larger studies of people with cancer, show that certain bacteria in stool may predict who will respond or fail to respond to treatments.

Who can participate?
We will recruit 1,325 patients starting biological therapy in IBD as part of routine NHS care from 40 centres across the UK.

What does the study involve?
We will collect stool, blood and where possible intestinal biopsies during routine endoscopy (camera into the gut), to study the gut bacteria before, and during, these treatments.

What are the possible benefits and risks of participating?
Benefits: In the short term this study will not help the participant directly as the results will not change any standard of care treatment received. However, the information we get from this study will help to improve our understanding of the links between gut microbes, genes, diet and Inflammatory Bowel Disease. Our goal is to better understand the complicated relationship between these different factors and Inflammatory Bowel Disease. Our aim is to use this information to create a tool that can predict response to treatment in Inflammatory Bowel Disease. In the future, we hope it will benefit lots of Inflammatory Bowel Disease patients, by helping to select the best drug at the right time for individual patients.

Risks: By joining the study, participants will donate blood samples and biopsies (only if you have an endoscopy during the study period), which are routinely collected as part of the participants clinical standard of care. Blood sampling can cause momentary discomfort and may cause a small bruise. The biopsy procedure carries a small risk of bleeding and there is a very minimal risk, that the procedure could create a hole in the bowel (perforation). The specific risks of undergoing a colonoscopy or flexible sigmoidoscopy are discussed with the participant in line with the NHS consent process for each endoscopic procedure as part of standard NHS practice.

Where is the study run from?
Newcastle Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2026

Who is funding the study?
1. Medical Research Council (UK)
2. Leona M. and Harry B. Helmsley Charitable Trust (USA)

Who is the main contact?
IBD.Response@newcastle.ac.uk

Study website
https://www.ibd-response.co.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295742

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 49964, MR/T032162/1, IRAS 295742

Study information

Scientific Title
Defining microbial predictors of responsiveness to biologic therapies in Crohn’s disease and ulcerative colitis

Acronym
IBD-RESPONSE

Study objectives
To identify and validate a predictive model for response or failure to respond to biologic and janus kinase inhibitor (JAKi) therapies in Crohn’s disease (CD) and ulcerative colitis (UC), the major forms of inflammatory bowel disease (IBD), using microbiome (including microbial species and functional data), metabolome and integrated clinical and human genome data.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/08/2021, Wales Research Ethics Committee 5 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 1874 615950;
Wales.REC5@Wales.nhs.uk), ref: 21/WA/0228

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Crohn’s disease and ulcerative colitis

Interventions

Current interventions as of 19/12/2024:

This is a multi-centre, observational cohort study with 40 centres across the United Kingdom. We will aim to recruit 1325 participants over 27 months. Patients will be identified by the gastroenterology teams and be screened against the study eligibility criteria using the patients' medical records. Eligible patients will have the study explained to them by a member of the study team and be given the Patient information sheet for further information. Patients (up to 300 patients) who are diagnosed with Crohn' disease may be asked to be part of the sub-study called CD-metaRESPONSE, which means they complete some extra questionnaires and collect additional samples.

To be eligible for the study, the participant will need to be starting a biologic therapy (an injectable medication used to control inflammation in inflammatory bowel disease e.g. infliximab, adalimumab, vedolizumab or ustekinumb) or a JAK inhibitor medication (tofacitinib) as treatment for Crohn’s disease or ulcerative colitis.

The majority of the study will be completed remotely, at participants' home. Each participant will be provided with access to the online database, REDCap, which will be used to provide informed consent, complete questionnaires and track samples. Participants will be enrolled for approximately 54 weeks, with assessments performed at baseline (prior to starting treatment), week 14 (14 weeks after starting treatment) and at week 54 (54 weeks after starting treatment). These visits should align with patients dosing regimen. The IBD-RESPONSE research team at site will be available to support and help with any questions or concerns about the study.

Assessment 1 (Baseline) - (up to 6 weeks prior to starting treatment)
1. Complete questionnaires assessing Health related quality of life; PRO-2 (CD) or PRO-2 (UC), PROMIS-Fatigue, IBD-Control, International Physical Activity Questionnaire (IPAQ) and EQ-5D-5L. Participants dietary habits will also be assessed using Scottish Collaborative Group Food Frequency Questionnaire and for participants in the CDmetaRESPONSE cohort - Kings College London 4-day food diary.
2. Collect Stool Samples at home and send to research team at Newcastle University.
3. If attending a routine clinical appointment, approximately 20ml of blood samples will be collected for analysis.
These samples will be sent to by the research team to Wellcome Sanger Institute for analysis.

Assessment 2 - (14 weeks after starting treatment (ideally +/- 2 weeks but data can be collected between weeks 10-20))
1. Complete questionnaires assessing Health related quality of life; PRO-2 (CD) or PRO-2 (UC), PROMIS-Fatigue, IBD-Control, International Physical Activity Questionnaire (IPAQ) and EQ-5D-5L. Participants dietary habits will also be assessed using Scottish Collaborative Group Food Frequency Questionnaire and for participants in the CDmetaRESPONSE cohort - Kings College London 4-day food diary.
2. Collect Stool Samples at home and send to research team at Newcastle University
3. If attending a routine clinical appointment, approximately 20ml of blood samples will be collected for analysis.
These samples will be sent to by the research team to Wellcome Sanger Institute for analysis.

Assessment 3 - (54 weeks after starting treatment (+/- 6 weeks))
1. Complete questionnaires assessing Health related quality of life; PRO-2 (CD) or PRO-2 (UC), PROMIS-Fatigue, IBD-Control, International Physical Activity Questionnaire (IPAQ) and EQ-5D-5L. Participants dietary habits will also be assessed using Scottish Collaborative Group Food

Frequency Questionnaire and for participants in the CDmetaRESPONSE cohort - Kings College London 4-day food diary.
2. Collect Stool Samples at home and send to research team at Newcastle University
3. If attending a routine clinical appointment, approximately 20ml of blood samples will be collected for analysis.
These samples will be sent to by the research team to Wellcome Sanger Institute for analysis.

If a participant change their treatment prior to first follow-up (Assessment 2), they will be asked to complete questionnaires/provide samples required at Assessment 2 at the time of stopping treatment. If you start a new treatment after this, the planned follow-up timeline will restart at Assessment 2, 14 weeks after starting the new treatment.

If the participant changes their treatment after Assessment 2 but before completing Assessment 3, they will be asked to complete questionnaires/provide samples required at Assessment 3 at the time of stopping treatment. If you start a new treatment after this, the planned follow-up timeline will restart at Assessment 2, 14 weeks after starting the new treatment.

If a participant is scheduled for an endoscopy (colonoscopy or flexi sigmoidoscopy) during the study, they will be asked to consent to research team taking up to 12 biopsies for the study. The biopsies will be sent by the research team to Wellcome Sanger Institute (up to 6 biopsies) and to Newcastle University (up to 6 biopsies) for analysis.

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Previous interventions:

This is a multi-centre, observational cohort study with 40 centres across the United Kingdom. We will aim to recruit 1325 participants over 27 months. Patients will be identified by the gastroenterology teams and be screened against the study eligibility criteria using the patients' medical records. Eligible patients will have the study explained to them by a member of the study team and be given the Patient information sheet for further information. Patients (up to 200 patients) who are diagnosed with Crohn' disease may be asked to be part of the sub-study called CDmetaRESPONSE, which means they complete some extra questionnaires and collect additional samples.

To be eligible for the study, the participant will need to be starting a biologic therapy (an injectable medication used to control inflammation in inflammatory bowel disease e.g. infliximab, adalimumab, vedolizumab or ustekinumb) or a JAK inhibitor medication (tofacitinib) as treatment for Crohn’s disease or ulcerative colitis.

The majority of the study will be completed remotely, at participants' home. Each participant will be provided with access to the online database, REDCap, which will be used to provide informed consent, complete questionnaires and track samples. Participants will be enrolled for approximately 54 weeks, with assessments performed at baseline (prior to starting treatment), week 14 (14 weeks after starting treatment) and at week 54 (54 weeks after starting treatment). These visits should align with patients dosing regimen. The IBD-RESPONSE research team at site will be available to support and help with any questions or concerns about the study.

Assessment 1 (Baseline) - (up to 6 weeks prior to starting treatment)
1. Complete questionnaires assessing Health related quality of life; PRO-2 (CD) or PRO-2 (UC), PROMIS-Fatigue, IBD-Control, International Physical Activity Questionnaire (IPAQ) and EQ-5D-

5L. Participants dietary habits will also be assessed using Scottish Collaborative Group Food Frequency Questionnaire and for participants in the CDmetaRESPONSE cohort - Kings College London 4-day food diary.
2. Collect Stool Samples at home and send to research team at Newcastle University.
3. If attending a routine clinical appointment, approximately 20ml of blood samples will be collected for analysis.
These samples will be sent to by the research team to Wellcome Sanger Institute for analysis.

Assessment 2 - (14 weeks after starting treatment (ideally +/- 2 weeks but data can be collected between weeks 10-20))
1. Complete questionnaires assessing Health related quality of life; PRO-2 (CD) or PRO-2 (UC), PROMIS-Fatigue, IBD-Control, International Physical Activity Questionnaire (IPAQ) and EQ-5D-5L. Participants dietary habits will also be assessed using Scottish Collaborative Group Food Frequency Questionnaire and for participants in the CDmetaRESPONSE cohort - Kings College London 4-day food diary.
2. Collect Stool Samples at home and send to research team at Newcastle University
3. If attending a routine clinical appointment, approximately 20ml of blood samples will be collected for analysis.
These samples will be sent to by the research team to Wellcome Sanger Institute for analysis.

Assessment 3 - (54 weeks after starting treatment (+/- 6 weeks))
1. Complete questionnaires assessing Health related quality of life; PRO-2 (CD) or PRO-2 (UC), PROMIS-Fatigue, IBD-Control, International Physical Activity Questionnaire (IPAQ) and EQ-5D-5L. Participants dietary habits will also be assessed using Scottish Collaborative Group Food Frequency Questionnaire and for participants in the CDmetaRESPONSE cohort - Kings College London 4-day food diary.
2. Collect Stool Samples at home and send to research team at Newcastle University
3. If attending a routine clinical appointment, approximately 20ml of blood samples will be collected for analysis.
These samples will be sent to by the research team to Wellcome Sanger Institute for analysis.

If a participant change their treatment prior to first follow-up (Assessment 2), they will be asked to complete questionnaires/provide samples required at Assessment 2 at the time of stopping treatment. If you start a new treatment after this, the planned follow-up timeline will restart at Assessment 2, 14 weeks after starting the new treatment.

If the participant changes their treatment after Assessment 2 but before completing Assessment 3, they will be asked to complete questionnaires/provide samples required at Assessment 3 at the time of stopping treatment. If you start a new treatment after this, the planned follow-up timeline will restart at Assessment 2, 14 weeks after starting the new treatment.

If a participant is scheduled for an endoscopy (colonoscopy or flexi sigmoidoscopy) during the study, they will be asked to consent to research team taking up to 12 biopsies for the study. The biopsies will be sent by the research team to Wellcome Sanger Institute (up to 6 biopsies) and to Newcastle University (up to 6 biopsies) for analysis.

Intervention Type
Other

Primary outcome measure

1. Stool frequency and rectal bleeding measured by PRO-2 at 14 weeks
2. Absence of rectal bowel surgery up to 14 weeks (yes/no) measured using patient records
3. Use of oral corticosteroids at 14 weeks (yes/no) measured using patient records

Secondary outcome measures
1. Stool frequency and rectal bleeding measured by PRO-2 at baseline, week 14, and week 54
2. Absence of rectal bowel surgery up to 54 weeks (yes/no) measured using patient records
3. Use of oral corticosteroids at 14 weeks and 54 weeks (yes/no) measured using patient records
4. Time to treatment escalation (if applicable) up to 54 weeks measured using patient records, defined as:
4.1 Biologic or JAKi switch due to lack of efficacy/those with loss of response (does not include biosimilar switch or switch from i.v. to s.c.).
4.2 Dose intensification of drug due to lack of efficacy (does not include intensification based on therapeutic drug monitoring without flare in responders).
4.3 Re-sectional intestinal surgery (does not include examination under anaesthesia procedures in patients with perianal Crohn's disease).
4.4 Induction or dose escalation of corticosteroids.
5. Time to discontinuation of index drug (if applicable) up to 54 weeks measured using patient records
6. Adverse events up to 54 weeks measured using patient records
7. Development of anti-drug antibodies measured using blood test at week 14 and 54
8. C-reactive protein (CRP) measured using blood test at baseline, week 14, and week 54
9. Faecal calprotectin measured using stool sample at baseline, week 14, and week 54
10. Remission measured by endoscopy during follow up (Mayo endoscopic subscore ≤1 for ulcerative colitis or SES-CD ≤2 for Crohn's disease)
11. Quality of life measured using EQ-5D-5L and IBD-Control questionnaires at baseline, week 14, and week 54
12. Physical activity measured using International Physical Activity Questionnaire (IPAQ) at baseline, week 14, and week 54
13. Dietary intake measured using the Scottish Collaborative Group Food Frequency Questionnaire (FFQ) and the Kings College London 4-day food diary for CD-metaRESPONSE sub cohort participants only, at baseline, week 14, and week 54
14. Fatigue measured using the PROMIS-Fatigue 8a Short Form at baseline, week 14, and week 54

Overall study start date
01/01/2021

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adults aged 16 years and over.
2. Established diagnosis of inflammatory bowel disease: Crohn's disease, ulcerative colitis or IBD-U.
3. Already participating or willing to participate in IBD BioResource.
4. Willing and able to provide informed consent.
5. Willing to undertake the following study procedures:

5.1. Completion of questionnaires.
5.2. Collection of stool specimens at home.
5.3. Provision of the requested biosamples during visits to hospital.
6. Intention of clinical team to commence anti-TNFα (infliximab or adalimumab), anti-integrin (vedolizumab), anti-IL12/23 (ustekinumab) biologic or JAKi (tofacitinib) therapy, for active luminal IBD within 6 weeks.
7. Additional inclusion criteria for patients with Crohn's disease
8. Patients with Crohn's disease must have at least one of the following documented within 12 weeks prior to consent:
9. Faecal calprotectin >=250 µg/g.
10. CRP >=6 mg/L.
11. Any endoscopic evidence of active Crohn's disease, defined as ulceration (with at least one ulcer >=5mm) judged locally from available clinical data (as an approximation equivalent to SES-CD of >=4 for ileal disease or >=6 for ileocolonic or colonic disease. This can be estimated retrospectively from clinical record and does not have to be prospectively calculated).
12. Active inflammatory disease on imaging (MRI/CT/ultrasound) judged locally from available clinical data.
13. Additional inclusion criteria for participants with ulcerative colitis
14. Patients with ulcerative colitis must have at least one of the following documented within 12 weeks prior to consent:
15. Faecal calprotectin >=250 µg/g
16. CRP >=6 mg/L
17. Any endoscopic evidence of at least moderately active ulcerative colitis (of any extent including proctitis), defined as features of Mayo endoscopy sub-score > = 2 (marked erythema, lack of vascular pattern, friability, erosions, spontaneous bleeding or ulceration). This assessment will be judged locally and retrospectively from available clinical data and does not have to be prospectively calculated.
18. NOTE: Patients do not have to be biologic-naïve. Any additional biologics or small molecule newly licensed for Crohn's disease or ulcerative colitis during the IBD-RESPONSE planned study period will also be suitable to allow inclusion.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 1325; UK Sample Size: 1325

Key exclusion criteria
1. Receiving oral corticosteroids for any indication where the dose is unlikely to be weaned by week 14.
2. Planned bowel resection surgery within 14 weeks of commencing therapy.
3. Biologic or JAKi being commenced as rescue therapy for acute severe ulcerative colitis (ASUC).

4. Biologic or JAKi being commenced as part of CTIMP.
5. Ileal pouch anal anastomosis.
6. Presence of a stoma.
7. Perianal Crohn’s disease in absence of active luminal inflammation.
8. Faecal microbial transplantation (FMT) within the preceding 12 weeks or planned FMT within 14 weeks of commencing biologic or JAKi.
9. Antibiotics or short-term (<=4 weeks) course of probiotics within the preceding 2 weeks.
10. NOTE: Use of long-term (>4 weeks), stable doses of probiotics is not an exclusion from this study but should be noted in the CRF. Use of antibiotics or prior FMT outside of the exclusion time period are not exclusions. Antibiotic use in the preceding 1 year and ever having received FMT will be noted in the CRF.

Date of first enrolment
31/12/2021

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Freeman Hospital
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon and Exeter NHS Hospital Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
NHS Lothian
2 - 4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
The Royal London Hospital
80 Newark Street
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E1 2ES

Study participating centre
St. Mary's Hospital
Imperial College Healthcare NHS Trust
Praed Street
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W2 1NY

Study participating centre
John Radcliffe Hospital
Headley Way
Oxford
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OX3 9DU

Study participating centre
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Hull
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HU3 2JZ

Study participating centre
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East and North Hertfordshire NHS Trust
Coreys Mill Lane
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SG1 4AB

Study participating centre
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The Royal Wolverhampton NHS Trust
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WV10 0QP

Study participating centre
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Study participating centre
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Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
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Royal Berkshire Hospital
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Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
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Birmingham
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B15 2GW

Study participating centre
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Leeds Teaching Hospitals NHS Trust
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Swansea Bay University Local Health Board
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Hills Road
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Study participating centre
Darlington Memorial Hospital
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Macclesfield District Hospital
Victoria Road
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Canada Avenue
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Study participating centre
Wythenshawe Hospital
Southmoor Road
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Colney Lane
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NR4 7UY

Study participating centre
Fairfield Hospital
Fairfield Hospital
Crank Road
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WA11 7RS

Study participating centre
North Tyneside General Hospital
North Tyneside General Hospital
Rake Lane
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NE29 8NH

Study participating centre
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Pond Street
London
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Salford Royal Hospital
Stott Lane
Eccles
Salford
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M6 8HD

Study participating centre
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Kings Mill Hospital
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Sutton-in-ashfield
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Study participating centre
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South Shields
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UB1 3HW

Study participating centre
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St Marks Hospital
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HA1 3UJ

Study participating centre
Royal Sussex County Hospital
Eastern Road
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BN2 5BE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
United Kingdom
NE7 7DN
+44 1912824452
christopher.price6@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Leona M. and Harry B. Helmsley Charitable Trust

Alternative Name(s)
Helmsley Charitable Trust, The Leona M. and Harry B. Helmsley Charitable Trust, Leona M. & Harry B. Helmsley Charitable Trust, The Helmsley Charitable Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
Raw data files in the original format (e.g., fastq) and the accompanying phenotypic data will be uploaded to the NCBI database of Genotypes and Phenotypes (dbGaP) at https://www.ncbi.nlm.nih.gov/gap/. Appropriate fully anonymised study data will be also be linked from the data.ncl.ac.uk institutional research data repository, and archived by the HDRUK IBD Digital Innovation Hub "G.I. Know" funded by UKRI. Our policy is to make the study data available 6 months after the full, cleaned data set is available.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 5.0	09/06/2023	23/01/2024	No	Yes
Protocol article		17/04/2024	18/04/2024	Yes	No