

An international multicentre randomised controlled trial to assess the effect of **A**ppendectomy on the **C**linical **C**ourse of **U**lce**R**ativ**E** colitis; UK Arm

**Site Feasibility Assessment and Registration Form**

**ACCURE-UK 2** is the new UK arm of a group of studies that are being run here and in the Netherlands. The ACCURE study was developed by researchers at the Academic Medical Centre (AMC), Amsterdam. In parallel to this the ACCURE-UK study, a randomised external feasibility trial, was developed by the University of Birmingham and Birmingham Clinical Trials Unit and successfully completed in 2016 - confirming the safety, acceptability and optimal patient pathway for a trial of this intervention.

The **ACCURE-UK 2** trial is funded by the Efficacy and Mechanism Evaluation (EME) programme of the National Institute for Health Research (NIHR) and funds the UK arm of the ongoing main Dutch ACCURE study. It will recruit 90 patients, to both increase the statistical power of the Dutch trial to 90% and help the main trial complete recruitment in a more expedient manner. The University of Birmingham is the sponsor for **ACCURE-UK 2**; it is led by Professor Tom Pinkney and co-ordinated by the University of Birmingham Clinical Trials Unit (BCTU).

**ACCURE-UK 2** will be conducted at approximately 10 UK sites and this feasibility assessment is intended to ensure that your site has the necessary workload and infrastructure to run the trial effectively.

**Things to consider when deciding whether to participate in the ACCURE-UK 2 Trial:**

* Coordinated IBD working practices between surgeons and gastroenterologists, perhaps including joint clinics
* Research nursing support is necessary to assist with running the trial.
* The lead local researcher for a multi-centre study is the local Principal Investigator (PI); they must have a GCP training completion certificate dated within 2 years at the time of opening and prior engagement with clinical research, although not necessarily at PI level – we are happy to provide training and support for new PIs.
* The site must be able to adhere to the requirements of the trial and its protocol and have adequate facilities, capacity and qualified staff, including enthusiastic surgical trainees, for the period the trial will run.
* Lack of conflict of existing trials run by the site that might either compete with ACCURE-UK 2 for participants or introduce recruitment bias.

**The following points outline what will be expected of a site if they take part in the trial so please think about whether your site can meet them.**

* All staff involved with the trial must be informed about the protocol, the investigational procedures and their authorised trial related duties. As a minimum the Principle Investigator (PI), Lead Gastroenterologist and a Research Nurse must attend initiation visit training.
* The site will maintain Investigator Site Files (ISF) that will contain all documents essential for the trials conduct.
* All trial data will be submitted in a timely manner using relevant Case Report Forms (CRFs).
* All SAEs will be reported to BCTU within 24 hours of the research staff becoming aware of the event.
* All trial related documents will be retained by site for at least 25 years after the trial is closed and will not be destroyed without permission from the Sponsor or their delegates, the BCTU.
* Monitoring will mainly be performed centrally but if onsite monitoring is required, a working space must be provided.
* In the **ACCURE-UK 2** trial the role of PI carries certain responsibilities:
  + Ensuring that site adheres to the principles outlined in the UK Policy Framework for Health and Social Care Research, GCP guidelines, the Sponsor’s SOPs and other regulatory requirements as amended.
  + Ensuring the agreed protocol is followed, day-to-day conduct of the research, recruitment into the study at site, reporting adverse events, integrity of records and ensuring they are kept confidential.
  + Ensuring the Research Governance requirements for the centre and the study are met.
  + Helping healthcare professionals ensure participants receive appropriate care while involved in the trial.

**All sites require confirmation of capacity and capability from their Trust before the trial can commence at site.**

* No patients can be approached for consent or enrolled to join the study until this is in place.
* The **ACCURE-UK 2** Trial Office can assist in the approval process when a completed form is returned to the **ACCURE-UK 2** Trial Office (contact details on back page).
* There are excess treatment costs associated with the trial; £1,216.50 per participant. The CRN validated and CCG confirmed Schedule of Events Cost Attribution Tool (SoECAT) is available on request.

**Please Note:**

* BCTU strongly encourages that all people working on trials should be GCP trained.
* The local PI and anyone assessing eligibility and taking informed consent must be GCP trained; a copy of the certificate should be held at site and will be requested by R&D and the **ACCURE-UK 2** Trial Office.
  + Doctors and research nurses can take consent for entry into the **ACCURE-UK 2** Trial.

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| Privacy Notice  This statement provides information about how the University uses the personal data you have provided by completing this ACCURE-UK 2Site Feasibility Assessment and Registration Form. It supplements the page on our website ‘Data Protection – How the University Uses Your Data’: <https://www.birmingham.ac.uk/privacy/index.aspx>  On this form, we collect hospital name, full names, position, qualifications, addresses, employers and contact details. This information, together with other data provided on this form, will be processed for the assessment of site feasibility and registration purposes by the ACCURE-UK 2Trials Office. It is also necessary for research which is a task we carry out in the public interest. The information you provide on this form will also enable the ACCURE-UK 2 Trial Manager to contact you with further information about the ACCURE-UK 2 Trial set up process at your site. You and your collaborators may be contacted using the email addresses you provide in this form.  The data collected on this form will not be shared outside the University of Birmingham and it will be kept indefinitely as long as it is still useful, or if you tell us you no longer want us to hold your details. If you want your data removed from our database please contact: [ACCURE@trials.bham.ac.uk](mailto:ACCURE@trials.bham.ac.uk). |

**PRINCIPAL INVESTIGATOR**

**Details of local Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | | |
| Position |  | | |
| Qualification |  | | |
| Department |  | | |
| Trust |  | | |
| Hospital |  | | |
| Address |  | | |
| Telephone |  | Fax |  |
| Email |  | | |
| Main employer  (if not Site) |  | | |
| & State details of any honorary contacts: |  | | |

**Experience of the local Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Has the proposed PI previously undertaken this role for any previous trials (completed or ongoing)?**  If answered YES, please provide the following details: | Yes 🞏 | No 🞏 |

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| --- | --- | --- | --- |
| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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|  | **Has the proposed PI been a co-investigator for any other trials? (completed or ongoing)**  If answered YES, please provide the following details: | Yes 🞏 | No 🞏 |

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| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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|  | **Has the PI (or Lead Colorectal Surgeon if PI is a Consultant Gastroenterologist) performed at least 20 laparoscopic appendicectomy procedures?** | Yes 🞏 | No 🞏 |

**Role as Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Does the PI agree to take clinical responsibility for the trial at the site, and so confirming the interest of the site participating in the ACCURE-UK 2 Trial?** | Yes 🞏 | No 🞏 |
|  | **Does the PI agree to the HRA/REC being informed that they will be PI for this site?** | Yes 🞏 | No 🞏 |
|  | **Are there any conflicts of interest for this trial for the PI and/or site?** | Yes 🞏 | No 🞏 |

***Declaration of Principal Investigator (confirming accuracy of data recorded on this form)***

Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

*(must be wet-ink signature)*

**Site information**

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|  | **Does your site have a joint IBD clinic?** | Yes 🞏 | No 🞏 |
|  | Comments on joint working between surgery and gastroenterology :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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|  | **Does your site have the staff capacity to undertake this trial?** (e.g. research nurses, data managers) | Yes 🞏 | No 🞏 |
|  | If ‘No’, please comment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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|  | **The appendix will be removed (in those allocated to the intervention arm) using a laparoscopic endostapler enabling a total appendicectomy with the cross-stapling line at the base of the appendix at the junction with the caecal pole.**  **Can a laparoscopic stapler be used for an appendicectomy at your site currently?** | Yes 🞏 | No 🞏 |
|  | If ‘No’, funding of £360 is provided to sites to pay for a basic stapler, encapsulated within the per patient payments. | | |

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|  | **Relapse rate / maintenance of remission is the primary outcome so it is essential that disease relapses are robustly confirmed prior to commencement of medical therapy. Patients who feel that they are developing symptoms of a flare will be asked to contact their local investigator team who will arrange an urgent clinic appointment for clinical review, blood tests +/- endoscopy.**  **Please indicate where/how this research activity will take place/ be achieved at your site.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Recruitment**

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|  | **How many UC patients were seen at your site last calendar year?**  Please estimate if information is not readily available | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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|  | **How many of those patients would have been eligible for participation in ACCURE-UK 2 based on the inclusion and exclusion criteria?**  Please estimate if information is not readily available | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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|  | **Please state the number of patients expected to be recruited:** |
|  | **i. Average per month?** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **ii. For the duration of the study?** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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|  | **Are there any trials currently recruiting at your centre, which may conflict / compete for patients within this trial?** | Yes 🞏 | No 🞏 |
|  | If ‘Yes’, please provide details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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|  | **Will your site be interested in participating in sample collection for the future mechanistic sub-study?**  Participation is optional for both sites and participants, and sites can opt in at a later time. The samples collected are: 1) colonic mucosal biopsies at baseline and 12 months, 2) blood samples collected at baseline, 3 and 12 months, and 3) appendix and appendiceal effluent (appendicectomy group only).  *PLEASE NOTE: The mechanistic sub-study has not been implemented yet – more information and details of the processes involved will be provided in due course (either within an appendix to the main protocol or a separate sub-study protocol).* | Yes 🞏 | No 🞏 |
| To be decided  later 🞏 | |

**Local Research Team** (individual fields can be left black if they are not know)

**Lead Gastroenterologist (or Lead Colorectal Surgeon if PI is not a surgeon)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Department |  |
| Position |  |  | Telephone |  |
| Qualification |  |  | Email |  |

**Research nurses**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Full Name (incl. title) |  |
| Position |  |  | Position |  |
| Qualification |  |  | Qualification |  |
| Department |  |  | Department |  |
| Telephone |  |  | Telephone |  |
| Email |  |  | Email |  |

**Other trial administration staff (trial co-ordinator, data manager)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Full Name (incl. title) |  |
| Position |  |  | Position |  |
| Qualification |  |  | Qualification |  |
| Department |  |  | Department |  |
| Telephone |  |  | Telephone |  |
| Email |  |  | Email |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Is there a clinical trials office or department that BCTU should correspond with to help in the set-up of your site?** | | | | | | Yes 🞏 | No 🞏 |
|  | If answered ‘Yes’, please supply a contact name and contact details below: | | | | | | |
| Full Name (incl. title) | |  |  | Department |  | | |
| Position | |  |  | Telephone |  | | |
| Qualification | |  |  | Email |  | | |

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| **Who in your Local R&D Office should the ACCURE-UK 2 Trial Office liaise with regarding set-up of the trial?** | | | | |
| Full Name (incl. title) |  |  | Department |  |
| Position |  |  | Telephone |  |
| Qualification |  |  | Email |  |

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| **Please provide any other pertinent information regarding the local team who will deliver the trial at site that you wish to make us aware of below:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Thank you for the completing the Site Feasibility Assessment & Registration Form.**

Please return to the **ACCURE-UK 2** Trial Office by post, email or fax:

E-mail: ACCURE@trials.bham.ac.uk Fax: 0121 415 8871

Post: **ACCURE-UK 2** Trial Office, Birmingham Clinical Trials Unit (BCTU), Public Health Building,

University of Birmingham, Edgbaston, Birmingham, B15 2TT

**If available, the following documents should also be sent with the completed assessment form:**

* **Signed and dated CVs for researchers** (PI CV must be within 12 month of opening)
* **Latest GCP certificates when available** (should be within 2 years when site opens)
* **Local Trust headed paper** (electronic version)