

Recruitment procedure and first act of recruitment.

1	How will potential participants be identified? <i>(e.g. publicising the trial or via existing patient lists)</i>
<p>Subjects with moderate to severe ulcerative colitis (UC) will be enrolled by clinicians who are Principle Investigators (PIs) or Sub-Investigators (Sub-Is) for the study. If the PI is also the treating physician, the PI will approach the patient first. If the PI is not the treating physician, the treating physician could refer the patient to the investigator site rather than the site directly approaching the patient.</p> <p>Eligible subjects include adults aged 18-80 with a diagnosis of UC for at least 90 days prior to the Baseline visit. Additionally, subjects must have moderate to severe disease activity at Baseline with a modified Mayo Score (mMS) of 5 to 9 points and Mayo Endoscopic Subscore (ESS) of 2 to 3 points (confirmed by central review). Subjects must also have demonstrated an intolerance or inadequate response to one or more of the following categories of drugs: aminosalicylates, oral locally acting steroids, systemic steroids (prednisone or equivalent), immunomodulators. Subjects must be naïve to Targeted Therapies. Subjects will also need to meet the other pre-determined eligibility criteria as outlined in the protocol.</p>	
2	What resources will be used for recruitment? <i>(Describe the format of the resources, e.g. paper or electronic and how these will be presented to potential participants e.g. via the post, in the clinic, through social media or on the radio; copies of the advertising material, including any printed materials, and audio or visual recordings, should be uploaded in part II application CTIS)</i>
Site staff will review their database for suitable patients and contact them to inform about the study.	
3	Who will be approaching potential participants (or their legal representative) and who will be obtaining informed consent? <i>(Describe the professional role and whether there is a prior clinical relationship with potential participants and how are the interests of the potential participants safeguarded)</i>
Appropriately trained site staff (i.e., Investigator, Study Nurse, Study Coordinator) will be responsible for identifying potential participants and will contact by phone, written communication (letter or email), or during a routine clinic visit. In all scenarios, site staff will discuss details of the study with potential participants. The PI will ultimately be responsible for answering all questions the study participant may have and obtaining informed consent.	
4	How long will potential participants (or their legal representative) be given to decide whether to participate?
Potential participants will be given as much time as needed, but a minimum of 48 hours to review the informed consent, discuss and or ask any questions from the investigator or a member of the research team. By choice, potential participants can discuss the informed consent with friends, family, and general practitioner before deciding to participate. Please note, as the recruitment for this study is competitive, there is no guarantee that enrollment will be open when/if the patient decides to participate. Legally Authorized Representatives (LARS) are not required for this study.	
5	How will be ensured that potential participants (or their legal representative) have understood the information and that consent is informed? <i>(This should include how the informational needs of individuals will be identified and addressed and how this understanding is verified)</i>
The investigator will explain the nature of the study and risks anticipated from participation in the study to the potential participant, and answer all questions regarding this study. Prior to any study- related screening procedures being performed, the informed consent form will be reviewed, signed, and dated by the potential participant, the person who administered the	

<p>informed consent, and any other signatories according to local requirements. A copy of the signed informed consent will be given to the participant. The ICFs will be provided in the local language written to an appropriate reading level for the potential study participant. The site's ability to ensure the participant's understanding of the informed consent will be evaluated as part of the site evaluation process. Legally Authorized Representatives (LARS) are not required for this study.</p>	
6	<p>What arrangements are in place to obtain informed consent from potential participants (or their legal representative) who do not speak the national language (if applicable)?</p>
<p>Informed consent forms will be approved by ethics committees in the local language. Potential participants must be able to understand the informed consent form and to ask questions in discussion with the investigator in local language. Legally Authorized Representatives (LARS) are not required for this study.</p>	
7	<p>Please provide any further information, in relation to the procedure for recruitment and informed consent for the clinical trial, which has not been provided elsewhere in the clinical trial application (e.g specific recruitment and informed consent procedures in an emergency clinical trial)</p>
N/A	
8	<p>Please provide a clear indication of what the first act of recruitment is to recruit potential participants for the clinical trial (advertisement, contact between investigator and potential participant, subject information letter). (If described in protocol, please refer to protocol section; see also CTR, annex I, section K59)</p>
<p>First act for recruitment on the study will be for sites to review their database/own practice and the sites will have the option to choose if they wish to use any recruitment resources offered by the Sponsor. Obtaining informed consent would be the first procedure the patient undergoes related to the study.</p> <p>The EUCTR notification for Start of Recruitment will be submitted when the first subject signs the informed consent.</p>	