



Participant Registration and Randomisation Guidelines for Participating Sites

Participant Approach and Screening Number

- Appropriately delegated site staff should approach a potential participant with the relevant PROFILE Participant Information Sheet & Informed Consent Form localised for their site
- After giving sufficient time for the participant to consider the trial and ask any questions, the PI or designee will obtain written informed consent from participant.
- Each site has a screening/ recruitment log tailored for their site and **every** participant must be added to the screening log once they have consented to the PROFILE trial. The screening log must be completed for participants if they have consented to the trial **even** if participant does not enter the trial.
- The **screening ID** is a 7 alpha numeric character comprising the below:
 1. The first 4 characters are your short site name (e.g. Cambridge = N001)
 2. The following 3 numbers are the participants in ascending order in which they were screened starting with 001
 - E.g. the 10th participant screened at Cambridge would have the screening number **N001-010**
- Refer to **Section 10.1.1 of the current PROFILE Protocol** for screening information.
- The screening number is used as the unique study number for the duration of the study.

Using Sealed Envelope

- Participating site staff that have been delegated to randomise participants on the PROFILE Site Signature and Delegation Log, will be given a log-in to access the randomisation system by the PROFILE coordinating team.
- When you have been set up and trained you will receive an email with a link to sealed envelope and your log in details (email address and temporary password).
- You will be prompted to change your password on your first login, and will need this new password to log in thereafter. If you forget your password you will need to contact an administrator from the PROFILE coordinating team to reset it.
- When you log into the randomisation system you will see a screen. From here you can:
 1. Change your password through My Account
 2. Log out
 3. Click on your role to randomise a participant
- Please refer to the Sealed Envelope website for minimum browser requirements and contact details for any technical issues should the PROFILE office not be available: <http://www.sealedenvelope.com/>

Adding a Trial Participant in Sealed Envelope

- Following the screening visit the trial participant needs to be added to the randomisation system
- Appropriate delegated site staff can add the participant by logging in to the web-based central randomisation system "Sealed Envelope": www.sealedenvelope.com/redpill/PROFILE/ and selecting the "adds a subject" link.
- The following information is necessary for registration of a participant, and are subject to validation checks within the system:
 - Subject screening number

Adding the Biomarker Status to a Trial Participant in Sealed Envelope

- The biomarker status stratification variable will be entered into the system centrally from the coordinating centre.
- Sites will be blinded to the biomarker status.
- The biomarker status will need to have been added to the trial participant record before randomisation can take place.

Randomising a Participant in Sealed Envelope

- When participant eligibility for the PROFILE trial is confirmed the appropriate delegated site staff can randomise the participant by logging in to the web-based central randomisation system "Sealed Envelope": www.sealedenvelope.com/redpill/PROFILE/ and selecting the "Subject" link, selecting the correct trial number of the participant and clicking the "add" randomisation button on the right hand side of the screen.
- The following information is necessary for randomisation of a participant, and are subject to validation checks within the system:
 - Subject screening number
 - Subject initials (first and last only)
 - Subject Date of Birth
 - Mucosal inflammation (mild / moderate / severe)
 - Disease location (colon only / other)
 - Confirmation of inclusion and exclusion variables. (yes/no)
- Sites must complete the required fields in the on line Randomisation Form as stated above in order to randomise the participant and obtain the Randomised Treatment Allocation.
- You will need to enter your password to confirm that the above information entered is correct and then you will be allocated treatment allocation.
- The **Trial ID** is the same as you **screening ID** for the participant.
- After a successful randomisation the following personnel will receive an email confirmation that the participant has been randomised, including details of the participant's Allocated Treatment Number and the participants Trial ID:
 1. PROFILE trial office
 2. Randomiser
 3. Investigators at randomising site
 4. Pharmacist at randomising site
- If for any reason site staff is not able to randomise a participant, please contact the PROFILE office on Tel: 01223 254 666, who will assist, and if necessary can randomise a participant on behalf of the site.

Unblinding a participant in Sealed Envelope

- There is no unblinding to the biomarker status in the PROFILE Trial.