GREAT-2
GRemubamab ErAdication Trial

Discontinuation of Trial Medication
Withdrawal from Trial
Completion of Trial

Discontinuation of trial medication

Trial medication will be discontinued in the following circumstances:

- Pregnancy (a pregnancy notification form must be completed)
- Allergic reaction ≥ grade 3, including anaphylaxis, assessed as related to the trial drug

- Allergic reaction grade: Assessed using Common Terminology Criteria for Adverse Events
  - Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
  - Grade 2 Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental activities of daily living.
  - Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living.
  - Grade 4 Life-threatening consequences; urgent intervention indicated.
  - Grade 5 Death related to AE.

Discontinuation of trial medication – continuation of trial visits

- If a participant has been randomised and given one or more dose of IMP, they will be asked to complete trial visits as per the protocol, to allow for an intention to treat analysis
- Participants are free to refuse to do so.
- The Investigator may discontinue a participant's trial medication at any time, if it is in the best interest of the participant and treatment continuation would be detrimental to the participant's wellbeing.
- The Investigator will make a clinical judgment as to whether or not an adverse event (AE) is of sufficient severity to require discontinuation of a participant's trial medication .
- A participant may also voluntarily discontinue trial medication due to what he or she perceives as an intolerable AE.
- If a participant discontinues trial medication but remains on the study, a Discontinuation of Trial Medication Form should be completed on the eCRF (Repeating Data Form)
- Record on TRuST that participant has Discontinued Study Drugs

Withdrawal from trial – stops all trial activity

- Participants are free to withdraw at any time and are not obliged to give reason(s).
- Discuss with the participant the value to the trial of discontinuing trial medication but continuing with trial follow up rather than withdrawing completely.
- Make a reasonable effort to ascertain the reason(s), both for those who express their right to withdraw and for those lost to follow up, while fully respecting the individual's rights.
- The participant should be offered an end-of-trial assessment.
- If a participant withdraws and does not remain on the study, the Completion of Trial/Early Withdrawal visit should be completed on the eCRF.

Completion of Trial

- Once a participant has completed all trial visits, the Completion of Trial/Early Withdrawal Visit must be completed