Participant name:	
Hospital ID:	
CHI/Date of Birth:	

GREAT-2 GRemubamab ErAdication Trial

Sponsor	University of Dundee-NHS Tayside
Chief Investigator	Professor James Chalmers
IRAS number	1005993

Principal Investigator	
Contact number	
Contact email	

Visit 1 – Screening
to be filed in medical notes as source data

Date of visit: | Participant trial ID | | | | |

Please tick to indicate the following have been completed:

Participant has had the Participant Information Sheet for at least 24 hours	
Confirmed participant's identity	

Method used to confirm participant's identity ……..

NHS lab samples:

Full blood count	
Urea & electrolytes, creatinine	
Liver function tests	
Sputum sample for P. aeruginosa testing	
Serum pregnancy test, if applicable	

Research samples:

Research blood samples	

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Participant name:	
Hospital ID:	
CHI/Date of Birth:	

Vital signs

Height	cm	Weight	kg
Blood pressure	mmHg	Pulse	bpm
Oxygen saturation (room air)	%	Tympanic temperature	°C

Spirometry

What method of bronchodilation was used?

nebulised salbutamol	☐	Dose	mg		
inhaled salbutamol	☐	Dose	mcg	Number of puffs	☐

File copy of spirometry results in notes.

ECG

Please tick:

Normal	☐
Abnormal, not clinically significant	☐
Abnormal, clinically significant	☐

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:

Physical exam

Please tick:

Normal	☐
Abnormal, not clinically significant	☐
Abnormal, clinically significant	☐

If abnormal document abnormality and any actions taken, if any:

Name of doctor making assessment:

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Participant name:	
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Contraception

Is the participant a woman of childbearing potential? yes ☐ no ☐

If female but not of childbearing potential, how has this been confirmed?

Post-menopausal ☐ Date of last period ☐

Permanent sterilisation ☐

If female and of childbearing potential:

Has the participant agreed to either abstain from sexual activity or use a form of a medically approved birth control method? ☐

If male with a female partner of childbearing potential:

Has the participant agreed to either abstain from sexual activity or use a form of a medically approved birth control method? ☐

The following must have source data documented in the medical notes. If not documented elsewhere these should be written in the notes.

- Concomitant medications, file a copy of repeat prescription if available, **ensure this is accurate for what the participant is taking at the time of visit**, update if necessary.
- History of bronchiectasis
- Medical history
- Smoking history (*document figures used for calculation of pack years in medical notes)*
- Bronchiectasis severity index
- Any notable findings and actions taken

The following should be filed in the participant's medical notes:

- Front coloured card/sheet/sticker to state they are a research participant
- Copy of the signed Informed Consent Form
- Copy of the Participant Information Sheet, version which the participant consented to
- Copy of GP letter informing GP of participation
- ECG signed and dated by doctor on delegation log
- Blood results signed and dated by doctor on delegation log
- Pregnancy test results, if applicable, signed & dated by doctor on delegation log
- Sputum results signed and dated by doctor on delegation log
- Spirometry results signed and dated by doctor on delegation log
- If the participant was withdrawn from the trial at this visit, document reason

Any further information of note:

GREAT-2
GRemubamab ErAdication Trial

Participant name:	
Hospital ID:	
CHI/Date of Birth:	

The visit has been carried out as per protocol.

Signature:	
Name:	
Job title:	
Date:	