

# Completion of Screening & Enrolment Logs









### **Participant Identification & Pre-screen**

#### Potential participants identified from clinic lists:

- Clinical team will review the patient's medical notes to see if they are potentially eligible (Pre-screen)
- If identified at clinic, a member of the clinical team will give the patient a copy of the brief Participant Information Sheet (bPIS).
- The clinical team will pass on potential participant details to the RNs
- Potential participant details added to pre-screening log

#### Potential participants identified from locally held databases/SHARE:

- RNs check the potential participants medical notes to see if they meet eligibility criteria
- Check screening log to ensure potential participant has not been approached in clinic
- Database invitation letter and PIS sent to potential participant
- Potential participant details added to pre-screening log







# (Pre) Screening Log







#### SCREENING LOG

VitalBE: Value of inhaled treatment with aztreonam lysine in bronchiectasis							
R&D Protocol ID:	2016RC27	Sponsor:	University of Dundee / NHS Tayside		Principal Investigator:		
IRAS ID:	252929	Chief Investigator:	Professor James Chalmers		Site:		
EudraCT ID:	2018-001590-24	- 88		38			

Date of Screen	Participant Name	CHI/ hospital number	Contact details	Eligible Y/N	If No, Reason for Ineligibility
0 .				50	50









### **Completing of Enrolment and Randomisation Log**

- Only consented participants will be included in the enrolment & randomisation log
- All consented participants will have their details included, and if they are not randomised the reason should be recorded
- CHI/Hospital Number to be used to confirm participant's identity









# **Completion of Enrolment and Randomisation Log**







#### **ENROLMENT & RANDOMISATION LOG**

VitalBE: Value of inhaled treatment with aztreonam lysine in bronchiectasis							
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IRAS ID:	252929	Chief Investigator:	Professor James Chalmers		Site:		
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PARTICIPANT NAME	CHI/ Hospital number	DATE OF CONSENT	RANDOMISED YES/NO	IF RANDOMISED PARTICIPANT ID (Y/N)	DATE OF RANDOMISATION OR REASON NOT ELIGIBLE	RN INITIALS TO CONFIRM ELIGIBILITY CHECKED BY DR ON DEL LOG









## Reporting Screening & Enrolment Figures to Trial Management Team

- TMT will request monthly figures (no identifiable data will be requested, numbers only)
- TMT will compile Screening, Enrolment & Randomisation report for monthly TMG meeting





