

DOCUMENTS TRAINING LOG

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

DOCUMENT	VERSION	DATE READ	INITIAL	VERSION	DATE READ	INITIAL	VERSION	DATE READ	INITIAL	VERSION	DATE READ	INITIAL
Protocol												
IMP Management Plan												
SmPC												
Laboratory Manual												
Operations Manual												
TRuST User Guide												
OpenClinica User Guide												
Trial Medication Guide												
TASC SOP11												
TASC SOP59												

To be completed by each member of the trial team. Read the documents relevant to role. Enter the version number of documents read, date of reading and initial to confirm that you have read, understand and agree to carry out the VitalBE trial according to these documents. **File in ISF section 7.5 / PSF section 6.3** TASC SOPs can be found on the following web pages:
 SOP11 Identifying, Recording and Reporting Adverse Events for Clinical Research <http://www.ahspartnership.org.uk/tasc/for-researchers/sops/safety-and-pharmacovigilance>
 SOP59 Reporting Breaches in Clinical Research <http://www.ahspartnership.org.uk/tasc/for-researchers/sops/research-governance>

DOCUMENTS TRAINING LOG (cont.)

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NAME:	ROLE:						SITE:					

DOCUMENT	VERSION	DATE READ	INITIAL	VERSION	DATE READ	INITIAL	VERSION	DATE READ	INITIAL	VERSION	DATE READ	INITIAL
WPG ECG												
WPG Height & weight												
WPG Nasopharyngeal swab												
WPG Questionnaires												
WPG Spirometry												
WPG Sputum induction												

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TRIAL SPECIFIC TRAINING LOG

VitalBE: Value of inhaled treatment with aztreonam lysine in bronchiectasis

NAME:	ROLE:	SITE:
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DATE	TYPE OF TRAINING e.g person to person, training day, webinar, teleconference, self- directed	TOPICS COVERED	VERIFIED BY e.g. signature, certificate, self- directed
15-05-19	VitalBE Training Day	As per agenda	

To be completed by each member of the trial team.

File in ISF section 7.5 / PSF section 6.3