Ambition Trial Coordinating Centre
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AMBITION-*cm*
AMBIsome Therapy Induction OptimizatioN

Work Practice Document: 20
Quantitative Cryptococcal PCR Sub-study

Title of study	High Dose AMBISOME© on a Fluconazole Backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Phase III Randomized Controlled Non-Inferiority Trial		
Acronym	Ambition-cm – AMBIsome Therapy Induction OptimizatioN		
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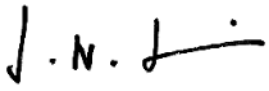
Approved by	Joseph Jarvis CI		21/09/2017

Revision History:		
Version Number	**Effective Date**	**Reason for Change**
1.0		First version

Working Practice Document 20: Quantitative Cryptococcal PCR sub-study

Purpose

This document describes the processes to be followed in study sites where the quantitative PCR (qPCR) sub-study will take place.

Scope

This WPD applies to the schedule and timing for the blood and CSF sampling for qPCR sub-study.

General

1. The aim of this sub-study is to obtain a global picture of the dissemination at diagnosis by using new qPCR methodologies to allow detection of the total nucleic acids of the yeast in various samples (CSF, Blood, plasma).
2. This sub-study will recruit patients from each arm, from two study sites, Blantyre (Malawi) and Gaborone (Botswana).
3. There will be 160 patients recruited from each treatment arm to this sub-study.
4. Accurate documentation of the time of drug administration and of blood and CSF sampling are key to this process.
5. If doses of treatment have been given at the wrong times or omitted, it is crucial that this is honestly documented in the eCRF.

Blood qPCR

1. qPCR studies will take place on D1, D3, D7 and D14
2. 5ml of blood (EDTA tubes) will be taken for each sample
3. Timings of bloods are as follow: D1 – pre-dose, D1 – 23-24 hours post-dose, D3, D7, D14.

CSF qPCR

1. Minimum 1ml of CSF will be taken from the LPs on D1 – pre-dose, D7 and D14 for qPCR studies

Training

Each staff member receives or has direct access to applicable Working Practice Documents (WPDs).

Each staff member reviews the applicable WPDs once a year.

All WPD training is documented and tracked in the WPD training logbook located in the Project Coordinator's office.

New staff is trained on applicable WPDs within 30 days of employment and all WPDs within 90 days of employment.

Staff members whose duties fall within this WPD scope are retrained within 14 days of the approval of each WPD revision.

References

1. Declaration of Helsinki, 2013: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ accessed 12th June 2017
2. International Conference on Harmonisation (ICH) Guideline For Good Clinical Practice E6(R1), 1996
3. Integrated Addendum To ICH E6(R1): Guideline For Good Clinical Practice E6(R2), 2016
4. Ambition Trial Protocol

Staff signatures: (signing below indicate that you have read this SOP and understand the material contained in it)

Date	Name (Please print)	Signature