Working Practice Document 15b:
Daily Clinical Review form completion

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AMBIsome Therapy Induction OptimizatioN

Work Practice Document: 15b **Daily clinical review form completion**			
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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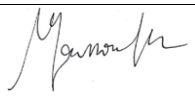
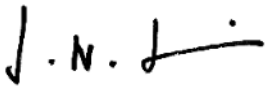
Reviewer(s)	Nabila Youssouf Trial Manager		17/06/2019
Approved by	Joseph Jarvis CI		17/06/2019

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

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Purpose

The purpose of this Working Practice Document (WPD) is to describe the process for completing the daily clinical review form

Scope

This WPD applies to the Ambition trial conducted by the Ambition Trial Coordinating Centre and will be carried out according to applicable aspects of International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) standards

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

Appendices

- Daily Clinical Review form template
- Telephone Review form template

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Procedure

The study doctors are responsible for this daily clinical review form completion. Completed forms will be used as a source document and will be cross referenced with entries on eCRFs.

a. When to complete the form?

1. The form should be completed at Day 1, with all clinically relevant information.
2. The form should then be completed on a daily basis from day 2 to day 14. While the participant is an inpatient, the information source should be the clinical examination, the hospital notes, and ward drug chart. If the participant is discharged before Day 14, a form should still be completed each day up to an including D14. This may be a face-to-face outpatient appointment documented on this form or a telephone call documented on a telephone review form.
3. The form must then be completed at each follow-up visit, scheduled and unscheduled.

b. What to report in this form?

On all forms, information regarding participant's ID, date and time, study day, study arm, and name of the physician should be reported. Clinical examination including vital signs and GCS level should also be reported.

1. **Day 1**

   All clinically relevant information regarding patient's history including the ART history, previous TB history, any opportunistic infection history and all significant diagnosis, as well as recent treatment history since patient's admission should be reported. Clinical examination including day 1 weight should also be transcribed. The result of a pregnancy test, visual acuity, and other relevant investigations should be documented here too.

2. **Days 2-14**
   All relevant clinical examination should be reported, any adverse event, any new drug prescribed or new diagnosis.
   - On each day, the physician should report on this form if any study bloods were taken.
   - On each day, the physician should also report if any lumbar puncture has been performed – either protocol-driven or therapeutic. The CSF opening pressure, volume of CSF removed and closing pressure should be reported here.
   - On relevant days, switch in study drugs should also be reported.

   When you feel a participant is well enough to go home before day seven, but must remain an inpatient as per the protocol, please document this.

3. **Each follow-up visits**
   The form should be completed each time there is an interaction with the participant, therefore it should be completed at each follow-up visit, scheduled and unscheduled. All relevant clinical examination should be reported, any adverse event, any new drug prescribed or new diagnosis and anything of clinical relevance.

c. Where to keep this form?

The form should be kept in participant's trial file.
A copy is also kept in the patient's hospital notes during hospitalisation, or given to the patient or their relatives, once discharged.

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.

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

Date	Name (Please print)	Signature