PODCAST
Prevention of Decline in Cognition After Stroke Trial

PODCAST – Working Practice Document – Closedown

Introduction

To ensure that the PODCAST trial is closed down in accordance with Good Clinical Practice (GCP) and regulatory requirements, it is mandatory for each centre to follow the closedown procedures as described in this document. Due to the number of centres and the resources available, the Sponsor of PODCAST (University of Nottingham) has agreed a procedure to allow the close down of all PODCAST centre remotely using the PODCAST Closedown Checklist (Appendix 1), unless specific issues are identified by the Principal Investigator (PI) or Trial Coordinating Centre to indicate that a monitoring visit will be required.

Purpose of this document

To define the procedure for closing out centres participating in the PODCAST trial and ensure all essential documentation for PODCAST is complete and archived to demonstrate compliance with GCP. To outline the responsibilities of the PI to ensure the requirements have been met.

Scope of this document

This document is applicable to all PIs and principal contacts delegated the responsibility of ensuring that the closedown procedures outlined in this document are carried out in accordance with Sponsor requirements and GCP.

Essential documentation and archiving

It is a GCP requirement that the essential documentation is reviewed prior to the closedown visit (where appropriate);

"Trial master files should be established at the beginning of the trial, both at the investigator/institution site and at the sponsor's office" ICH-GCP-E6

The trial Sponsor Standard Operating Procedure (SOP QA005 Archiving) defines that for a multi centre trial "documents and electronic data should be retained locally to allow reconstruction of the trial at that site. Only one copy of each document needs to be retained. Electronic documents and databases should be transferred onto a suitable storage medium and archived as for paper documents".

Archiving

The trial Sponsor Standard Operating Procedure (SOP QA005 Archiving) states that "archiving of research data shall be for a **minimum of seven years after the date of any publication that is based on them**". For PODCAST Feasibility stage, trial will run until August 2013 so documents must be archived until 2020 In accordance with local archiving protocols. Please note that the PI at each hospital site will need to ensure that responsibility for archiving is delegated to a named individual. The PI is also obliged to notify R&D in any

change of ownership of the Investigator Site File (ISF). Audits by trial sponsors, competent authorities or local boards can occur for this trial for the duration of the archiving period.

End of randomisation

The last day of randomisation for PODCAST is 31st January 2014. The web randomisation will be closed to recruitment at midnight (24:00hours; GMT) on this date. Close down of PODCAST will be performed after the final follow up 31st August 2014.

A centre will not be closed until all trial data, scans and queries have been received for all patients randomised into the trial. Any final per patient payments due will only be paid once all documentation is received.

Closedown procedure

The attached PODCAST Closedown Monitoring Checklist must be completed, signed and returned to the trial-coordinating centre to confirm that all the essential documentation is present and ready to be archived at your site.

The PI is responsible for all patient related data, regulatory and trial correspondence and patient records being archived appropriately. The responsibility may be delegated but the list must be checked and signed off by the PI.

Each section of the checklist must be completed and outstanding tasks dealt with (e.g. medical records marked with a PODCAST label).

Every attempt should be made to ensure that all missing documents are found and present in the file before archiving. If a document is deemed to be unrecoverable a file note to state this should be added to the section.

Once the end point of the trial has been reached, the PI must notify R&D or any other appropriate bodies.

Please note that whilst we intend to ensure that all data checks are complete prior to closedown, please be aware that there may still be some outstanding queries that will require your attention after the closedown paperwork has been submitted. We will do our best to ensure that these are, if any, kept to a minimum.

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PODCAST Closedown Monitoring Checklist

This must be completed and signed by the PI and returned to the Trial Coordinating Centre to complete closedown for the trial. Each item must be initialled. Once completed and signed, this checklist provides documented proof that all activities required for your centre closedown are completed and copies of all essential documents are held in the appropriate files in accordance with Good Clinical Practice and sponsor requirements.

Centre Name **Centre Number:……** **Name of PI:……**	**Number of PODCAST Patients recruited:……**			
Investigator site file requirements	**Comments**	**Initial**		
Essential documentation required for closedown and archiving		YES	NO	N/A
INVESTIGATOR SITE FILE contains:				
• Contact details of trial office & emergency numbers.				
• Completed Signature log to include end dates of all investigators				
• All investigator CVs signed & dated (updated at least 2-3 yearly)				
• Signed & dated current protocol (and any relevant amendments)				
• Relevant archived protocols.				
• All current PIS/IIS and consent forms				
• Relevant archived PIS and consent forms				
• Current GP letters				
• Archived GP letters				
• Local R&D approval letters				
• Copies of correspondence with Ethics and approval letter for trial				
• Sponsor letters				
• Insurance letters				
• Signed contract				
• Site monitoring reports				
• Annual reports (R&D)				
• Clinical trial final report. (The trial site will be closed before the report is available. Please confirm that the report will be added to the file.)				
PATIENT FILES all contain:				

• CT/MR/carotid reports				
• CRFs				
• Any completed SAE forms				
• Data correction forms (where applicable)				
• File notes (where applicable)				
• Source documents (medical records for all trial patients have been labelled that the patient is in PODCAST trial and will be required to be archived)				
• Patient details form (may be stored separately)	If stored separately, where…… …… …… …… ……			
• Consent forms (may be stored separately)	If stored separately, where…… …… …… …… ……			
DATA ENTRY is completed for all:				
• CT/MRI scans (Sent to PODCAST Centre)				
• SAE forms (if applicable)				
LABORATORY (if applicable)				
• Blood sample freezer log completed				
• All blood samples sent to Coordinating centre				
MISCELLANEOUS				
• OMRON machines returned to Coordinating Centre or disposed of/retained at site. **(please note that if OMRON machines are disposed or retained, the University of Nottingham takes no responsibility of the equipment).**	Date sent:…… …… …… …….			

I can confirm that all queries relating to any trial participant involvement have been resolved and all essential documentation is in place before archiving.

Principal Investigator Signature: ……

Name (block capitals): ……...

Signature of those who have initialled work as completed:

Name	Signature	Initials	Date
…….	……...	…….	…….
…….	……...	…….	…….
…….	……...	…….	…….
…….	……...	…….	…….

Please list PI Name and all co-investigators to be listed on the PODCAST final paper

Name	Role	Current email address