Data Management Plan Version 1.11

Study Title:	Functional Strength training for upper limb recovery after stroke
Study name:	FAST_INDICATE
Protocol No./Trial Registry No.:	N/a
Protocol Version No.:	Version 7.3 15 May 2015
Effective date:	14/03/16
Sponsor	University of East Anglia

Approval

Version 1.11

Prepared by:	Lorna Gillespie	Signature	Date
Approved by:	Sharon Kean	Signature	Date
Client review	Nick Leavey	Signature	Date

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1. Introduction

Overview

The aim of this document is to describe the roles, responsibilities and activities of the Robertson Centre for Biostatistics (RCB) as the Data Centre for the FAST INDICATE study commissioned by the University of East Anglia . All procedures and applications used will be in accordance with the RCB SOPs which are in accordance with current regulations.

1.2 Definitions and Acronyms

AE = Adverse Event
ARF = Amendment Request Form
CI – Chief Investigator
CPT = Conventional Physical Therapy
CRF = Case Report Form
CTM = Clinical Trial Manager
DM = Data Manager
DMEC = Data Monitoring and Ethics Committee
DMP = Data Management Plan
Data Validation Plan = Outline of data validation testing as detailed in the Data Validation Specification
Data Validation Specification = details of all data validation checks
DQF = Data Query Form
DSMB = Data & Safety Monitoring Board
FST = Functional Strength Training
ICH = International Conference on Harmonisation
IMP = Investigational Medicinal Device
ISD = Information Services Division
IVRS = Interactive Voice Response System
MQ = Manual Query
MRI = Magnetic Resonance Imaging
PI = Principal Investigator
QC = Quality control
QA = Quality Assurance
RCB = Robertson Centre for Biostatistics
SAE = Serious Adverse Event
SAP = Statistical Analysis Plan
SOP = Standard Operating Procedures
TMG = Trial Management Group
TMS = Transcranial Magnetic Stimulation
TSC = Trial Steering Committee

23 Personnel & Responsibilities

2.1 Overview

2.1.1 Sponsor

University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ, UK

2.1.2 Data Centre

The Robertson Centre for Biostatistics (RCB), University of Glasgow, Glasgow G12 8QQ will be known as the study Data Centre.

2.1.3 Project Co-coordinating Centres

Glasgow Clinical Trials Unit, University of Glasgow and Greater Glasgow & Clyde Health Board, Tennent Building, 38 Church Street, Western Infirmary, Glasgow G11 6NT

Norwich Clinical Research Trials Unit, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ, UK

2.2 Data Centre

2.2.1 Data Centre Data Management Group (DMG)

Liz Anderson	Director Projects Administration
Sharon Kean	Director Information Systems
Dr Sarah Weeden	Project Manager
Lorna Gillespie	Lead Clinical Data Manager
Isobel Docherty	Data Manager
June Allan	Administrative Data Manager

Key project Contacts:

Michele Robertson	Lead Statistician

2.3 Study contact details

Chief Investigator:

Professor Valerie M Pomeroy
Professor of Neurorehabilitation
Director of Research, School of Allied Health Professions
Acquired Brain Injury group
Faculty of Medicine and Health Sciences
Queen's Building
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

Study Site co-coordinator:

Nick Leavey
School of Health Sciences, Room 1.21, Queen's Building,
University of East Anglia,
Norwich Research Park,

Norwich, NR4 7TJ
Email: [redacted]
Tel: [redacted]

Sponsor Personnel:

Dannelle Breach,
Project Officer
HSC
REN: Research & Enterprise Services
University of East Anglia,
Norwich Research Park,
Norwich NR4 7TJ
[redacted]

3 Study Details, Communication & Timelines

3.1 Study Objectives

To determine: the relative efficacy of FST+CPT and CPT+CPT; the neural correlates of improvement in response to FST+CPT and CPT+CPT; whether any one or combination of baseline measures predict improvement in motor function in response to FST+CPT or CPT+CPT; and estimate of cost-effectiveness to inform a subsequent definitive clinical trial.

3.2 Study Design

Randomized, controlled, observer-blind, 2-group multi-centre efficacy trial with embedded explanatory measures.

3.3 Data Analysis Plan

The Statistical Analysis Plan (SAP) is the responsibility of the study statistician.

3.4 Study timelines

See study details on Data Centre SharePoint site . GANT chart maintained by Nick Leavey.

3.5 Study communication

External communication will be mainly by email. Any significant decisions made during telephone conversations should be documented in an email from the Robertson Centre and sent to the client for confirmation. Teleconferences should be documented using the RCB meeting report template unless minutes of the meeting are to be supplied. These should be filed in the Data Management folder.

4 CRF Design

4.1 CRF design

Data capture is based on a paper CRF. The study CRF has been designed by the RCB according to SOP 06.001 and was fully reviewed prior to release by both Data Management and Statistics (SOP 06.002). The current version of the CRF in use is Version 1.1.

4.2 CRF revisions

Revisions of the CRF will be dealt with according to the CRF design guidelines (SOP 06.001, 06.002)

5 Data Sources

The Data Centre will be responsible for accumulating, reviewing and reporting on data from a number of primary and secondary sources.

5.1 Primary data sources

The primary sources of data arise from:

a. Paper copies of study Case Report Forms (CRFs) completed at study site

5.2 Secondary data sources

Secondary sources of data arise from:

a. Database Amendment Requests
b. Responses to Data Queries

5.3 External data sources

The data centre will be taking receipt of third party data including the results of the following tests/procedures:

1. Transcranial Magnetic Stimulation (TMS)
2. Functional MRI
3. Structural MRI

Note: It is expected that the data centre will receive the final scores/data and not the raw source data

Data received by the Data Centre from external source/s will be logged and uploaded to the study database. These data will be considered to be a *copy* of the validated source data and any amendments must be made to the source data and the file/s resubmitted to the Data Centre.

6 Study setup

6.1 Overview

The study setup will begin at the Study Setup meeting at which the major project details, milestones and roles and responsibilities will be outlined and recorded in the Project Management documentation. A standard set of study folders will be created on the RCB filestore and both a test and 'live' database will be created. Project Management will be organised through a dedicated SharePoint Site which can be accessed by all members of the RCB Project Team.

6.2 Database setup

Details of the study database design and testing are held in the study setup folders according to SOPs 07.001, 07.011 and 07.013. The study database will reflect the structure of the study CRF and each data table will be created, tested and validated and authorised in the test database before release to the live

system. The data dictionary will contain the following information and the current version will be available on the Data Centre filestore.

- Variable names
- Variable data types
- Derived data fields
- Data validation checks

The table structure and data processing issues are outlined in Appendix 1.

6.3 Study Identifiers

6.3.1 Subject Identifiers

A unique 6 digit Participant (screening) number will be allocated to each subject at the screening visit and will be used to identify the subject throughout the trial. The first 2 digits are unique to the study researcher doing the screening, and the last 4 digits are allocated sequentially by study researcher. If participant fails the screening process, they may be invited to return for re-screening. Note: a new screening number will be generated for each round of screening and any previous screening numbers will be recorded on the CRF. A randomisation number will be allocated via the IVRS and will be applied to the header on each page of the CRF.

6.3.2 Site numbers

There are 3 participating sites in the study:
Birmingham – Site 1
Norfolk – Site 2
Staffordshire – Site 3

6.3.3 CRF Identifiers

Site number, Screening Number, Randomisation Number and Initials. Each CRF type will be identified by a form name and visit number (where appropriate).

6.3.4 Data Item Identifiers

Each data field will be given a name which identifies the data item on the CRF according to SOP 07.011. An annotated CRF maps the item on the CRF to the database variable.

7 Monitoring

7.1 Level of monitoring prior to delivery of CRFs to data centre

Timelines for monitoring and receiving CRF pages will be expected to be timely i.e. should be sent to RCB as soon as possible after monitoring has taken place. The current agreement is for data to be sent on or around the first Monday of the month. Initially, all CRFs will be reviewed by the CTM.

8 Recruitment

288 participants will be recruited from the 3 sites. If informed consent is obtained, the patient will be screened and if suitable will be invited to return for the baseline visit at the end of which the participant will be randomised if eligible to participate in the trial.

9 IVR system

9.1 Overview

The IVR system (IVRS) will be a touch-tone telephone system which will allow trial sites to:

Randomise a subject
Review a subject

There is no requirement to monitor the system 24/7.
Further details can be found in Appendix 4.

9.1.1 Randomisation

A call must be made to the IVRS to randomise each subject. The system will allocate a treatment for the participant
An email with the participant's site number, screening ID, randomisation ID, and date of randomisation will be sent to CTM at the time of each randomisation.

10 Data Entry and processing

10.1 Overview

The Case Report Form (CRF) consists of demographics, medical history, eligibility test results, Eligibility criteria, functional test results, neuro-imaging status, TMS results, Randomisation details, Intervention details (CPT or FST), Resource use questionnaire, Pain/fatigue form, Adverse Event report, carer form, SAE report and withdrawal form

10.2 CRF Transfer to Study Data Centre

- Prior to transfer to the Data Centre, the CRF pages must be removed from the subject's binder, photo copied single sided and organised into batches accompanied by a CRF Transfer Forms (see Appendix 2).
- Where possible, all CRF pages for a given visit should be sent in the same batch. Forms for more than one visit can be sent in the same batch. Multiple screening visits are possible and screening visits will normally only be received accompanied by the baseline visit unless the subject is not suitable for inclusion in the study.
- CRF pages should be sent to the Data Centre as soon as possible after any required monitoring by courier or recorded mail.

10.3 Receipt and transfer form check at Study Data Centre

10.3.1 CRF checking

CRF pages will arrive at the Study Data Centre along with a Transfer Form and transferred to the Data Processing department where they will be placed in the study specific area. The completed Transfer Form information will be compared with the CRF pages received and any discrepancies will be flagged to the

study site or via the monitors. Each CRF page attached for a subject will be checked to ensure all header information is complete and consistent and any discrepancies will be queried. If the information can be clearly identified from the other pages received then a working copy of the affected page/s will be made with the correct values to allow them to be processed. A query will be sent to obtain confirmation. The CRFs will also be checked for legibility and will be returned to site if illegible. Any subject identified CRFs will be returned to site immediately after working copies with any identifying information redacted are made to ensure processing of these forms is carried out.

10.4 Preparation for processing

All CRF pages will be scanned and logged using the RCB Document Management software.

Each CRF page will form part of a data processing batch. Each batch will be allocated a unique batch number and will contain a manageable number of CRF pages from several subjects, for a particular visit or CRF type.

10.5 CRF Data Entry

Batches of CRF pages will be entered and verified by a separate operator and a record of the entry details will be stored electronically. Numerical data are entered by the first operator and entered (blind) by the second (verifier). Any discrepancies are adjudicated by the verifier. Text data are entered by the first operator and the verifier makes a visual review of this and it is either accepted or updated. Data files generated at entry and verification are automatically archived by the Data Entry application and the verified data file uploaded into the Study database.
There are no study specific Data entry guidelines and all CRFs will be entered as seen. The batches will then be re-assembled into subject 'packs' and stored in locked cabinets in a restricted access room.

10.6 Data Amendment Forms

10.6.1 External amendment requests

A Data Amendment form (ARF) (see Appendix 3) will be used by the investigator, his/her designee or the study monitor to request a change to a CRF page that has already been sent to the Data Centre. These forms, each with a unique identifying number, will be reviewed by the Data Manager on receipt at the Data Centre, compared with queries already generated, and acted on as appropriate.

10.6.2 Internal amendment requests
An internal Data Amendment form (ARF) will be completed by the data manager for any data entry errors that require data updates to be made. All amendment requests will be checked and authorised prior to the database being updated.

10.7 Database Updates and Audit Trail

All changes to the study data will be authorised and a reason for the change given. Changes will be initiated by a resolved query or a database amendment request or internally via a change request. Details of all changes to the data will be stored electronically and the database record will be archived prior to any change to provide a complete audit trail. (SOP 07.015)

11 Data Validation

11.1 Validation of Study CRF data

Validation checks will be created and run using the Data Dictionary application. Checks will include missing data, out of range values, illogical entries and invalid responses. Cross form checks comparing data items across different forms will also be performed. Details of the validation checks are documented in the study Data Validation Specification. Ranges will be agreed with the client and will be documented in the Validation Specification.

11.2 Validation Plan

The data checks detailed in the Validation Specification will be tested by (a) reviewing the Validation Specification against the CRF and (b) reviewing the Query Review output produced from the test data. All discrepancies will be reported, reviewed by the Lead Data Manager and any revisions re-tested.

11.3 Query generation

11.3.1 Automated Data Queries

Data validation will be carried out at intervals dictated by the receipt of data but will normally be within 2 working days after data entry Failed validation checks will generate reports for review by a Data Manager. Each failure will be classified as a query, data entry error, do not query, invalid query or other reason.

Queries will normally be sent by email to the Study Coordinator within one week after receipt of CRFs . Data entry errors will be updated by the completion of an internal ARF.

11.3.2 Manual queries

Manual queries (MQ) may also be raised to enable other data issues that might arise to be queried (see Appendix 6 for a sample MQ).

11.4 Query Management

Queries will be produced from validation and cross form checks. The maximum number of queries per Data Query Form (DQF) will be one and each DQF will be uniquely identified by a sequential umber. (See Appendix 5 for a sample DQF) Manual Queries (MQ) will be generated when required. (see Appendix 6 for a sample MQ). DQFs & MQs will be sent by e-mail as pdf files to the CTM.

11.4.1 Query resolution at site

All resolved queries will be returned to the Data Centre – by email or post. One copy only should be returned to the Data Centre, a copy must be kept at site and a copy held at GFA.

11.4.2 Data Centre

Emailed queries will be logged in the Document Management System and printed out for review. Hard-copy queries will be scanned and logged using the Document Management System.

Resolved queries will be reviewed against the current data and marked-up where data updates are required. The marked-up queries will be reviewed by a second Data Manager and the updates made (see Section 10.7).

Queries will be tracked by the Data Centre and routine reports will be issued as required for outstanding queries that require resolution. Query tracking reports will be available by email.

11.5 Allowable Changes

Defined in the Allowable Changes document

12 Medical Coding

Medical coding will be carried out by trained personnel within the RCB according to SOP 07.006 and the General Coding Guidelines and will be subject to Quality Control procedures.

12.1 Study Specific Coding guidelines

None

12.2 Coding Medical Conditions

Data Sources:

- Adverse Events
- Serious Adverse Events

Note: The same version of the dictionary will be used throughout the study.

13 Safety data

13.1 Safety reporting

The study does not involve IMP and no safety reporting to the authorities is required.

14 Quality Plan

14.1 Quality control

Quality control procedures will be in accordance with the Data Centre's Standard Operating Procedures (SOP 13.005). QC is done at regular intervals and each QC batch is given a unique identifying number. The QC output will be reviewed by the QC committee along with error rate reports and any deviations from the RCB standard (error rates >0.1%) may result in additional checks being made. Data Entry errors identified during query review will also be updated and reviewed by the QC committee.

14.2 Quality Assurance

Quality Assurance will be carried out throughout the course of the study.

14.1.1 Database creation

The design and testing of a new study database will be reviewed and approved by a senior member of the project team prior to release.

14.1.2 Query production

- The validation checks will be checked and approved as part of the Database Design phase
- Any changes to the validation checks during the course of the study will be approved by a senior member of the Data Management team.
- The query output will be QC'd for consistency and correctness of the coding procedure

14.1.3 Routine DM checks

The following are checks that do not form part of the routine data validation procedure and will be reported on the Centre's AdHoc report:

General DM checks

- Checks for duplicate records
- Checks for missing forms/CRF pages

Study specific data checks

Additional data management checks that do not form part of the routine data validation procedure will be carried out routinely e.g. Unscheduled and repeat visit date checks

14.1.4 Metrics gathering

The following metrics will be gathered to assess quality of the data capture.

1. Form processing metrics
2. Query processing metrics
3. Data entry error rates

14.1.5 End of Study QA

A full review of 5% of subjects CRFs will be carried out which will include all change request forms and queries. A detailed list of all CRFs, database updates and amendment requests will be checked against the stored patient CRF. The resulting report will be reviewed by a senior member of the Data Management Team and any actions resulting will be documented.

14.3 Problem reporting

Data issues and problems will be reported on a series of Data Centre Doc Notes. Each will be uniquely identified and indexed and stored in the Doc Note section of the Data Management folder and electronically in the study diary on the filestore. All will be reviewed by a senior member of the DMG. All other issues identified during the study will be recorded on a Data Management filenote. All filenotes will be recorded in the filenote index, copied with the original filed sequentially in the filenote section of the Data Management Folder and the copy in the relevant section of the Data Management folder.

15 Reporting

The Data Centre will provide the following reports to the client via email on request.

Processing metrics

- Number of CRF pages received
- Number of forms entered

Query metrics

- Number of queries issued by type
- Number of queries outstanding

Quarterly Reports will be made available for the TMG, TSC and DMEC. For such reports a minimum of 28 days notice will be provided. The CTM and CI will discuss the requested contents of these reports with the various committees but should include blinded 132andomization data, AE data, and a data summary on protocol compliance and data completion and quality.

For the DMEC, which will initially meet 6-monthly, an un-blinded version of the above should also be made available and sent directly from a RCB representative to the members of the DMEC. Details of such members and the dates of meetings will be provided by the CTM

16 Database Management & Security

16.1 Maintenance of user roles and access

16.1.1 RCB Database access

Access to the study database is restricted. User access is requested using the FAST INDICATE User Access request form which is held in study folder on filestore. These forms include a section where the type of access required can be specified

16.2 Database backup

The Data Centre will be responsible for the design, production, maintenance and back-up of the CRF database (see Section 20.4). This will include other applications that are required to manage the study data.

16.3 Modification to study database

Any change to the study database or any other data problem will be recorded on an RCB Doc Note which is identified with a unique, sequential number and is subjected to testing/review where required and authorised by a senior member of the DM team. All Doc Notes should be listed in an index to allow ease of review.

17 Study Closedown

17.1 Study closedown and database backup

Study closedown will be carried out in accordance with SOP 07.017.

17.2 Study specific closedown issues

Closedown issues will be defined on the study closedown checklist which will be created as part of the study closedown process.

17.3 Archival

Archiving will be done in accordance with SOP 07.018.

17.5.1 Study Database Archive

A copy of the final database, in an agreed format, will be provided by the Data Centre to the sponsor at the close of the study (see Section 19.2).

17.5.2 Study CRF Archive

Study CRFs will be returned, from the Data Centre, to the sponsor at the close of the study for appropriate archival.

18 Internal Audit Plan

The Study system and its documentation will be audited according to the RCB audit schedule but should occur during the active phase of the study in accordance with SOP 12.001. Aspects of the study may come under other audit schedules relating to tasks e.g. coding, data entry.

19 External data transfers

19.1 Ad Hoc requests

Requests for data will be made by email to a member of the Data Management Group. The transfer will be documented in accordance with SOP 07.008 and the relevant document templates completed and approved by a member of the Senior Management Team.

19.2 End of Study Database Transfer

The study database will be exported to the sponsor in a format to be determined. Documentation will be provided and the export will be in accordance with SOP 07.008.

20 Software

20.1 Data Entry

SPSS Data Entry Module will be used for data entry, and data entry output data files will be stored as ASCII comma delimited text.

20.2 Data management

20.2.1 Study Database

Microsoft SQL Server 2000 will be used for data management.

20.2.2 Data Management Applications

All significant DM applications will be developed in-house. Microsoft Visual Basic and Visual Basic.Net will be used for applications development.

Current applications in use:

- Data Dictionary application (ver 2.3)
- Manual query application (ver 1.21
- Database Update application (ver 1.61)
- Form Processing application (ver 1.23)
- Coding application (ver 1.1)

20.3 Statistical Analysis

See the Statistical Analysis Plan (SAP).

20.4 Backup policy

The study database will be backed up daily. Tapes will be stored in a fire-proof safe every two days and stored off-site every seven days.

21 Computer Hardware & Operating Systems

21.1 Computer hardware

All computer hardware will be based on IBM PC compatibles.

21.2 Operating Systems

All operating systems will be from the Microsoft Windows 2000/XP family.

21.3 Documentation

The Data Centre will maintain its own Standard Operating Procedures and other documentation as is required for compliance with standards detailed in the ICH Guideline for Good Clinical Practice.

22 Standard Operating procedures

The SOPs adhered to are available on request.

23 Referenced documents

Allowable Changes document

Document History

Version	Date	Description
Draft 1.0	16/08/2012	Initial creation
Draft 2.0	05/09/12	Incorporating SW comments & discussion with client
Draft 3.0	10/10/2012	Incorporating updated IVRS worksheet and Transfer form
Draft 4.0	05/12/12	Incorporating client feedback
Version 1.0	07/03/13	Release
Version 1.1	14/03/16	Minor changes: Study contacts and addition of SAE data to coding
Version 1.11	04/04/16	Change to Sponsor contact.

Appendices

Appendix 1 Database details

	Form name	Pages	Template name	Visit/s
1	Visit 1, Screening	1-7	V01	1
2	Visit 2, ARAT	1-2	ART	2-4
3	Visit 2, Grip Force and Pinch Force	3-4	GPF	2-4
4	Visit 2, WMFT	5-6	WMF	2-4
5	Visit 2, EQ-5D	7-8	EQ5	2-4
6	Visit 2, Randomisation	9	V02	2
7	Visit 2, Neuro-imaging	10-11	NUI	2-3
8	Visit 2, TMS	12-17	TMS	2-3
9	Visit 3, Assessor Rating	7	ASR	3-4
10	Visit 3, Resource Use Questionnaire	12	RQ1	3-4
11	Visit 3, Resource Use Questionnaire	13	RQ2	3-4
12	Visit 3, Resource Use Questionnaire	14	RQ3	3-4
13	Visit 3, Resource Use Questionnaire	15	RQ4	3-4
14	Visit 3, Resource Use Questionnaire	16	RQ5	3-4
15	Visit 3, Resource Use Questionnaire	17	RQ6	3-4
16	Visit 3, Resource Use Questionnaire	18	RQ7	3-4
17	Visit 3, Resource Use Questionnaire	19-21	RQ8	3
18	Adverse Events		ADV	
19	Withdrawal/End of Study		EOS	
20	Additional Carer Form		ACF	
21	Admission/Discharge Information		ADI	
22	Clinical Team-Delivered CPT	1	CDC	
23	Researcher-Delivered CPT	1-2	RDC	
24	Researcher-Delivered FST	1-2	RDF	
25	Pain and Fatigue	1-2	PAF	

Appendix 2 Sample CRF Transfer Form

Robertson Centre for Biostatistics

FAST INDICATE Study **CRF Transfer Form** Site No. _____

Version_1

Transfer Form No. _____

The following completed Case Report Forms (CRFs) were dispatched to:
June Allan, Robertson Centre for Biostatistics, Level 11, Boyd Orr Building, University of Glasgow, University Avenue, Glasgow G12 8QQ

By _____ (signature) on _____ (date)

Note: 1. PLEASE INSERT A ONE (1) FOR EACH SET OF COMPLETED CRFS SENT AND A ZERO (0) FOR CRFS NOT BEING SENT

2. FOR CRFS WHICH ARE BEING SENT BUT HAVE NOT BEEN COMPLETED, PLEASE INSERT B (FOR BLANK) – ALL HEADER INFORMATION MUST STILL BE COMPLETED ON THESE CRFS

3. FOR CRFS WHICH MAY BE SENT IN MULTIPLES *(E.G. ADVERSE EVENTS) PLEASE RECORD THE TOTAL NUMBER OF PAGES SENT

	Screening No.	Random No.	Visit 1, Screening - Pages 1-7	Visit 2, Baseline - Pages 1-17	Visit 3, Week 6 - Page 1-29	Visit 4, 6 Month follow-up Pages 1-18	Adverse Events*	Pain and Fatigue*	Clinical Team-Delivered CPT	Researcher –Delivered CPT Pages 1+2	Researcher-Delivered IST Pages 1+2	Additional Carer form	Admission/discharge Information	Withdrawal/End of Study
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														

Please detail any problems and/or discrepancies noted at Robertson Centre:

The above CRFs were received at the Robertson Centre by:

_____ (signature) on _____ (date)

Please email completed form back to: Andrew Walker Email: Andrew.Walker@uea.ac.uk

Appendix 3 Sample Data Amendment form

FAST INDICATE Study Amendment Request

Randomisation Number ☐☐☐☐ Subject Initials ☐☐☐ Date of Completion ☐☐/☐☐/☐☐ (D D / M M / Y Y)

CRF Type ARF No #####

Visit number ☐ Page No ☐☐	Adverse Events ☐ Page No ☐☐	Withdrawal / End of Study ☐	Additional Carer Form ☐ Page No ☐☐	Admission/ Discharge Information ☐ Page No ☐☐
Clinical Team-delivered CPT ☐ Form No ☐☐	Researcher-delivered CPT ☐ Form No ☐☐	Researcher-delivered FST ☐ Form No ☐☐	Pain and Fatigue ☐	Resource Use Questionnaire ☐ Visit No ☐☐ Page No ☐☐

Question:	Change from	Change to
Reason:		

Question:	Change from	Change to
Reason:		

Data Centre Use only:

Table name	Record No.	Field ID	Change to	Review by+date	Auth. by+ date

Raised by (tick one) Study Site ☐ 1 Sponsor/Monitor ☐ 2 Data Centre ☐ 3

Signature (Requested) & date

Robertson Centre for Biostatistics
Glasgow Clinical Trials Unit
Doc Ref: Form_07.010AG Amendment Request template V2.0

Appendix 4 IVRS sample worksheet – V1.1

FAST Indicate Study worksheet: Randomisation

IMPORTANT:
- Please ensure that you have gathered all information required before making a call to the system.
- Steps will proceed sequentially unless otherwise noted.

IVRS NUMBER: 0141 337 4199

Step	*Voice Prompt*	*Data values*	*Value entered*
1	**Welcome to the FAST Indicate Study IVRS**		
2	**Please enter your Site ID**	Site ID	☐☐
	The Site ID will be checked for validity. If the Site ID does not exist an error message will result: *"The Site ID you entered was not recognised. Please try again."* and step **2** will be repeated.		
3	**Please enter your PIN**	PIN	☐☐☐☐☐
	Your PIN will be checked for validity. If the PIN does not exist in the system an error message will result: *"The PIN you entered was not recognised"* will play and you will be sent back to the start of step **3**.		
4	Menu options **To Randomise a patient, press 1**	Menu choice	1
5	**Please enter the Screening Number of the patient that you want to randomise**		☐☐/☐☐☐☐
	• If an invalid response is given then the message *"You entered an invalid value. Please try again."* will play and you will be sent back to the start of step **5**. • If a valid Screening Number is entered and it has not already been randomised then proceed to step **6**. • If a valid Screening Number is entered ***but it has already been randomised on the system*** then the message *"The Screening Number you entered has already been randomised. To randomise a patient with a different Screening Number press 1 or press any other button to end the call."* will play. Pressing 1 in response to this message will return you to the start of step **5**. Any other button will end the call.		
6	**Please specify the Time After Stroke:** **Press 1 for <= 30 days** **Press 2 for 31-60 days**	Time After Stroke	☐
	Range: 1 (<=30 days) or 2 (31-60 days) If an invalid value (non-numeric) or out of range value is entered you will be notified and asked to repeat this step.		
7	**Please specify the patient's ability to use paretic upper limb as assessed by 9HPT:** **Press 1 for "1 peg or less (in 50 seconds)"** **Press 2 for "2-8 pegs (in 50 seconds)"**	9HPT	☐
	Range: 1 (1 peg or less) or 2 (2-8 pegs) If an invalid value (non-numeric) or out of range value is entered you will be notified and asked to repeat this step.		
8	**You have now entered all values required to randomise the patient. Press 1 to continue with randomisation;** **Press 2 to review all the values you have just entered; or** **Press 3 to end the call without randomising**		Enter: 1, 2 or 3 as appropriate
	Instructions: Pressing 1 will take you to step **9**. If any errors occur at the randomisation step a message will play back with specific details of the error and the call will then end. Pressing 2 will play back a summary of all the values you entered above. The option will then be given to go back and re-enter the values again (Option 2) or to continue with the randomisation process (Option 1). Selecting 2 will return you to step 5, selecting 1 will proceed to step 9. Pressing 3 ends the call Range: 1, 2 or 3		

9	**The patient with Screening Number ☐☐/☐☐☐☐ has been successfully randomised and has been allocated:** **Randomisation Number ☐☐☐☐** **with treatment group ☐ CPT + CPT** **☐ CPT + FST**		
10	**To hear this information again press 1 or press any other button to end the call**		Enter: 1 to hear details in 9 again; any other button to end the call
	Range: 1 – hear again; any other button – end call		
11	**Thank you for calling goodbye**		

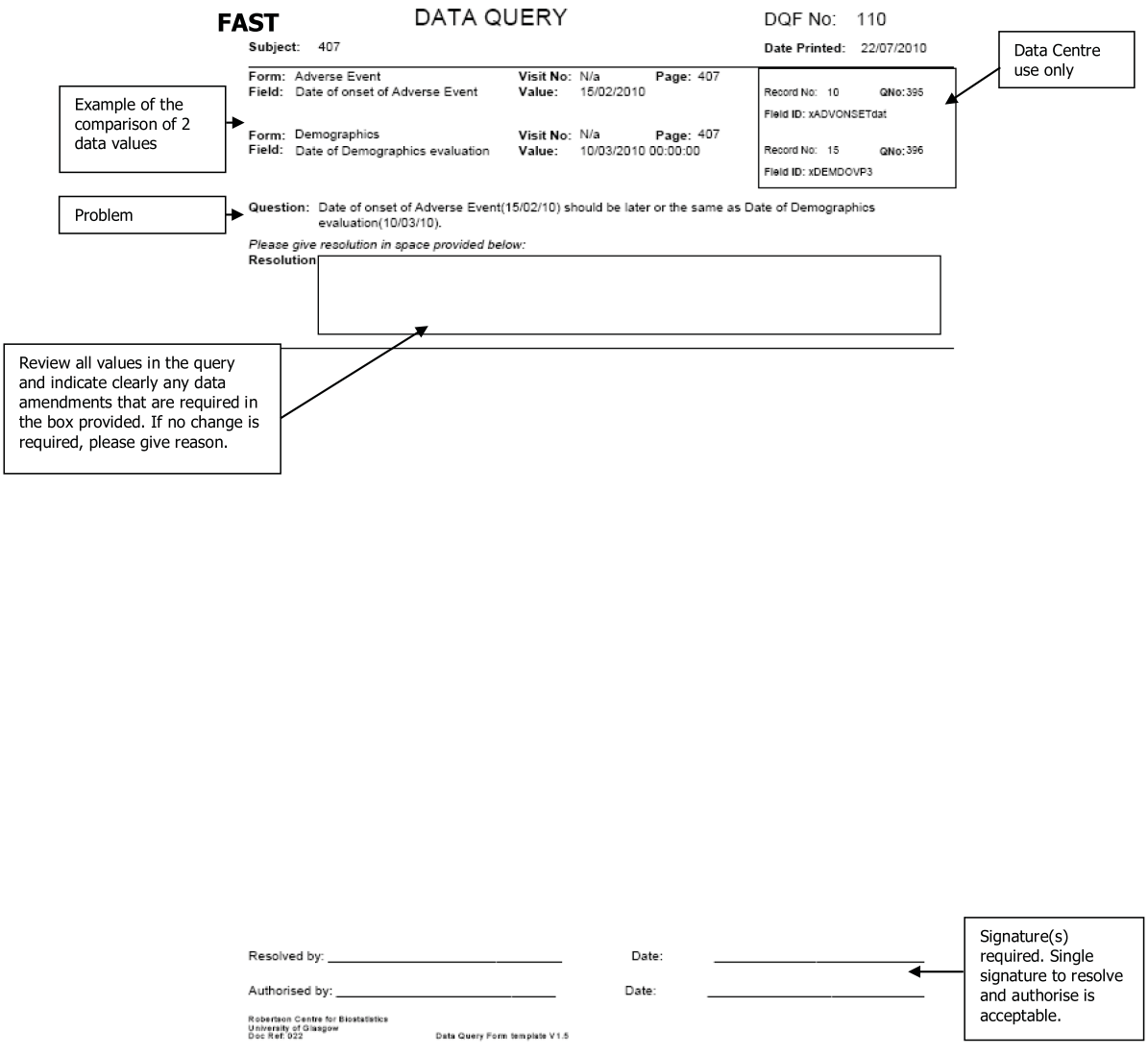
Errors:
If the call error allowance is exceeded during a call then the caller will be played the message *"The maximum number of acceptable call errors has been exceeded, the call will now end"* and the call will end.

If a system error is encountered a message will play to notify you of this. If this problem persists please contact the Robertson Centre for Biostatistics for additional help.

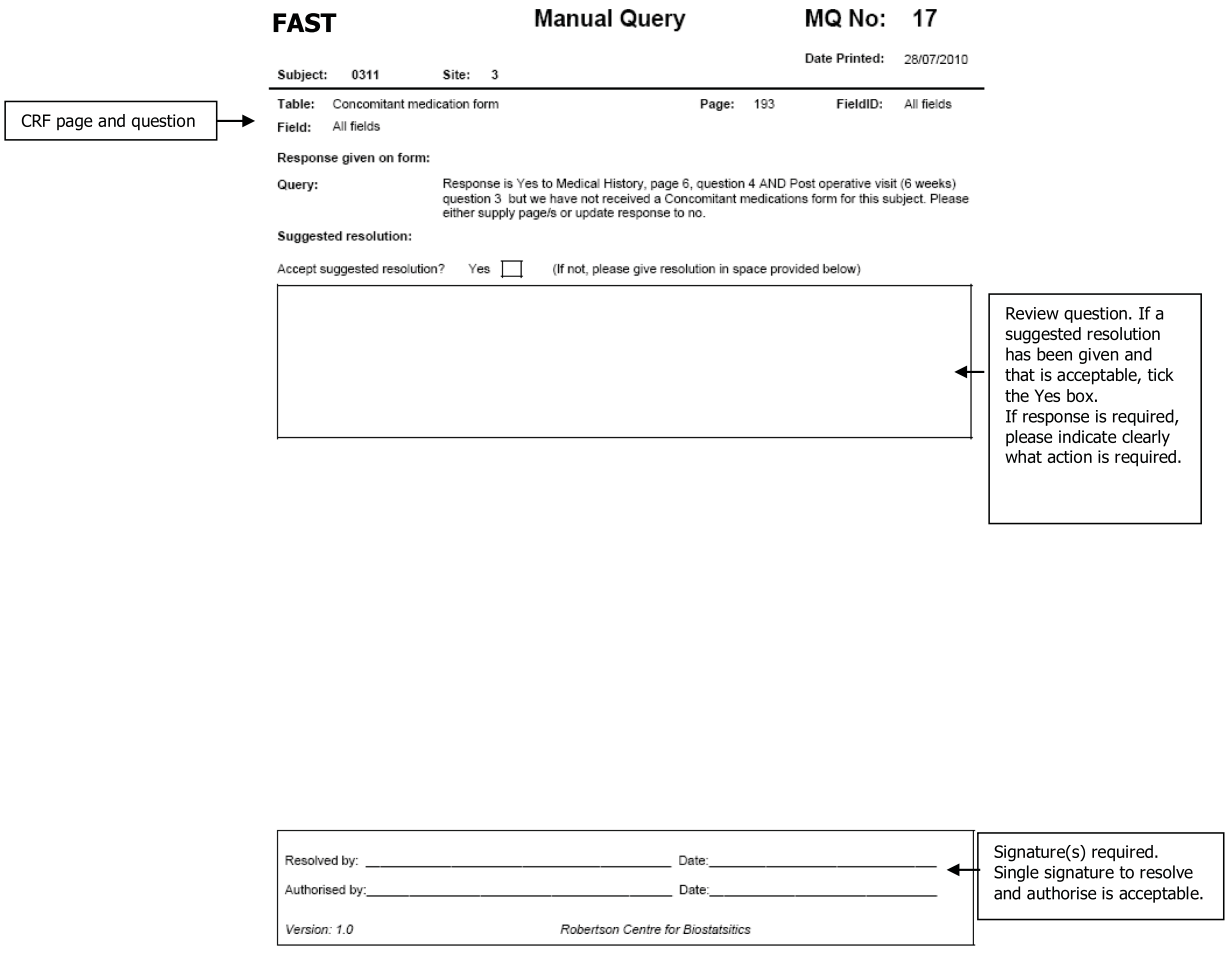
WORKSHEET VERSION HISTORY

Version	Date	Description	Created by
Draft 1	05/09/2012	Initial version release	Robbie Wilson
1.0	12/09/2012	Updated to add IVRS number and amend incorrect step numbers	Sarah Weeden
1.1	02/10/2012	Updated to provide live IVRS number following release of live system	Sarah Weeden

Appendix 5 Sample Data Query Form (DQF)



Appendix 6 Sample Manual Query (MQ)



FAST **Manual Query** **MQ No: 17**

Date Printed: 28/07/2010

Subject: 0311 **Site:** 3

Table: Concomitant medication form **Page:** 193 **FieldID:** All fields

Field: All fields

Response given on form:

Query: Response is Yes to Medical History, page 6, question 4 AND Post operative visit (6 weeks) question 3 but we have not received a Concomitant medications form for this subject. Please either supply page/s or update response to no.

Suggested resolution:

Accept suggested resolution? Yes ☐ (If not, please give resolution in space provided below)

CRF page and question

Review question. If a suggested resolution has been given and that is acceptable, tick the Yes box.
If response is required, please indicate clearly what action is required.

Resolved by: _____ Date: _____

Authorised by: _____ Date: _____

Version: 1.0 *Robertson Centre for Biostatsitics*

Signature(s) required. Single signature to resolve and authorise is acceptable.