



## **TARDIS - Working Practice Document No: ???**

### **Day 90 Data Entry Checks**

The purpose of the Day 90 Data Entry Checks is to check the primary outcome of the trial by comparing the source document entries to the database entries. Follow-ups may be completed on a paper CRF, or entered directly online.

When a paper CRF is completed, the source document is classed as the paper record. Where inconsistencies arise between the paper and online record, the paper record will be taken as the source document unless it is clear to see that the database is correct e.g. if some of the answers on the paper record are conflicting.

Paper forms will only be corrected where no entry is found on this source but an entry is on screen. (e.g. where mRS has been left blank on paper form, ranking will then be taken from database entry)

Corrections to the database from the paper source document will need submitting as Data Corrections at the end of the Data Entry Check, as part of the process.

When you first log into the database, continue to the 'Data Entry Checks' and you will be taken through to the list of all follow-ups that require data checking. It is very important that you check the follow-ups in the order shown, starting from the top.

**Please check each Day 90 in the order shown below, starting from the top.**

Participant ID	Date of collection	Date entered
C001/0017/JS	<u>15 Jul 2011</u>	15 Jul 2011 09:44
C001/0009/RR	<u>3 Mar 2011</u>	7 Apr 2011 18:14
C001/0022/ZZZ	<u>30 Sep 2009</u>	12 Nov 2013 14:36
C001/0024/MJA	<u>11 Oct 2009</u>	13 Mar 2014 16:47
C002/0032/ABC	<u>16 Apr 2010</u>	10 Feb 2014 11:01
C001/0004/AA	21 Jul 2009	21 Jul 2009 14:32
C001/0023/WE	18 Oct 2009	12 Nov 2013 14:42
C001/0013/VV	28 Jul 2009	24 Sep 2010 20:42
C001/0066/FRS	15 Aug 2012	10 Feb 2015 15:23
C002/0033/MJM	14 May 2010	22 Apr 2014 14:52

To start the first data check, click on the Date of Collection, underlined in blue. This will take you into the screen showing the completed follow-up.

If a paper CRF was completed, work your way through the paper copy of the follow-up, checking each answer against the entry on screen, and making a note of any differences in pencil on the paper form.

Once you have checked all the entries you will need to complete the results box at the top of the screen.

**Result of data entry check** [Select...]

**How many amendments were made to the handwritten source document?** [Select...]

**If yes, what changes were made and why?** [Select...]  
[Select...]  
[Select...]  
[Select...]  
[Select...]

If a required option is not present, contact a programmer *before* amending the source document

**Enter PIN to confirm**

For the first box you need to select the result of the entry check by selecting one of the following:

**Result of data entry check**

- [Select...]
- [Select...]
- Errors found in online record
- No errors found in online record
- No handwritten CRF was found

If the data was entered directly online, select 'No handwritten CRF was found'.

If no errors are found on the paper CRF, write 'Checked' and your initials and date on the top right corner of the paper form and simply select 'No errors found in online record' and then enter your PIN and click 'Submit'. You will then be taken straight back to the data check participant list where you can start the next data check.

If no errors are found but you have made amendments to the paper form, you need select 'No errors found in online record', then select how many amendments have been made to the paper form. Then select the appropriate reason why the change was made, for each change (if the reason is not available in the drop-down list you will need to contact the TARDIS programmer before amending the document). Then enter your PIN and select 'Submit'. You will be taken straight back to the data check participant list where you can start the next data check. You will also need to write 'Checked', your initials and date on the top right corner of the paper form and initial and date any changes you have made to the paper form.

If you come across an error on the online form, select 'Errors found in online record', enter your PIN and click submit. Please note that if you also come across amendments to the paper form as well, you need to select the number of changes and select the reasons before you enter your PIN and click submit.

You will now be taken through to the 'Data correction request – participant identity check' screen.

**Data correction request – participant identity check**

**It is essential that data collected is entered against the correct trial participant.  
Please complete the following identity questions to continue to the data correction request CRF.**

<b>Trial number</b>	209
<b>Initials</b>	<input type="text"/>
<b>Sex</b>	<input type="radio"/> Male <input type="radio"/> Female
<b>Date of birth</b>	- Day - <input type="text"/> - Month - <input type="text"/> - Year - <input type="text"/>
<input type="button" value="Confirm identity"/>	

On this screen you need to enter the participants Initials, Sex and Date of Birth. You will need to get these from Adara. Once you have entered the details you click 'Confirm identity'

This will take you through to the Data Correction screen.

Section A: Data correction details		
A1	Affected CRF	Day 90 follow-up <input type="text"/>
A2	Event/Result Number	<input type="text"/> Not Applicable <input type="text"/>
A3	Existing data Please list each: <i>Question ID</i> <i>Question label</i> <i>Data shown on report</i>	<input type="text"/>
A4	New data Please list each: <i>Question ID</i> <i>New value(s)</i>	<input type="text"/>
A5	Reason for change	<b>Please do not edit the first line</b> Found by checking against handwritten source document. <input type="text"/>
<b>FOR OFFICE USE ONLY</b>		
A6	Amendments	-
A7	Action taken	-

On this screen you need to enter the **existing** online data in box A3 and then enter the **corrected** information from the paper form into box A4. The reason for the change, box A5, should be already populated with 'Found by checking against handwritten source document'. Once you are happy with the entries, enter your PIN and click 'Next'.

You will be asked to check your answers again and then enter your PIN and click 'Submit'. You will then receive a 'Thank you' message on screen and can then click on 'Back to data entry checks' to return to the data check participant list where you can start another data check.

You will need to put the data check to one side until your data correction request has been applied by the TARDIS programmer or a trial co-ordinator. You will receive an email to inform you when the data correction request has been applied: this will typically be within a few minutes unless there are any issues. Once the data correction request has been applied, open the Data Correction form again, which should now include the Amendments (A6) and Action Taken (A7). You will need to print this and staple it to the back of the follow-up form. To finish, write 'Checked', your initials and date on the top right corner of the paper form and also initial and date any corrections you have made on the paper form.