

BRL029060_329_CRFs README FILE

This README file provides information on the Case Report Forms (CRFs) provided for study **BRL029060_329** in the Data Access System.

There are approximately 700 CRFs in total. These relate to 150 screen failures, 275 patients in the acute phase of the study and 125 patients in the continuation phase of the study. A number of patients have more than one CRF. These CRFs are named accordingly – see section 2 below.

Please note that CRFs for patient 00010 at centre 005 and patient 00198 at centre 009 could not be located. Both patients received placebo. We have contacted the MHRA who have the original CRFs for this study and asked for their return. We will add CRFs for these patients should they be returned.

The CRFs are being uploaded in batches. This Readme file will be revised and re-loaded to provide updates.

1. Folder Structure

The CRFs are provided in PDF format and placed within studyID = **BRL029060_329_CRFs**

Two formats for the CRFs are provided which are accessed in separate folders: **OCR** and **Non_OCR**.

OCR: These have been formatted for Optical Character Recognition to make searching within the CRF easier. Each CRF ending in “-ocr” has been formatted in this way.

Non_OCR: These have not been formatted for Optical Character Recognition.

A file called “**View and navigate PDFs**” has been provided for reference. This is available from within the “Files” directory.

2. Naming Convention

Each CRF has been named as follows: “**studyID-centreID-subjectID-redact**”

- For example, “brl029060-329-000001-000123- redact” represents subject 00123 at centre 001.

Screen failures were not assigned a subject ID. The CRF tracking number has been used instead of the subject ID.

- For example, “brl029060-329-000001-090183-redact” represents a screen failure at centre 001. Tracking numbers are identified by ‘9#####’.

For some patients there are duplicate or additional CRFs. These can be identified from the 'A' or a 'B' after the subject-ID number.

- For example, for subject 00086 at centre 003 there are 3 CRFs, "brl029060-329-000003-000086", "brl029060-329-000003-000086A" and "brl029060-329-000003-000086B"

The Main CRF is contained in each file. Additional files may contain additional pages e.g. Routing sheets, Lab data queries

3. Redaction

Date of birth, names, initials, signatures, email addresses and phone numbers have been redacted (masked from view with a black bar). Redacted documents are locked as secure PDF files.

4. Number of Files Uploaded

As of 21 February 2014, the following numbers of files have been loaded into the Data Access System:

Centre	Number of Files	Number of Unique Patient CRFs
001	20	19
002	61	37
003	49	34
004	22	11
005	34	25
006	5	3
007	9	6
008	9	6
009	33	24
010	7	4
011	8	7
012	13	9
TOTAL	270	186