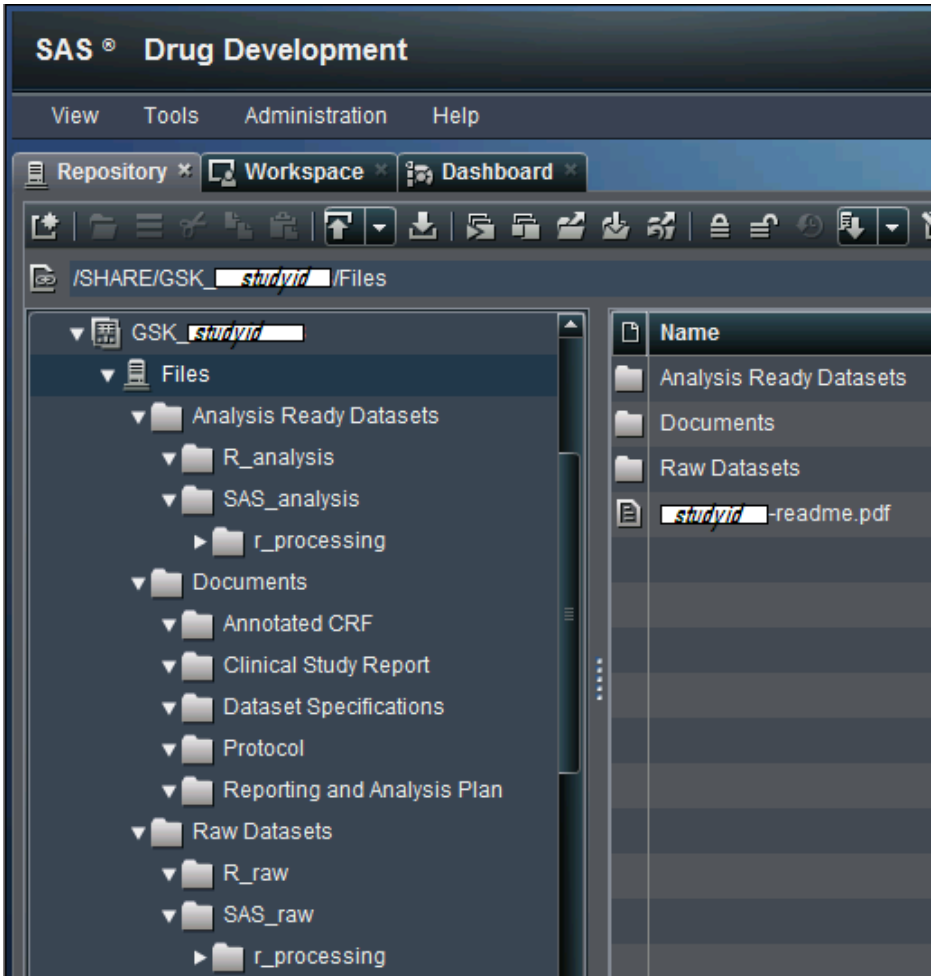
BRL029060-329 README FILE

This README file is an overview of the data and documents provided for study **BRL029060-329** in the Data Access System SAS Drug Development (SAS DD) research environment and the steps taken to anonymize/redact these.

Explanatory notes about the data:

- 275 subjects received study treatment. These subjects are in both the Raw and AR datasets.
- 150 subjects were screen failures and are identified with the number '9' in first character of the last 5 digits of their patient ID (PID). For example, '329.001.**9**0077'. These subjects are in the Raw DEMOG dataset and in some of the other Raw and AR datasets (screening visit data) but are not present in the AR DEMOG dataset.
- 1 subject (PID=329.005.00296) was randomised but elected not to continue in the study and received no study medication (see AR dataset **brl029060_329_p329term,** variable ENDTEXT). This subject is in both the Raw and AR DEMOG datasets but does not contribute to the N=275 of the final analysis.
- The Raw dataset **brl029060_329_died** has no data observations as there were no subject deaths in this study. All other datasets have NOBS>0.

The study package is provided in different folders, as shown below (where studyid = **BRL029060-329**):



1. DOCUMENTS

- **Annotated CRF:** This is a blank case report form with descriptions of the data collected and how they are described in the dataset.
  For this study the blank CRF is provided in the Clinical Study Report (please use the bookmarks in the document to navigate to this).

- **Clinical Study Report:** This is the report of efficacy and safety data from the study. It forms the basis of submissions to regulatory authorities such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Appendices which include patient level data are not included as these data are provided in the datasets GSK provide. To protect research participants' privacy and confidentiality, case narratives are not routinely included. They may be provided where they are needed for a specific research proposal, provided research participants' privacy can be protected.

- **Dataset Specifications:** This is the meta-data which describes the data e.g. variable labels, variable descriptions, formats. For this study the instructions file is provided.

  Instructions file: This file is called **"brl029060-329-instructions"** and contains meta-data about the study data including the anonymization function applied to each SAS variable. Note, only one variable has been anonymized in this study: DOB (date

of birth), which has been set to blank (FUNCTION=REMOVE). The instructions file has one row for each SAS variable in this study, and the following columns:

Column header	Column description
TARGET	This relates to the SAS DD folder in which the particular dataset can be found. Value 'TG_RAW' equates to the Raw Datasets folder, value 'TG_ANA' equates to the Analysis Ready Datasets folder.
MEMNAME	dataset name
NAME	variable name
TYPE	variable type: 1=numeric, 2=character
LENGTH	variable length
LABEL	variable label
FORMAT	variable format name
FUNCTION	anonymization process applied to the variable. Values:

Function values	Function description
REMOVE	redacted (set to blank)
<blank>	none

Other columns in the Instructions file are created and used during the data anonymization process and can be ignored.

- **Protocol:** This is the final version of the protocol, including any amendments and describes the objectives, design, methodology, statistical considerations, and organization of a clinical study. For this study the Protocol is provided in the Clinical Study Report (please use the bookmarks in the document to navigate to this).

- **Reporting and Analysis Plan:** The RAP describes methods of analysis, procedures for data handling and data displays (figures and tables) we used for the study.For this study the RAP is provided in the Clinical Study Report (please use the bookmarks in the document to navigate to this).

2. RAW DATASETS

These are the most recent version of raw data used for an analysis leading to a study report. Raw data includes data captured on the CRF, subject data transferred from other sources (e.g. laboratory data) or technical data (e.g. treatment group description). The raw data are System Independent (SI) datasets following GSK's standard.

The raw data are in the SAS DD repository in the form of SAS datasets (/SAS_raw), and as CSV files (/R_raw). Details of the conversion from SAS to CSV are also provided (/SAS_raw/r_processing):

/SHARE/GSK_BRL029060_329/Files/Raw Datasets/SAS_raw
/SHARE/GSK_BRL029060_329/Files/Raw Datasets/SAS_raw/r_processing
/SHARE/GSK_BRL029060_329/Files/Raw Datasets/R_raw

SAS format catalogues are not provided. Use OPTIONS NOFMTERR. Decoded data variables are in the analysis ready datasets or can be determined by referring to the CRF.

3. ANALYSIS READY DATASETS

The analysis ready data were used to generate the key study results. The analysis ready data are in the SAS DD repository in the form of SAS datasets (/SAS_analysis), and as CSV files (/R_analysis). Details of the conversion from SAS to CSV are also provided (/SAS_analysis/r_processing):

/SHARE/GSK_BRL029060_329/Files/Analysis Ready Datasets/SAS_analysis
/SHARE/GSK_BRL029060_329/Files/Analysis Ready Datasets/SAS_analysis/r_processing
/SHARE/GSK_BRL029060_329/Files/Analysis Ready Datasets/R_analysis

SAS format catalogues are not provided. Use OPTIONS NOFMTERR. Decoded data variables are in the analysis ready datasets or can be deduced by referring to the CRF.

4. DATA ANONYMIZATION

Only minimum data anonymisation has been performed for this study because the non-anonymised patient data listings are available on www.gsk.com . Therefore only date of birth has been removed and set to blank.

5. DOCUMENT REDACTION

The Clinical Study Report, which includes as Appendices, the Protocol, RAP and Blank CRF is the same as that listed on www.gsk.com
No further redaction has been performed of these documents.

6. DEFINITIONS

Personally Identifiable Information (PII): refers to information that identifies or that reasonably could be used to identify an individual. PII includes Sensitive Personally Identifiable Information (SPII)

Sensitive Personally Identifiable Information (SPII): refers to a subset of PII relating to an individual's race or ethnicity, political opinions, religious or philosophical beliefs, trade union membership, commission of criminal offences (and related proceedings), health, sex life or sexual orientation, government issued identification numbers (e.g., social security numbers or national IDs), credit or debit card details or any other PII whose unauthorized acquisition, use, modification, loss or disclosure presents a greater risk of harm to the relevant individual.