SAS MACRO TOOL DEVELOPMENT

A deeper plunge into broad ranges of oncology trials data

OVERVIEW

The customer is a global biopharmaceutical company developing innovative medicines in the fields of proprietary commercial products focused on addiction and schizophrenia, along with a pipeline of product candidates in development for schizophrenia, bipolar disorder, neurodegenerative disorders and cancer.

CHALLENGES

Difficulty in analysing input of different database structures from paper CRF, eCRF, inhouse and outsourced data management, and local investigator files

Existing standard programs were only study/client specific and lacked key variables for broader use

Non-availability of Macros for derived responses and efficacy endpoints on RECIST criteria

Creation of Kaplan Meier graphs for end points was going through a lot of manual programming

Study Integration efforts were experiencing untimely hick-ups because of no standards across studies

SOLUTION

1. Created SAS Macro tool from scratch consisting of a set of SAS macros that produced a series of derived datasets, including different requirement specifications for a broad range of studies
2. Modular programming approach for ease of development and review during different stages of a clinical trial and made sure that the newer versions were backward compatible in view of interim and final analysis submissions
3. A team of highly experienced Programmers and SMEs from Oncology to ensure Tumor assessment schedule for different studies is considered
4. Clear documentation was prepared for future usage and updates in terms of endpoint derivations

OUTCOMES

- Maximized the functionalities of end output production to have submission ready outputs like Kaplan Meier graphs for PFS, OS, ORR, DOR endpoints
- Drastic reduction in timeline to derive all the information needed in terms of content and layout
- Creation of a standard norm in terms of handling RECIST data that improved the efficiency and consistency across all projects
- Considerable reduction in programming resources used for manual programming

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