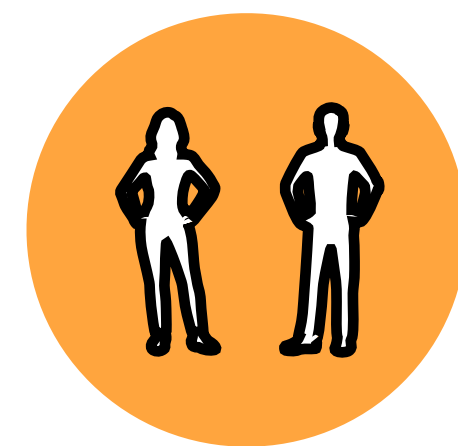


Data validity frame concept

Grünenthal utilities for independent data overview

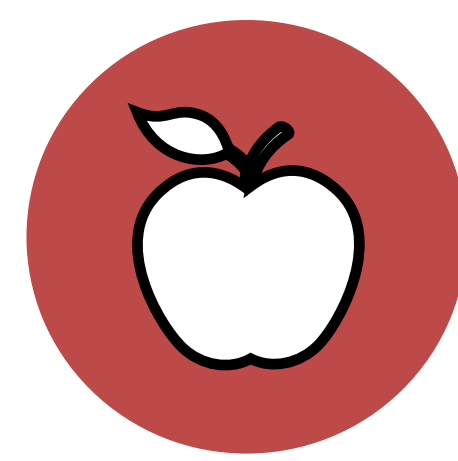


A great benefit of the Pinnacle 21© is its ability to detect non-compliance of data with industry standards, finding basic inconsistencies and data discrepancies. It is an important instrument for both the sponsor and the service provider. Despite its utility, the Pinnacle 21 does not fully meet the needs of many sponsors with respect to data quality verification. Many pharmaceutical companies have SDTM/ADaM standards that differ from industry standards. Moreover, sponsors require an in-depth trial and design-specific overview of the data and data quality which the standard tool does not provide. To address these shortcomings the programming team at Grünenthal has created a tool called Grünenthal utilities for independent data overview aka GUIDO tool.



User

- Although user is not necessarily a programmer, minimal programming knowledge is required, for example to call and parameterize the '%frame' macro.
- The user selects and/or overview programs from the standard metadata which they would to perform. The programs are categorized, making their selection easier.
- A user who's unable to find the check they require should inform the programming team.



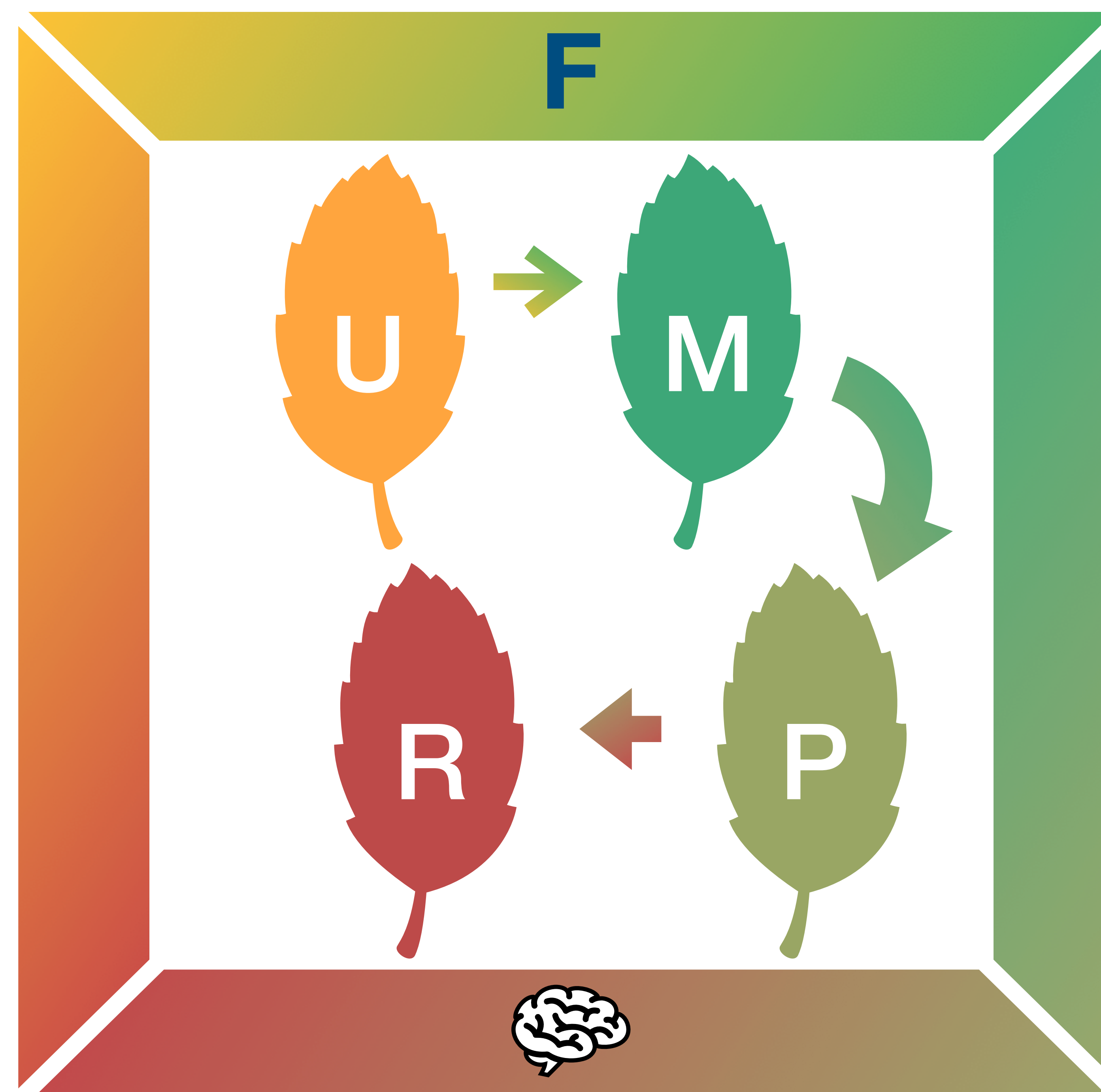
Results

- The %frame macro collects all available outputs and combines these into an Excel file. This file contains a spreadsheet summarizing the individual program responses. The user can click on a link to review the results of the overviews or the detailed results, if available.
- Results are of 3 types: positive, negative, and failed. A positive result signifies that the data has passed the check. A negative result indicates shortcomings in the data, information about which can be viewed in the detailed files. A failed result is the outcome of an incomplete program run.



%frame

- The %frame macro serves as a driver program to submit the individual programs.
- It uses an Excel metadata file to select the checks to be run.
- It downloads the data and, based on the metadata, creates a query file (*.bat file).
- After submitting the query file, it combines the individual results.



Metadata

- Each program has a record in the standard metadata file. The record contains the name and the ID of the program, the name of the corresponding result files, and a short explanation of the program, typically the expected outcome and the purpose.



Programs

- The programs are independent from each other and follow preliminary agreed rules to create outputs and responses identical in format and appearance. Integration of a new program is therefore straightforward.
- Running independently, the performance of the programs do not impact each other. All overview programs create detailed files. Check programs create a detailed file when they encounter a problem.
- At present, 6 overview and around 80 check programs are available. The tool currently operates using SDTM data. It is expected that the tool can be easily used with other types of data, such as ADaM data. The use of raw level datasets to facilitate central data review can even be envisaged.



Programming Team

- The programming team is accountable for the creation and testing of user-requested check and overview programs. They add records of new programs to the standard metadata file.
- They are responsible for the maintenance and repair of existing programs.