

Concept of a clinical trial reporting system

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ABSTRACT

During the process of clinical trial analysis, information is presented in tables, listings, and graphs and most pharmaceutical companies and outsourced service providers use SAS to prepare the outputs.

Oftentimes, statistical programmers spend a lot of time creating standard outputs like demography or adverse event tables, rather than spending their time and efforts working on more complex statistical outputs.

The reporting system concept presented in this paper would produce validated statistical outputs in one click – thereby increasing efficiency and saving companies time and money if implemented in the future. This paper focuses on the concept of the reporting system, describes all main features that should be present in the system, and explains some technical issues that programmers can face while using the system.



INTRODUCTION

SAS is the current standard tool in the pharmaceutical industry to create analysis datasets, tables, listings, and graphs (TLGs). Using SAS, programmers can create any type of statistical output independently regardless of the level of complexity. However, in spite of many positive attributes, SAS has some drawbacks such as:

- Price of the product is high;
- Users must be trained in SAS and be very experienced for high complexity output;
- Some TLGs can be a very time-consuming process.

The concept reporting system presented here eliminates these drawbacks. This is a web-based system where users without special proficiency can create TLGs based on existing templates (like demography or AE tables) and can create their own templates using visual editor or SQL-based language.

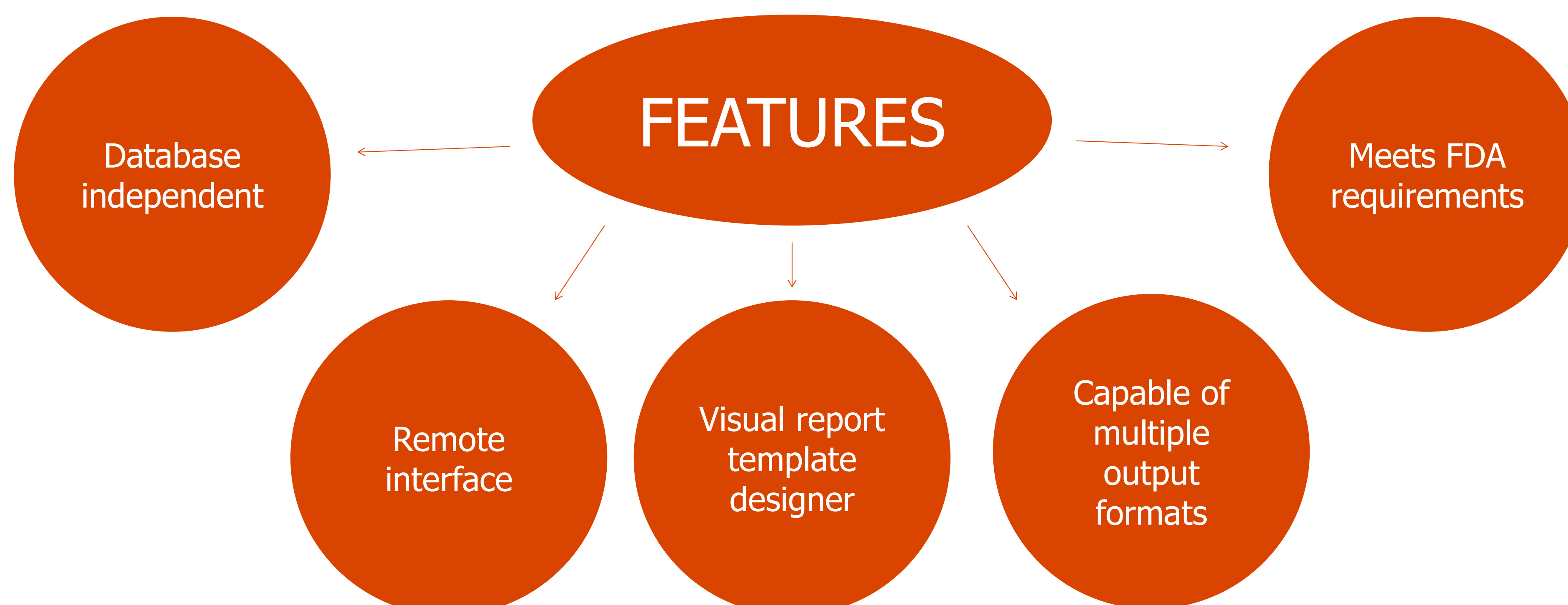


OVERVIEW

The concept reporting system presented here shows what needs to be done to improve the existing process of analyzing clinical-trial data. Many pharmaceutical companies and contract research organizations (CROs) still spend a lot of time and effort creating simple, standard TLGs (for example demography, adverse event, or laboratory). This process is also costly including the analysis system license (SAS or something similar), statistical programmer salaries for time spent creating the TLGs, and the statistician's salary for time spent developing specifications and reviewing the TLGs. Ideally, a new reporting system would reduce time, effort, and cost with the ability to produce standard TLGs from any type of device, from any part of the world, in just a few minutes, with just a few simple clicks.

Remote interface: No additional software installation required. Users only need to have the latest version of web-browser (IE, Google Chrome, etc.) and authorized users can have access to the system from any part of the world and from any type of device (even mobile phones or tablets).

Visual report template designer: Users can create a new template for any type of TLG or update existing templates using a visual interface (such as Microsoft Office Word). Users can create TLGs and apply simple statistics to anywhere in their template and in any possible form [ie, n, n (%), n/m(%)].



Capable of multiple output formats: TLGs can be generated in PDF, RTF, TXT, HTML, etc.

Database independent: Data from any database can be used, even from SAS7BDAT files.

Meets FDA requirements: The FDA wants to see not only outputs as a result of statistical analysis, but are also asking for SAS code. In this case, the reporting system should be able to create the SAS code that the FDA can run using SQL language.



INTERNAL DOCUMENT FLOW

In order to create their output, statistical programmers rely on related documents such as the statistical analysis plan.

The reporting system should have an internal document flow that can store and control any related documents. In general, most of these documents are created by statisticians and sometimes stored in multiple places. This reporting system will store them all in one place.

Because it is important for statistical programmers and project statisticians to communicate, the reporting system should also have some communication tools to facilitate communication between programmers and with statisticians.



SECURITY

Due to the sensitivity of clinical trial data, security is critical. A reporting system should support a role-based permission architecture to protect the data. For this purpose, the following user groups should be available in the web-based reporting system and can be changed as needed:

Manager: Can create, remove, and update any projects, templates, or outputs, as well as upload clinical data. The manager can add user groups and set their permissions.

Project lead: Can create a new project, create, remove, and update any type of output or template within the project.

Statistical programmer: Can create any type of output or template within the project.

Statistician: Can review all created output and add their comments. They can create and update any type of document.



CONCLUSION

The described idea of the reporting system presented in this paper shows what main steps should be incorporated in the future to save time and money to produce standard TLGs. The web-based reporting system should be a flexible and easy-to-use application. The demo version of the system should be ready next year.