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Levista - An Integrated Programming Environment with Visualization

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ABSTRACT

Today's industry process to generate ADaM datasets is tediously manual dependent heavily on spreadsheets for ADaM specifications and manually written SAS programs. Enormous amount of time is spent in the creation of ADaM specifications as the author switch between various meta-data tabs and documents. As often times, addition of new variables, new codelists, and value-level metadata, during the course of a study is error prone, and unfortunately these errors are identified close to database lock. To address these and various other issues, at LEVSTAT, we utilized a single-screen interface to implement data visualization and standardization. Our platform enables user to visualize the input data, codelist and value level metadata on the same screen. Visualization of various components of the specification document in one screen, increases the efficiency of the specification development process and decreases the error rate by eliminating the need to switch between multiple documents/tabs. The time spent on generating the specifications, value-level metadata and codelist is greatly reduced when using the graphical interface. This ability to connect the individual components on a single screen provides a better interface for the user to input information and helps gain control over the information being input for various components. Aside from spec development, the platform helps integrate and manage the statistical review of outputs generated. Clients, Statisticians and Managers will be able to enter their comments after review as part of the output document, which is integrated into a tracking database. The utility of tracker database is extended to store key milestone information for each study enabling the team to keep track of timelines, amount of work completed and outstanding, current status of each output. The platform provides the ability to graphically project all the information from the tracker database on a customizable dashboard. In summary, this platform integrates project management, review management, ADaM development, and metadata management under a single visual environment. This environment enables the study team to complete the programming tasks in the most efficient manner and establishes a unified platform to communicate accurate information throughout the team at any instant. Through this paper we intend to share the overall functionality of the interface, highlighting the most useful features, and present metrics of productivity which show increase in efficiency and reduction in error rate.

INTRODUCTION

The mandatory requirement of providing submission datasets in SDTM format has pushed the pharmaceutical industry towards developing standard processes to automate the generation of outputs for submission. The first step towards generation of submission-ready datasets is to create programming instructions. These instructions, also known as mapping or study specifications, are generated and maintained as individual tabs in spreadsheets. Once the datasets are generated, the outputs are developed and reviewed by the internal biostatistician team. The outputs are further reviewed by the sponsor or the clinical team for the final report. These review processes are spaced out to accommodate the whole team's availability and yet, the programmers do not get ample time to generate the final deliverables. As part of the final deliverables, the programming team is expected to generate all outputs in a specific sequence to ensure the final outputs are indeed generated with the latest data cut..

CHALLENGE

There are numerous challenges in this process and the programmers deal with this every day. We, at Levstat®, identified the major challenges as the metadata management, review, tracking and communication of project deliverables. The metadata needed for submission purposes include definitions for value-level metadata and codelists, which are tedious to manage and define during the development process. Study metadata is currently managed using spreadsheets, which the programmers find very challenging to use during the development stage. The continuous switching between multiple tabs to complete metadata for a single variable could lead to errors that may not be identified until the final outputs are generated. As the metadata evolves continuously during the course of study, the

programmers have to ensure the metadata stays updated throughout the study, which is a major challenge. Similarly, the biostat and clinical counterparts generate their own review tracking spreadsheets which are finally passed on to the programming team for updates. Multiple tracking spreadsheets create a much bigger challenge for the programmers along with their availability during the course of the study. There is no single mechanism of tracking these comments and alerting the appropriate study programmer.

To address these and various other issues, at LEVSTAT, we utilize a single-screen interface to implement data visualization and standardization. Our platform enables user to visualize the input data, define codelist and value level metadata on the same screen. Visualization of various components of the specification document in one screen increases the efficiency of the specification development process and decreases the error rate by eliminating the need to switch between multiple documents/tabs. The time spent on generating the specifications, value-level metadata and codelist is greatly reduced when using the graphical interface. This ability to connect the individual components on a single screen provides a better interface for the user to input information and helps gain control over the information being input for various components.

ABOUT LEVISTA

Levista is a modular, graphical user interface to support development and management of analysis deliverables for a clinical trial. The interface also includes multiple tools for metadata, document, resource, and timeline management. This tool can greatly reduce the time spent in specification development, document management, review and tracking of deliverables. This interface can be accessed as a stand-alone application or as a web page in a browser. Data continues to remain in the host system or network and is not transferred into this application.
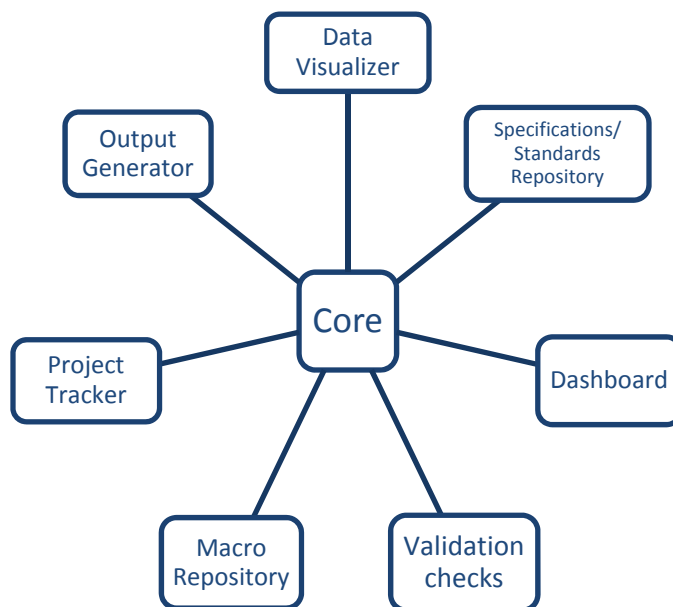
Levista consists of seven base modules which support in the development and management of study deliverables, including SDTM and ADaM metadata. The dashboard, which is also the welcome screen of the interface, provides a role-based overview of the study status, deliverables, timelines, and at-risk indicators. The specifications/standards repository module is a warehouse for all available SDTM/ADaM structures and houses the study specifications. Data visualizer module enables user to view data in graphical environment. The graphs are interactive and can be filtered or updated in real-time. Output generator module is primarily used for generation of study deliverables including datasets, outputs, and define.xml documentation. This module includes individual sub-modules to generate various types of outputs.

Project tracker module manages the review process during development of the deliverables. This module tracks and communicates the validation and biostatistics comments to respective personnel involved. This module helps in keeping track of the updates made to the source programs/specifications during the review process. Macro repository module is a warehouse of all user-defined macros, where users can store their macros to call where necessary within their programs. The validation checks module runs FDA recommended checks and sponsor-defined checks based on the user input. This module provides a report for each set of checks run using the interface. Along with the data visualizer and the validation checks, all issues would be resolved during development resulting in minimal rework. The core module acts as the central nervous system which interacts with all other modules.

KEY MODULES

SPECIFICATIONS/STANDARDS REPOSITORY

This is a warehouse for all standard and study-specific metadata documents. When the user selects the list of standard datasets/domains needed for a specific study, the core module sifts through this repository to retrieve all the requested standards for further processing. This module includes a standards development feature that allows the user to develop new standards to fit the sponsor needs.

DATA VISUALIZER

This module enables the user to visually inspect the data either as graphical representations or as simple statistical computations like frequencies and/or measures of central tendency. The user is allowed to choose any dataset (raw, SDTM, or ADaM) to visualize or summarize the information available. This is a great asset for anyone who depends on reviewing data visually. This tool also has the capability to generate data listings along with the graphical representations.

DASHBOARD

An overview of all projects and assignments are graphically represented through this module on the welcome screen. This is customized based on the user's role in the organization or project, which is provided during the setup process. The user can set up alerts to flag any at-risk deliverables or to indicate the list of new tasks on their dashboard. The interface provides wide variety of functionality to aid in project management, tracking, and audit trails.

PROJECT TRACKER

This module enables users to review and comment on deliverables in the real-time. Any user with biostatistician level study access can add comments for each output during their review. Also, any user with manager level access will be able generate reports of these review comments, assign users to each comment, or add responses to these review comments. Similarly, any programmer with study level access is able to add responses to each of these comments. The unique feature of this module is the communication. The core module interacts with this module to update the dashboard with key project information based on the assigned role. The platform helps integrate and manage the statistical review of outputs generated. Clients, Statisticians and Managers will be able to enter their comments after review as part of the output document, which is integrated into a tracking database. The utility of tracker database is extended to store key milestone information for each study enabling the team to keep track of timelines, amount of work completed and outstanding, current status of each output. The platform provides the ability to graphically project all the information from the tracker database on a customizable dashboard.

CONCLUSION

In summary, this platform integrates project management, review management, ADaM development, and metadata management under a single visual environment. This environment enables the study team to complete the programming tasks in the most efficient manner and establishes a unified platform to communicate accurate information throughout the team at any instant.

CONTACT INFORMATION

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