FreshGravity™
Driving Digital Success®

Clinical Study Build Automation Tool (CSAT)

An end-to-end platform to design and develop all the components of a clinical study build process, while enhancing the use of standard libraries with a review workflow mechanism and library management.

Background

The clinical study build processes of today are manual and dependent on the efficiency of the people undertaking them. There are several issues in the current method, such as –

- *The process is not streamlined to take full advantage of the curated and standardized library of forms as well as the past experiences*
- *The eCRF (electronic Case Report Form) design and edit check validation rules are not intuitive and do not use the standard libraries and the historic metadata from similar therapeutic areas*
- *The current process is complex and requires specialized skills and therapeutic experience. To tackle this complexity,* ***a significant amount of time*** *and resources are spent on building a EDC database*
- *The quality issues arising after the testing and reviews further lead to an increase in time and resources spent on completing the eCRF build*
- *To resolve the quality issues, the process has to undergo eCRF changes along with associated training and data management changes. This makes the overall process expensive*

About CSAT

Developed by Fresh Gravity, the Clinical Study Build Automation toolkit leverages Natural Language Processing and Machine Learning capabilities to effectively generate the study build components. The tool can generate the design of the eCRFs specifications and data validation checks directly from the clinical protocol, using standard CDASH and therapeutic area libraries.

The main aim of the tool is –

- To reduce database startup time (DB go-live and First Patient In) by reusing standard eCRFs, edit checks and mappings from previous studies
- The effective management and use of library components
- To improve the quality of the build process

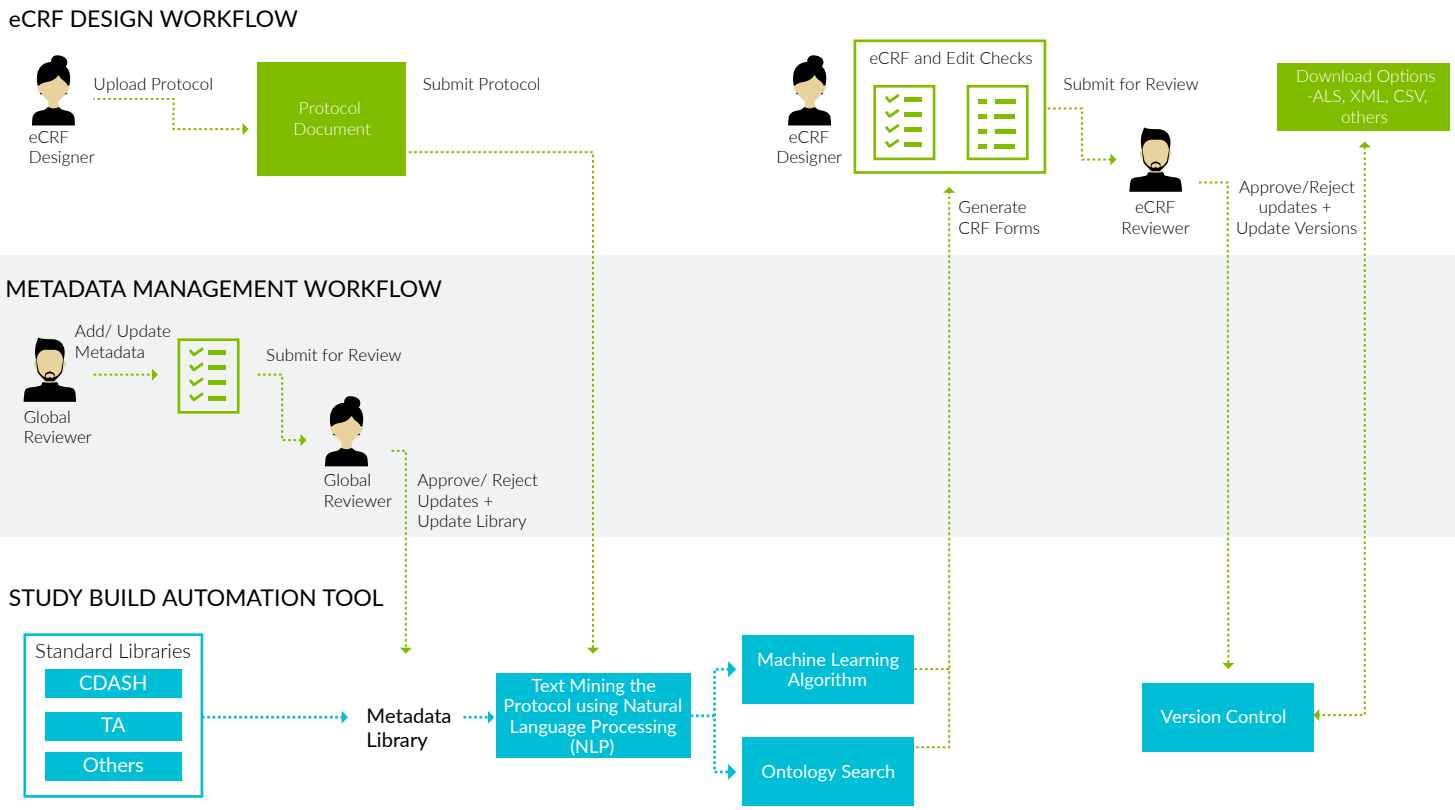
Key Benefits

In clinical trials, the creation of electronic Case Report Form (eCRF) is a tedious and manual process involving the scanning of several documents to extract relevant information. The CSAT tool is an end-to-end platform to efficiently generate various study build components and reduce the time and resources spent in the manual process. It can –

- Automate the process of creating eCRF from the protocol document (PDF format). Using advanced NLP techniques, it extracts the required paragraphs from the protocol document and compares the text with the standard library maintained within the tool to identify the eCRF and the questions to be captured in the study
- Utilize machine learning modules to predict the eCRF design and required questions. The resultant output can lead to at least 70-80% reduction in manual efforts
- Predict the edit check rules (data validation rules) to be programmed in the EDC (Electronic Data Capture) system
- Depict the SDTM (Study Data Tabulation Model) mapping for the generated eCRFs in the tool

Clinical Study Build Tool Process

Clinical Study Build Automation Tool is an ideal solution for speeding the start up timelines for a clinical study, while keeping the total cost and time spent, in check. Here is a look at the CSAT process –



Key Components

Library Management

The tool is capable of handling multiple libraries that can be loaded into the tool and efficiently managed thereafter. The workflow mechanism ensures that the global librarian has the control to maintain the integrity of the library and its validated components.

eCRF Generation and Version Management

The tool utilizes advanced NLP capabilities to read the protocol and identify the list of eCRF and associated questions from the library. Its robust ML-based model built can predict the contents of the eCRF and continually enhances its learnings based on the user modifications. Every iteration of the eCRF review process within the tool is maintained as a separate version which helps in managing the version control within the tool.

Schedule of Times and Events

The tool can effectively maintain a schedule of time and events for the study. It does so by allowing the eCRF Designer to extract the time and events table from the protocol and perform the necessary modifications to the table within the tool.

Workflow for the Review Mechanism

The tool has built-in collaboration workflow to ensure that the eCRFs generated are routed through an appropriate review mechanism by the reviewers. It also provides users the ability to enter detailed comments, approve, and reject the study build components.

Role-Based Access and User Management

The tool has the capability to create new users and manage them within the system. It can assign them appropriate roles to be performed for the study. This helps in ensuring that the integrity of the study build components is maintained by the review process.

Downloads

The solution provides an API framework for end-to-end integration, thereby avoiding the effort of manual data entry. The tool provides the capability to download the eCRF in native CSV format or in an EDC system consumable format such as the ALS (Architect Loaded Sheet) for Medidata Rave or the CSML format for Oracle InForm. Additionally, the other downloads include the data validation (edit checks) check specifications for the study, SDTM mapping document for the study, annotated eCRF in PDF formatand standard SAS macros for SDTM programming.

Reports and Dashboard

The tool dashboard furnishes reports to provide an overview of the status and the progress of various studies. It also provides the metadata library reuse reports for user consumption.

About Fresh Gravity

Founded in 2015, Fresh Gravity helps Life Sciences companies adopt digital transformation through innovation driven by modern technologies. Our clinical study build tool is a result of our steadfast commitment to find solutions to the most pressing problems in the industry. To know more about us and our offerings, contact us at ***info@freshgravity.com***

U.S. Corporate HQ – San Francisco Bay Area
5201 Great America Pkwy
Unit 320
Santa Clara CA 95054

www.freshgravity.com

Other Offices

U.S.A.
Dallas, TX

India
Pune
Bangalore