

## Presenting Study Results From A Metadata Driven Ecosystem

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### ABSTRACT

Presenting study results is an important part of conducting a study. However, managing the results to ensure only the correct results are presented and no changes are made is always a challenge. We will show how to generate presentation materials from a study results database using metadata. The application allows a user to create an improved version of traditional presentation by adding dynamic results directly from the study results database. Users can create the presentation by configuring the metadata or by using the traditional method. User can embed tables and charts directly which ensures that the presentation contains same information which was in the study results. Created presentation will be web based and platform independent, while it may contain live and animated charts. Whether the presentation is generated by Programmers, Statisticians or Medical Writers, they will all be using the same results database, and so will automatically be consistent with the study report.

### INTRODUCTION

Clinical trials are one of the most visible components of the biomedical research field which finds new evidence about drugs or preventive interventions. Due to the nature of clinical trials, it is very common that trial reports need to be presented in different forms of reports and often to different types of audiences. As scope of clinical trials gets bigger and larger everyday, the process becomes gets complicated and needed to break down in several stages, which frequently leads to more complexity and is prone to error.

Generally reporting from a study results have several stages. It includes gathering study results, choosing correct results, creating presentable format for results and presenting to the audience. Before any presentations are produced, the outputs required need to be programmed by the programmer and validated by statisticians. Only validated outputs are used within any presentations that are produced and presented. It is important to keep this in mind when deriving any system to generate presentations regardless of whether they are for internal or external use.

### AN ALL-IN APPROACH

We developed an application to make the whole clinical trial reporting process more robust and interconnected. A metadata driven ecosystem is used as the core of this application. The idea of this application is that it should be as simple as using a word processor, hide all of the complex bits from the user, yet reports dynamically updatable results, charts and all other traditional presentation components.

### A METADATA DRIVEN ECOSYSTEM

Our existing application, **Metadata Driven Output Management System** (MeD-OMS) can manage the all output creation process from whole study, which includes creating analysis results from source data and store them in result database (RDS) and then report the final outputs as TLFs. As the title of this application implied, the whole process is metadata driven and easily controllable.

In MeD-OMS, all of the little segments were driven by the corresponding metadata. Study statistical analysis plan was broken down into small analyses and analysis programs were used to create the analysis results, which uses SDTM/ADaM data from study as source. These analysis results were stored in a result database (RDS).

Analysis results stored in result database were further processed to generate desired TLFs which were designed based on table shell. Generated TLFs were the final output for the system. The whole process is metadata driven, which ensures that it is easy to handle, it is traceable and manageable.

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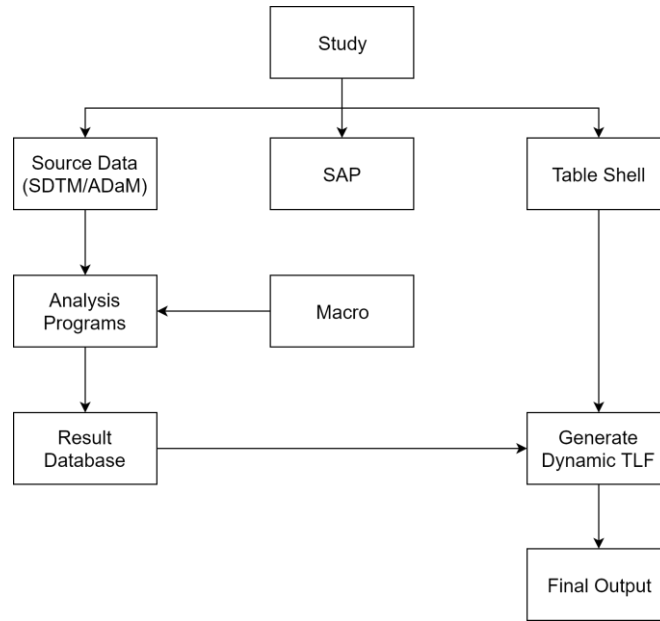


Figure 1: MeD-OMS Process Flow

## ADDING PRESENTATION OF RESULTS

Presentation of study results can be done in different way. Most common practice would be gather all required results from study, create presentation using presentation tool and publish. However, in our approach we have implemented to include the results directly from the study summary by using a system and make those presentation more dynamic.

To add the presentation capability directly from metadata driven ecosystem (MeD-OMS), we have developed **Interactive Presentation Tool (IPT)**. We will discuss the details in next few sections.

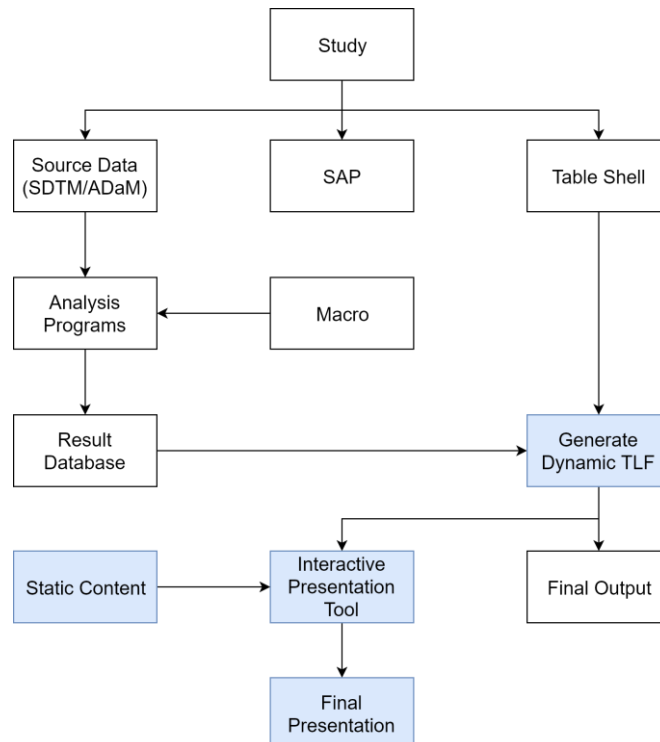


Figure 2: Simplified process flow of MeD-OMS and IPT combined

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## TOOLS & COMPONENTS

Interactive presentation tool is a web based tool, like the MeD-OMS. It uses PHP in the backend and JavaScript in the frontend. We have also used famous HTML presentation framework reveal.js for creating presentations from user input.

The application was built in a modular approach, where components were separated based on homogeneous functions. Core components were as follows -

- Application core
- User and Project Management
- Theme and Slide Management
- Data Management
- Share management
- Editor

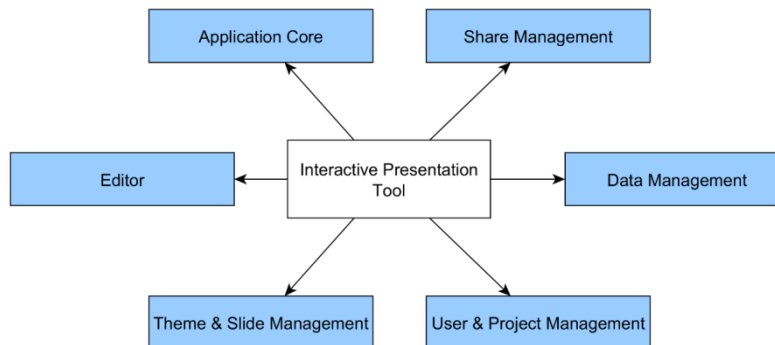


Figure 3: IPT Application Modules

## APPLICATION CORE

The application core is the heart of this application. It handles and connects request from all of the modules. It also converts user modified contents to a reusable presentation format. Different module sent their final request to the application core and it decides what to do the next. This allow each module to be separated and works independently, except for the application core. This also ensures that the whole application will not go down due to the fault of individual modules.

## USER AND PROJECT MANAGEMENT

The focus of this module is to handle all user and project management tasks and pass this information to the application core. This ensures that those who have access in MeD-OMS system can also login to this system too, and get the exact same privilege.

## THEME AND SLIDE MANAGEMENT

This module focuses on creating and using different themes for the presentation slides. Themes help presentation slides to be presented in different styles. This module also manages how a user organise existing presentations which were created by that user.

## DATA MANAGEMENT

Data management module is all about managing the data which comes as different tables and figures from MeD-OMS application. As all data from MeD-OMS is stored in RDS (result database), when a table or figure is inserted in a presentation, corresponding summary information need to be embedded within the presentation file. For tables, this information is presented as tables and for charts this will help the charts to be interactive. Data management module also ensures that the location of the source also embedded in the presentation in coded format as metadata, to allow creators to quickly update the tables and figures with the updated data in case there is updated information available in the RDS for corresponding table or figure.

## SHARE MANAGEMENT

Presenting the study reports outside of the system is an important part of this application. Share management module ensures that user can present their content to whomever they want and wherever they want. Sharing can be done online or offline. Online share allow user to share a presentation link to others, which ensures that these presentations

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can be viewed from any browser. Share management also ensures that user can take out their presentation outside of the application and this done in offline sharing method. The whole presentation can be downloaded by the author to present somewhere else.

## THE EDITOR

The editor is build using JavaScript and HTML5. This ensures that once loaded, the editor itself works without any delay in server response. The editor has all of the required functionality in place to generate a complete presentation.

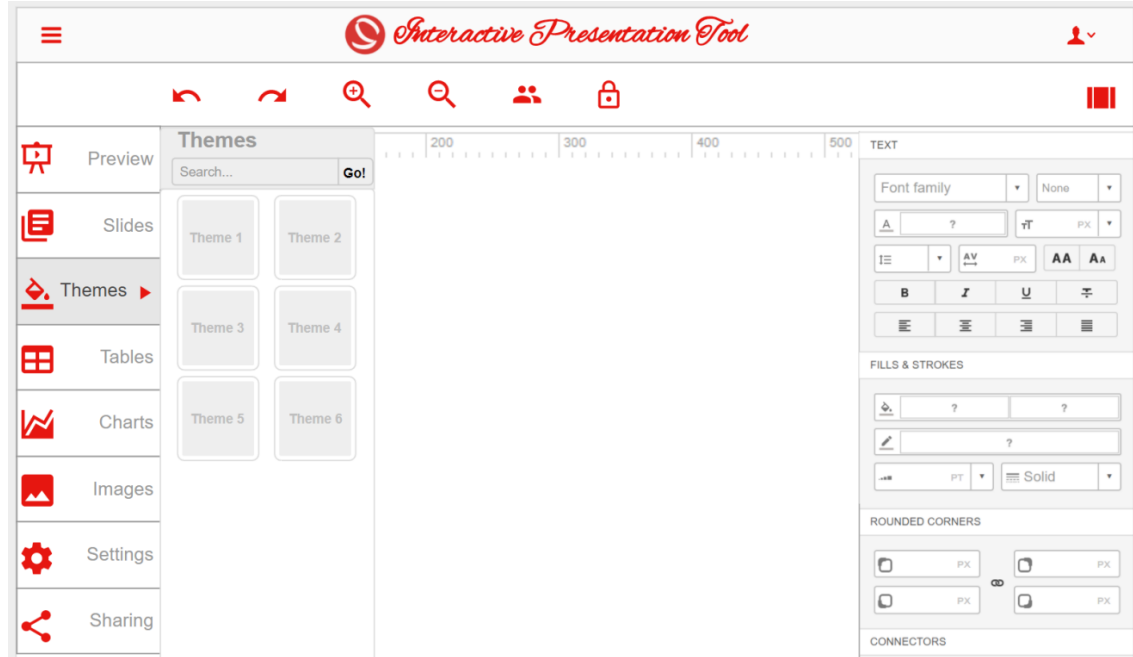


Figure 4: Editor Interface

Top menu includes Preview, Slides, Themes, Tables, Charts, Images, Settings and Sharing. This menu provides the core functionality for the editor. By clicking preview, one can preview the whole presentation, without any menu and other clutter. Slides menu help with organising the slides. From Themes menu, user can select different themes for the presentation, which will apply different font and colour scheme to the whole presentation.

Once the connection between this application and MeD-OMS is authorised, Tables and Charts menu provide the facility to import tables and graphs directly from the MeD-OMS system. More details about the table and chart importing process will be described later. It means that outputs used already do not have to be re-generated elsewhere.

Images menu allow user to manage all image related tasks in the presentation slides. User can see the list of used images in here as well as they can upload the images to be used for the presentation. Settings menu provide interface to configure the editor settings for the current presentation slides.

Share menu allow user to share the created presentation to another user or to the public. This menu links the share module with the editor via the application core.

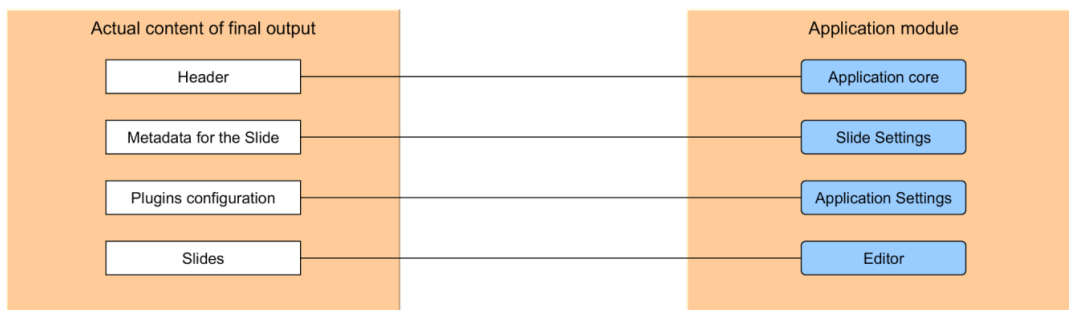


Figure 5: Relationship of actual content and application module

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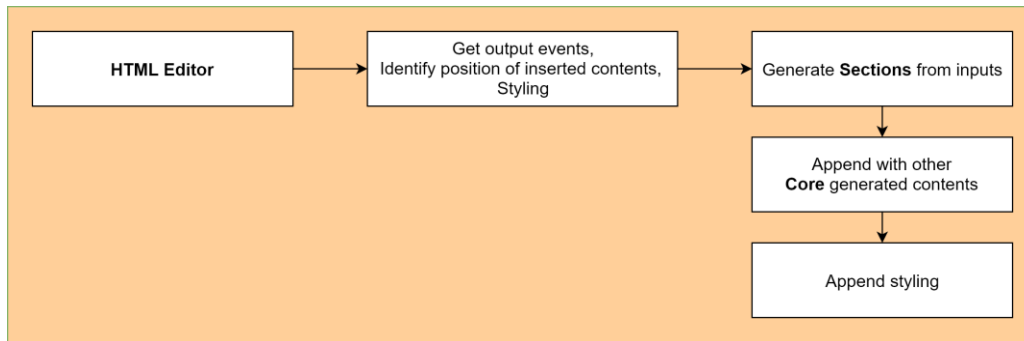


Figure 6: Editor Process Flow

## INSERTING TABLES AND CHARTS

Using live and up-to-date information is one of the key points for building this application. This tool is directly connected with the MeD-OMS and will use the same philosophy for using the TLF information from a study. All tables and charts are inserted directly from the study area, without needing to copy and paste.

If a user wants to include a table or chart from a study, they will need to select the project from the available list. IPT communicates with the MeD-OMS system and gathers the appropriate list based on the user's authorization. When a user selects a study from the list, a list of available tables will be available to include, and those table titles will be visible. By selecting a specific title, the user can see a small preview of the output. Then they can confirm to include the table within the presentation slide. All of the table data will be copied automatically to the presentation slide. This ensures that the presentation slides are free from any unwanted changes in the source tables. Once the table is linked, the editor provides a facility to update the data when source data is changed, without reimporting the whole table again.

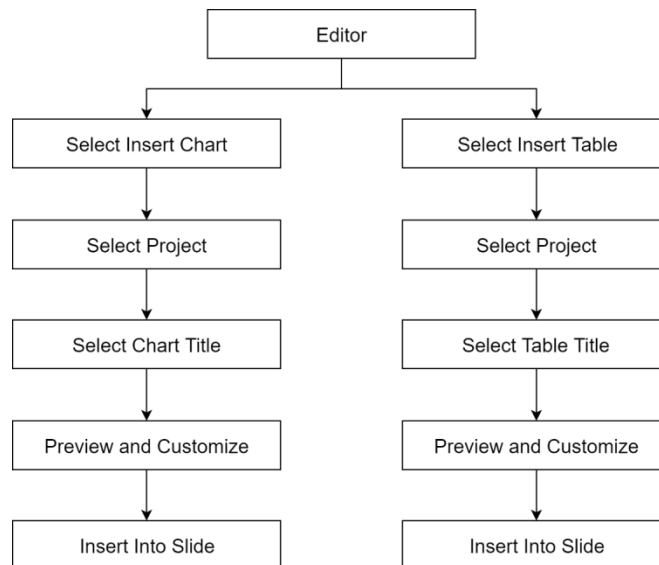


Figure 7: Inserting Tables and Charts

If a user wants to include a dynamic chart within the presentation, they will follow the same procedure as tables. First, the user will select the project, then select the expected chart title from the list of titles. After selecting the appropriate figure to be included, the preview window will allow the user to customize the chart visuals, show or hide components, add reference lines, change colour, etc. All of the customisation is only applicable for the currently selected chart, and only stored within this presentation slide. This will not affect the source charts which come from the MeD-OMS. All of the customisation will be stored as meta-information with this chart info in the presentation, so that it can be easily edited in the future.

## FINAL OUTPUT

The created presentation will be web-based and thus platform-independent. It only takes a web browser to show these presentations, which is more convenient than traditional software-dependent presentations. Besides these, unlike the traditional presentation, the user can present interactive charts using these presentations without any additional complex programming.

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These presentations also hold the latest saved data from metadata driven tables and figures. This ensures that the presentation remain consistent and everyone view the same output. As these presentations can be shared from the application itself, when author updated the presentation and publish, everyone who have the link, gets the updated view of the presentation. This also ensures the quickest distribution of an updated study results.

### **METADATA DRIVEN REVERSIBLE PROCESS**

The whole process is metadata driven and reversible. This also ensures that everyone who have access to these dynamic results can create some dynamic and stunning presentations without knowing any technical knowledge of the system or having the nightmare of traditional copy pasting results from different ecosystems. Every presentation created from this tool stores all customisation as meta information so that it can be editable and reusable. This also uses the study results database directly, which ensures the results presented are exactly same as in the study area. This application fills the missing part of the analysing, reporting and presenting study reports of a complete study, where the whole process the metadata driven and completely reusable.

### **CONCLUSION**

This paper has shown the process of reporting study results from a metadata driven ecosystem by using a web tool. The use of interactive presentation tool enables great improvement in the way someone present the results from study as well as it enables someone to directly use the produced reports into the presentation effortlessly. This greatly reduces the risk of human copy paste error for results. Generated dynamic slides allows the presenter to drill down within their presentation by using the interactivity and make them confident about their presentation. The use of a metadata driven presentation tool with metadata driven ecosystem will change the way of traditional presentation of study results by enabling dynamic and interactive results to be included in the presentation.

### **ACKNOWLEDGMENTS**

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### **CONTACT INFORMATION**

Your comments and questions are valued and encouraged. Contact the author at:

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