

Using Metadata to Drive Standards, Speed, Consistency and Quality in Reporting

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1. Introduction

The word Metadata is widely used all around us with the promise that one day it will make our lives easier. One day we will be able to push that button and the metadata that was once so time consuming to populate will give us everything we ever wanted.

This poster will show how company standards, therapeutic areas and project standards, together with a small number of selected metadata, can help us get closer to the dream.

It may not write the report for us (yet!), but it can auto-generate analysis programs in a standard structure that are easy to run and maintain over time. These programs will follow the agreed standards, and be quick to produce and validate. Metadata can finally deliver on the promise of driving standards, speed, consistency and quality in reporting.

2. Metadata

Metadata is 'data about data' by which we can provide and keep track of information about other bits of data. It may surround data sources within an organization, within a project or study, or all projects or studies in an organization.

Sometimes it contains the descriptive information about the structures and contents of data, as well as the application that processes and manipulates the data.

Metadata can be viewed as an essential tool that helps you to maintain information which will in turn allow you to concentrate more on your business, instead of your data.

3. Having a Structured Approach

There is tremendous value in knowing what was planned to be analyzed, what was analyzed, how it was analyzed, what the results were, where they are stored and where they are used and reused. All of these have internal operational efficiency possibilities outside of the department and for the good of clinical research opportunities.

It is important that we can carefully move all Metadata information into structured, reusable, findable and analyzable information.

The benefits of Metadata are achieved over time; as more data is generated, the more useful the data becomes. Therefore it is important to ensure that the structure of the Metadata is one that can survive the test of time. If the structure needs constant updates then the system becomes more burdensome as those providing the data will also need to perform some kind of updates, and it will very quickly fall out of favour.

4. Getting Started

As standardised analysis dataset are already generated by companies using various methods, generating structured shells that are pulled in together with structured analysis results to produce the tables required is the most effective approach as a starting point. There are two key details that are required for this to be successful:

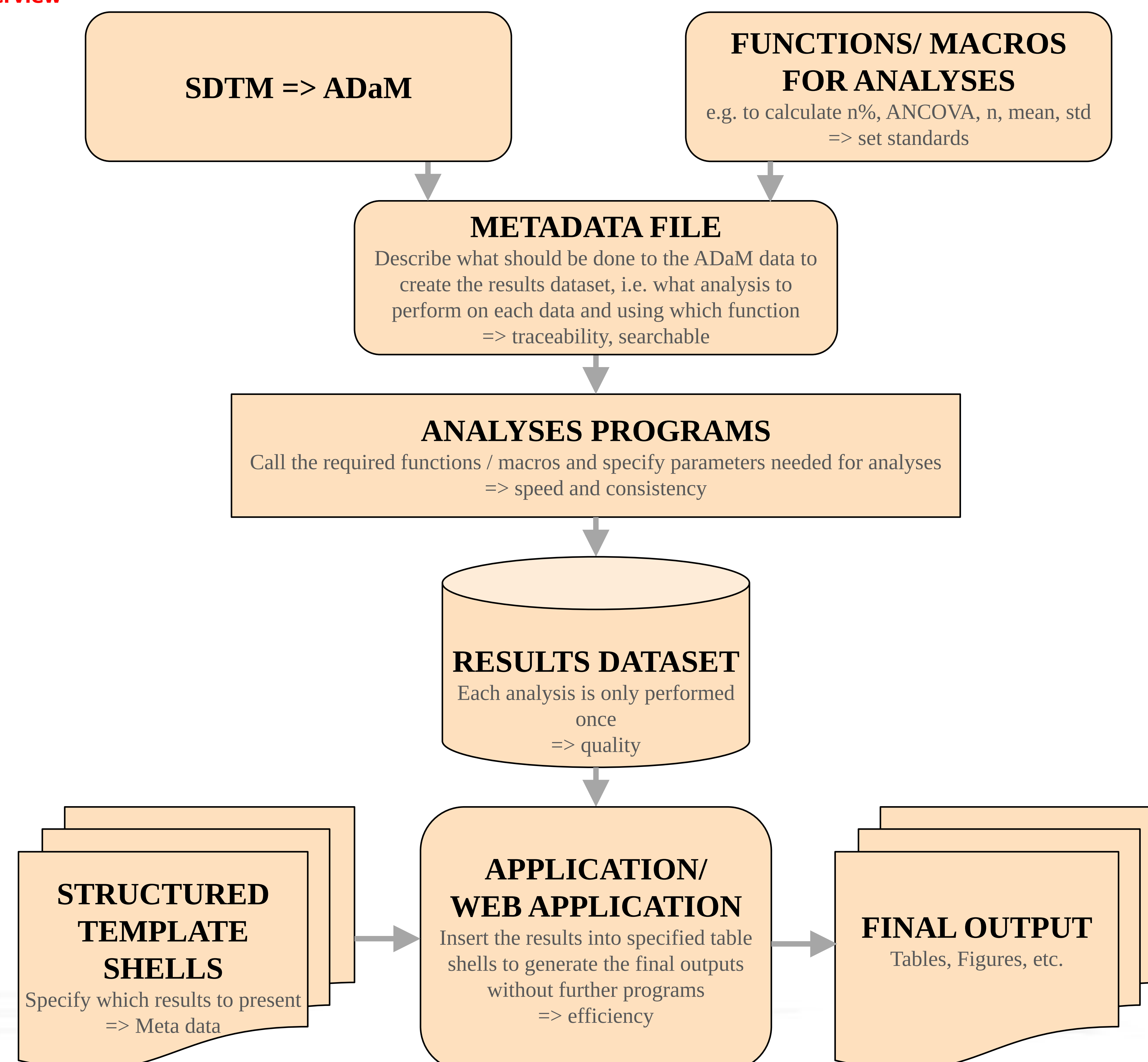
- List of analysis to be displayed
- Shells specifying which analysis are to be displayed and how

Once the list of analyses to be displayed is determined, then standard pre-programmed functions/ macros can be called to produce the analysis results. These functions will store the results in a pre-specified structured dataset that can then be selected as and when required. This means for example, the number of patients in the treated analysis set is only derived once, but the value will be used in many different table shells and may be displayed in a hundred different tables.

The Metadata associated with each shell will specify which results are to be used for each of the different parts of the display template. This will ensure that when this shell is called, the pre-calculated results are then simply displayed in the appropriate places. No further derivations are performed at this stage.

This ensures there is full traceability. One can see which shell is used for a particular table, the functions used to populate that table, and the structured analysis datasets where those numbers are generated from. As there is traceability from the analysis dataset to the original data, the link is therefore complete from the raw data to the individual values within a table.

5. Overview



6. How Far Do We Go?

We can reach a place where we have:

- Structured analysis datasets
- Structured table shells
- Structured results datasets

This then allows table shells to be created where the user only needs to select what data they want to show and what analysis they want to do with it. The results are then automatically derived using the pre-defined functions and then simply displayed later on as required.

Current process:

- Develop table shells
- Write programs
- QC output
- Perform thousands of iterations of this process to generate the different outputs.

Future process:

- Decide what summaries to present
- Derive those once using pre-programmed functions into a structured dataset
- Use the values as and when needed in each table shell

Aim: Analysis results can be seen during shell design.

This approach means that we replace programs and use functions, create structured analysis results based on standard data and use these results directly to produce the tables.

7. Conclusion

To repeat the process that has got us here is one way of thinking, and to try and find new ways of doing the same thing is another approach. However, to make a leap instead of just a step or a jump, we need to aim further than we think we can achieve.

Maybe it is time to stop thinking about programs, logs and outputs. Let us think about the analysis, and drive the delivery from that approach. What data do we have? What analysis do we want to perform? Show the results in the most appropriate manner and standardise that display template.

This process then takes us away from the mundane, time consuming efforts of managing output and shells, and gives us more time to look at innovative ways to analyse the data and present those results.

Contact Information

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