



Metadata Driven Clinical Trial Reporting Application

Improve Efficiency, Standards, Quality and Oversight



Designed by programmers, for programmers.

PRESENTATION OUTLINE

TODAY'S DISCUSSION



Introduction to Shafi Consultancy

What is Metalytics

Philosophy Guiding Metalytics

Evolution Driven by Users

Common Challenges in Reporting Trials

Demo

Common Challenges in Reporting Trials - Resolved

SHAFI CONSULTANCY

Origins: 2001

Programming Analysis datasets, Tables, Listings and Figures as well as NONMEM and WinNonLin datasets.

Age of applications: 2010

Our Applications have been used by thousands of users across more than 70 countries in clinical trials with up to 16,000 subjects, supporting them for over 10 years.

The Present

Program CDISC datasets, TLFs and NONMEM datasets to the highest quality and efficiency, with **Metalytics** Reporting Application providing easy oversight, project management, standards implementation and automation.

What is Metalytics

SEAMLESS INTEGRATION



Builds on your existing infrastructure

METADATA DRIVEN EFFICIENCY



Enables automation and consistency across trials

ENABLES OVERSIGHT



Supports global project management workflows and resource allocation

INTUITIVE INTERFACE



Designed by programmers for programmers

Philosophy Guiding Metalytics

QUALITY BY DESIGN

Intuitive environment where
Quality is driven by standards
Efficiency harnessed by reducing, reusing and recycling.



Evolution driven by users



ToC Concept

Most companies arrange work using **Table of Contents**. So why not drive the process with the ToC? So its easy to see what is required.

Version Control

As the titles are driving the programs, it makes sense to keep all **versions** of programs and **auto-generate** them if appropriate.

Validation Report

Stating that the program is ready for validation & setting it to validated with an **automatic report**, documenting who did what and when.

RDS & E-template

Using a single **Results Database** and E-templates means output can be generated without programs and results can be **visualised**.

Project Management

Being able to Assign Primary and QC programmers means all aspects programming and management can be done by **Metaltyics**

WORDS TO LIVE BY

**Simplicity is the ultimate
sophistication.**

Leonardo Da Vinci

Common Challenges in Reporting Trials

Oversight

Assigning primary programmer and validator roles to individuals and checking status of tasks when programmers are spread across the world in multiple time zones is **time consuming and inefficient**.

Standards

There are company, project, trial as well as client standards that organisations have to maintain. Their **versions and usages** also have to be documented in the trials where they are used.

Environment

Automation can help to produce most of the TLFs, but standard macros and templates as well as **developing programs** from scratch are still required. Programmers should be able to do all these easily.

Traceability & Reusability

Programmers are all too often writing programs for things that have already been programmed by others within the organisation. **Ability to search** what has been done is critical in this **global environment**.



Common Challenges in Reporting Trials - Resolved

Oversight

Easy for PMs to see current status, changes over time and to assign tasks, while for programmers its easy to see what they have to do and what's left for them and others to do.

No more spreadsheet.

Standards

Easy to implement standards at different levels and for programmers is easy to define which macros and versions to use within a study.

No more risk of using multiple versions.

Environment

Programming in the native environment means programmers can benefit from all the advances from SAS environment, like abbreviations, colours, ease of data review. Same with R.

No more limited editors.

Traceability & Reusability

Automatic report shows what went into every output, from macro name to the dataset and variable names. Search means everything produced can be found and reused.

No more re-inventing.

CONTACT US FOR AN IN-DEPTH DEMO

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