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H2H Portal App

Julian Schmocker, MSD, Zurich, Switzerland

Qian Wang, MSD, Brussels, Belgium

X. Gregory Chen, MSD, Zurich, Switzerland

A Shiny Automation of Reproducible and Traceable Analysis and Reporting Using Metadata Framework

Agenda

1 Introduction

2 Main Design

3 Demo: Request Workflow

4 Demo: A&R Workflow

5 Conclusion

Glossary

ADaM	Analysis Data Model
A&R	Analysis and Reporting
CSR	Clinical Study Report
H2H	Health Economic modelers <-> HTA statisticians/programmers
HECON	Health Economics
HTA	Health Technology Assessment
LDS	Late Development Statistics
PICO	Population, Intervention, Comparator, Outcome
RTF	Rich Text Format
TLF	Table, Listing, Figure
UI	User Interface

Introduction

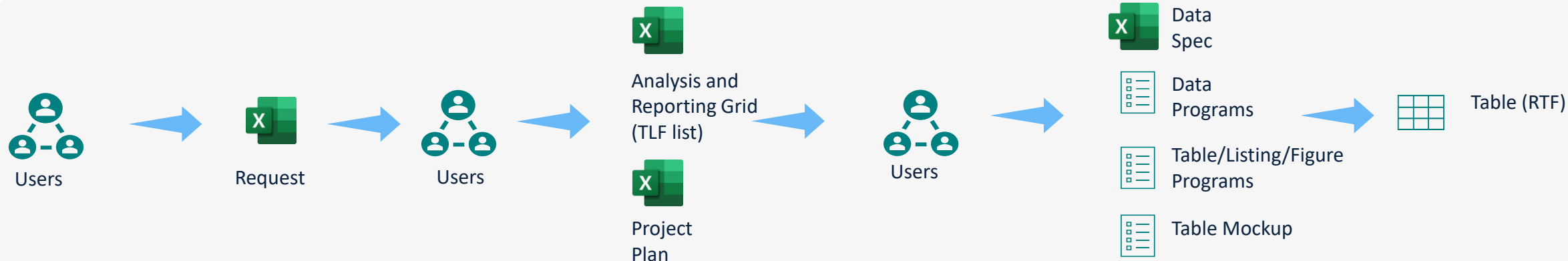
Use Case

- Collaborative workspace with multiple stakeholders in the HTA process
- Reproducible and traceable analyses and reporting from user requests to result generation
- Integration of analysis and reporting assets in SAS and R programming languages

Challenges

- Complex work process
- Multiple existing processes independent from each other
- Repeated data entry for the same information by different users in different documents
- Manual process heavily centered around using Excel spreadsheets and email communication

Process before H2H



Product Overview

End-to-End Automation of Project Deliverables

- Easy completion of project requests with version tracking
- Automated creation of key A&R process documents and Mockup table package
- Tracking of relevant project metadata to enable automation
- Support of standardized as well as project specific TLF
- Target User: Economic Modeler, HTA Statisticians and Programmers

Business drivers:

- Move away from Excel based request process
- Leverage Ongoing standardization effort for majority of HECON deliverables
- Streamline project processes and documentation
- Efficiently produce large volume of outputs with high quality
- Provide an example of R based analysis & reporting (A&R)
- Provide an example of end-to-end A&R automation using the Shiny framework

Main Design



Main Principles

Principle 1 End-to-End

Integrate separate parts in the A&R process

- Project Request
- Project Plan
- Mock table package
- Analysis Dataset specification
- A&R specification
- Table/Listing/Figure generation
- A&R process documentation

Principle 2 Automation

Single-Entry

- Collect necessary info only once at the right time, and propagate automatically in the A&R process

Guided Entry

- Provide user-friendly UI
- Perform input entry checks
- Ensure consistency with standards

Auto-generation

- R function calls
- TLFs
- Project A&R process documents

Principle 3 Reproducibility and Traceability

Reproducibility

- Same results can be obtained by running the same code with the same parameters

Traceability

- Provenance of the outputs can be tracked back to the original sources.

The H2H Portal tracks the relevant project metadata (regarding operation, data, analysis, TLF) with versioning in order to ensure reproducibility and traceability.

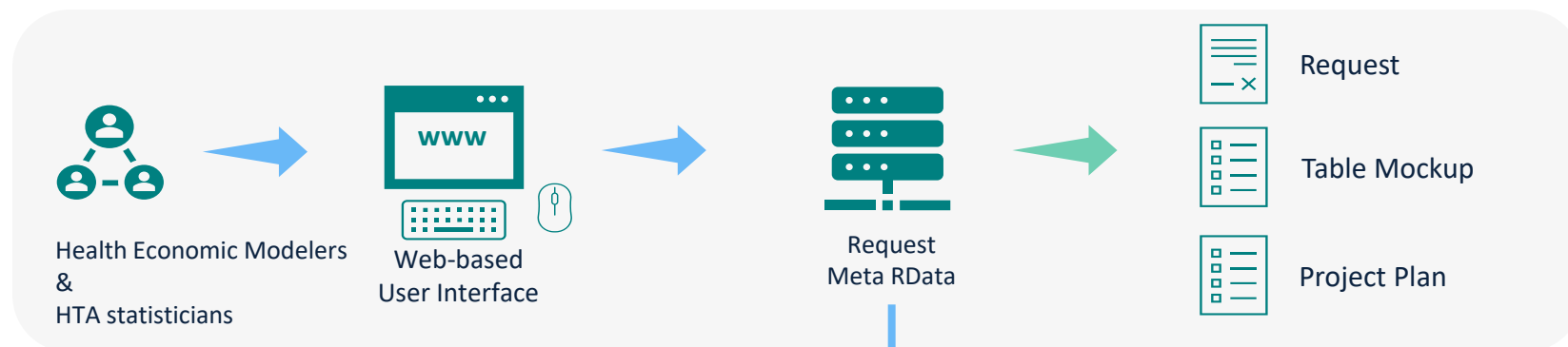
All the links between the different parts (analysis datasets, study details, function calls) are recorded.

Full Process

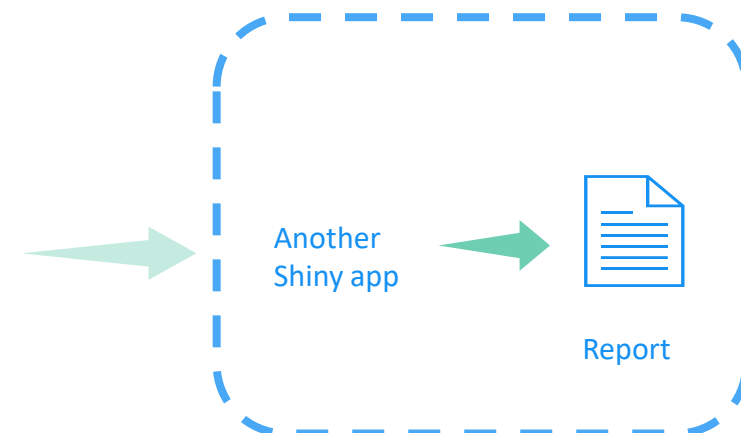
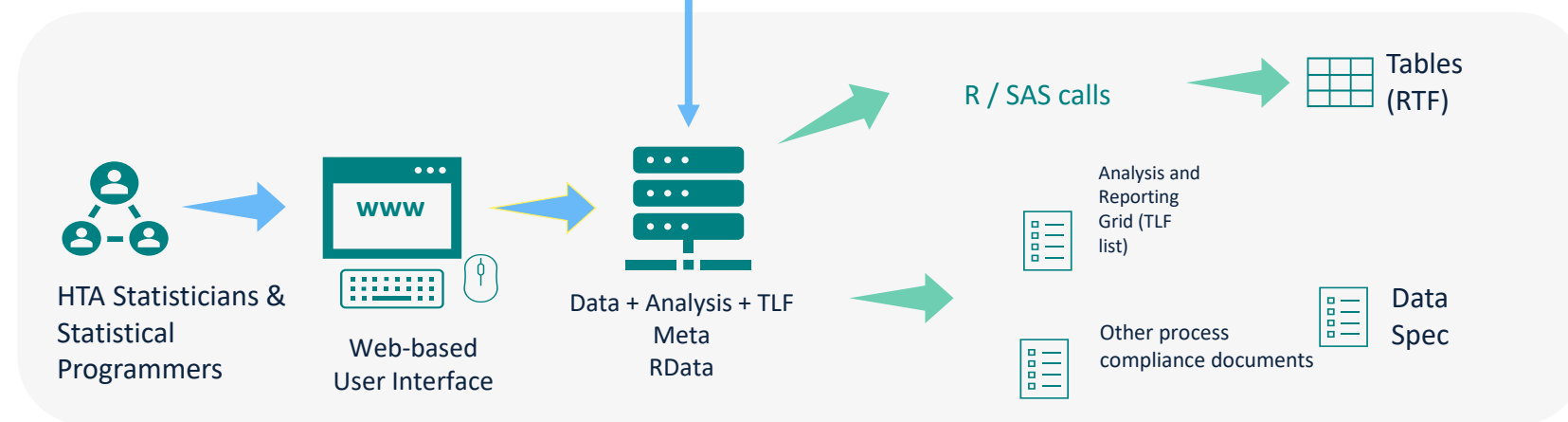


Request Workflow

➡ Automated



A&R Workflow



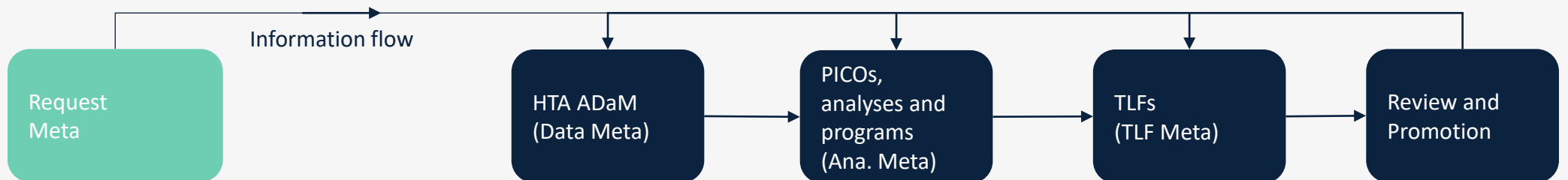
Details Workflows

Request Workflow

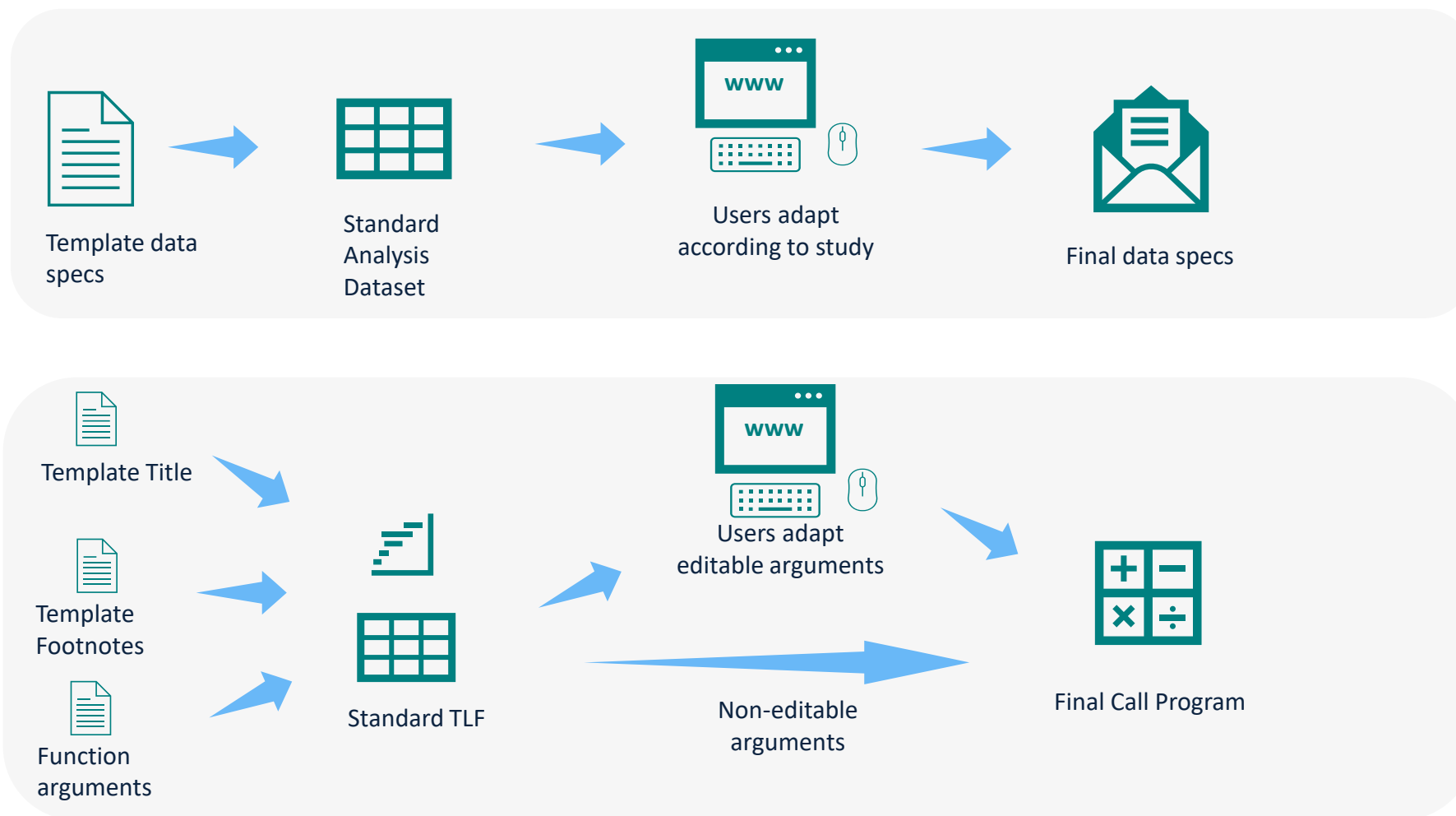
- *Request Meta Rdata*
 - General Study Info (Protocol, Data Cutoff Date, ...)
 - PICO (Population, Intervention, Comparator, Outcome) definition
 - ✓ Subpopulations
 - ✓ Treatment and Comparators
 - ✓ Requested analysis TLFs and datasets
 - Timelines

A&R Workflow

- *Data + Analysis + TLF Meta RData – built upon Request Meta with further details*
 - Data Meta
 - ✓ Analysis Datasets and specification
 - Analysis Meta
 - ✓ PICOs
 - ✓ Analysis methods
 - ✓ Programming assets
 - TLF Meta
 - ✓ TLF layout, title, footers, filename...
- Review and Promotion

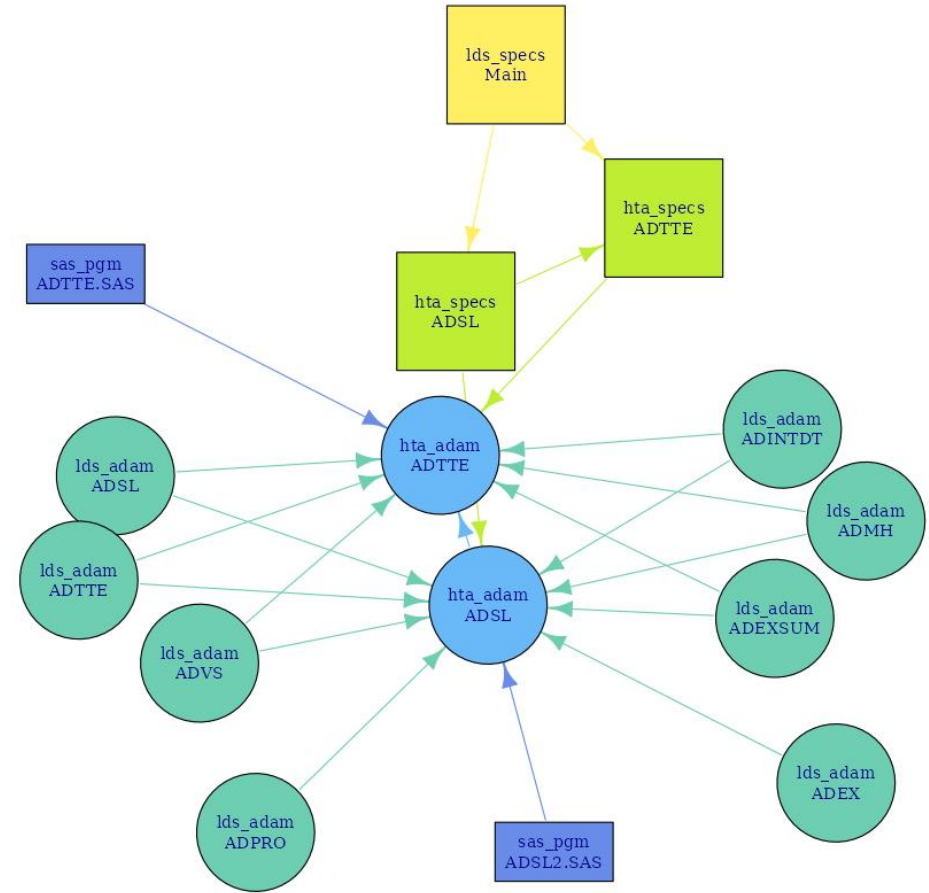


Use standard templates to facilitate automation



Traceability Map

- Captures and visualizes the dependencies between the items used within the A&R workflow
 - HTA datasets
 - CSR datasets
 - HTA specifications
 - CSR specifications
 - SAS programs
- Identifies potential risk when linked objects are out of sync



Demo Request Workflow



Demo A&R Workflow

Conclusion



Conclusion

Expected Results:

- Enhanced quality
The app ensures completeness and correctness of inputs, improving output consistency.
- Improved efficiency
The app streamlines the process, reducing time and effort.
- Increased reproducibility
The app collects metadata, ensuring reproducibility of results.
- Improved collaboration
The app facilitates communication and coordination among stakeholders.
- Comprehensive traceability
The app's traceability association map provided a clear overview of information flow.
- Scalability and adaptability
The app successfully handles various projects, showcasing potential for future enhancements.

Future Development

- Integrate User feedback
Gather user feedback and then enhance the apps functionality and user experience.
- Comparison module
Implement a module that allows for the comparison between different version of items (like dataset specs, datasets,...). This will improve the impact assessment.
- Cross-study metadata reporting

Acknowledgements



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Thank you

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

- Julian Schmocker
julian.benjamin.schmocker@msd.com
- Qian Wang
qian.wang1@msd.com
- X. Gregory Chen
xiangyi.gregory.chen@msd.com