MSD

Analysis Specification to Execution

An internal effort to facilitate processes with R/Shiny

June 12th 2025

Agenda

- Introduction
- The Challenge
- The Solution
- The Product
- The Approach
- The Difficulties
- Closing

Introduction: Who am I

Brian Lang

- Dr. Sc. ETH Zurich (Biosystems Science and Engineering)
- Based in Zurich, Switzerland
- Statistician at MSD in the Health Technology Assessment (HTA) space
- Lead teams to develop and maintain:
  - R packages to create analysis tables, listing, and figures
  - R/Shiny apps to facilitate our business processes
  - DevOps support for other teams

Introduction: What is HTA

Health Technology Assessment (HTA)

- Informs reimbursement and coverage decisions by payers
- Focuses on comparative effectiveness, and patient outcomes, and market-specific subpopulations
- Seeks to answer, "Is this treatment worth paying for, compared to existing alternatives?"
- Typically occurs after regulatory approval
- Key bodies: NICE (UK), IQWiG (Germany), CADTH (Canada)

The Challenge: Diversity and Multitude of Evidence Needs

Each country is special

NICE
National Institute for
Health and Care Excellence

IQWiG

CDA-AMC

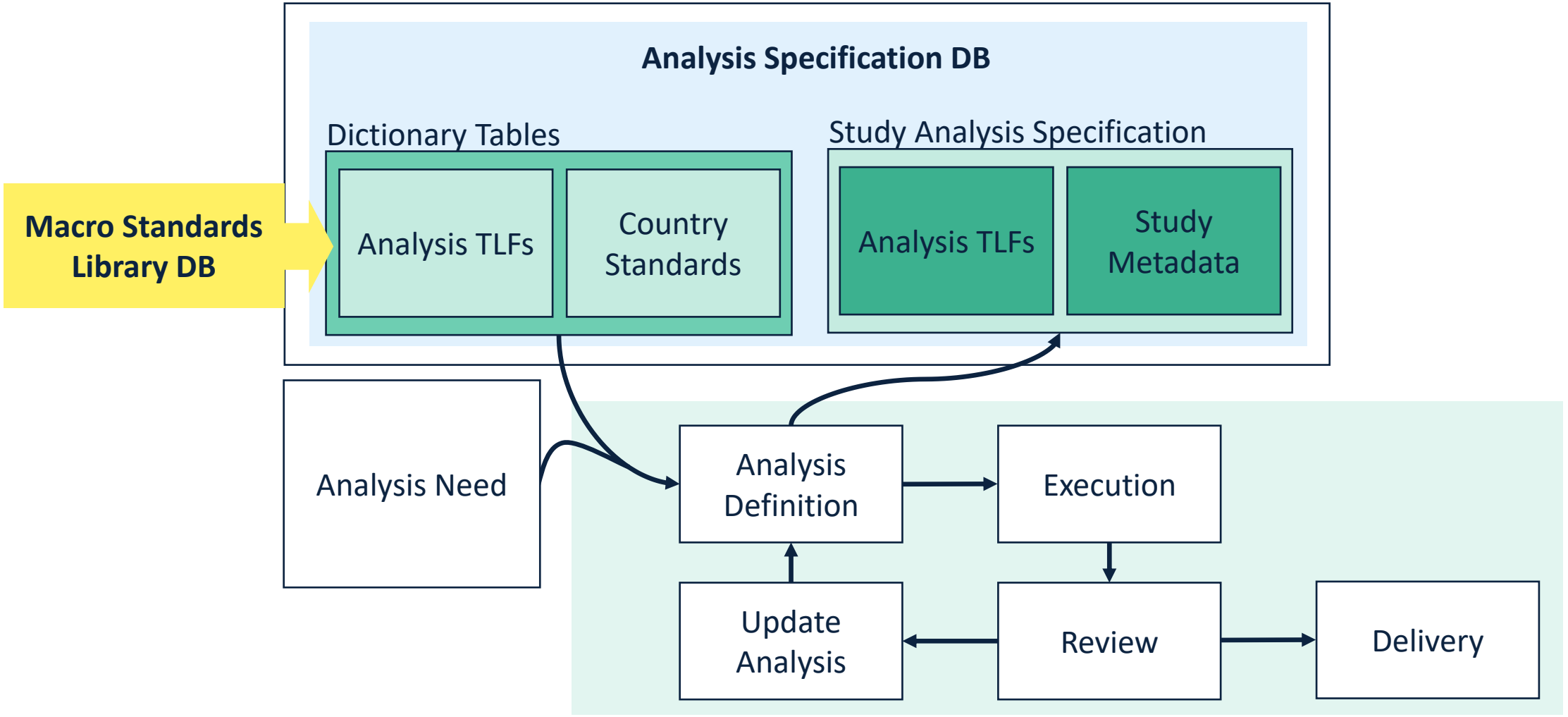
AIFA

The Challenge: The Business Process

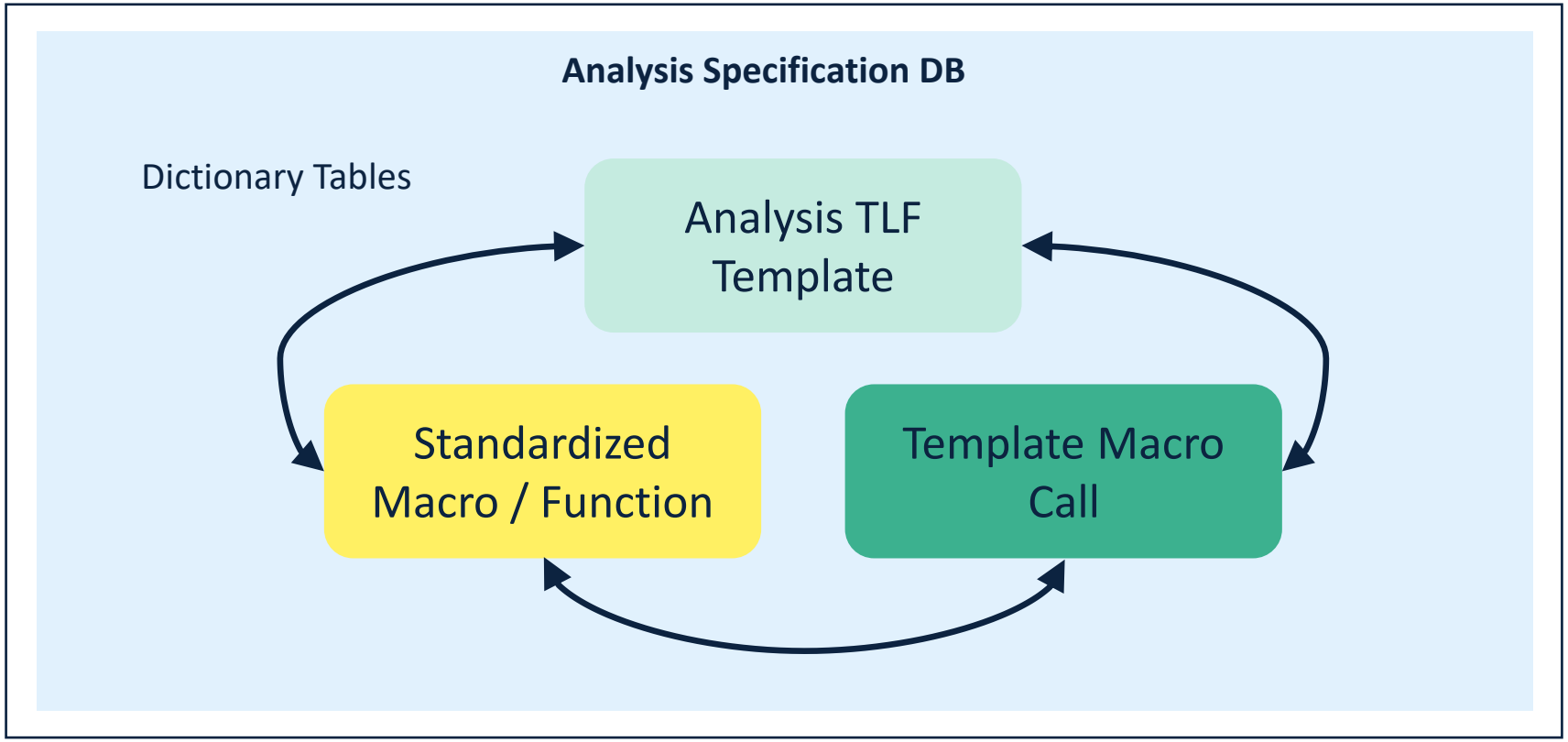
Non-scalable processes

- Project directory for each study for each market
- Duplicated processes (excel sheets) for analysis specification
- Heavily copy-paste based specification process

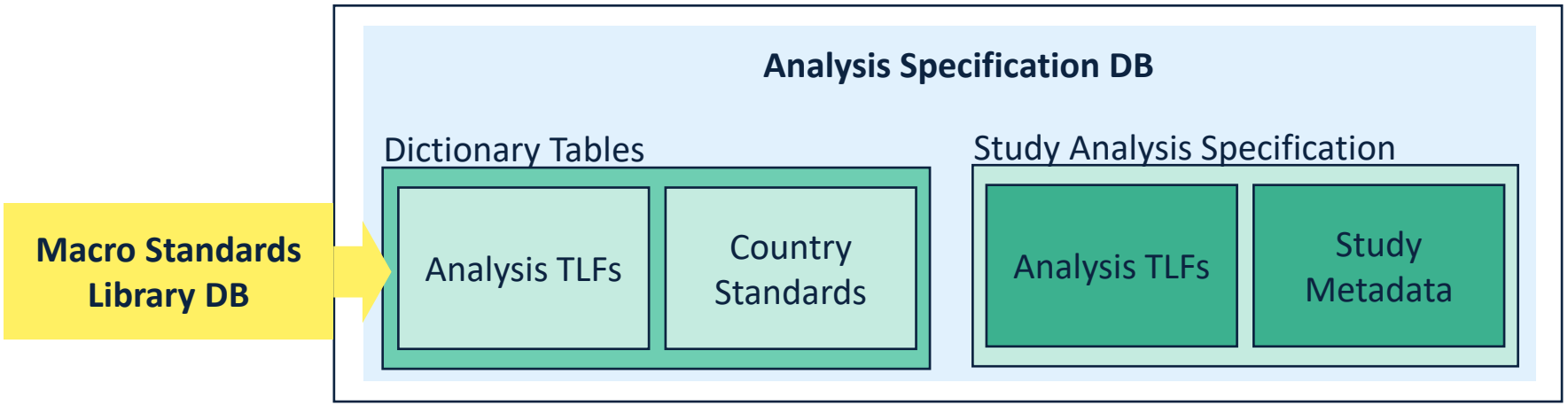
The Solution: Database-first analysis specification and data flow



The Solution: Explicit Table Standards and Macro Linkage

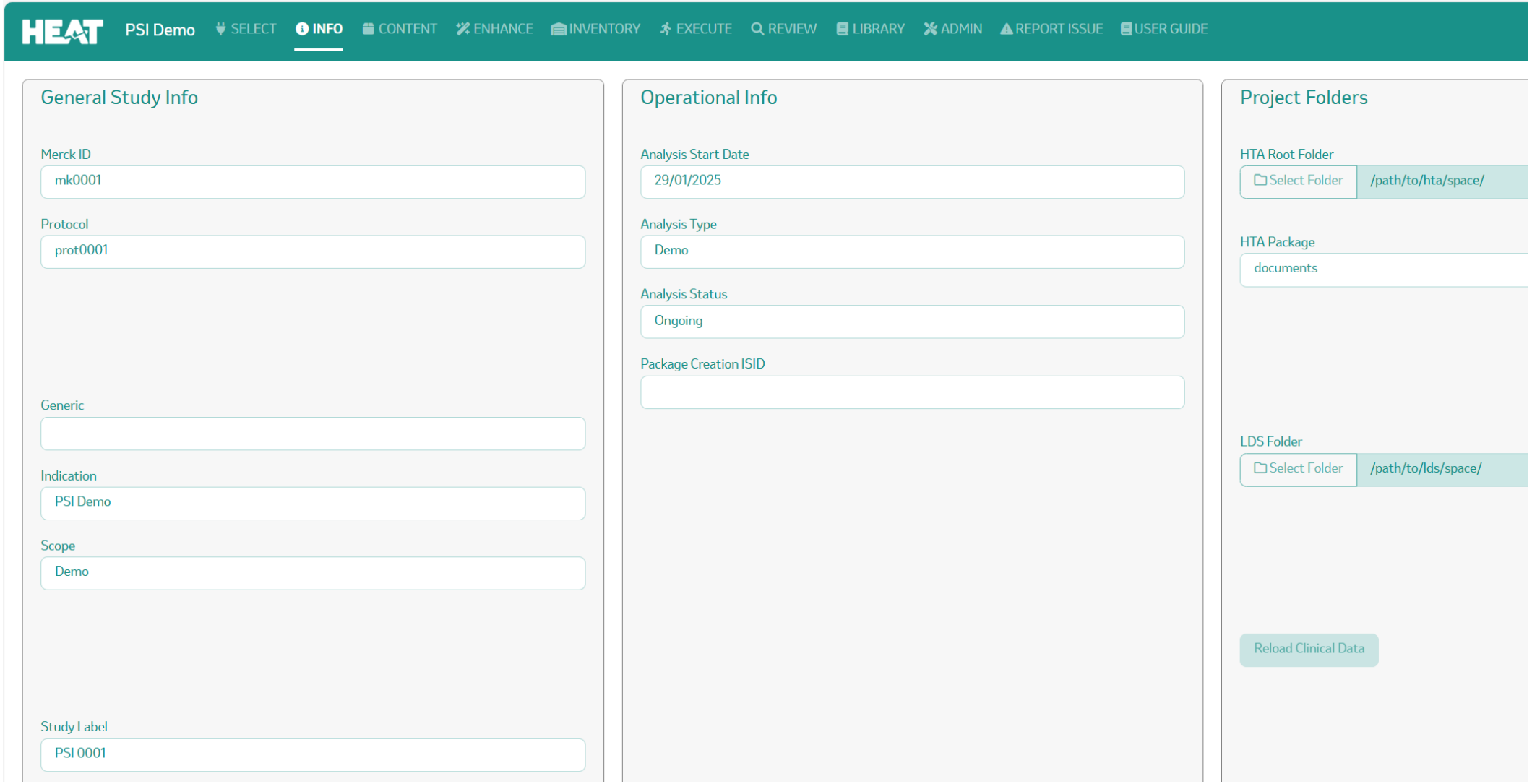


The Solution: Study Analysis Specification

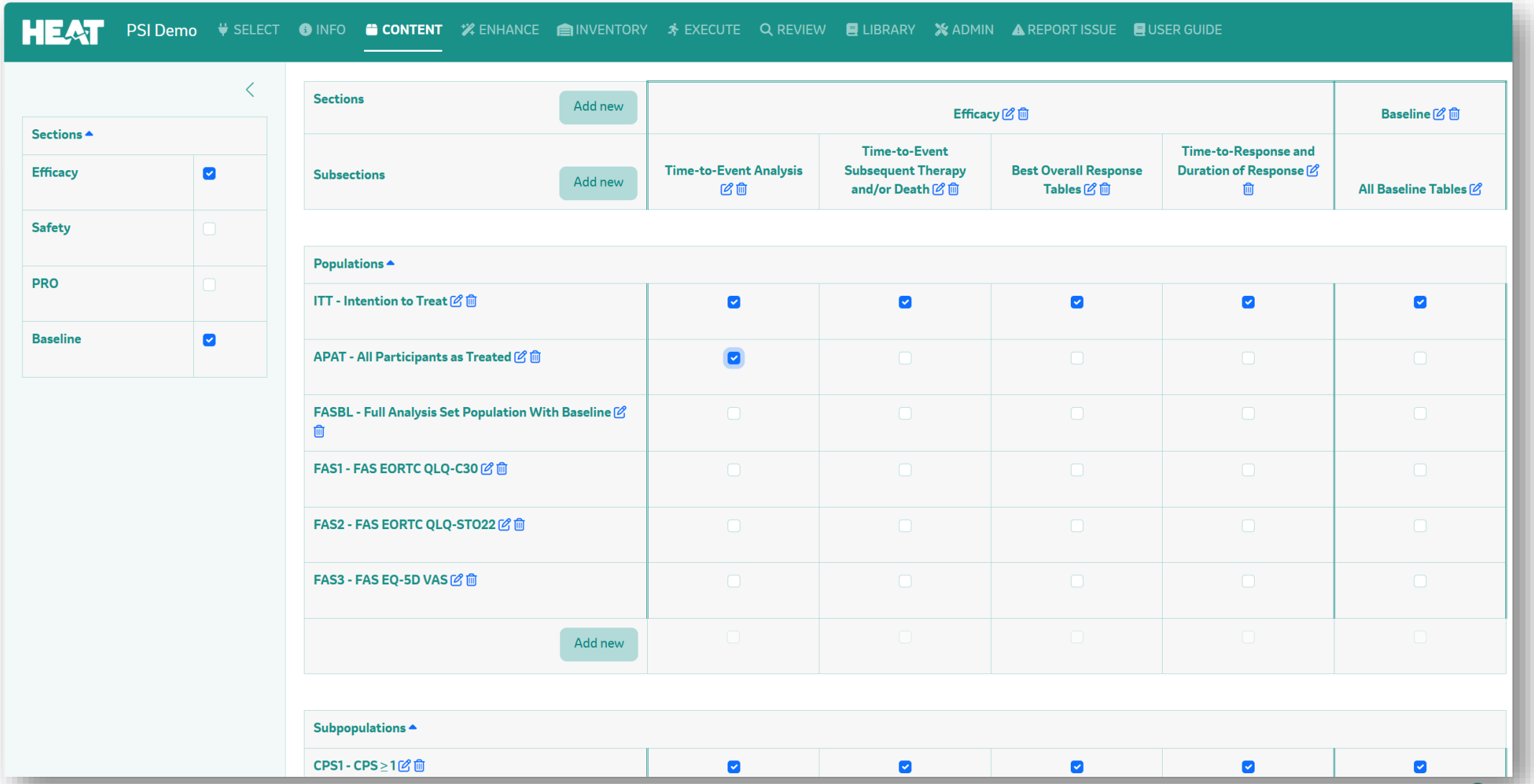


Study Metadata
Endpoints linked to title placeholders linked to footnotes linked to dataset variable
Methodology linked to footnotes linked to macro parameters linked to macro parameters
Subpopulations linked to title placeholders linked to footnotes linked to dataset filters
Etc…

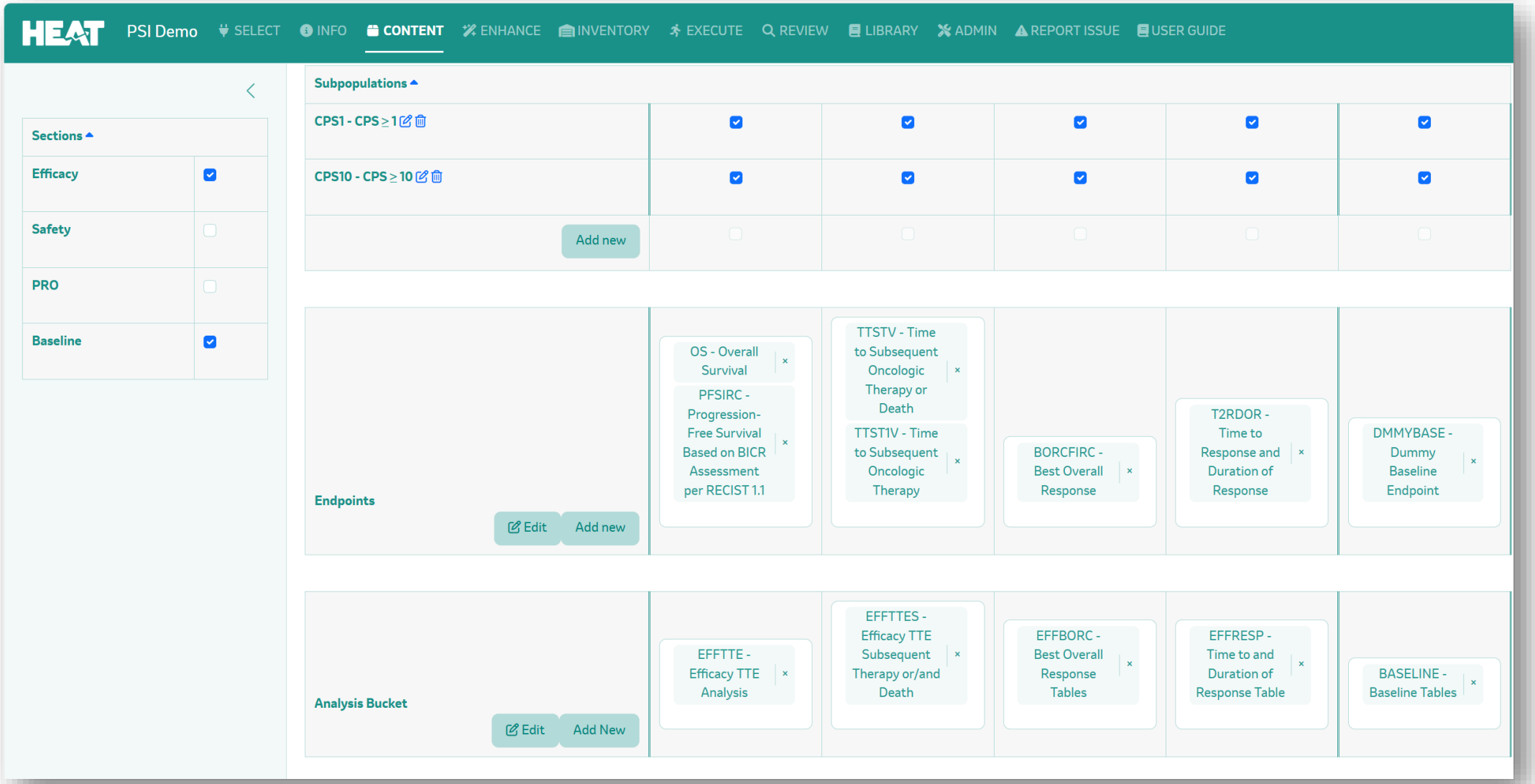
The Product: Shiny Analysis Specification and Execution Platform



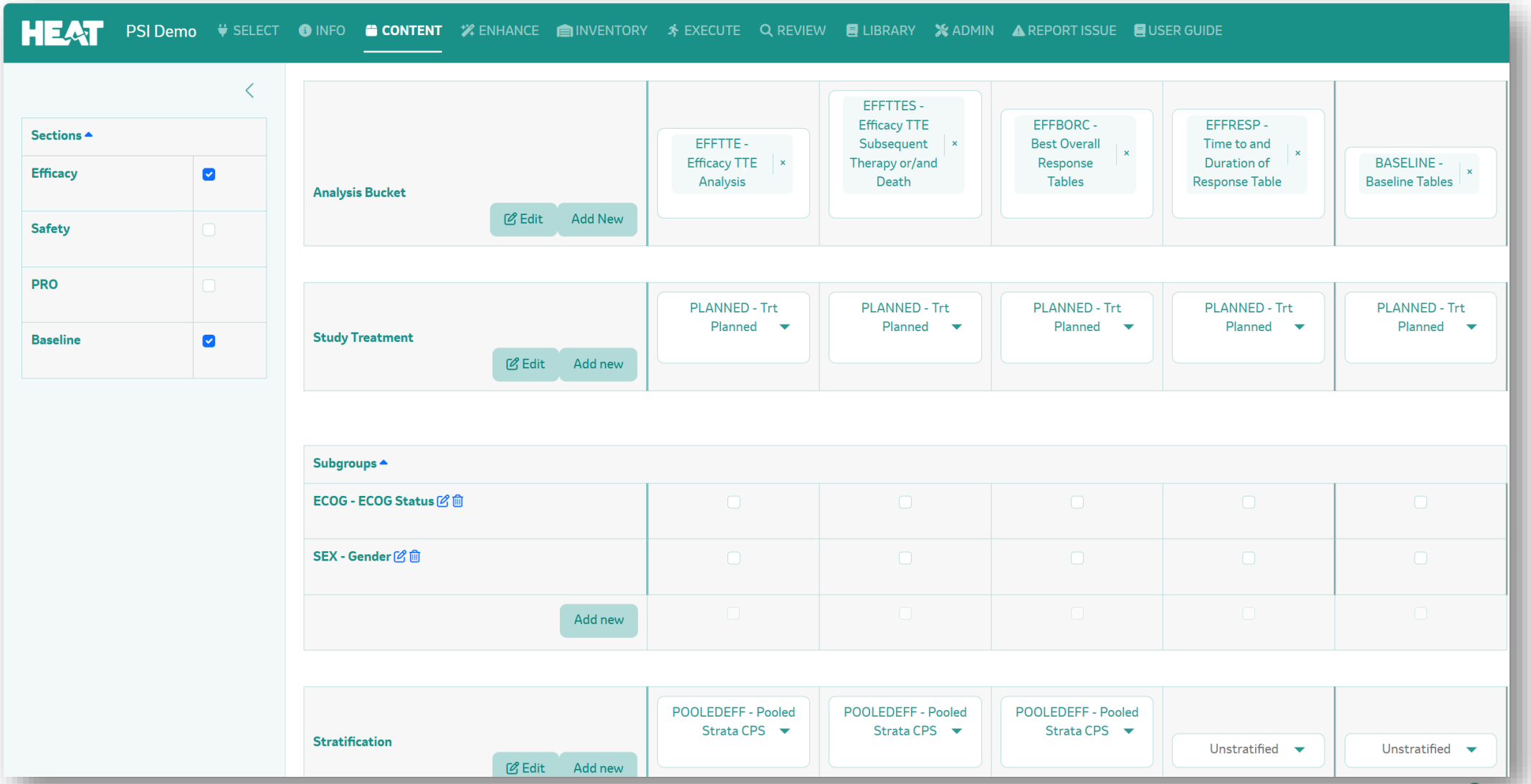
The Product: Shiny Analysis Specification and Execution Platform



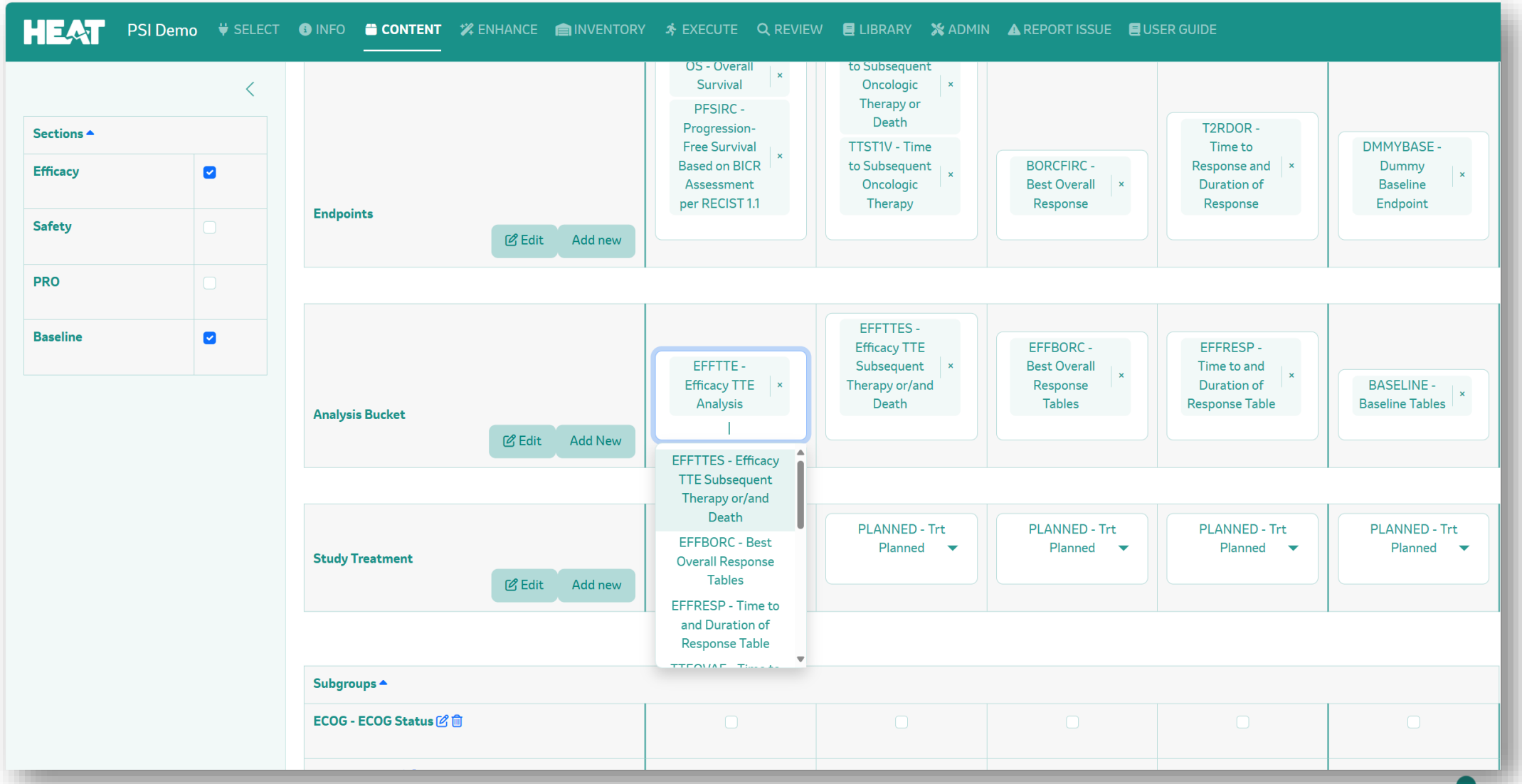
The Product: Shiny Analysis Specification and Execution Platform



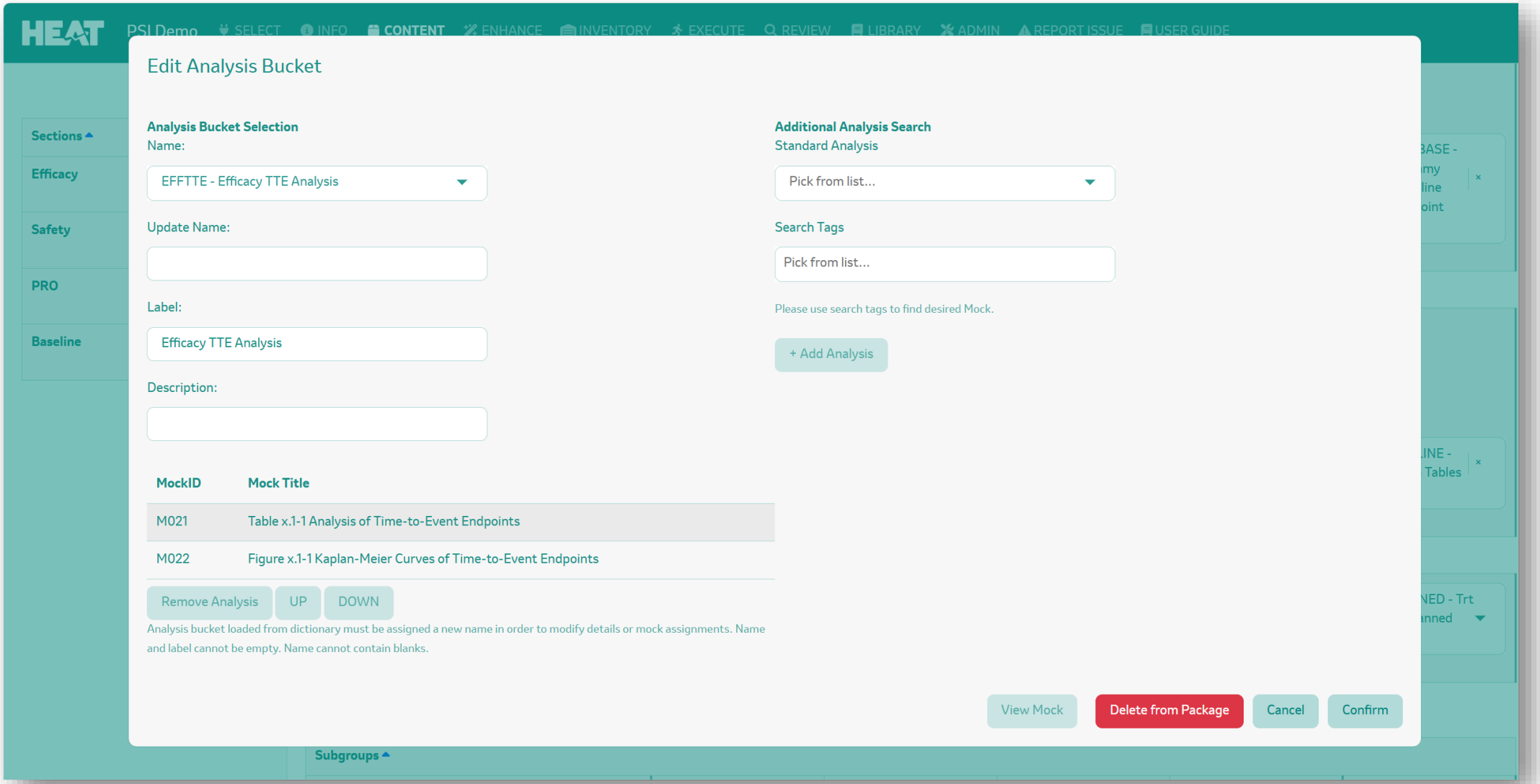
The Product: Shiny Analysis Specification and Execution Platform



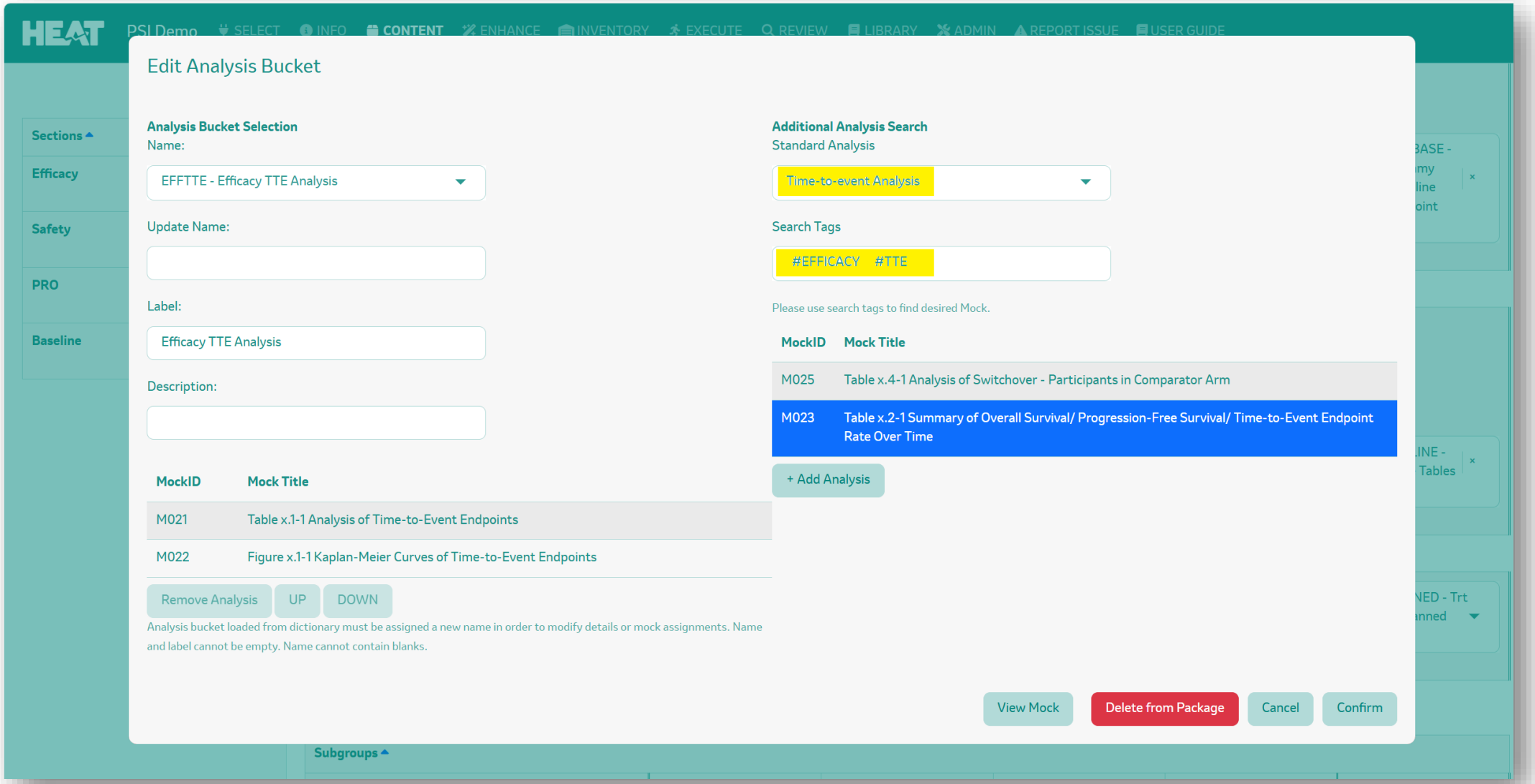
The Product: Shiny Analysis Specification and Execution Platform



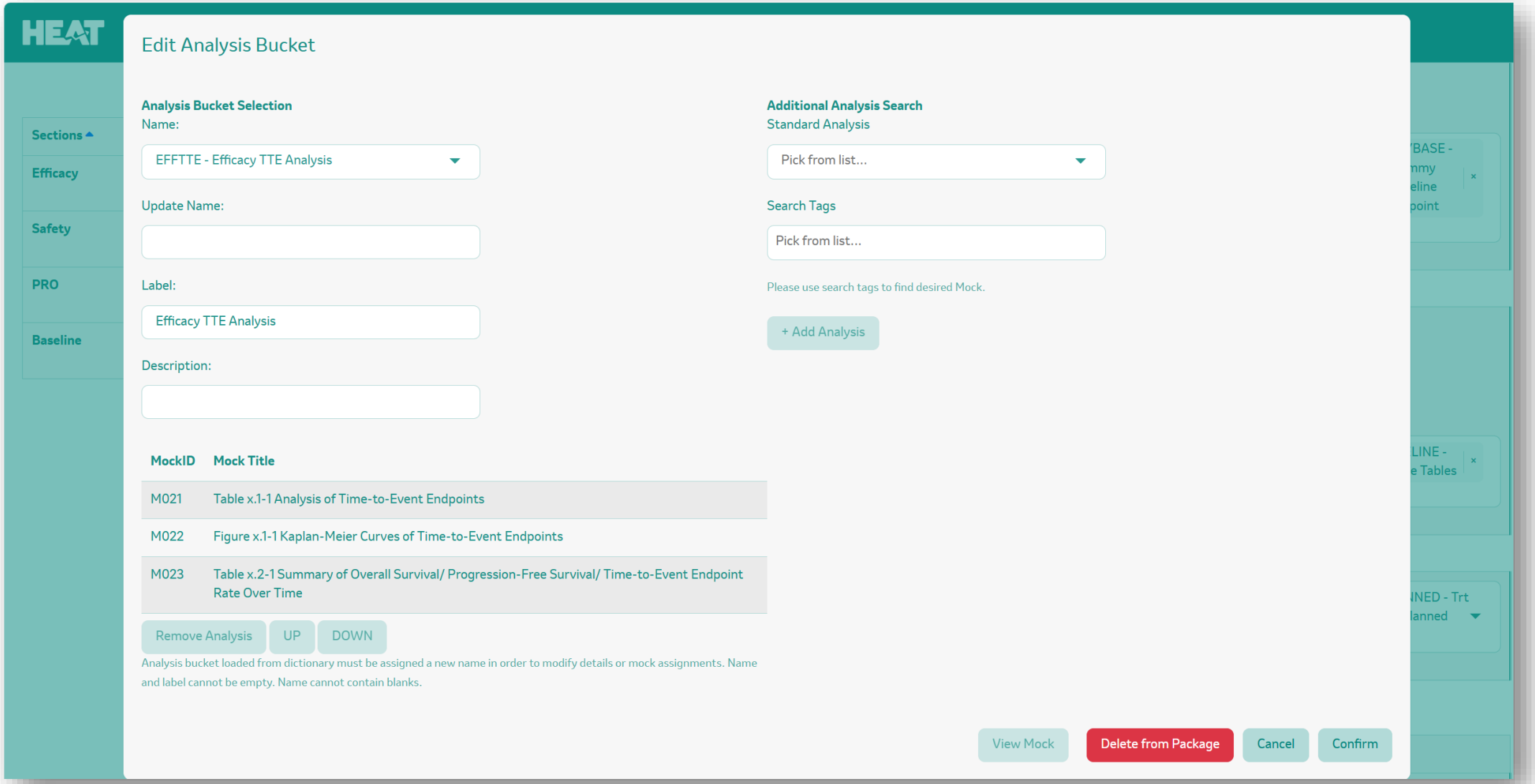
The Product: Shiny Analysis Specification and Execution Platform



The Product: Shiny Analysis Specification and Execution Platform

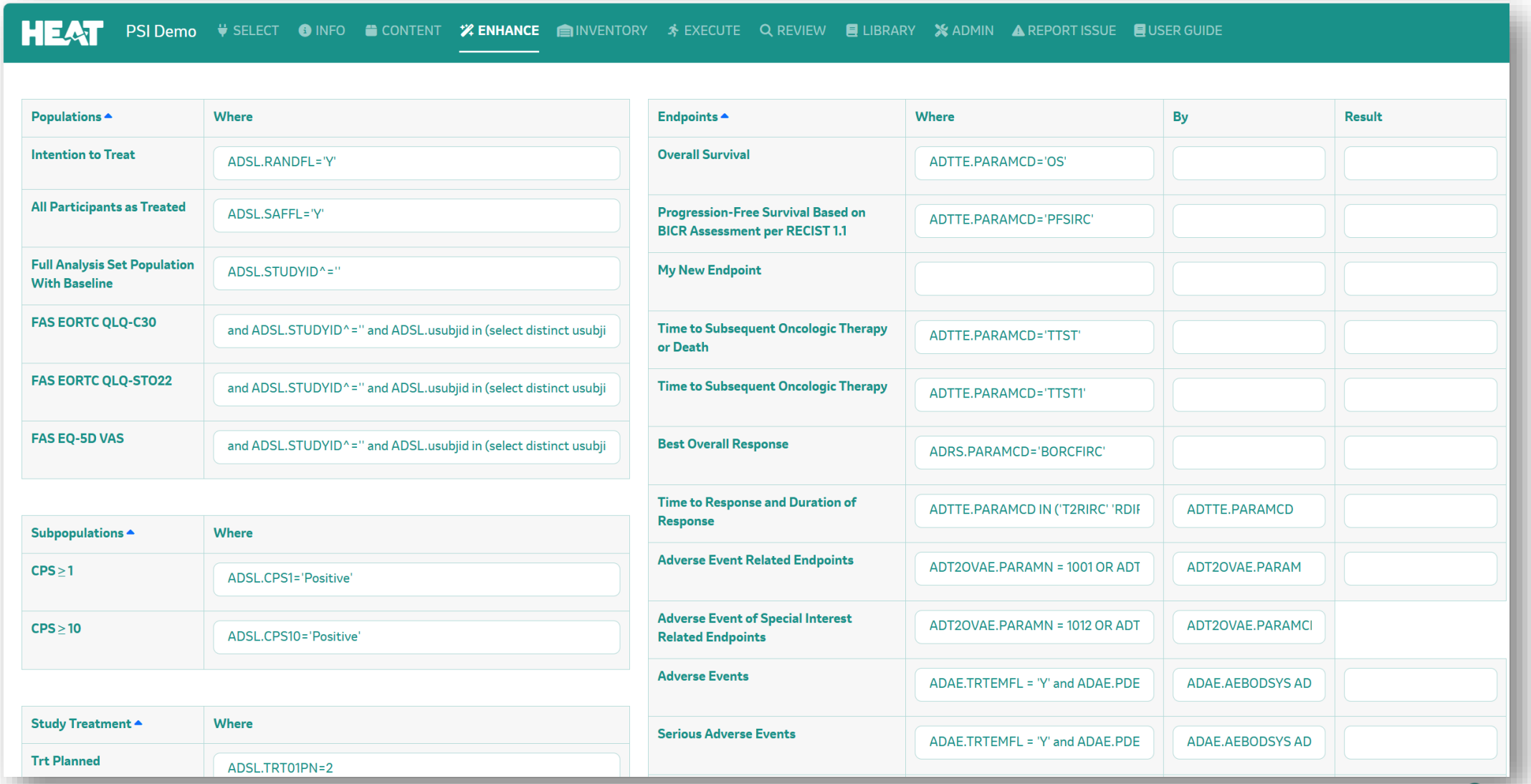


The Product: Shiny Analysis Specification and Execution Platform

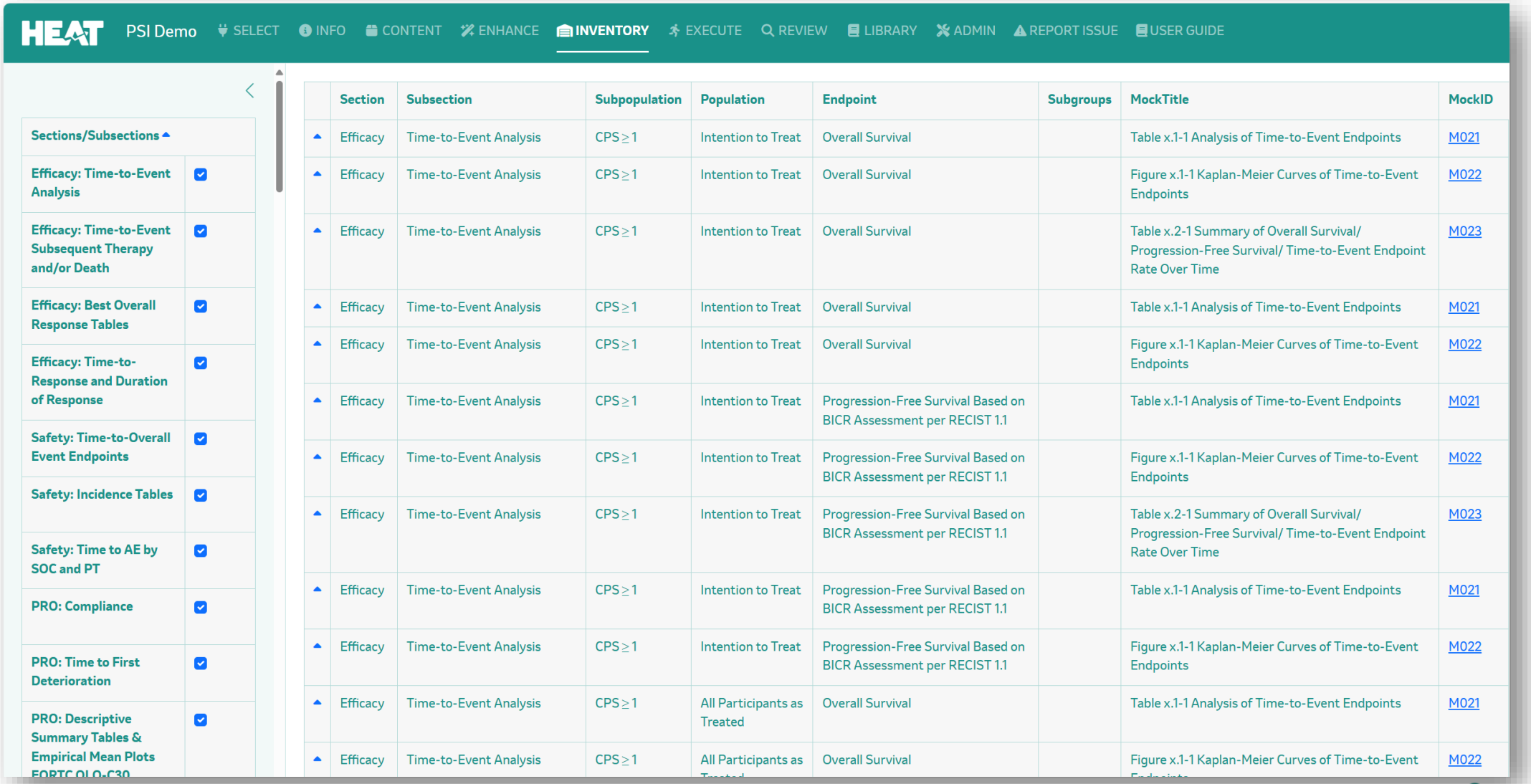


The Product: Shiny Analysis Specification and Execution Platform

The Product: Shiny Analysis Specification and Execution Platform



The Product: Shiny Analysis Specification and Execution Platform



Section	Subsection	Subpopulation	Population	Endpoint	Subgroups	MockTitle	MockID
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Overall Survival		Table x.1-1 Analysis of Time-to-Event Endpoints	M021
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Overall Survival		Figure x.1-1 Kaplan-Meier Curves of Time-to-Event Endpoints	M022
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Overall Survival		Table x.2-1 Summary of Overall Survival/ Progression-Free Survival/ Time-to-Event Endpoint Rate Over Time	M023
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Overall Survival		Table x.1-1 Analysis of Time-to-Event Endpoints	M021
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Overall Survival		Figure x.1-1 Kaplan-Meier Curves of Time-to-Event Endpoints	M022
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Progression-Free Survival Based on BICR Assessment per RECIST 1.1		Table x.1-1 Analysis of Time-to-Event Endpoints	M021
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Progression-Free Survival Based on BICR Assessment per RECIST 1.1		Figure x.1-1 Kaplan-Meier Curves of Time-to-Event Endpoints	M022
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Progression-Free Survival Based on BICR Assessment per RECIST 1.1		Table x.2-1 Summary of Overall Survival/ Progression-Free Survival/ Time-to-Event Endpoint Rate Over Time	M023
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Progression-Free Survival Based on BICR Assessment per RECIST 1.1		Table x.1-1 Analysis of Time-to-Event Endpoints	M021
Efficacy	Time-to-Event Analysis	CPS ≥ 1	Intention to Treat	Progression-Free Survival Based on BICR Assessment per RECIST 1.1		Figure x.1-1 Kaplan-Meier Curves of Time-to-Event Endpoints	M022
Efficacy	Time-to-Event Analysis	CPS ≥ 1	All Participants as Treated	Overall Survival		Table x.1-1 Analysis of Time-to-Event Endpoints	M021
Efficacy	Time-to-Event Analysis	CPS ≥ 1	All Participants as Treated	Overall Survival		Figure x.1-1 Kaplan-Meier Curves of Time-to-Event Endpoints	M022

The Approach:

- Team of five statistical programmers and statisticians
- Biweekly standup
- Developing on Posit Workbench
- Database is MS Dataverse
- Function and Module-focused development for R/Shiny

- GitHub for:
  - Single source of truth
  - Issues for project planning
  - Actions (GHA) for:
    - R CMD Check
    - Code coverage
    - Deployment to RConnect

The Difficulties:

- Exploratory Mindset -> Production Mindset
- Testing when a DB is involved
  - Fully-spoofed DB with Plumber::
    - Used for testing suite
    - Used for dev work
- Convincing team of the relevance of testing

- Documentation
- Organic development

- Team was rather inexperienced at the start -> code improves over time, but refactoring is never a priority

MSD

Gianluca Mortari
David Maher-McWilliams
Quincy Kaka
Michael Allie
Rob Livermore
Chiara Bin
Matt Gale
Gosia Wojtecka-Glod
Nan Xiao

Thank you!

With special thanks to the **openstatsware**