

Guiding the Direction of Open-Source Development for Faster End-to-End HTA Submissions

OS04

Stephen McCawille – Daiichi Sankyo

Christian Haargaard Olsen – Novo Nordisk

November 2025
Phuse EU Connect 2025
Hamburg



Left: Harbour of Genova, 1920. FORTEPAN / Bejczy Sándor, License: <https://creativecommons.org/licenses/by-sa/3.0/deed.en>

Right: Longshoremen on a [New York](#) dock load barrels onto a barge on the [Hudson River](#). Photograph by [Lewis Hine](#), c. 1912.

Shipping before 1950s



Every cargo type needed different handling equipment
Barrels, boxes, crates, and pallets each required specific gear

Loading times were absurdly long
A single ship could take weeks to load

Massive labor requirements
Armies of longshoremen were needed to move cargo

Cargo damage and theft were rampant
Goods were constantly broken or stolen during shipping

Coordination across transport modes was a nightmare
Different handling methods between trucks, trains, and ships created huge inefficiencies



.. after 1950

Ships could be purpose-built for containers

Ships could be purpose-built for containers - Vessel design was optimized specifically for container handling

Ports could invest in universal equipment

Specialized cranes worked with any container

Trucks and trains became universally compatible

Haulage rigs would fit any load

Independent innovation became possible

Companies could innovate without coordinating with each other

Global trade exploded

The friction of moving goods disappeared



What is Health Technology Assessment (HTA)?

REGULATORY

*Do benefits
outweigh risks?*

Can we use the treatment?

*Is quality
acceptable?*

HTA

Is it good value?

... for whom?

Should we use the treatment?

*Is it better than what
we currently have?*

**Regulation (EU) 2021/2282 of the European
Parliament and of the
Council of 15 December 2021 on health
technology assessment
and amending Directive 2011/24/EU (Text with
EEA relevance)**

Yay!

**Align HTA requirements
within the European union**

**Clearer expectations and
predictability for required
evidence generation**

Streamlined processes

Nay

Compressed timeline

Potential simultaneous regulatory and HTA submissions

Limited time for producing additional analysis

**Different opinions within member states:
interpretations, comparators,
methodologies**

Helicopter view

Serve all health systems in Europe at once!

- Determine what is required
- Generate large quantities of evidence

Short timeline means frontloading

- Guesstimate PICOs

Programmers view

Huge amounts of different types of analyses, on short timeline, with last minute changes.

- Majority of analyses can be standardized and automated
- Some analyses need to be custom
- Enable changes and quick updates
- (Transparent and reliable)



Work across the HTA ecosystem to promote the use of R in Health Technology Assessment. Develop standardized, transparent, and reproducible analytics tools that address increasing regulatory pressures and complex evaluation demands.

Collaboration

- Multi-stakeholder dialogue
- Unified R initiative
- Shared understanding

Standardization

- Develop best practices
- Transparency and reproducibility
- Validated frameworks

Enable automation

- Practical tools
- Efficient workflows



Two workstreams

1. Mapping of landscape
2. Mapping out available R packages

Takeaways

- Mapping shows complexity of EU HTA evidence generation process
- Broad interest in general solution
- Challenges in sourcing resources for development
- Doubts about orchestration of large-scale solution
- JCA is a good motivating factor for collaboration

A slight detour: Modular system design

Dividing a system into smaller pieces called modules, each with distinct independent functionality, working together to provide the needed functionality.

Core principles

- Separation of concerns
- High cohesion
- Low coupling
- Information hiding
- Well-defined interfaces

Benefits

- Parallel, modular development
- Easier maintenance
- Scalability, add/upgrade modules
- Impact of customization clear
- Reusability of modules

Another detour: Open source



Open Source

Available code

Software freedom

Access to source

User autonomy

Community of peers

Ethical imperative

Freedom

Collaboration

Zero cost

Transparency and security

Community Support

Rapid Innovation

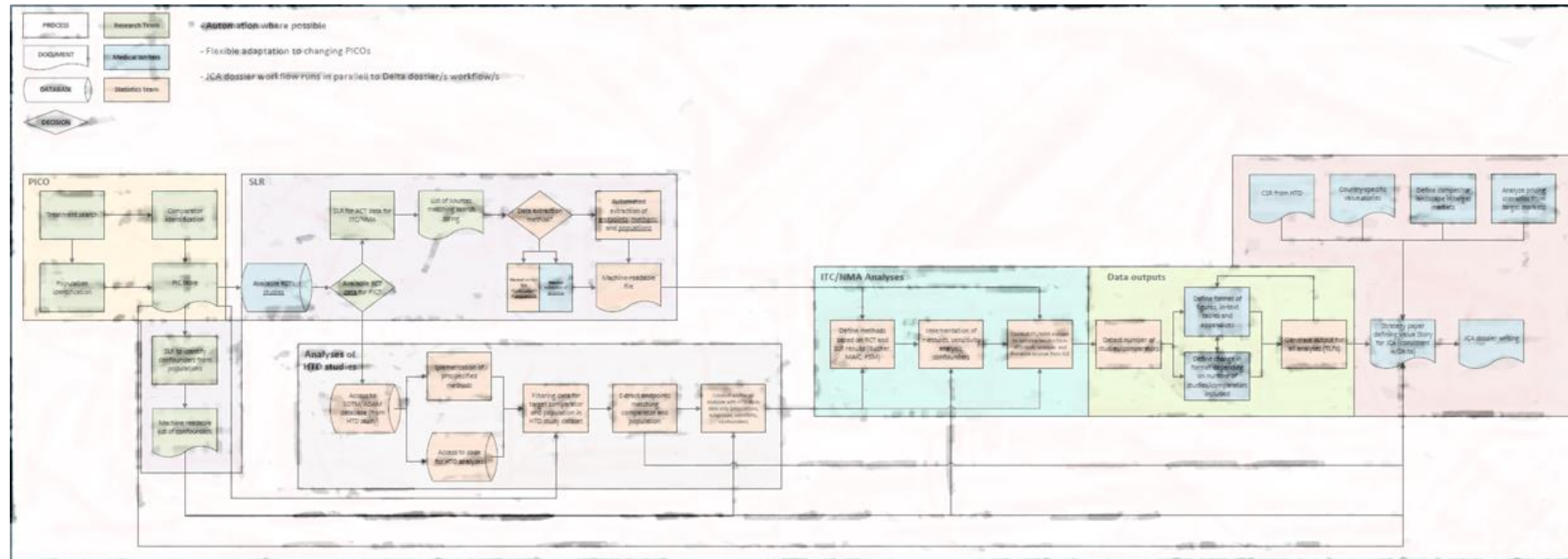
Vendor Independence

Free beer

Our proposal

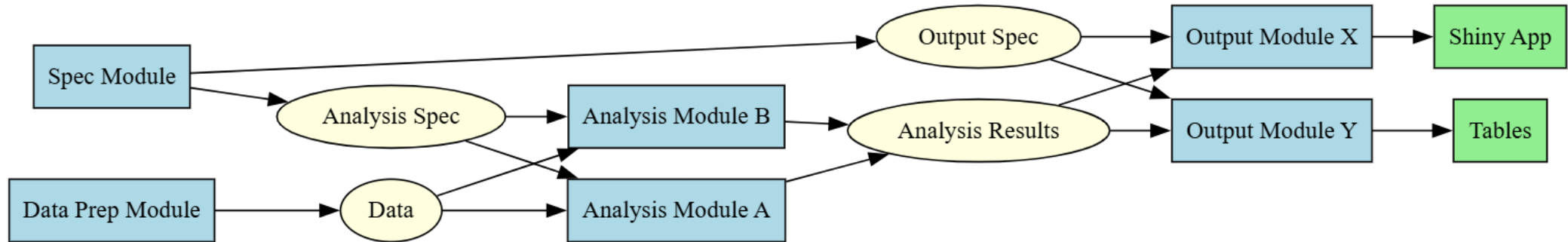
Use **open-source** collaboration to apply **modular** design principles to enable and coordinate **open-source** collaboration in directed organic growth towards end-to-end HTA automation.

From process mapping



Process mapped by Karolin Struck, Smartstep Consulting

To modular blueprint





Community

- Develop modules
- Develop blueprint

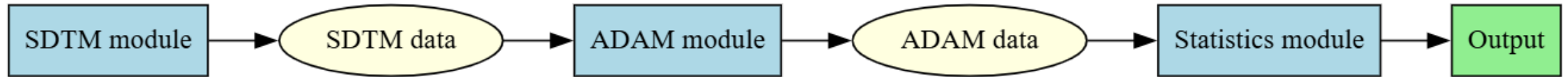
Modular design

- Limit scope of each module
- Make interfaces clear
- Provide clear value proposition

Community

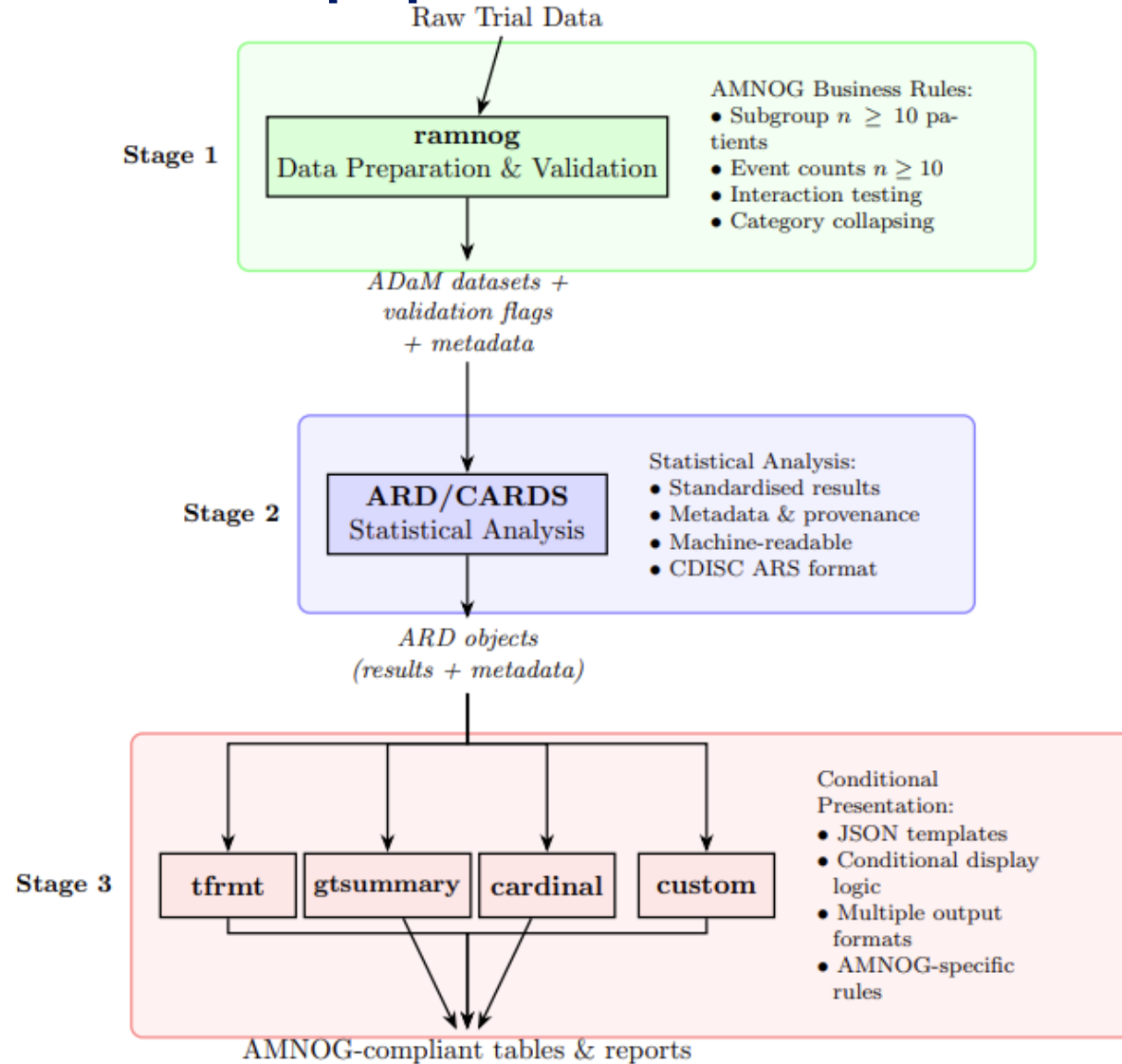
- Ensure understanding of processes stripped of company bias.
- Ensure suitable modularization stripped of company bias.

Example - CDISC



- ☒ Separation of concerns
- ☒ High cohesion
- ☐ Low coupling
- ☒ Information hiding
- ☐ Well-defined interfaces

Example – AMNOG pipeline



Conclusion

Use **open-source** collaboration to create a blueprint for end-to-end HTA automation based on **modular** design principles to enable and coordinate **open-source** development in directed organic growth.

For you

- Company agnostic solution
- Manageable pieces
- Extendable and upgradeable
- Diverse resource pool

For your boss

- Immediate value generation
- Reduced coordination overhead
- Clearer business case
- Flexibility in module coverage