



Bridging the Gap - Enhancing Analysis Results Generation with CDISC ARS Model and Community TFL Designer

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Current State: The construction of TFL mock-up shells and analysis results metadata in our industry faces challenges stemming from variability, lack of standards, and manual processes.

Analysis Results Generation: Top 5 pain points

Manual process in designing TFL shells/layout and ADaM specifications

Programmer writes the SAS code to generate analysis deliverables (sometime with macros or re-using the code)

Too much variability across studies, disease areas, and organization

Static results with No or limited linking facility (e.g., to Protocol, SAP, ADaM data)

There is no industry standards for analysis results

Survey results from 253 participants conducted during the TFL Designer Design Thinking Workshop, 13th Sep 2022, highlight the pressing need for standardized, machine-readable TFL display shells and analysis results metadata to bolster efficiency and collaboration.

Survey Results from Design Thinking Workshop

Who generates TFL shells?
57% - Biostats
41% - Biostats & Programmers

74% organization have TFL standards or templates

80% responders uses MS Word / Excel for TFL shells generation

87% responders confirmed their TFL shells are NOT machine-readable

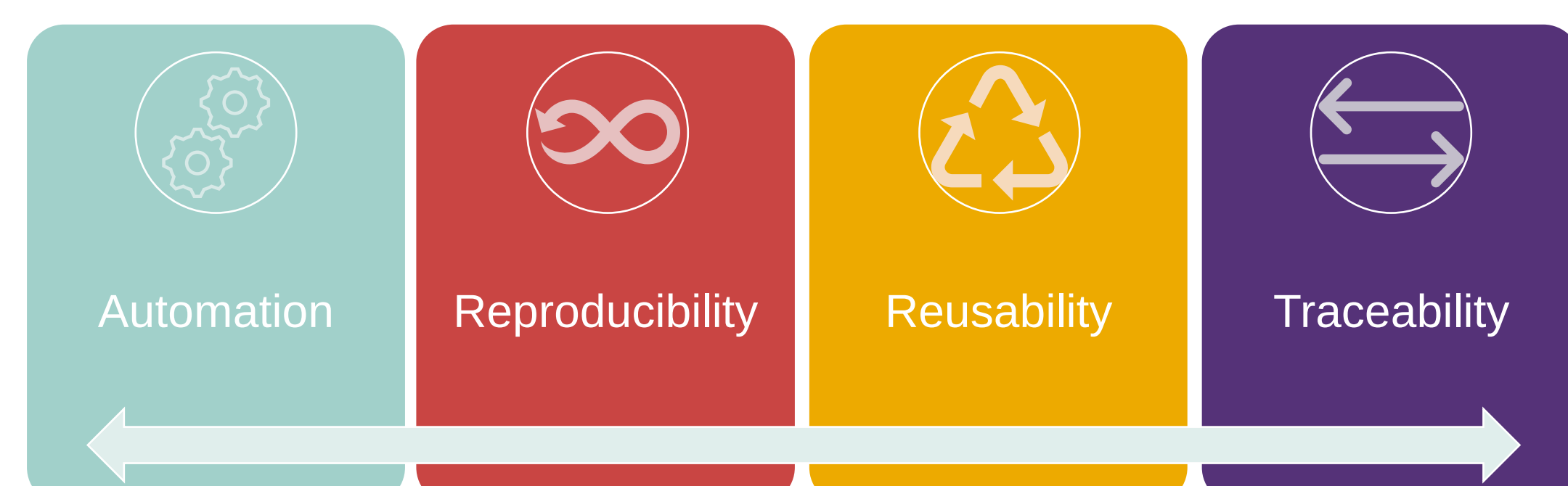
40% annotate their TFL mock-up shells

24% generate analysis results metadata (ARM) prospectively

18% uses machine-readable TFL analysis results metadata

Programming is more of a Science (50%) than it is an Art (39%)!

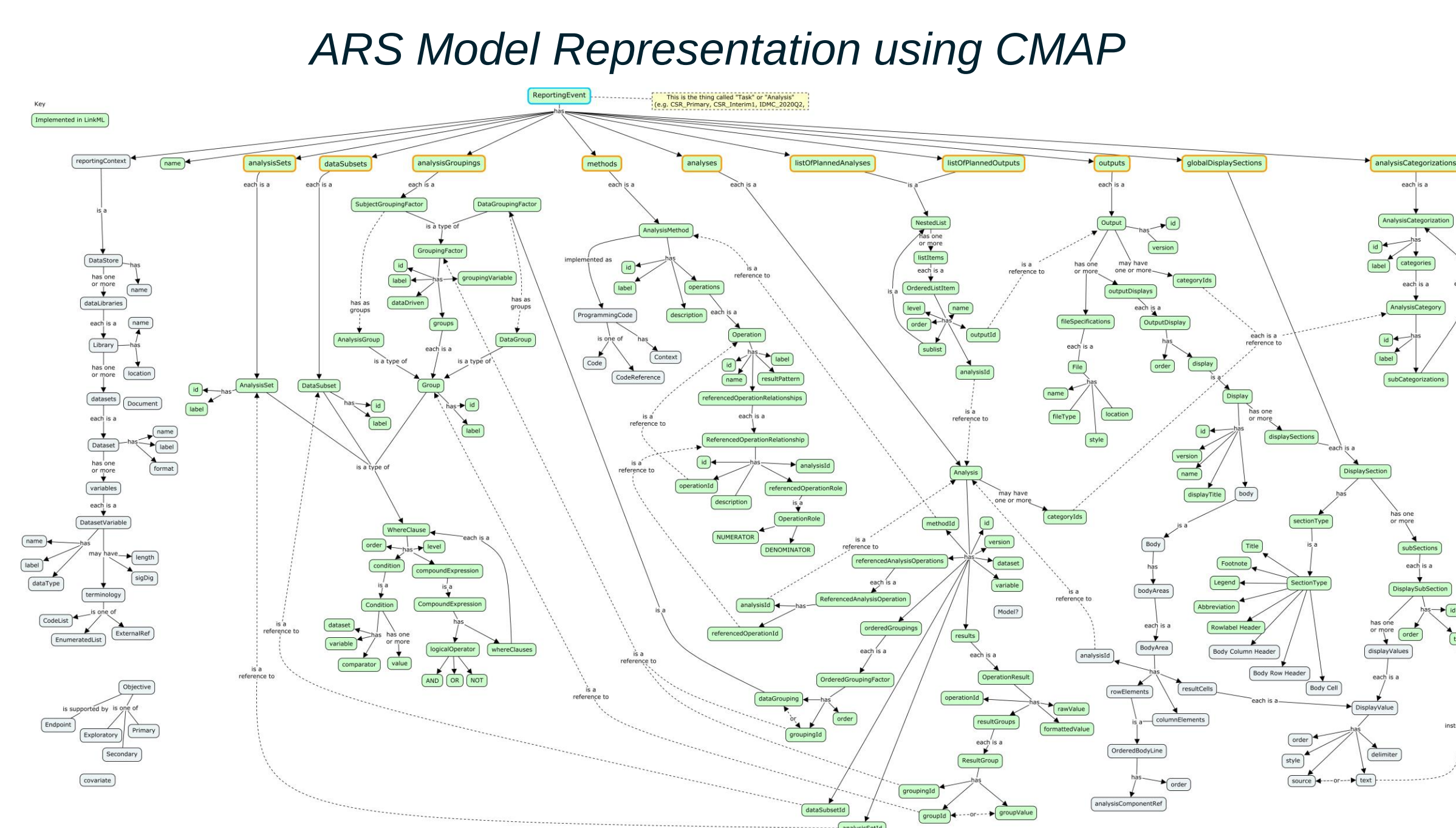
CDISC Analysis Results Standard (ARS)¹: The CDISC ARS Model and accompanying user guide have been developed to provide a logical model that fully described analysis results and associated metadata to support automation, consistency, reuse, and traceability of results data.



[¹ ARS Schema <https://cdisc-org.github.io/analysis-results-standard/>]

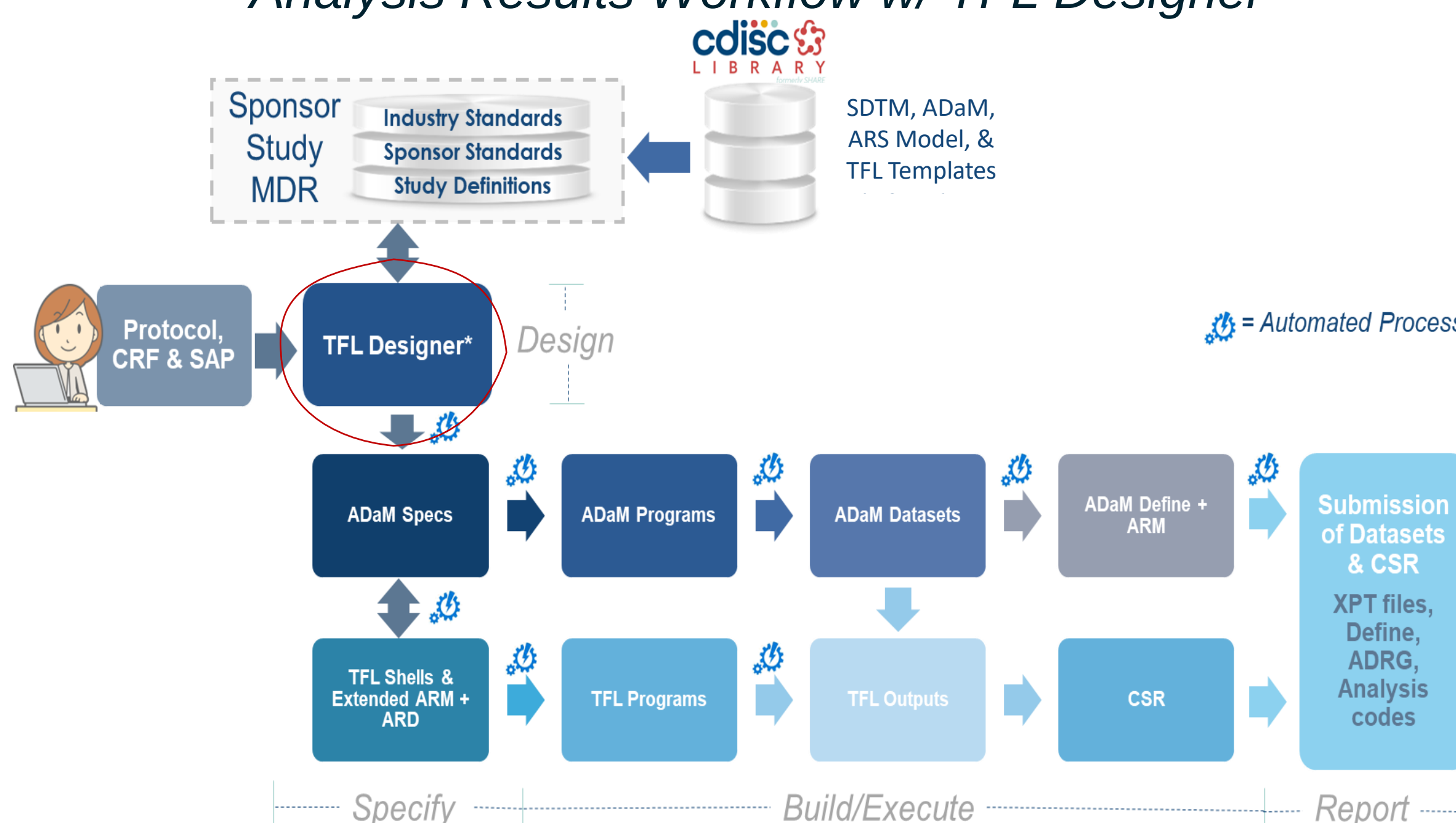
To address the current limitations of analysis results and associated metadata reporting, we are proposing a new workflow that shifts the focus from retrospective reporting to prospective planning.

ARS Model is complex! How do I operationalize it and generate analysis results metadata prospectively?



Design, Specify, Build and Execute: In our vision for the future state, we anticipate the availability of open-source or community tools, such as the TFL Designer Community, in the industry.

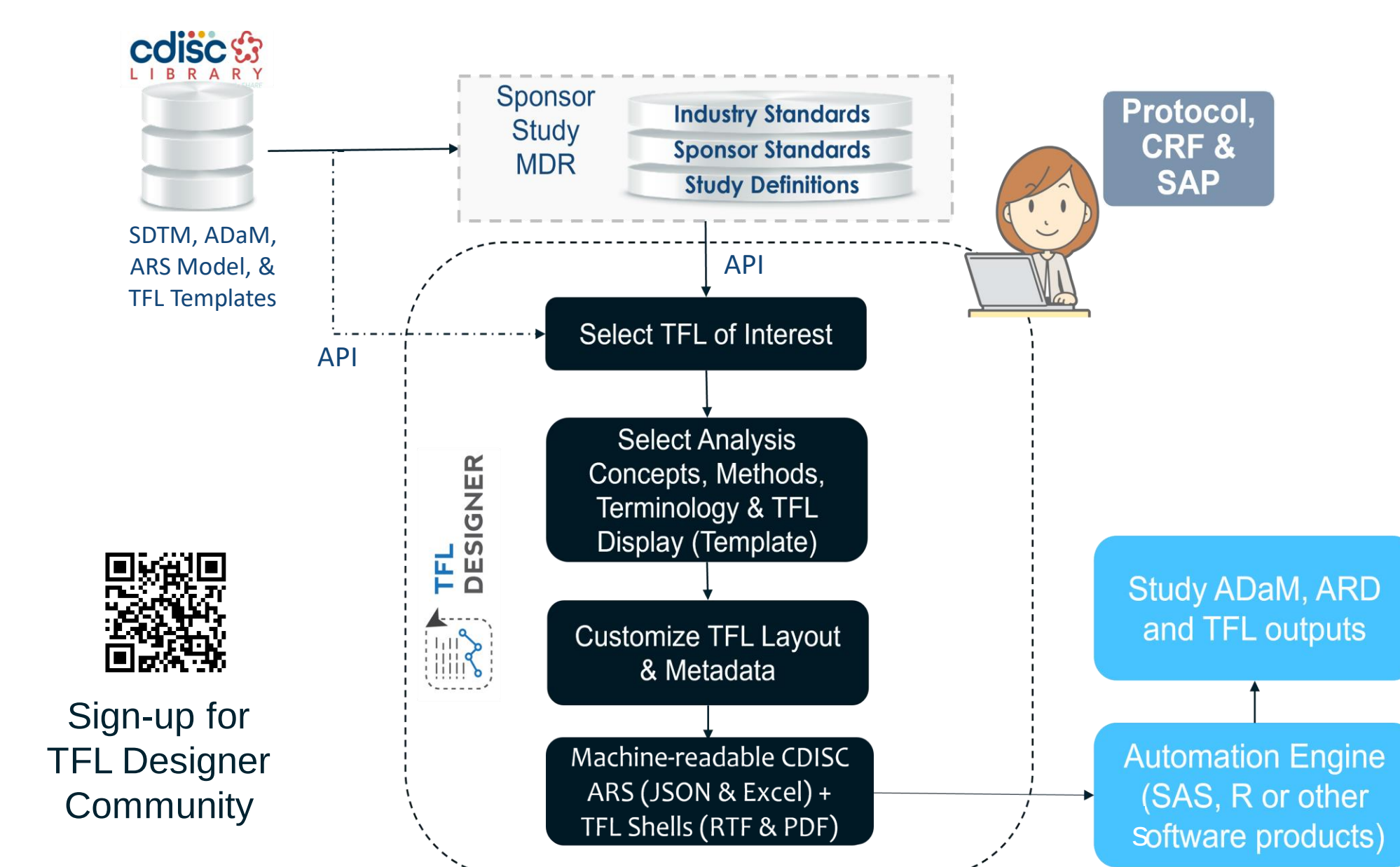
Analysis Results Workflow w/ TFL Designer



TFL Designer (Community, free version)²: This platform automates the creation of TFL shells and provides machine-readable metadata, which can then be seamlessly ingested for downstream automation in the programming of the TFLs.

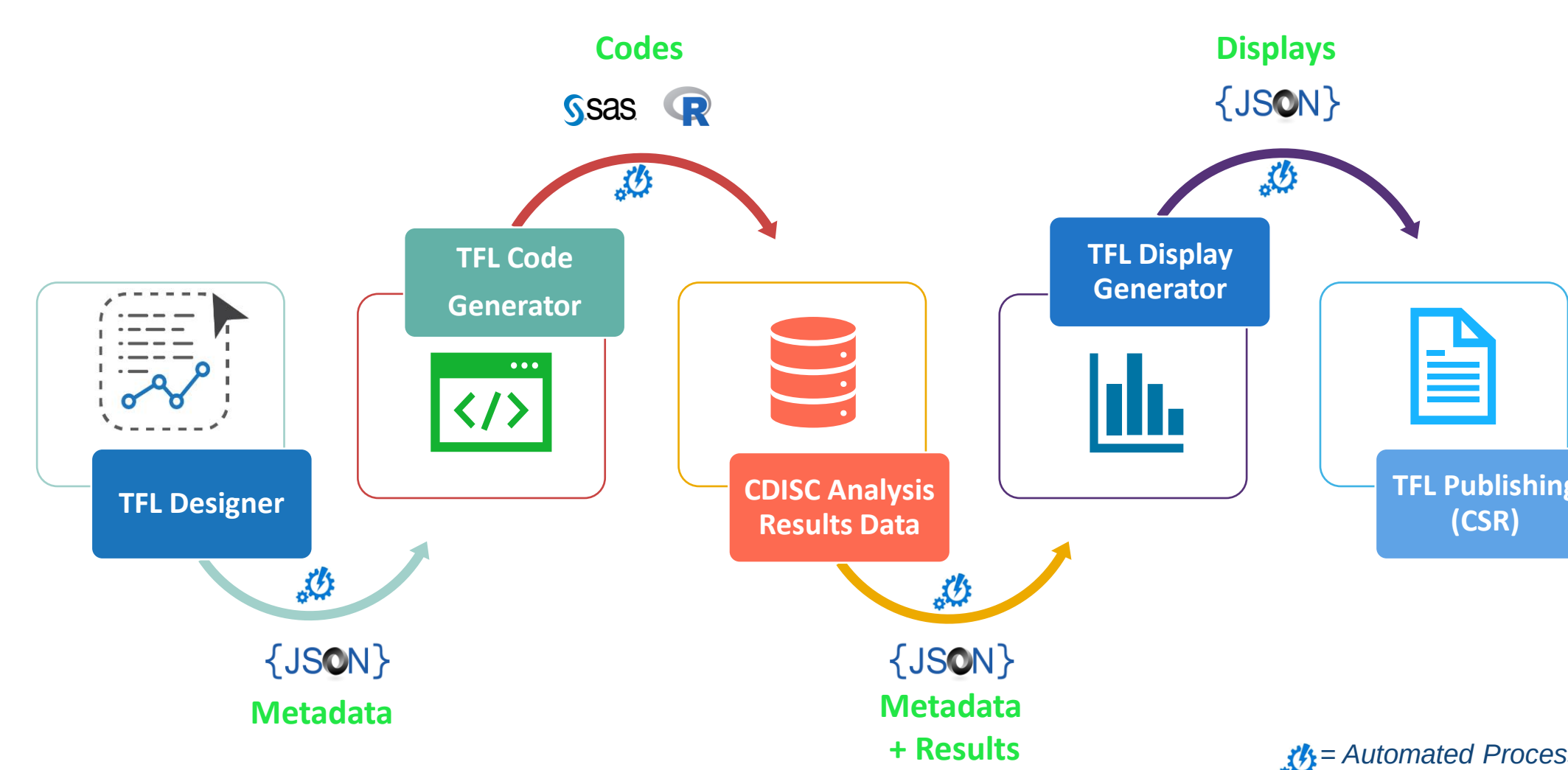
[² TFL Designer Community <https://tfl designer.org/>]

Enhancing Analysis Results Generation:



The Community version of the TFL Designer will empower the industry (including CDISC/PHUSE community, FDA and other regulatory agencies) with broader access to a tool, fostering collaboration and knowledge sharing among stakeholders. Users of the community version will benefit from a growing library of templates, use cases, and standards, accelerating TFL design and automation. Furthermore, the incorporation of FDA templates, based on recent FDA Standard Safety Tables and Figures - Integrated Guide (STF-IG), in the community version enhances its utility and aligns it with the latest regulatory requirements.

Development Vision & Conclusions:



Embracing CDISC ARS, along with a TFL design tool and workflows (including use of Analysis Results Data), will bridge the existing gap in analysis results generation. We are confident that this will foster an open-source community in line with the CDISC Open-Source Alliance (COSA) & PHUSE/pharmaverse vision, facilitating the creation of shareable TFL templates, metadata and codes (in both SAS and R languages) by the community.