

PP14

Harnessing the Power of Analysis Results Standard (ARS) Lessons from the Cytel PRISM Initiative

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Abstract

Awaiting CDISC's finalized **Analysis Results Specification (ARS)**, companies have implemented their own ARS solutions. The model we implemented at Cytel through our **PRISM application** is aligned with CDISC's vision, featuring **"metadata"** and **"results data"**; through PRISM we can generate approximately 60% of the required study outputs.

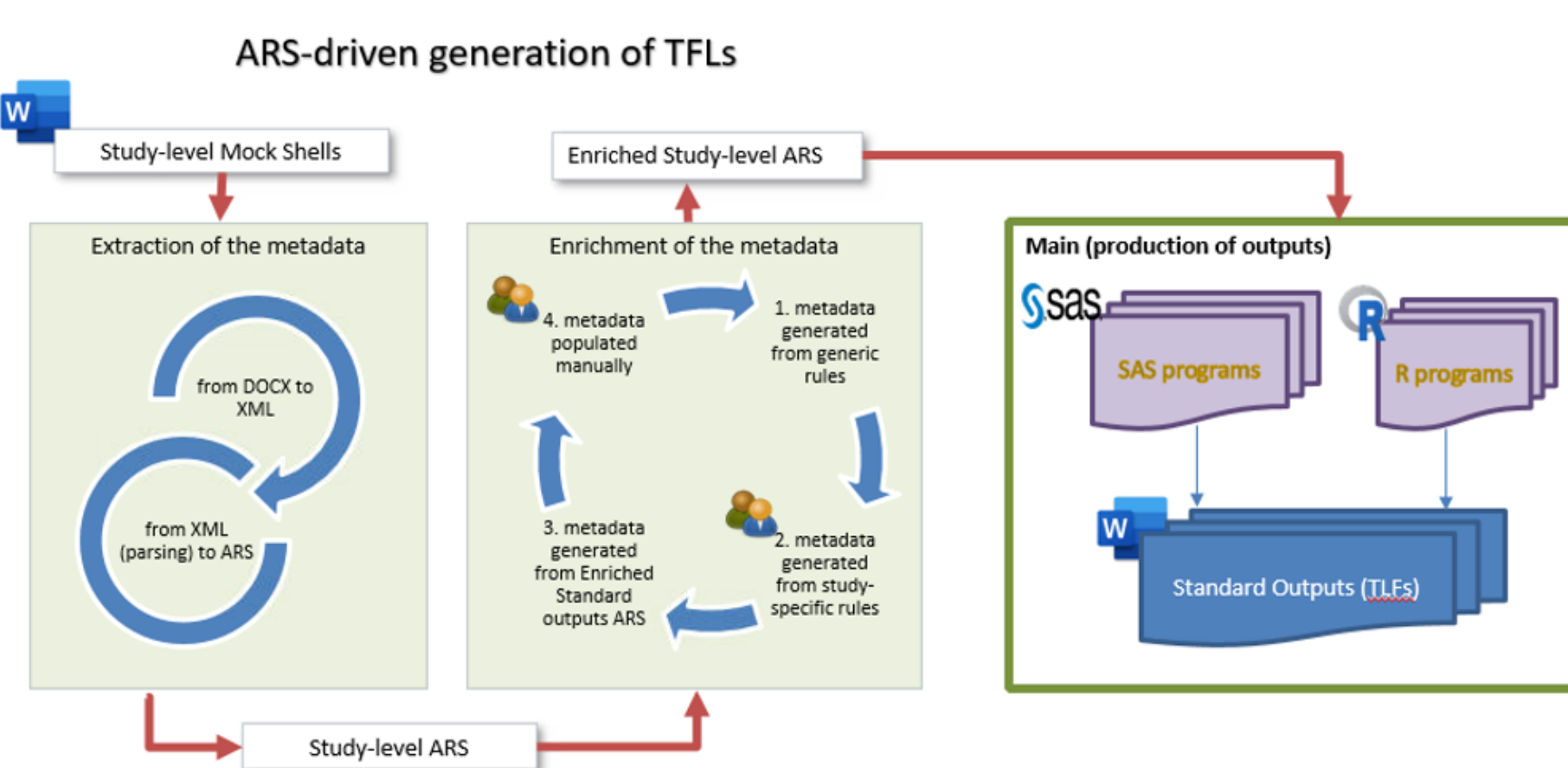
With our poster, we will outline our ARS modelling approach, drawing comparisons to CDISC's ongoing developments.

Furthermore, we will delve into technical aspects, exploring the utilization of **backend data structure such as XML**, widely employed in standard software like Microsoft Word.

PRISM Concept

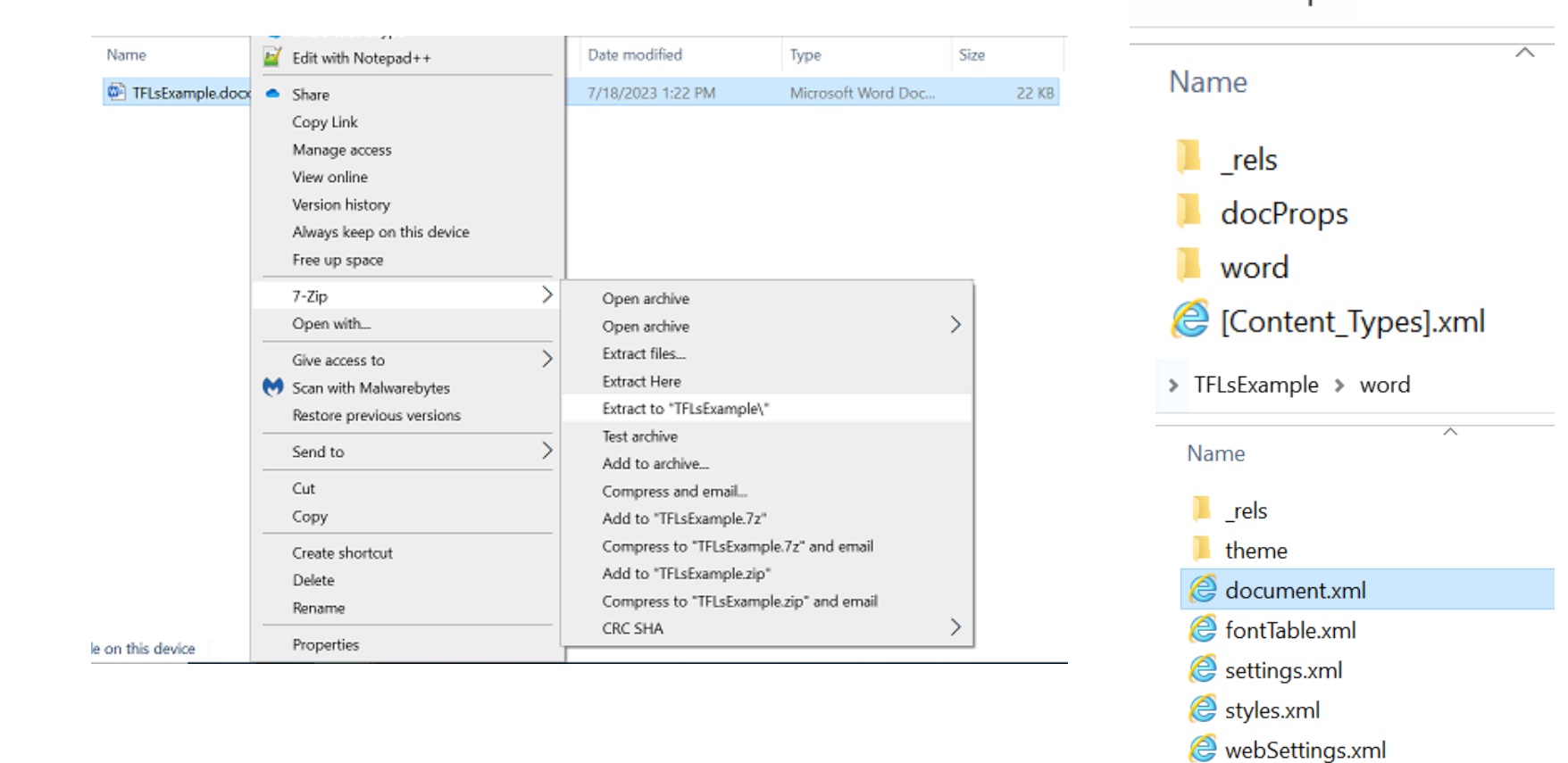
- PRISM is a tool developed by Cytel allowing the user to **create TFL SAS and R code from Mock Shells**
- The main idea behind the tool is to convert the **DOCX mock shells into XML** and **parse this XML data into an Analysis Results(ARS) Data Model** (metadata)
- After creating this initial ARS, we have **a process to enrich that metadata** (e.g., add population filter to be applied to an output based on the title of that output)
- We then utilize this enriched metadata to generate SAS or R code based on **the reference standard code template**

PRISM Concept (cont.)



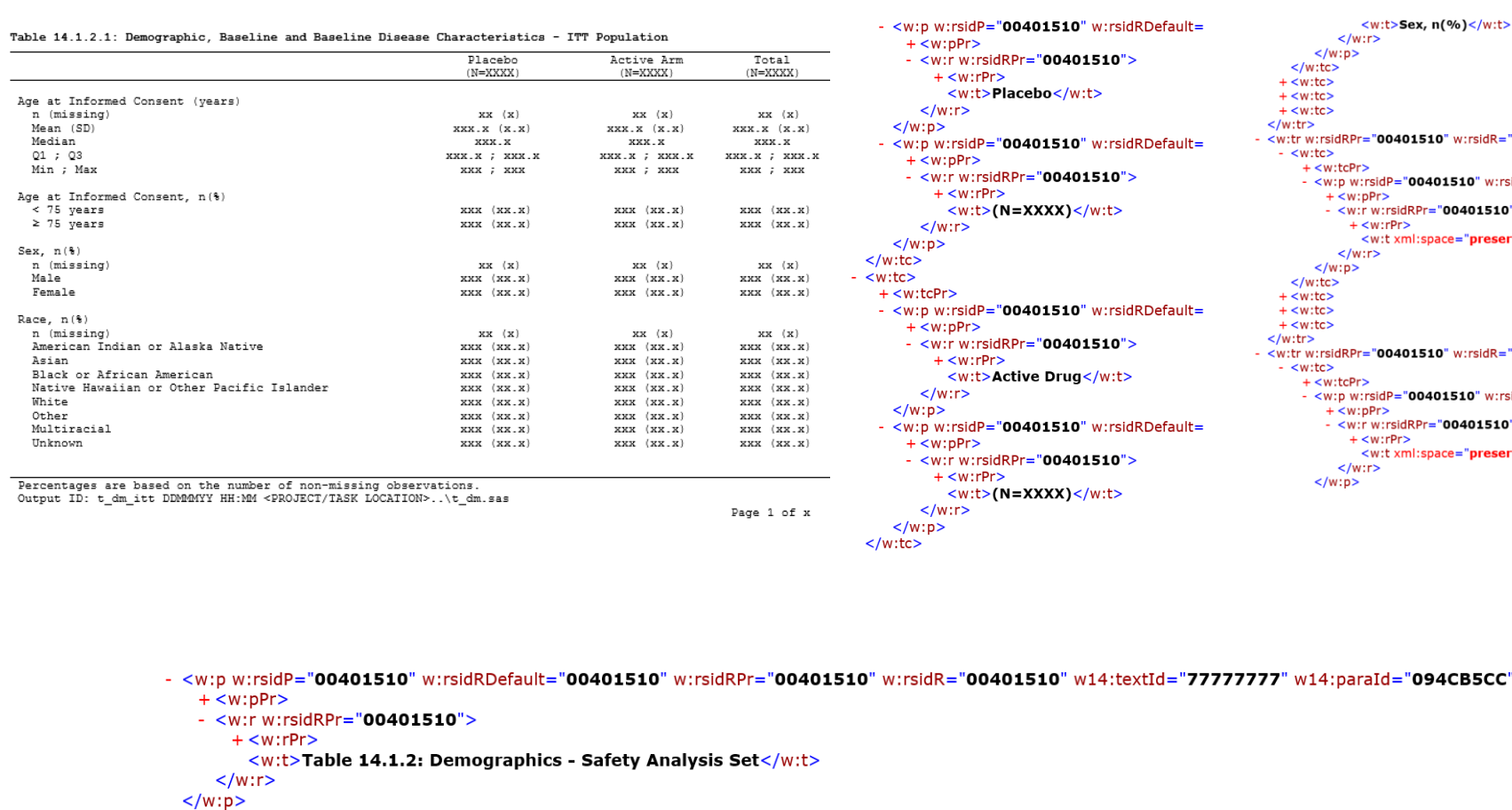
DOCX → XML → Metadata

XML is employed in Microsoft Word tools, and **you can easily access to those XML files “Unzipping” the DOCX files.**



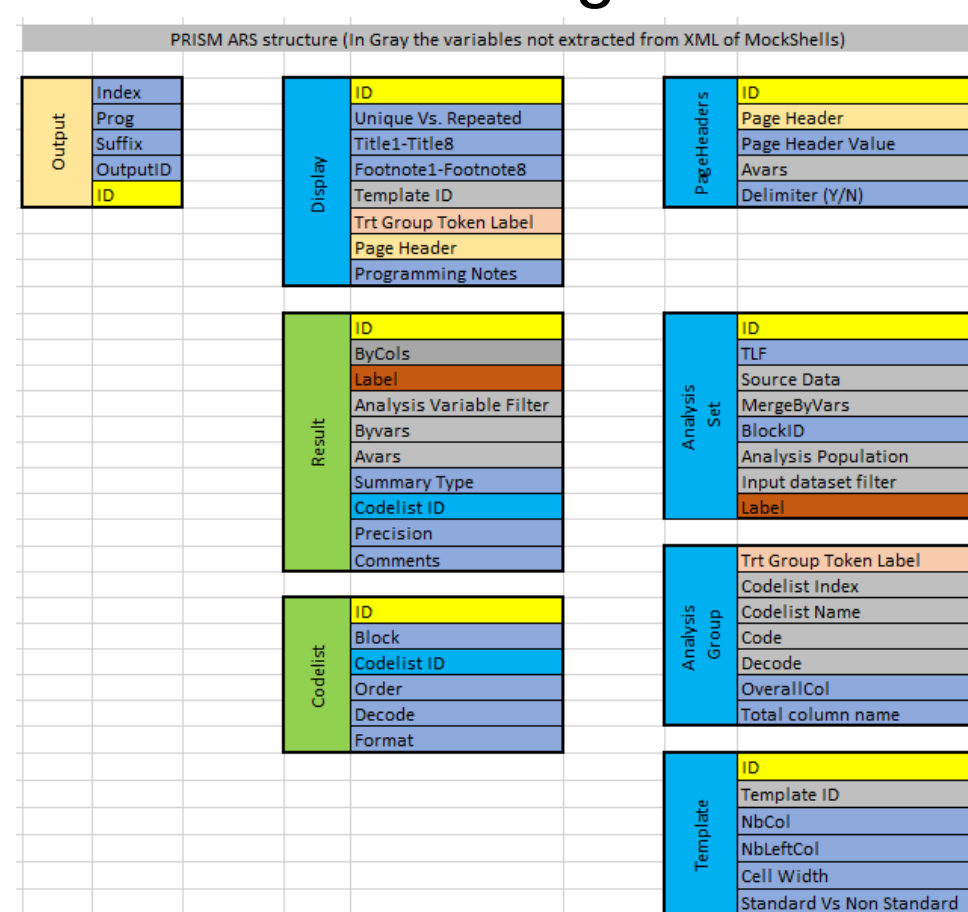
DOCX → XML → Metadata (cont.)

After extracting the XML files from the DOCX file, we have **converted the mock shell into multiple XML files**



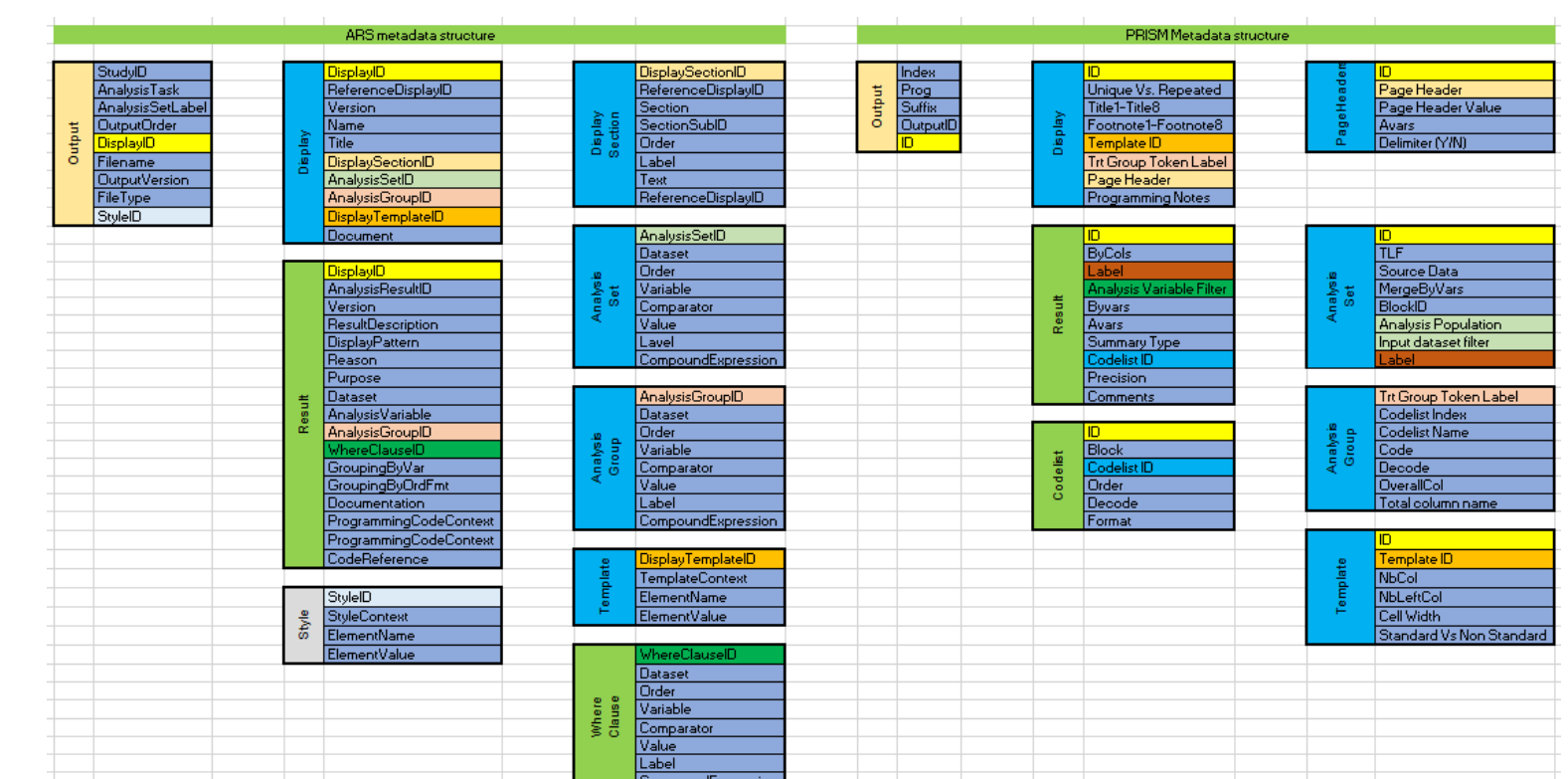
Initial PRISM ARS

- The DOCX XML files** contain a significant amount of metadata, which can be parsed into a database model that better suits your specific needs
- PRISM extracts the following initial metadata from XML files



Enriched PRISM ARS vs CDISC ARS

After enriching the extracted metadata and applying a set of predefined or specific rules, **our ARS PRISM model closely resembles the ARS model that CDISC is developing**



Metadata Tag in SAS Template Code

Captured Metadata will be then used to replace **tagged items** in the SAS Standard Template Code

```
%*--- source data;
proc sql noprint;
  create table dsain as select distinct <MERGEBYVAR>
  , <BYTRT> format=(<SYTRT_FMT><AVAR_REPEAT:START>
  , <AVAR_N> <AVAR_LABEL_N> format=(<AVAR_FORMAT_N><AVAR_REPEAT:END>
  from <SOURCE_DATA> (where=(<selpop>));
%*-- list of trt arms (when total column has not to be displayed);
select distinct (<bytrt>) format=0. into :lstr separated by ',' from dsain;
quit;

%*--- summary statistics;
%tab( d
  = dsain
  , t
  = <bytrt> . %sysfunc(ifc(<upcase(<total>)>) ne Y, (<lstr>), %str()))
  , pn
  = <MERGEBYVAR>
  , l_var
  = <AVAR_REPEAT:START><AVAR_N> <AVAR_REPEAT:END>
  , v_cont
  = [<ACATVAR_REPEAT:START><ACATVAR_N> <ACATVAR_REPEAT:END>]
  , v_cat
  = [<ACATVAR_REPEAT:START><ACATVAR_N> <ACATVAR_REPEAT:END>]
  , <ACATVAR_CODELIST_N><ACATVAR_CODELIST_REPEAT:END> <ACATVAR_REPEAT:END>]
  , lab_overall=<TOTAL_COLUMN_NAME>
  , label_nmisse=n (missing)
  );
```

References

- CDSIC Analysis Results Standards.
<https://www.cdisc.org/standards/foundational/analysis-results-standards>
- All you need to know about the new CDISC Analysis Results Standards! B. Busa, R. Marshall, B. LeRoy. PharmaSUG 2023
- From Artifact to Metadata: A Divergent Approach to Automation through Standardization. N. Rouillé, C. Britton, A. Tinazzi. PHUSE-EU 2022

How are you today driving TFLs
automation at your company?
Any ARS-like model in place
at your company?

Learn more about the Cytel approach to
automate through standardization



Cytel

phuse-advance
18-20 September
Silver Spring, MD

CSS 2023
The Computational
Science Symposium

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