

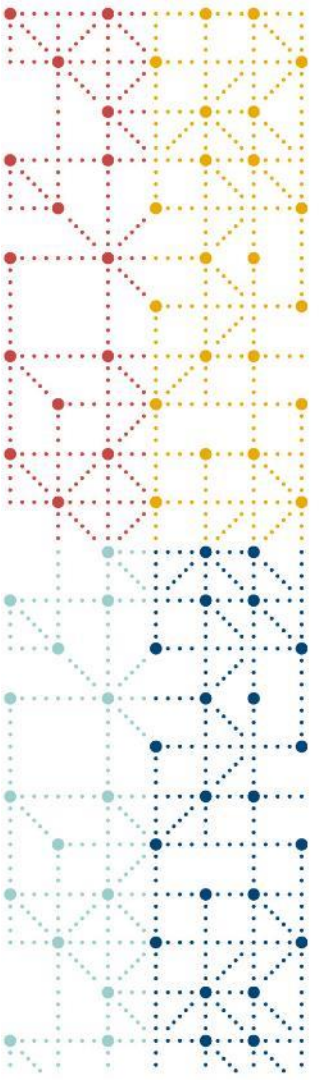


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INTERCHANGE
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Can We Do It Better? Real-Time Validation of SDTM Mapping is Superior to Double Programming

Presented by Daniel Rolo, Director, Statistical Programming, Bioforum



Meet the Speaker

Daniel Rolo

Title: Director, Statistical Programming

Organization: Bioforum

Daniel is a Director of Statistical Programming at Bioforum The Data Masters and has over 10 years' experience in the Biometrics space within the clinical trials industry. Daniel holds a B.Sc. degree in Computer Science and Geographic Information Systems from the University of the Free State in South Africa. Daniel is passionate about process optimization and harnessing the potential in individuals through structured development and innovative approaches to daily tasks.



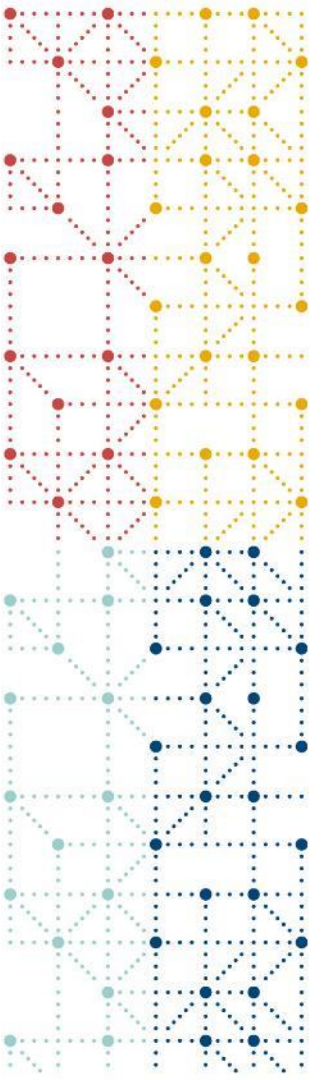
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. Introduction & Current Validation Practices
2. The 3 Key SDTM Quality Components & Real-Time SDTM Validation Solutions
3. Impact of Real-Time SDTM Validation Solutions & Future Considerations



Introduction & Current Validation Practices

Setting the scene for our journey...

Meet John, a SDTM Programmer from South Africa...



John
South Africa



Specification



Program

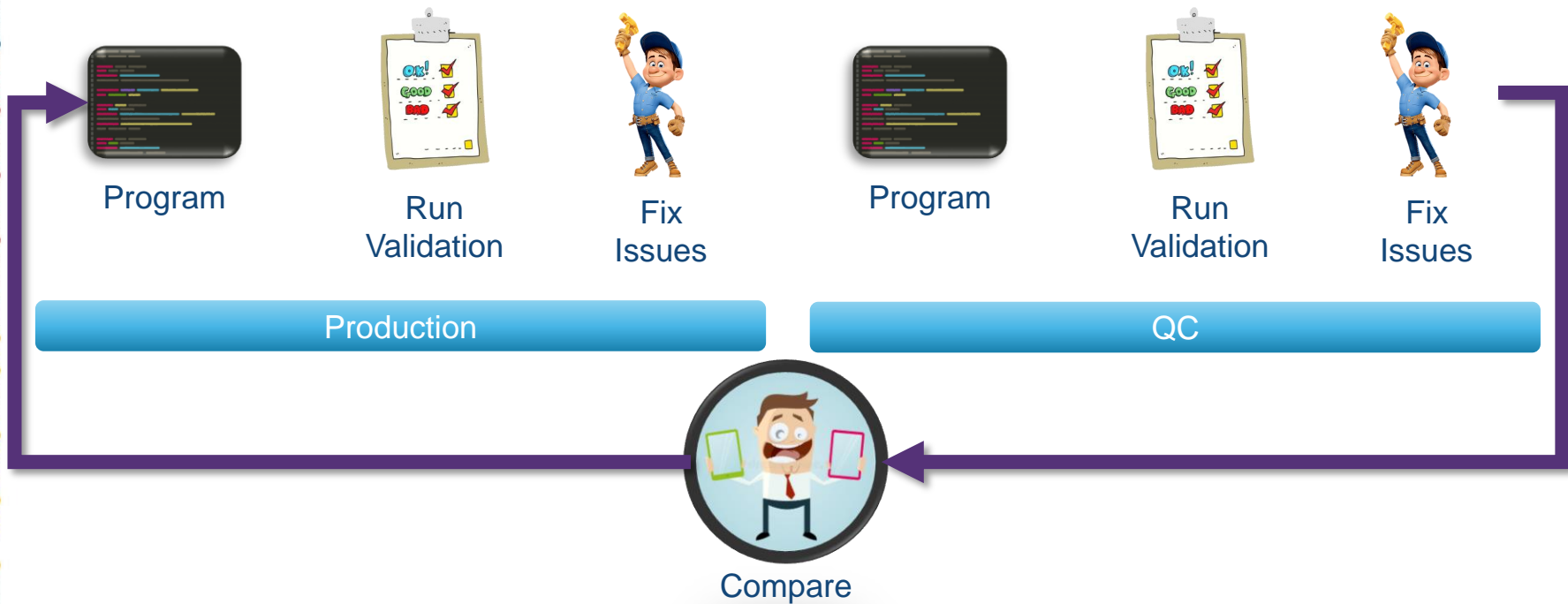


Run Validation



Fix Issues

John is well-versed in current industry validation trends...



Gaps begin to form during the validation process...



Why is there missing source data?

Issues can arise from all manners of sources...

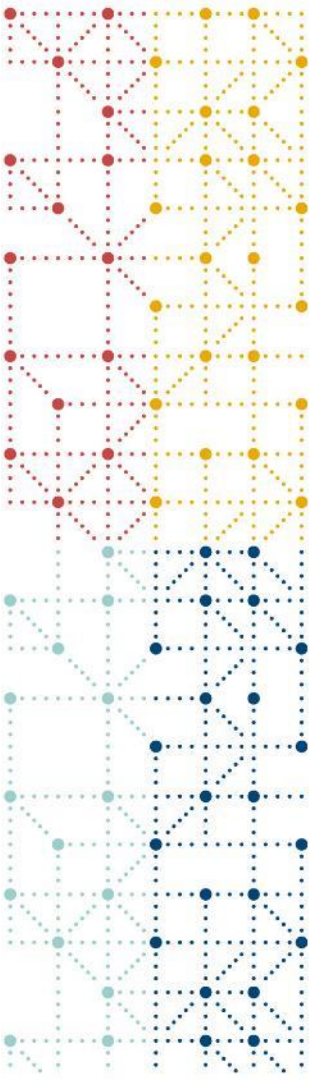


Specification

- Protocol amendment
- Lab test added
- Specification not updated
- Issues/anomalies only identified late in the process
- Miscommunication on data transfers
- ...



Can We Do It Better?



The 3 Key SDTM Quality Components & Real-Time SDTM Validation Solutions



SDTM Quality

Mapping Logic Correctness

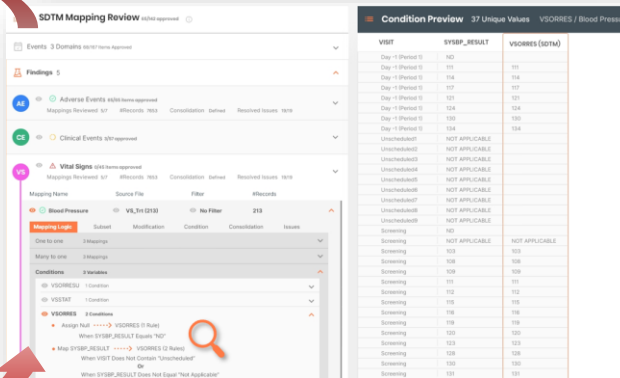
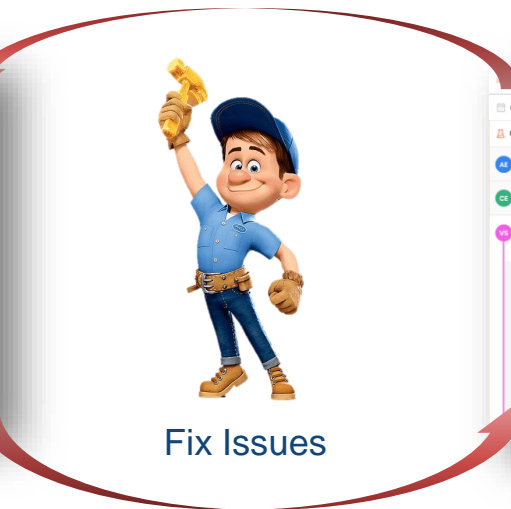
SDTM Compliance

SDTM Completeness

Mapping Logic Correctness



Mapping GUI
+ ML recommendations



Review Tool

Compliance Feedback



Data Completeness Tracking

COVAL Value: ("BGL conducted on 02Apr2022 does not have a Safety lab report as conducted by a hand monitor.;RP request") Sources:

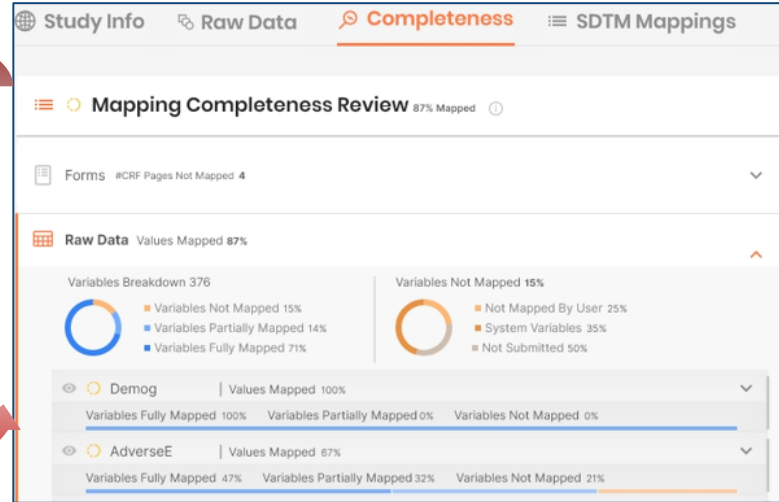
Raw Data File	Raw Data Column	Record Number	Mapping Name
UNS	UNCREAS	32	Comment_Unscheduled
CO	COVAL	27	Comments_General

Close



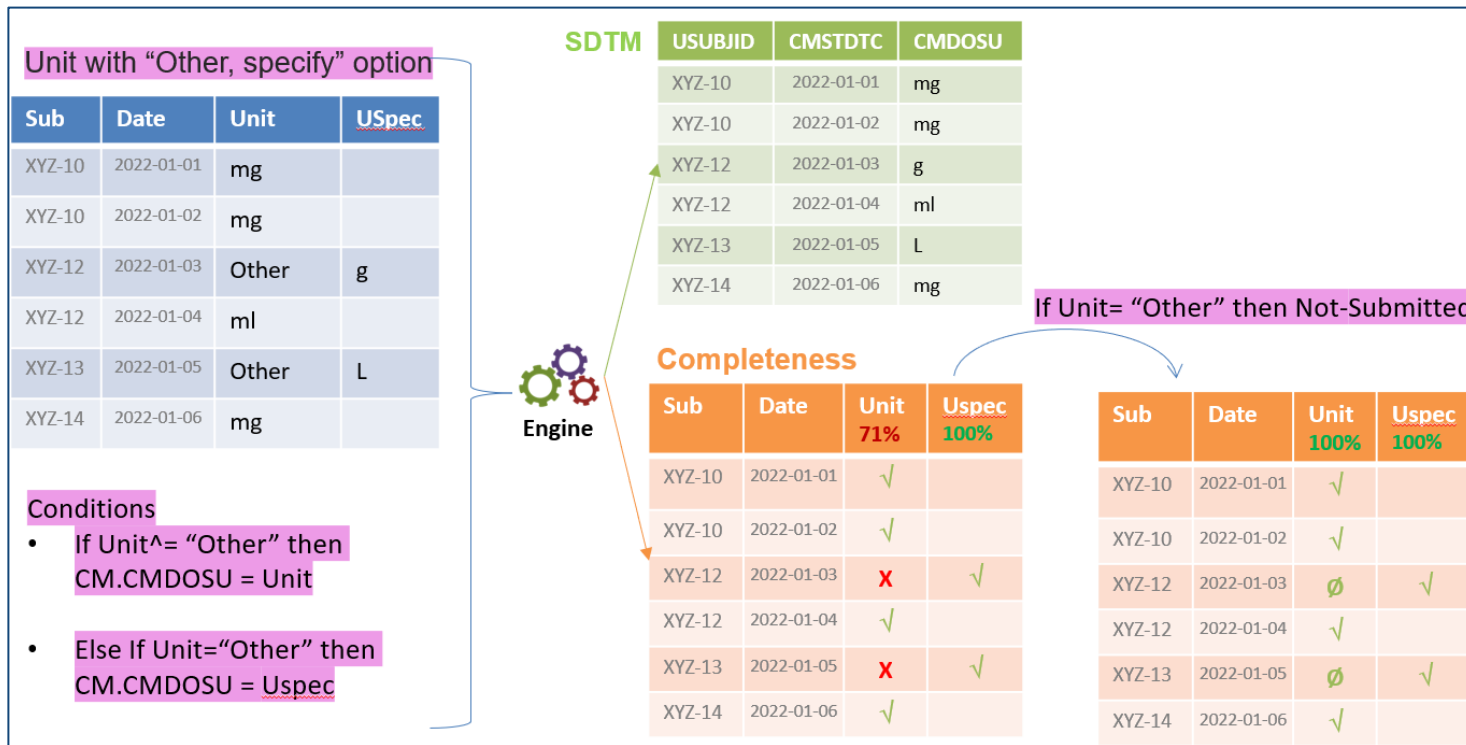
Ensure Data Completeness

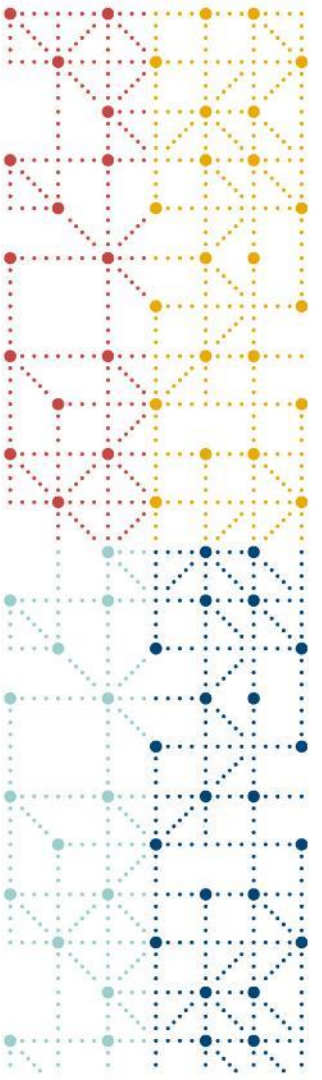
Tagging: Datapoint traceability



Built-in Data Accountability Tracking

Data Completeness: SAS-based tagging approach

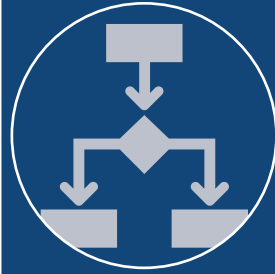




Impact of Real-Time SDTM Validation Solutions & Future Considerations



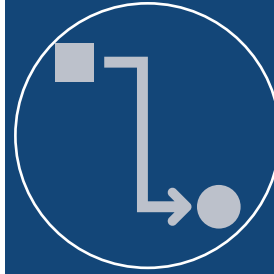
Eliminate
double
programming
& manual
review cycles



Empower
SDTM
developers to
make better
mapping
decisions



Provide a
reliable
measure of
quality



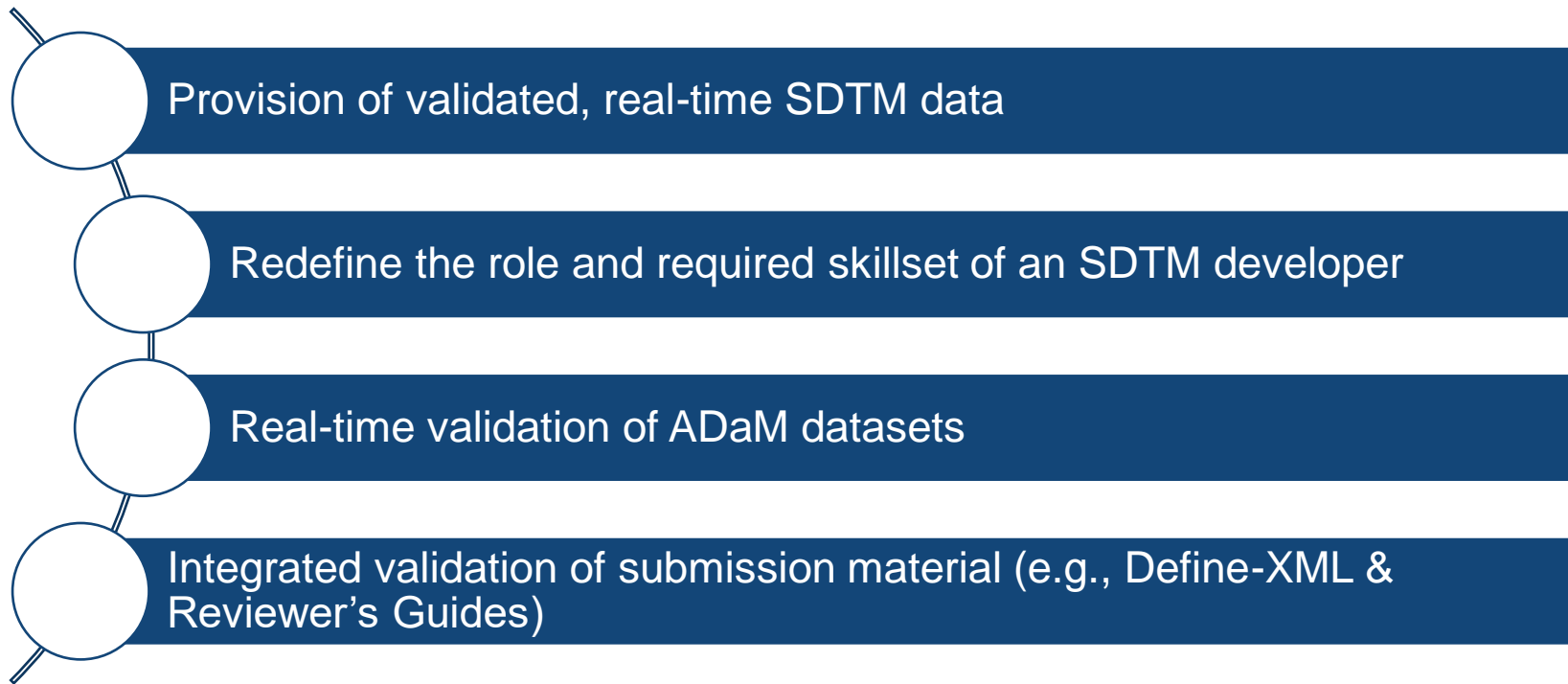
Reduce
impact of
quality issues
on the
downstream
analysis



Reduce # of
programming
staff

An integrated system with real-time validation solutions

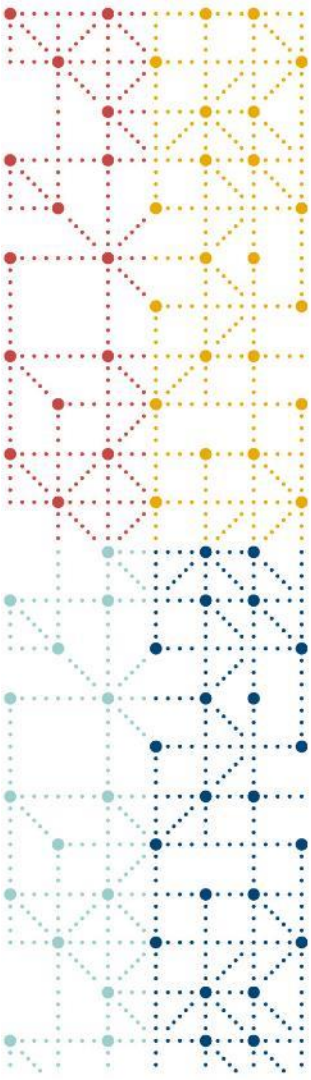
Future Implementations & Benefits



Can we do it better?

Yes, we can!





Thank You!

Feel free to contact the author for any further information on the content presented:

Name: Daniel Rolo

Affiliation: Bioforum

Email: daniel.rollo@bioforumgroup.com

Website: www.bioforumgroup.com

LinkedIn: <https://www.linkedin.com/in/daniel-rollo-a4266778>

