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2022

US

INTERCHANGE

26-27 OCTOBER | AUSTIN

Automation enabling standardization or Standards enabling automation? A preview of MOSAIC Biometrics, a tool for the AstraZeneca Output Standards

Presented by Suman Nayak, Ph.D., Director, Specialist Programming, Data Automation, AstraZeneca

Meet the Speaker

Suman Nayak

Title: Director, Specialist Programming

Organization: AstraZeneca

Suman holds a Ph.D. in Biomedical Engineering from Louisiana Tech University. She brings over 20 years of diverse experience in her current role in AstraZeneca as Director, Specialist Programming, spanning over leading and managing clinical data analysis related activities in the Pharmaceutical, Biotech and CRO industries, Biomedical research involving development of micro/nanoscale devices for interfacing with biology with particular emphasis on sensors and biomaterials, teaching and developing applications using computer languages such as C, C++ and Visual Basic. She has been with AstraZeneca since 2014 starting with the role of Global Programming Lead for Oncology drug products, leading business process improvements as a member of the Biometrics Operations Leadership Team before joining her current role in the Data Automation group within the Clinical Data & Insights (CDI) group. Outside of work, Suman enjoys anything sporty (her latest craze is swimming), cooking, gardening, and Lego but more importantly, spending quality time with her husband and daughter.
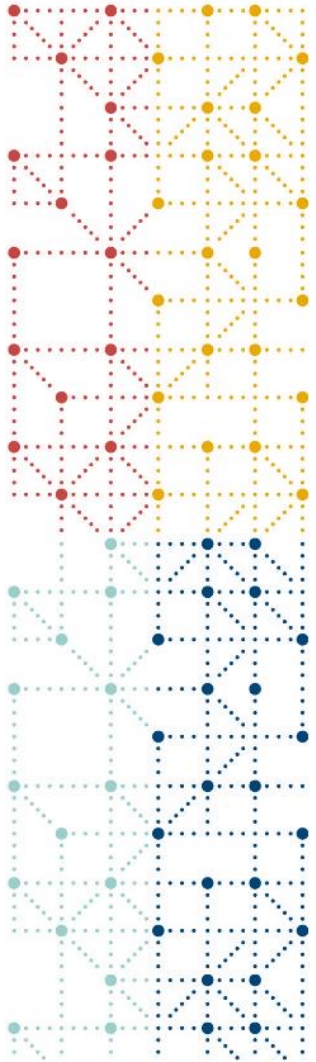
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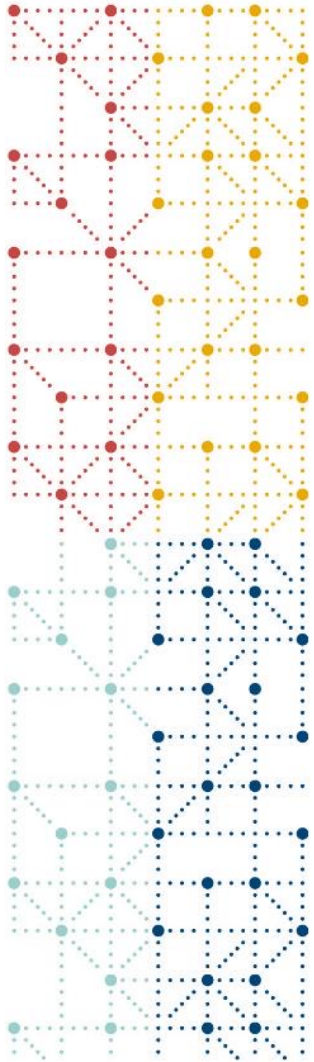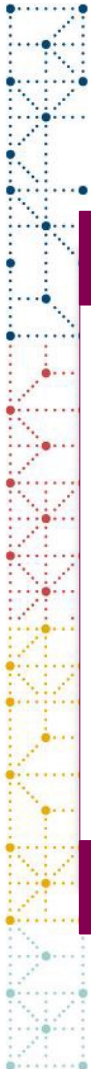
Agenda

1. E2E Standardization and Automation – The Big Picture

2. AZ Output Standards - AZSOL

3. MOSAIC Biometrics – AZ tool for TLF automation based on machine readable metadata

4. AZSOL & MOSAIC Biometrics
   - Symbiosis
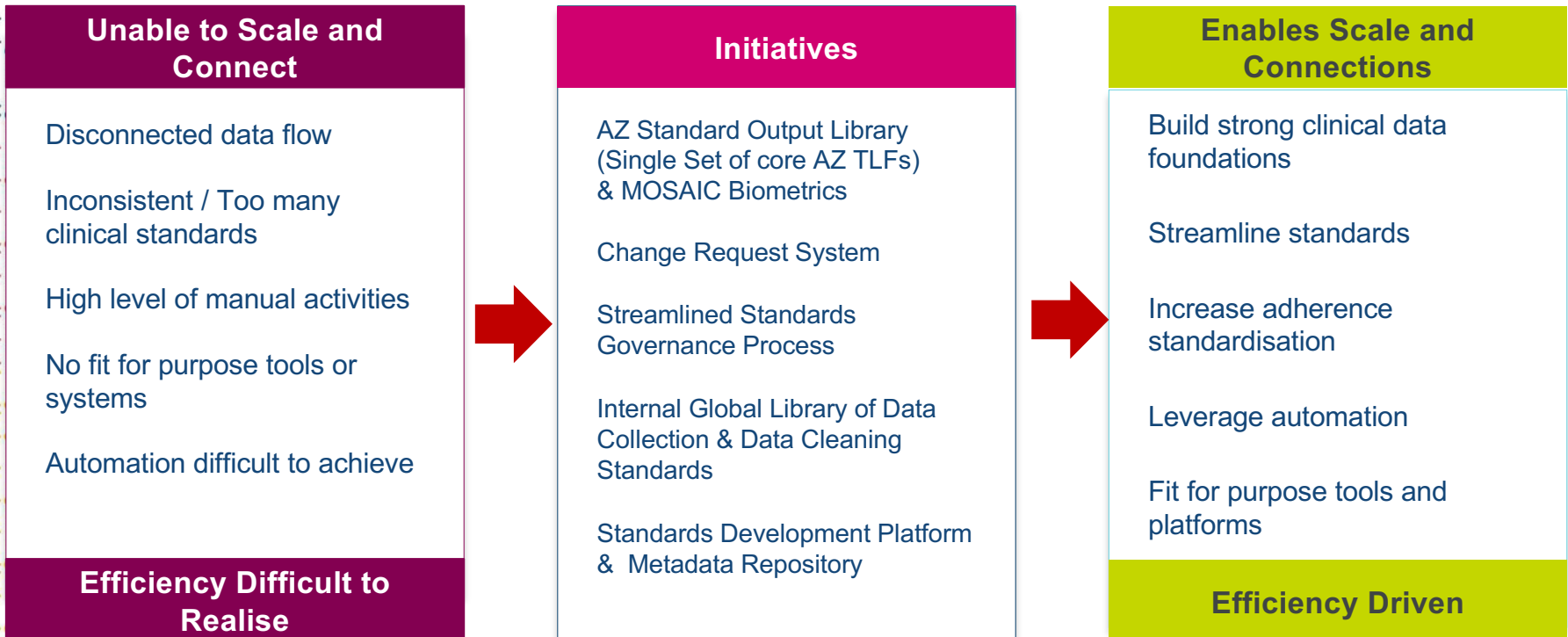   - MOSAIC Biometrics Development Journey

5. Meet our team
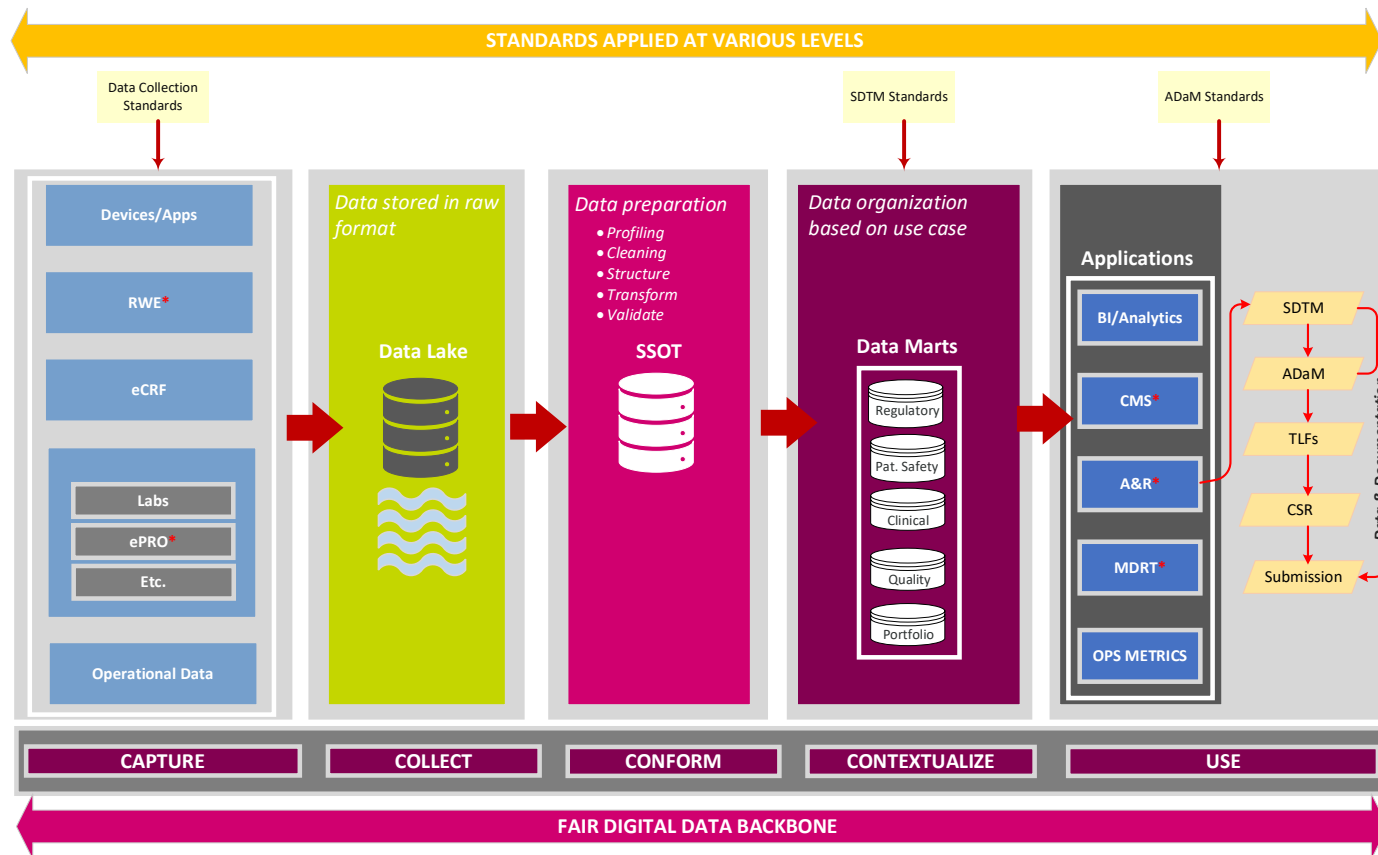
E2E Standardization and Automation – the big picture

A brief overview of AstraZeneca's approach

End-to-End Clinical Data Standards at AZ – Current State

Unable to Scale and Connect

Disconnected data flow

Inconsistent / Too many clinical standards

High level of manual activities

No fit for purpose tools or systems

Automation difficult to achieve

Efficiency Difficult to Realise

Initiatives

AZ Standard Output Library (Single Set of core AZ TLFs) & MOSAIC Biometrics

Change Request System

Streamlined Standards Governance Process

Internal Global Library of Data Collection & Data Cleaning Standards

Standards Development Platform & Metadata Repository

Enables Scale and Connections

Build strong clinical data foundations

Streamline standards

Increase adherence standardisation

Leverage automation

Fit for purpose tools and platforms

Efficiency Driven

E2E Standardization and Automation – Future State

STANDARDS APPLIED AT VARIOUS LEVELS

Data Collection Standards

SDTM Standards

ADaM Standards

| CAPTURE | COLLECT | CONFORM | CONTEXTUALIZE | USE |

FAIR DIGITAL DATA BACKBONE

Devices/Apps, RWE, eCRF, Labs, ePRO*, Etc., Operational Data*

Data stored in raw format — **Data Lake**

Data preparation — • Profiling • Cleaning • Structure • Transform • Validate — **SSOT**

Data organization based on use case — **Data Marts** (Regulatory, Pat. Safety, Clinical, Quality, Portfolio)

Applications: BI/Analytics, CMS*, A&R*, MDRT*, OPS METRICS

SDTM → ADaM → TLFs → CSR → Submission — *Data & Documentation*

__RWE__: Real World Evidence, __ePRO__: Electronic Patient Reported Outcomes, __CMS__: Centralized Monitoring System, __A&R__: Analysis and Reporting, __MDRT__: Medical Data Review Tool

E2E Standardization and Automation – AZ approach

RCDF Vision — Enabling efficient and quality delivery of data for primary and secondary use

- The AZ Redefining Clinical Data Flow (RCDF) Initiative, aims to overhaul our E2E clinical data flow
    - Right-time foundational data flow – sustainable and agile
    - Transformation of current approach to collection, access and management of patient data
    - New data sources and increasing volumes of data
    - Tools and systems maximizing use of clinical data. Efficient, and effective work
    - Overall goals: *simplify* ways of working, *improve* quality of deliverables, *increase* standardization and automation, *reduce time* to delivery.

TLF standardization and automation are important components of the initiative

- *Standards Metadata repository*
- *TLF specification (mockshell) creation tool*
- *TLF standards adherence tracking*
- *TLF output code generation – automating output creation*
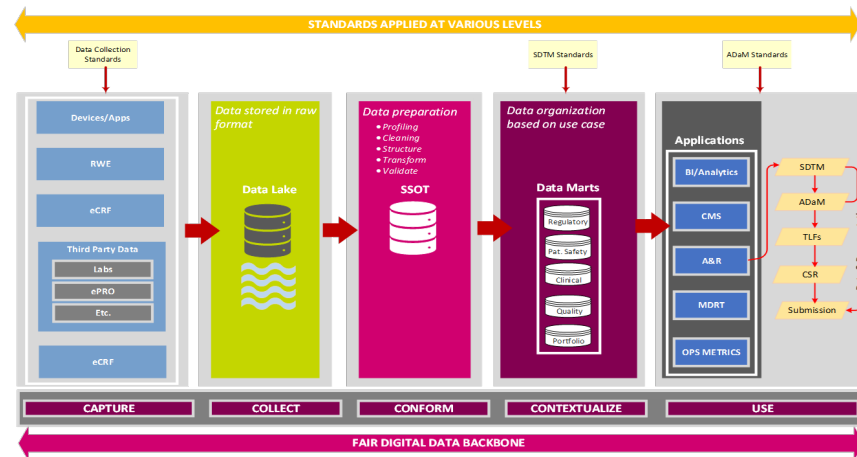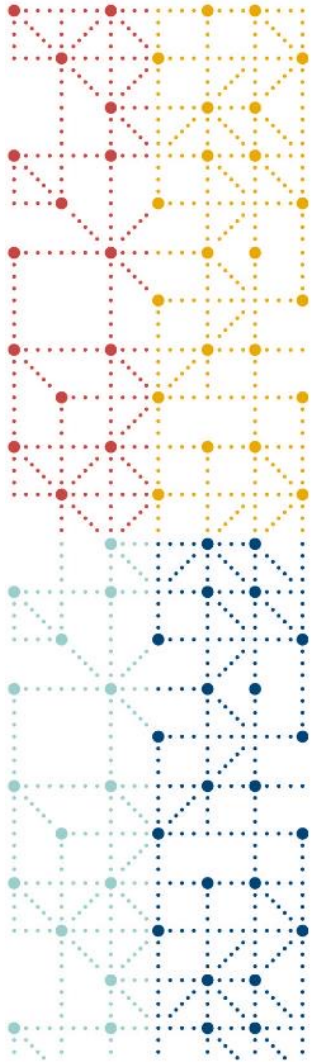
AZ Output Standards - AZSOL

Streamlined and simplified AZ TLF output standards

AZ Standard Output Library (AZSOL)

AZ Standard Output Library

- First step towards a single set of end-to-end clinical data standards

- Based on general principles and basic layouts

- Driving E2E standards by beginning with the end in mind

- Fully incorporated within MOSAIC Biometrics
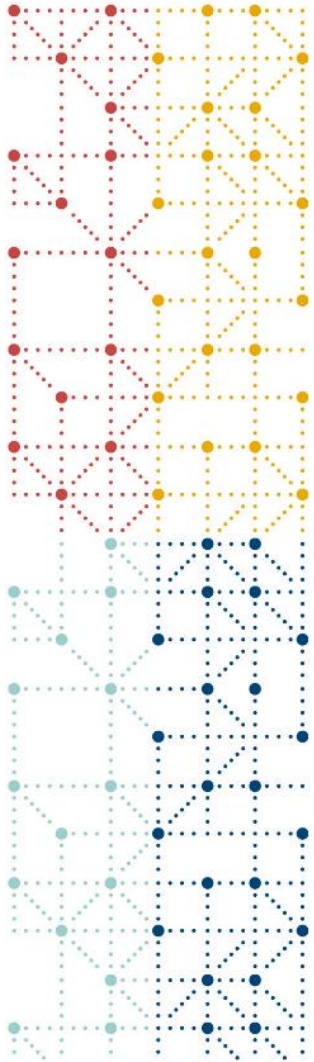
STATISTICIANS

PROGRAMMERS

MEDICAL COMMS, CLINICAL SCIENTISTS, CLINICIANS

(PATIENT SAFETY) PHYSICIANS

ALLIANCE MANAGERS (& SUPPLIERS)

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MOSAIC Biometrics – AZ tool for TLF automation based on machine readable metadata

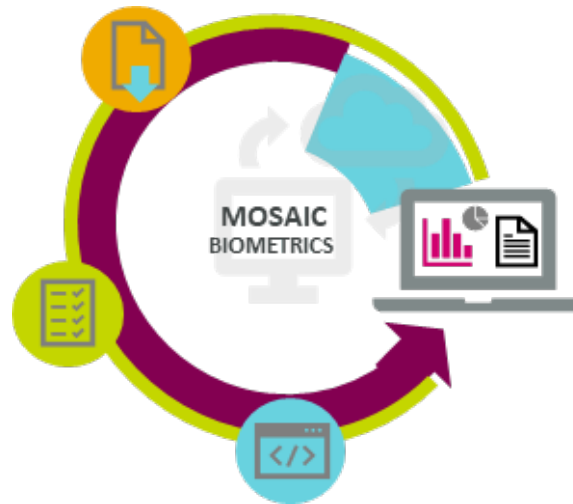Why do we need it?

MOSAIC* Biometrics

A tool that automates the creation of electronic Tables, Listings & Figures (eTLFs) using AZSOL templates and principles

Ease-of-use

- Intuitive web-based interface makes it easy for users to build TLF shells directly in the tool

Automation

- Reducing or removing manual coding of outputs

Standards Adherence

- Improving consistency and compliance

Flexibility/Control

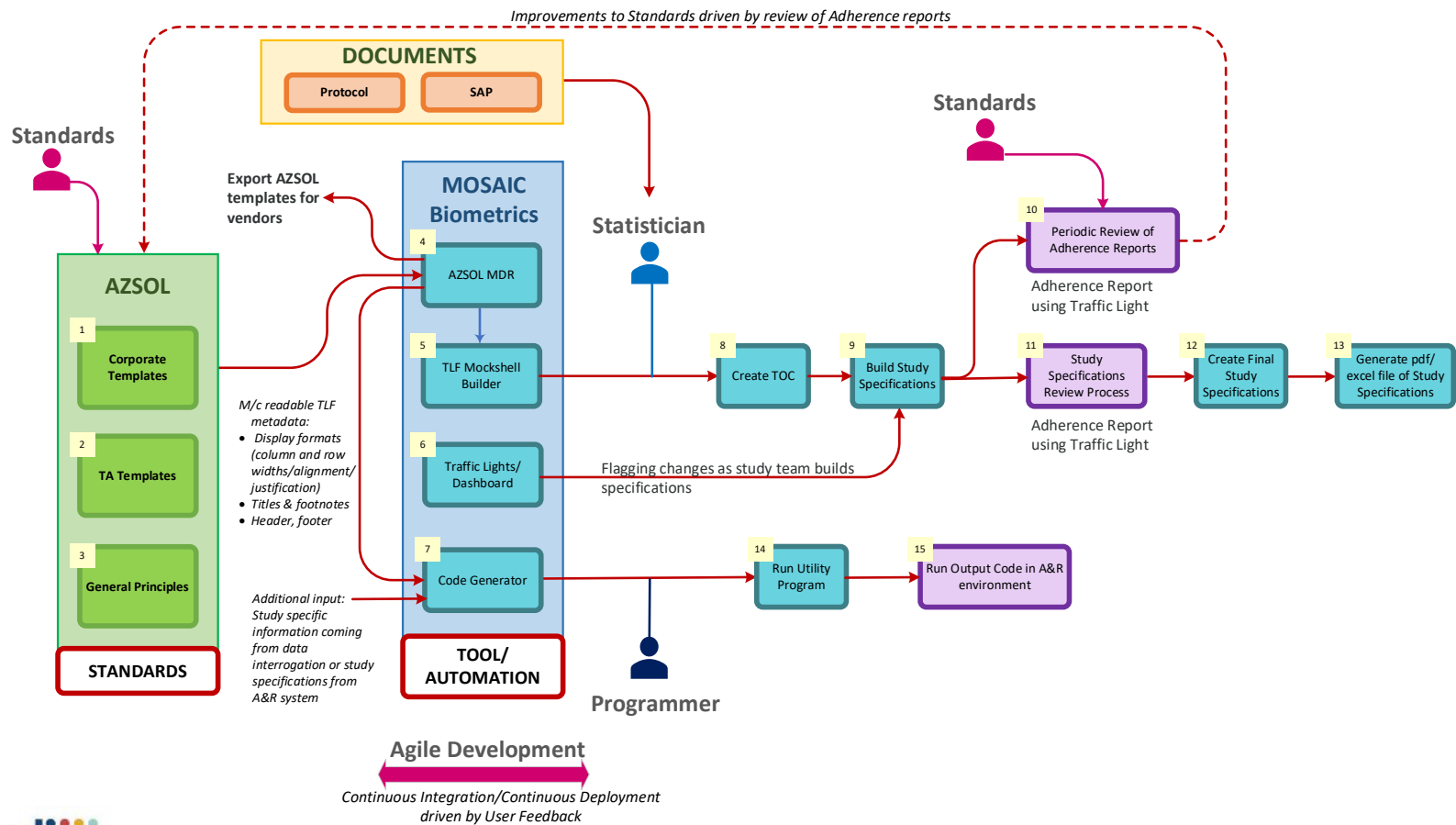- Designed in-house with enhanced integration with other AstraZeneca systems

*MOSAIC = MOckShell Standardization and Automated Integrated Code

AZSOL & MOSAIC Biometrics

Automation enabling standardization or Standards enabling automation?

AZSOL & MOSAIC Biometrics – Workflow, Roles & Deliverables

AZSOL & MOSAIC Biometrics - Workflow

- Built for: Stats, Standards and Programmers

- *AZSOL is the **content** (output standards/templates) and **MOSAIC Biometrics** is the **MDR** for output standards. Stored TLF metadata is used to **generate mockshells** and dynamically **generate code for TLFs**. In addition, the tool **tracks adherence to standards** with metrics dashboards to display key metrics related to standards adherence.*

- The plan is to ramp up the ability of the system to produce code for safety and efficacy outputs by a certain % every year. The final goal is to be able to produce code for 80% safety and 20% efficacy outputs over the next few years.

- Developed in an Agile manner – Continuous Improvement/Continuous Development (CI/CD) based on user feedback and dashboard metrics.
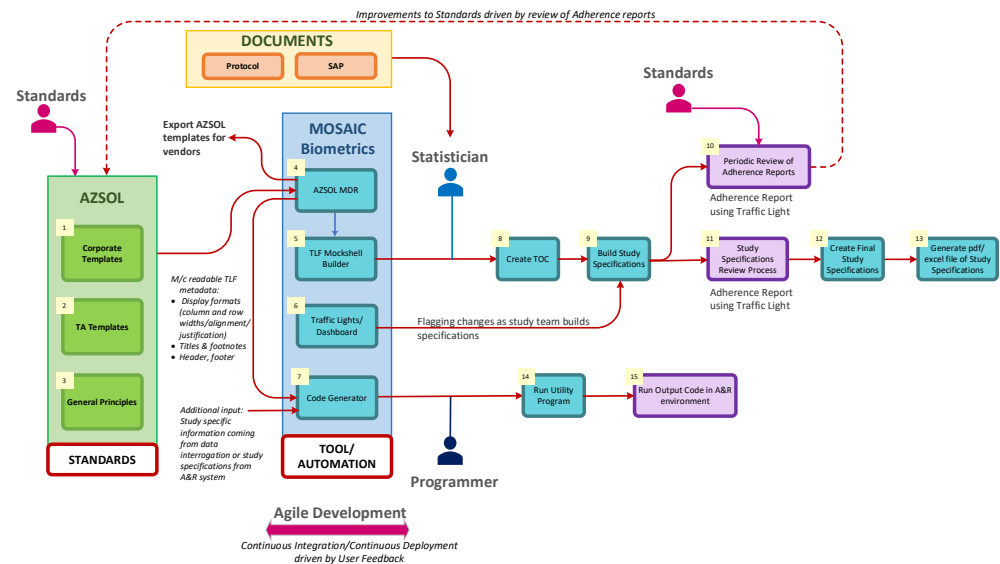
AZSOL & MOSAIC Biometrics - Symbiosis

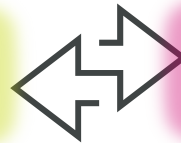**AZ Standard Output Library**

Simplification

- One AZ approach – single corporate identity
- General principles to be used for all TLF shells
- Layout for clarity and reduce programming
- Improved layout, reduced # of TLF templates
- Find what you need easily and apply to create study mock shells
- Improved Change Request (CR) process. Only necessary changes with a strong rationale are approved

Drive automation

Time/Cost savings

- Streamlined output and stricter decision making on CRs limit changes to those that add most value
- Cost savings with vendors & internally

AZ Standard Output Library within MOSAIC

Automation

- Study specific information applied only once for a study
- Eliminates copying and pasting tables mock shells
- Footnotes are automatically added
- Ensures consistency across the mock shells for a study
- Improves consistency across studies/TAs
- Dynamic output code generation
- Improved quality
- Connects Change Request process

Automatic adherence to standards

Time/Cost savings

FTE savings related to both Safety and Efficacy TLF creation

Integrating tools

Study teams will gain most benefit when using the AZ Standard Output Library in MOSAIC Biometrics

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MOSAIC Biometrics – Development Journey
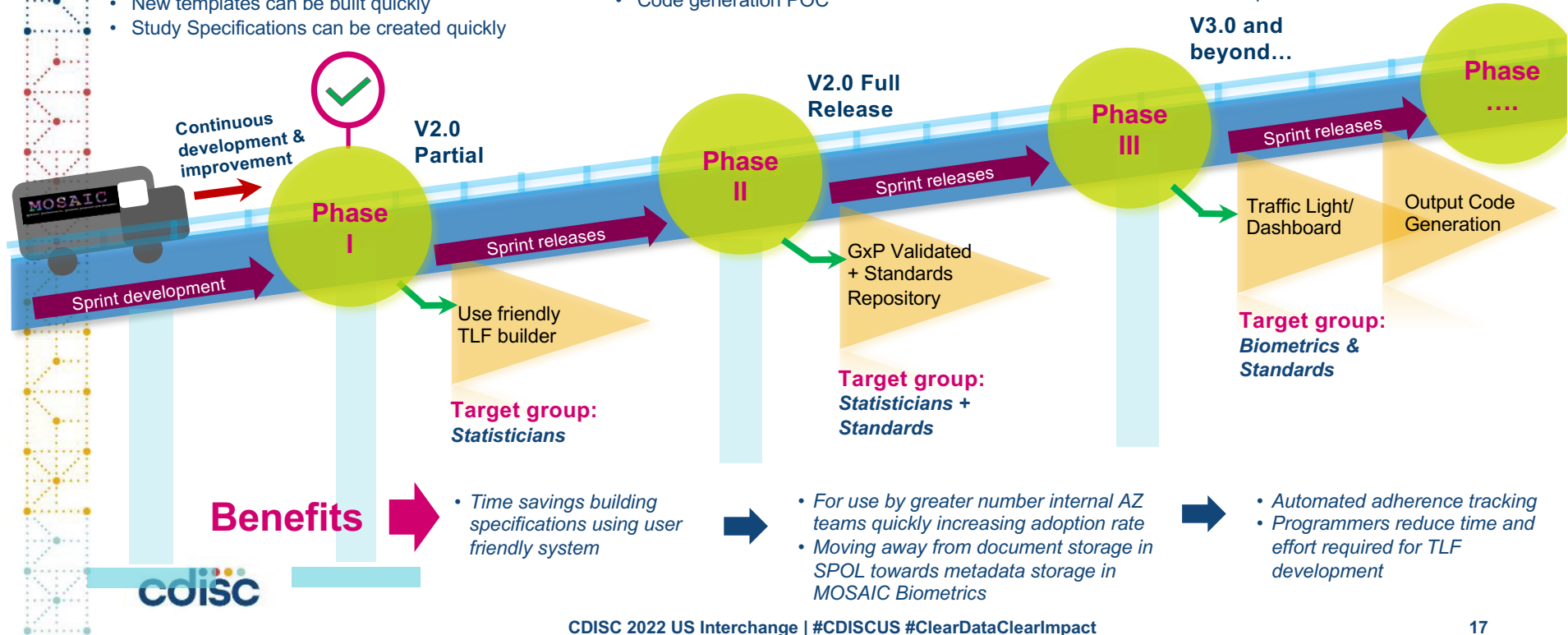
User driven tool – AZSOL Standard

Interactive tool where TLF specifications can be created using electronic CORP And TA templates
- Templates can be modified to meet study requirements
- New templates can be built quickly
- Study Specifications can be created quickly

Validated and open

GxP validated TLF Builder open to all internal AZ study teams
- Improvements to TLF builder
- Standards repository features (version control)
- Code generation POC

Adherence to Standards, automated TLF output generation

Traffic light system with dashboards, dynamic code generation
- Track adherence to AZSOL, drive efficient review
- Dynamic code generated/automate creation of outputs
- Use data to drive improvements

Continuous development & improvement

V2.0 Partial

Phase I

Sprint development

Sprint releases

Use friendly TLF builder

Target group: Statisticians

V2.0 Full Release

Phase II

Sprint releases

GxP Validated + Standards Repository

Target group: Statisticians + Standards

Phase III

Sprint releases

V3.0 and beyond…

Phase ….

Traffic Light/ Dashboard

Output Code Generation

Target group: Biometrics & Standards

Benefits

- Time savings building specifications using user friendly system

- For use by greater number internal AZ teams quickly increasing adoption rate
- Moving away from document storage in SPOL towards metadata storage in MOSAIC Biometrics

- Automated adherence tracking
- Programmers reduce time and effort required for TLF development

Automation enabling standardization or Standards enabling automation?

Nothing truly valuable can be achieved except by the unselfish cooperation of many individuals *~Albert Einstein*

AZ Data Automation Group		AZ Standards Group

JUST OUTSIDE THE BOX

I always give, give, give and all you do is take, take take

Symbiotic relationship trials and tribulations

https://justoutsidetheboxcartoon.wordpress.com/tag/symbiotic/

STOP YOUR COMPLAINING! YOU OWE ME!

https://www.cartoonstock.com/directory/c/cleaning_symbiosis.asp

"We're not a couple. He's just my ride."

https://www.cartoonstock.com/directory/s/symbiotic_relationship.asp
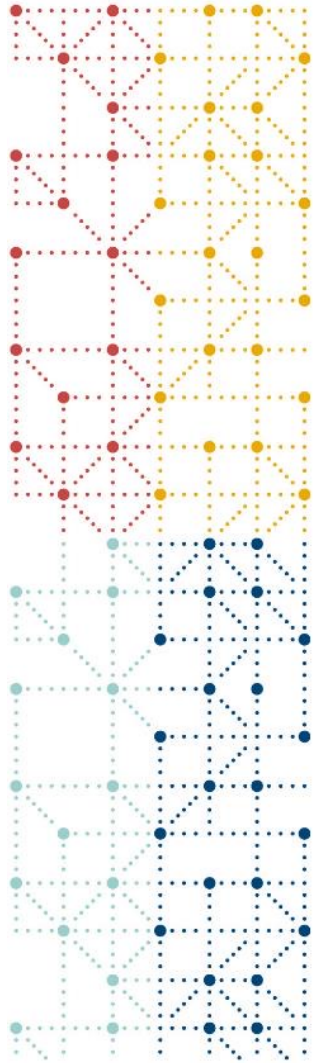
Acknowledgements
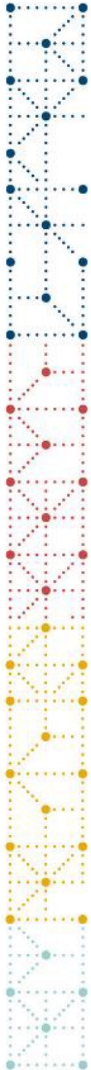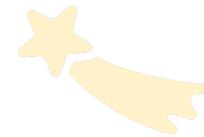
Acknowledgements

Thanks to all the talented members of our project team for all their contributions to this presentation!
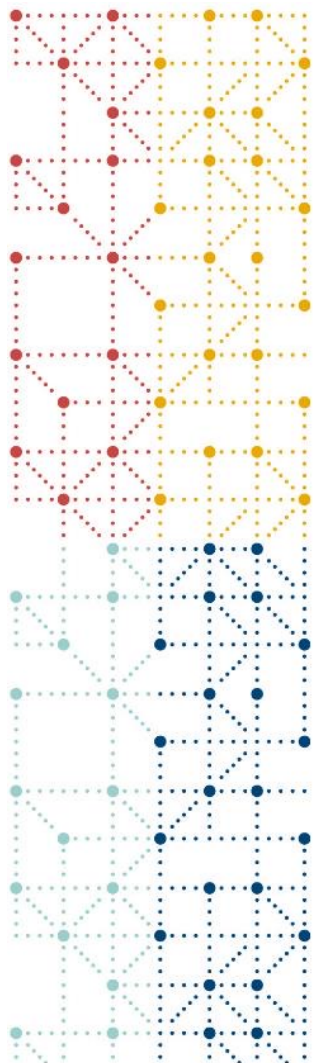
Dziekuje!

Tack!

Gracias!

We are made of star stuff ~Carl Sagan

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Thank You!

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