

Leadership & Innovation - LI07

Scaling within a fast-moving Biotech company

Key learnings for leaders and innovators

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Scaling within a fast-moving Biotech company

- **COMPANY OVERVIEW**
- **EVOLUTION CLINICAL DATA MANAGEMENT**
- **ESTABLISHING A STRONG FOUNDATION**
- **AS IS VS. TO BE**
- **CRITICAL SUCCESS FACTORS & CHALLENGES**



Company

Overview

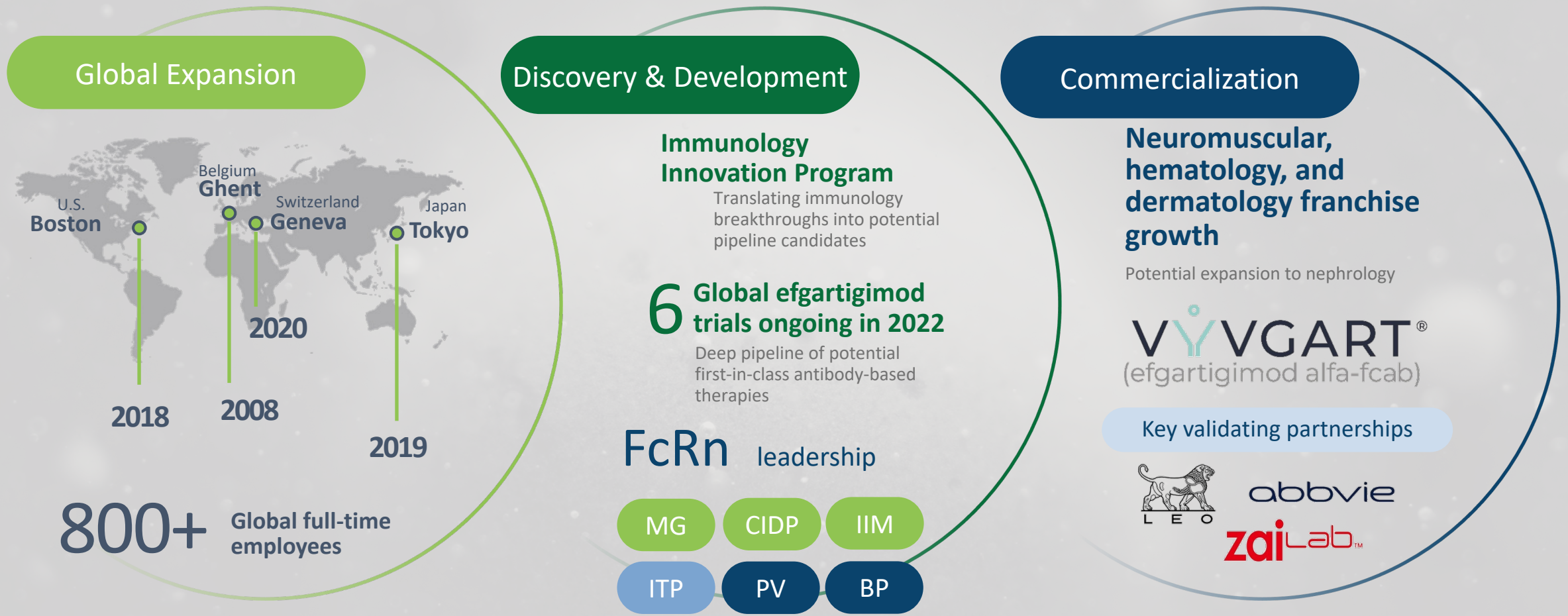
argenx 

Together We Discover

Reaching Patients Through
Immunology Innovation



Rooted in groundbreaking immunology research, growing through collaboration into integrated organization



Our Plan to Build a Leading Immunology Company

Committed to
our Patients and
their
Communities

Enviably
Immunology
Pipeline

Rooted in
Science through
our IIP

Global autoimmune market has surpassed \$150B

Reaching patients globally

Vibrant neuromuscular, hematology, skin and kidney franchises

Efgartigimod in 15 indications (commercial and development)

ARGX-117 in multiple late-stage trials

Proof-of-concept demonstrated with ARGX-119

New asset each year from IIP

argenx 2025

We believe the future belongs to those who collaborate best

Leadership & Innovation embedded in our core values

argenx Core Values



Innovation



Co-Creation



Empowerment



Excellence



Humility

The Evolution of Clinical Data Management into Clinical Data Science

*An SCDM Position Paper on **how to create a
Clinical Data Science Organization***

“Your path toward Clinical Data Science”

12 SEP 2022



Society for Clinical Data Management
DATA DRIVEN

Society for Clinical Data Management

© Society for Clinical Data Management

Clinical Data Management

EVOLUTION

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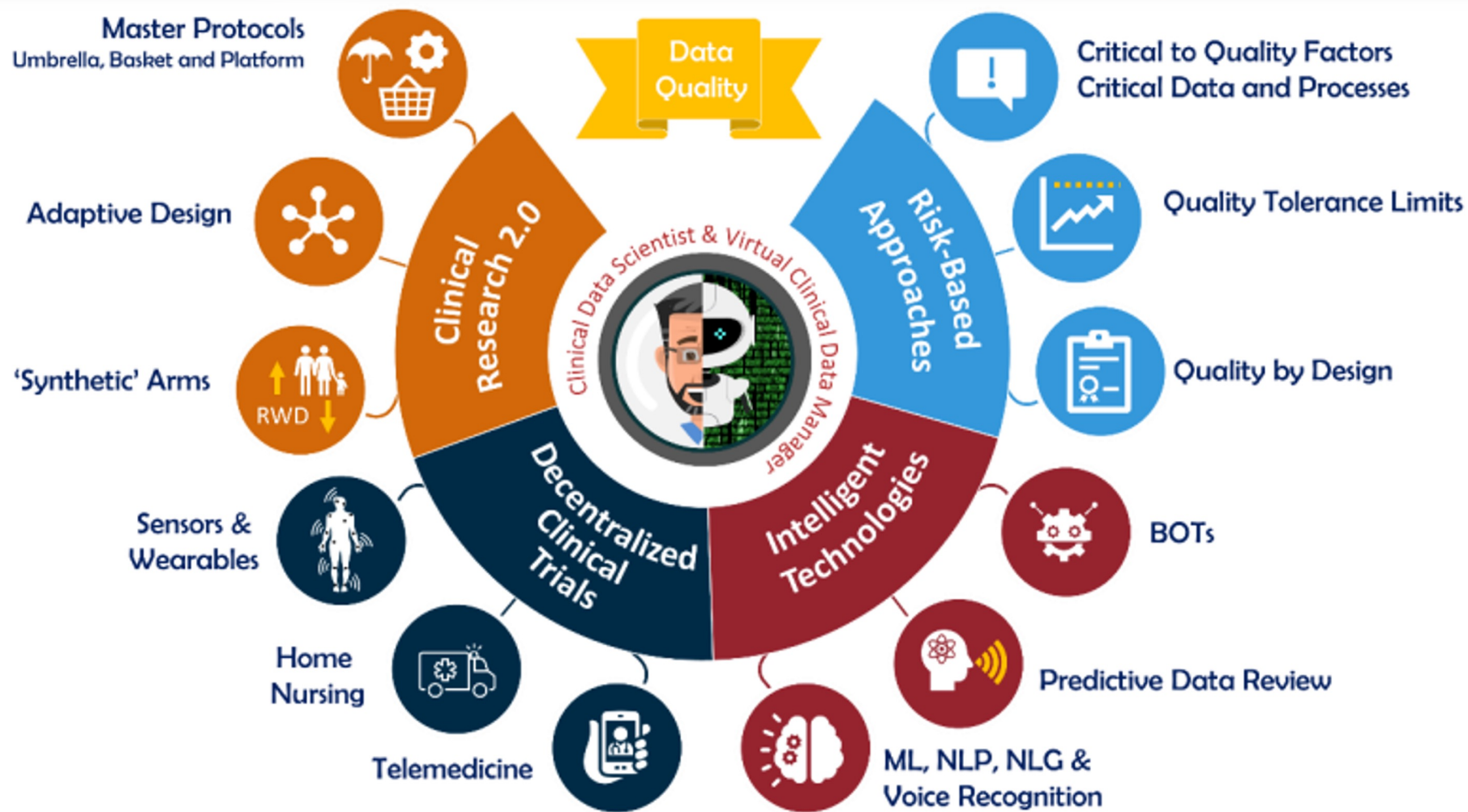
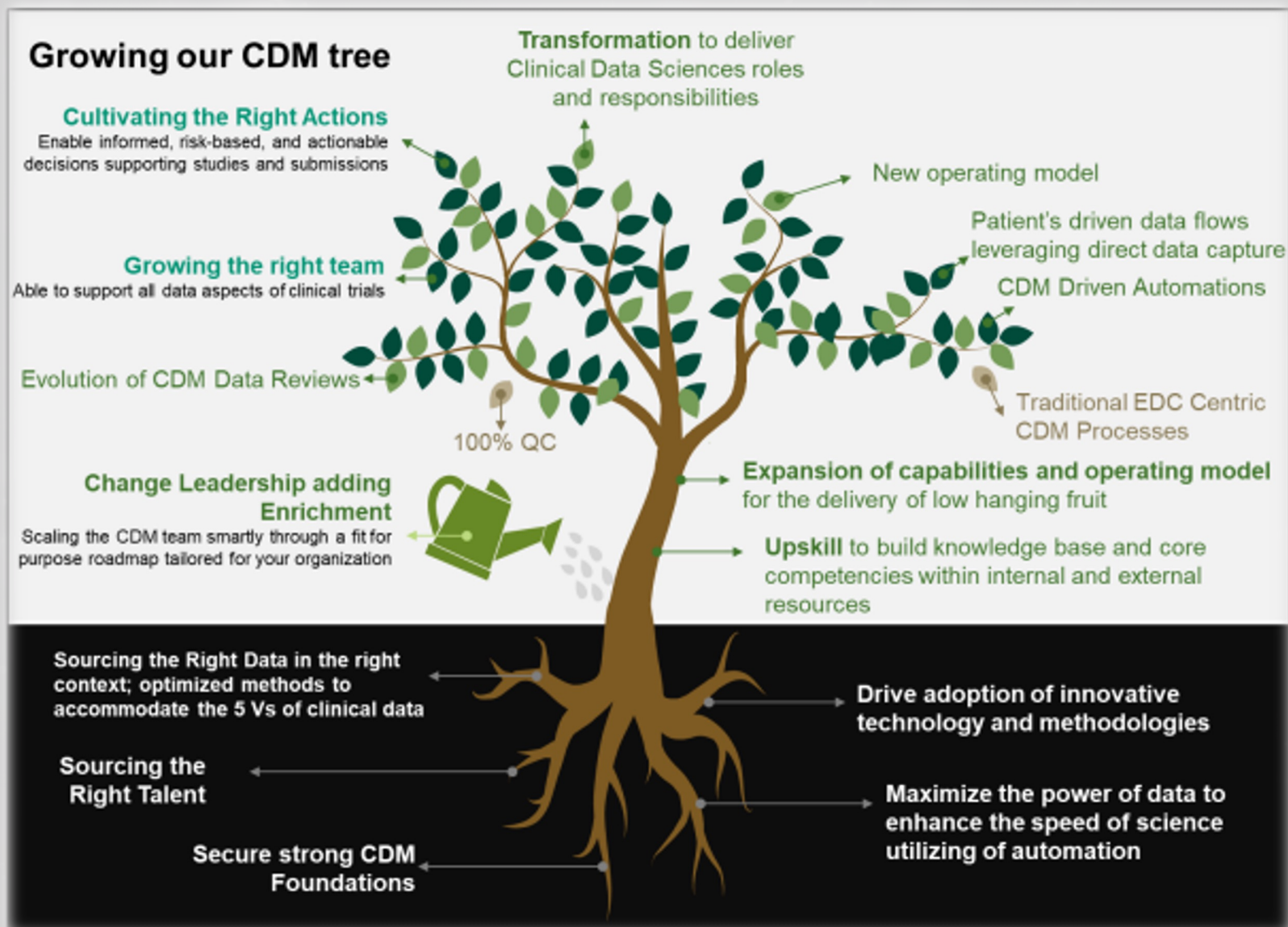


Fig 1: Driving forces behind the evolution toward CDS





Establishing a Strong Foundation

2019-2021 Track Record

argenx 

2019 – 2021

*Establishing a **strong foundation**
for efficiency, scalability and de-risking staff dependency*

1. Selection & Implementation of a **Structured Data Repository** and **Statistical Computing Environment** for Clinical Development

In alignment with the following Requirements

- ✓ Storage and maintenance of clinical and analysis data and documents
- ✓ Collaborative Work Environment: Internal and External
- ✓ Support development and execution (production) of programs – SAS and R
- ✓ Must be Configurable; managed Centrally; Secure Storage; Easy Retrieval of data & documents
- ✓ Technical Req's*
- ✓ Regulatory Req's*

** Detailed Technical and Regulatory requirements available as separate lists at argenx.*

Partner Eco System: **SAS Institute & OCS Consulting**
Solution: **SAS Life Science Analytics Framework (SAS LSAF)**

2019 – 2021

*Establishing a **strong foundation**
for efficiency, scalability and de-risking staff dependency*

- **Governance team**



Core team members



Ad hoc team members

- **Chair:**

Data Integration & Standards Team





Clear Data.
Clear Impact.

2023
EUROPE
INTERCHANGE

26-27 APRIL | COPENHAGEN



CALL FOR ABSTRACTS

The Europe CDISC Coordinating Committee (E3C) kindly invites you to share your insights, use cases and experience related to implementing CDISC Standards. The E3C is now accepting abstract submissions for session presentations and posters at the 2023 Europe Interchange.

Here are high-interest topics: International Privacy Regulations, Real World Data and Real World Evidence, Business Optimization, Automation, Artificial Intelligence/Machine Learning, CDISC in Academic Research, Regulatory Submissions, Data Sharing, and Conformance Rules and Validation.

For the complete list of topics and more information about how you can submit your abstract, please visit the submission page.

SUBMIT AN ABSTRACT

[2023 Europe Interchange | CDISC](#)

CONFIDENTIAL & PROPRIETARY INFORMATION

2019 – 2021

*Establishing a **strong foundation**
for efficiency, scalability and de-risking staff dependency*

2. Selection & Implementation of a **Clinical Metadata Repository** for Clinical Development

In alignment with the following Requirements

- ✓ Develop, maintain, and govern the Argenx clinical data standards, both front end (CRF visualizations, Completion Guidelines, Checks) and back end (SDTM / define)
- ✓ Optional extension: incorporate analysis standards (ADaM/define) and non-clinical data standards (SEND/define)

** Detailed Technical and Regulatory requirements available as separate lists at argenx.*

Partner Eco System: **Formedix**

Solution: **Ryze**

FOR DEEPER DIVE ...

STANDARDS IMPLEMENTATION (SI 05)

Maturing standardization.
The switch from spreadsheet-
based standards to an MDR.

Jasmine Kestemont
Louella Schoemacher



FUTURE
SO BRIC

AS-IS versus TO-BE

PROCESS EXCELLENCE

Short Term (2022/2023)

- **METADATA DRIVEN TRIAL SETUP using ARGENX STANDARDS** in Formedix Ryze
Specs for DM-CRO → Build in Medidata Rave

- **DATA TRANSFER AGREEMENTS STANDARDIZATION**
argenx DTAs (replacing different CRO DTA Templates)

- **NEAR REAL TIME DATA FLOWS**
Weekly (or ad hoc daily)

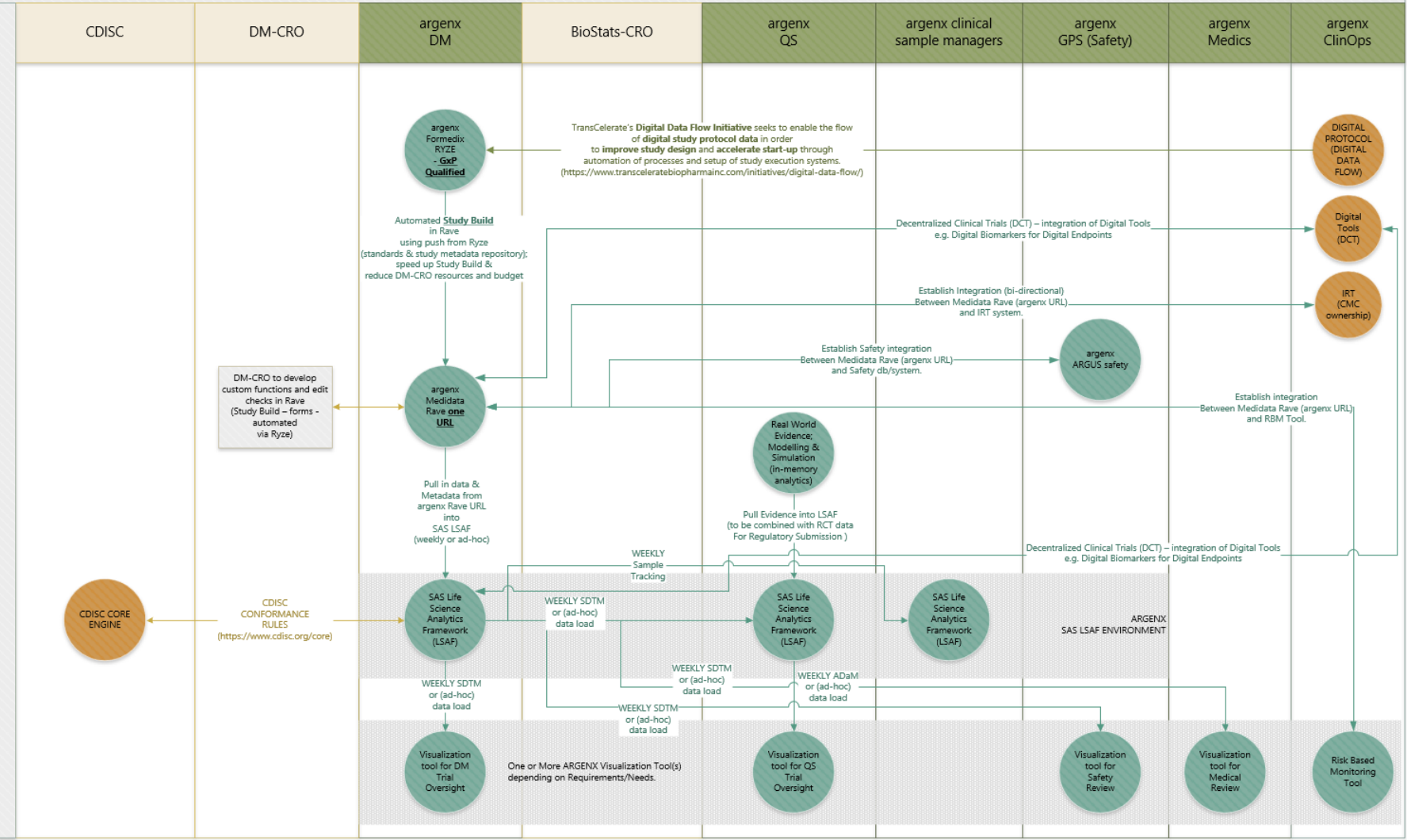
Data Loads From Medidata Rave and Central Labs into SAS LSAF
Generic SDTM > ADaM > Patient Profiles > Medical Review

Note: This is NOT replacing the monthly SDTM (submission ready) DM-CRO SDTM transfers

- **TRIAL OVERSIGHT**
Standard Packages (QC Jobs/Programs) & Trial Specific
Change Request Flow

DATA FLOW "TO BE" [STEADY STATE systems landscape by 2023/2024]

Metadata Driven Standards Approach





CRITICAL SUCCESS FACTORS

Key Learnings

CRITICAL SUCCESS FACTORS

ENTREPRENEURIAL SPIRIT

- Requirements > Budget Approval > Vendor Selection > Implementation (e.g., RYZE, LSAF,...)
- Go-Live within 3-6 Months

EMPOWERMENT & EXCELLENCE

- CROSS-FUNCTIONAL TEAMS (ARGONAUTS) WORKING AS ONE TEAM WITH SAME OBJECTIVES
- EMPLOYEES EMPOWERED TO TAKE DECISIONS
- DATA DRIVEN DECISION MAKING

CO-CREATION

- EXTERNAL COLLABORATIONS WITH LEADING TRANSLATIONAL BIOLOGY LABS; TECH VENDORS & CRO PARTNERS
- 'NOT INVENTED-HERE SYNDROME' - NOT APPLICABLE
- QUALITY BY DESIGN (no legacy)

CHALLENGES AHEAD

- KEEP ARGENX “DNA” WHILE BECOMING MID-SIZED BIO-TECH COMPANY
- KEEP RECRUITING TOP TALENTS (WITH SAME DNA)
- INCREASE LEVEL OF STANDARDIZATION (FROM PROTOCOL DESIGN TO SUBMISSION ... AND BEYOND)
- INTEGRATE and AUTOMATE
- PIPELINE (VOLUME OF TRIALS)

Thank You