



2025 CDISC + TMF
EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

argenx eTMF Migration Factory

Francesco Fiorentini, BIS Development Lead, argenx
John Blunden, Consulting Director, NNIT



Meet the Speakers

Francesco Fiorentini

Title: BIS Development Lead

Organization: argenx

As the BIS Lead - Development, I'm responsible for the strategy and implementation of information systems to address the business needs of the Development organization. My team leads the development projects according to guidelines, ensuring alignment with relevant capability stakeholders and establishing and supporting cross-functional groups to achieve strategic goals and prioritize roadmaps.



John Blunden

Title: Consulting Director

Organization: NNIT

At NNIT, John has led a number of GxP data migration programs across Regulatory, Quality and Clinical domains.

Currently focussed on frameworks that enable repeat migration and/or repeat data verification and/or data surveillance – as customers press ahead with new transformation initiatives, M&A transactions and Data Exchange.

Disclaimer and Disclosures

- *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.*



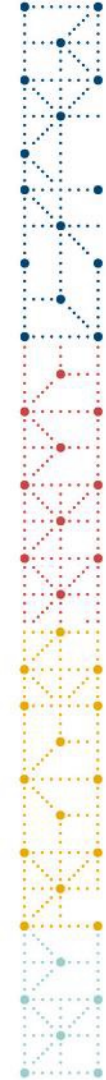
Agenda




1. Background – Data Migration Evolution
2. The Challenge
3. The Solution
4. Results
5. The Future



Background – Data Migration Evolution

Data Migration Evolution

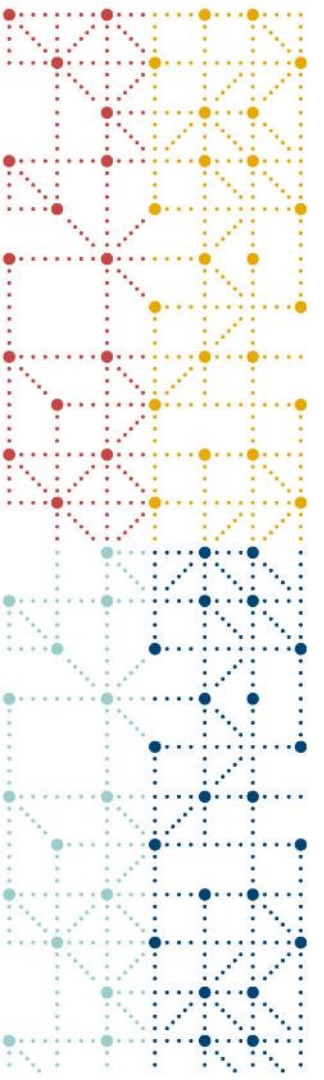


	  		
	Documents - eTMF	Data - CTMS	Both - eTMF & CTMS
Effort	#Documents	#Transforms	#Docs + #Transforms
Complexity	Low	High	Very High
Dependencies	Project Specific	Data Quality	Strategic
Verification	Low	High (Step-Wise)	High
Management	Tactical Project Mgt	Intense Project Mgt	Programme Mgt
Benefits	Short-term	Transformative	Transformative
Scope	Focused	Focused	Focused

Data Migration Evolution



	Continuous Migration/Verification
Effort	Internal & External teams
Complexity	Medium
Dependencies	Strategic
Verification	High -> Low
Management	Partnership
Benefits	Economies of Scope & Scale
Scope	Repeatable, Expandable



The Challenge

The Challenge – CRO to SPONSOR eTMF Migrations



Diverse Sources remain the main challenge to automation.



Time-consuming process

Handover,
Technical Logistics,
Clinical Review,
Manual Upload,
Final Review

Repeat, Repeat,
Repeat



Quality Concerns

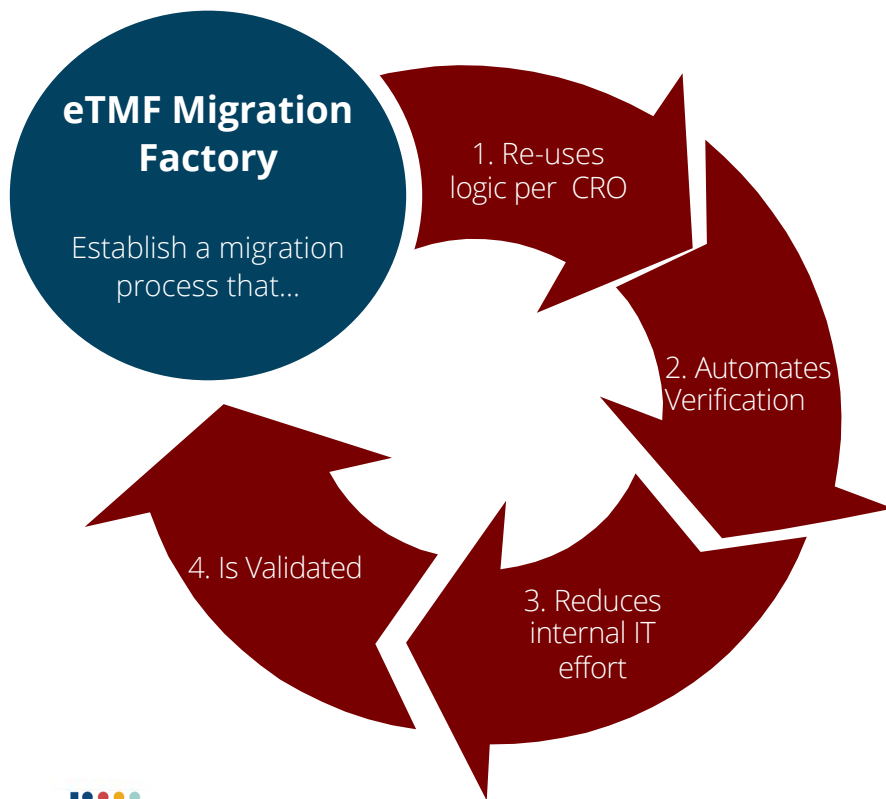
Quality and Data Integrity paramount.



High Business Effort

Lack of automation forces manual verification.

A new approach



Reduce project duration from months to weeks

Apply lessons from large-scale eTMF migration.

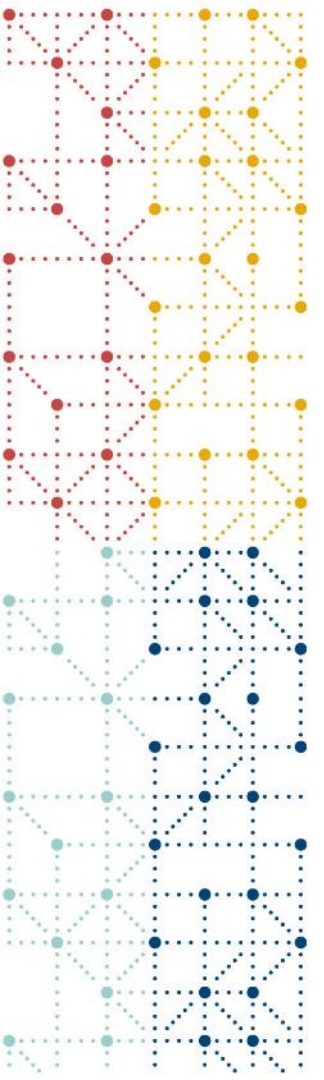
Validate once, re-use often

Ensure predictability for busy teams.

Align with future needs

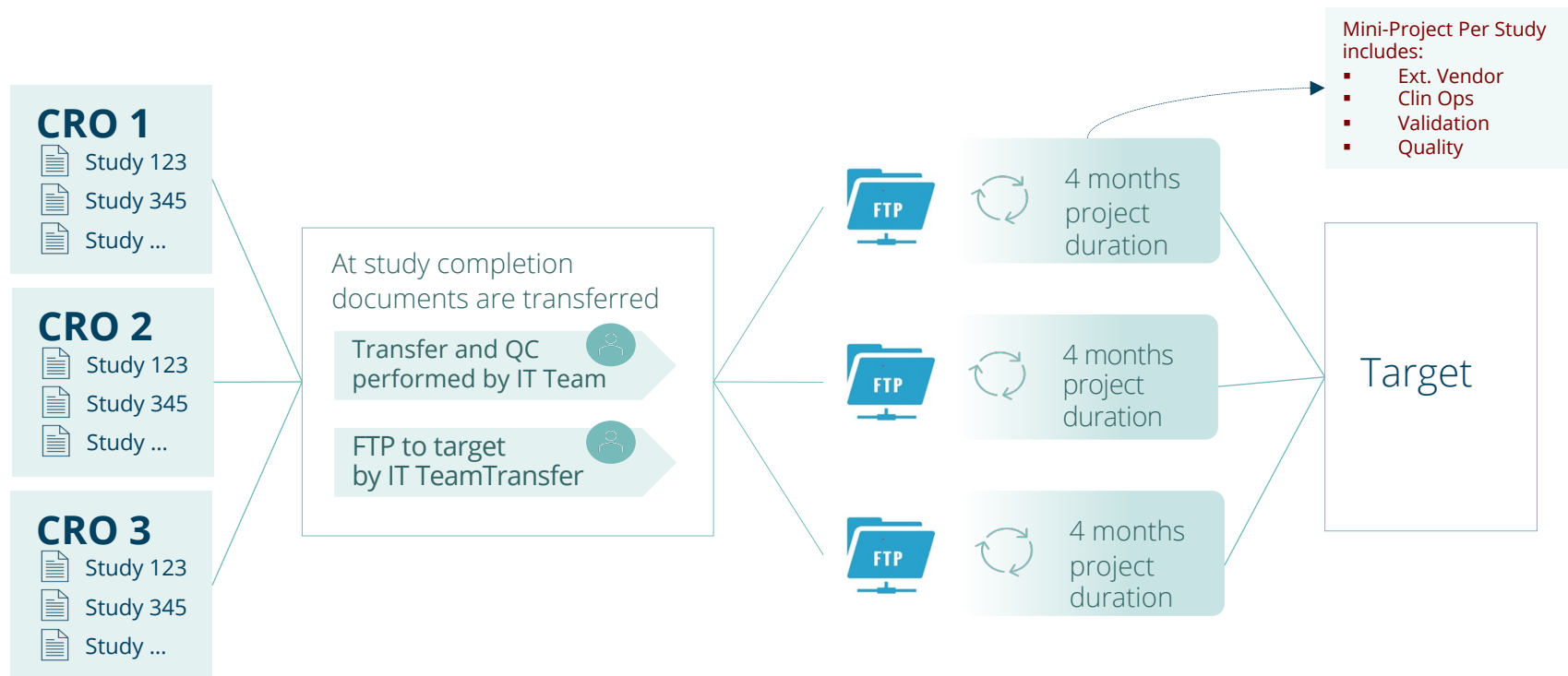
Ready to **verify** Exchange Standard Transfers

Ready to **verify** Platform to Platform TMF Transfers

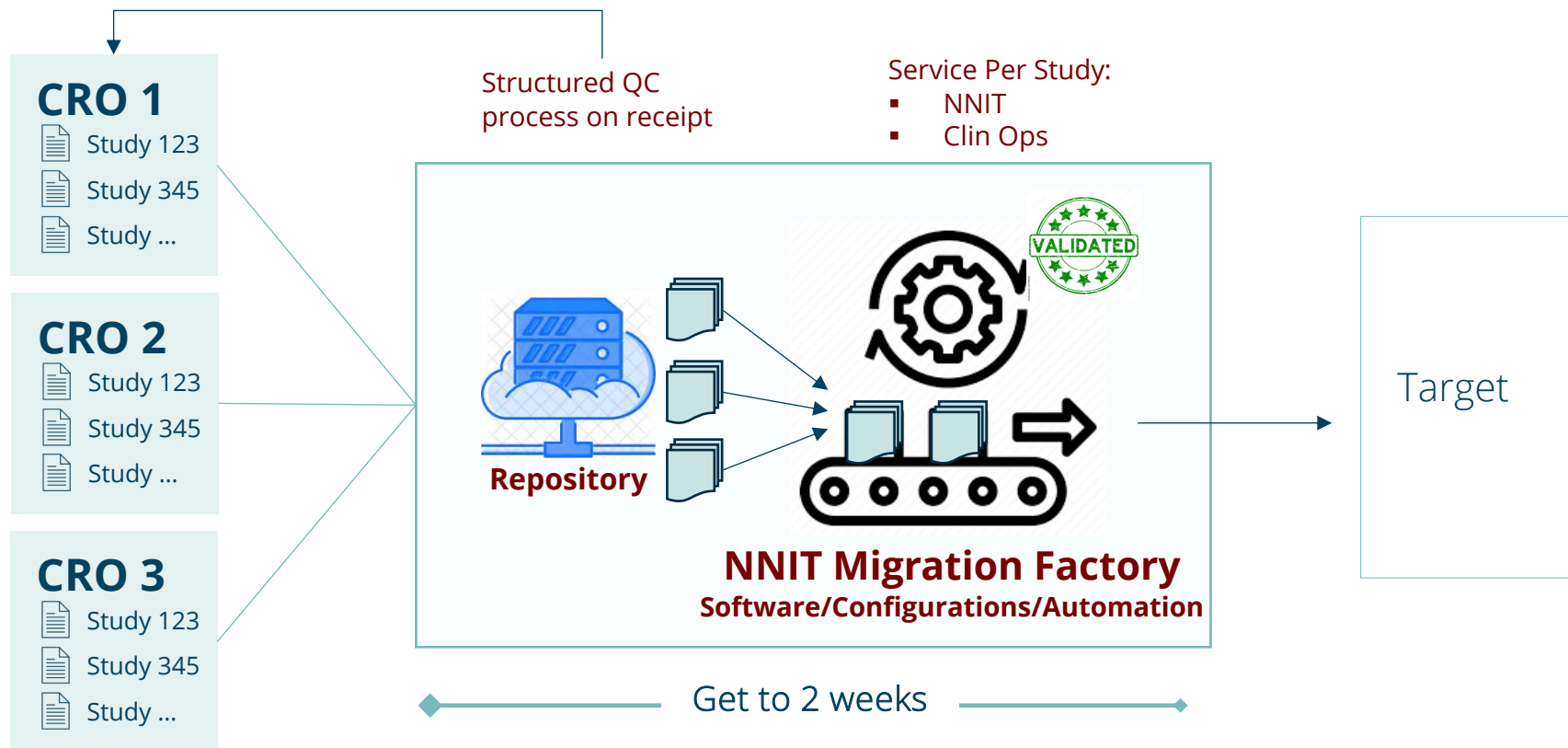


The Solution

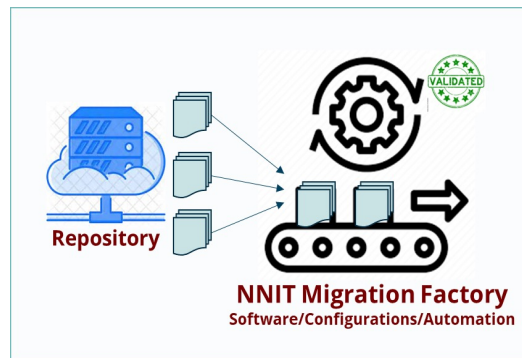
AS-IS flow characterized by complexity



TO-BE: Introduce the eTMF Migration Factory

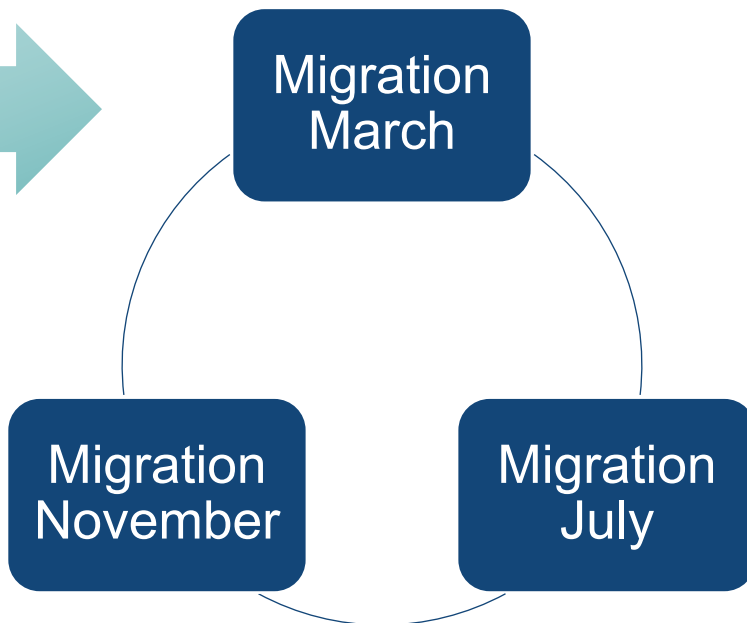


Predictable schedule of periodic eTMF Migration



Objectives for Year 1

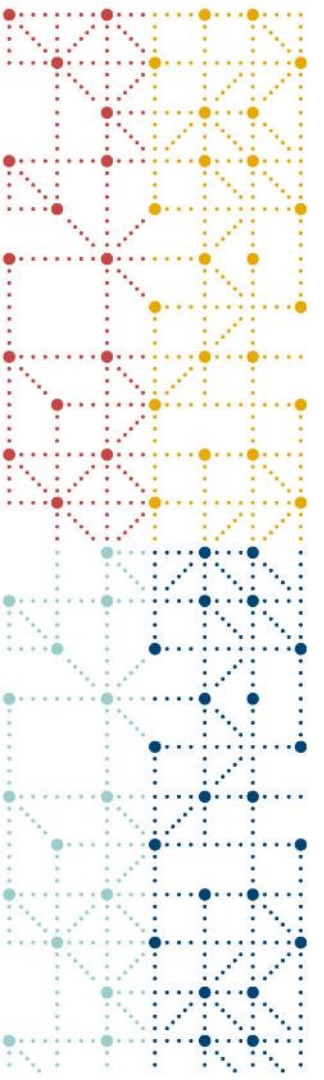
- Migration Factory fully validated and operational
- 2/3 Migration cycles per Year (Predefined)
- Known engagement for Vendor and Sponsor



Expectations

- Lower Effort and Cost for each migration

	Planning, Requirements & Analysis	Configuration & Testing	Qualification & Validation	Production Execution	Sponsor Business Engagement
Phase I 4 New Sources 5 Studies	\$\$\$	\$\$\$	\$\$	\$	\$\$\$
Phase II 2 New Sources 7 Studies	\$\$	\$	\$	\$	\$
Phase III 0 New Sources 4 Studies	\$	\$	\$	\$	\$



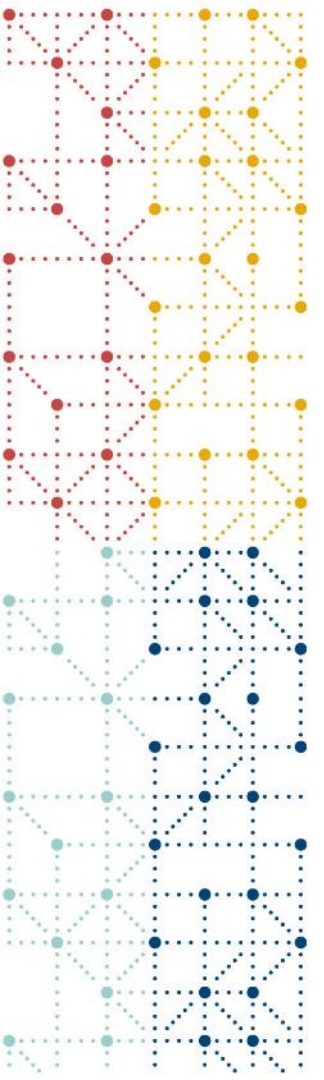
The Results

Results

Clinical Teams		
Before	After	
Informal Testing	Informal Testing	Reduction/Increase -
Formal Testing	Automated Testing Review Discrepancies/Exceptions Only	55%

Results

		Validation Team Medium Effort for first file from each CRO, Then Zero.					QA Team Medium Effort for first file from each CRO, Then Zero.				
		Before		After			Before		After		
Study Size	Per CRO	Validation Effort	Hours	Validation Effort	Hours	Reduction/Increase	QA Effort	Hours	QA Effort	Hours	Reduction/Increase
1,000	1st	Low	40	Medium	50	25%	Low	20	Medium	20	-
1,000	2nd	Low	40	N/A	2	95%	Low	20	N/A	0	100%
1,000	3rd	Low	40	N/A	2	95%	Low	20	N/A	0	100%
10,000	1st	Low	40	Medium	50	25%	Low	20	Medium	20	-
10,000	2nd	Low	40	N/A	2	95%	Low	20	N/A	0	100%
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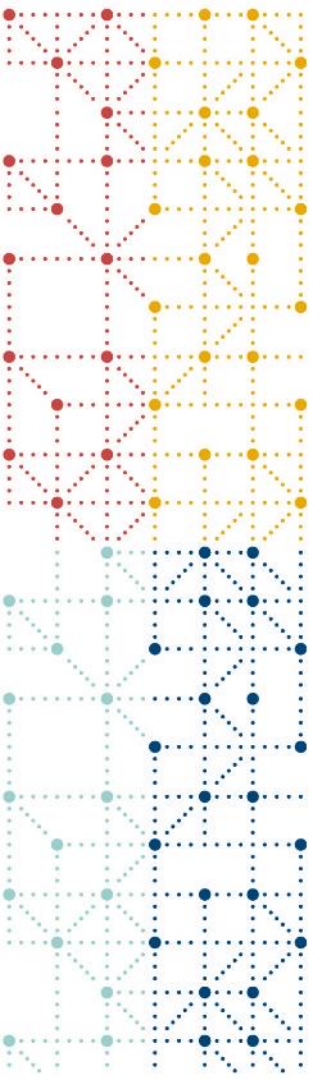


The Future



Thank You!





Thank You

Slides Using Images