



**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

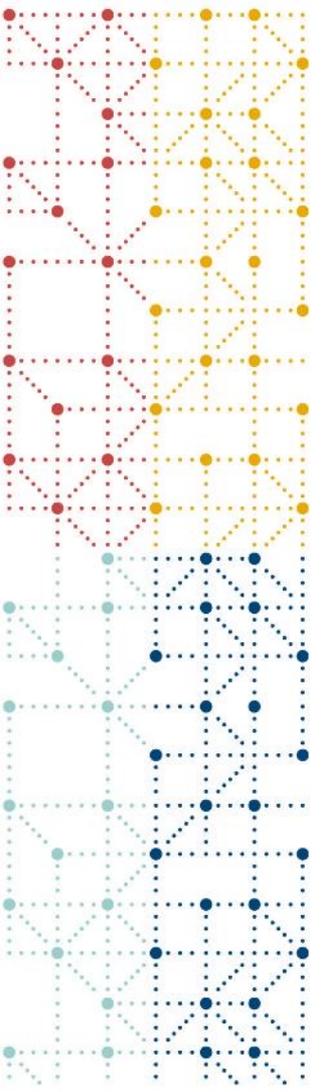
At NNIT, John has led a number of GxP data migration programs across Regulatory, Quality and Clinical domains.

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.



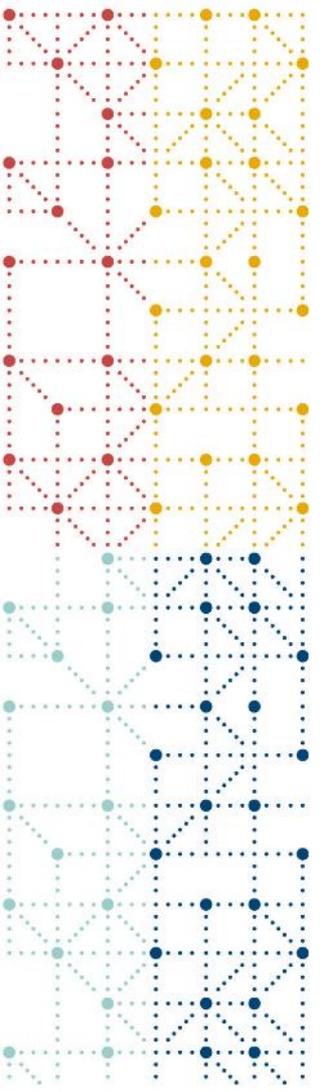
# Disclaimer and Disclosures

- *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

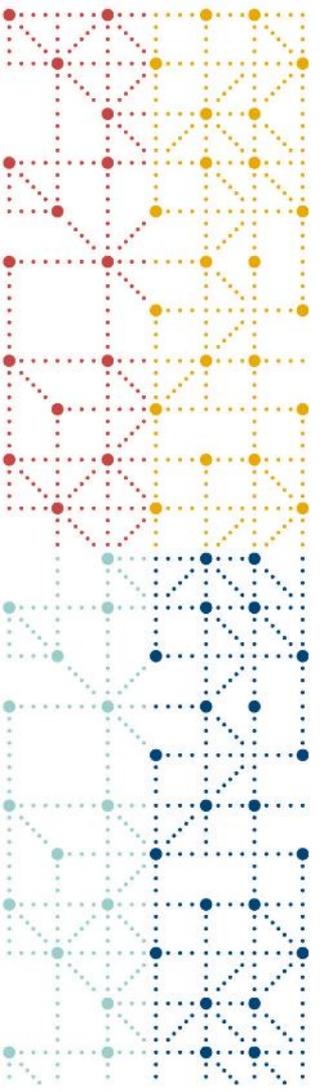


	Documents - eTMF	Data - CTMS	Both - eTMF & CTMS
<b>Effort</b>	#Documents	#Transforms	#Docs + #Transforms
<b>Complexity</b>	Low	High	Very High
<b>Dependencies</b>	Project Specific	Data Quality	Strategic
<b>Verification</b>	Low	High (Step-Wise)	High
<b>Management</b>	Tactical Project Mgt	Intense Project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

# Data Migration Evolution



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



## 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

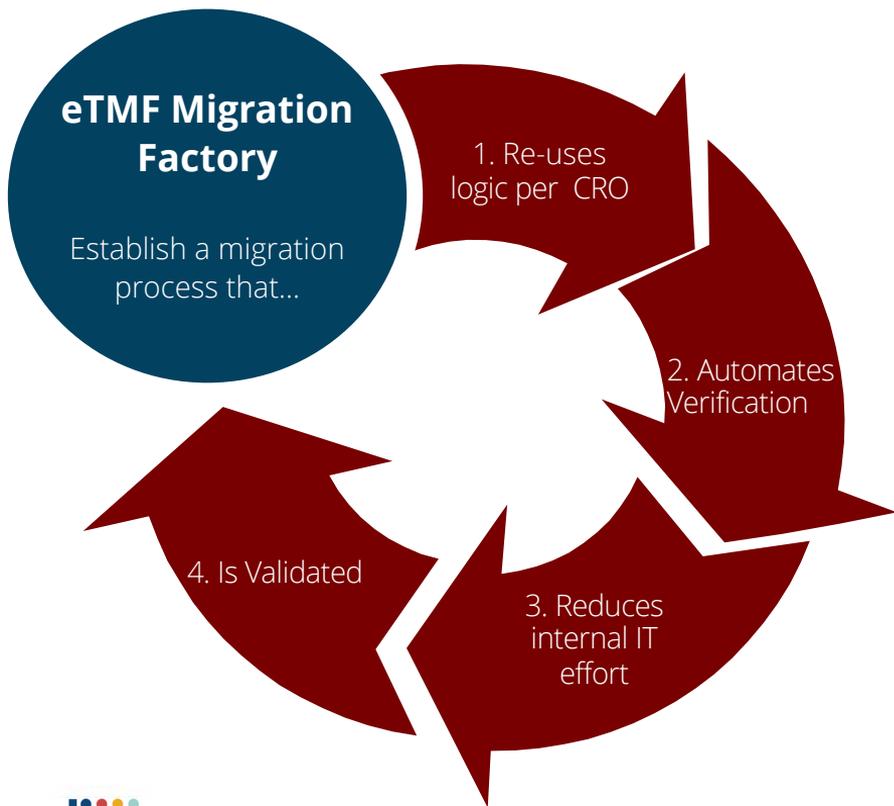
Quality and Data Integrity paramount.



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.

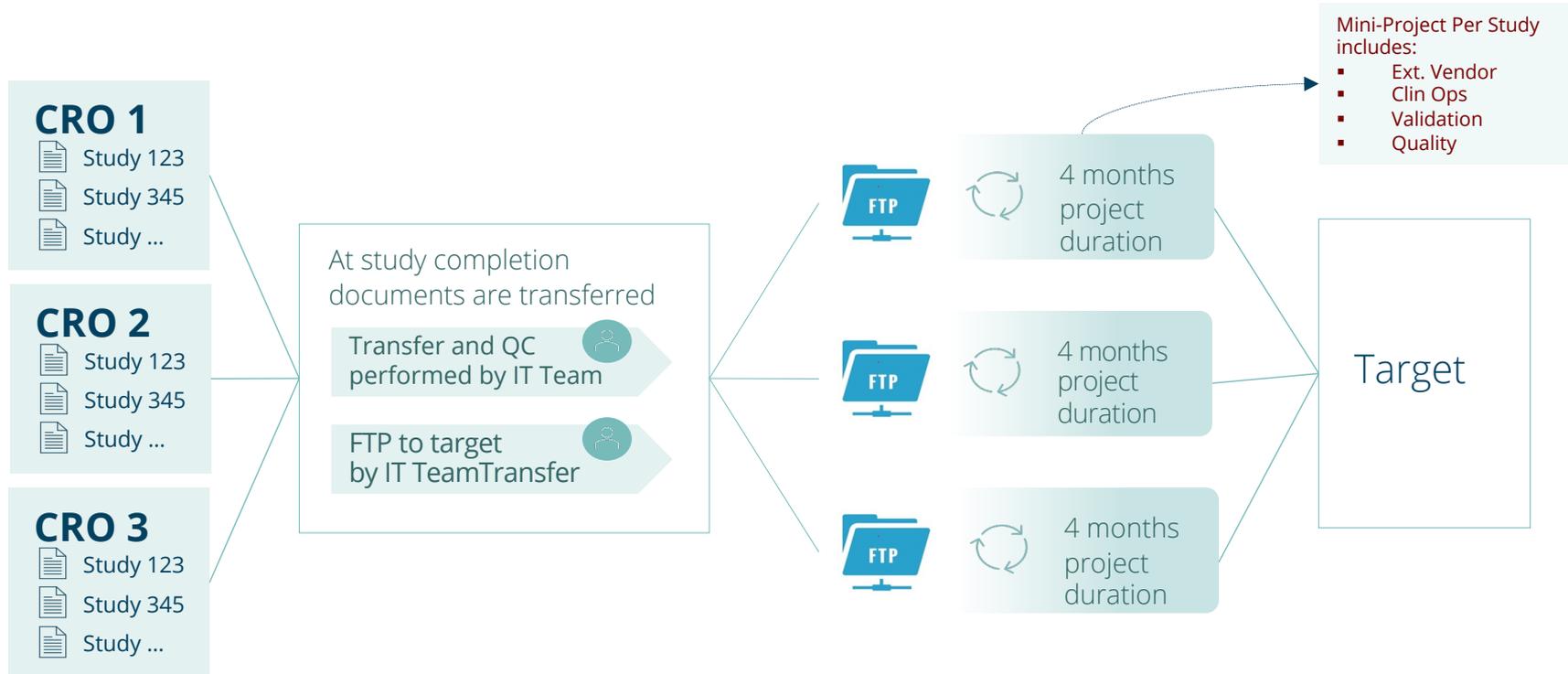
Align with future needs

Ready to **verify** Exchange Standard Transfers

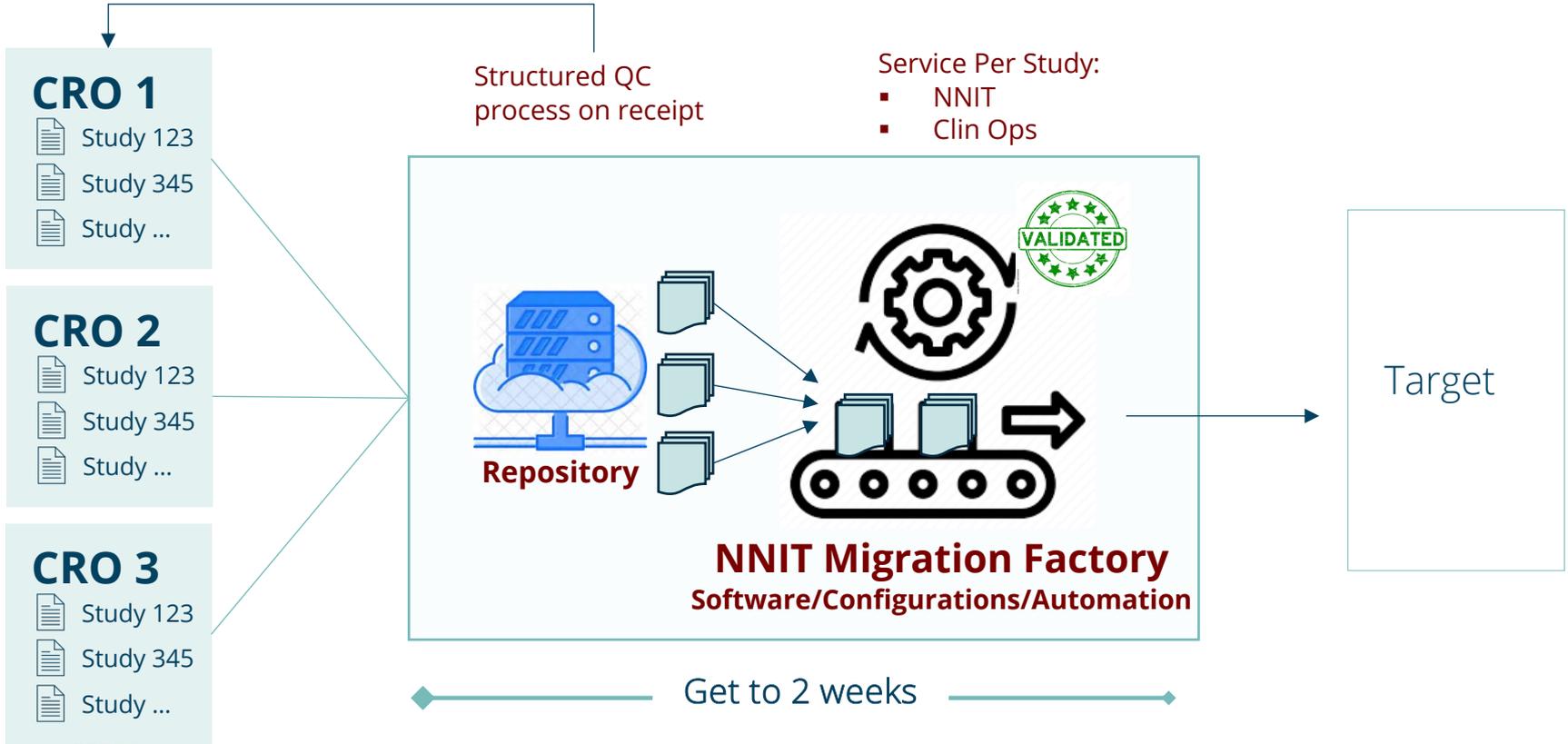
Ready to **verify** Platform to Platform TMF Transfers



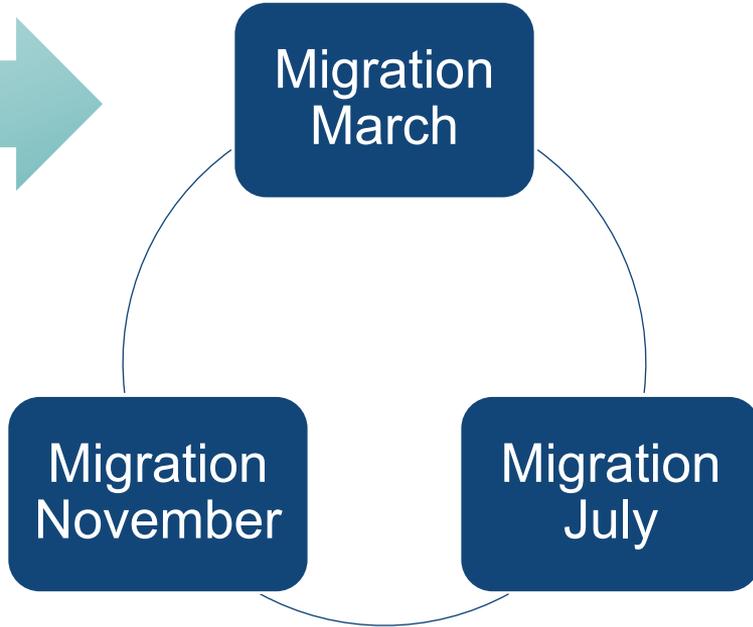
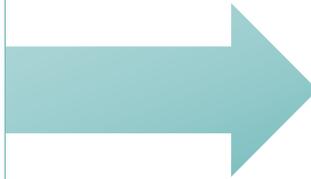
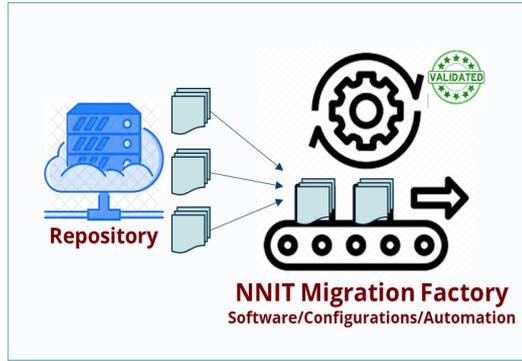
# AS-IS flow characterized by complexity



# TO-BE: Introduce the eTMF Migration Factory



# Predictable schedule of periodic eTMF Migration



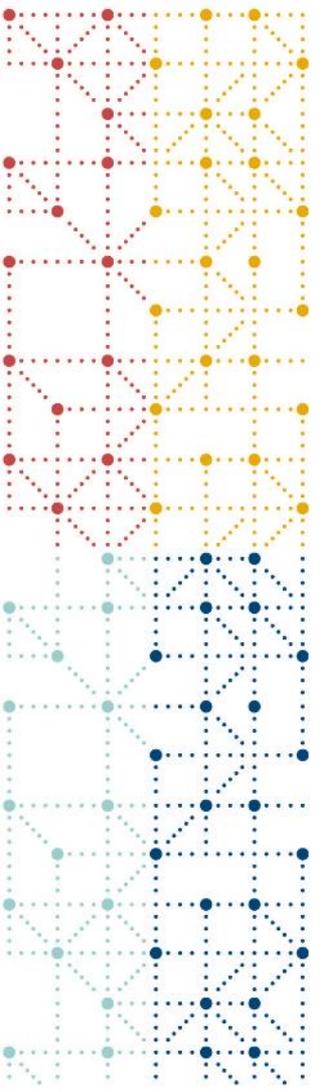
## Objectives for Year 1

- 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	\$	\$	\$	\$	\$



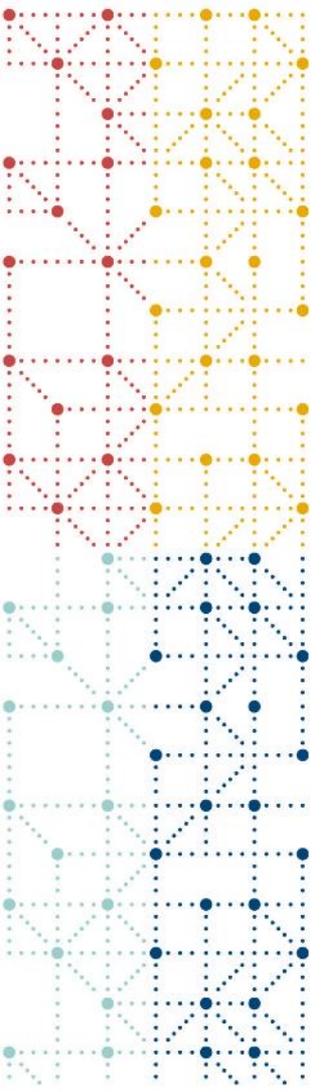
## The Results

# Results

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

# Results

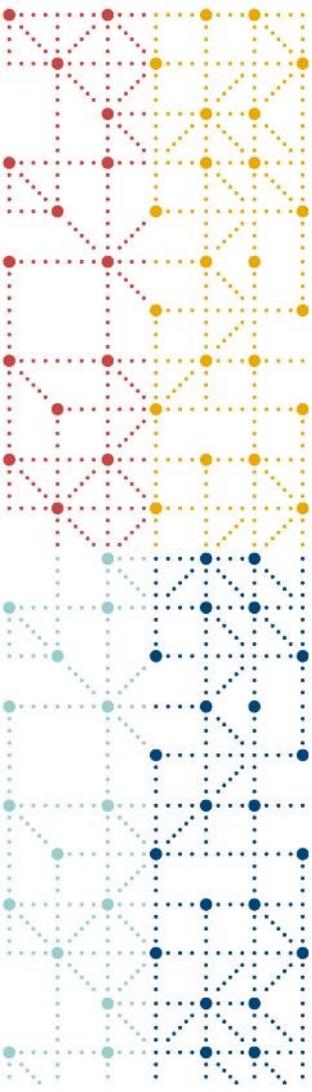
		Validation Team Medium Effort for first file from each CRO, Then Zero.					QA Team Medium Effort for first file from each CRO, Then Zero.				
		Before		After			Before		After		
Study Size	Per CRO	Validation Effort	Hours	Validation Effort	Hours	Reduction/Increase	QA Effort	Hours	QA Effort	Hours	Reduction/Increase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



# The Future

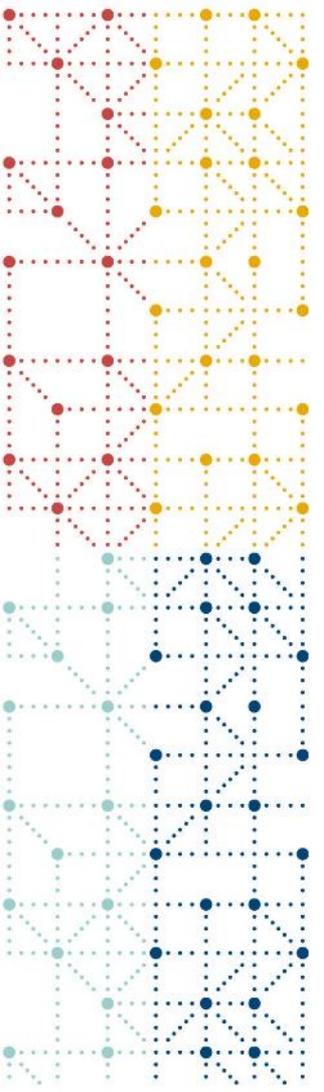
# Future Plans

		Now		Future	
		<b>Hybrid System Usage</b>		<b>eTMF Transfer Schedules</b>	
eTMF	Mostly CRO 's	Mostly argenx	Transfer Frequency	Mostly at Study Close only.	Mostly at Study Close Only (Rationale - Higher Volume Inhouse)
CTMS	CRO's	CRO's			
CTMS Data Exchange	Hybrid Batch/Integration	Mostly Integration			
		<b>Hybrid Migration Approach</b>		<b>Migration Factory Beyond eTMF</b>	
Migration Configuration			Migration Factory Scope	Expand Continuous Migration	Explore Continuous Verification - Data Surveillance
Migration Validation	NNIT	argenx/NNIT (When Required)			
Migration Execution	NNIT	argenx/NNIT (When Required)			
Automated Verification	NNIT	argenx			



**Thank You!**





# Thank You

Slides Using Images