DDF: The Art of the Possible Becomes Reality

Presented by Frederik Malfait, SVP Information Architecture, Nurocor

Meet the Speaker

Frederik Malfait

Title: SVP Information Architecture

Organization: Nurocor

Frederik Malfait is Senior VP of Information Architecture at Nurocor, focused on delivering the Nurocor Clinical Platform for digitalized clinical development. Before that he has consulted for the biotech industry with assignments across Drug Safety, Clinical Data Management, Statistical Programming, and Clinical Data Standards. He has designed a semantic MDR for a large pharma, co-initiated the PhUSE CSS Semantic Technology working group and the CDISC Protocol Entities project, consulted for TransCelerate, and designed the initial implementation of the CDISC Library API and Browser.

He holds a Master Degree in Mathematics.

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. Digitalized Clinical Development
2. Platform based delivery
3. SDR integration
4. Value proposition
5. Outlook

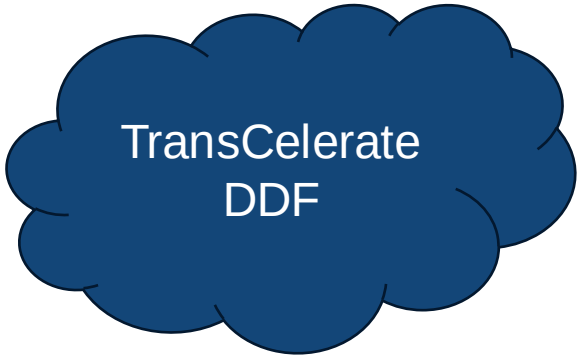
Digitalized Clinical Development

The landscape of Digital Data Flow

Stakeholders

TCB Members

SDO



Pharma at large

Vendors

Regulators

Copyright 2024 Nurocor

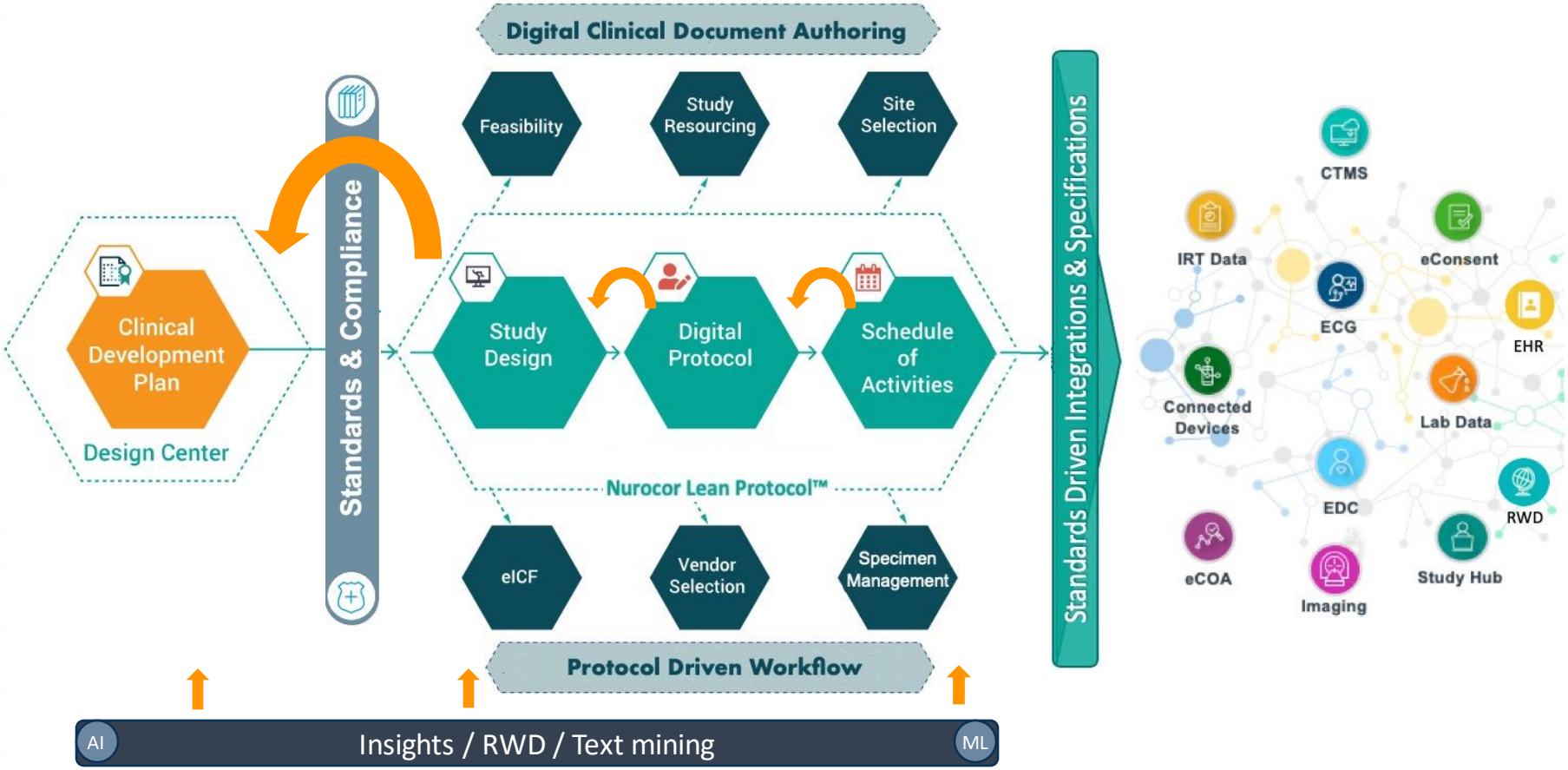
Timeline

	TransCelerate DDF	Nurocor Clinical Platform
2018		Infrastructure
2019	Nov. white paper	Study Designer and SoA
2020	Feb. hackathon	Study and Protocol Elements
2021		Lean Protocol
2022	USDM / SDR / hackathon	Specimen Management
2023	USDM / SDR v2 Discovery Day	Clinical Document Authoring

Copyright 2024 Nurocor

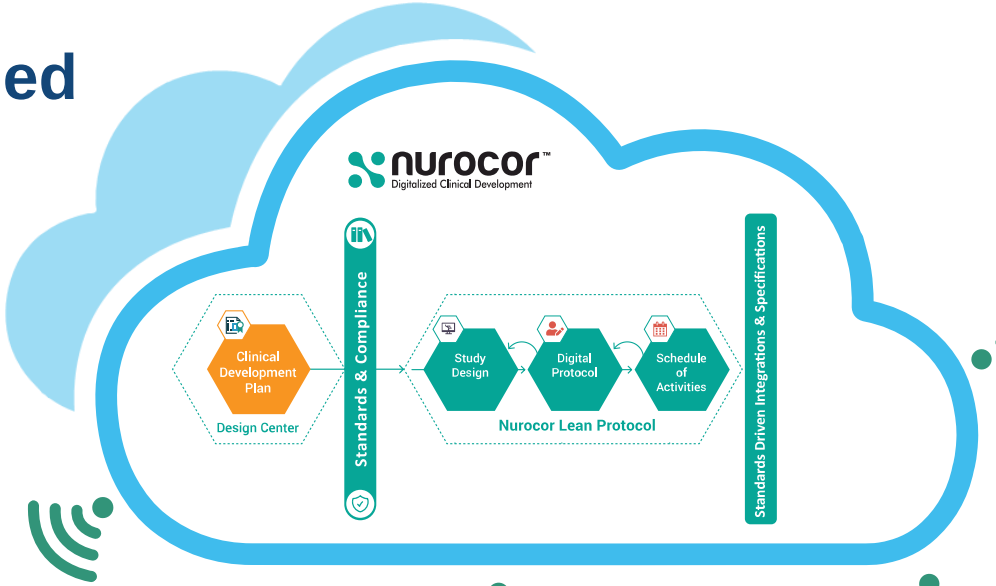
Platform based delivery

From the viewpoint of an upstream provider



Copyright 2024 Nurocor

Persona based



Study Designer
- Clinical Scientist
- Statistician
- Functional Representatives
- Digital Architect

Vision / DAR
- Data Manager
- Standards
- Database Builder

Study & Protocol Elements
- Digital Architect
- Clinical Scientist
- Medical Writers
- Statistician
- Specimen Manager
- Functional Representatives

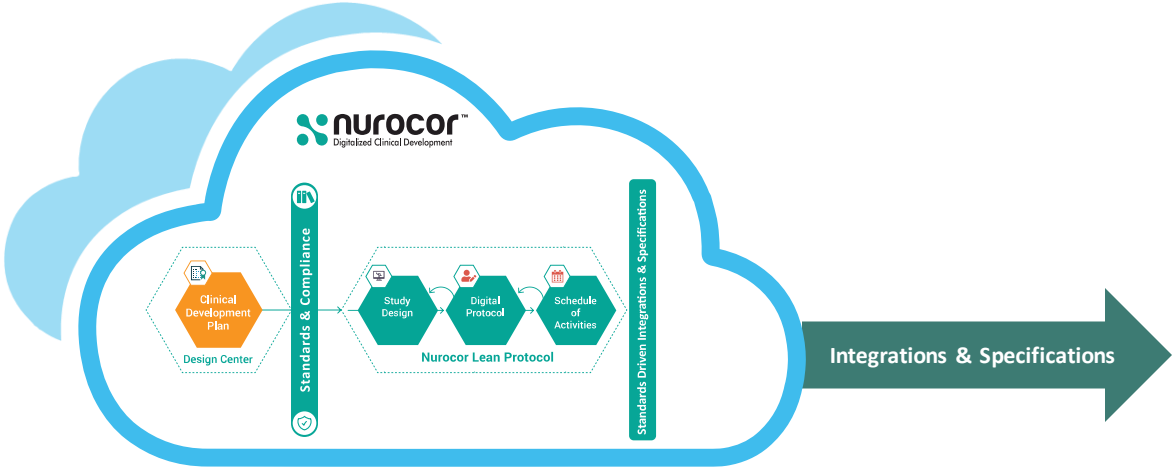
Lean Protocol
- Clinical Scientist
- Functional Representatives

Schedule of Activities
- Digital Architect
- Clinical Scientist
- Specimen Manager
- Data Manager

Specimen Management
- Digital Architect
- Specimen Manager

Copyright 2024 Nurocor

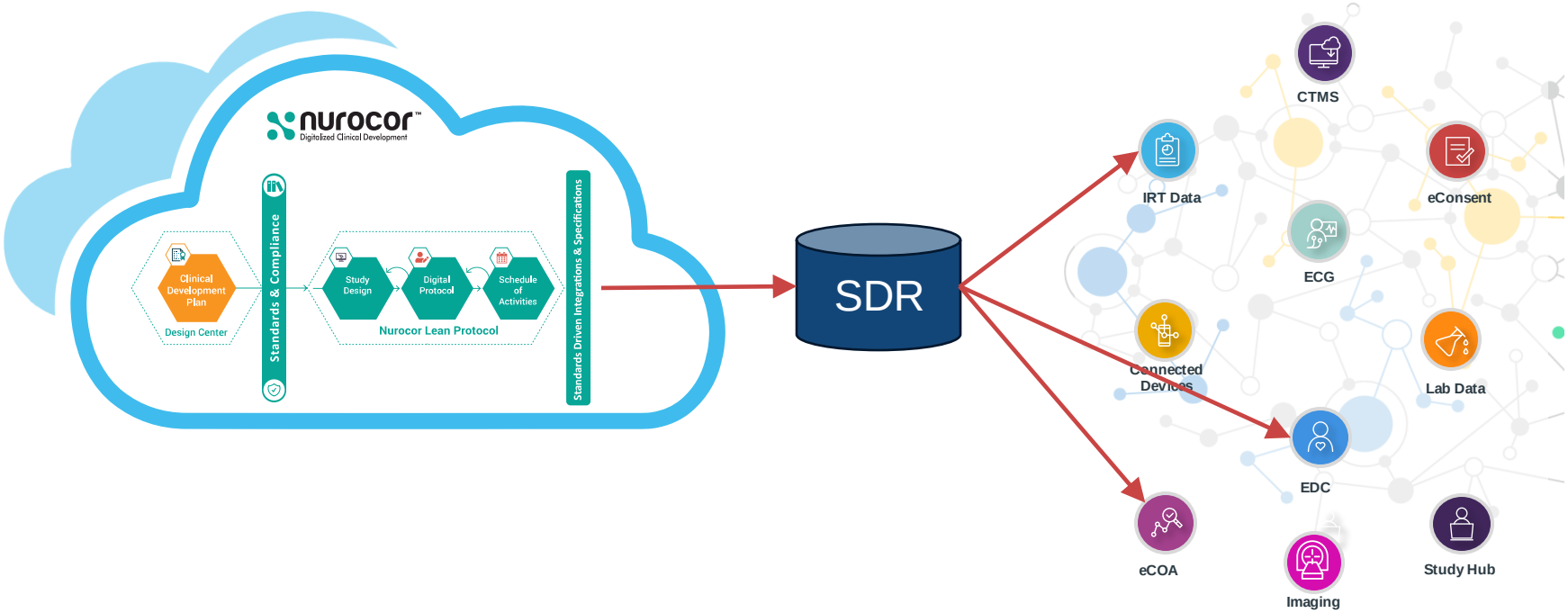
Driving digitalization



Integrations & Specifications

Copyright 2024 Nurocor

Driving digitalization – Hub Architecture



Copyright 2024 Nurocor

SDR integration

Workflow based integration of the Nurocor Clinical Platform (NCP) and the Study Definitions Repository (SDR)

DDF Discovery Day

Connecting NCP to SDR

What will this demonstration show?

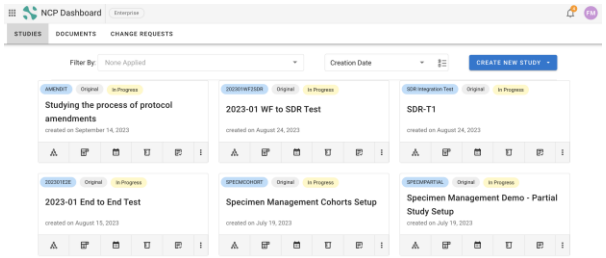
The Nurocor Clinical Platform (NCP) enables end-to-end digitalized clinical development. We demonstrate how to create a fully digitalized protocol in NCP, start a workflow process, and submit the study to the SDR. We compare the content in NCP and SDR side by side.

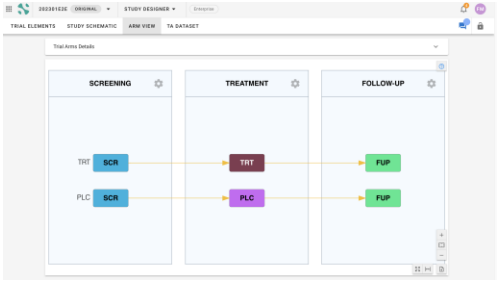
What can the audience take away from this demo?

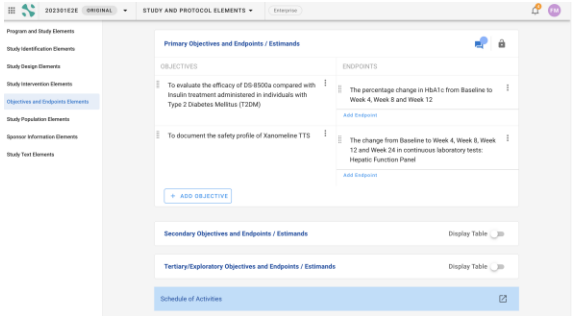
- Advanced study definition capabilities exist today on the validated Nurocor Clinical Platform (NCP)
- NCP implements all USDM elements and connects to the SDR through an integrated Lean Protocol (tm) process workflow

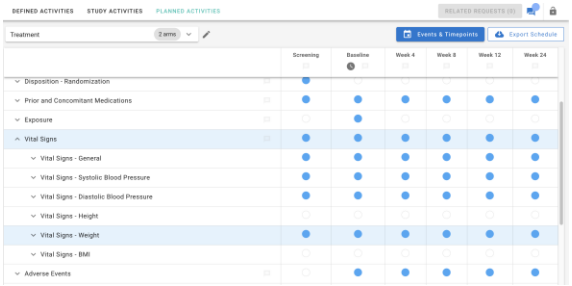
Copyright 2024 Nurocor

Creating a study definition



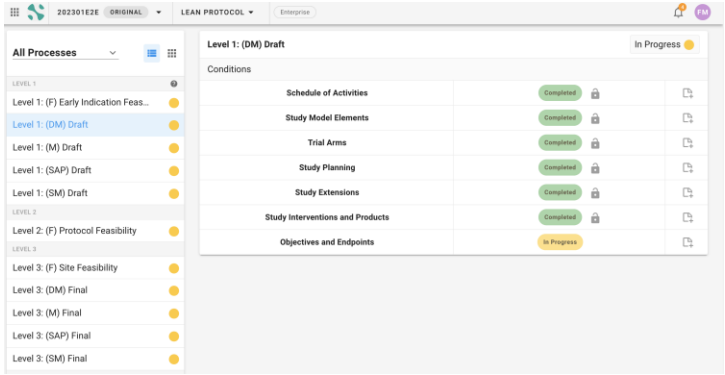


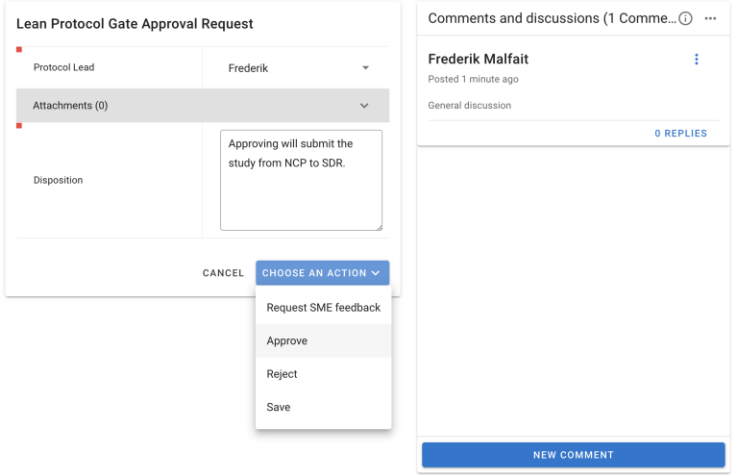




Copyright 2024 Nurocor

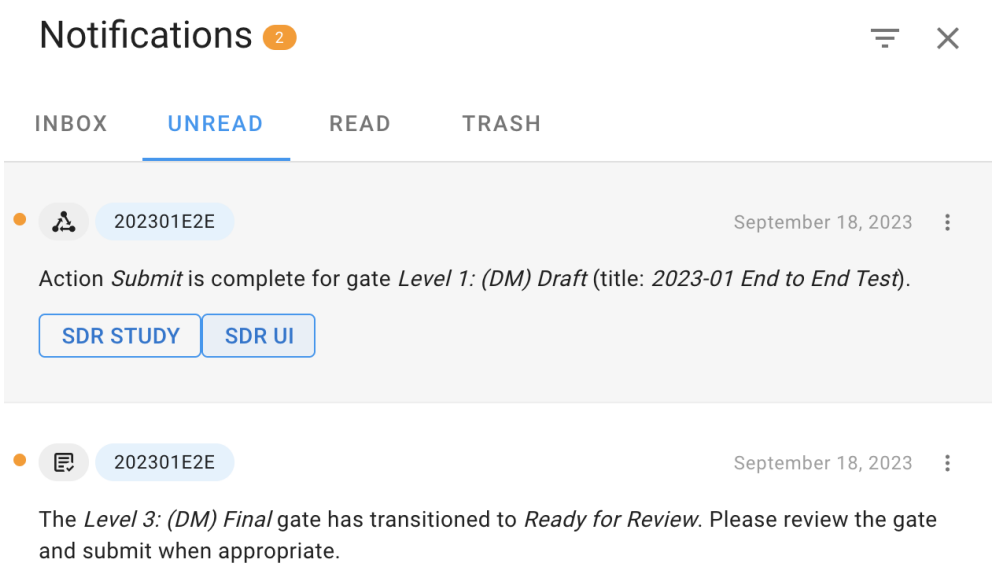
Approving a study workflow





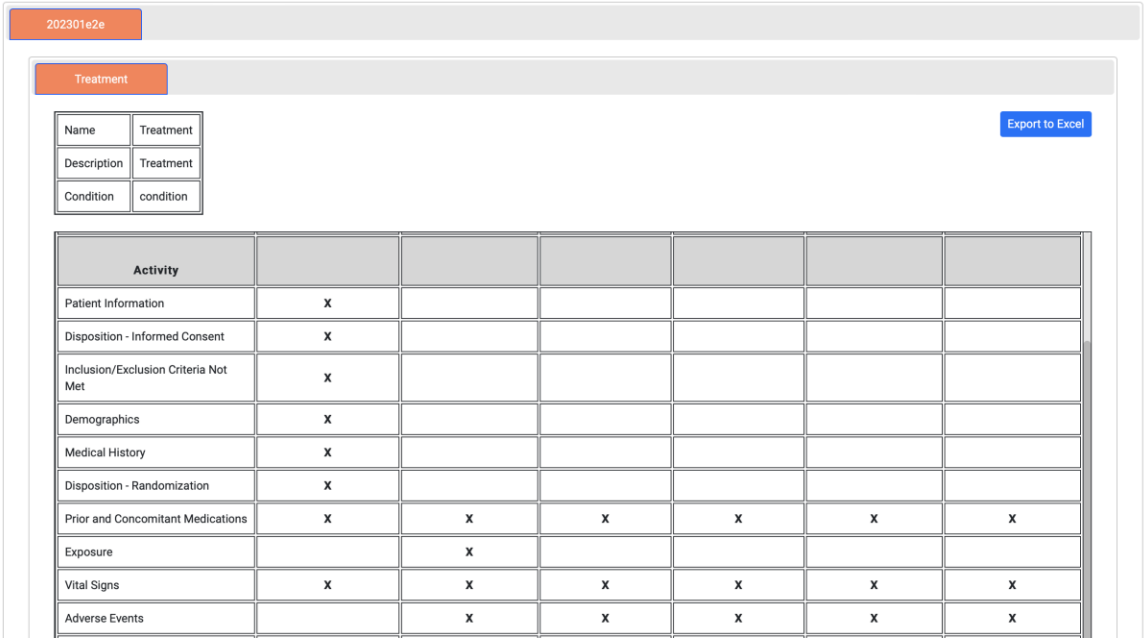
Copyright 2024 Nurocor

Posting the study from the NCP to the SDR



Copyright 2024 Nurocor

Viewing the study in the SDR



Name	Treatment
Description	Treatment
Condition	condition

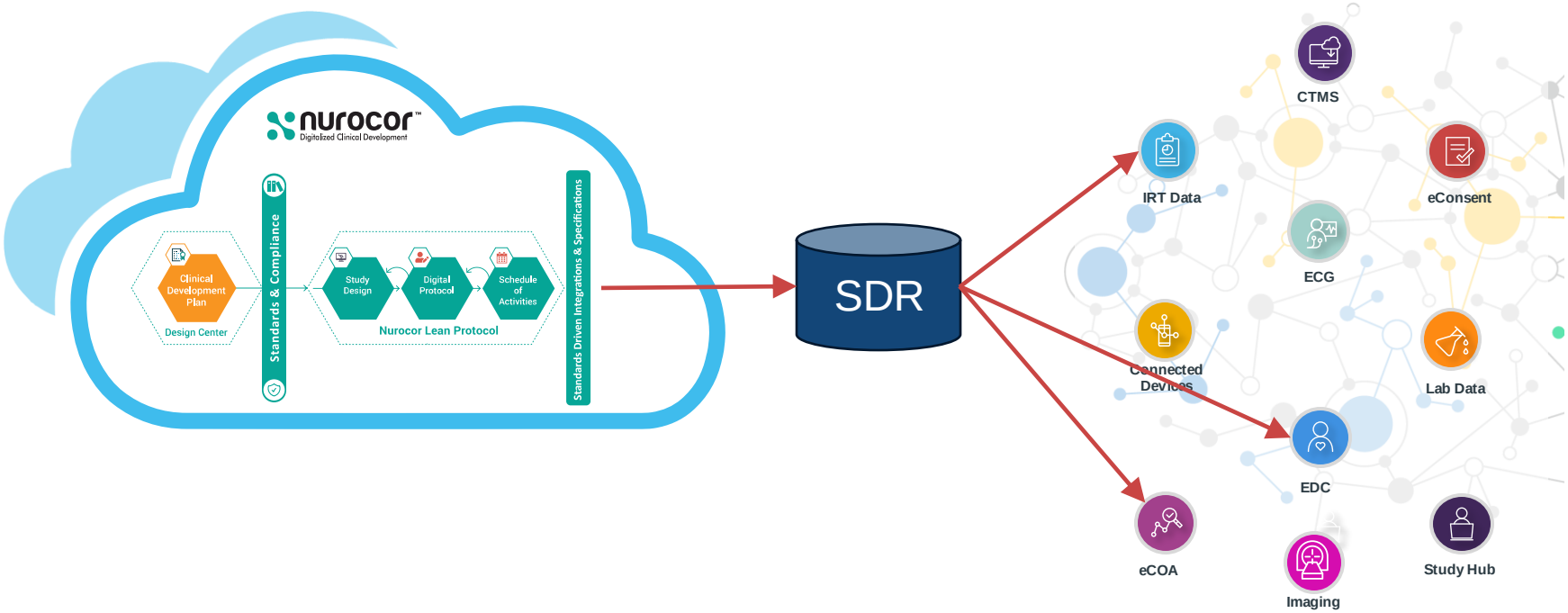
Activity						
Patient Information	X					
Disposition - Informed Consent	X					
Inclusion/Exclusion Criteria Not Met	X					
Demographics	X					
Medical History	X					
Disposition - Randomization	X					
Prior and Concomitant Medications	X	X	X	X	X	X
Exposure		X				
Vital Signs	X	X	X	X	X	X
Adverse Events		X	X	X	X	X

Copyright 2024 Nurocor

Value proposition

Benefits of digitalized clinical development today

Driving digitalization



Copyright 2024 Nurocor

Time to Market

PROBLEMS IN THE INDUSTRY

$35,000,000.00

Up to 30 % of all clinical data collected is not used in NDA submissions

45%

Less than 45% of data collected is related to primary /secondary outcomes

$2,000,000.00

The top 20 pharmas average at least 4 protocol amendments per study

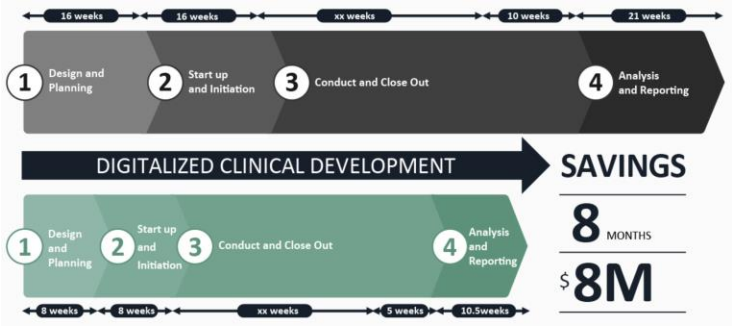
28,000

The number of hours spent on programming and query management

THE SOLUTION

Drive quality and consistency, focus on outcome driven critical data, eliminate avoidable amendments, and automate provision of specifications for data collection and analysis

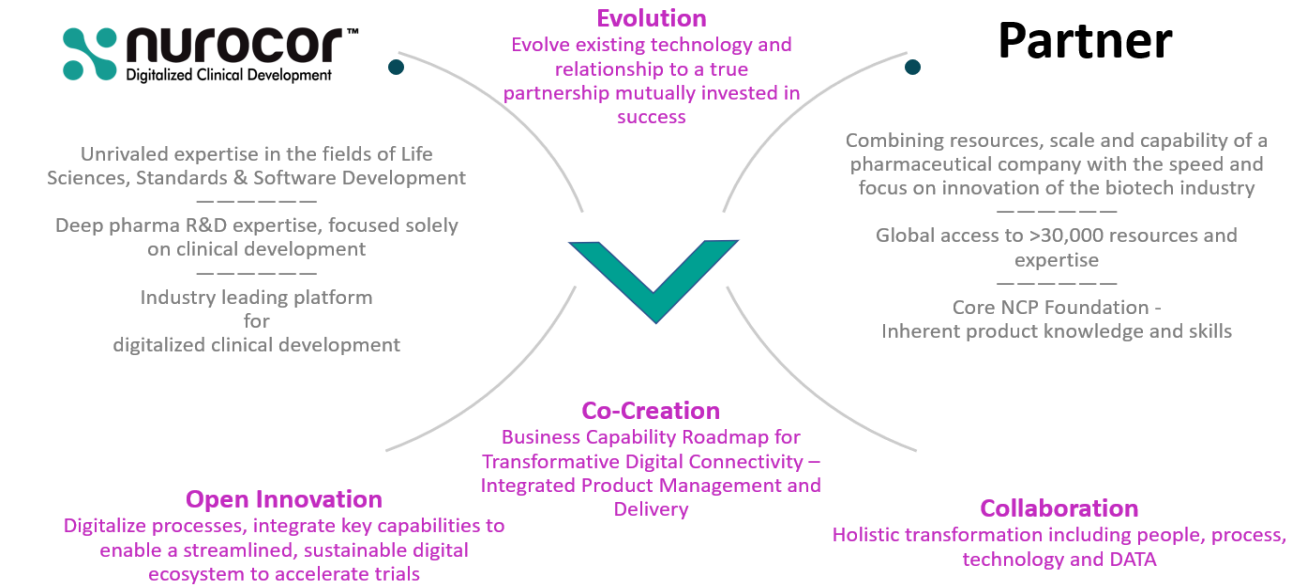
This digital disruption revolutionizes clinical development, accelerating trial lifecycles up to 50%



Copyright 2024 Nurocor

Implementation Strategy and Change Management

Partnership and Innovation



Copyright 2024 Nurocor

The Art of the Possible is Reality

- "We have the technology... Better... Stronger... Faster" (the bionic man)
- Production level adoption of prospective study designs and protocols
- Change management is hard and requires executive sponsorship
- Scaling is the next challenge in progress...
- We see interest in digitalization from different perspectives
  - Process automation
    - Use the Schedule of Activities to drive EDC and further downstream automation
    - Export CDISC trial design domains from a study definition
  - Use digitalized study definitions to make information actionable
    - Link SoA activities to endpoint coverage
    - Use digitalized eligibility criteria and medical coding to drive study feasibility analysis
  - Reuse digitalized study definitions (study templates) and protocol standards libraries
  - Use digitalized study definitions to support optimized study designs

Copyright 2024 Nurocor

Outlook

The future of digitalized clinical development

Timeline

	TransCelerate DDF	Nurocor Clinical Platform
2018		Infrastructure
2019	Nov. white paper	Study Designer and SoA
2020	Feb. hackathon	Study and Protocol Elements
2021		Lean Protocol
2022	USDM / SDR / hackathon	Specimen Management
2023	USDM / SDR v2 Discovery Day	Clinical Document Authoring

Copyright 2024 Nurocor

Timeline

	TransCelerate DDF	Nurocor Clinical Platform
2023	USDM / SDR v2	Clinical Document Authoring
2024	USDM / SDR v3 Templated I/E criteria ICH M11 alignment	Innovative study designs Integrations and Insights Downstream automation
2025	USDM / SDR v4	Design Center

Copyright 2024 Nurocor

Thank You!

For further questions and info, you may contact

frederik.malfait@nurocor.com