



2023

US

INTERCHANGE

FALLS CHURCH, VA | 18-19 OCTOBER



Automating study setup through a digitalized protocol

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.



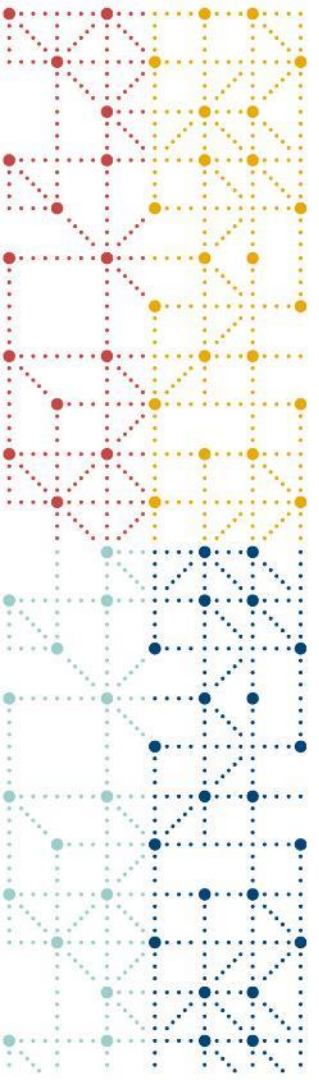
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



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

TransCelerate
DDF

Pharma at large

Vendors

Regulators

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

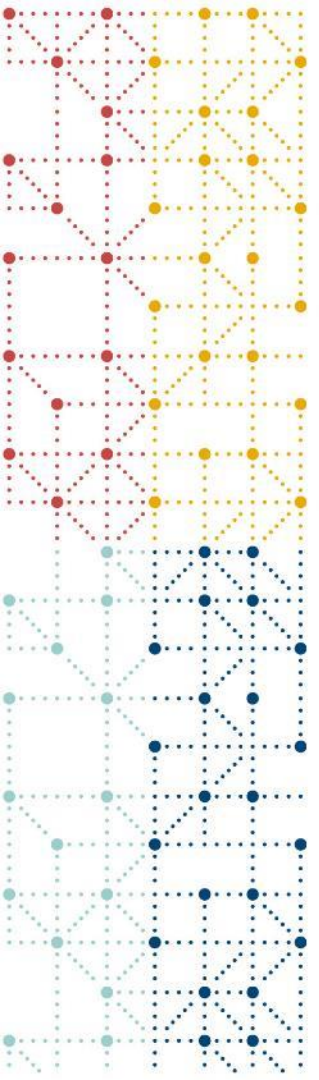
2023



USDM / SDR v2
Discovery Day

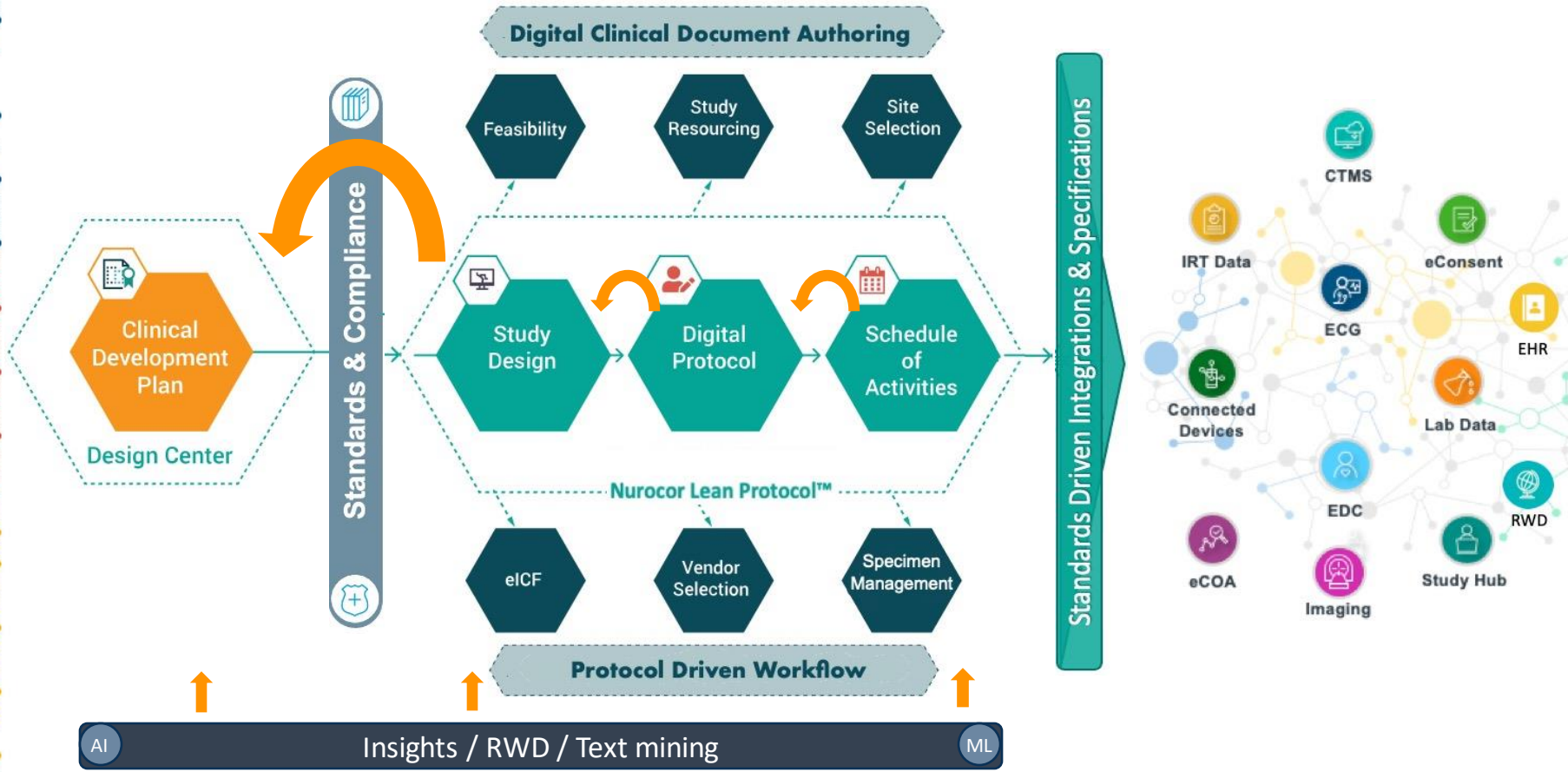


Clinical Document Authoring

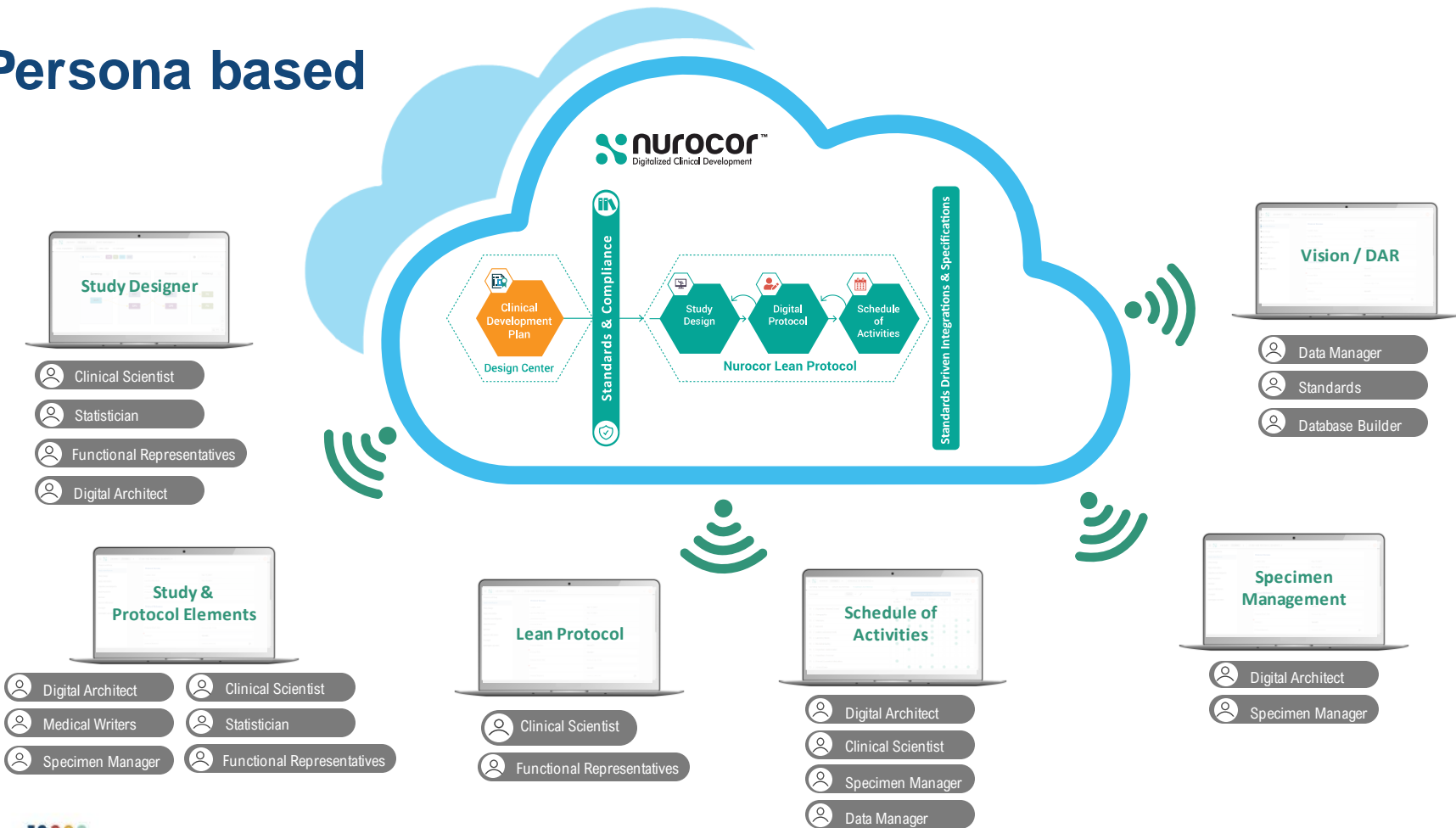


Platform based delivery

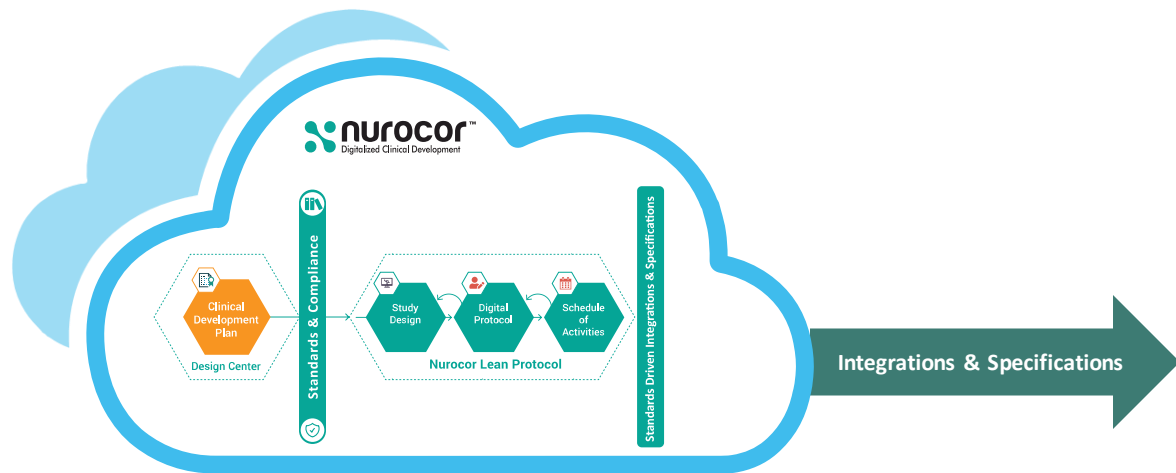
From the viewpoint of an upstream provider



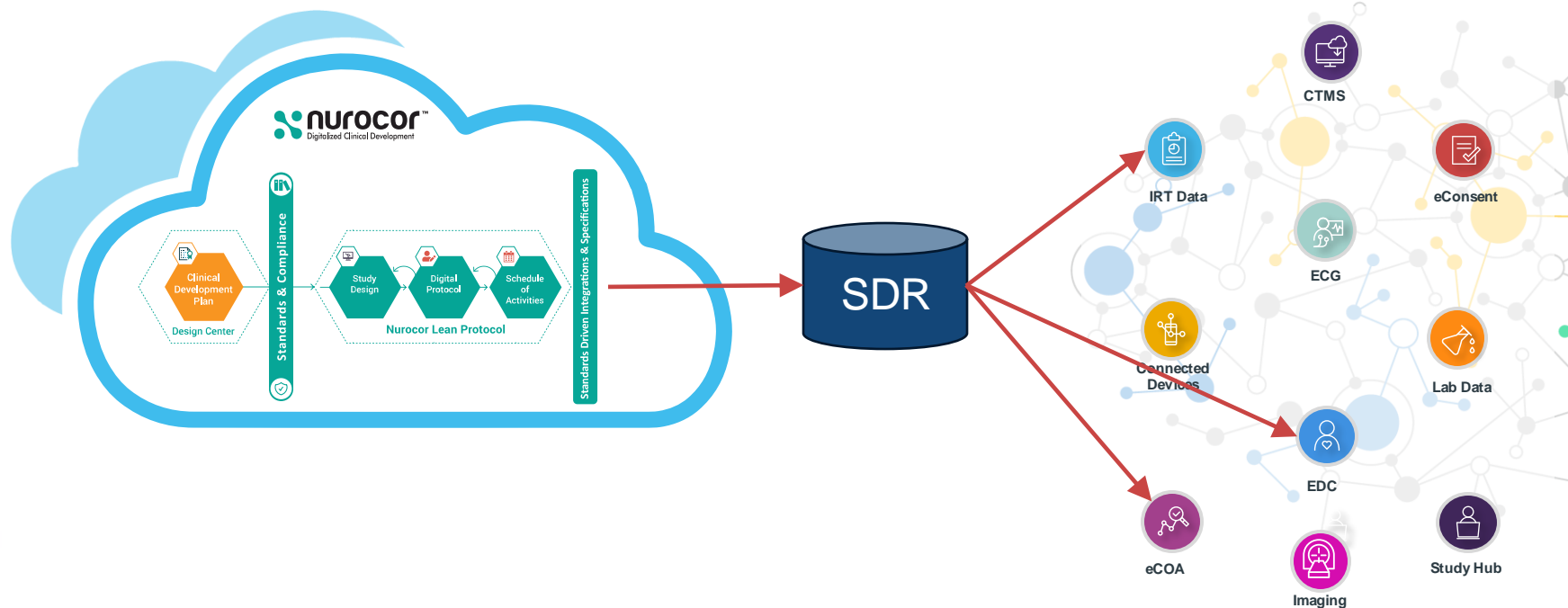
Persona based



Driving digitalization



Driving digitalization – Hub Architecture





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

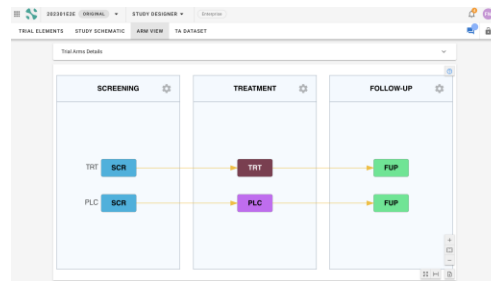
Creating a study definition

NCP Dashboard - Overview

STUDIES DOCUMENTS CHANGE REQUESTS

Filter By: None Applied | Creation Date | [CREATE NEW STUDY](#)

- AMEND** Original In Progress
 - Studying the process of protocol amendments
 - created on September 14, 2023
- 2023-01 WF to SDR Test** Original In Progress
 - created on August 24, 2023
- SDR-T1** Original In Progress
 - SDR-Integrative Test
 - created on August 24, 2023
- 2023-01** Original In Progress
 - 2023-01 End to End Test
 - created on August 15, 2023
- SPECIMENMGT** Original In Progress
 - Specimen Management Cohorts Setup
 - created on July 19, 2023
- SPECIMENMGT** Original In Progress
 - Specimen Management Demo - Partial Study Setup
 - created on July 19, 2023



STUDY AND PROTOCOL ELEMENTS - Overview

Program and Study Elements

Study Identification Elements

Study Design Elements

Study Intervention Elements

Objectives and Endpoints Elements

Study Population Elements

Source Information Elements

Study Test Elements

Primary Objectives and Endpoints / Estimatds

OBJECTIVES

- To evaluate the efficacy of DS-850a compared with insulin treatment administered in individuals with Type 2 Diabetes Mellitus (T2DM)
 - The percentage change in HbA1c from Baseline to Week 4, Week 8 and Week 12
 - [Add Endpoint](#)
- To document the safety profile of Xanmelone TTS
 - The change from Baseline to Week 4, Week 8, Week 12 and Week 24 in continuous laboratory tests: Hepatic Function Panel
 - [Add Endpoint](#)

[+ ADD OBJECTIVE](#)

Secondary Objectives and Endpoints / Estimatds [Display Table](#)

Tertiary/Exploratory Objectives and Endpoints / Estimatds [Display Table](#)

[Schedule of Activities](#)

PLANNED ACTIVITIES

RELATED REQUESTS

Treatment	Screening	Baseline	Week 4	Week 8	Week 12	Week 24
- Disposition - Randomization	●	○	○	○	○	○
- Prior and Concomitant Medications	●	●	●	●	●	●
- Exposure	○	●	○	○	○	○
- Vital Signs	●	●	●	●	●	●
- Vital Signs - General	●	●	●	●	●	●
- Vital Signs - Systolic Blood Pressure	●	●	●	●	●	●
- Vital Signs - Diastolic Blood Pressure	●	●	●	●	●	●
- Vital Signs - Height	○	○	○	○	○	○
- Vital Signs - Weight	●	●	●	●	●	●
- Vital Signs - BMI	○	○	○	○	○	○
- Adverse Events	○	●	●	●	●	●

Approving a study workflow

The screenshot shows the CDISC LEAN PROTOCOL interface. On the left, there is a sidebar with 'All Processes' and a list of levels: LEVEL 1 (Early Indication Feasibility, (DM) Draft, (M) Draft, (SAP) Draft, (SM) Draft), LEVEL 2 (Protocol Feasibility), and LEVEL 3 (Site Feasibility, (DM) Final, (M) Final, (SAP) Final, (SM) Final). The main area displays 'Level 1: (DM) Draft' with a status of 'In Progress'. Below this is a table of conditions:

Conditions	Status	Lock	Icon
Schedule of Activities	Completed	🔒	📄
Study Model Elements	Completed	🔒	📄
Trial Arms	Completed	🔒	📄
Study Planning	Completed	🔒	📄
Study Extensions	Completed	🔒	📄
Study Interventions and Products	Completed	🔒	📄
Objectives and Endpoints	In Progress	🔒	📄

The screenshot shows a 'Lean Protocol Gate Approval Request' dialog box. It includes a 'Protocol Lead' dropdown set to 'Frederik', an 'Attachments (0)' dropdown, and a 'Disposition' field. A text box contains the message: 'Approving will submit the study from NCP to SDR.' At the bottom, there are 'CANCEL' and 'CHOOSE AN ACTION' buttons. A dropdown menu is open under 'CHOOSE AN ACTION', listing: 'Request SME feedback', 'Approve', 'Reject', and 'Save'.

The screenshot shows the 'Comments and discussions (1 Comment)' section. It features a comment by 'Frederik Malfait' posted '1 minute ago', categorized as a 'General discussion'. Below the comment is a 'NEW COMMENT' button.

Posting the study from the NCP to the SDR

Notifications 2



INBOX UNREAD READ TRASH

202301E2E September 18, 2023

Action *Submit* is complete for gate *Level 1: (DM) Draft* (title: *2023-01 End to End Test*).

[SDR STUDY](#)

[SDR UI](#)

202301E2E September 18, 2023

The *Level 3: (DM) Final* gate has transitioned to *Ready for Review*. Please review the gate and submit when appropriate.

Viewing the study in the SDR

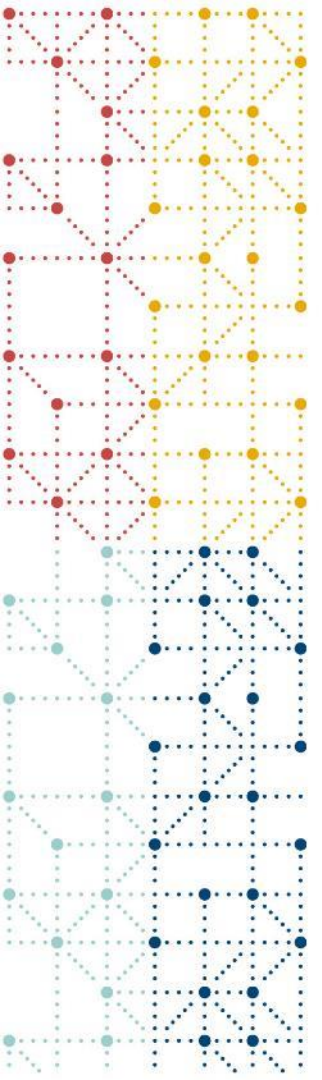
202301e2e

Treatment

Export to Excel

Name	Treatment
Description	Treatment
Condition	condition

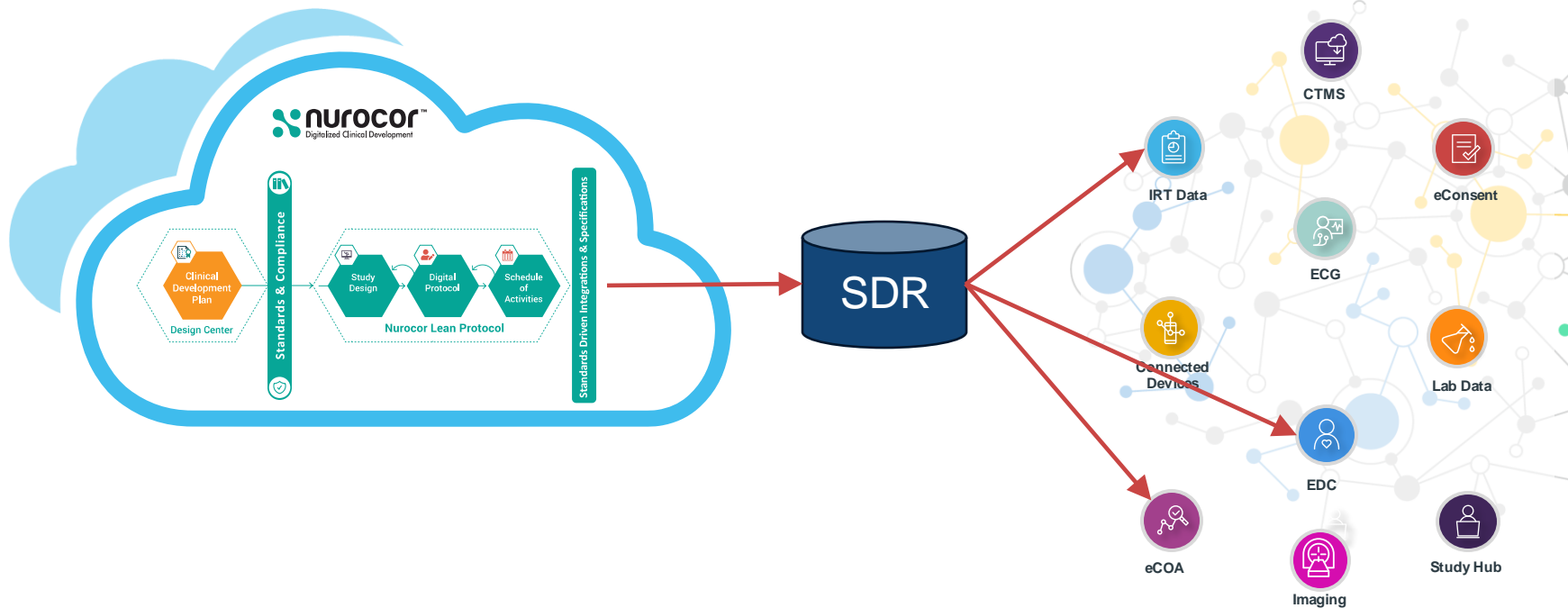
Activity						
Patient Information	X					
Disposition - Informed Consent	X					
Inclusion/Exclusion Criteria Not Met	X					
Demographics	X					
Medical History	X					
Disposition - Randomization	X					
Prior and Concomitant Medications	X	X	X	X	X	X
Exposure		X				
Vital Signs	X	X	X	X	X	X
Adverse Events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



Value proposition

Benefits of digitalized clinical development

Driving digitalization



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

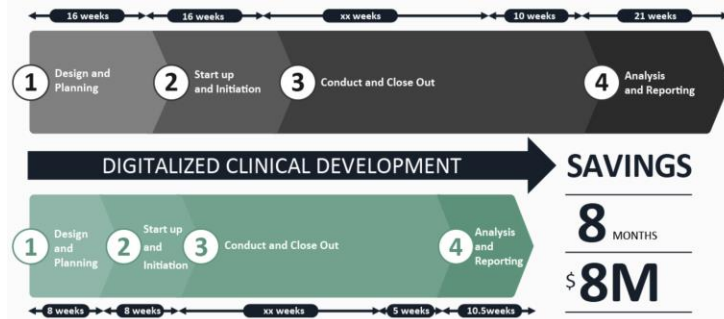
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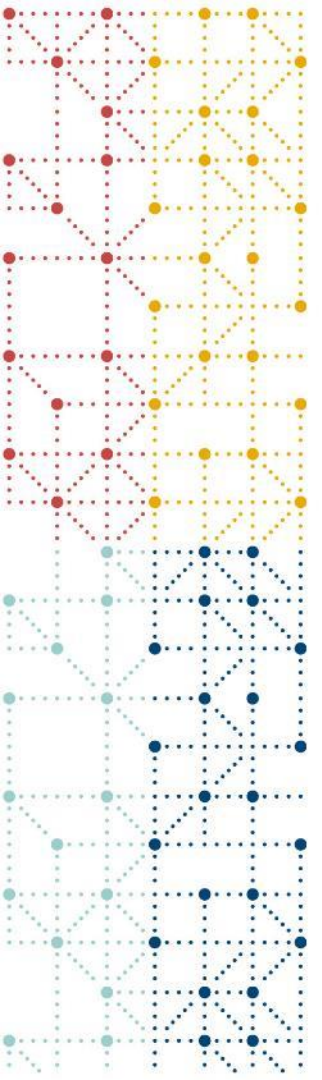
The number of hours spent on programming and query management

THE SOLUTION

The Nurocor Clinical Platform drives quality and consistency, focus on outcome driven critical data, eliminates unnecessary amendments and automates provision of specifications for data collection and analysis

This digital disruption revolutionizes clinical development, accelerating trial lifecycles by at least 50%





Outlook

The future of digitalized clinical development

Timeline

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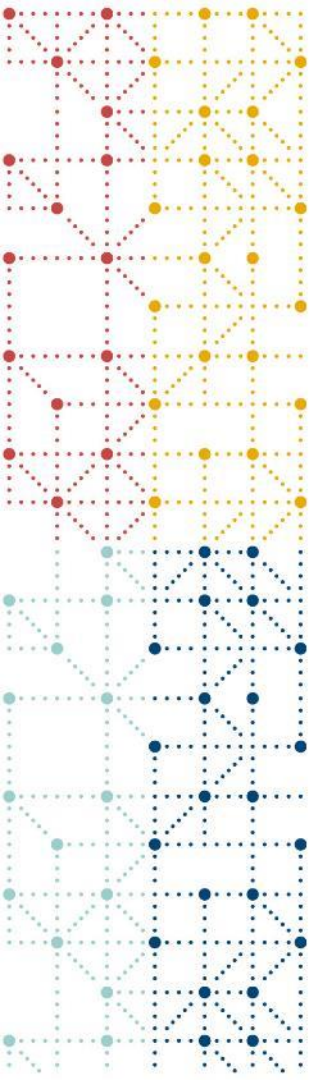
USDM / SDR v3
Templated I/E criteria
ICH M11 alignment

Innovative study designs
Integrations and Insights
Downstream automation

2025

USDM / SDR v4

Design Center



Thank You!

For further questions and info, you may contact
frederik.malfait@nurocor.com

