

A panoramic view of the Berlin skyline at sunrise or sunset, featuring the TV Tower (Fernsehturm) and various city buildings under a clear sky.

2024 CDISC + TMF
EUROPE INTERCHANGE

BERLIN

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

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.



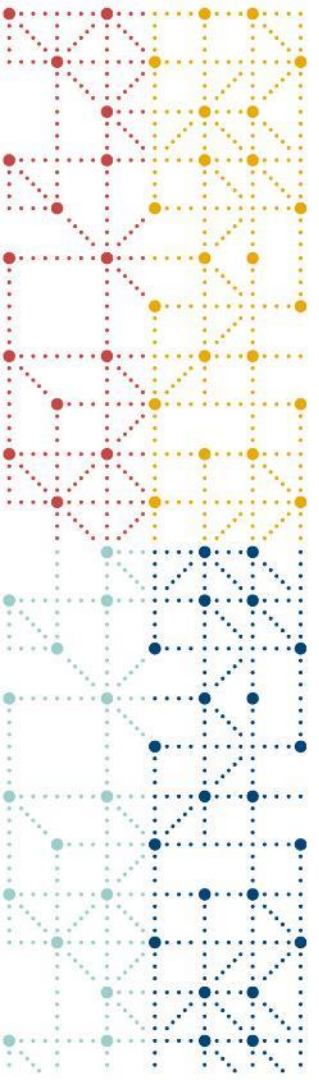
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



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

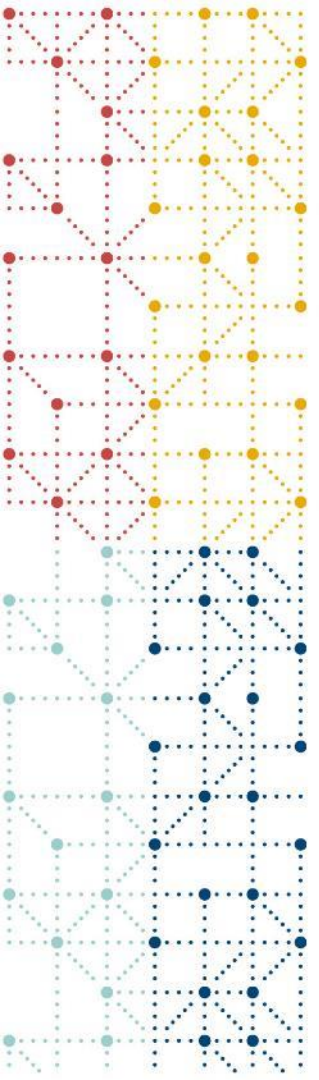
2023



USDM / SDR v2
Discovery Day

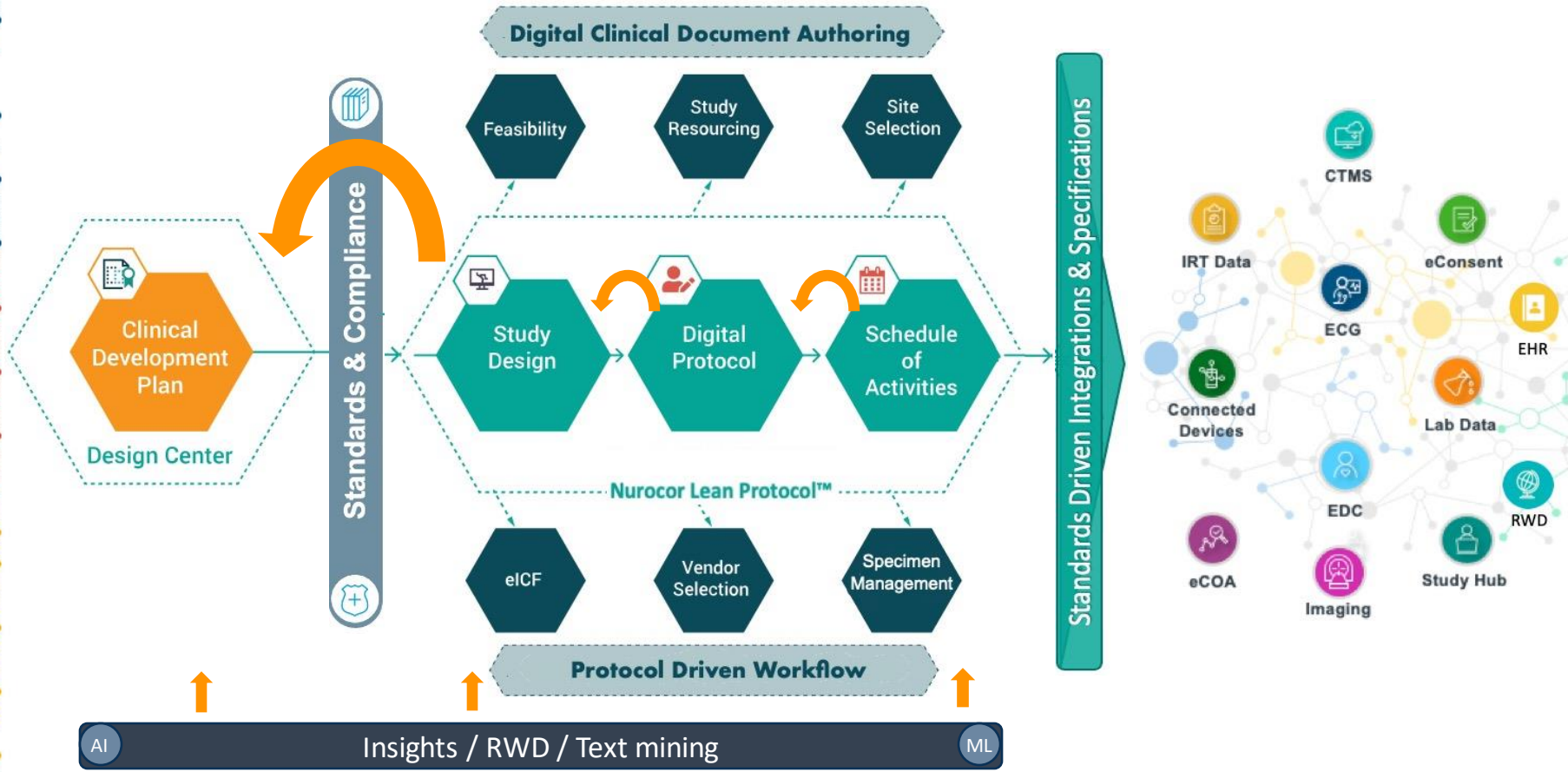


Clinical Document Authoring

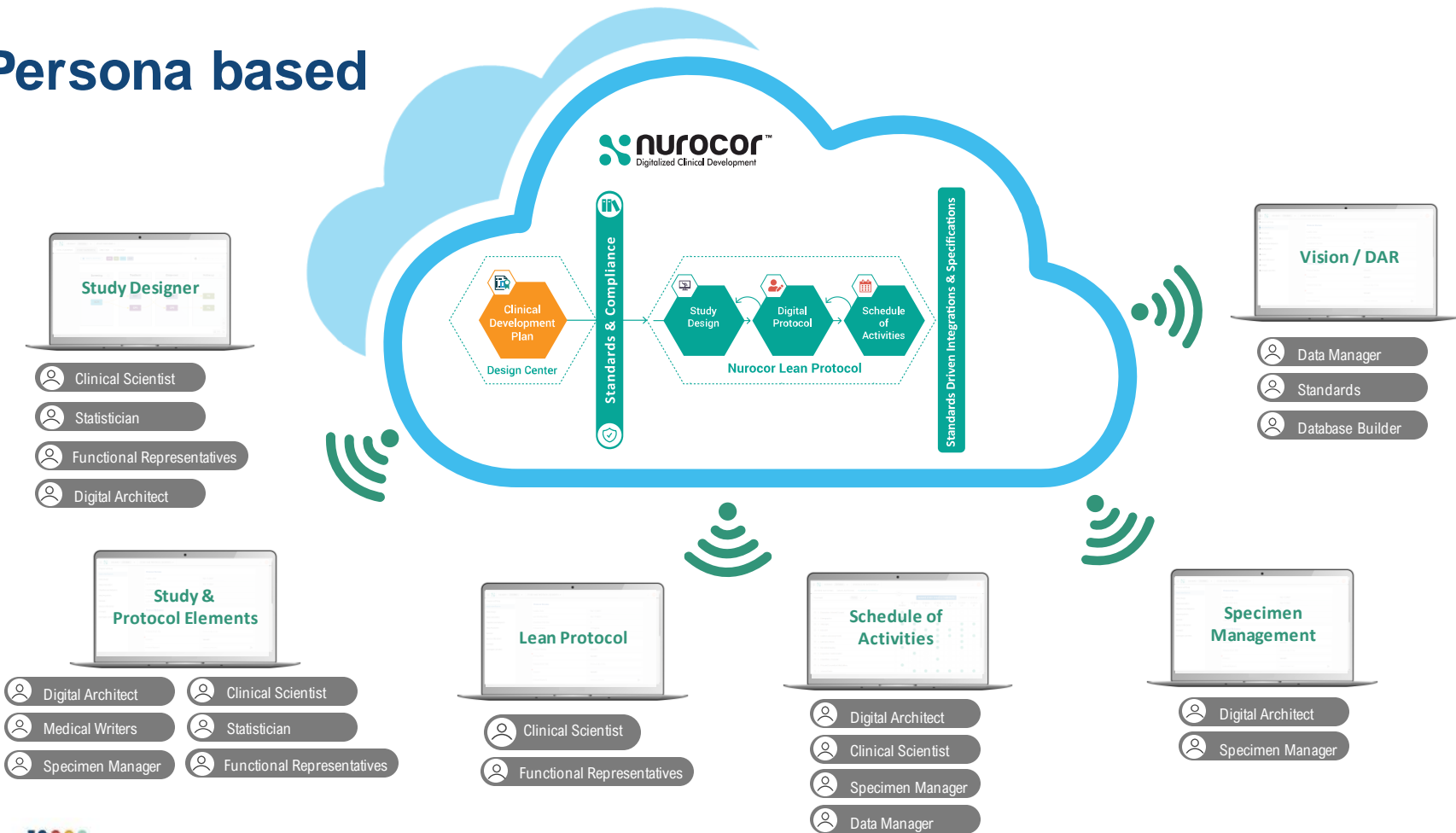


Platform based delivery

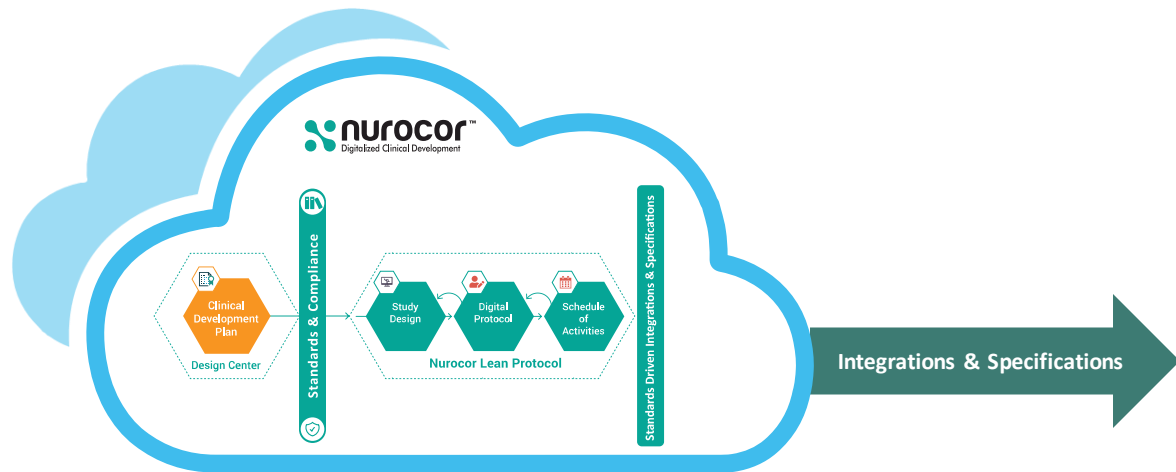
From the viewpoint of an upstream provider



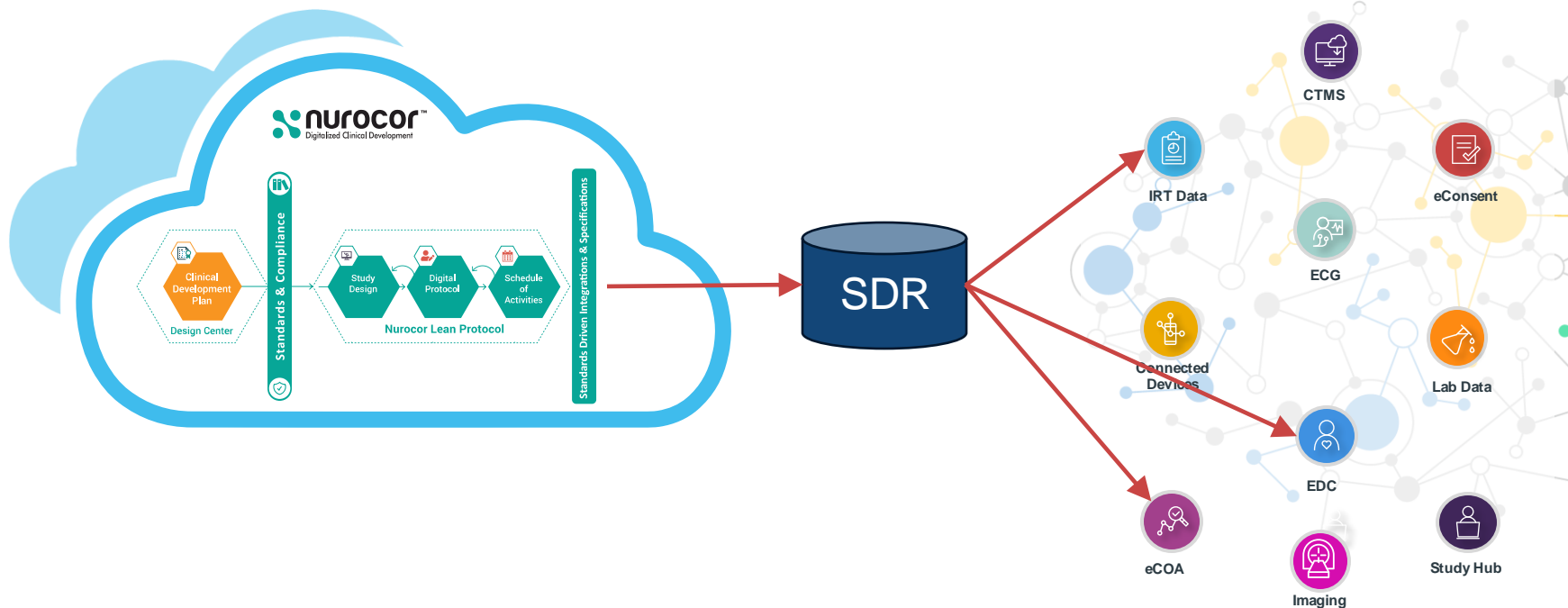
Persona based



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

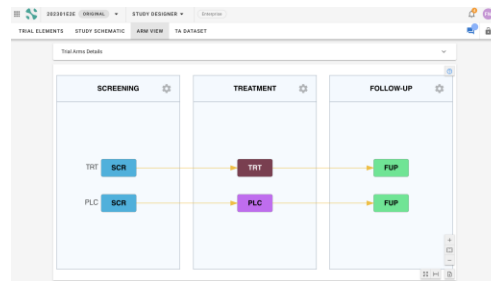
NCP Dashboard - Overview

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
- 2023WF1SDR** | Original | In Progress
 - 2023-01 WF to SDR Test
 - created on August 24, 2023
- SDR-TR1** | Original | In Progress
 - SDR-TR1
 - created on August 24, 2023
- 2023TR1** | Original | In Progress
 - 2023-01 End to End Test
 - created on August 15, 2023
- SPECMCHORT** | Original | In Progress
 - Specimen Management Cohorts Setup
 - created on July 19, 2023
- SPECMTRIAL** | 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
- sponsor 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)
 - Endpoints: The percentage change in HbA1c from Baseline to Week 4, Week 8 and Week 12
 - ADD ENDPOINT**
- To document the safety profile of Xanmelinone TTS
 - Endpoints: The change from Baseline to Week 4, Week 8, Week 12 and Week 24 in continuous laboratory tests: Hepatic Function Panel
 - ADD ENDPOINT**

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

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

Schedule of Activities [Schedule of Activities](#)

PLANNED ACTIVITIES

Treatment [Zims](#) [Events & Treatments](#) [Export Schedule](#)

	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, a sidebar lists various process levels from Level 1 to Level 3, including 'Early Indication Feas...', '(DM) Draft', '(M) Draft', '(SAP) Draft', '(SM) Draft', 'Protocol Feasibility', 'Site Feasibility', and 'Final' stages. The main area displays a table for 'Level 1: (DM) Draft' with the following conditions:

Condition	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 'Lean Protocol Gate Approval Request' dialog box shows the following details:

- Protocol Lead: Frederik
- Attachments: (0)
- Disposition: Approving will submit the study from NCP to SDR.

At the bottom, there are two buttons: 'CANCEL' and 'CHOOSE AN ACTION'. A dropdown menu is open under 'CHOOSE AN ACTION', listing the following options: 'Request SME feedback', 'Approve', 'Reject', and 'Save'.

The 'Comments and discussions' section shows a comment by 'Frederik Malfait' posted 1 minute ago. The comment is a 'General discussion' and has 0 replies. At the bottom of the section is a blue button labeled 'NEW COMMENT'.

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

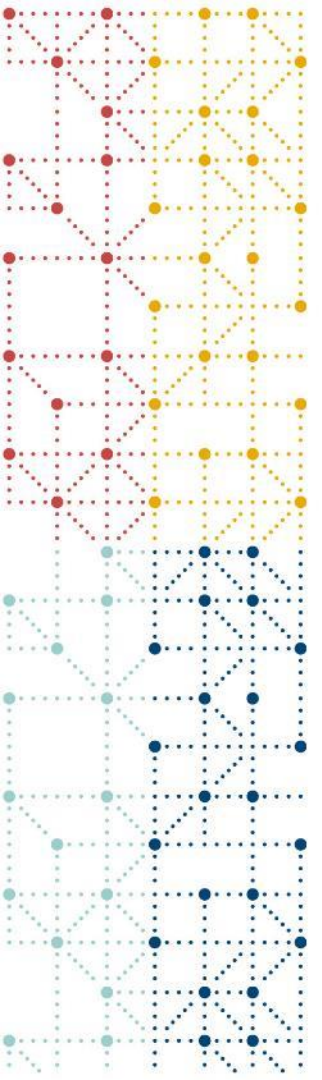
202301e2e

Treatment

Export to Excel

Name	Treatment
Description	Treatment
Condition	condition

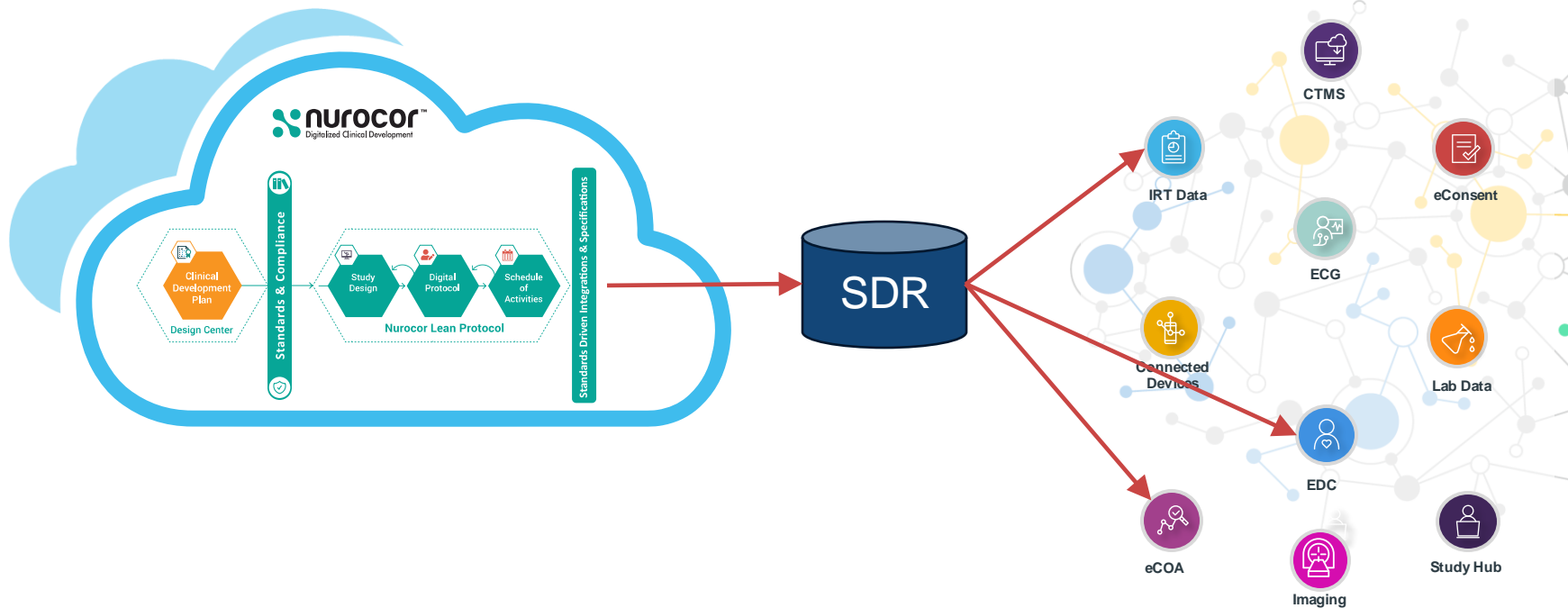
Activity						
Patient Information	X					
Disposition - Informed Consent	X					
Inclusion/Exclusion Criteria Not Met	X					
Demographics	X					
Medical History	X					
Disposition - Randomization	X					
Prior and Concomitant Medications	X	X	X	X	X	X
Exposure		X				
Vital Signs	X	X	X	X	X	X
Adverse Events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



Value proposition

Benefits of digitalized clinical development today

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

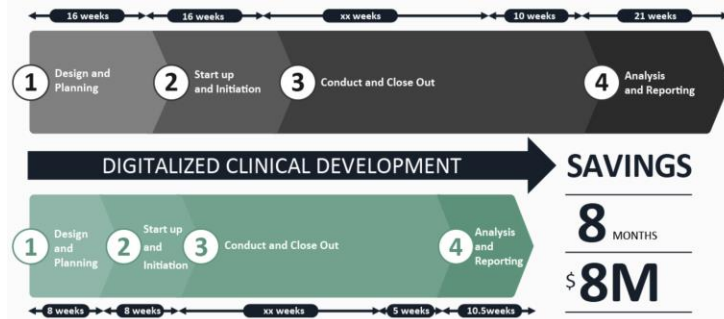
28,000

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%



Implementation Strategy and Change Management

Partnership and Innovation



Unrivaled expertise in the fields of Life Sciences, Standards & Software Development

Deep pharma R&D expertise, focused solely on clinical development

Industry leading platform for digitalized clinical development

Evolution
Evolve existing technology and relationship to a true partnership mutually invested in success

Partner

Combining resources, scale and capability of a pharmaceutical company with the speed and focus on innovation of the biotech industry

Global access to >30,000 resources and expertise

Core NCP Foundation - Inherent product knowledge and skills

Open Innovation
Digitalize processes, integrate key capabilities to enable a streamlined, sustainable digital ecosystem to accelerate trials

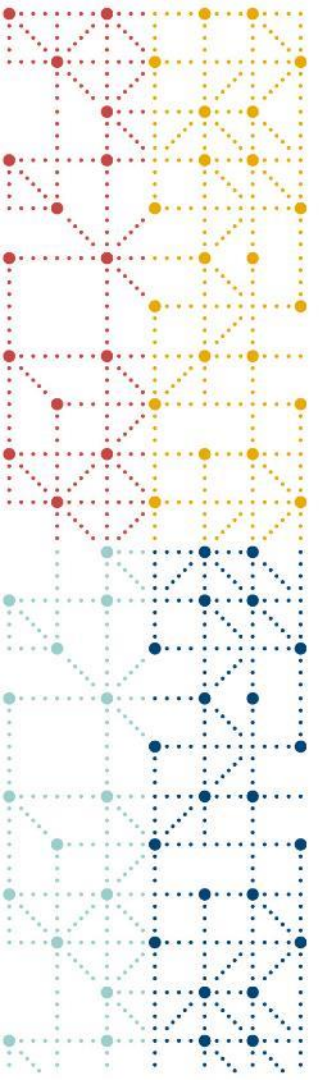
Co-Creation
Business Capability Roadmap for Transformative Digital Connectivity – Integrated Product Management and Delivery

Collaboration
Holistic transformation including people, process, technology and DATA



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



Outlook

The future of digitalized clinical development

Timeline

TransCelerate DDF

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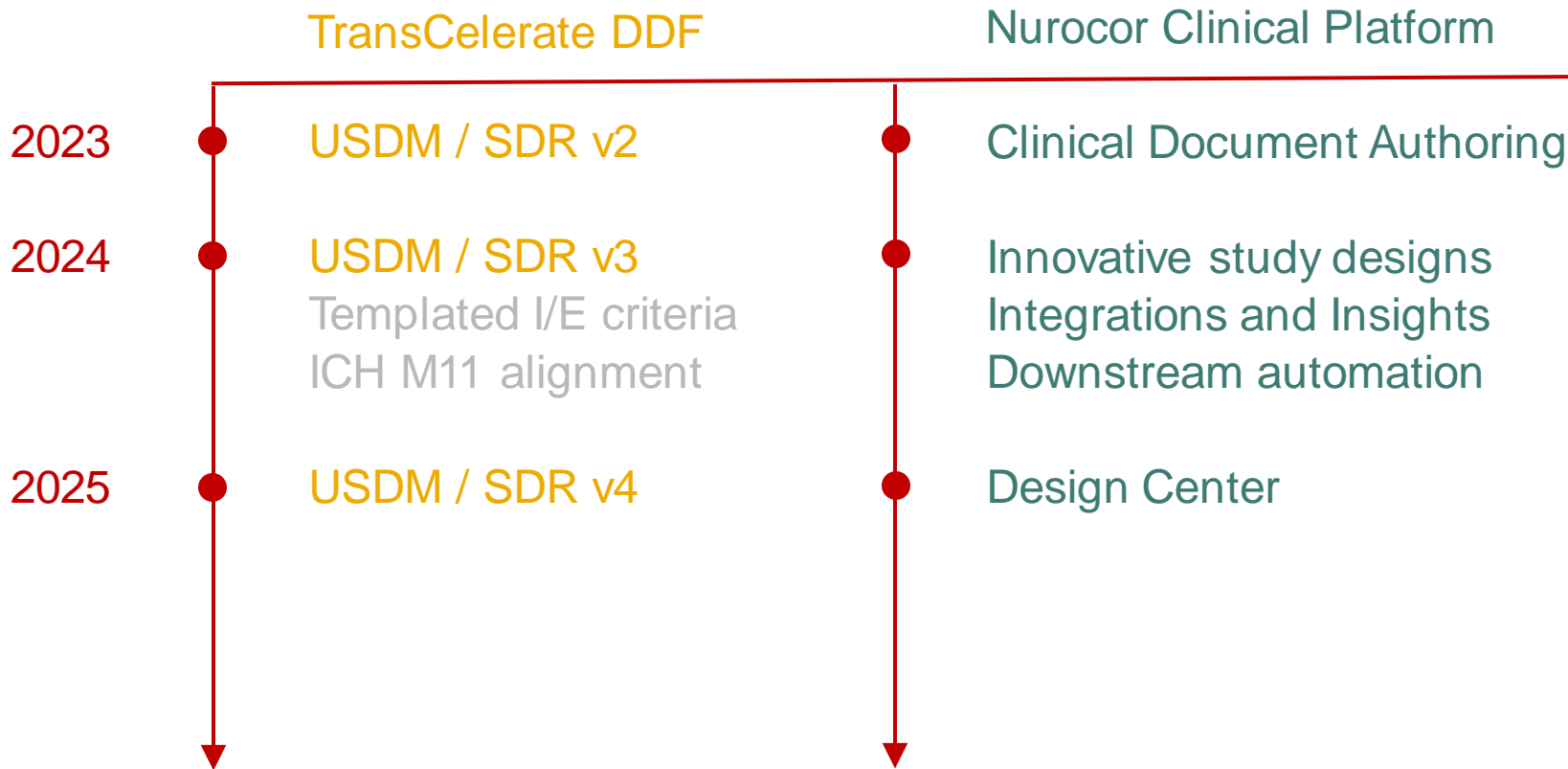


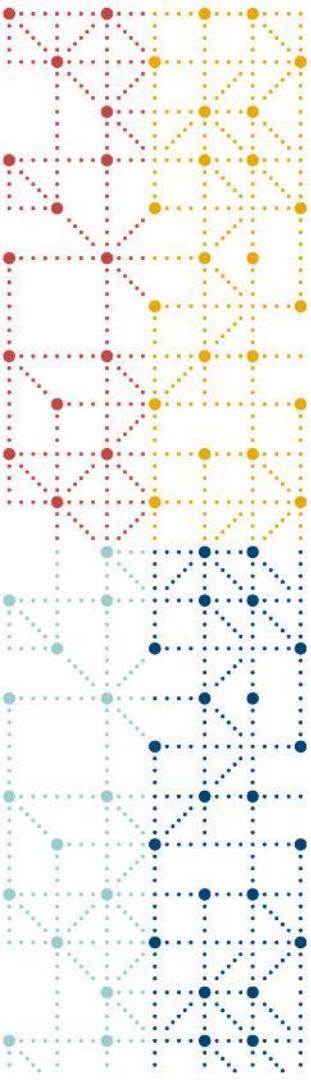
USDM / SDR v2
Discovery Day



Clinical Document Authoring

Timeline





Thank You!

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

