

Leadership Through Innovation (LI02): Closing the Knowledge Gap with a Knowledge Management Strategy Empowered by Dashboards and AI

Jannick Reymann Ravnborg, *Standards Developer*

Vicky Poulsen, *Standards Director*

Novo Nordisk A/S



The Clinical Data
Science Conference

EU 2025

16–19 November
CCH – Congress Center Hamburg

Disclaimer

The views and opinions expressed in this presentation are those of the authors' and do not necessarily reflect the official policy or position of Novo Nordisk A/S

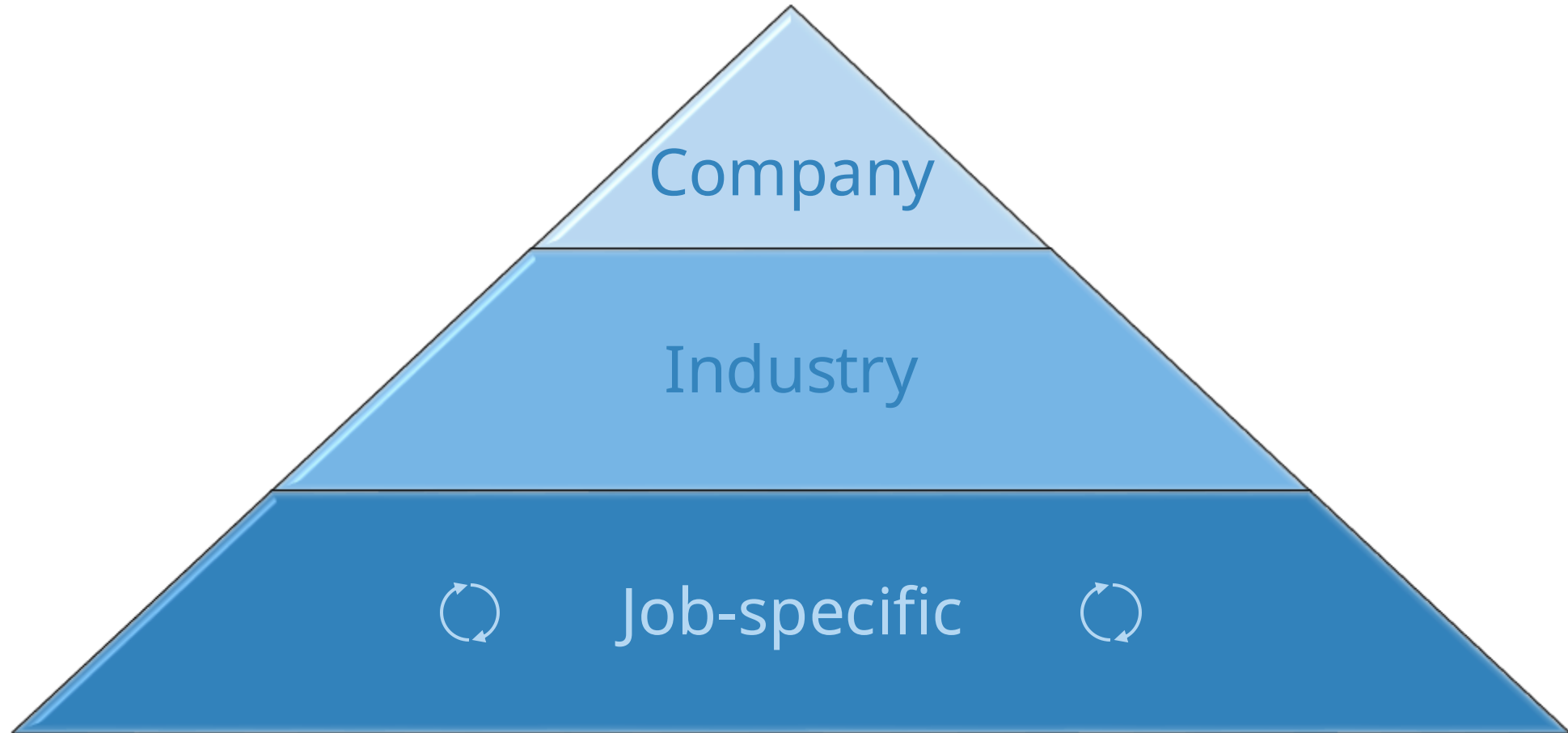
The Challenges

Knowledge Management Strategy

Innovation: Dashboards and AI

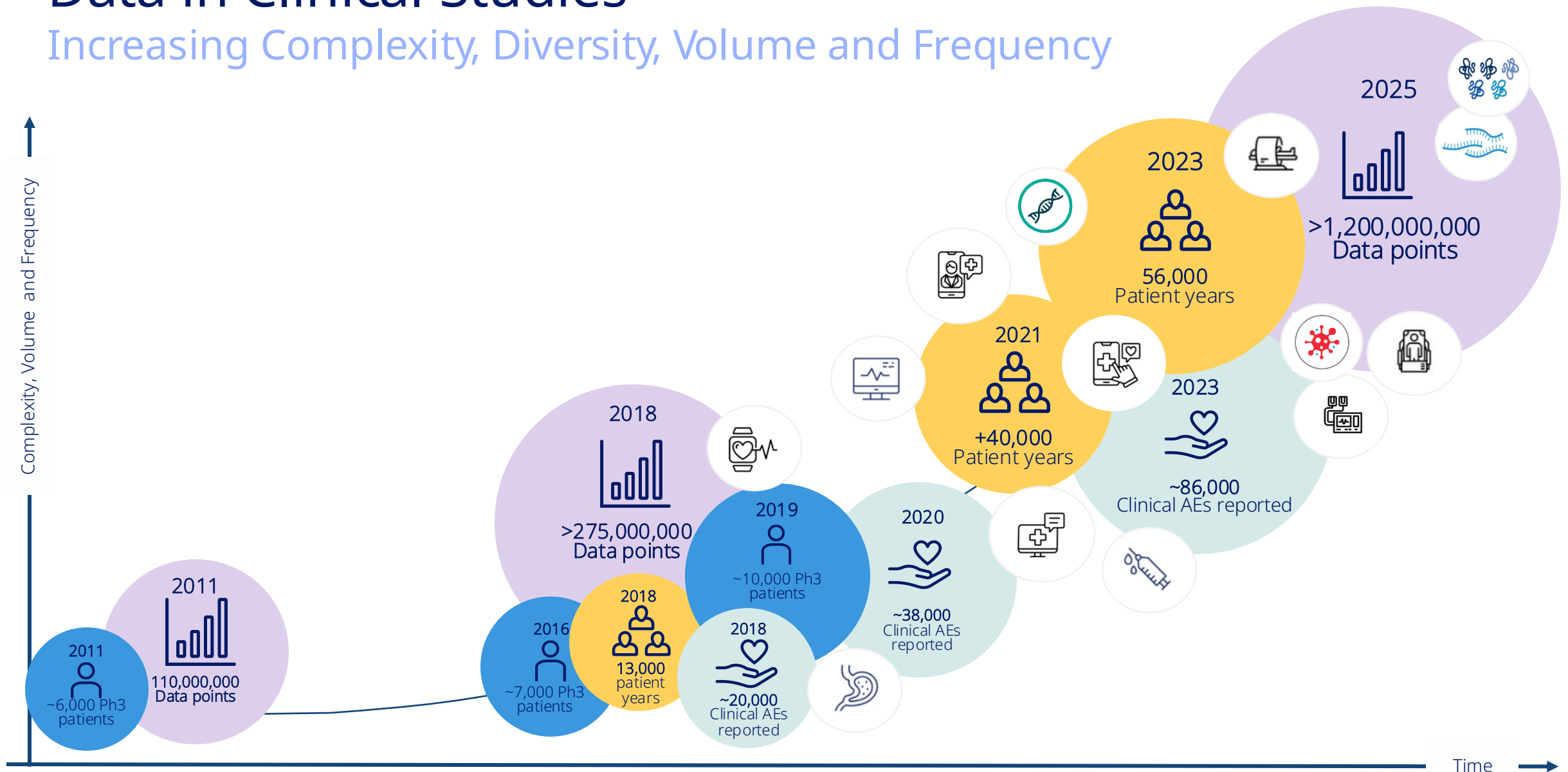
Learnings and Reflections

Onboarding



Data in Clinical Studies

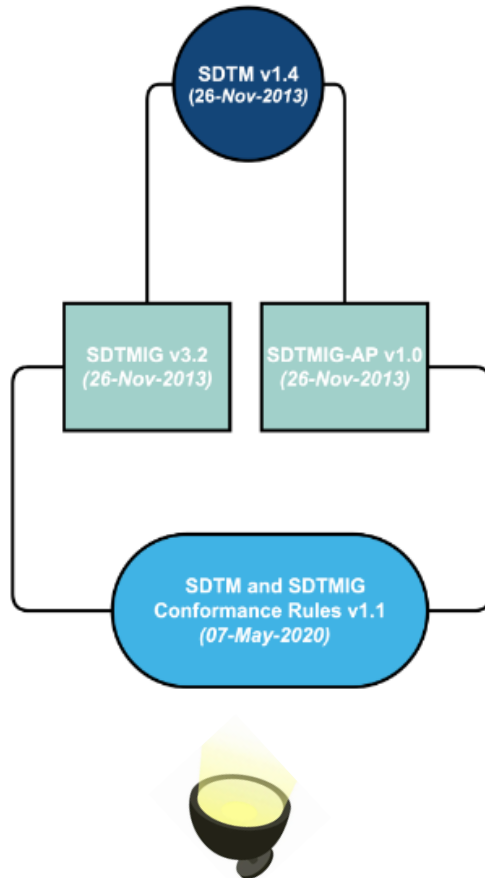
Increasing Complexity, Diversity, Volume and Frequency



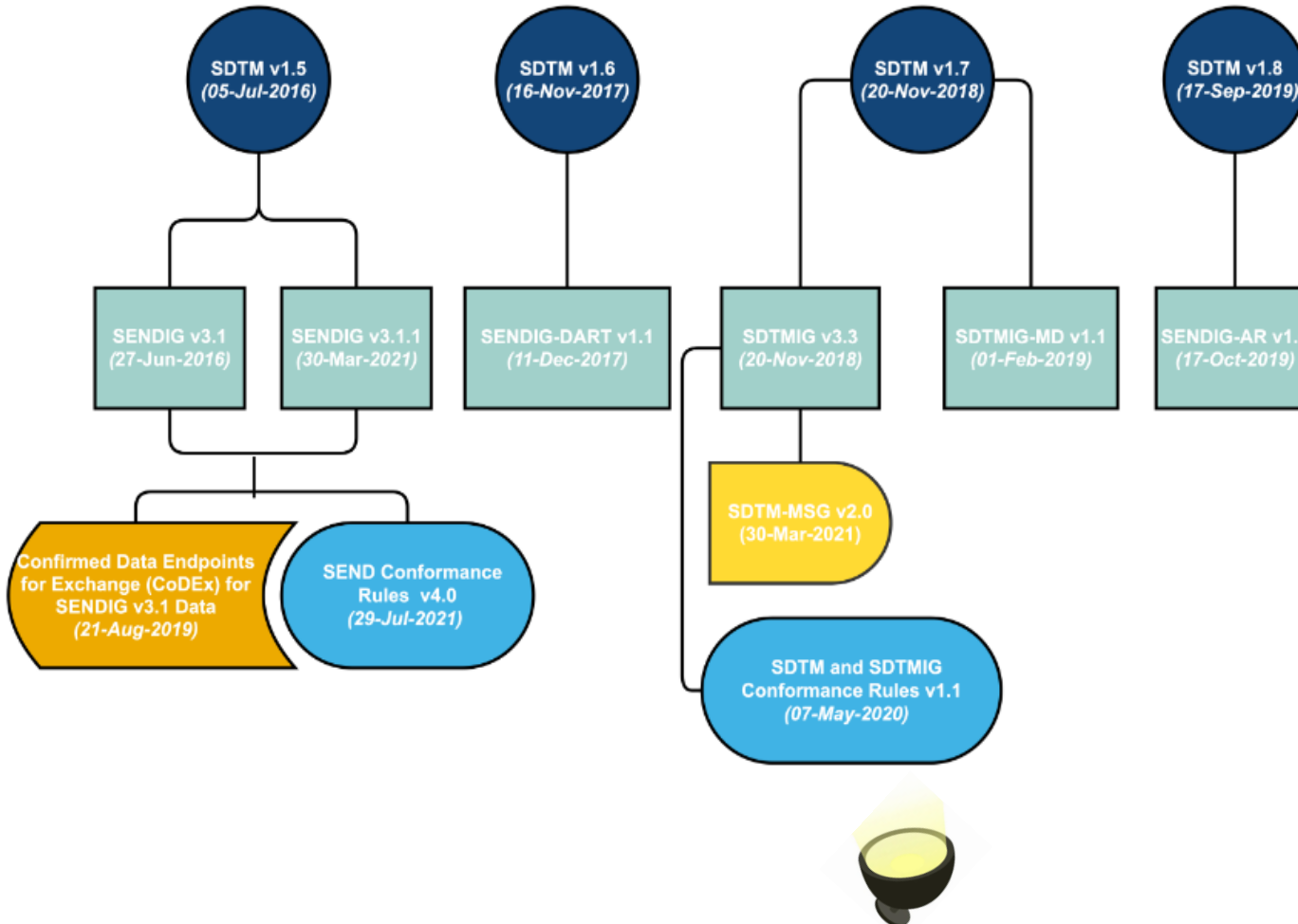
Stringent Requirements



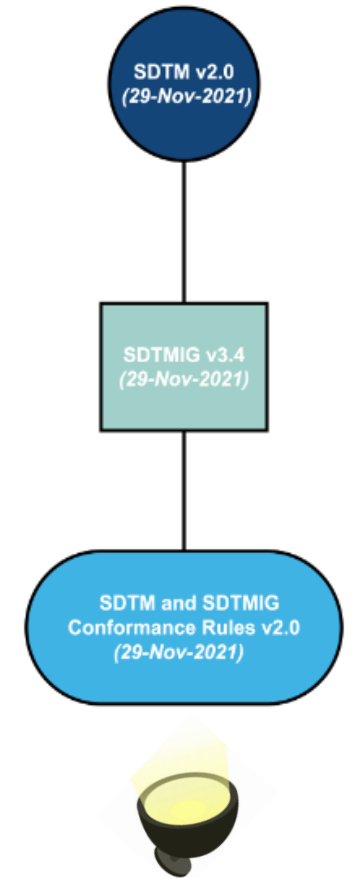
17-Dec-2017
Define-XML 2.0



15-Mar-2023
Define-XML 2.1

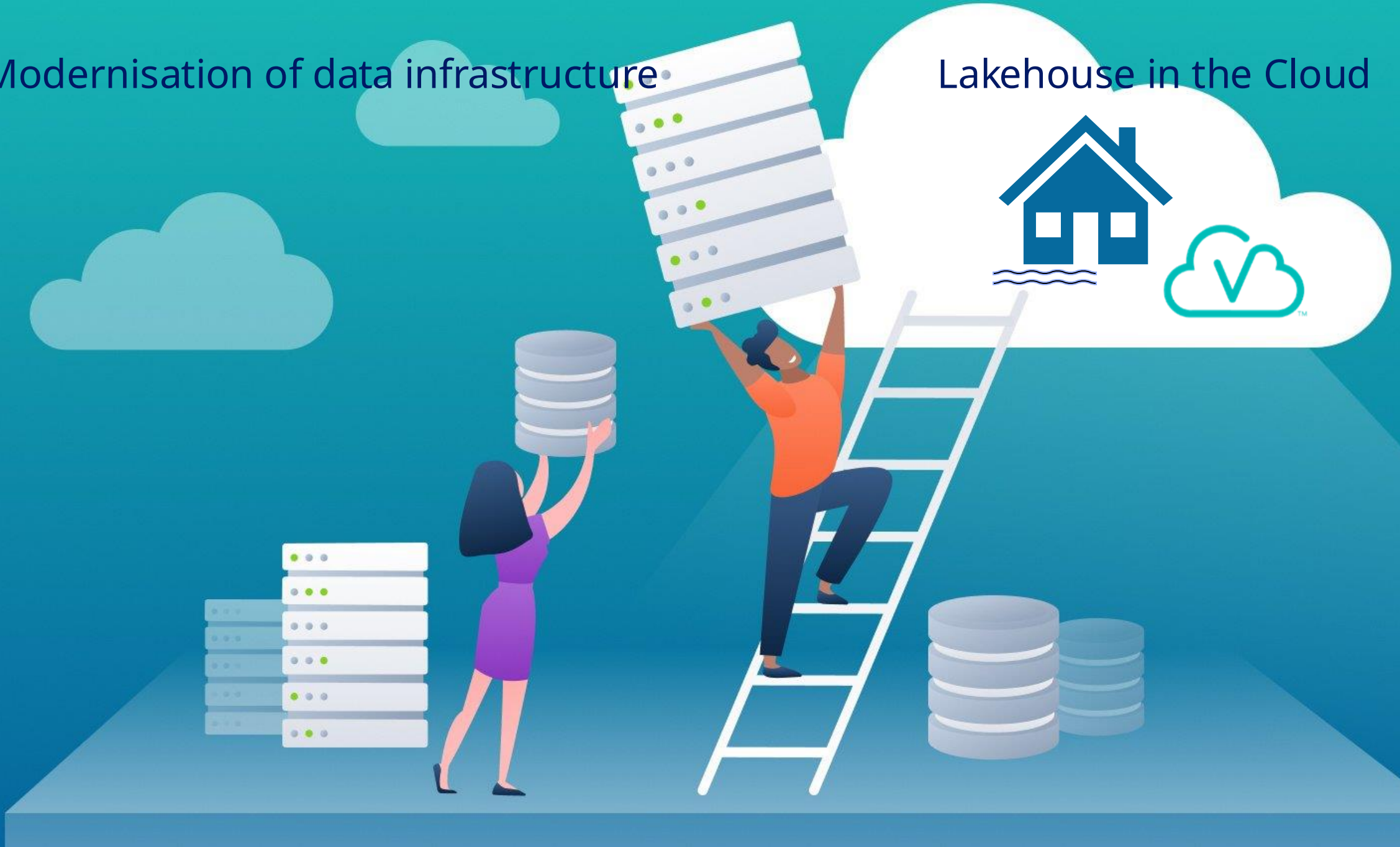


15-Mar-2025



Modernisation of data infrastructure

Lakehouse in the Cloud



Organisational Setting



Standards Developers

Global Standard Implementation

Development

Maintenance

Governance

Training



Clinical Data Programmers

Clinical Data Managers

Clinical Data Scientists

Study Operation

Knowledge Management Strategy



Personalisation

Super User Community
Online Training
Mentorship



Codification

Super User Help Desk
Knowledge Base
(Training Material and FAQ)



Innovation

Dashboards
AI Chatbot

Dashboards Enabling Personalised Interactive Learning

Doc Type: Training (74)			
ARM assignment.pdf	ARM assignment	DM; Trial Design	27/04/2022
Arm + Branch + Cohort.pdf	Arm, Branch and Cohort	DM; ARM Assignment; Trial Design	23/06/2022
autoSDRG.pdf	autoSDRG	SDRG	27/08/2025
Baseline Flag in SDTM.pdf	Baseline Flag in SDTM	Baseline Flag; Findings Domain; Interventions Domain	23/05/2025
Baseline Flag, Treatment Emergent Flag an...	Baseline Flag, Treatment Emergent Flag and Trial Summary Parameters Recording	--BLFLAETREMSIS	03/05/2025
Biospecimen metadata.pdf	Biospecimen metadata	BE; BS	12/05/2024
CGM and ePID eDiary Data in SDTM Recor...	CGM and ePID eDiary Data in SDTM Recording	LRC; CGM; ePID eDiary	20/06/2025
CGM Data in SDTM.pdf	CGM Data in SDTM	LRC	20/06/2025
CRF Annotation and define.pdf	CRF Annotation and define.xml	wCRF; define.xml	22/05/2024
Cross Study Data.pdf	Cross-Study Data	PRVTRID; PRVTSUB	16/07/2023
CT Validation and Unit Conversion.pdf	CT Validation and Unit Conversion	CT	13/06/2025
CT Validation and Unit Conversion Recordi...	CT Validation and Unit Conversion Recording	CT	13/06/2025
Define.xml validation_20180808.pdf	Define.xml Validation	define.xml	08/08/2021
Trial Level Define XML specifications_2018...	Define.xml: Trial Level Define-XML specifications	define.xml	09/05/2018
Defining time point metadata.pdf	Defining time point metadata	Time point	07/10/2024
Demographics and Disposition.pdf	Demographics (DM) and Disposition (DS)	DMDS	11/04/2025
Demographics and Disposition Recording...	Demographics (DM) and Disposition (DS) Recording	DMDS	11/04/2025
Device in SDTM.pdf	Device in SDTM	Device Domains	28/03/2025
Domains driven by Trial Metadata.pdf	Domains driven by Trial Metadata	MMA[Trial Metadata	28/03/2025
Domains driven by Trial Metadata & Devic...	Domains driven by Trial Metadata & Device in SDTM Recording	SDTM Generation[Device Domains	28/03/2025
ePID eDiary Data in SDTM.pdf	ePID eDiary Data in SDTM	ePID; LR; EC; XH	20/06/2025
Loading EA comment_SDTMProg_2020050...	Event Adjudication Comments in SDTM	EQ; ZA	06/05/2020
Exposure Domains EX vs EC and Relating R...	Exposure Domains EX vs EC and Relating Records Recording	EC[X]RELREC[EC]--LINKOBJ.NEGRP	09/05/2025
Exposure Domains EX vs EC.pdf	Exposure Domains EX vs EC	EX; EC; --LINKID	09/05/2025
Fake Randomisation and blinded PK data.p...	Fake Randomisation and blinded PK data	DM; PC	27/10/2023
Generation of SDTM PP domain.pdf	Generation of SDTM PP domain	PP	20/03/2025
Handling Data Cut-off.pdf	Handling Data Cut-off in Extension Trial/for interim analysis	SDTM Generation[Data Cut-off][Extension][interim analysis	20/03/2025
Handling Data Cut-off.mp4	Handling Data Cut-off Recording	Data Cut	27/03/2021



Overview : Relations

	Grouping ▲	Protocol Outline	Trial Setup	Trial Conduct	Submission	Closure
Category ▲						
ADM						
Auxiliary Devices						
Biospecimen						
Data Cut-Off						
Device Domains						
Diary Data						
Disposition						
EDC						
Epoch and Elements						
Exposure						
Hypoglycaemia						
Labranges and Units						
Large Data						
Protocol Metadata Doc						
Rescreening and reuse of subjects						
Stack Datasets						
Timepoints						
Define.xml						
SDTMIG						
Pinnacle 21 Enterprise						
Protocol Deviations						
SDRG						
Validation						
Baseline Flags						
Controlled Terminology						
CRF						
Data Origin						
Event Adjudication						
Non-Standard Variables						
RELREC and --LNKID						
Trial Design						



Info

Reset

Category

Grouping

Topic

Study Timeline

Area

Role

Biometrics

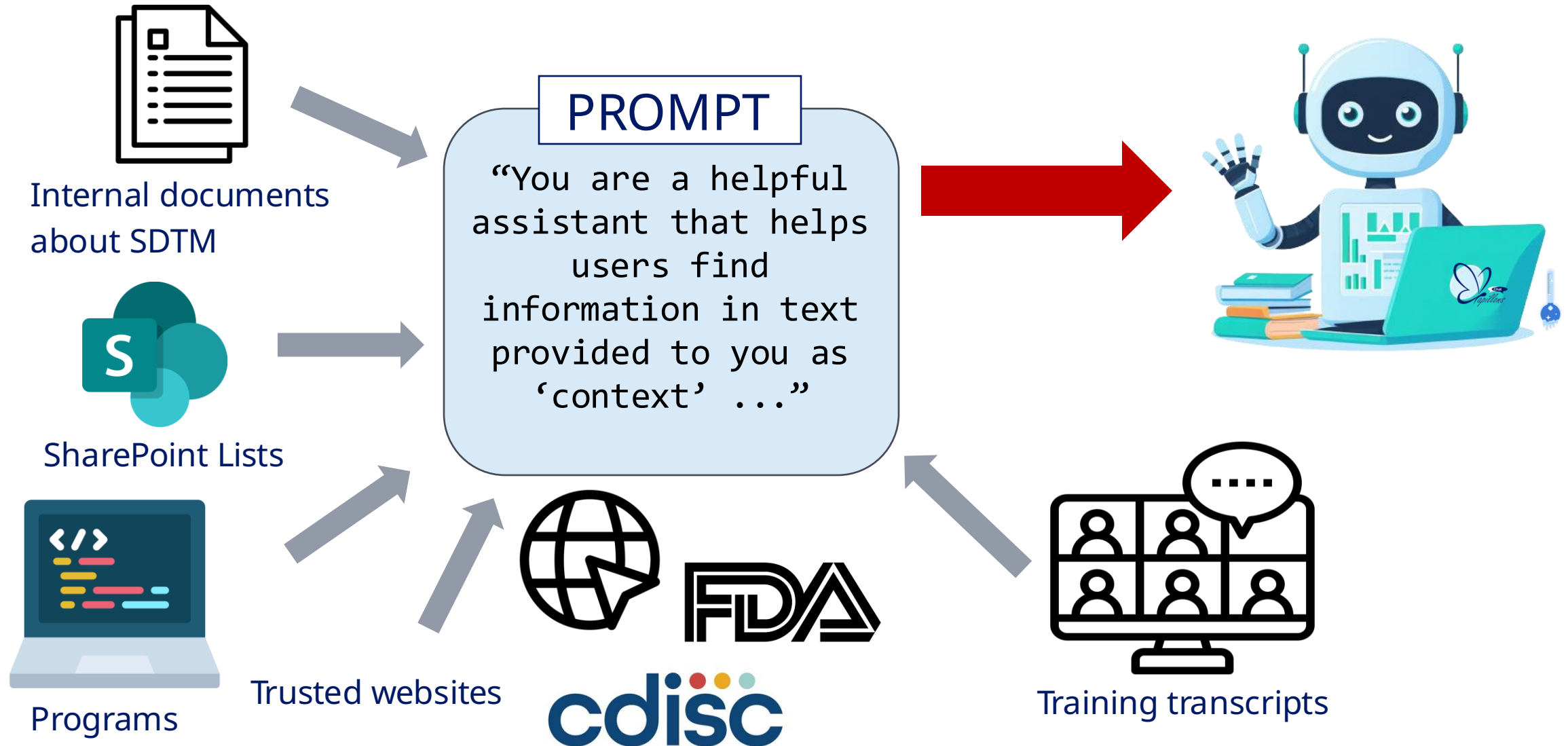
CDS

Title ▲	Domains
ARM assignment	DM
Arm, Branch and Cohort	DM
autoSDRG	Any
Baseline Flag in SDTM	Findings
Baseline Flag, Treatment Emergent Flag and Trial Summary Para...	AE TS Findings
Biospecimen metadata	BE BS
CGM and ePID eDiary Data in SDTM Recording	LB EC XH

Abstract: CGM Data in SDTM

Continuous Glucose Monitoring (CGM) produces large amounts of data. This training outlines the process flow for CGM data and how CGM data is stored in SDTM using the 'stack' dataset approach.

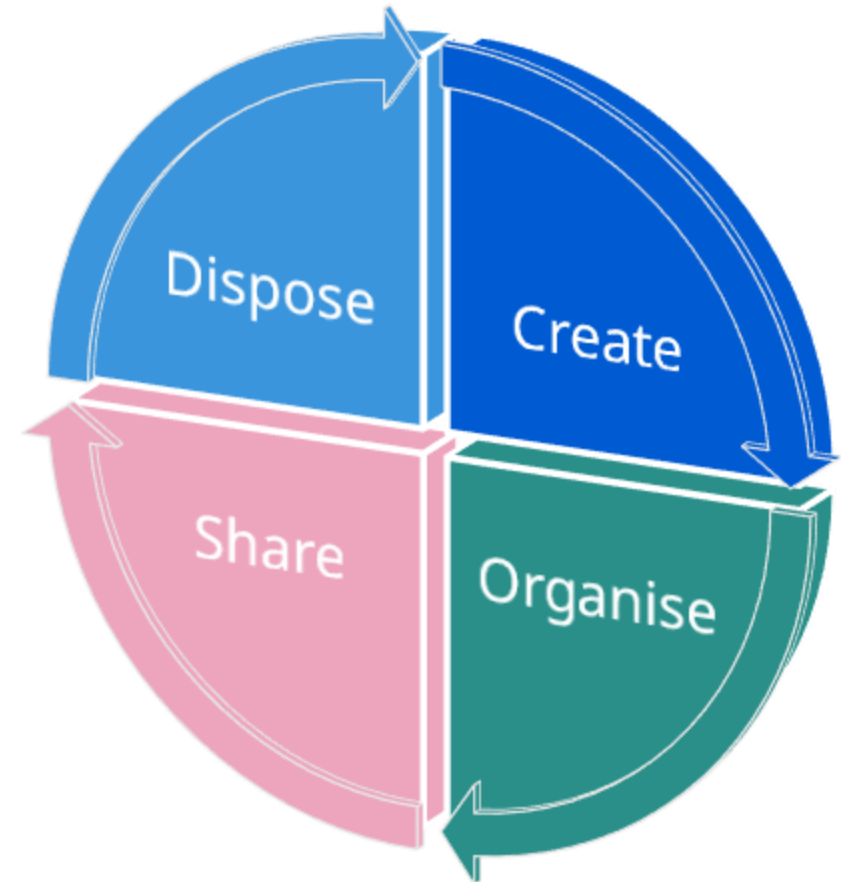
Deterministic Chatbot Providing Domain Knowledge



[illegible]

Learnings and Reflections

- Recognise individual learning preference and needs
- Foster continuous learning culture
- Adapt to company culture and organisational setting
- “New and shiny tech” doesn’t solve everything



Thank You!

Jannick Reymann Ravnborg
rrnj@novonordisk.com

Vicky Poulsen
vicp@novonordisk.com