Bringing the USDM Model to the Catwalk

Julie Jacobsen Bryndum, Clinical Project Lead & Anja Lundgreen, Standards Director

14-May-2025

Meet the Speakers

Julie Jakobsen Bryndum

Title: Clinical Project Lead

Organization: Novo Nordisk A/S, Trial Management

10 years at Novo Nordisk A/S within trial management. 20+ years of experience with Clinical Research in various job roles and therapeutic areas. SME in the StudyBuilder Team.

Anja Lundgreen

Title: Standards Director

Organization: Novo Nordisk A/S, Submission Standards & Implementation

12+ years at Novo Nordisk A/S within e2e standards, metadata setup, mapping, repository, SDTM and currently SME in the StudyBuilder Team.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the authors and do not necessarily reflect the official policy or position of CDISC.*

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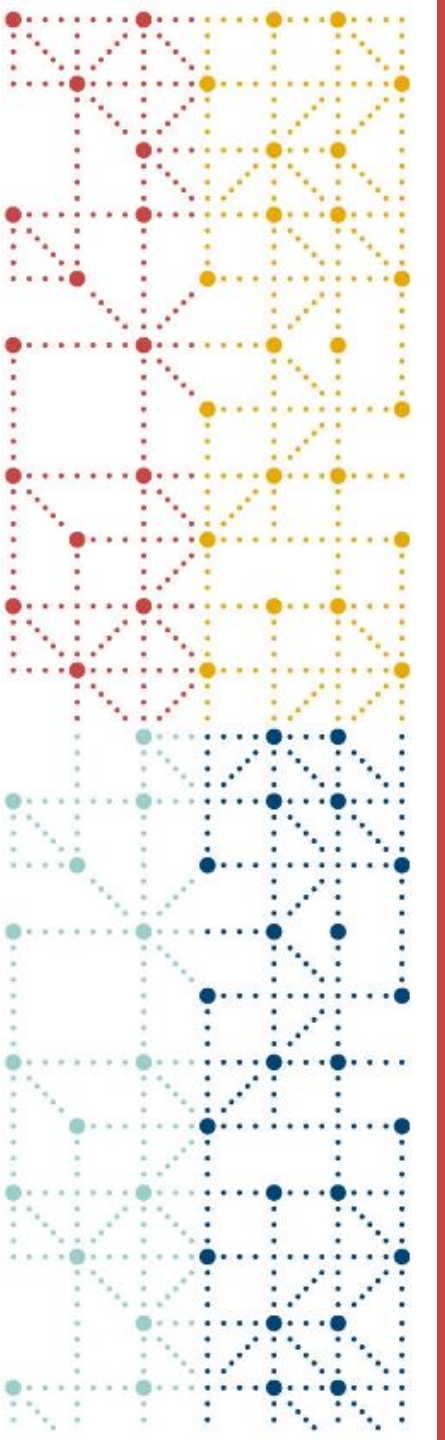


Agenda

1. Scope
2. The Protocol Process and the History
3. The Amendment Challenge
4. Pros and Cons when utilizing USDM
5. Same but different

What happens when we bring USDM to the Catwalk

- With no requirement for ICH M11 yet, but a system based on USDM

Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 3.0 (Final)

Scope of this presentation

To connect and build a common understanding of the different worlds we work in

Data follows process or the opposite?

Defining the datapoint first (*protocol authoring*) vs Definition of the datapoint first (*USDM*)

We are all working with data but with different perspectives

We are interdependent on each other

Ensure that the protocol process can support the data standards

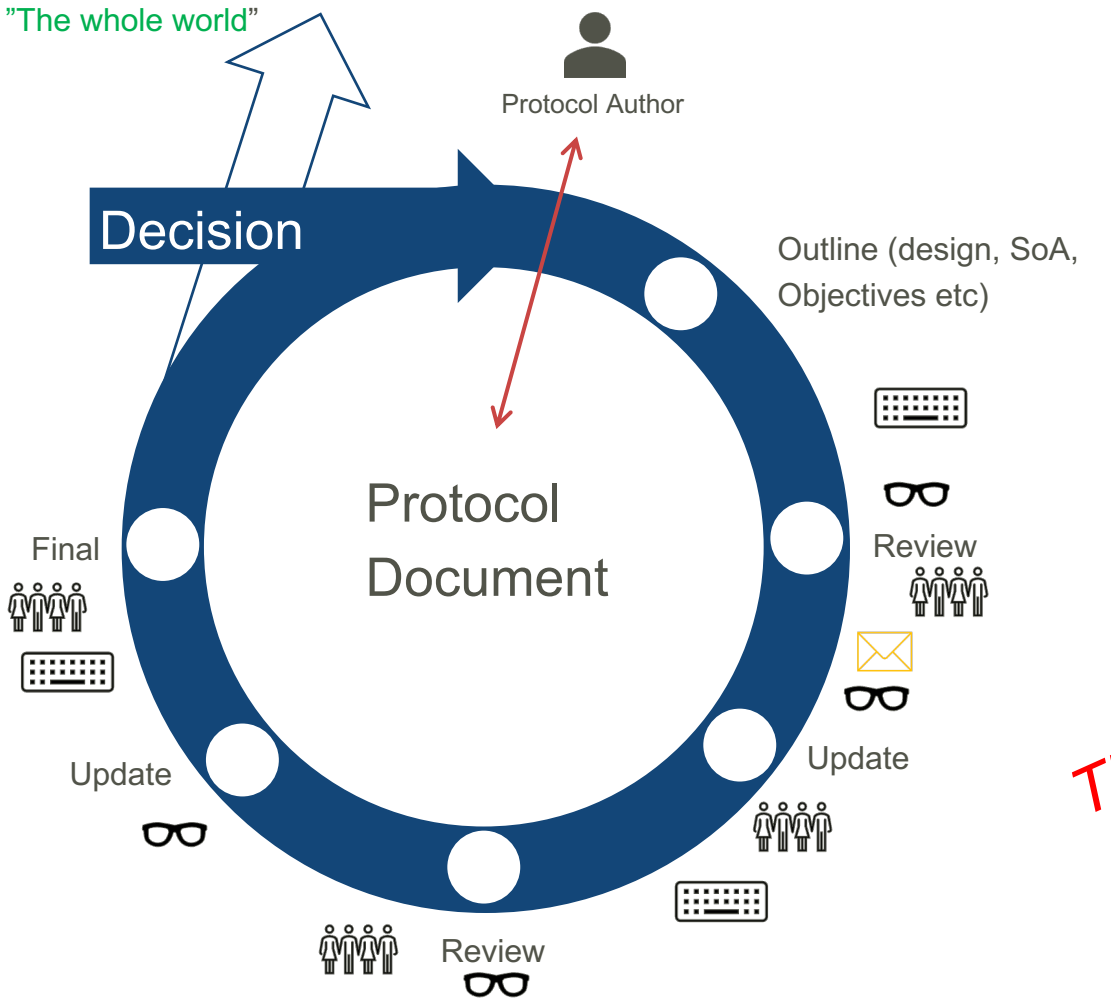
What is mandatory and what is nice in the USDM model?

Models should take into considerations impact covering economy, product supply, labelling, site needs etc

The scope of the USDMIG

The USDM Implementation Guide (USDM-IG) is intended for companies and individuals involved in the set-up of clinical studies—sponsors or stakeholders involved in upstream (protocol and content authoring tools)—and downstream consumers of system (e.g., electronic data capture (EDC), clinical trial management, trial master file) and document (e.g., protocol, clinical study reports, statistical analysis plans) standardized digitized study definitions.

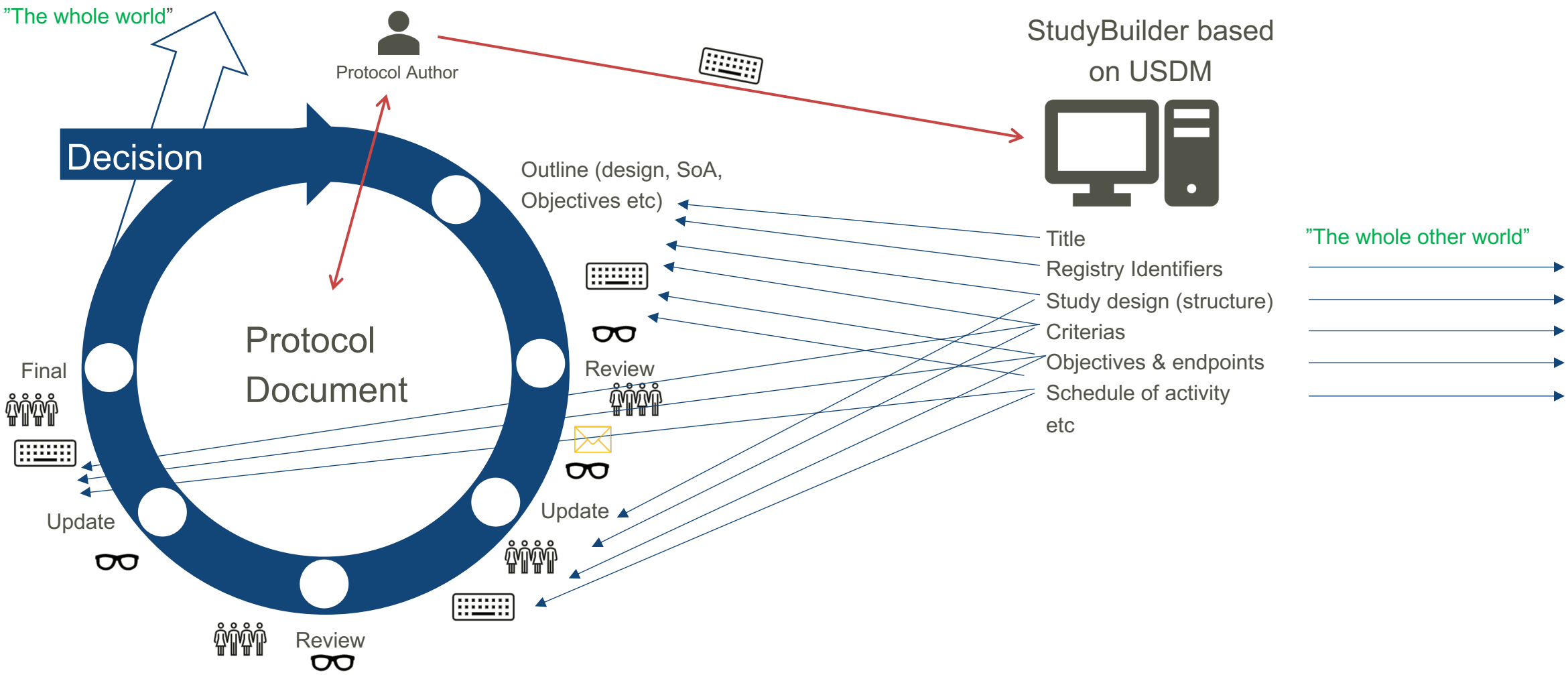
The Existing Protocol Process – an Intro



This is not a data proces

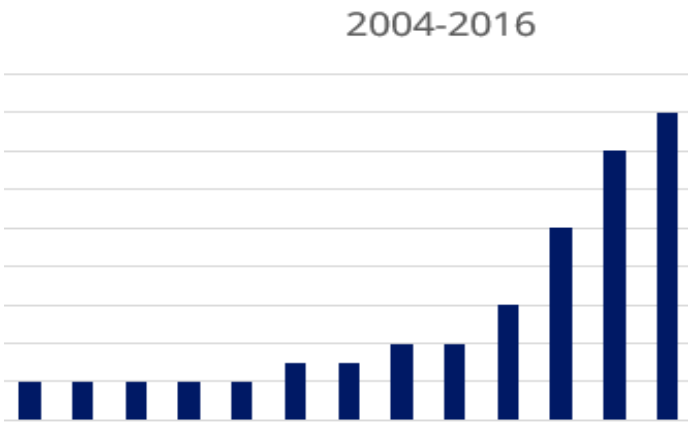
Trial Squad (ClinOps, Medical & Science, Safety, Data Management, Statistics etc)

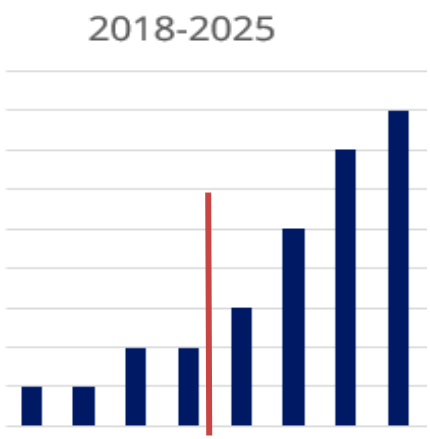
The Protocol Process with Metadata Support



Trial Squad (ClinOps, Medical & Science, Safety, Data Management, Statistics etc)

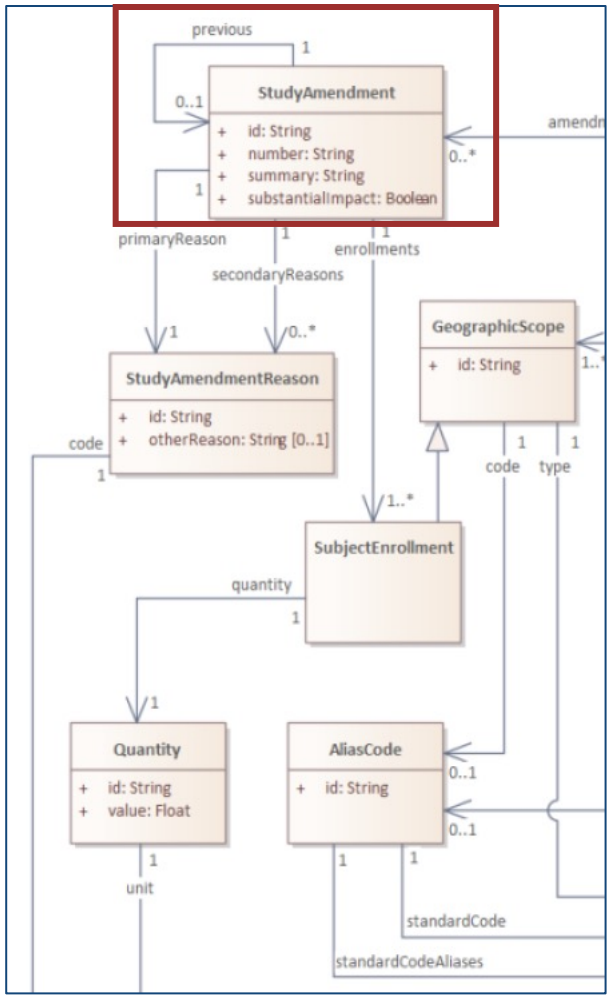
The History

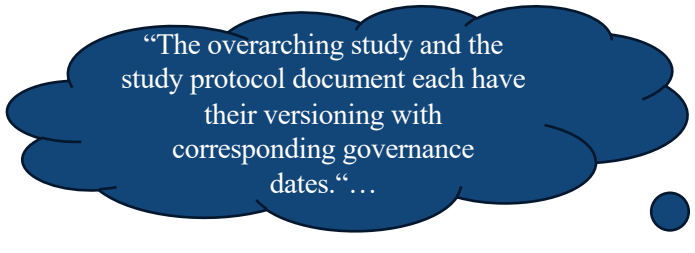

2004-2016


2018-2025


First mention of SDTM
SDTM v1.0
SDTM required in submissions
First mention of ICH M11
DDF launched
First mention of USDM
First USDM version
Let's see
1999
2004
2016
2018
2020
2021
2022
2025

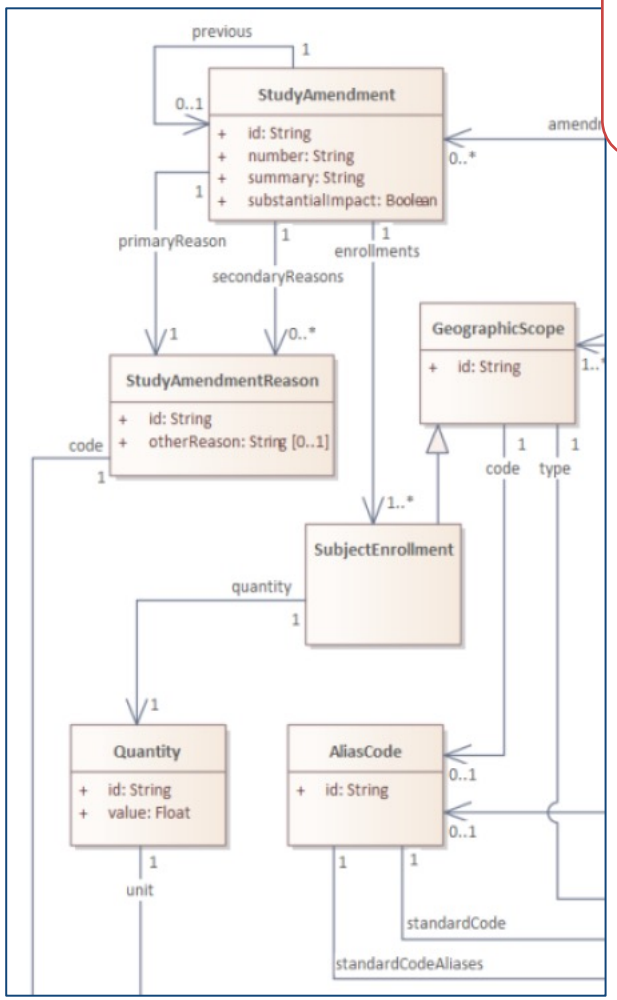
The Protocol Amendment Challenge





What is the *'selling point'* for adding all amendments to a tool based on USDM? Why should Trial Management do double book-keeping?

The Protocol Amendment Challenge



An update to the Section 9: Statistical considerations is required for the handling of missing data in the trial.
No change to data definitions

Action	StudyVersion	Date	StudyProtocolDocumentVersion
Draft	0.1	01-jan-24	
Lock	1.0	07-jan-24	1.0
Draft	1.1	01-sep-24	
Timestamp	1.2	19-sep-24	
Lock	2.0	14-okt-24	3.0

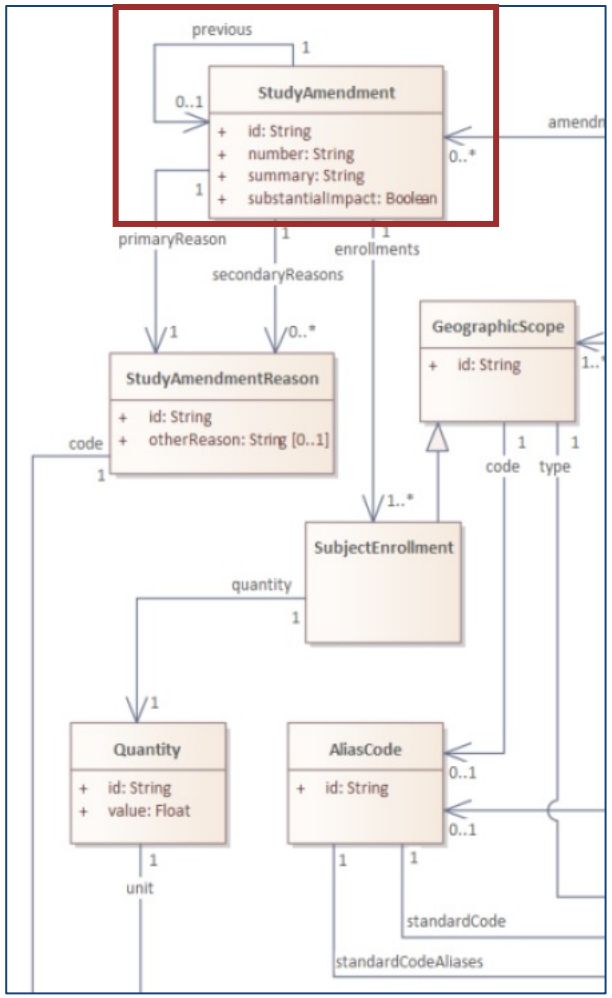
Add manual protocol version

Action	StudyVersion	Date	StudyProtocolDocumentVersion	Manual version	Manual date
Draft	0.1	01-jan-24			
Lock	1.0	07-jan-24	1.0		
Draft	1.1	01-sep-24			
Timestamp	1.2	19-sep-24			
				2.0	01-OCT-2024
Lock	2.0	14-okt-24	3.0		

Hello Trial Manager, which study metadata version should we link to?

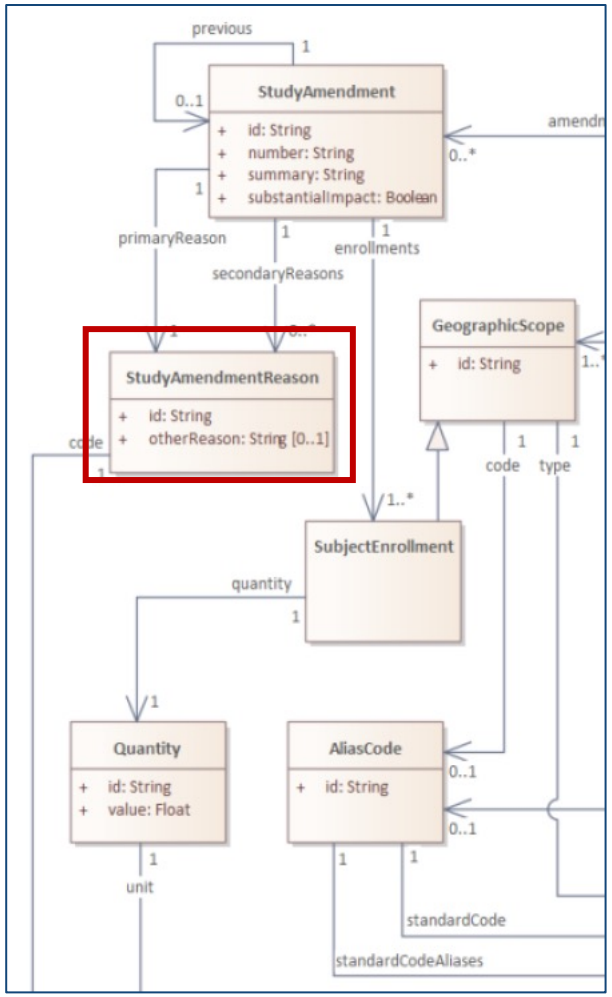
Hi USDM expert!
We are flexible as long as there are no changes to the protocol.

The Protocol Amendment – data life vs. real life



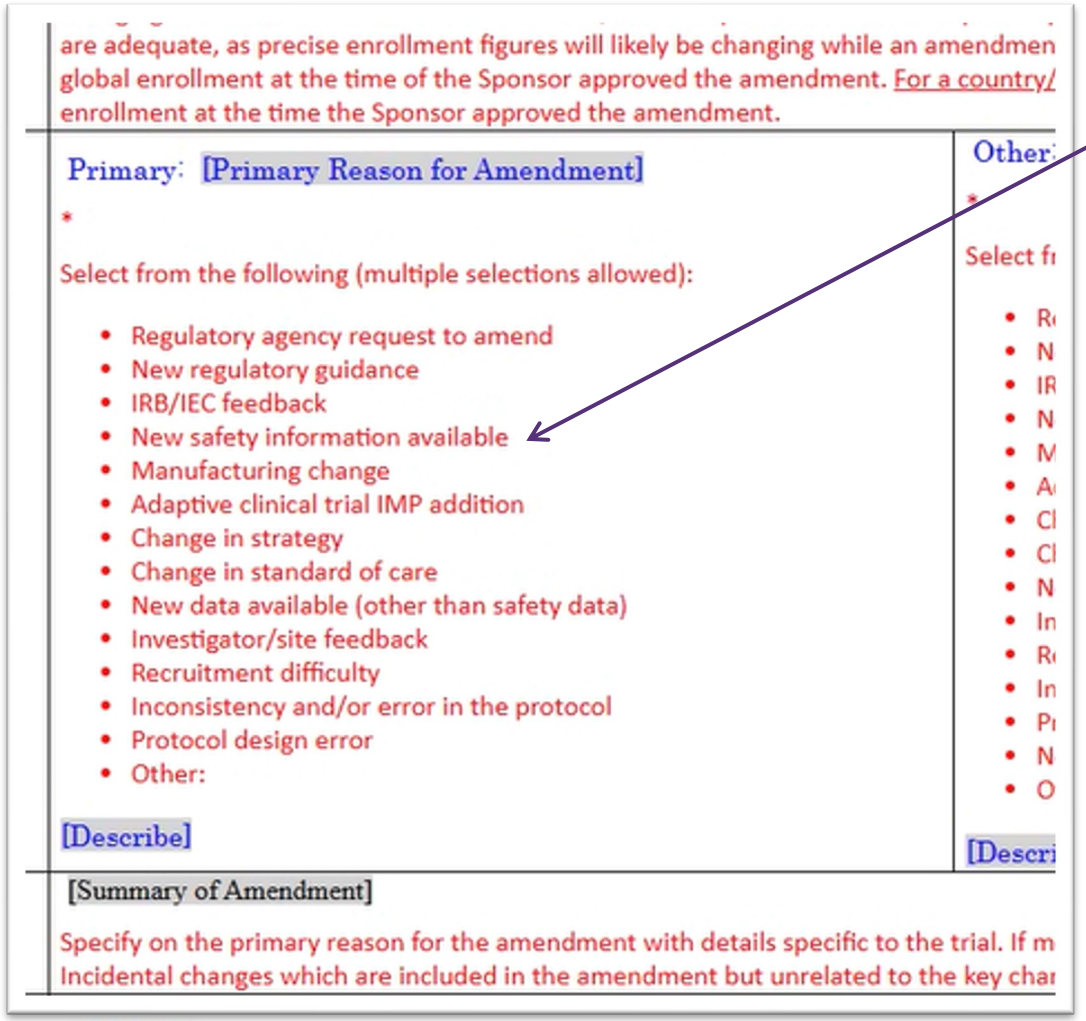
The relevant stakeholders of your internal trial team has agreed to an update to the protocol.

The Protocol Amendment – data life vs. real life



According to the USDM model primary reason(s) and all secondary reasons must be selected

The Protocol Amendment – data life vs. real life



are adequate, as precise enrollment figures will likely be changing while an amendmen
global enrollment at the time of the Sponsor approved the amendment. For a country/
enrollment at the time the Sponsor approved the amendment.

Primary: [Primary Reason for Amendment]

*

Select from the following (multiple selections allowed):

- Regulatory agency request to amend
- New regulatory guidance
- IRB/IEC feedback
- New safety information available
- Manufacturing change
- Adaptive clinical trial IMP addition
- Change in strategy
- Change in standard of care
- New data available (other than safety data)
- Investigator/site feedback
- Recruitment difficulty
- Inconsistency and/or error in the protocol
- Protocol design error
- Other:

[Describe]

Other:

*

Select fr

- R
- N
- IR
- N
- M
- A
- Cl
- Cl
- N
- In
- R
- In
- Pr
- N
- O

[Descri

[Summary of Amendment]

Specify on the primary reason for the amendment with details specific to the trial. If m
Incidental changes which are included in the amendment but unrelated to the key char

Example 1

Protocol 3.0 was prepared to include the potential risk 'dysaesthesia' in the study protocol.

This amendment is considered to be substantial based on the criteria set forth in Article 2(13) of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014.

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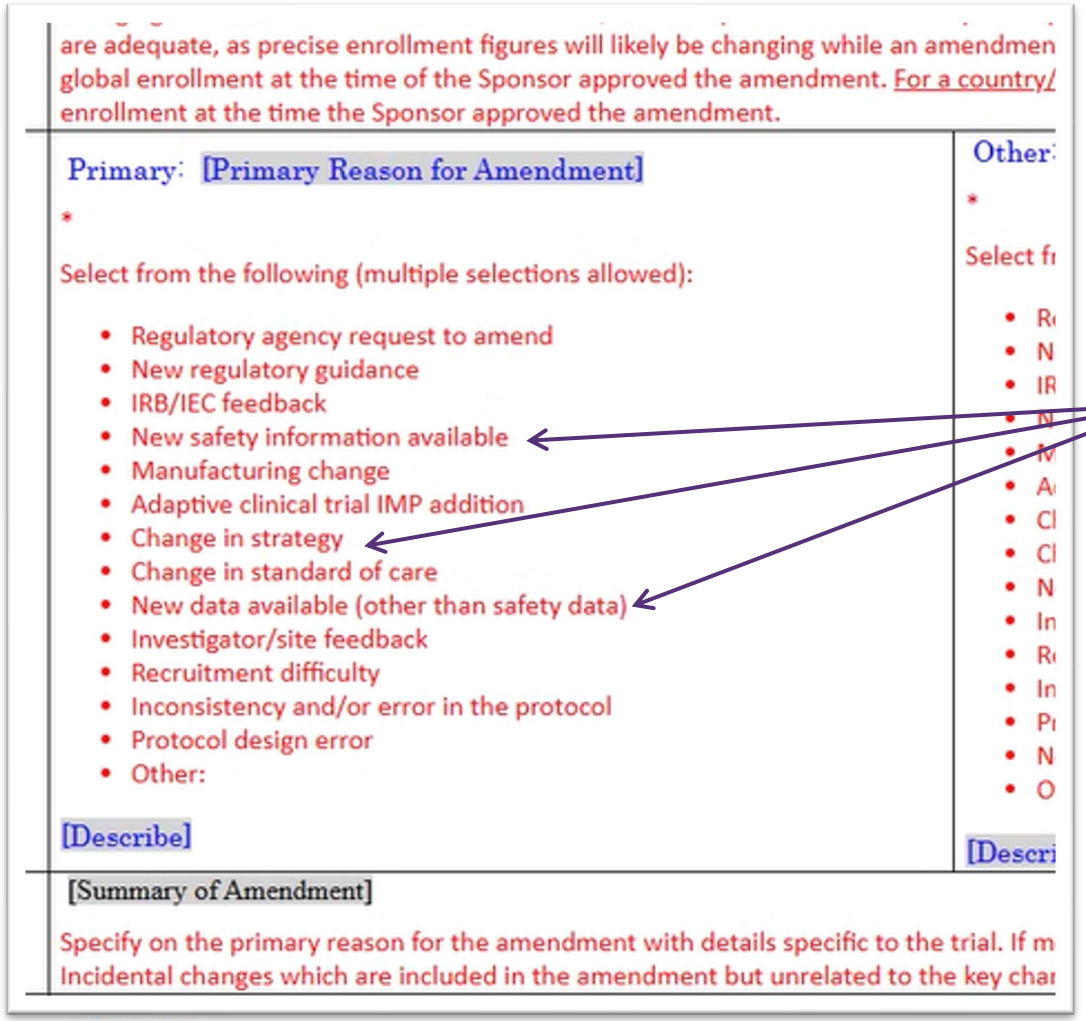

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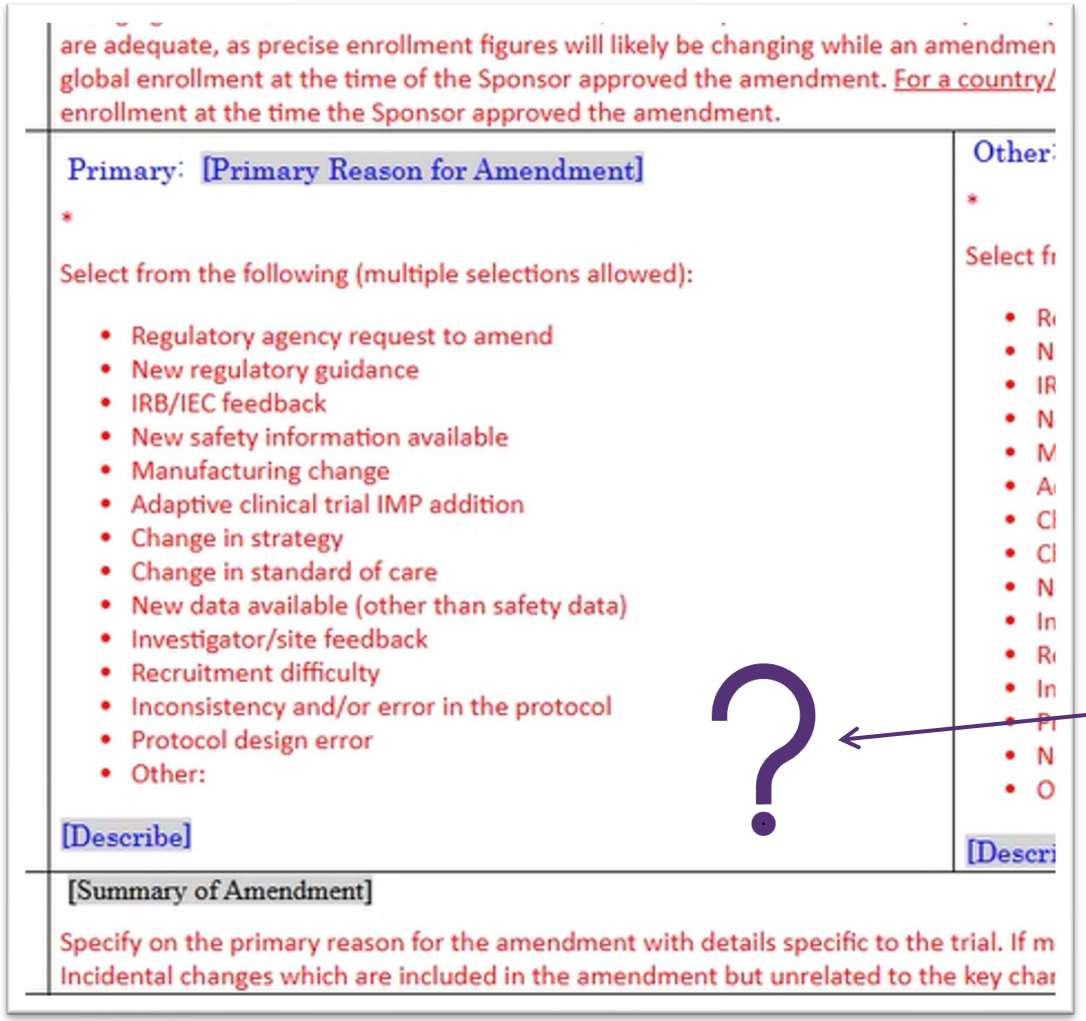
Protocol 2.0 was prepared to adjust the dose levels. The doses in this protocol are based on the highest safety-cleared dose and additional information related to exposure gathered to date from the study XXXX

The Protocol Amendment – data life vs. real life



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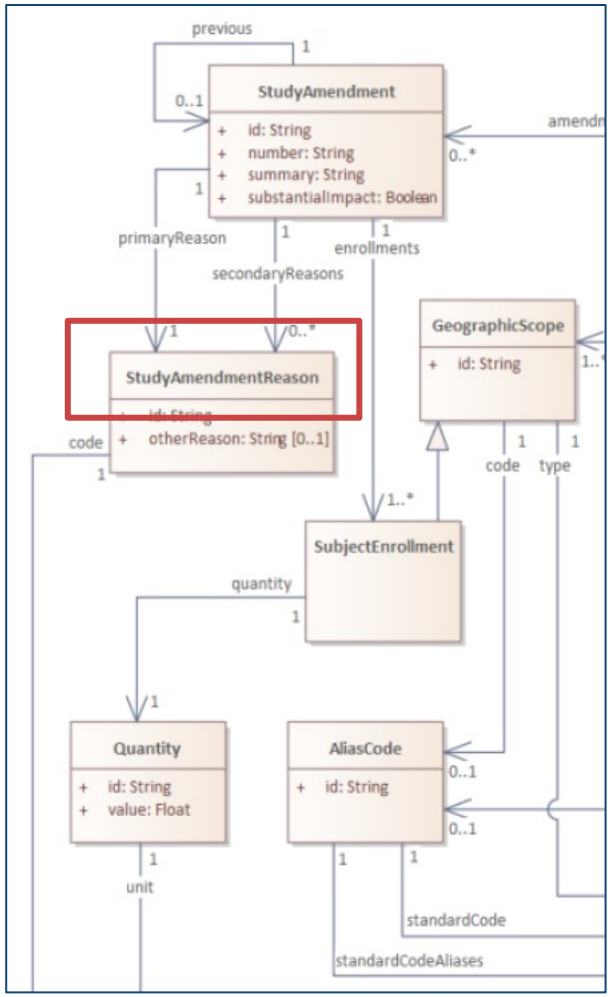
Example 3

Protocol version 3.0 has been updated to ensure that the total blood volume does not exceed 550 mL, to add flexibility in the clamp procedure and correct minor inconsistencies and inaccuracies.

The Protocol Amendment - data life

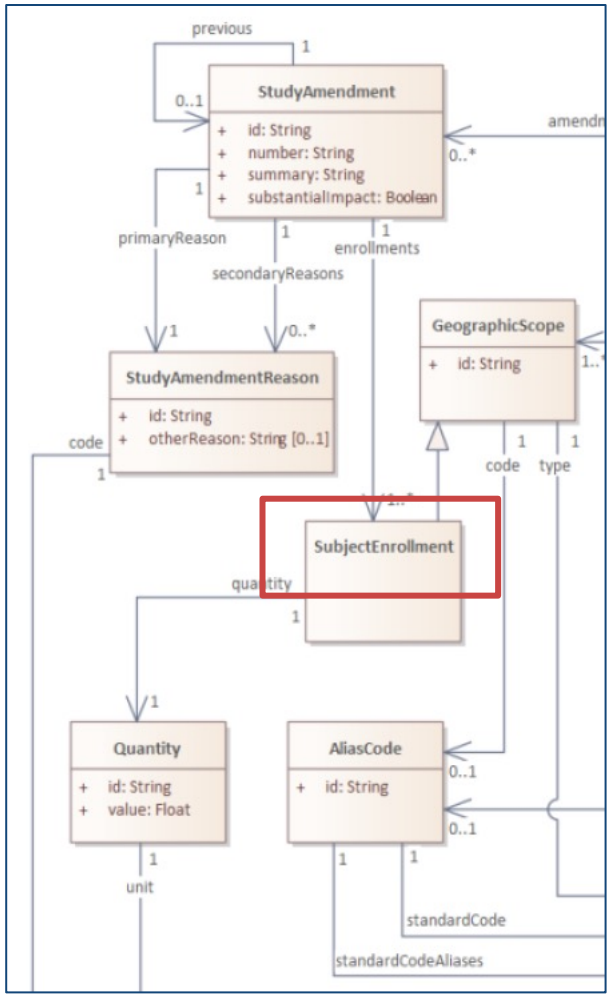
Trial Management Team



- Reason for Amendment?
- Subject Enrollment
- Quantity
- Geographical Scope

The Protocol Amendment - data life

Trial Management Team



- Reason for Amendment?
- Subject Enrollment

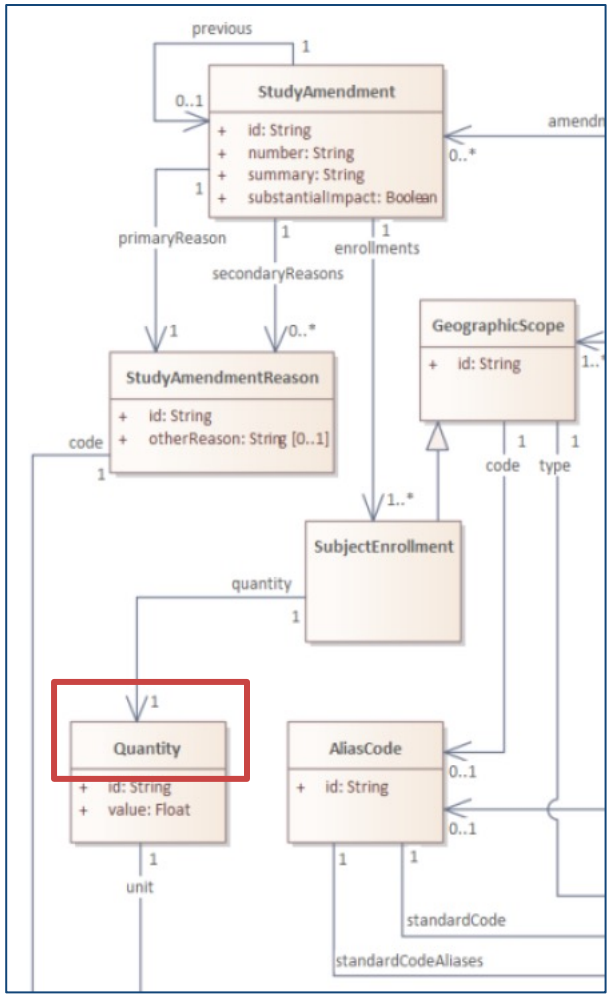
Hi USDM expert,
When do you want the enrolment number?
Amendment initiation or finalisation?

- Quantity

- Geographical Scope

The Protocol Amendment - data life

Trial Management Team



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Hi again USDM expert,
What do you mean with quantity?

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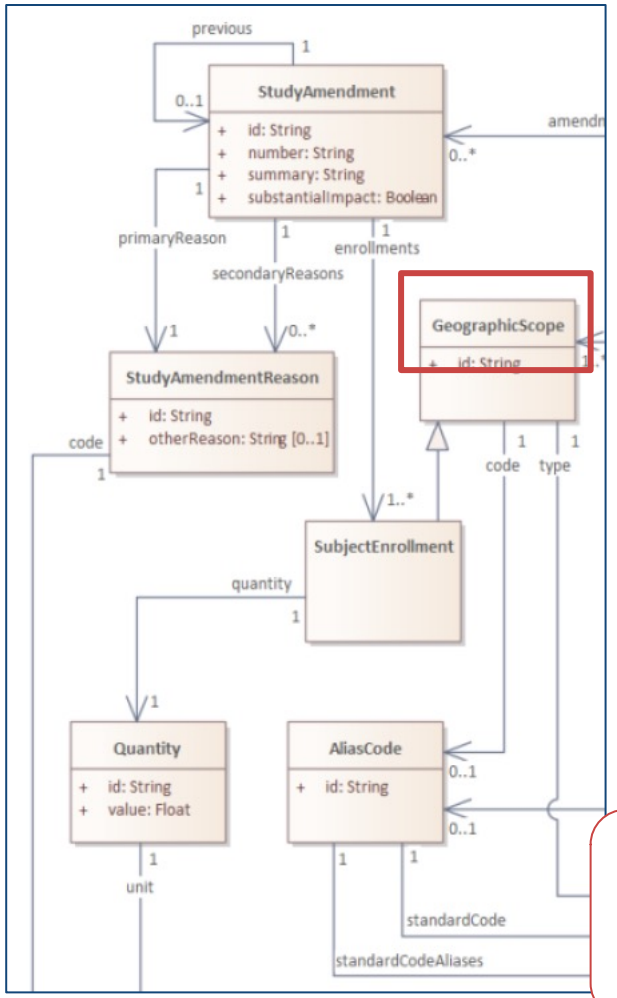
The Protocol Amendment - data life

Trial Management Team



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Hi USDM expert,
When do you want the enrolment number?
Amendment initiation or finalisation?

- Quantity

Hi again USDM expert,
What do you mean with quantity?

- Geographical Scope

Hi again again USDM expert,
We are doing the amendment due to recruitment issues. Do you want to know subject re-allocation or rescue countries?

Sorry for disturbing again again again but …
yet another thing. Are there any deadlines for when I need to update?

… one more thing. If we get a rejection from a country – should I then re-update again?

CON's and PRO's – because USDM mindset makes a difference

Where there are challenges…..

- Lost in translation
  - Are we losing th
    submission of p
    ICH M11 ➔ US
- Are we aligned
  - Flexibility and c
- Can we set the
  - API integration

…there are also opportunities.

- Protocol/amendment Submissions to Regulatory Agencies via OPEN-SOURCE portals across all countries
  - Shortening approval timelines
- ALIGNMENT on Protocol sections, e.g. section 8* in the protocol across industry:
  - improve site training
  - minimizing number of Protocol Deviations
  - Improve data quality
- CDISC 360i etc

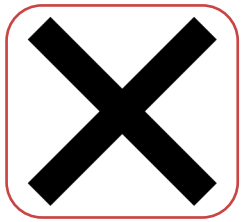
*Study Assessments and Procedures

It’s the same – but yet different

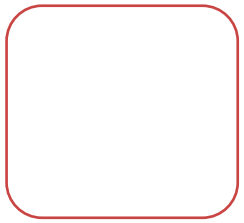
It’s the same – but yet different

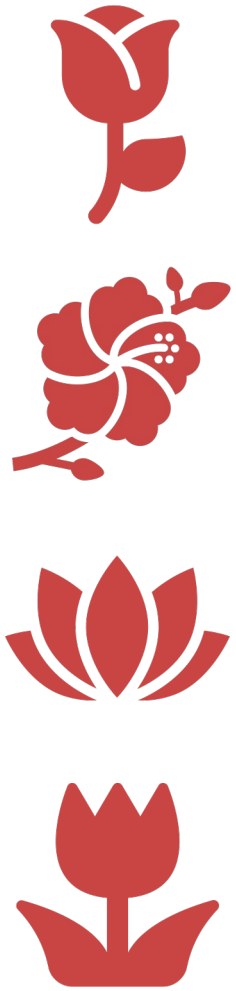
RED FLOWER

Yes



No





Thank You!

Anja Lundgreen ajld@novonordisk.com

Julie Jacobsen Bryndum jujb@novonordisk.com