MANATO OHARA
Japan
Manato has type 1 diabetes

SEND at Novo Nordisk A/S

Learnings in Non-clinical Data Management

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Who are we?

Gitte Koch Ullmann

B.Sc. in Mech. Engineering

In the clinical area since 1997

In the non-clinical area since 2016

Principal Standards Scientist
Non-clinical Data Management

Pia Jellinggaard

M.Sc. in Clinical Data Management

In the clinical area since 1994

In the non-clinical area since 2013

Manager
Non-clinical Data Management

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Non-clinical submissions before SEND 3.0

CRO studies

Novo Nordisk A/S systems

Novo Nordisk A/S & CRO Scientists

CRO systems

Document repository

FDA Submission requirements

Before Dec-2016:

Final study report

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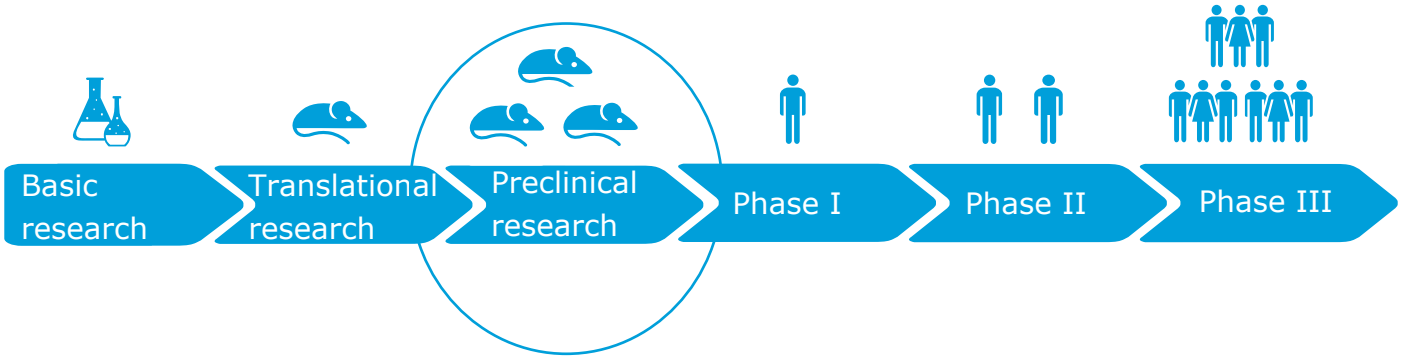
Submission of preclinical data



- **SEND**: **S**tandards for **E**xchange of **N**onclinical **D**ata used for preclinical studies (animal testing)
- SEND Implementation Guide corresponds to SDTM Implementation Guide

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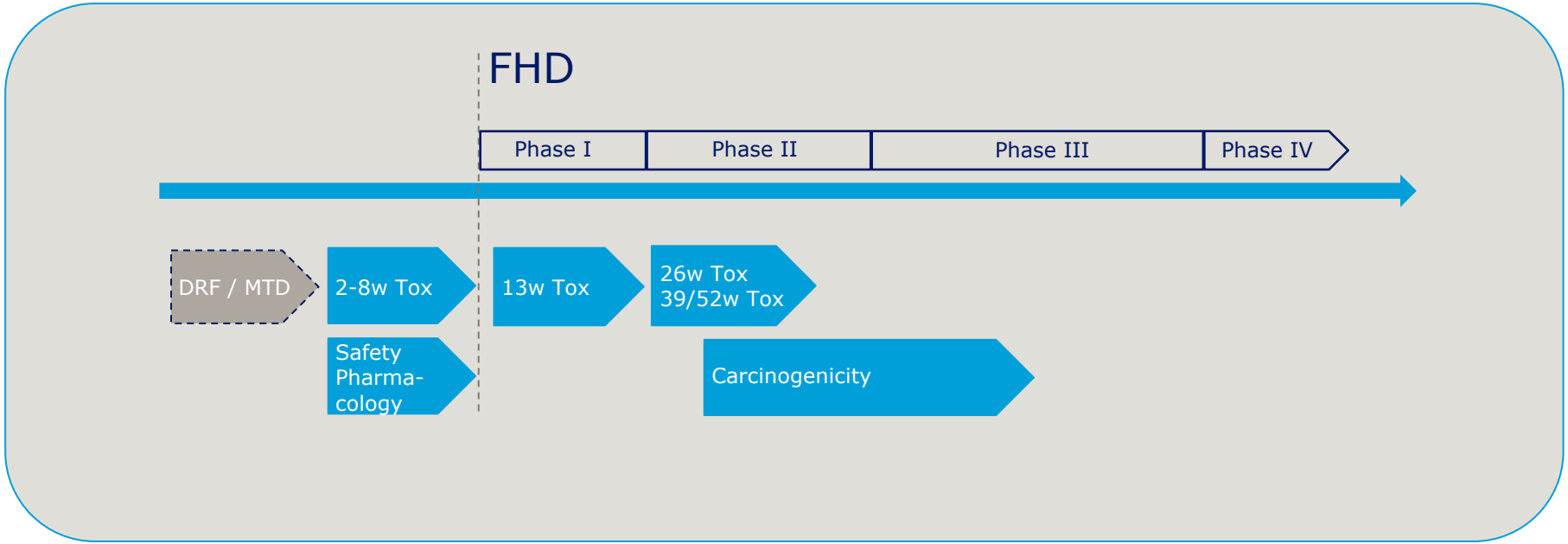
Study Types covered by SEND



Non-clinical submissions after SEND 3.0

1 All data to be captured electronically

2 Data standardisation and controlled terminology enforced

CRO studies

Novo Nordisk A/S systems

Novo Nordisk A/S & CRO Scientists

CRO systems

Document repository

SEND data repository

3 Central data repository holding all data sets

Submission requirements

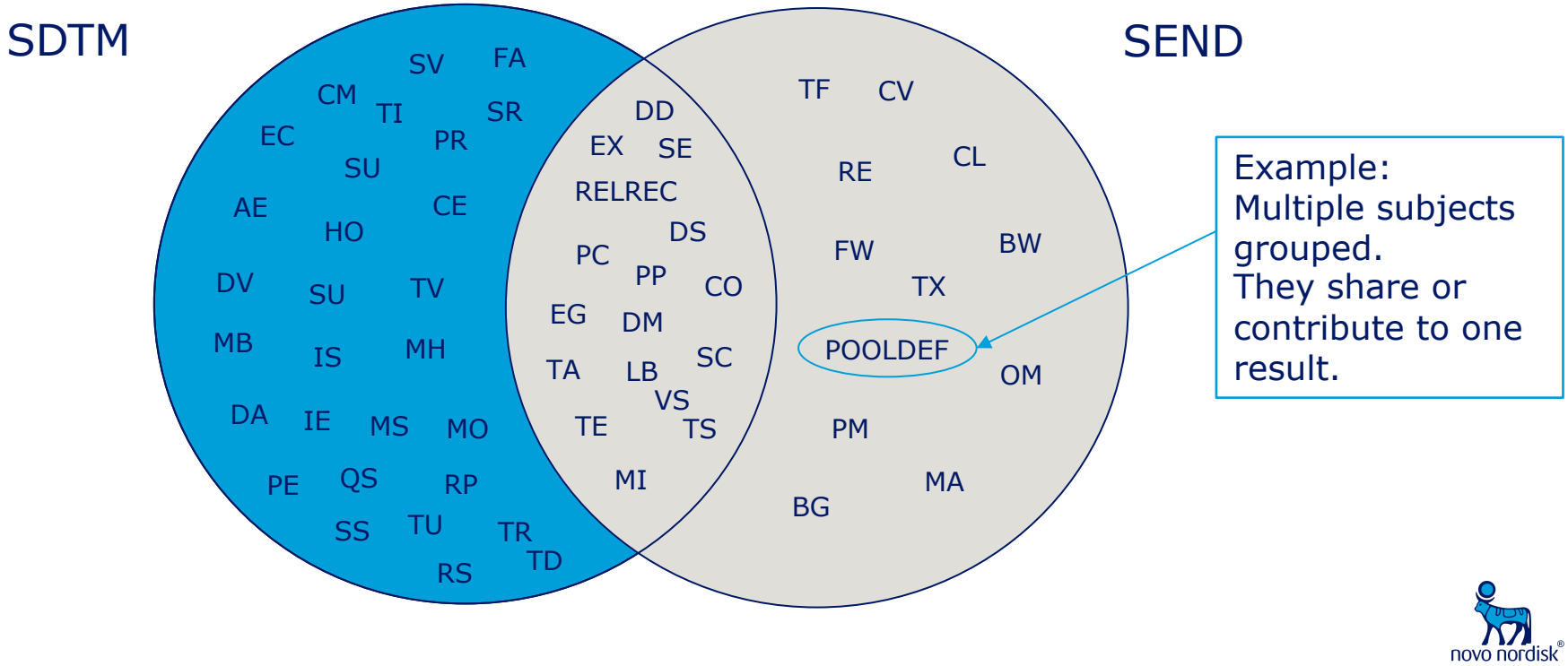
After Dec-2016:

- Final study report
- SEND datasets
- Define file
- Data reviewer's guide

What did we (re-)learn?

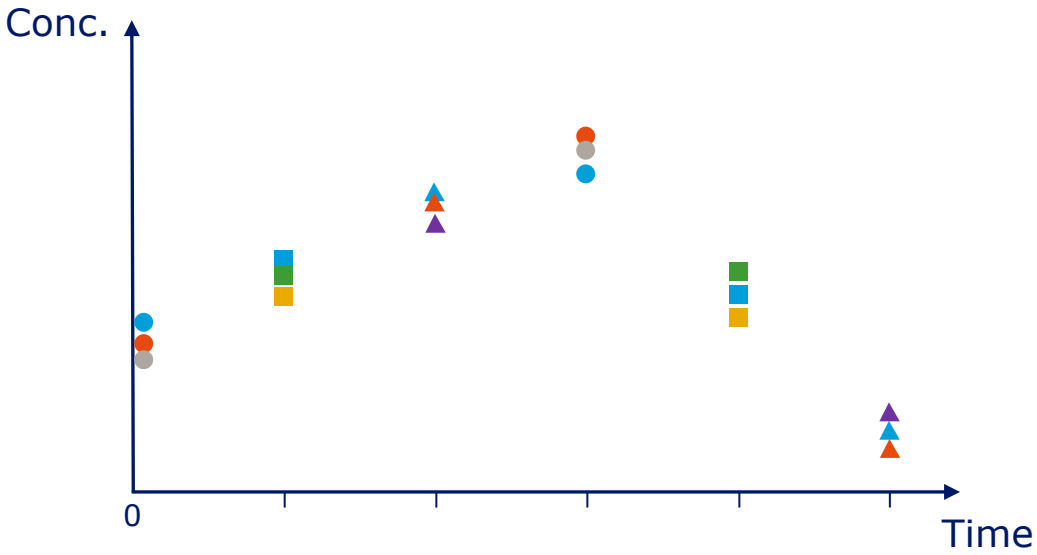
- The waterfall model is not user-friendly
- Simplicity and agility must be thought into all solutions
- So we had to change our ways!
- Today all system changes are preceded with custom programming

SDTM & SEND domains

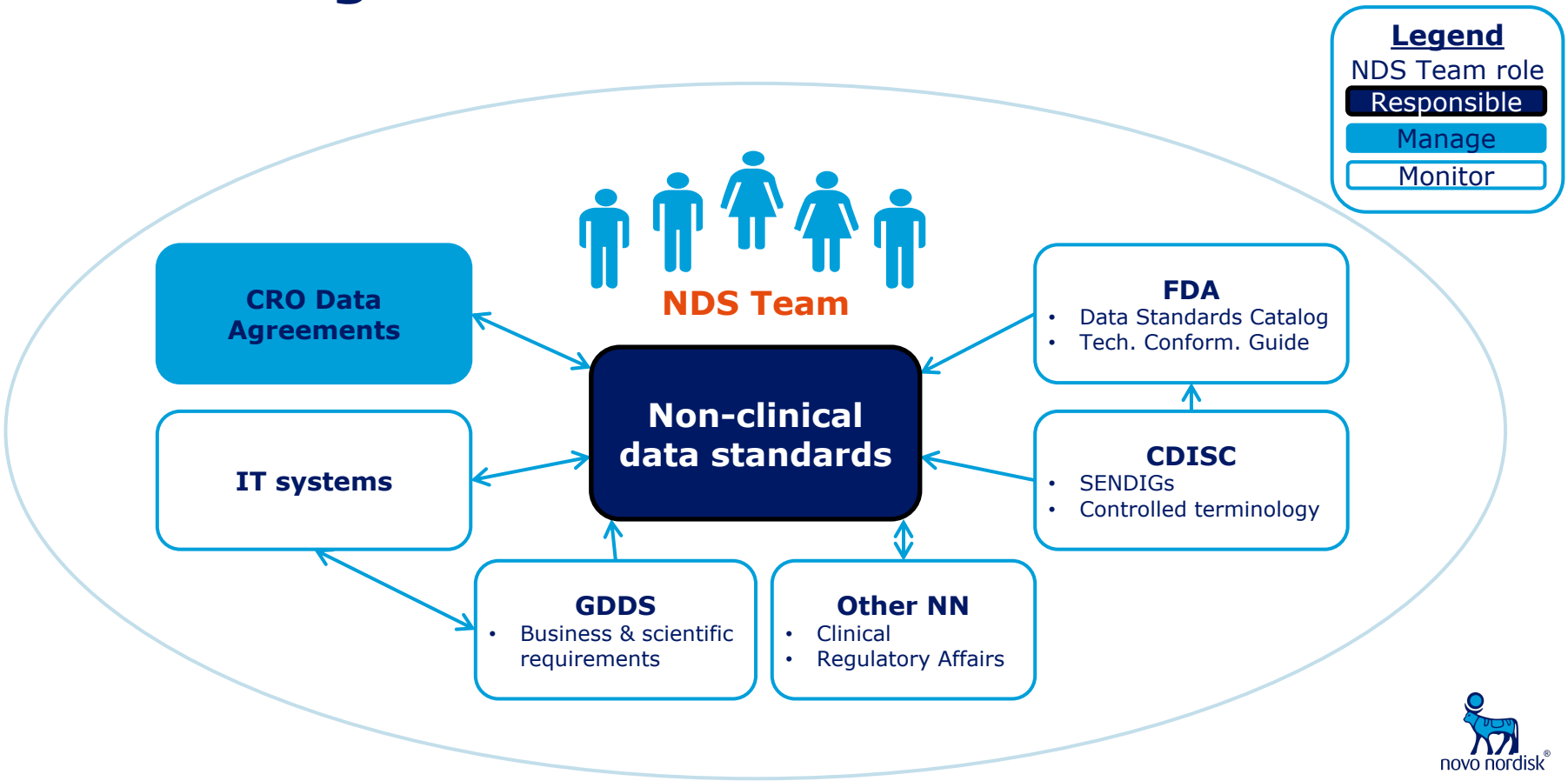


Pharmacokinetic Parameters for small animals

- Multiple subjects contribute to one overall time-concentration profile



Standards governance



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So – what did we learn?

- Changes might be necessary – but are difficult to accept
- Once implemented - maintaining the standards and systems in the non-clinical area is a pleasure
- FDA is very interested in further development of the SEND standard and in using the reported data

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