

DS01

UNORDINARY
DRIVES
CHANGE



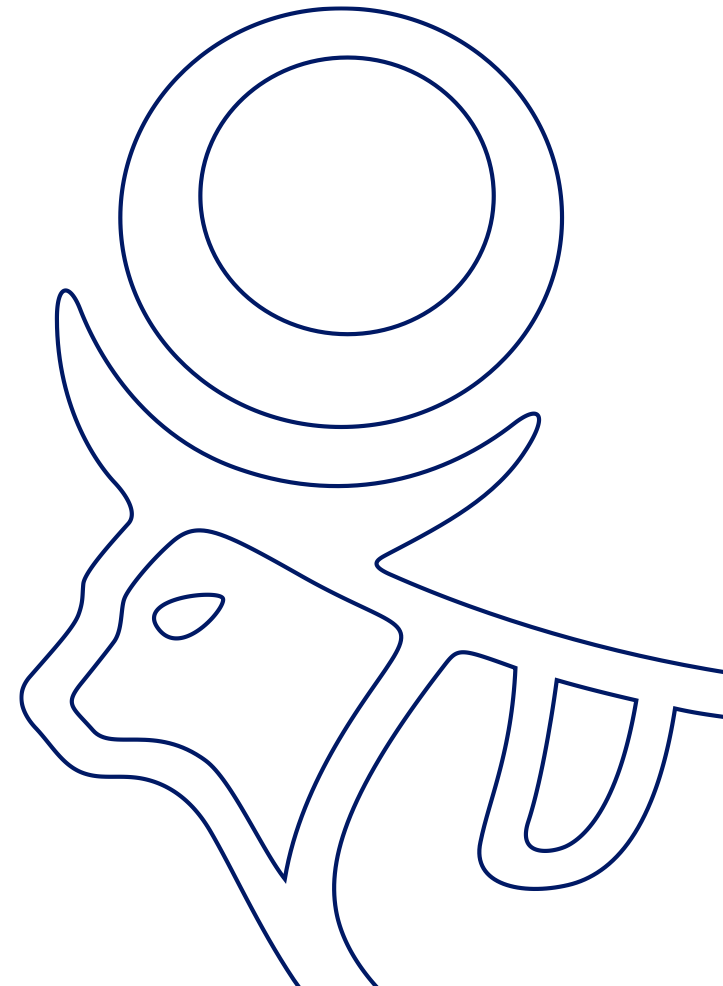
Enabling Standardised Data Collection Through Governance Processes and Automation

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Lara Langensee

Clara Giménez Arteaga

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Who are we?

The challenges with the past landscape of standards governance

The solutions: Standards governance processes & Monitoring the use of standards

Looking ahead

Today's presenters



Christine Mathiesen
Senior Standards Developer
Responsible for governance process optimization



Clara Giménez Arteaga
Standards Developer
Responsible for automation



Lara Langensee
Senior Standards Developer
Responsible for standards governance oversight

Vital Signs

VS=Vital Signs

Design Notes

VSCAT=VITAL SIGNS

See CRF Guidance document for details on the different guidance text used in different visits.
The text '<...>' should be updated to reflect the protocol.

V1, Vn

Vital Signs (VS)

[VITAL_SIGN_2] - Non-repeating form

Study ID: NN0000-XXXX

Integration

<Visits A, B>: If abnormal, clinically significant, record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM).

<Visits X to Y>: Any clinically significant deterioration of a pre-existing condition as well as any new clinically significant sign, symptom or illness is considered an adverse event. Complete an Adverse Event form (AE). If medication is taken remember to record in the Concomitant Medication form (CM).

Date of examination [de-activated]

Req/Req/Req (2022-2035)

VSDTC

Blood pressure and pulse – Second last measurement

VSREPNUM=1

Blood pressure

Systolic [N3] mmHg

Diastolic [N3] mmHg

VSORRES/VSORRESU when VSTESTCD=SYSBP,DIABP

BP_SYSTOLJC

BP_DIASTOLJC

Pulse

[N3] beats/min

VSORRES/VSORRESU when VSTESTCD=PULSE

PULSE

Blood pressure and pulse – Last measurement

VSREPNUM=2

Blood pressure

Systolic [N3] mmHg

Diastolic [N3] mmHg

VSORRES/VSORRESU when VSTESTCD=SYSBP,DIABP

BP_SYSTOLJC

BP_DIASTOLJC

Pulse

[N3] beats/min

VSORRES/VSORRESU when VSTESTCD=PULSE

PULSE

The challenges with the past landscape of standards governance

1. Ineffective distribution of responsibilities within standards governance
2. Lack of knowledge about which updates are needed to current standards
3. Limited overview of deviations from standards in trials
4. No indication of which updates are needed to current standards
5. No data-driven way to prioritise new or updated standards

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Project Standardisation Team (PST)

- The team is responsible for:
 - Review and collection with SMEs
 - Oversight the use of standards
 - Facilitate development of new standards

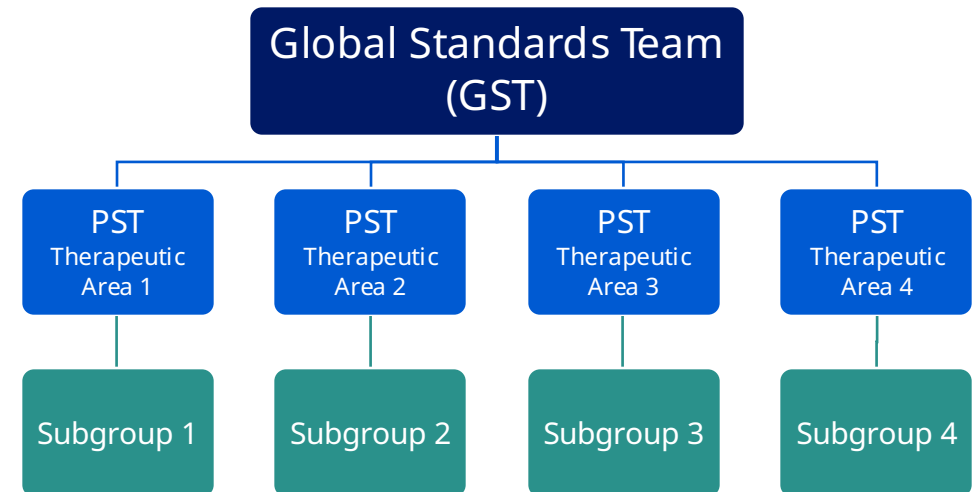
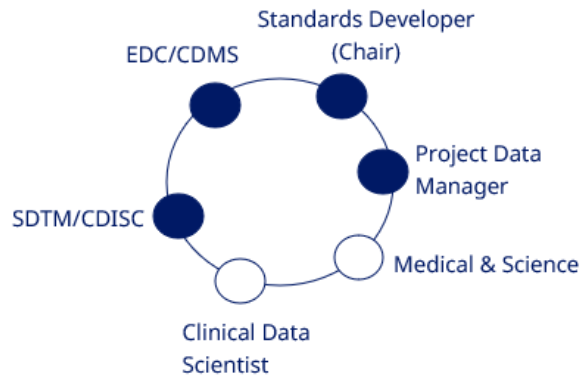
Too many tasks to be discussed with bi-weekly meetings

PST meetings are occurring bi-weekly



Therapeutic Area Standards Development (PST subgroup)

- Oversight the use of existing standards and identification of new standards candidate
- Facilitate development of new global standards based on project requirements, specialist knowledge and data-driven insights



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The solution:

Standards Monitoring and Evaluation System



How does SENSE work?

Trial EDC Setup



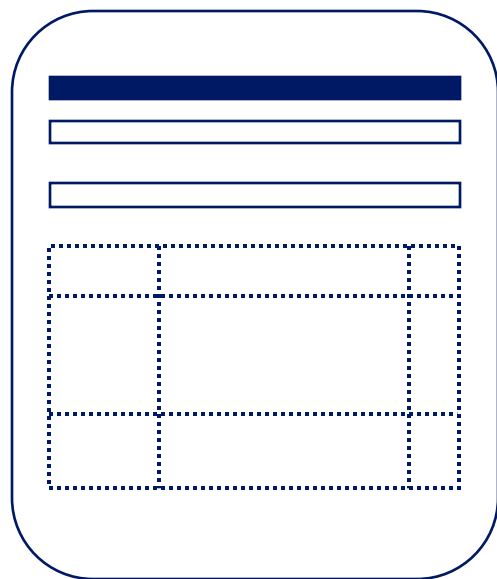
Standards Library



Baseline for comparison

How does SENSE work?

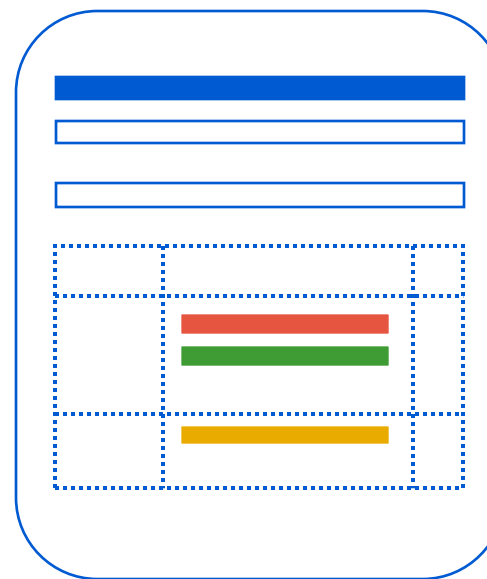
Standards Library form



A diagram of a 'Standards Library form' represented as a rounded rectangle. It contains three horizontal bars at the top: a thick dark blue bar, a thin white bar with a dark blue outline, and another thin white bar with a dark blue outline. Below these is a table with a dotted border, consisting of 3 rows and 2 columns.



Trial form

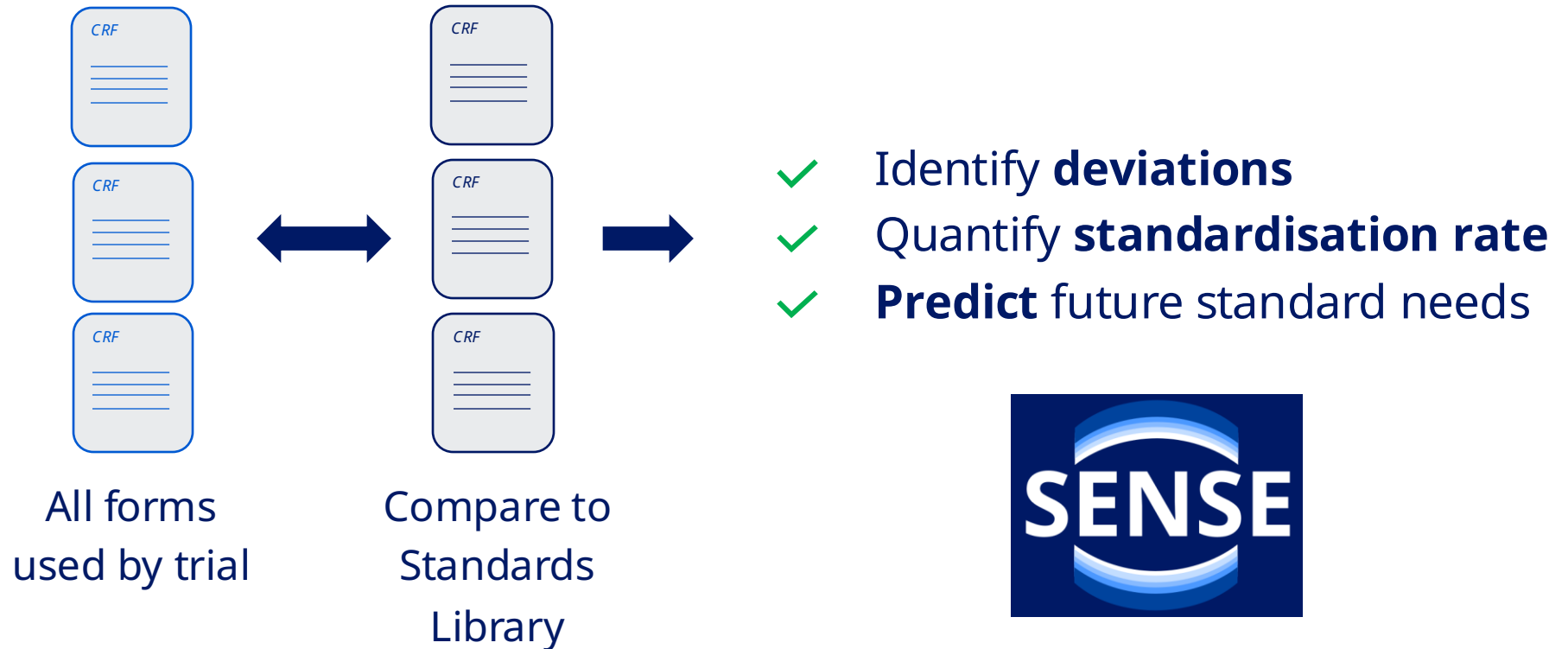


A diagram of a 'Trial form' represented as a rounded rectangle. It contains three horizontal bars at the top: a thick blue bar, a thin white bar with a blue outline, and another thin white bar with a blue outline. Below these is a table with a dotted border, consisting of 3 rows and 2 columns. The middle row of the table contains three horizontal bars: a red one, a green one, and a yellow one.

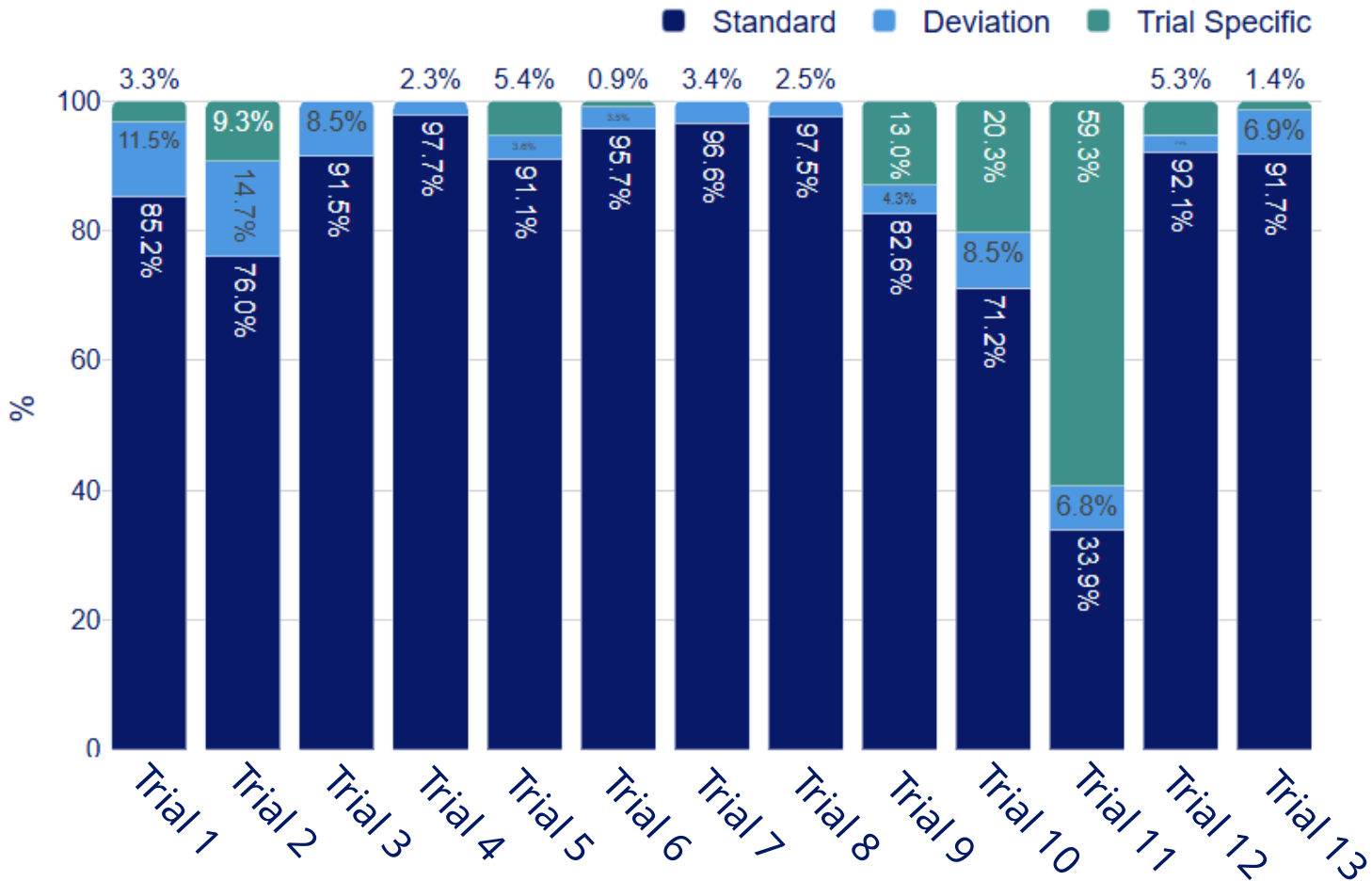
Deviations?

How does SENSE work?

For each trial

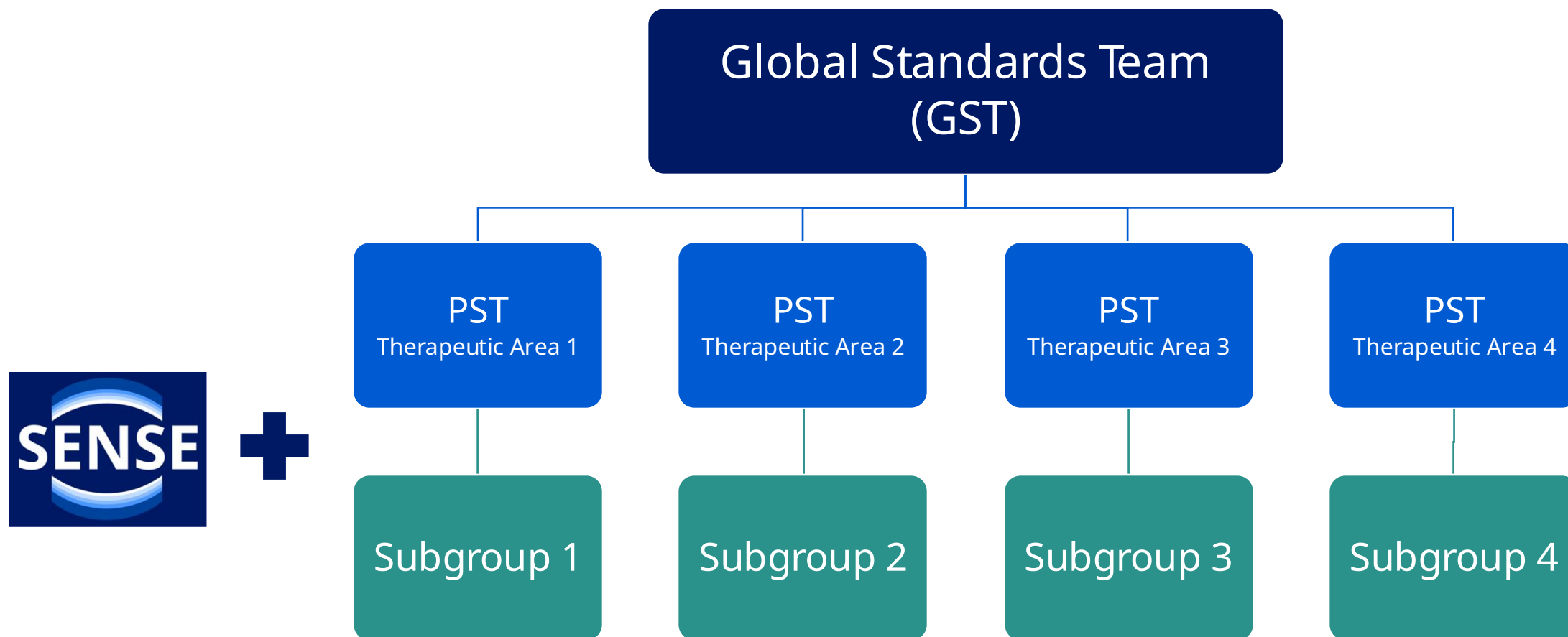


Monitoring the use of standards to guide development of global standards



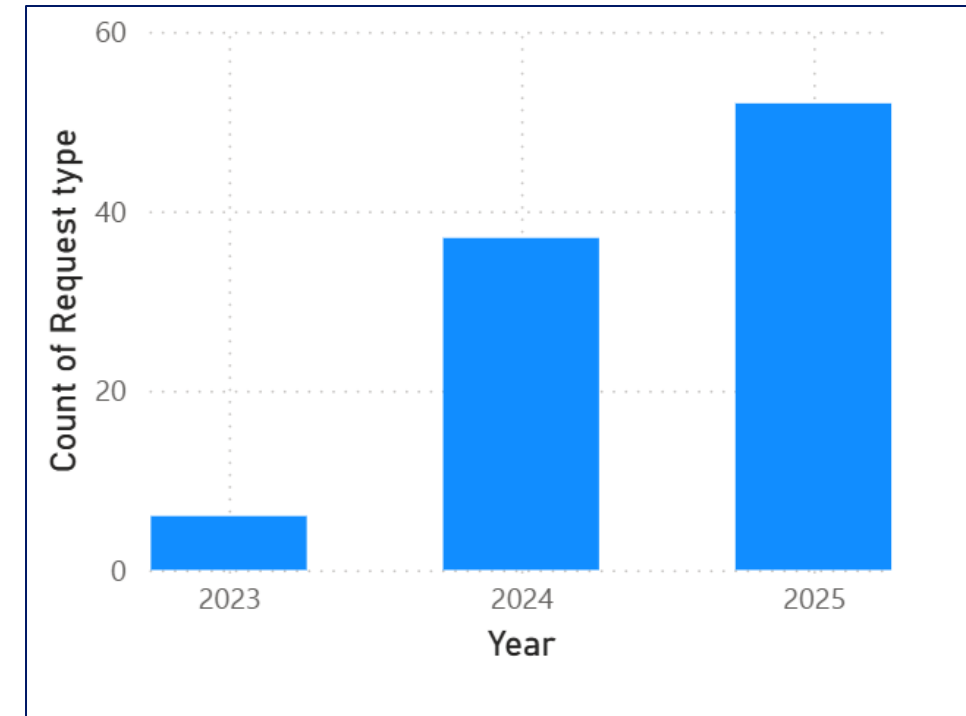
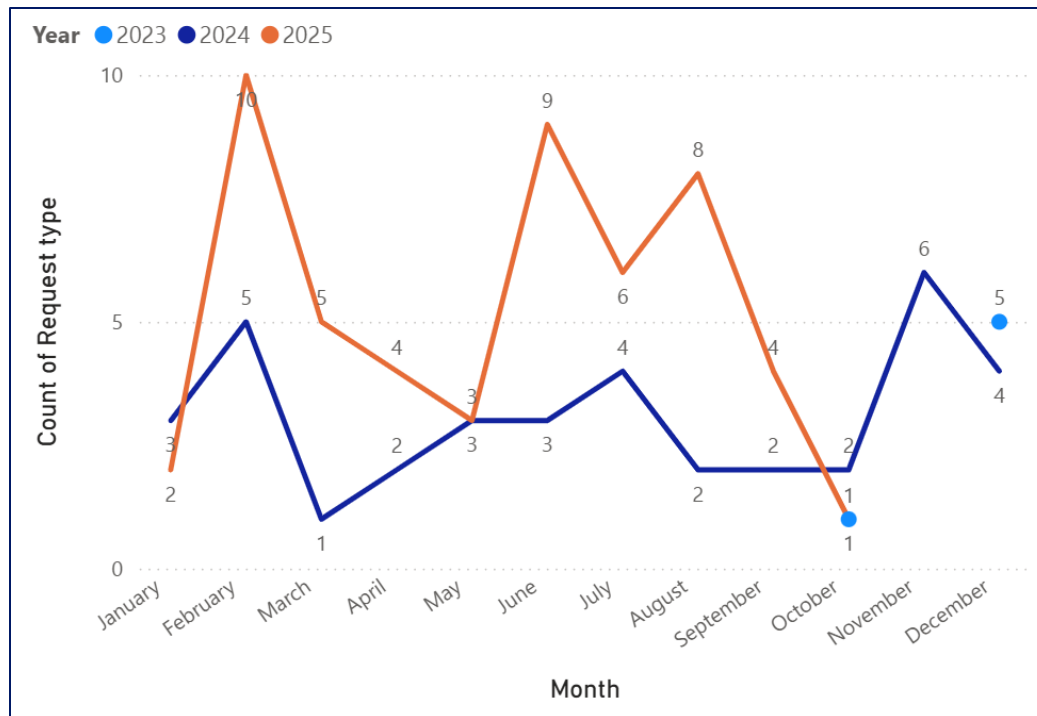
- ✓ Quantify **standardisation rate**
- ✓ Identify **most used forms**
- ✓ Identify reoccurring **deviations**
- ✓ Guide **development** of new standards

Standards Governance in NN



Global Standards Team

- Governance of all global standard CRFs in NN
- Consisting of SDTM, Standards, DM and EDC SMEs



Where are we at?



What next?

- Multiple EDC systems
- Automated standards generation
- Standards governance from protocol drafting

Questions?



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