Spine Tango Industry Update Meeting. March-2025

Agenda:

1. EUROSPINE
   I. Update on dataset changes
   II. Update on the Spine Atlas Initiative
   III. New developments: Intraop Neuromonitoring Form, Spine Tango App
   IV. Invitation to consider conducting nested studies

2. International Spine Registries (ISR) updates

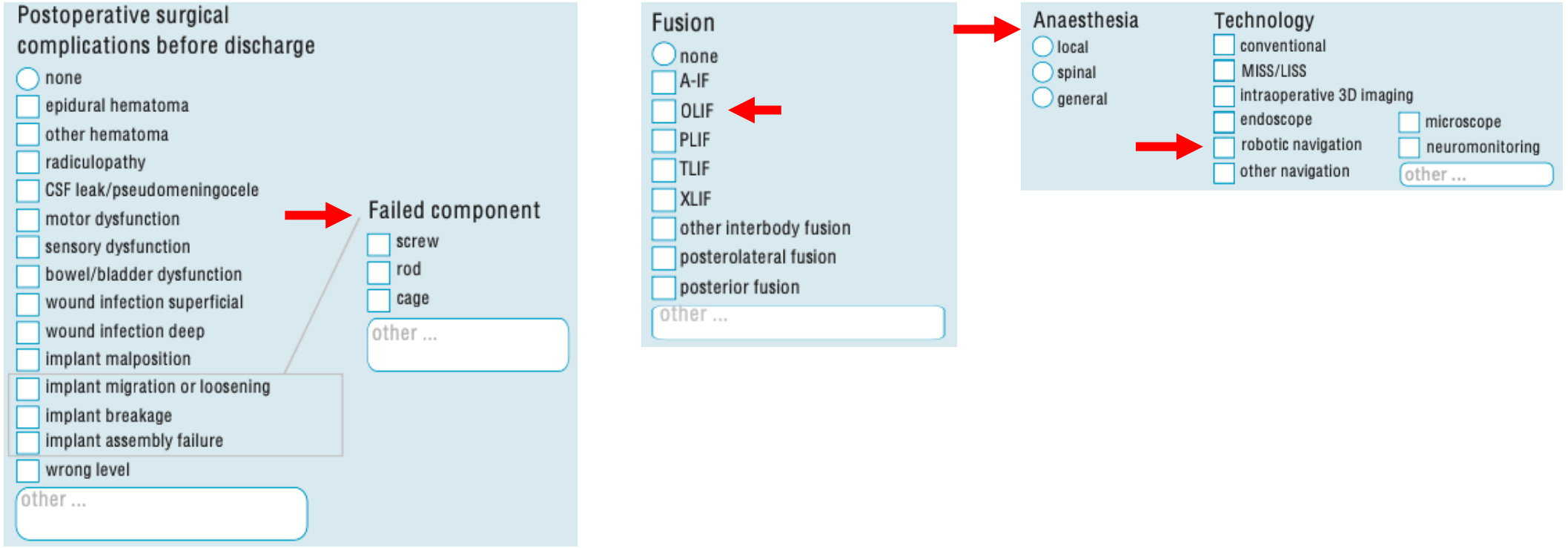
3. Implant catalogue: Access for national and regional spine registries to support UDI level device recording

4. Relevant change requests

5. Request for industry feedback on implant report methodology – refining comparators

6. Q & A Session

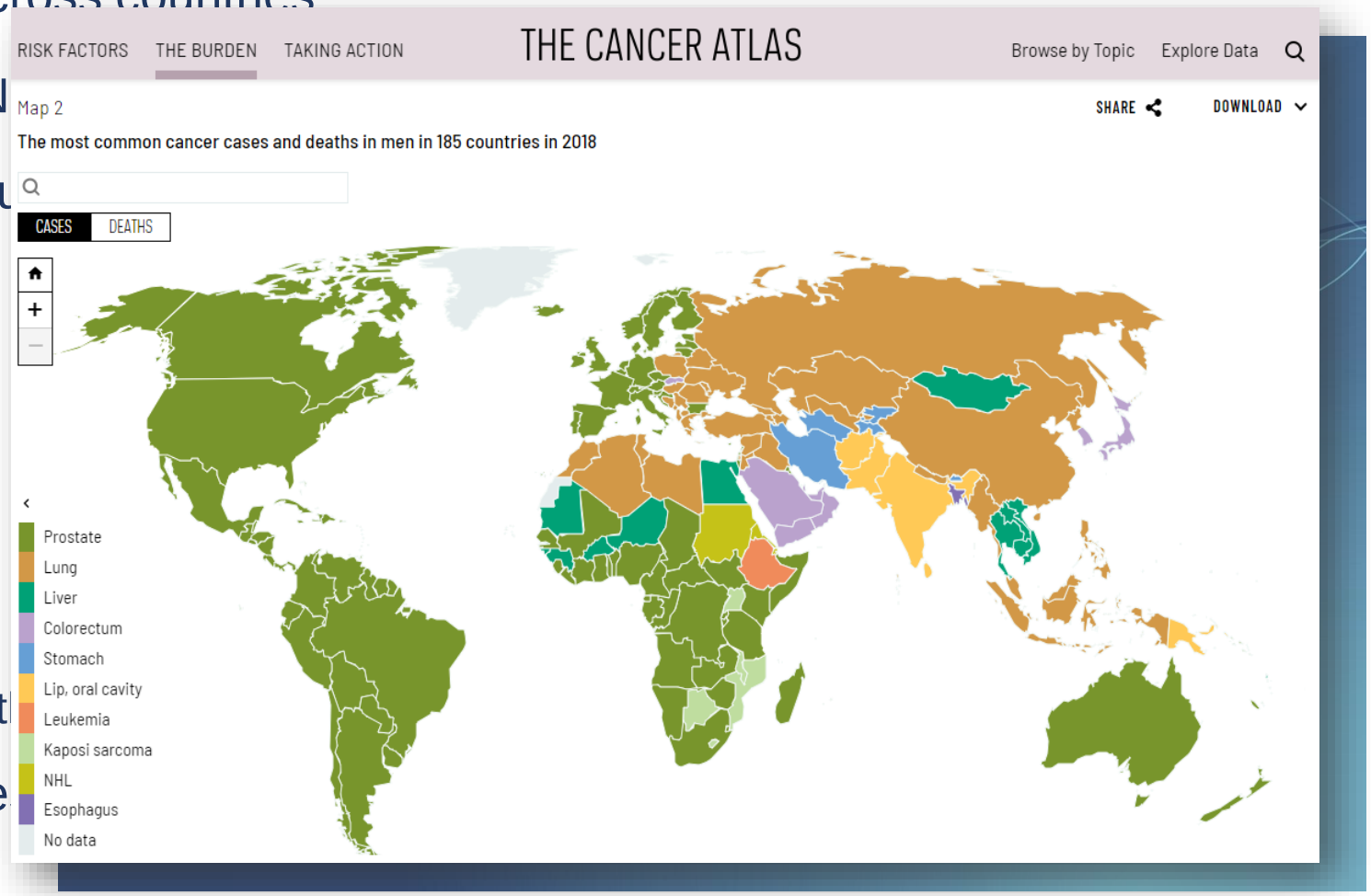
1. EUROSPINE updates: dataset changes



- since January 2025
- minimal (=Swiss mandatory content) and extended versions

1. EUROSPINE updates: Spine Atlas Initiative (SAI)

- Inspired by cancer registration across countries
- Supported by EUROSPINE, EAN
- Aiming at visualisation across cou
  - epidemiology
  - spinal services
  - practice variation
- Low-barrier annual data calls
  - 1 pathology
  - 8 key parameters
  - all treated patients within 3 mont
- Combined database for further re



1. EUROSPINE updates: Spine Atlas Initiative (SAI)

Data call 2025

- Anonymous data only
- Lumbar degenerative Spondylolisthesis (LDS)
- Patients surgically treated from February to April 2025
- Maximal coverage with minimal efforts
- Benefits for participants:

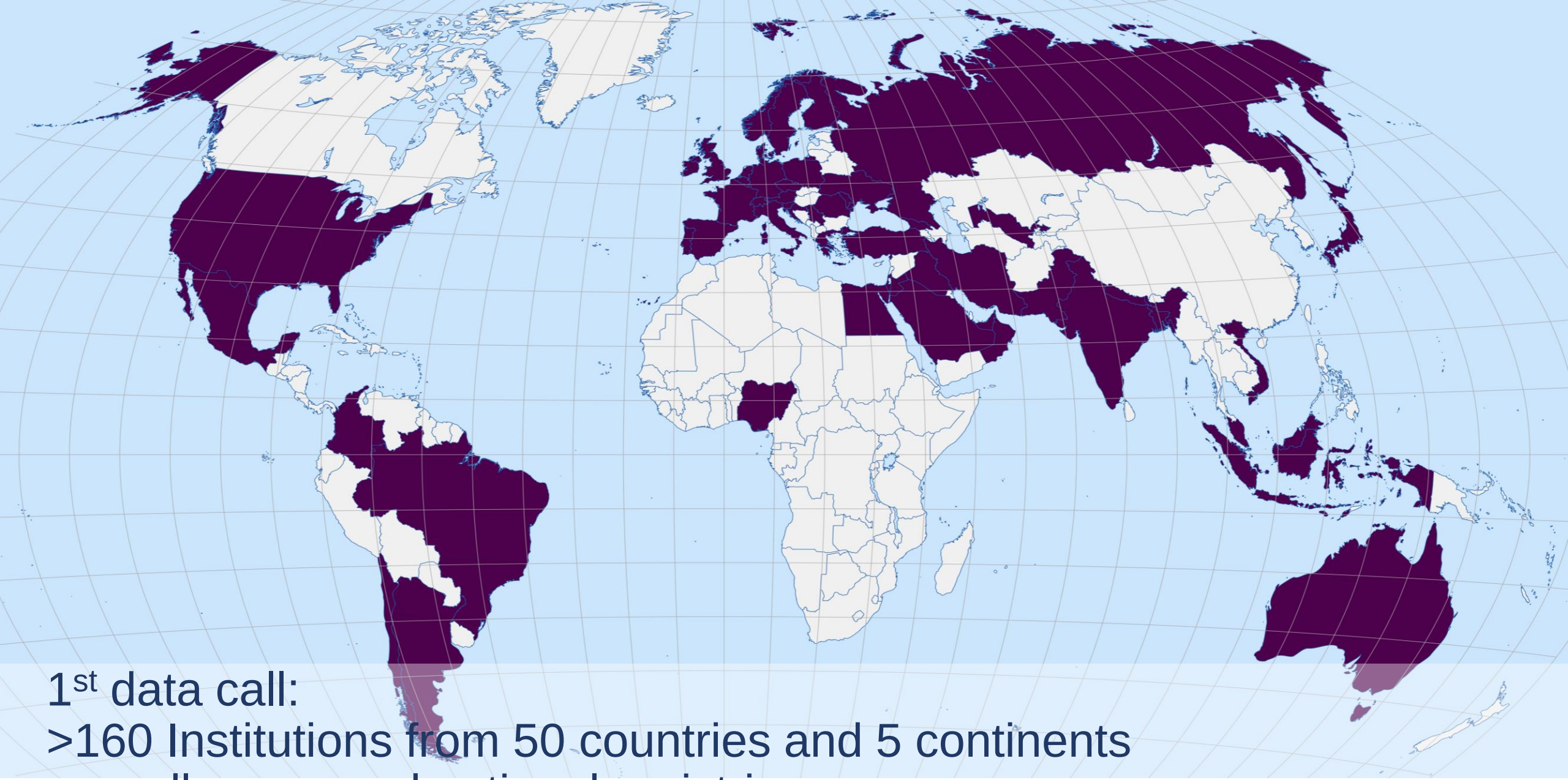
Group authorship in all key publications

Visibility of the spine service, Benchmarking

Network with leading international spine units

Understanding practice variation across countries

Website: www.eurospine.org/spineatlas Email: spineatlas@eurospine.org



1st data call:
>160 Institutions from 50 countries and 5 continents
as well as several national registries

(31.1.2025)

1. EUROSPINE updates: Intraop Neuromonitoring

- The International Society of Intraoperative Neurophysiology (ISIN) has developed a case report form to examine the individual protocols of IONM and their value for patient safety. In collaboration with EUROSPINE, this new IONM form has been implemented on the international Spine Tango platform in January 2025 and can now be completed together with the surgery form.

- Spine Tango App is being developed and shall be presented in Copenhagen.

2. International Spine Registries (ISR) updates

- The International Spine Registries (ISR) have shared the policy papers with all Spine Registries
- Discussions on the implications of using ODI PROMs are ongoing
- Harmonisation of information is essential in all discussions
- The Agenda Setting Group to meet next month to discuss next steps
- Definitions of data items for MDS are to be provided
- Ability to provide a centralised implant library

3a. Implant catalogue: Access for national and regional spine registries

1. Principles of a single global spine implant repository for registry use

2. Benefits:
   - Single source of the truth
   - Single location for adding device data for wider sharing amongst registries
   - Harmonisation on registry analysis outputs, including comparator (benchmark) groups

3. Considerations:
   - Collaboration and access by other third parties, such as EUDAMED, to avoid duplication

4. Terms of Use

3b. Implant catalogue: Proposed registry sharing models

1. Registry decides to adopt the agreed classification specification and manage a catalogue within its own infrastructure.

2. Registry already records Device UDI-DI/PI and would like the classification (attribute) data to support harmonised analysis. A POC was completed on this option and was succesfull.
    - Device matching service – matched devices return reference data to registry (type of device, material, etc)
    - Unmatched devices are followed up by EUROSPINE, with local registry support and added to the catalogue. They then match next time the registry takes the service.

3. Registry does not capture UDI-DI/PI
    - Possibility for registry to undertake a look-up to EUROSPINE implant catalogue to record devices against surgical records (API web service).
    - Registry will require development within their own applications to have a barcode search functionality which connects to EUROSPINE.

4. Relevant Change Requests Under Review

PROMs analysis changes

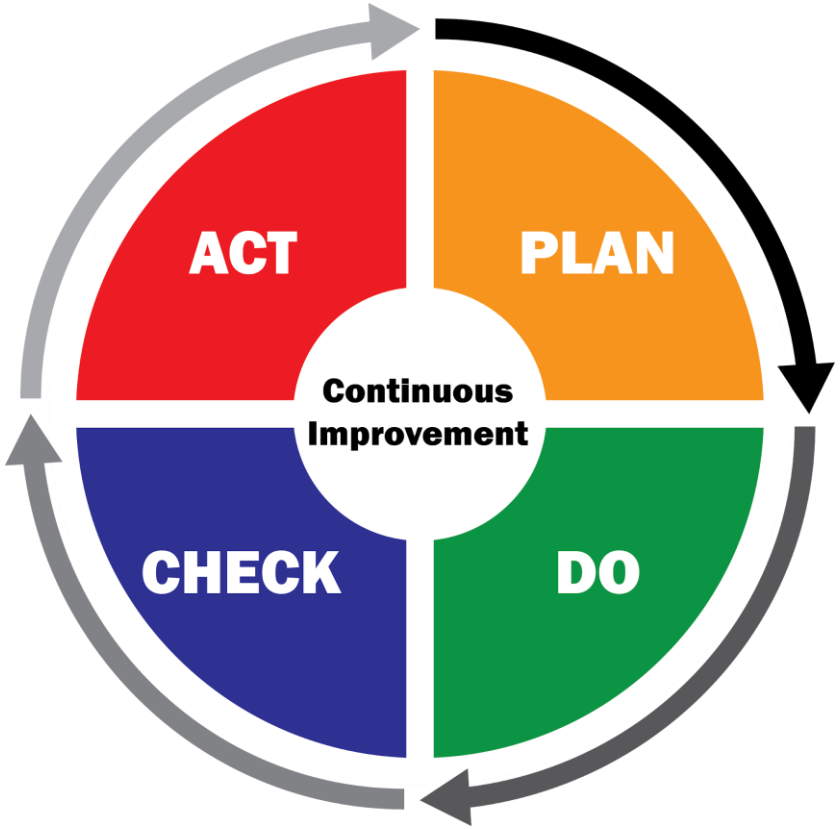
- Provide mean scores by post operative intervals, e.g. 6M, 1 year, 2 year, etc.
  Due in November-25

Add Kaplan Meier (KM) Survivorship Analysis

- Subject to on-going internal discussion, may be released in November-25, TBC
- **Discussion** – relevance to spine? Literature suggests reoperation rates?

Capturing Fusion Assessment outcomes within the registry

- EUROSPINE propose on discussing form changes to the “Surgery Follow-up Form” internally and presenting proposal back to MedTech



4. Relevant Change Requests Under Review

Capturing Fusion Assessment outcomes within the registry

Today (based on the principle of minimum efforts)

- The surgeon can select "non-union" as a complication on the follow-up form (= failure of bone consolidation at least 6 months after surgery). Otherwise, bony consolidation is assumed. Thus, the rates of (assumed) fusion are assessed by identifying cases with non-union.
- Question 1: Is this measure sufficient?
- If not --> Question 2: How should fusion/non-fusion shall be documented (with minimum effort)?
- Depending on how focused/granular the documentation of fusion rates should be, it may be reasonable to do this only for a selected, limited patient population as a nested study.

5. Refining comparator groups

1. Implant database gap population on-going. Thank you All!

2. Please provide missing / new to market device data to EUROSPINE, including barcode details Supports..
   - Hospital data entry
   - Device traceability / MedTech reporting services
   - Third party registry use of implant database to record UDI-DI

3. Feedback from industry on requested comparator group changes invited to be submitted before 10th of April. EUROSPINE convening Working Group for consideration and feasibility. Email invitation to follow

Industry Feedback – Q&A