Clinical Trials Information System Webinar: Last Year of Transition

Sponsor's Perspective

Martin O'Kane

Regional Head of EU Regulatory Affairs Policy & Liaison, Novartis, representing EFPIA

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One key message…

The entire research community has a responsibility to accomplish timely transition of clinical trials to ensure that patients continue to have uninterrupted access to innovative therapies and that Europe remains an attractive region for the conduct of clinical trials

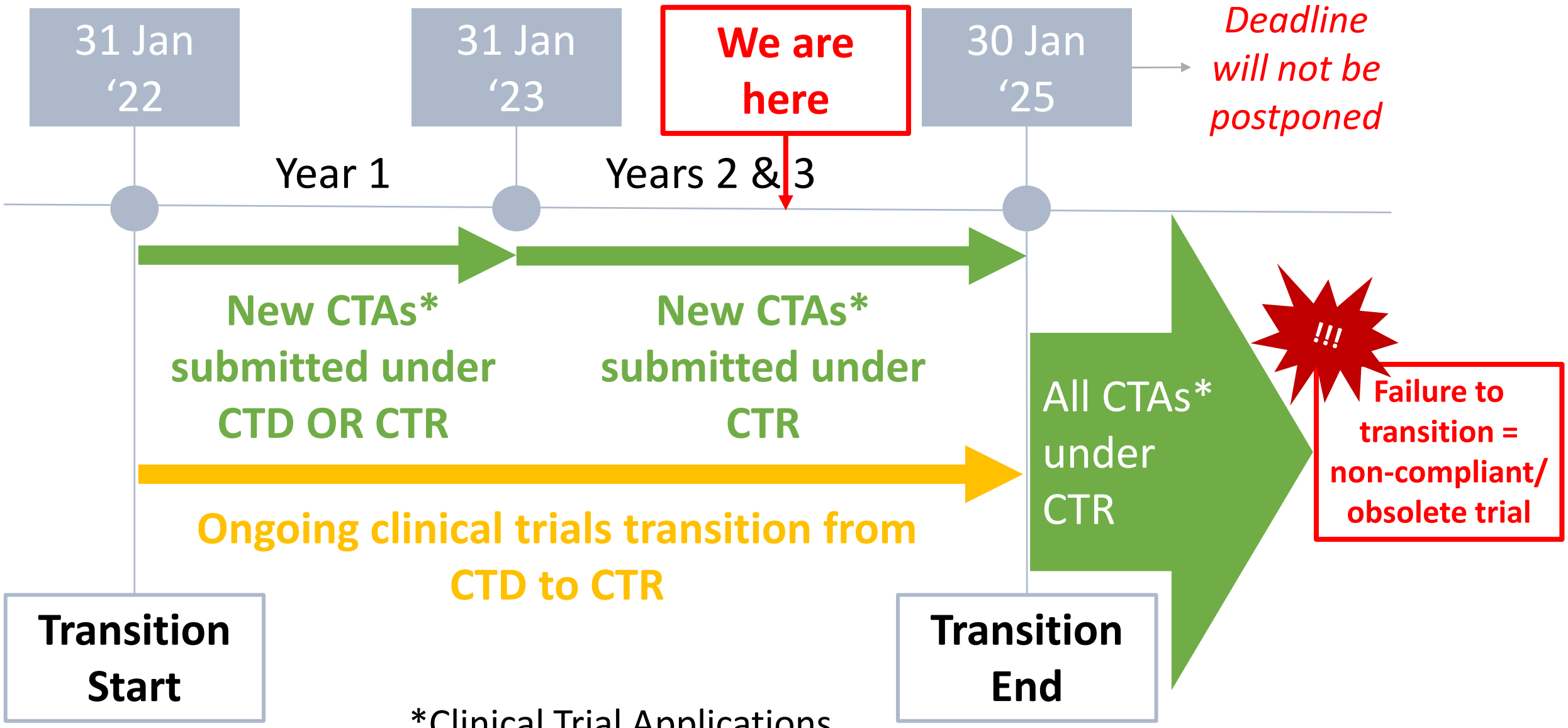
Our Vision

- Our vision is to **re-establish a highly competitive environment for global clinical trials in Europe**, one that facilitates **faster, smarter, and more patient-centric trials**.
- We are dedicated to working together to close the gap between Europe and other regions and reversing the erosion of innovation.
- We envision a future where Europe is at the forefront of pioneering research, improving healthcare outcomes, and enriching the lives of patients worldwide.




Timely and efficient transition of trials from CTD to CTR is key to progress this vision

Less than 1 year left to transition trials



*Clinical Trial Applications

Industry is committed to ensure timely transition

Many companies have a dedicated project plan in place

Trade associations are sharing experience and best practices

Data on transition status is being collected on a regular basis by a cross-trade group

Issues and challenges are escalated to regulators

A collaborative effort to achieve transition

Industry effort across small & large companies, commercial and non-commercial sponsors – a similar goal

- 2021: EFPIA Transition group created to raise concerns around practical application of transition provisions ahead of transition period start
- 2023: Cross-Trade Association Transition Group created

Advocacy activities – a dynamic and productive few years

- 4 position papers/letters to European Commission, CTCG & EMA highlighting proposals for more flexible and pragmatic transition approach
- Collection of transition numbers & case studies to share with authorities/regulators
- Participation in workshops, EMA trainings and conferences

A collaborative effort between sponsors and authorities/regulators

- Frequent interactions with CTCG Co-Chairs, European Commission, EMA to find pragmatic solutions
- Local conversations between national trade associations & Health Authorities
- Willingness to include Ethics Committees in the conversations

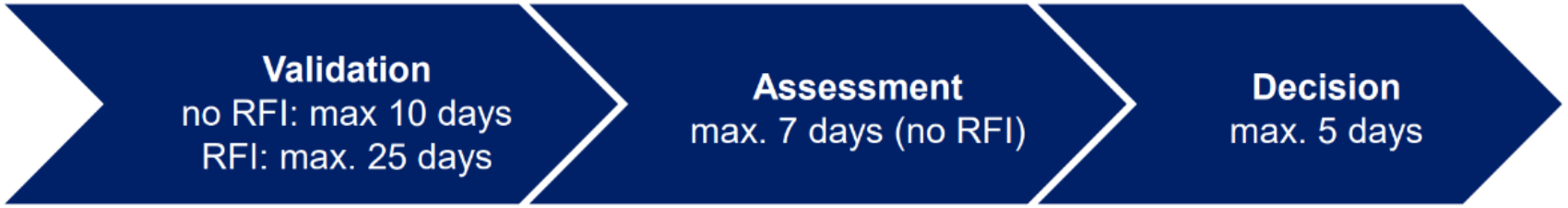
Practical considerations

Pre-transition

- Do I need to transition this trial?
- Do I need to complete an amendment under CTD before my trial can transition?
- Should I redact my documentation according to the new transparency rules now?
- How do I manage my non-IMPs (AxMPs under CTR)?
- What about my trial that is on temporary halt?
- How do I manage my safety extension study when treatment has stopped?
- How will I manage IVDs in the clinical trial?
- Is my product being used in an investigator-initiated trial?

Practical considerations

During transition



- Can I expect a predictable 22-day (or 37 day) approval?
- Will I receive unexpected RFIs during validation stage?
- Will I receive unexpected RFIs during assessment phase?

Practical considerations

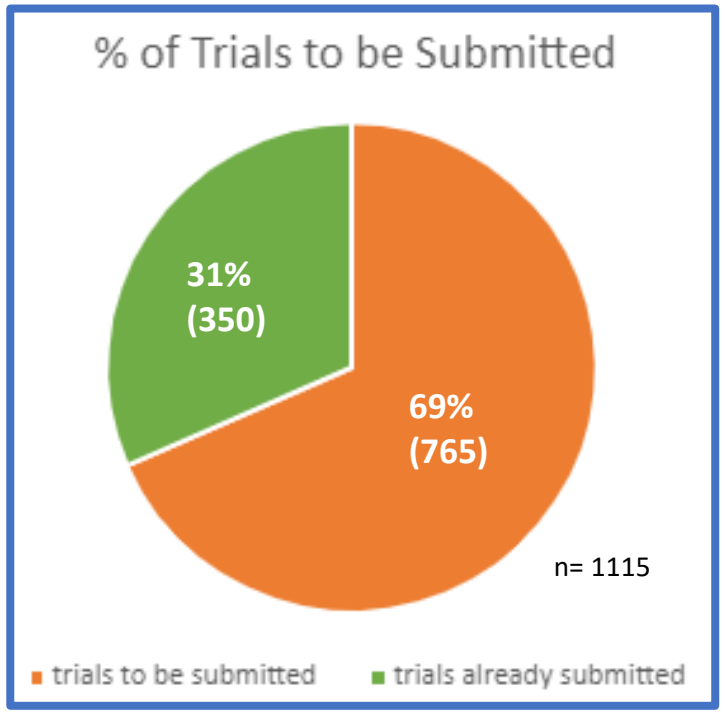
Post transition

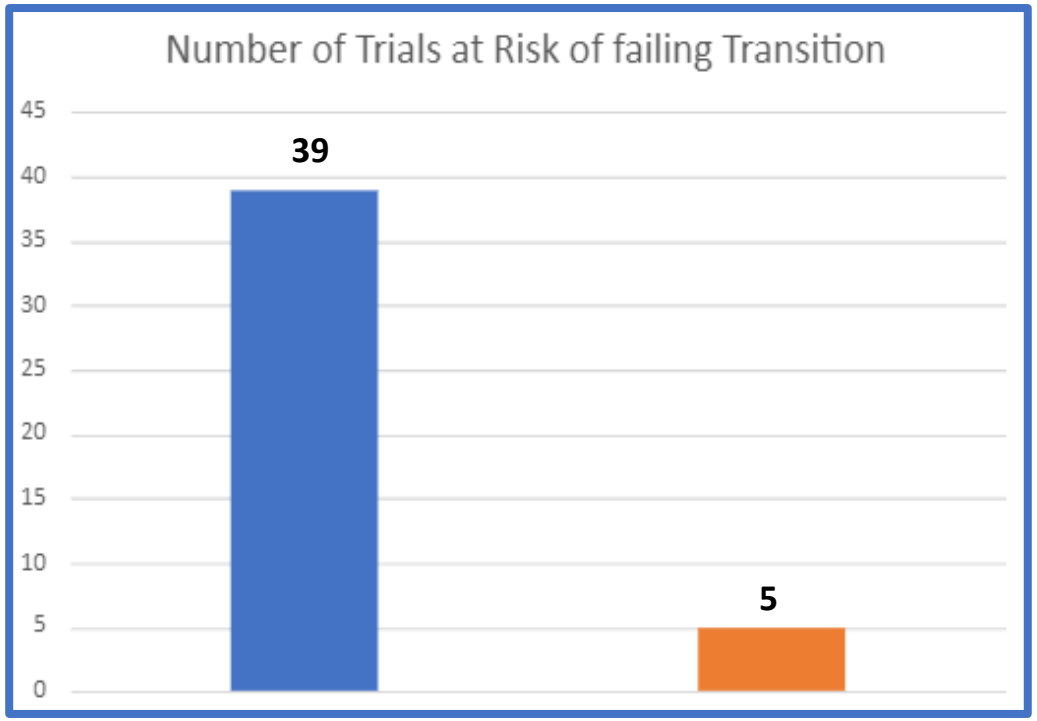
- Do I need to request this trial to be categorised as ‘low intervention’?
- When is the best time to submit my SM?
- Will I need to include an additional MS soon?
- Am I ready for the new transparency rules?
- Have I (re)classified my IMPs and AxMPs correctly? (and considered CTR safety reporting requirements for AxMPs)

EU-CTR Transition in Numbers

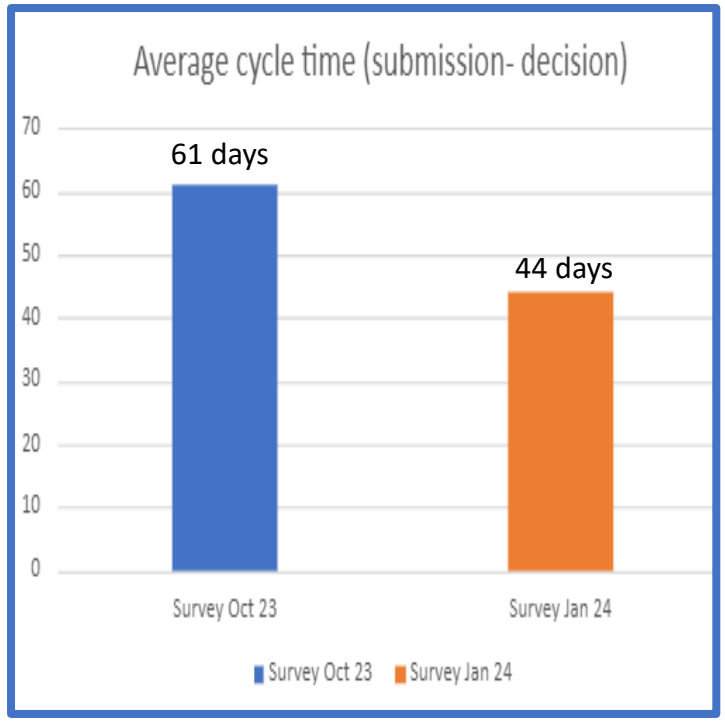
Cross Trade organization survey data from 29 sponsor companies

Number of Trials which are at risk to fail the transition deadline of 30 January 2025.





Survey Oct. 2023 Survey Jan.2024



Range <7 to >96 days

Remaining challenges for the transition of all trials by 30 January 2025

- **Silent period to transition within study lifecycle cannot be found** – Trials at risk of failing transition may need to be rescued
- **Additional documentation requests in transition application** – even though new Annex to guidance introduced to provide transparency on documents per MS for Part II
- **Transition review timelines predictability** – we request that Member States follow the 22-day review timeline and not 'run out the clock'.
- **Varying understanding of how transition is supposed to operate** – we welcome events like today!
- **CTIS issues**– Members have experienced IT issues outside of their control when trying to transition studies

The entire research community has a responsibility to accomplish timely transition of clinical trials to ensure that patients continue to have uninterrupted access to innovative therapies and that Europe remains an attractive region for the conduct of clinical trials

Conclusion

- Sponsors are committed to submitting transition applications in a timely manner
- Sponsors welcome the strong collaboration with CTCG, the European Commission & EMA, who have been open and have implemented flexible and pragmatic approaches to transition; these need to be understood and applied **by all parties**
- **In the next 7 months, let's collectively make sure the remaining transition applications are concluded and take necessary creative steps for trials at risk of failing transition**

THANK YOU