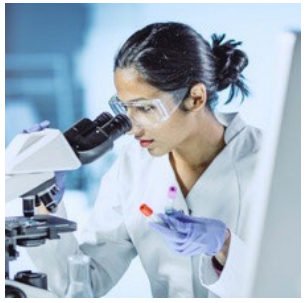
European Federation of Pharmaceutical Industries and Associations

Clinical Trials Information System Information Day Webinar
Feedback on progress on CTIS and CTCG/CTAG guidance: Industry Perspective





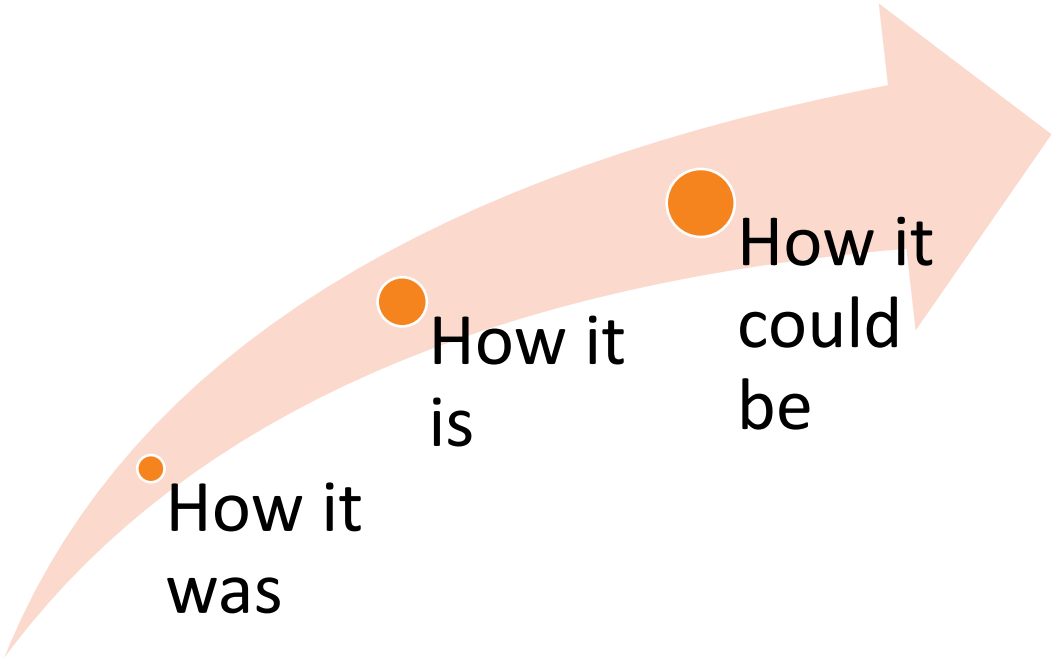



Martin O'Kane, EFPIA

22 May 2025

Agenda

- **Change of Sponsor**
- **Cover Letter Template**
- **IMPD-Q and Cross Reference**
- **AxMP Update**
- **Transparency**
- **Conclusion**



Change of Sponsor

How it was

How it is

How it could be

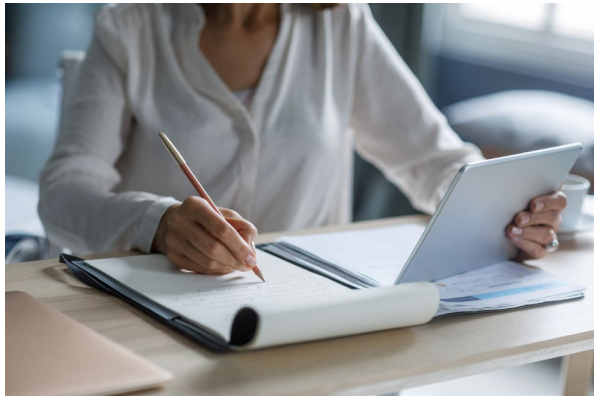
Extremely difficult!
-scheduling
-slow process

Good example of progress!
Both CTIS and guidance

Core Process works
Streamlining of associated changes (labels etc) would be useful

Expedited model used for sponsor change applied to other areas e.g. SAP updates, change of PI

Cover letter



How it was

Clear requirements
Limited structure
Potential for RFIs

How it is

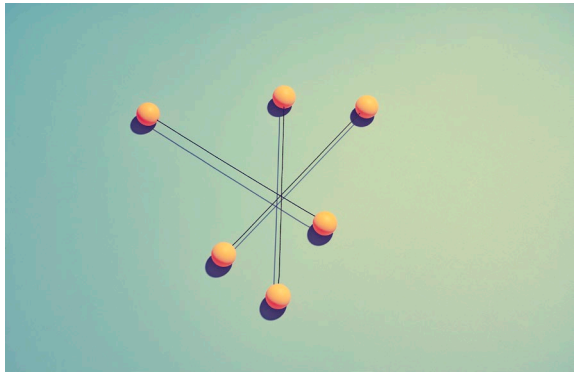
Clear requirements and template
-Change management issues
-Duplication for SM cover letter
- ‘backdoor’ for new requirements

How it could be

CTIS (partially) generates CL
-esp for SMs

--metrics on RFI reduction

IMPD-Q and Cross Reference



How it was

No ability to securely share IMPD-Q
Investigator initiated studies impacted

How it is

IMPD-Q only submission
-interim solution (now perm)

X-referral possible
BUT – only overlapping CMS

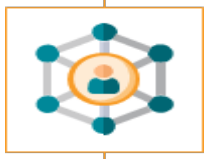
How it could be

X-reference visibility for all CMS
-- with reliance

Core Dossier Model
"quality assessor MS" (qaMS)
IMPD-Q assessed for all of EU
Updated and x-referenced over development

Core Dossier /Product based submission: Impact for sponsors and Health Authorities

More efficient use of resources: avoid multiple submissions and reviews of same documents → Simplification



Can leverage the already established saMS concept and use for quality assessment (qaMS)

Enables a life-cycle approach to IMPs in line with Dynamic Regulatory Assessment and centralises document / knowledge management

Enables reliance and faster review/approval processes. Would support academic sponsors

Enables more harmonised global submission process

AxMPs

How it was

New concept replacing NIMP

How it is

Recommendation update in 2024
-some clarification but residual confusion in areas
- Guidance fragmented

Consultation on revision of CTCG recommendation ☺

How it could be

Anticipating new CTCG recommendations

Review and update of Q&A Annexes

Transparency

How it was

Interpretation resulted in complex and burdensome 'transparency' that was not useful for patients, public or HCPs

How it is

Simplified and clear rules
-updates to CTIS and guidance
- Easier to find trials

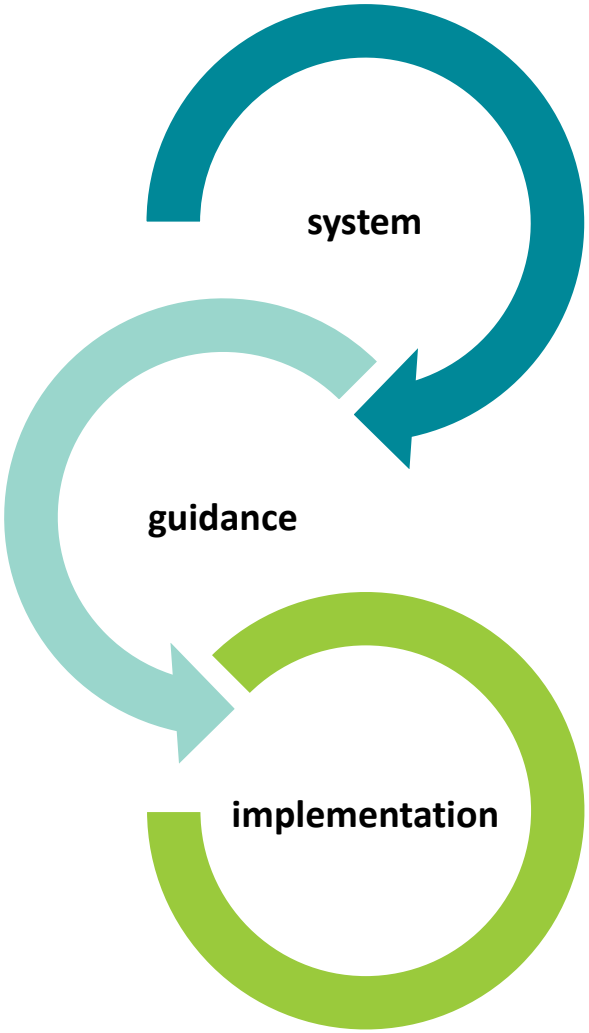
Trial Map launched

How it could be

CTIS and EHRs linked to identify suitable trials for patients
-supports research along care pathway
-supports recruitment

Summary

- Demonstrable Progress has been made to both CTIS and Guidance Documentation ☺...
- Continue (accelerate) flexibility and simplification of CTIS along with consolidated guidance and pragmatic implementation
- Apply learnings to other areas e.g. modification types for PI change or Statistical Analysis updates
- **Consider the future today:**
  - Interoperability and convergence of pathways
  - Learn from use of CTIS in COMBINE pilot
  - Core dossier model (IMPD-Q/IB) to facilitate-referral and reliance



efpia

European Federation of Pharmaceutical Industries and Associations

Thank you