TMF Completeness

- A Major Component of Inspection Ready TMF

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Meet the Speaker

Sagar Sutar

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Organization: Emmes Group

I’m Senior Director - Global Head TMF Operations at Emmes Group and I’m based out of India. I have over 16 years of experience in TMF Operations that includes sponsor as well as CRO perspectives. Apart from process set-up, implementation, and improvement, I have worked extensively on Robotic Process Automation (RPA), system integrations and laid the foundation of AI/ML in TMF space. Understanding eTMF applications (such as Wingspan and Veeva Vault) technically and configuring them to make the best of the technology is one of my strong suits.

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

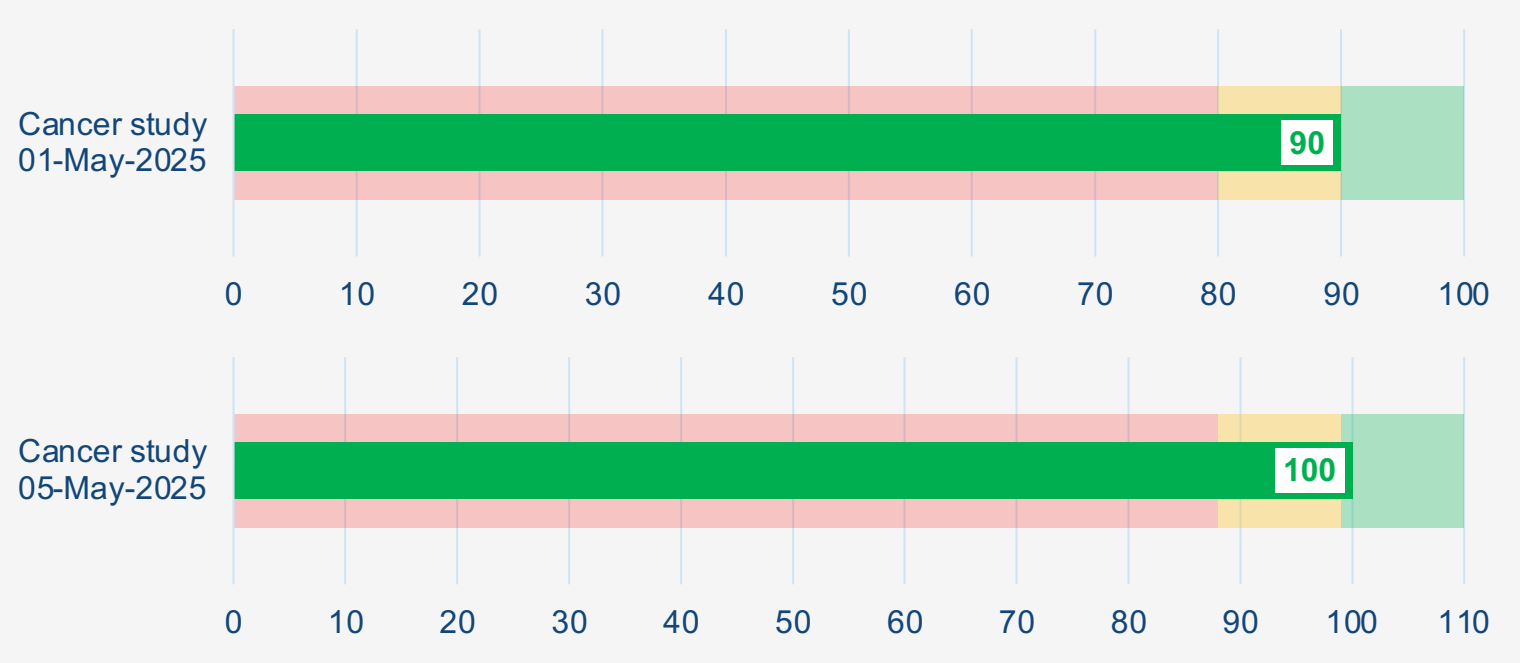
Inspection Ready TMF

- TMF Completeness – A major component
- Role of eTMF application
- Build process around the application
- The right resources

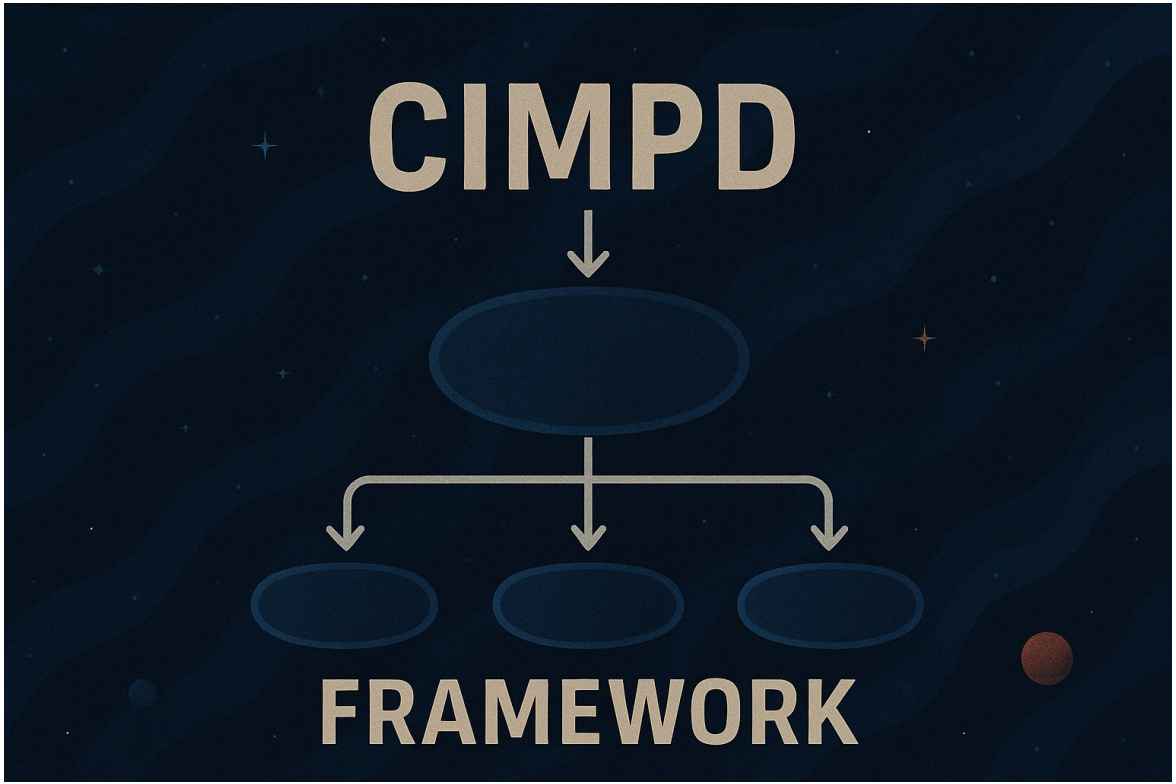
Agenda

1. The TMF Completeness assessment hierarchy
2. CIMPD Framework
3. Process flow impact

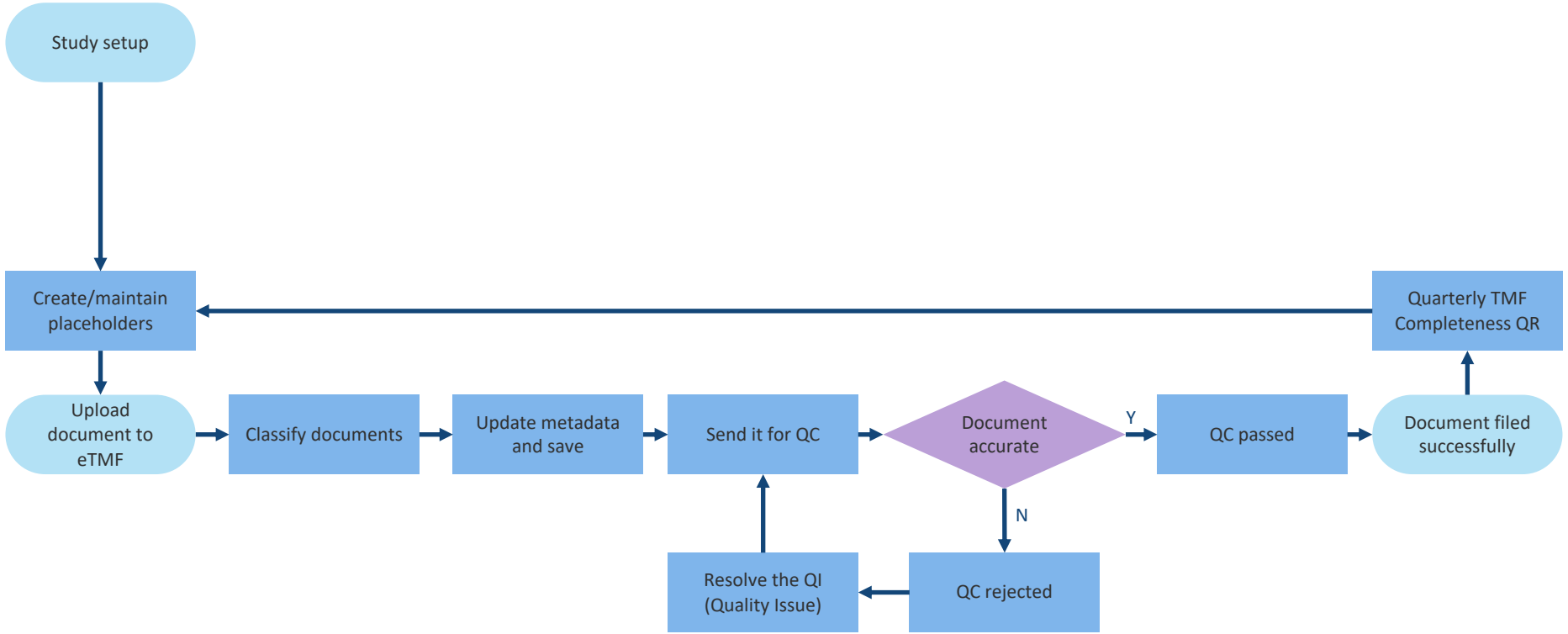
The assessment hierarchy



CIMPD Framework



Process flow impact



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Thank You!