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KEY TO EU-CTIS SUCCESS: PLAN, PREPARE, PARTICIPATE

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PP10

Introduction:

All new clinical trials within the European Union (EU) must now be uploaded to the Clinical Trial Information System (CTIS). This requirement poses a significant challenge for many sponsors. They must interpret the regulations accurately and act swiftly to meet stringent regulatory timelines. To ensure compliance with the CTIS, sponsors are managing multiple responsibilities and staying updated with the ever-changing EMA guidance, like the recent reintroduction of Policy 0070, revised transparency rules for EU-CTIS.

This poster delves into how sponsors can align their resources effectively. It emphasizes the importance of gathering a team of knowledgeable subject matter experts and meeting additional submission criteria, including translating clinical documents.

The poster also highlights how a seasoned CRO can offer invaluable advice on submission planning, enhancing process efficiency, and liaising with the EMA. This guidance ensures the smooth integration of teams for successful submissions and adeptly manages requests for information throughout the clinical trials' CTIS life cycle.

Methodology:

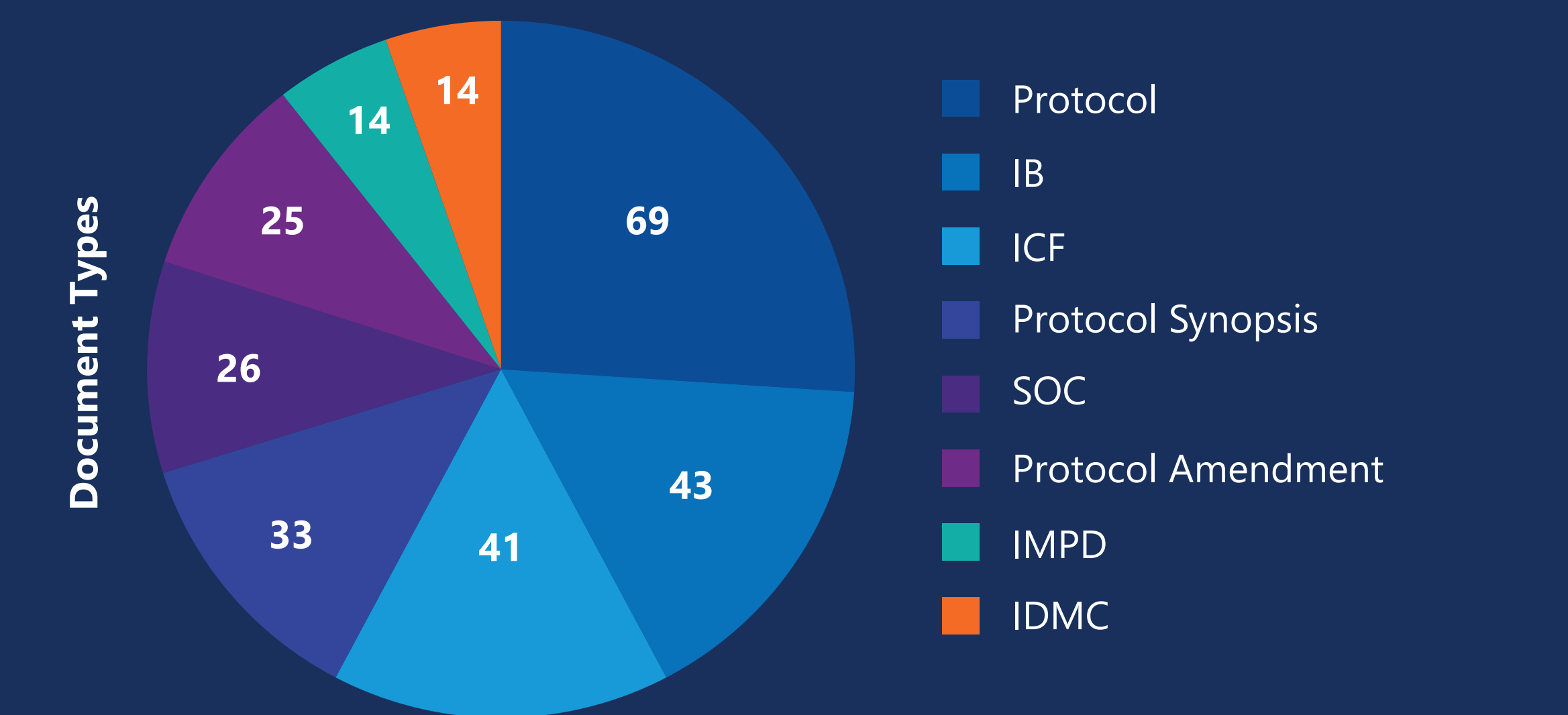
MMS has been instrumental in assisting a diverse range of sponsors with their CTIS submission process. These sponsors bring a unique set of requests in terms of type of documents, complexity and team expectations. We delved into data from seven handpicked sponsors collected over a time frame of 11 months (Jan 2023-Nov 2023), providing a comprehensive overview of four key aspects of the EU-CTIS submission process: Planning, Stakeholder alignment, Project Management and Consulting Support.

Planning & Forecasting	Stakeholder Alignment	Project Management	Consulting Support
Transition Vs New Trials	Cross-functional Teams	Turn Around Time	SOP/WP Review
Types of Documents	Vendors	Submission Timeline	CCI workshop
Types of Documents	Regulatory Agency (EMA)	Query - RFI Handling	Regulation
Identify stakeholders	Identify and Validate CCI	Best Practices	Transparency Review (Lean)

Results:

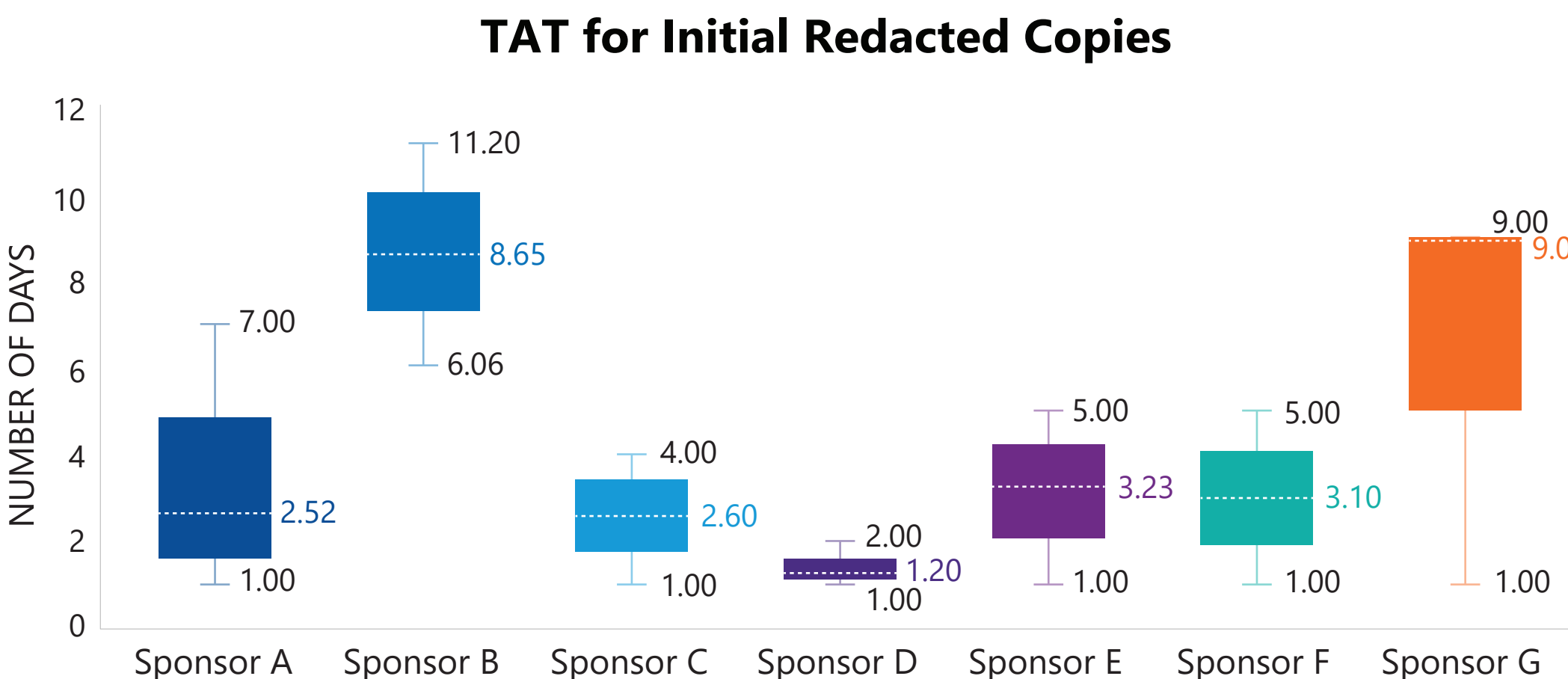
A document pool of over 250 documents were evaluated to understand the document complexity, type of requests and TAT for EU-CTIS redaction.

Type of Redacted Documents for CTA: From the pool of requests 26% were for protocols, while IB accounted for 16% , ICFs (15%), and IMPD (5%). Around 30 distinct plain language protocol synopses were written and redacted for the CTAs. Figure 1



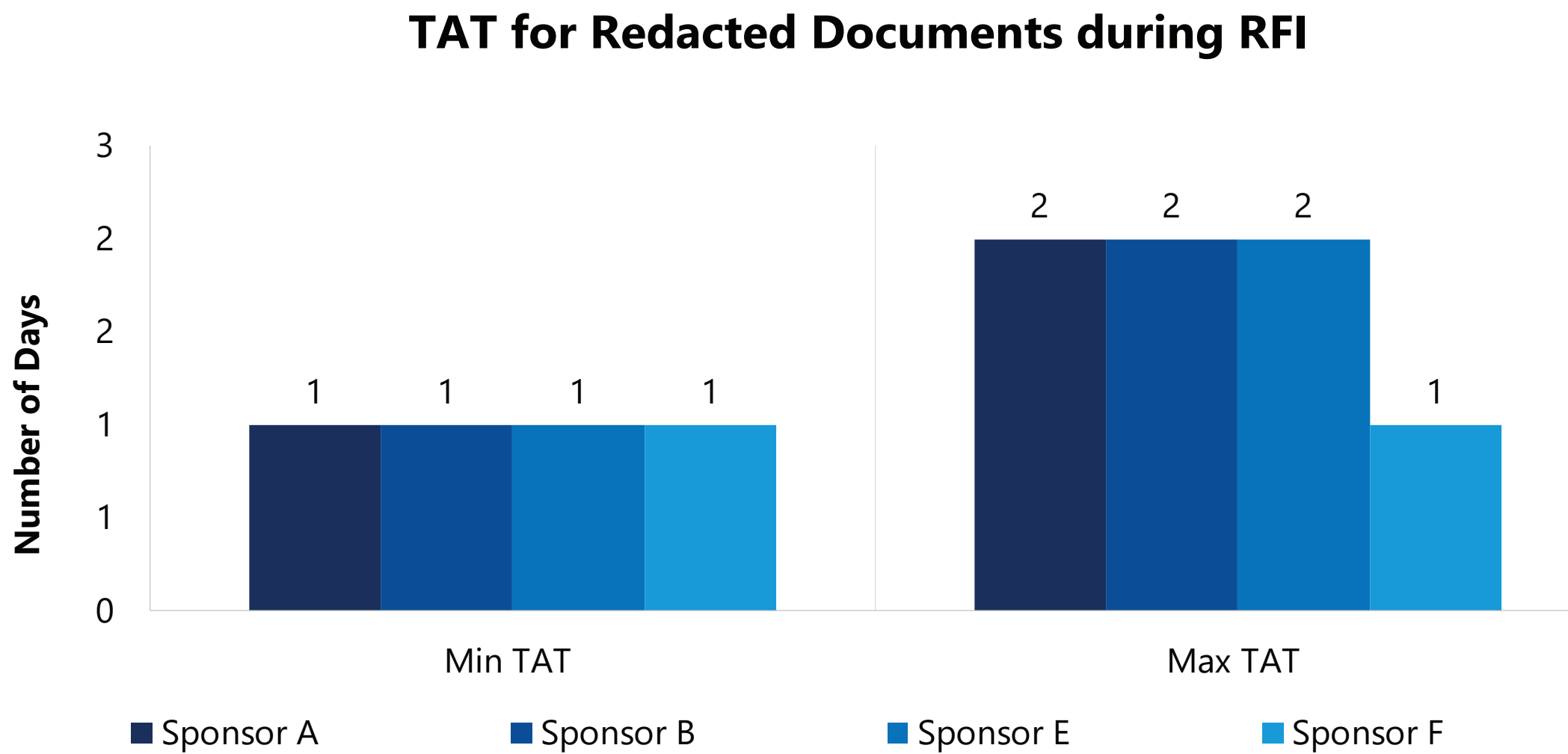
TAT for Initial Redacted Copies:

An average turn-around of 5 days was achieved for preparing initial redacted copies of 250 documents. Figure 2



TAT for Redacted Documents during RFI:

Redaction of 37 documents for RFI stages was expedited in majority of cases as seen by a quick turn-around of one day (Maximum TAT – 2 days). Figure 3



Discussion

Our experience suggests that mandatory implementation of EU-CTIS for new trials since Jan 2023 prepared the sponsors to plan CTAs proactively. Factors such as redaction tools, technology, deferrals, timelines, request for information queries, protecting CCI and constant revisions in the transparency rules added further complexity to set the teams for success. A typical EU-CTIS submission necessitates efficient collaboration of various departments like medical affairs, regulatory writing, regulatory affairs, transparency, clinical operations, legal representative, vendors conducting the clinical trials, translation partner.

Plan	Planning Tracker	Compliance Tracker	Meeting Planners	Stakeholders Involved
Stakeholder Alignment	RACI for Study team/Vendor	CCI Validation	Translation/ Local CRO	Escalation Mechanisms
Project Management	New Deliverables/ Updates	RFI Triage	Redaction	Translation
Consulting Support	Process Documents and Templates	CCI Workshop	Lean Authoring Workshop	Cross-functional collaboration

Roadblocks	Ensure Path to Success
Plan	- Planning tracker with assessment of transition vs new trials, in-scope documents - Compliance tracker with timelines to efficiently manage work. - Kick off meetings for every study to address specific questions regarding volumes, types, and scope of redaction. - Monthly meetings between partner and sponsor for forecasting of new work - Triage meetings to handle RFIs
Stakeholders	- CCI identification and validation to ensure consistency among documents. - Comment resolution meetings to resolve queries e.g., CCI justifications. - Coordination with translation partner for Part II non-English documents - Establish RACI between partner and sponsor to set up roles, responsibilities, and expectations
Timelines and metrics	- Dedicated Project Leads, point of contacts for cross-functional lines. - Quick turn-around for document redaction for initial copies (e.g., 5-10 days) - Triage for RFI handling to meet expedited timelines (e.g., 24-48 hours) - Cross-functional communication to increase efficiency. - Strong Key Performance Indicators e.g., sigma scores for redaction
Trainings and Templates	- Implement/revise SOP/WP to ensure EU-CTIS compliance. - Set new templates/ update document templates to incorporate EU-CTR guidance. - Conduct learning sessions for teams: CCI review, deferrals, and lean authoring best practices

Conclusion:

We identified common pitfalls that can disrupt EU-CTIS submissions as process challenges, CCI justifications, expedited timelines and managing multiple stakeholders. Our recommendations after the successful submission of over 100 applications for EU-CTIS portal are to plan, prepare your teams and proactive participation to register the CTAs and report the results.

Plan	- Partnership among all stakeholders - Pre-submission activities 3 months ahead - Roles and responsibilities
Prepare	- Subject matter experts for CCI review - Seamless handoff of submission documents - Smooth interaction with translation partner - Stakeholders for RFI timelines
Participate	- To resolve questions quickly, Document every decision! - To tie up cross-functional departments

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- MMS Blog: EMA Revised Transparency Rules Eliminate the Deferral Mechanism for Clinical Trial Data Publication

<https://www.mmsholdings.com/ema-clinical-trial-transparency-rules/>

No potential competing interest was reported by the authors.

CCI- Commercially Confidential Information; CRO- Contract Research Organization; CTA- Clinical Trial Application; EMA- European Medicines Agency; EUCTIS- European Union Clinical Trial Information System; IB- Investigator Brochure; ICF- Informed consent form; IDMCIndependent Data Monitoring Committee; IMPD- Investigational Medicinal Product Dossier; RACI- Responsible, accountable, consulted, and informed; RFI- Request for Information; SOC- Summary of changes; SOP- Standard Operating Procedure; TAT- Turn Around Time and WPWork Practices

