CTIS Progress: Sponsors’ Perspective

CTIS InfoDay – 17 June 2026

Member State (MS) Lack of Alignment

CTR Alignment Challenges

- Alignment to CTR requirements remains inconsistent.
- Evolved positively, but pushing back on MS/EC requests is difficult.

Specific Hurdles

- Requests for non-required patient-facing documents.
- Inefficient payment info requests via CTIS (e.g., CZ, SK).
- Diverging expectations for PI and site documents.

Predictability and Frequent Updates

Predictability

- Greater consistency across MSCs remains essential.
- Continued variability in interpretations and practices creates uncertainty and delays operational readiness.

Change Management

- Numerous Q&A updates clarify CTR but shift interpretation.
- Multiple guidance sources (Sponsor Handbook, EMA Q&A, CTCG) complicate alignment for users.

System Limitations and CTR Timelines

CTIS & CTR Limitations

- Limitation on Parallel Substantial Modification (SM) submission is restricting CTR benefits.
- Upcoming BioTech Act (BTA) will bring highly welcome improvements.

Trial Timelines

- Current CTR timelines are longer than in most other regions, impacting EU attractiveness.
- Adopting FAST-EU timelines ahead of BTA implementation would be highly appreciated.

Transparency Rules

Rule Improvements

- Previous transparency rules caused extra work to ensure CCI and PPD protection.
- New rules implemented on 18 June 2024 are a significant and high improvement.

Remaining Hurdles

- xEVMPD information flows directly into the product section.
- Workarounds are still needed to prevent dose CCI from becoming public.

Assessment Timing (Part I & II)

Part II Before Part I

- Issuing Part II conclusions before Part I assessment causes trial start delays.
- Part I RFIs often imply changes that heavily impact Part II docs (e.g., ICF).

Consistent Application

- Best practice recommendations to avoid early Part II conclusions are not consistently applied.
- Substantial changes force sponsors to submit Part II SMs before study start.

Document and User Management

Document Limitations

- Current CTIS limitations prevent downloading clear lists of submitted or approved documents.
- Relying on workarounds makes proper TMF management cumbersome.

Future Improvements

- Announced updates for sortable document lists will be highly beneficial.
- Sponsors request the ability to download full lists of users and their respective access.

Submission Improvements

Core Dossier & BTA

- The Core Dossier planned in the BTA adds valuable flexibility and saves time.
- Sponsors would welcome testing the Core Dossier as a pilot before full implementation.

Workarounds & Synergy

- The Article 11 workaround keeps MS in submission via mock Part II docs.
- Future combined submissions (CTR + IVDR/MDR) will align decision timelines and accelerate starts.

RMS Empowerment & Approvals

RMS Empowerment

- RMS should manage non-critical issues without waiting for MSC feedback. This is clarified in BTA but already possible under current text.
- Avoids unnecessary timeline extensions (e.g., standalone payment RFIs delaying decisions by 14 days).

Conditional Approvals

- Conditional approvals cannot be resolved fast, delaying First Patient In (FPI).
- Sponsors request fast approval systems for modifications required to resolve conditions.

Ongoing Initiatives

FAST-EU & Timelines

- FAST-EU trains stakeholders on BTA timelines; expected to evolve further.
- Accelerated timeline assessments for mono-national studies are highly appreciated and used.

Sponsor Resources

- CTIS Sponsor Handbook update improves clarity by centralizing training info.
- Releasing Part II assessments only after Part I (BTA) is a major systemic improvement.