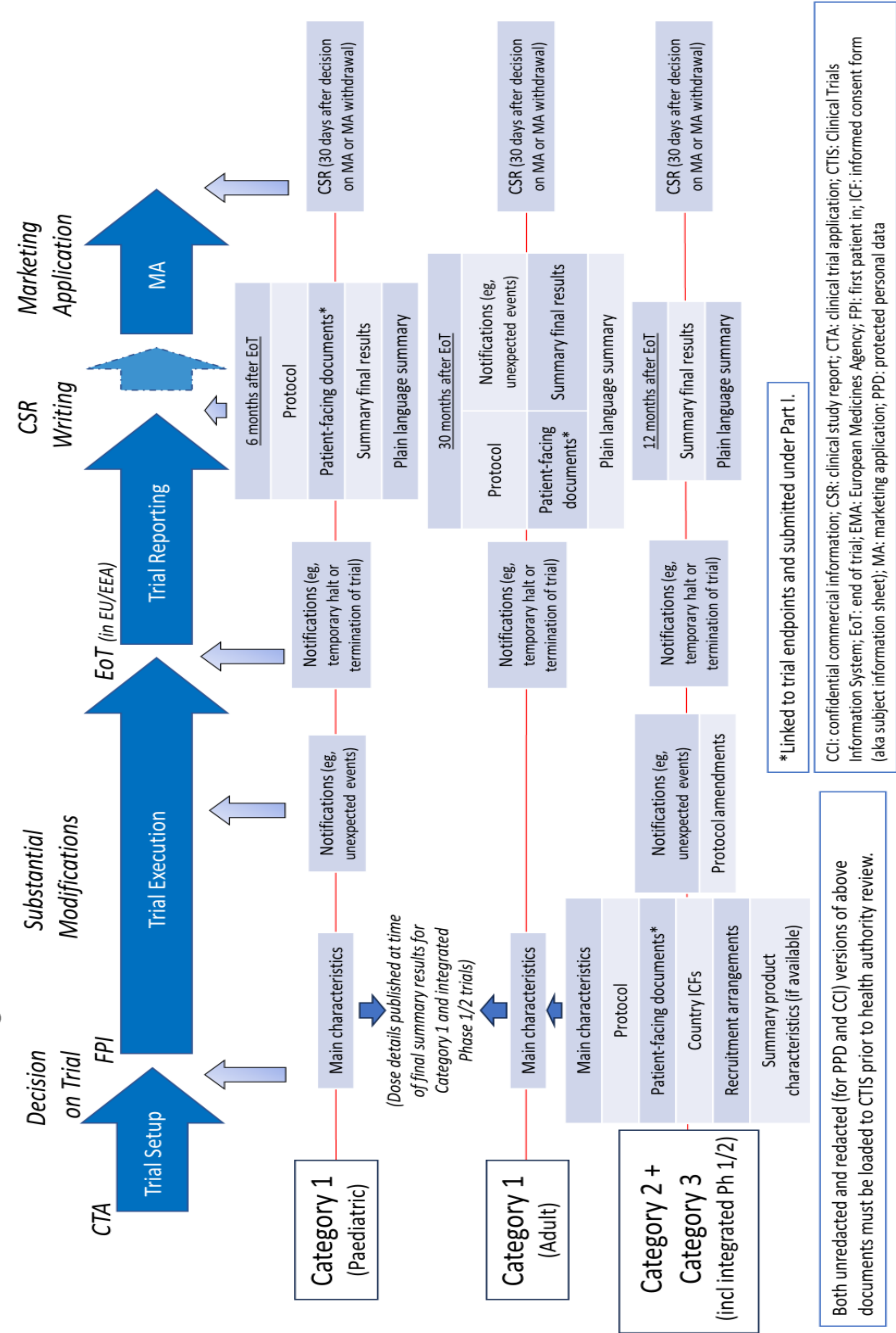


PP01: Transparency Requirements for EU Clinical Trials Regulation No 536/2014: An Update

Authors: PHUSE EU CTR Implementation Working Group
Email: gallan4@its.jnj.com

The [EU Clinical Trials Regulation](#) has been operational since 31 January 2022 and is now in the 3rd year of a 3-year transition period. The Regulation covers interventional clinical trials of investigational medicinal products for human use and impacts all aspects of trial setup, operation, and reporting in the EU/EEA. Anticipated benefits of the Regulation for the Agency, sponsors, patients, and the public include faster, more efficient trial setup; higher safety standards; and greater insight into trial management and outcome. Publication of information about trials is enhanced, with earlier publication of protocols and other study documents and a requirement to publish plain language summaries. The aim of this poster is to summarise the transparency requirements of the Regulation after more than 2 years of operation.

Timing of Publication of Clinical Trial Information and Documents



	Timing	Publication Scope	Publication Timing*	Publication Deferral Option	Redaction of CCI	Redaction of PPD
Before (former rules)	Prior to 5 Oct '23	Most trial documents	On decision unless deferred	Available for subset of docs; 1-7 years of deferral	Available but discouraged by EMA w/ deferral	Sponsor responsibility
Now (interim period)	5 Oct '23 to 17 Jun '24	Protocol, patient-facing & recruitment docs, final results**	Six (paediatric) or 30 mo (adult) post-EoT for Cat 1; on decision for Cats 2 & 3, unless deferred**	Available but discouraged by EMA; deferral to time of next trial modification post-17 June	Encouraged by EMA as alternative to deferral	Unchanged
Future (implementation in CTIS)	18 Jun '24 and onward	Same as interim	Same as interim (but no deferral)	Not available	Only option to protect CCI	Unchanged

*Excluding results documents; **see other panel for details
Cat=category, mo=month

Category 1	Category 2	Category 3
Pharmaceutical development; ie, Phase 1, bioequivalence and bioavailability trials and bio-similarity trials	Therapeutic, exploratory, and confirmatory trials; ie, Phase 2 and 3 trials (essentially those that are neither Category 1 nor Category 3)	Therapeutic use trials; ie, Phase 4 and low-intervention trials

Tips for your organization

- Understand latest guidance.
- Phase 2, Phase 3, Phase 4, and integrated trial protocols and patient-facing documents to be published at time of decision.
- In-scope documents for historical trials to be published when there is modification to a trial.
- Redaction is the method for protection of CCI.