## Location:

London, UK

## Dates:

September 19 & 20th, 2018

## Summarized by:

Nate Root

# Overview for the EU Clinical Trials Disclosure & Transparency Conference

* New Policy 0070 draft guidance will be released in Oct 2018 (in accordance to the yearly amendment updates of the policy – may or may not see updates in 2019)
	+ Will have updates on timelines, updated cover letter, new checklist for documents, and updates to the anonymization report
	+ Should continue to work on Policy 0070 submissions, but it was not stated if new guidelines will need to be implanted in current working submissions
* No Policy 0070 submission will be published in 2019, but they will continue to process (no sponsors will receive new requests)
* There will be a Technical Anonymization Group (TAG) publishing a Q&A on best practices
* EMA will not state if they will now accept HC submissions and would not comment on the push for transformation of data (quantitative anonymization vs. redaction), but will continue to accept redactions until further notice
* Health Canada did not state when final guidance for CSR submissions will be published, but still targeting implementation of the policy Jan 2019
	+ HC will accept EU Policy 0070 submissions, but may need to add sections that are included in the HC policy
	+ There will be the IFDR (electronic submission platform) for submitting HC CSRs
	+ Review and consultation will be similar to Policy 0070
	+ Retrospective access to legacy data will be implemented at the same time as the new policy
		- Requests for past submissions will have guidance of the ability of the sponsor to process these requests
		- HC will have the final decision on the information redacted, after consultation with Sponsor, similarly to EU
* CT.gov Metrics
	+ Currently receiving ~600 registrations per week and have seen an increase in results submissions by 40%
	+ Some sponsors are submitting protocols at the time of registration
	+ 21 Century cures act requires CT.gov to send a report to congress with the number of ACTs and how many results have been submitted to these
		- There is also a requirement for EAPs to be registered and linked
	+ Common Rule
		- Requirement to post ICFs for studies with federal funding
		- CT.gov houses an option to post ICFs, as well as Regulations.gov
* MDR: Eudamed Expansion for Devices
	+ All device studies will need a Eudram program in 2019 (although it has been operational since 2012)
	+ Devices are identified by the UDI#, while studies are identified by the SIN#
	+ Go live for new Eudamed ~ 26-Mar-2020
* Transcelerate Initiatives:
	+ Common Protocol Template
	+ Common CSR Template
	+ Improving Clinical Trial Registries – ROTF (Registry of the Future)
		- Not looking to create a new registry, but rather compile registry data into a new, more user friendly interface
		- Public users can bookmark and compare studies, see distance to sites from their location, and other user friendly sources for potential patients and care givers to use
	+ Common Registry Packet (coming in 2019)
* Plain Language Summaries – EU CTR Requirement and Best Practices
	+ If not familiar, review Annex V of the EU Clinical Trial Regulation
	+ The title is the hardest part to translate into lay language
	+ Bullets are better than paragraphs
	+ Limit graphics (but are useful in moderation)
	+ Links to additional information (keep to a minimum)
	+ Flow charts are helpful
	+ Use multiple versions of stats (i.e., 1 out of 5 (20%)) one may be more applicable than the other depending on the reader
	+ Challenge in which outcome measures to list (only primary or primary and key secondary – how to avoid cherry picking)
* Public Scrutiny
	+ EU Trials Tracker is now live – Ben Goldacre believes sponsors should focus on disclosing results for all trials ever registered and spend less time and resources on Data Sharing

Issues with “inconsistent data” on EU CTR and sponsors unable to rectify without the help of EMA