GLOBAL VIEW OF CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE EVENTS FOR A SINGLE STUDY AND PRODUCT SUBMISSIONS

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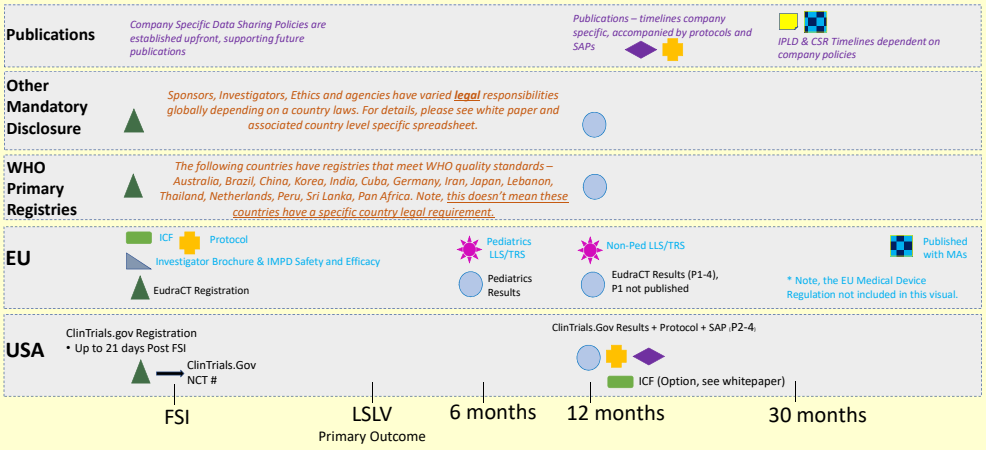
What is the purpose of these pictures?

Global requirements for Clinical Trial Transparency and Disclosure are growing rapidly across the world. This poster is designed to show the numerous Clinical Trial Transparency and Disclosure events over the life of a single study, and over the course of a product submission. We have included the global view for a single study and a full submission. The current scope of this poster is Phase 1-4 interventional trials with a single end point and no arms.

The poster demonstrates how the various clinical documents are re-used over time for different publishing and disclosure events over the documents lifecycle. For example, the protocol is used to support registration, will be published with results on the FDA ClinicalTrials.Gov site, and is one of the required documents to be publicly shared according to EMA Policy 0070 and potentially additional future global requirements. For further details around things such as delays and exceptions, please review the associated White Paper within the Phuse website.

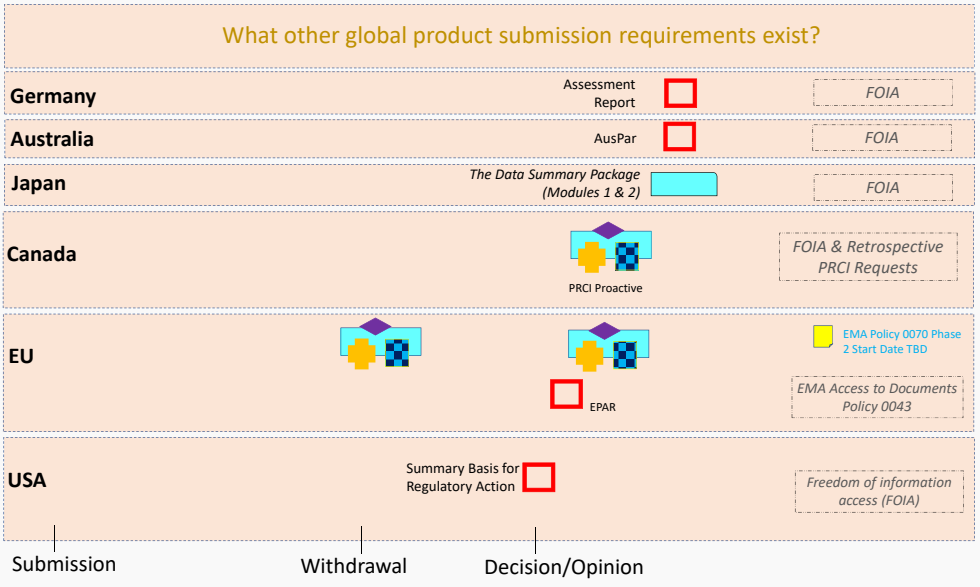
STUDY/TRIAL LEVEL CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE EVENTS MET BY INDUSTRY SPONSORS

SCOPE: This picture depicts study specific disclosure requirements for Phase 1-4 interventional studies, driven by Regulations and Legal Policies for current regulations as of May 2020. We have also included current requirements, future EUCTR requirements, Best Practices not mandatory, areas to further explore. (color coded accordingly)

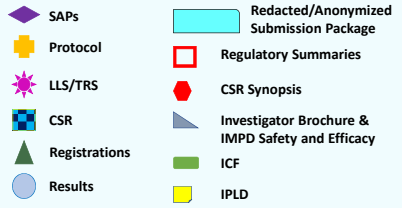


PRODUCT SUBMISSION CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE EVENTS MET BY INDUSTRY SPONSORS

SCOPE: This picture depicts submission based disclosures driven by global regulators for New Medicines and Line Extensions. We have also included current requirements, future EU requirements, Best Practices, and areas to further explore. (color coded accordingly)



Key



Definition of Key Terms

- **ClinTrials.Gov** - ClinicalTrials.Gov
- **FSI** – First Subject In
- **ICF** – Informed Consent Form
- **LSLV** – Last Subject Last Visit
- **LLS/TRS** – EMA Lay Language Summary aka Trial Results Summary aka Plain Language Summary
- **IPLD** – Individual Patient Level Data
- **IPMD** –Investigational Medicinal Product Dossier
- **SAP** – Statistical Analysis Plan
- **FOIA** – Freedom of Information Act or similar country law for sharing documents
- **Publications** – Manuscripts published in journals outside country requirements i.e. ICMJE but are increasingly playing a key role in the way clinical research information is disclosure to the public
- **CSR** – Clinical Study Report
- **MAs**- Marketing Applications
- **Redacted/Anonymized Submission Package** – This is the term for a package of anonymized documents and potentially data delivered to a health agency, such as Japan, EMA, and Canada.
- **WHO Primary Network Registries –** The World Health Organization has established standards for clinical trial registries. This poster includes those categorized as Primary Registries. These WHO Registry Networks meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries also meet the requirements of the ICMJE.