Keeping Up with the Regulatory Expectations

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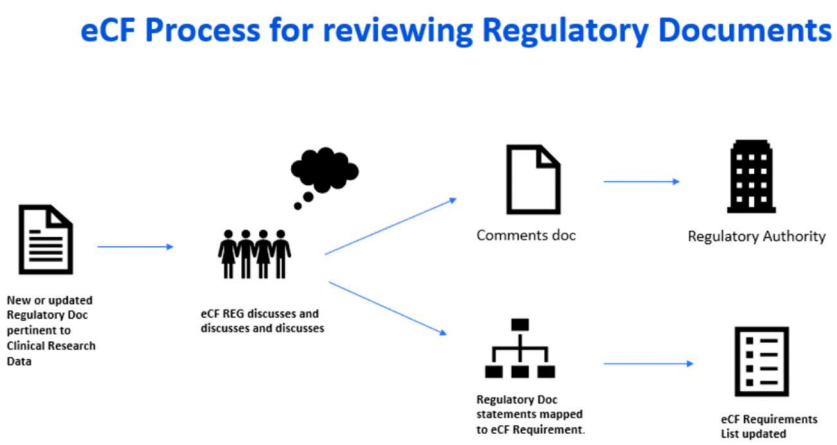
With expansion of clinical research across the globe, organizations need to consider a wide range of regulations, and guidance documents from multiple regulatory authorities, in addition to the country specific laws. Currently, there is an extraordinary number of regulations and guidance documents pertaining to electronic clinical research data that have been issued from ICH, FDA and EMA, PMDA, and MHRA, with full or partial adoption into similar documents by other regulatory bodies.

Sponsors and Contract Research Organizations (CROs) must interpret and attempt to follow them all if they are doing submissions in > 1 region. It is a daunting task. Each company must decide which are most constrictive/comprehensive and which are encompassed by others. In addition, these documents are of different “ages” and do not always agree with each other. They must also be interpreted in a way that is consistent with industry thinking, with backing to ensure a defendable position. It is imperative to garner this information in a practical way.

There are no “universal” guidance documents or tools … but by combining like items, the eClinical Forum has offered a method to assist in this review.

The eClinical Forum is a non-commercial, non-profit global organization with over 45 member companies active in regulated clinical research processes and technologies and has been involved since 2006 in the establishment of conformance criteria for electronic systems used in clinical research. The “eClinical Forum Requirements for Electronic Data for Regulated Clinical Trials” (or simply, “eCF Requirements”) is a list of succinct statements, all based on regulatory documents, that guide a user through this complex task. This is a significant accomplishment by the eClinical Forum’s “Regulatory Expert Group” (REG) as they have put in countless hours over several years to be able to produce such a comprehensive checklist for evaluating electronic systems, that will manage data used in regulated clinical research, against regulations and guidance from ICH, FDA, EMA, PMDA, and MHRA. This work is a result of the vast experience of the REG members who come from a variety of different eCF Member companies. They have spent hours debating each regulation or guidance and how to word the eCF Requirements to correctly meet the needs in the regulatory document.



The eCF Requirements are available publicly and for free via the eClinical Forum website. They are based upon statements in documents prepared and issued by regulatory authorities that pertain to the design, development, implementation, and management of electronic systems that support clinical research data, as well as those statements that pertain to the handling of data that will be used in a regulated clinical trial.

Each eCF Requirement has, as its basis, one or more statements from one or more of the regulatory authority documents. The eCF Requirements are in a linked .pdf file such that one can review the requirement and then the statements from regulatory authority documents used as a basis for the eCF Requirement.

The eCF Requirements can be used to determine if systems, which originate, process, manage and/or retain data that will become part of a regulated clinical trial are consistent with regulatory requirements and recommendations. In particular, the eCF Requirements can be used to assist with self-assessment of systems, planning for system upgrades, writing proposals, Requests for Information (RFIs) and contracts, writing system requirements, writing system test scripts, etc. Depending on the type of system being evaluated, not all eCF Requirements may apply. It is up to the user of these eCF Requirements to review the underlying regulatory basis statements of any eCF Requirement to determine if it should be included in what the user is working on. When it is used to develop test cases, the user should review all statements from the predicate regulatory documents in the mappings to be sure test suites confirm all required items.

There is also a separate tool called eSRA (eSource-Readiness Assessment), based on the eCF Requirements, which can be used for the evaluation of Electronic Health/Medical Record systems (EHR/EMR systems). It can be found on the eClinical Forum website in the eSRA tab. Sponsors are encouraged to use this assessment rather than their own custom assessment template such that sites can use the same completed eSRA for all of their sponsors.

The eCF Requirement work is an active process. eCF continues to proactively evaluate and map new regulatory authority documents as they come into effect. It is our intent to release updated mappings to the eCF Requirements yearly. The newest version is released for eCF members only with the previous release provided publicly for free.

Click here to read a previous article, *'Determining if Data from Electronic Health Record Systems Can Be Trusted in a Clinical Trial Setting.'*

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