The Veeda Newsletter

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CLINICAL TRIAL

EMA Publishes Draft Guideline on Complying with Clinical Trial Master File Requirements

The European Medicines Agency says clinical trial master files should also include quality reports and checklists, product certifications and trial-specific computer system guides — essential documents that are not listed as required in ICH Good Clinical Practice guidelines. **Read More:**http://www.fdanews.com/articles/181442-ema-publishes-draft-guideline-on-complying-with-clinical-trial-master-file-requirements

EMA Revises Clinical Data Publication Guidance, Updates on Program –

The revision updates the previous version released in March, which clarified the agency's expectations for the data required to submit for publishing under the agency's clinical trial transparency rules.

EMA says it has updated the section on the guidance's scope to clarify that "all clinical reports submitted as part of, or cross-referred to within a regulatory application will be subject to publication following the redaction of [commercially confidential information] CCI and [protected personal data] PPD."

READ MORE:http://www.raps.org/Regulatory-Focus/News/2016/12/09/26354/EMA-Revises-Clinical-Data-Publication-Guidance-Updates-on-Program/#sthash.OwM41Z7U.dpuf

ACRP partners with CRO Analytics to measure investigative sites' views of clinical trial quality

In an effort to directly measure the quality of clinical research, the Association of Clinical Research Professionals (ACRP) has formed a partnership with CRO Analytics to measure the views of investigative site personnel on clinical trial quality.

The collaboration is designed to provide important insights into the quality of specific trials, key drivers of that quality and methods to improve clinical research.

Read More:http://www.centerwatch.com/news-online/2015/05/26/acrp-partners-with-cro-analytics-to-measure-investigative-sites-views-of-clinical-trial-quality/

Senate Bill Would Speed Clinical Trials Process

There aren't too many bipartisan things happening on Capitol Hill these days, but a new U.S. Senate bill designed to speed clinical trials appears to be one of them.

As introduced earlier this month, the Enhanced Clinical Trial Design Act would mandate a public meeting between the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to analyze and discuss potential new criteria for clinical trials.

Read More:https://www.acrpnet.org/2017/05/24/senate-moves-speed-clinical-trial-pathways/