Key Questions related to this Rule to be addressed at #CTD17:

1. Effective January 18, 2017, the Final Rule describes the requirements for submitting clinical trial registration and summary results information to ClinicalTrials.gov and includes additional data disclosure requirements for trial registration and result reporting.

2. What are the requirements to report results under the Final Rule?

3. How does the Final Rule impact current processes within companies and research institutions?

4. How is NLM interpreting the Final Rule requirements?

References:

Key Questions related to this Policy to be addressed at #CTD17:

1. The purpose of the Policy is to help:
   - Encourage innovation and development of new medicines while avoiding duplication of clinical trials
   - Promote public trust and confidence in EMA’s scientific and decision-making processes
   - Provide researchers the opportunity to reassess clinical data

2. How are regulators thinking about public access to regulatory documents?

3. What are the similarities and differences in the implementation in EU, US, and Canada?

References:

Key Questions related to this Policy to be addressed at #CTD17:

1. What are the new features of EMA Policy 0043?

2. How will the revised policy impact companies?

3. What are some strategies companies can begin implementing now to prepare for the Agency’s proactive approach to transparency?

References:

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