Increased Clinical Data Transparency – 2013 Changes and 2014 Planning

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Overview
Clinical Data Transparency 2013 - 2014

• Transparency now!
• Key policies & regulations, stakeholders
• Risks
• Implementation
  • Collaboration between stakeholders
  • Within sponsor organizations
• Opportunities
• Appropriate transparency is good for Public Health: patients, HCPs, care givers, industry, regulators and governments

• It “is important for researchers, trial participants, regulators, and others acting in the best interest of patients to have access to clinical trial information to advance medical understanding and progress. It’s also important that this access works in ways that protect patient privacy, preserve regulatory authority and maintain incentives for those who generate data to conduct new research.” (see www.pfizer.com)
Principles for Responsible Clinical Trial Data Sharing

1. Data Sharing with Researchers
2. Public Access to Clinical Study Information (Synopses)
3. Sharing results with Study participants
4. Certifying Procedures for Sharing Clinical Trial Information
5. Reaffirming Commitments to Publish Clinical Trial Results
The Agency takes the following views and positions:

- Protect and foster public health
- Enable public scrutiny and secondary analysis of Clin. Trials
- Protect personal data (PPD)
- Respect the boundaries of patients' informed consent
- Protect commercially confidential information (CCI)
- Ensure future investment in bio-pharmaceutical R&D
- Address the consequences of inappropriate secondary data analyses
- Protect EMA's and the EC's decision-making process
- Ensure that transparency is a two-way street
• Summary of results of CTs to be published in a publicly accessible EU database within one year after the trial completion
  - Includes trials before approval
  - Lay summary required in addition

• Full Clinical Study Reports to be published after decision on EU marketing authorization (i.e., approval or rejection) or withdrawal of the marketing authorization application
Results Database EudraCT Version 9 went live Oct. 2013
Final version planned by EMA for June/July 2014
Summary results to be entered / uploaded within 12 mths of last patient out (6 months for pediatric studies)
- Applies to trials pre & post marketing authorization
- Phase II to IV trials will be published in EU Clinical Trial Database
- EMA will publish comparison of EudraCT with ClinicalTrials.gov data fields shortly
- Non-interventional or non-EU trials (except PIP trials) cannot be registered or disclosed in EudraCT
• Make available participant-level data from medical product applications to non-FDA researcher to further advance regulatory science

• Commercially confidential information and trade secrets would be excluded from any data release

• Data would be both masked and de-identified

• “Masked data” = data stripped of information that could link them to a specific product or application
The AllTrials campaign calls for all past and present clinical trials to be registered and their results reported:

1. Knowledge that a trial has been conducted, from a clinical trials register
2. A brief summary of the trial’s results
3. Full details about the trial’s methods and results

AllTrials is not concerned with individual patient data from trials.
• Many sponsors voluntarily register trials on ClinicalTrials.gov, in addition to “applicable trials” under FDAAA, e.g., registration of non-interventional and non-US studies
• There are many local registries, some mandatory
  • Example: results synopses in Germany
• Pharma companies posted enhanced transparency policies on or before Jan. 1\textsuperscript{st}, 2014, e.g., GSK, Roche, Novo Nordisk, Pfizer, Sanofi, Boehringer Ingelheim, etc.
Clinical Data Transparency: Risks & Critical Topics
- Points to be Considered

- Protection of personal data (PPD) of research participants and study personnel
- Boundaries of patients' informed consent
- Commercially confidential information (CCI) and Intellectual Property (IP) of study sponsors
- Ensure future investment in bio-pharmaceutical R&D
- Maintain worldwide regulatory data protection
- Inappropriate secondary data analyses, confusing patients
- Protection of regulatory decision-making process
- “Transparency as a two-way street”: Transparency principles apply to requestor as well
• Timing of data sharing
  • Most sensitive prior to approvals in US, EU, etc.
• “Responsible Data Sharing”
  • Redaction of documents for PPD and CCI
  • Anonymization of patient-level data
  • Document and data sharing agreements
  • Adequate qualification of requestors for data
  • Pre-specified, statistically sound secondary analyses
  • Unbiased publication of secondary analyses
  • Secure analysis environment (e.g., no downloading of patient-level data)
Many activities started or were intensified in 2013, and will be continued in 2014:

• Collaboration between stakeholders

• Implementation within sponsor organizations
Clinical Data Transparency: Implementation
- Collaboration Between Stakeholders (Pharma Related)

- EFPIA & PhRMA
  → Principles for Responsible Clinical Trial Data Sharing
- Association of the British Pharmaceutical Industry (ABPI)
  → Clinical trial disclosure toolkit (Aug 2013)
- TransCelerate (launched in September 2012)
  → Clinical Data Transparency initiative, e.g., developing redaction standards
- Other pharma related initiatives & collaboration
Clinical Data Transparency: Implementation - Collaboration Between Stakeholders (Non-industry)

- Dialog Regulatory Authorities with stakeholders
- DIA Clinical Trial Disclosure Community (formerly SIAC)
- Multi-Regional Clinical Trials Center at Harvard (MRCT)
  - CT Data Sharing and Transparency Conference (May 2013)
- Institute of Medicine (IOM) of the US National Academy of Sciences
- Scientific Journals & Organizations
- Patient Organizations
- Other non-industry related initiatives & collaboration
• Multi-sponsor platform for data requests
• Multi-sponsor, secure environment for analyzing patient-level data
• Vendors & customers of disclosure software

• Collaboration here at the conference!
Clinical Data Transparency: Implementation
- Topics for Collaboration

- Documents redaction standard
- Anonymization standards
- Informed consent not hindering transparency
- Investigator contracts not hindering transparency
- Analysis & publication standards for secondary analyses
- Analyses of multi-sponsor data
- Scientific review board for review of data requests
- Templates for document and data sharing agreements
- Technical use control for shared documents
- Lay summaries
- Etc.
- Update and publish transparency policy (if not yet done)
- Register your studies and list them as available for data requests as appropriate
- Prepare studies (data and documents) to address requests
- Revisit your standards and templates for CSRs
  - Write ICH E3 Synopses “transparency ready”
  - No PPD, no CCI, sufficient details for all primary & secondary endpoint results, statistical methods, etc.
  - Separate PPD from other information
  - CSR as complete source for all results disclosure in registries
• Prepare for results disclosure in EudraCT V9
• Consistent information EudraCT vs. CT.gov
• Check your patent and publication strategy:
  Is it compatible with earlier and broader transparency?
• Address topics mentioned above under “Topics for Collaboration”
Clinical Data Transparency: Opportunities

- Better meet patient needs
- Enable patients to make the right decisions for themselves
- Bring better therapies earlier to patients
- Lower the risk for patients in clinical studies
- Improve efficiency of drug development
- Enhance trust in science, study sponsors, and regulatory systems
Thank you!

The further presentations at this conference will elaborate on the topics highlighted above. Please actively participate in the discussions.

Enjoy the conference!