Life Sciences

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Clinical Data Transparency
PhUSE Single Day Event
22nd May 2014

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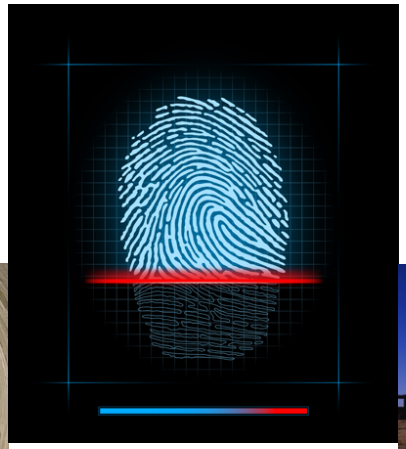
Setting the Scene for Transparency

- What is happening regarding Clinical Data Transparency?
  - Regulators Standpoint
  - Industry Outlook
- Scientific: The Patient
  - Higher quality, well designed trials with shorter development time lines
  - Influencing drug development through hindsight awareness





EMA and Transparency

- Announcement of intention to proactively disclose dossier content following regulatory approval – July 2012
- Public workshops to develop Transparency policy – March 2013
- EMA releases policy for public comment – June to Sept 2013
- Final policy was to be released Dec 2013 and to be effective Jan 2014 for new submissions as of 1 March 2014

EMA Policy 70
Current Status

- EMA postponed due to over 1000 comments

- The policy was discussed at the Management board Meeting
  – 19th and 20th March 2014

  We should hear soon in terms of any updated policy and timing

FDA – Masked and De-Identified

- FDA was seeking public comment on the proposed availability of de-identified and masked data – June 2013
  - 32 comments received and being reviewed
- FDA position
  - They have no legal basis to provide a sponsors CT data
- Clinical documents can only be provided through the established Freedom of Information (FOI) process

EU Clinical Trial Directive

- New draft of the EU Clinical Trial Directive was agreed to by the member states - 20 December 2013
- Transparency related information includes
  - A general and lay summary must be provided of each trial within 1 year of the end of the trial
  - Reinforcement of the requirement for CSRs to be posted that are included in an MAA
  - No requirement for provision of raw clinical trial data

Industry Outlook

July 2013,

- **EFPIA and PhRMA formally launched their Joint Principles for Responsible Clinical Trial Data Sharing to Benefit Patients.**
- Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:
  - Safeguarding the privacy of patients
  - Respecting the integrity of national regulatory systems
  - Maintaining incentives for investment in biomedical research

Industry Outlook

EFPIA and PhRMA

– Commitments

1. Enhancing Data Sharing with Researchers
2. Enhancing public access to Clinical Study Information
3. Sharing results with Patients who Participate in Clinical Trials
4. Certifying Procedures for Sharing Clinical Trial Information
5. Reaffirming Commitments to Publish Clinical Trial Results

TransCelerate

- TransCelerate
  - Personal Data redaction pilot on standard redaction of private information.

Institute of Medicine – Data Sharing

- A committee of individuals through the US National Academy of Sciences
- Sponsors include academic, industry and government charged to committee to provide two items:
  - A framework document for discussion on clinical trial data sharing released in January 2014. Public comments provided until March 2014
  - A final report with finding and recommendations for data sharing – scheduled to be released December 2014

Data Transparency

- Regulators looking for wider access to clinical data to be made available
- Their reasons are Scientific
  - Providing valuable data to aid research
  - Benefits in long term to public health

- Industry understand the benefits but realise further consequences
  - Marketing and commercial implications
  - Possible litigation
  - Patient identification
  - Analysis without regulation

The Regulators and the Industry

- EMA
  - Proposal to allow access (download) to CT data in analysable format
- FDA
  - Propose to make available De-identified and masked data
  - Access to data that has research value

- Industry
  - Data release via research proposal submitted to an independent review board to vet scientific validity, protect patient confidentiality and CCI
  - Continued commitment to publish CT data and make CSR synopses available

Regulation

Should Data Analysts operate to the same standards that are applied to the submission and approval process for a product?

- Work directed by Qualified Statisticians
- Requestor of data to provide valid objectives for the analysis
- Requirement of regulatory guidelines (design and analysis)
- Unified set of Standards
- All working towards the benefit of the patient
  - First and foremost, is the product safe?

Requirement : Valid, unbiased data analysis and interpretation with agreement to work in the best interests of the patient and public health in general

The Patient

- Improve surveillance of drug safety and effectiveness
- Facilitate secondary analysis of Clinical Trial data to help explore new scientific questions
- Speed up innovation in the R&D process
- Enable patient and advisory groups to learn more about their specific medical problem
- Possibly improve the speed of enrolment of clinical trials
- Improve the design of Clinical Trials to widen the indication for a product
- Characterisation of a disease and rare events
- **Improve trust in the industry**

Considerations

- Policy
- Legal
- Original Study Objectives and objectives of new analysis
- Protocol and SAP
- Standardisation and Data Aggregation
- Portals and Defined Access
- Document Repository
- Reporting and Distribution/Communication of Results
- Raw and/or derived data
- Independent Review committee
- Cost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