PhUSE Event: e-Submission and Public Disclosure

Keynote Talk

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Outline

- Trigger for Regulatory framework
- e-Submissions - Evolution
- Data Disclosure and Transparency
- Challenges

ICH: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

- **Need to Harmonise:**
  - Thalidomide disaster in Europe in The 1960s and other drug related tragedies
  - Increase in laws/regulations/guidelines in many countries on conduct/reporting/safety/quality/efficacy of clinical trials/products.

ICH harmonisation for better health

http://www.ich.org

Adobe Acrobat Document

- **Initiation of ICH**
  - Harmonisation of regulatory requirements: Pioneered by the European Community (EC, now the EU), in the 1980s
  - WHO International Conference of Drug Regulatory Authorities (ICDRA): Paris 1989
  - ICH started in 1990 (US, EU, Japan) in Brussels
  - WHO, Canada, and EFTA are observers

- Objectives:
  - to improve efficiency of new drug development and registration process
  - To promote public health, prevent duplication of clinical trials in humans and minimize the use of animal testing without compromising safety and effectiveness

e-Submissions: Evolution

- In the early 1990s, the Computer-Assisted New Drug Application (CANDA) was used by FDA reviewers to have rapid access to report and data together
  - Not standardized
  - Proliferated proprietary and unique CANDA formats which led to training overhead for the reviewers
- United States Food and Drug Administration (FDA) issued part11 guidelines on electronic records acceptance as equivalent to paper records and hand-written signatures in 1997
- IT Solutions has promoted electronic submission of clinical research data and dossiers enabling faster and robust review process

Why e-Submissions

- Consistent, efficient, and secured
- Enhances data re-usage, data back-ups, audit control and inspection readiness of clinical research records
- Enhances scope of harmonization of clinical data/documents submission across regulatory agencies
- Promoted health-care companies to adopt Electronic Data Capture, Software Applications enhancing data quality and veracity

Data Disclosure and Transparency

- Transparency whether Scientific, Political or Finance fundamental value to gain public trust
- European Medicines Agency (EMA) pioneered and advocated the benefits of data disclosure have set new standards for clinical trial data transparency by adopting two landmark policies.
- 2010 Policy: Enables interested parties to request data from clinical trials that have been submitted for marketing authorization of medicinal products
- 2014 Policy on publication of clinical data for medicinal products for human use

- Bio-pharmaceutical Companies such as Bayer, Daiichi Sankyo, GSK, Lilly, Novartis, Roche, Sanofi, Takeda had set an example by adopting data disclosure policies and following principles
  - Safe guarding Patience privacy
  - Complying with national regulatory policies

Benefits of Greater Access to Patient Level Data

- Enables the identification of trends and associations that may provide greater insight or help develop hypotheses and theories for further research
- Enables the review of results from individual clinical trials to validate the results
- Strengthens trust on clinical research and Pharma industry through enhanced openness and transparency
- Better understanding of the disease and drug safety profile
- Improves clinical trial designs

Challenges

- Risk of de-identification and breach of patient privacy
- Mammoth effort to anonymize large amount of data. Over head for companies
- May generate misleading data and erroneous conclusions about drug efficacy and safety.
- Negative publicity deprive patients drugs which are actually beneficial
- Legal complications for the sponsors

Refernces

www.fda.gov

http://www.appliedclinicaltrialsonline.com/

http://scienceinsociety.northwestern.edu/content/articles/2009/research-digest/thalidomide/title-tba

Thanks !

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