Asia Pacific R&D and Clinical Trial Compliance Discussion

Thursday, September 18
9:15 – 10:00

Introductions

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Current and Emerging R&D Compliance Challenges

- **Strategic (Risk Acceptance and Avoidance)**
- **Organizational (Compliance ownership across global functions and divisions)**
  - Commercial vs. Medical Affairs vs. R&D
  - Legal / IA / Corporate Compliance / QA / R&D Compliance
- **R&D Business / Ethics Compliance**
  - Post Marketing Commitments / Post Marketing Studies
  - Fair Market Value determination / approval
  - Academic Collaborations / Partnerships
  - Investigator Initiated Studies
  - Publications & Scientific Exchange of Information
  - Data / Research Integrity
- **Clinical Trial Compliance**

Growth in Clinical Trials outside of US

Russia

India

Brazil

Argentina

China

....and *others*

Challenges:-

Concept of “uninhibited consent” – language, age, literacracy, gender,

Wide disparity in “standards of care”

Access to patients or availability of qualified staff

New DoJ Focus Area: Conduct of Foreign Clinical Trials – Levinson Report

Daniel Levinson (HHS) Report of June 2010: identified a growing number of new drug applications submitted to FDA where dossiers are based upon clinical trials in foreign countries where ethical controls were deemed to be "less robust" than those expected in the US

- Finding that 80% of NDAs that were approved for sale in 2008 were based upon data taken in foreign trials; suspicion that "cherry picking" might be going on
- As patients are the "priority", HHS recommended a need for the FDA to "step up" its oversight of foreign clinical trials.
- DoJ is also becoming interested in how clinical trials are being conducted via the use of CROs and other Third Parties.
- Does not want to see "rigged" clinical trials being relied upon

Intense Scrutiny on Clinical Trials

- Increased requirement by Governments that Sponsor Companies disclose all payments made to Investigators and Researchers.
- Enrolment of “suitably qualified and consenting” patients is a key concern.
- Also of importance are the qualifications and experience of those persons who are conducting or managing clinical trials.
- Ethics Committees are becoming more robust and trial protocols are intensely scrutinized.
- The integrity of all data produced or discovered in a clinical trial needs to be preserved and reported on.

Leveraging Technology & Data to help inform Compliance Monitoring

- **Who is responsible for designing compliance monitoring programs and who oversees the implementation?**
- **What new technologies are being used specifically for compliance monitoring? What are being considered in the future?**
  - Reporting compliance relating to study performance and monitoring?
  - Monitoring payments to investigators?
  - Vendor and internal training monitoring?
- **How has your organization leveraged technology or data to help inform oversight of:**
  - Investigator contract compliance
  - CRO contract compliance
  - CRO personnel qualifications