2.3 – Good Regulatory Practices

Presentation to APEC Preliminary Workshop on Review of Drug Development in Clinical Trials

Celia Lourenco, PhD, Manager, Clinical Group I
Office of Clinical Trials
Therapeutic Products Directorate
Disclaimer: the information within this presentation is based on the presenter's expertise and experience, and represents the views of the presenter for the purposes of a training workshop
Good Regulatory Practices

✓ Develop regulations that are flexible
✓ Use risk management principles
✓ Be consistent in guidance and decision-making
✓ Be efficient in information and records management
✓ Measure and maintain performance and transparency
✓ Be reachable and reach out to stakeholders
✓ Be aware of changing regional and global factors in R&D and access to drugs
Flexibility of Regulations

- Regulations should:
  - Cover principles broadly
  - Provide sufficient protection to the public
  - Strike a balance between protection of the public and enabling R&D
  - Be forward-looking, allowing flexibility for regulating in the current and future environment
Use Risk Management Principles

• Science-based risk management, with risk-based decision-making

• Precautionary principle: “absence of full scientific certainty shall not be used as a reason to postpone decisions when faced with the threat of serious or irreversible harm”

• Proactive – take initiative to address and prevent public health & safety concerns:
  – Safety of Canadian blood system
  – Bovine spongiform encephalopathy / Creutzfeldt-Jakob disease
  – Pandemic influenza

• Know own strengths and weaknesses:
  – Consult with experts on complex scientific, medical, or regulatory issues
  – Implement and make use of scientific advisory committees
Consistency in Guidance and Decision-Making

• Adopt international guidelines when appropriate
• Develop SOPs:
  – Good guidance practices
  – Good review practices
• Develop and implement guidelines to address regional issues
• Be aware of drivers, such as globalization
Efficiency in Information and Records Management

- Develop and implement tools to manage documents and information submitted by sponsors
  - Maintain accurate records with a numbering system for sponsor/drug and submissions
  - Clinical trial applications, amendments and notifications
  - ADR database for integration and analysis
  - Submission allocation database
  - Clinical trial inspection database

- System to manage other information such as general enquiries
- Ensure security and maintain confidentiality of records
Measure and Maintain Performance and Transparency

- Measure workload and performance at periodic intervals (e.g., quarterly)
- Use information on workload and performance to develop/revise business plans
- Publish performance measures periodically (e.g., annually)
  - Number of clinical trials, protocol amendments, notifications, ADRs, types of trials, etc.
  - Submission processing and review times
Be Reacheable and Reach Out to Stakeholders

• Provide opportunities for dialogue with sponsors and stakeholders formally and informally (e.g., pre-clinical trial meetings, telephone conferencing, informal email enquiries)
• Provide for appeal processes and opportunities for reconsideration of final decisions
• Consult with all stakeholders before implementing or adopting new regulations, policies, and guidelines
• Consult with stakeholders as early as possible
• Communicate horizontally within organization
• Seek lessons learned through impact analyses
Impact on R&D: Regional Factors

• Analyze regional factors:
  – Population (e.g., demographics, disease prevalence)
  – Health care system and infrastructure
  – Available expertise
  – National support in research funding
  – Regulatory frameworks for importation and sale of drugs
  – Geographic location and neighbouring countries
Impact on R&D: Global Factors

Be aware of, and prepare for, global impact & trends:

- Multinational clinical trials
- Harmonization
- Decreased number of blockbuster drugs & exponential rise in generics
- Personalized medicine, pharmacogenomics
- Rising costs and emerging markets
- In choosing to place a clinical trial, companies will look for countries with the appropriate laws, along with the required population, disease prevalence, health care system, qualified investigators and staff, with high standards of professional integrity and ethics
## References

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