Developing Country Vaccine Regulator's Network

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The Development of Regulatory Authorities and the Process of Post Marketing Surveillance in developing countries

Les Pensières, Annecy (France)
The Original Idea

- **Formation of a Network of Regulators**
- **From Developing countries**
  - NRA Meets criteria of functionality & Expertise
  - Local PQ vaccine manufacture / Clinical trials
- **WHO selection of Founding Members**
  - Brazil, China, Cuba, India, Indonesia, Korea, Russia, South Africa, Thailand
- **1st Meeting – Bangkok in 2004**
Terms of Reference

• **Strengthen capacity of National Regulatory Authorities [NRA]**
  - both for Members and other Developing Countries
  - Initial focus on regulatory control of Clinical trials
  - Through exchange of experience and information

• **Areas of collaboration**
  - Information exchange
  - Mutual understanding of policies
  - Propose actions to assist the WHO positions
  - Interaction with members to build capacity
Outline of Activities

– Bi-Annual meetings in Member Countries
  • Members, Invited Regulatory Expert Advisors
  • Other NRAs with common interests - observers

– Scientific Sessions
  • Topics related to current vaccine trials
  • NGOs and Manufacturers present information
  • DCVRN drafts Points to Consider for WHO IVB/QSS

– Closed Sessions
  • Policies, Guidelines, Plan Training & Joint actions
Scientific Sessions

• Past Topics
  – New Vaccine Development
    • TB, Dengue, JE, HIV, Flu (Pandemic], Adjuvants
  – Clinical trials:
    • HIV, Typhoid, Flu (Seasonal]
  – Vaccine introductions:
    • Rotavirus, HPV; challenges and special groups
  – Trial Design
    • Bridging Studies
  – Interaction with DCVMN - manufacturers association
    • Development of an IND-like system
DCVRN Closed Sessions

- Discussions on Regulatory Activities
  - Review Progress with established procedures
  - Review Progress with developing activities
  - Formulate *Points for Consideration* from Scientific Session
  - Consider Proposals and decide on New Activities
  - Consider Input from WHO and other bodies
  - Review Membership and Policies
  - Plan next meeting
What has DCVRN done?

- **GCP Inspections**
  - Harmonized Methodology and Checklist development

- **Format for Clinical Trial Applications (with GTN/GLO)**
  - Common understanding of Procedures for evaluation

- **Draft IND-like system for Developing Country NRAs**
  - Pilot implementation in Indonesia & Brazil

- **Joint Evaluation of applications & Joint Inspections**
  - Pilot implementation in Thailand & South Africa

- **Input to Regional Vaccine regulatory forums**
  - AVAREF & ASEAN Vaccine Chapter (common members)
What can DCVRN do more?

- **Scientific Sessions**
  - Follow development of New Vaccines, and related products
  - DCVRN *Points to Consider* for WHO ECBS

- **Common Regulatory Procedures**
  - Further develop the harmonized IND-like system
  - Possible common format for inspections / NRA decisions
  - Monitoring of Clinical trials - Pharmacovigilance procedures
    - Development of Guidelines & checklists

- **Develop mechanisms of inter-NRA Communication**
  - Common policy to interact with NITAGs

- **Common Policy for Public Transparency**
EXTERNAL CHALLENGES

• Public expectations & Transparency*
• Novel medicines and technology*
• Emergent Diseases*
• New manufacturers – New NRAs
• Internationalization of Pharma Industry*
• Languages & Procedures

» * in common with EU Roadmap for Future 2004
INTERNAL CHALLENGES

– Funding - Sufficient & Sustained
– Independence from Industry & Politics
– Management Skills
  • Internal QA Systems and Monitoring
– Administrative Resources
  • Data Management – Document control – Language
– Scientific Expertise range & skill of assessors
– Developing Support Services
  • National Control Laboratory & Inspectors
  • Pharmacovigilance & Post-market surveillance
Special Challenges for Developing Country Regulators

- All of the above
- New, inexperienced, developing & expanding
  - Management and administrative systems
  - Scientific & Technical expertise
  - Defined Procedures (Best possible with current resources)
  - Language & Culture
- Independence & Authority - Influence & Funding
- Decision Making Procedures
- Cultural expectations for Public Transparency
- Support Services - NCL, Inspectors & Pharmacovigilance
The End

The DCVRN has a role to play helping Regulatory Authorities meet these challenges

Thank you

- Sérgio de Andrade Nishioka: Cad. Saúde Pública, Rio de Janeiro, 24(9):2191-2192, set, 2008 Cooperation between regulatory authorities from developing countries in the evaluation of vaccine clinical trials