Resources available for planning influenza vaccine clinical trials

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8th Meeting with International Partners on Prospects for Influenza Vaccine Technology Transfer to DCVM, Sao Paulo, Brazil
Regulatory Workshop, July 2014, Bangkok

- Regulatory requirements for the preclinical and clinical evaluation of influenza vaccines
  - Over 100 participants: 55 NRA reps, 30 DCVM reps, WHO staff and experts.
  - To enhance capacity of DCs to manufacture & license seasonal/pandemic influenza vaccines by providing training on design & regulatory review of preclinical and clinical studies in support of initial vaccine approval, annual strain change, process modification, and PQ.
  - To enhance the capacity of non-producing countries to evaluate, register and survey seasonal and pandemic influenza vaccines.
Regulatory Workshop Materials

- Examples of preclinical study plans
  - seasonal, pandemic, adjuvanted; immunogenicity, toxicity, efficacy

- Template protocols for phase I and phase II clinical trials:
  - Trivalent IIV split, trivalent LAIV, monovalent IIV, monovalent LAIV

- Clinical trial study instruments templates:
  - Case report form; DSMB charter; ICF checklist and template; Investigators brochure; diary cards etc.

- Summary of EMA & US FDA guidance on clinical trial requirements for seasonal/pandemic vaccines incl. special considerations for phase III

- WHO guidelines for preclinical/clinical evaluation of influenza vaccines
Workshop sessions:

1. Non-clinical studies supporting first approval (incl. CMC)
2. Phase I and II studies of influenza vaccines in healthy adults
3. Phase II or III trials leading to vaccine approval
4. Minor and Major changes to vaccine production
5. Annual Strain Changes to seasonal vaccine
6. Post-marketing Surveillance
7. WHO Prequalification
8. Regional distribution and role of national control laboratories
Comments

- Templates are available to guide manufacturers in the design of preclinical and clinical trials (sparrowe@who.int)

- These are guides only, NRA should always be engaged early in clinical trial planning

- Workshop focused on design and approval of preclinical & clinical trials

- But, did not go into details about the conduct & management of these trials

- Dedicated session this afternoon....
Thank you