Forum for Collaborative HIV Research

Global Surveillance of Antiretroviral Drug Safety

Stakeholder Perspectives

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Background

- Multiple efforts have been initiated to strengthen collection of ARV safety data in low- and middle-income countries
- FCHR sought to identify current needs, interests and gaps among stakeholders to inform this meeting
- Particular focus was placed on input from industry (innovator and generic); in addition we consulted representatives from WHO, UMC, regulatory agencies, donor organizations, implementers and academia

Stakeholder Perspectives:
Key Themes

- Systems perspective important
  - Drug safety as integral component of ART programs
  - Thinking beyond HIV
- Rethinking the industry role
  - Few examples of collaborations so far
  - Potential for channeling of safety data by industry
- Need for stronger regulators
  - Dealing with substandard products
  - Risk management
- Utilization of data from cohorts, clinical trials
  - Maximize use of available safety data
- Consider issues in special populations (children, pregnant women)

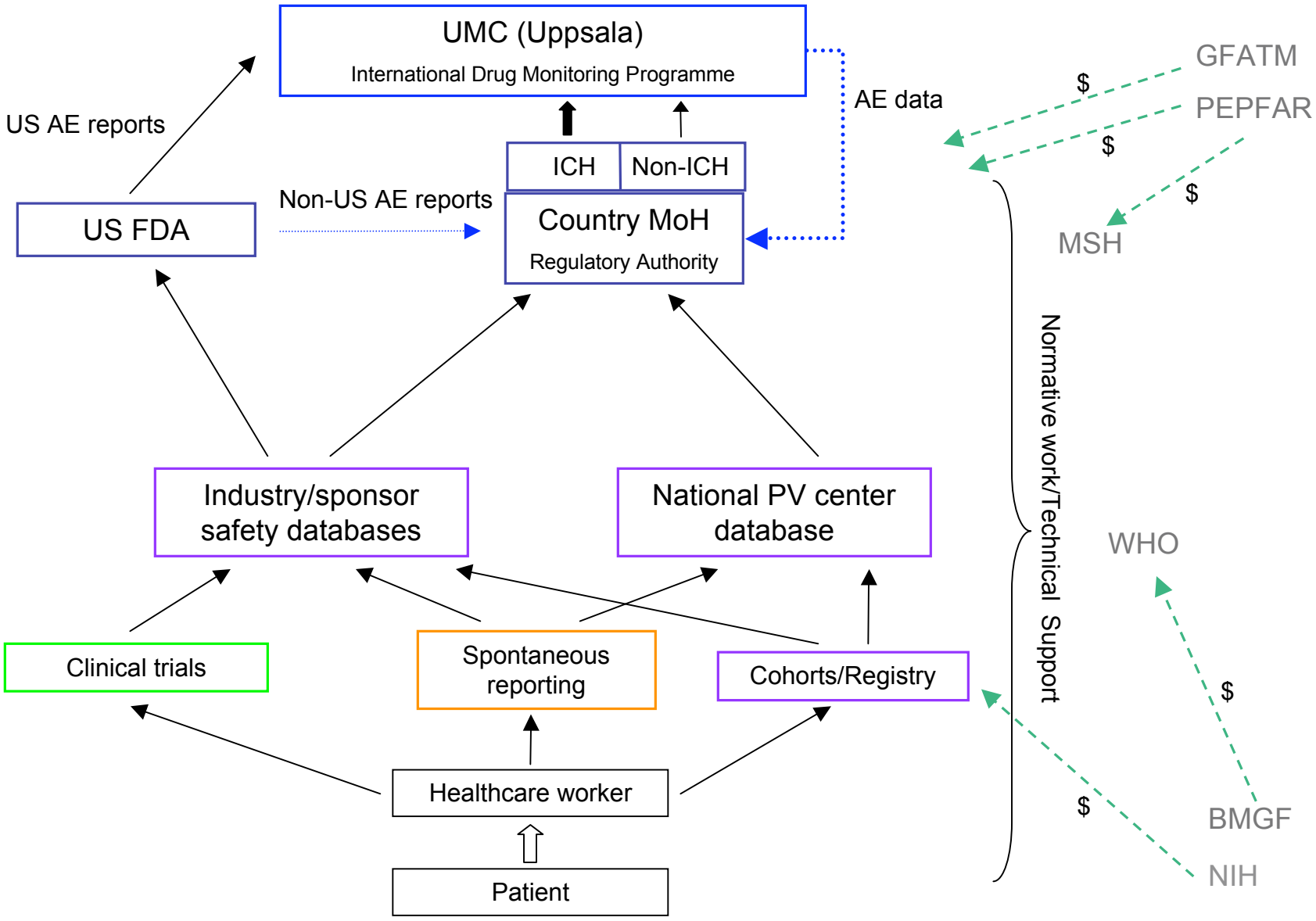
Stakeholder Perspectives:
Industry Views

- Significant expertise exists in drug safety monitoring in ICH countries
- In low- and middle income countries:
  - successful collection of AE data in clinical trials
  - limited experience with cohort studies
  - very few spontaneous AE reports received
- Some companies (generic, innovator) working to improve spontaneous reporting via clinician training; development of risk management plans
- Successful industry collaboration in place for the Antiretroviral Pregnancy Registry
- Future partnerships in this area conceivable with setting of clear goals

Conclusion

- Need for a coherent, sustainable approach to ARV drug safety surveillance in ART programs
- In view of various ongoing efforts, a mechanism for continued oversight of joint efforts could be discussed
- Several opportunities exist for new collaborations
- Follow up meeting planned to advance this agenda

What happens to ARV AE data?



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