IMDRF International Medical Device Regulators Forum

WHO Update

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What's new ?

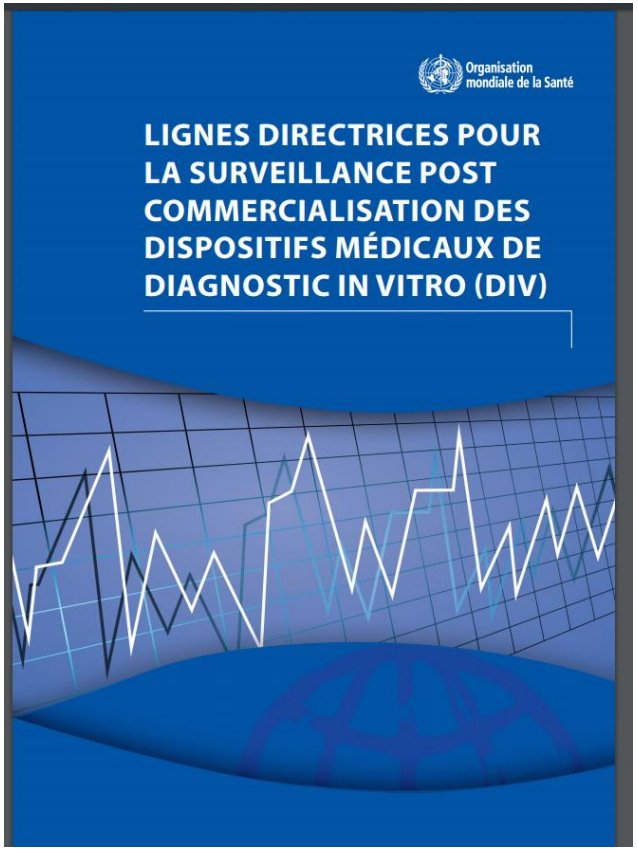
- Prequalification of IVDs
- Vigilance
- Regulatory strengthening

Prequalification of IVDs

- IVDs PQ-ed in 2017 include:
  - First HIV RDT for self-testing
  - First HCV RDT
  - First HCV NAT for PoC testing
- PQ scope expanded to Cholera RDTs
- 9 laboratories listed as evaluating sites for PQ purposes

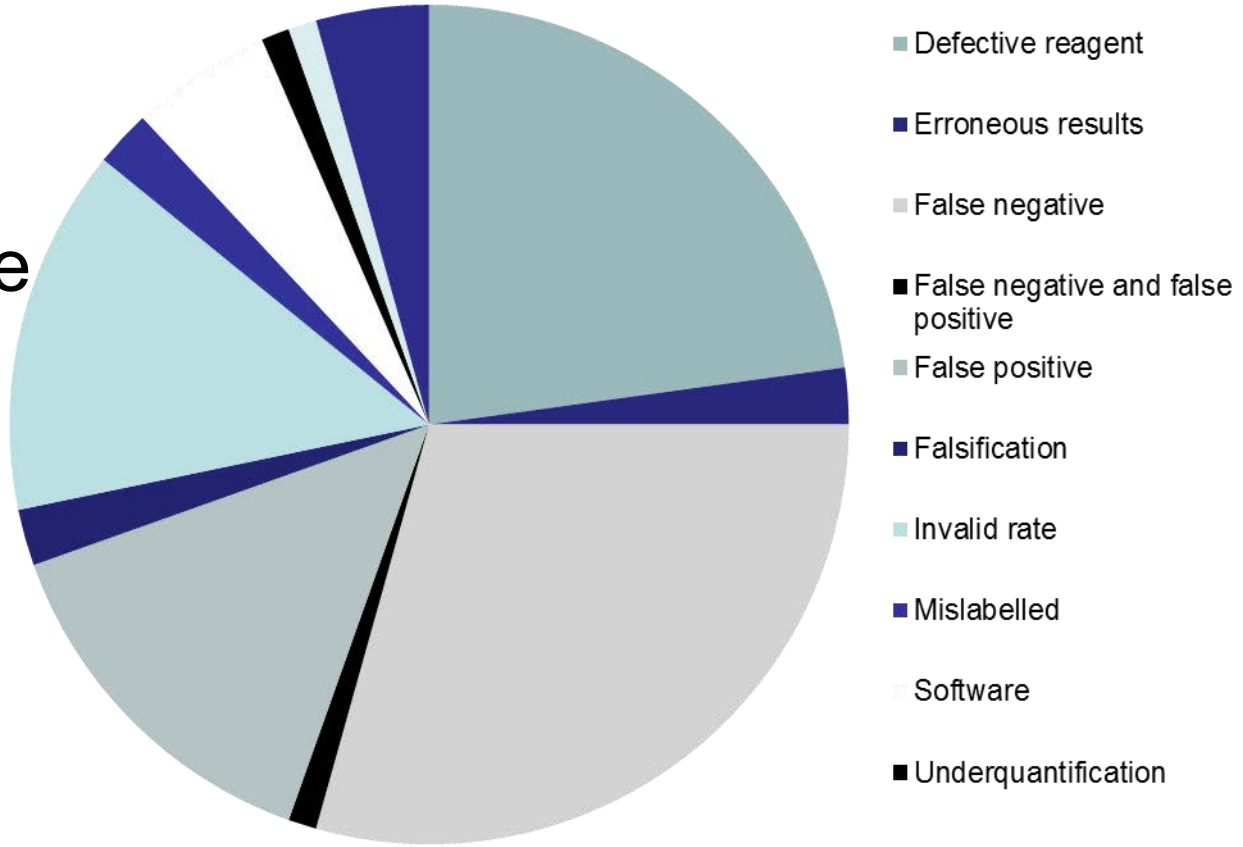
WHO Guidance on Post-market Surveillance

- Workshops to roll-out guidance
  - Anglophone and Francophone African countries
  - Planned for Russian-speaking countries
- National action plans for implementation drafted



WHO complaint handling (n=92)

- In order of frequency
  - False negative results (n=27)
  - Defective reagent (n=21)
  - False positive results and ↑ invalid rate (both n=13)



Global benchmarking tool

- Global context: different assessment tools collecting information from Regulatory Authorities and affiliated institution
- Strategic direction: Development of the WHO Global Benchmarking Tool (GBT)

Global benchmarking tool

- Integration of medical devices into the WHO GBT
  - Next steps:
    - O with involvement of the regulatory authorities
    - Piloting of the WHO GBT-medical devices tool in selected countries
    - Adjustment of the WHO GBT + medical devices.
    - Publication of the WHO GBT + medial devices.

Thank you