Accessible Quality-assured Diagnostics for Public Health Programmes: Global Challenges:

Considerations for Moving Forward

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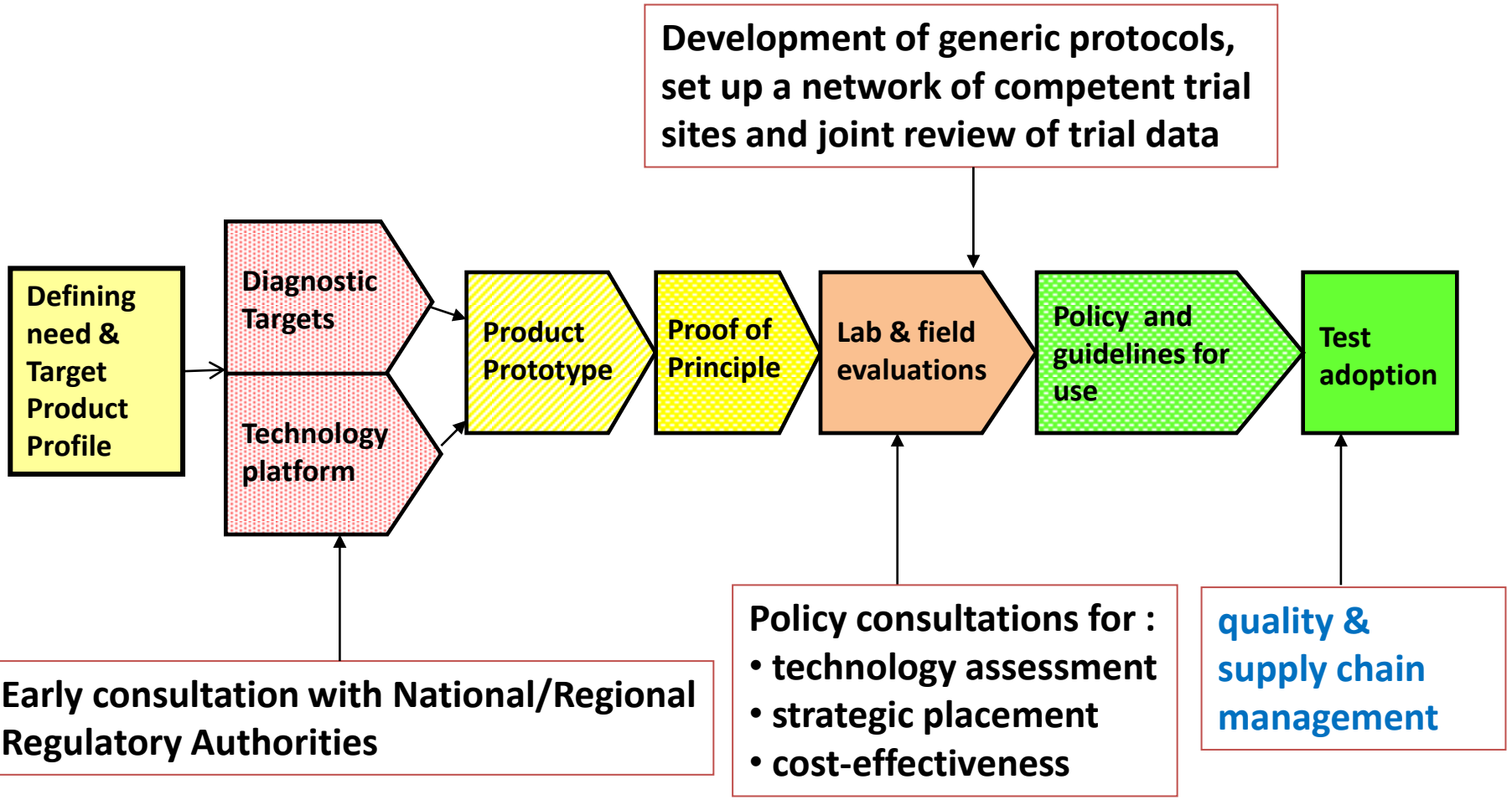
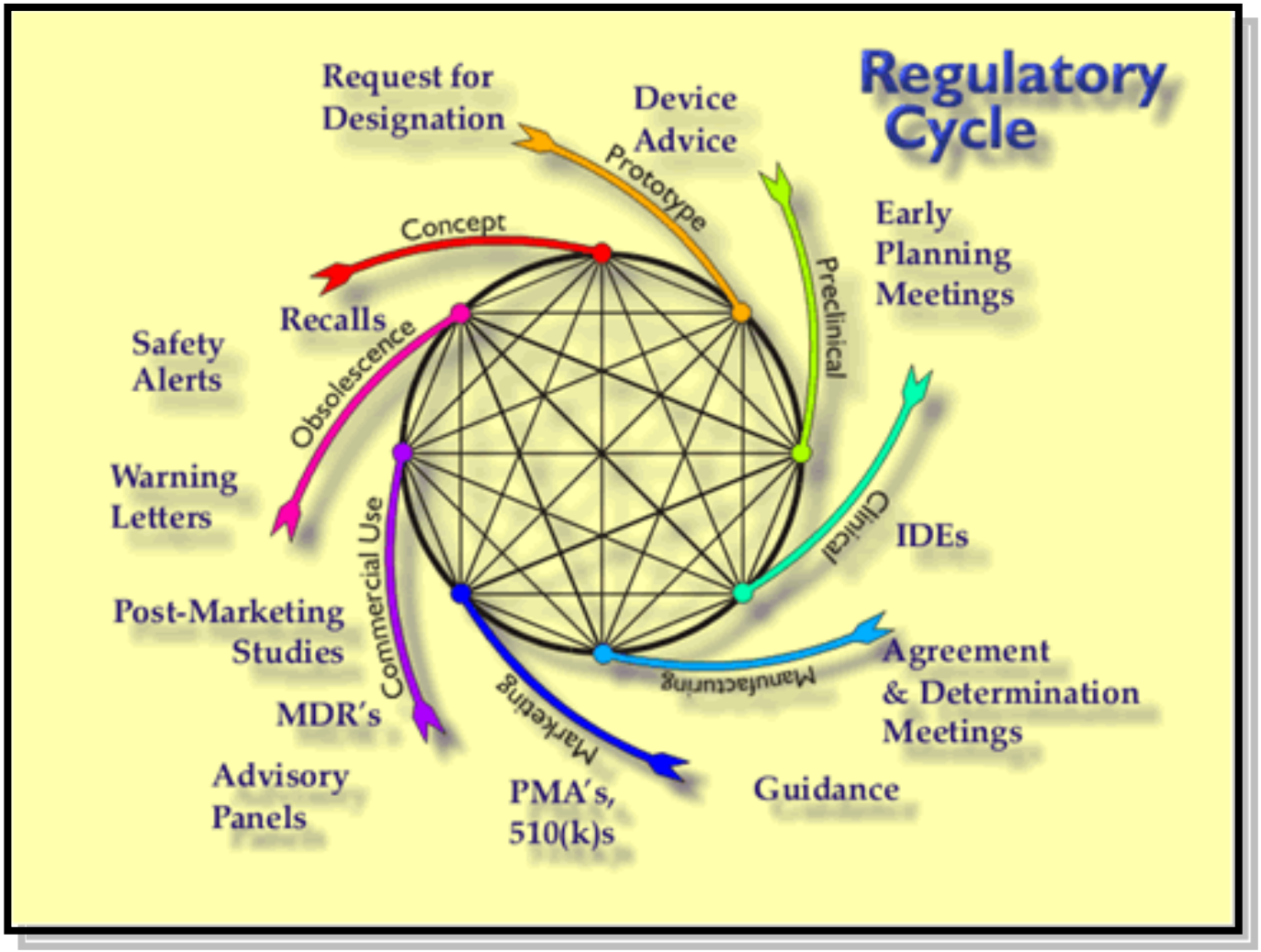
Affordable Access to IVDs: A Coordinated and Streamlined Approach – we can all do our part



Transition from Linear Bench-to- Bedside Pathway to a Product Life Cycle



Source: CDRH/FDA

Transition from Linear Bench-to- Bedside Pathway to a Product Life Cycle

- **To incentivise and accelerate innovation, we need to create more opportunities for interactions between industry, public health policy developers, regulators, and researchers/experts to better understand**:
  - Public health needs
  - Purpose of diagnostics and where diagnostics will be deployed (health technology assessment)
  - Target product profiles including performance expectations
  - Environmental requirements
  - where trade-offs are acceptable

- **Expected outcomes:**
  - **Policy/adoption:**
    - Diagnostic innovations that are fit for purpose and where diagnostics will have greatest impact
    - More clarity on price points and accelerate policy development and adoption
  - **Companies:**
    - will have improved product design
    - more clarity on price point to make a business case for investment, including cost of regulatory approval (currently a major disincentive where regulatory systems are not transparent)
  - **Regulatory authorities**:
    - Accelerate review process