External Validation of Rapid STI Tests

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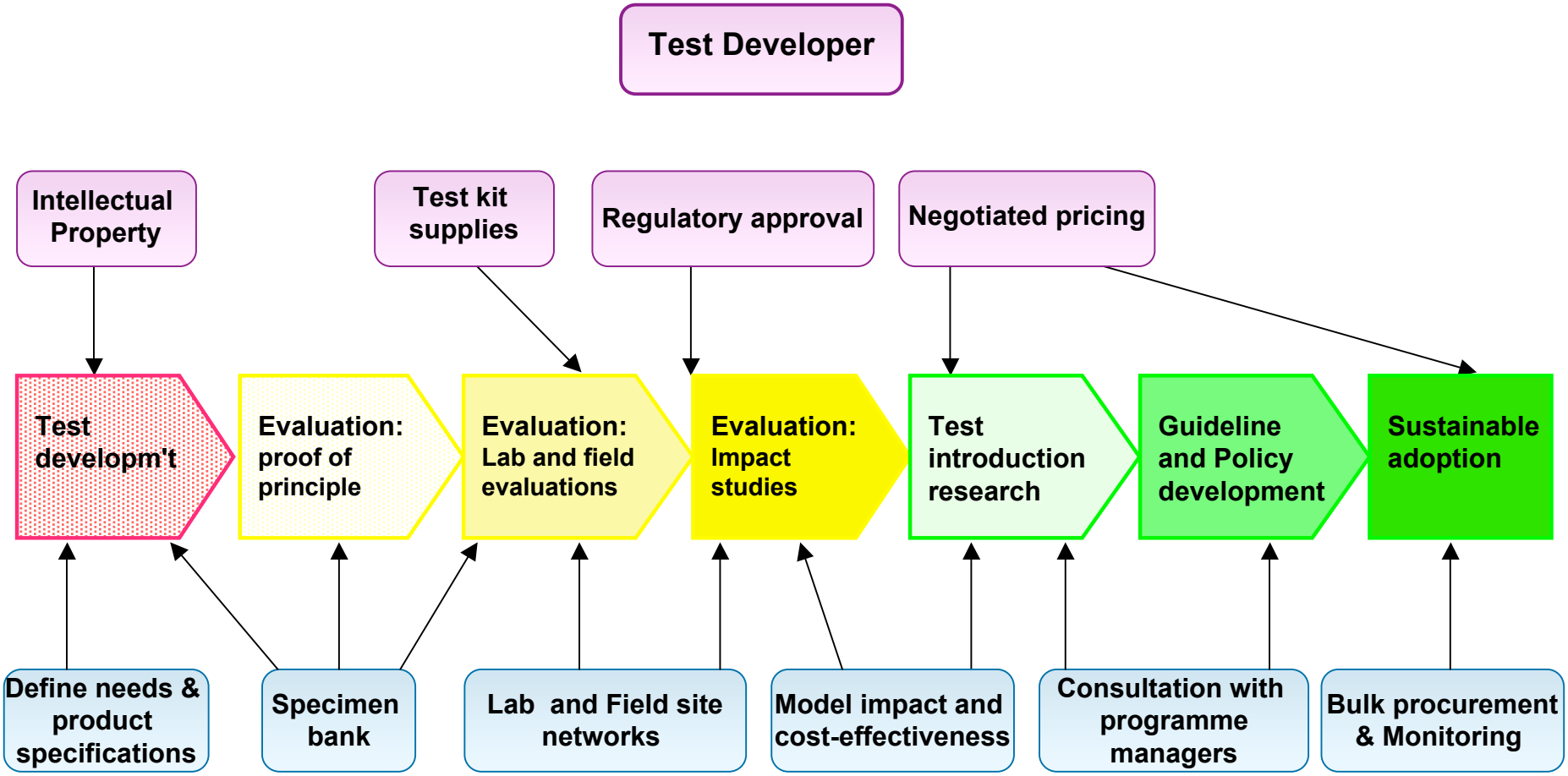
Plan of Presentation

- Objectives of external validations
- Planning an external validation
- Implementing the validation
- Lessons learnt

Background

- Numerous diagnostic tests being sold and used in the developing world without evidence of effectiveness
- Lack of quality standards for:
  - **diagnostic evaluations**
  - **regulatory approval**
- Lack of mechanism for translation of research evidence into policy and practice
- Challenge of introducing novel tests into frail or non-functional health systems



WHO/TDR DRD Strategy

Validating STI Rapid Tests: Syphilis

- **Lab-based evaluation conducted in 8 countries**
- **Field trials conducted in 6 countries**
- **Mathematical models developed for:**
  - Estimating potential impact
  - Estimating cost-effectiveness of different strategies for introduction
  - Assessing required tests performance
- **6 rapid syphilis tests with acceptable performance included in WHO Procurement**
- **Use of Rapid Syphilis Test Guide developed --- advocacy and to ensure appropriate use of new tests**
- **Use to be recommended in WHO STI management guidelines**

Objectives of External Validations

- To validate test performance characteristics in populations of intended use
- To validate operational characteristics of test

Accuracy and operational characteristics data to be used for:

- policy decisions
- regulatory approval
- procurement

Planning an External Validation

- Protocol development
  - consult regulatory agencies/control programmes/policy makers/end users
  - draft master protocol
  - post Request for Applications for sites
  - invite potential PIs to protocol development workshop
  - submit final protocol for ethical approval

Planning an External Validation

- Site selection
  - post RFA specifying requirements
    - Access to patients
    - Capacity to perform diagnostic evaluations in a timely manner
    - Proficient at performing reference standard tests (subscription to EQA)
    - Mechanism and time required for IRB approval
    - Good standard of care
  - Review applications and shortlist
  - Site assessment visits

External Validation: Site Preparation

- Translation of SOPs
- Training in GCP and GCLP for study team using study as example
- EQA for reference standard test, esp for quantitative assays
- Data management
- Procurement of supplies
  - Liaise with MOH to prevent delay in customs
  - Monitor temperature spikes

External Validation: Implementation

- Study initiation
- Study monitoring and trouble shooting
- Collect data for mathematical models
- Collect data for test format improvement
- Ongoing monitoring of stability of reagents

Lessons Learnt

- Delays in IRB approval
- Training
  - on safety issues in use of tests
  - for action on test results
- Lack of laboratory infrastructure for QA/QC
  - monitor stability of tests after import and in field settings
  - monitor quality of testing using proficiency panels
- Long delays in test adoption
  - Lack of mechanism for translation of research findings into policy and practice – need for policy platform
  - Lack of funding
  - Lack of functioning health infrastructure