Innovations, Laboratory Diagnostics and Networks: How can laboratory networks take up the innovations
At FIND we bridge science with patients to transform lives

### SCIENCE
- Tuberculosis
- Emerging Threats
- Neglected Tropical Diseases
- Hepatitis C & HIV
- Malaria & Fever
- E-Diagnostics

### PRODUCTS

### SOLUTIONS
- Catalyse development
  - Dynamic needs definition
  - S4S: Support programme for manufacturers
- Guide use & policy
  - Clinical trials
  - WHO evidence & guideline development
- Accelerate access
  - National policy
  - Roll-out planning
  - Gap analysis and solutions
  - QA tools and strategies

### PATIENTS
- Shape the agenda
  - Impact of diagnostics
  - Diagnostic ecosystem changes
  - Emerging diagnostics topics

**Catalyse development**

**Guide use & policy**

**Accelerate access**

**Shape the agenda**
Three ‘valleys of death’ for diagnostic innovation

1. Valley of death
   - Scientific & technical
     - Product design
     - 40% failure

2. Valley of death
   - Regulatory & policy
     - Utilizing results for care
     - 20% failure

3. Valley of death
   - Planning for adoption
     - Demand generation & evidence on impact
     - 40% failure
Tactical challenges to validating products

- **Disease Understanding**
  - Lack of scientific data eg: LOD, kinetics, epidemiology

- **Biosafe Reference Labs**
  - Lack of BSL-3 and BSL-4s is a significant bottleneck

- **Gold Standard Reference Test**
  - Imperfect or not established → perceived product failure

- **Assay Controls**
  - May be Research Use Only

- **Inclusivity & Exclusivity Panels**
  - Inclusivity for new pathogens is not guaranteed

- **Patient Samples**
  - Significant obstacle

- **Qualified Trial Sites**
  - Significant obstacle

- **Regulatory Approval**
  - WHO EUAL
  - FDA EUA
  - Home country

Outbreak product development & validation pathway becomes compressed when done during an outbreak but high quality is still required
Ensuring uptake and use of diagnostics

- Robust comparison of multiple new diagnostics is needed
  - In-country data, access to samples, qualified trial sites
  - Objective, comparative assessments of clinical and operational performance are needed for strong national policies

- Multiple regulatory pathways possible
  - WHO EUAL ≠ FDA EUA ≠ Home country requirements
  - Trial & data requirements need to be harmonized, i.e.: multi-country partnerships

- Pathway for post-PHEIC or EUAL
  - Emergency Use Authorizations necessarily allow for limited product validation studies in clinical and spiked samples
  - Ensuring sustainable access to high quality diagnostics post-emergency
Global Forum for Diagnostics Preparedness

Technical solutions

- **Critical assays**
  - Pathogen-specific assays to address critical gaps and WHO R&D Blueprint needs

- **Comprehensive platforms**
  - Diagnostic platforms with broad test menus allowing for rapid integration of new tests

- **Connectivity solutions**
  - Fully interconnected, real-time data reporting

Response speed

- **Trial sites & regulatory pathways**
  - Trial sites ready to validate new diagnostics
  - Improved regulatory pathway and rapid access to validated diagnostics

- **Sample access**
  - Established sample sharing commitments
  - Virtual specimen bank for priority pathogens

Market sustainability

- **Manufacturing**
  - Innovative business partnerships, subsidized dedicated manufacturing lines and other financing mechanisms

- **Global supply chain**
  - Product, rapid procurement and stockpiling with agencies with global reach and supply chain capacity