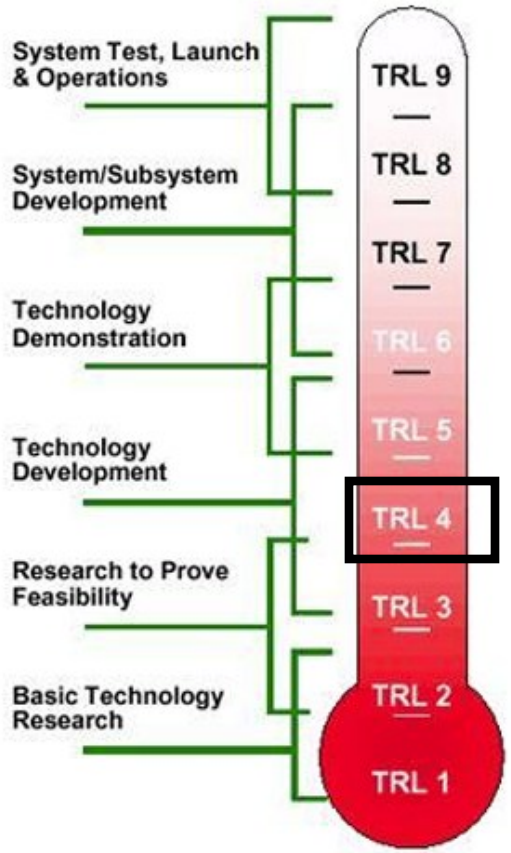
Critical Path Analysis (CPA) for new TB diagnostics: India

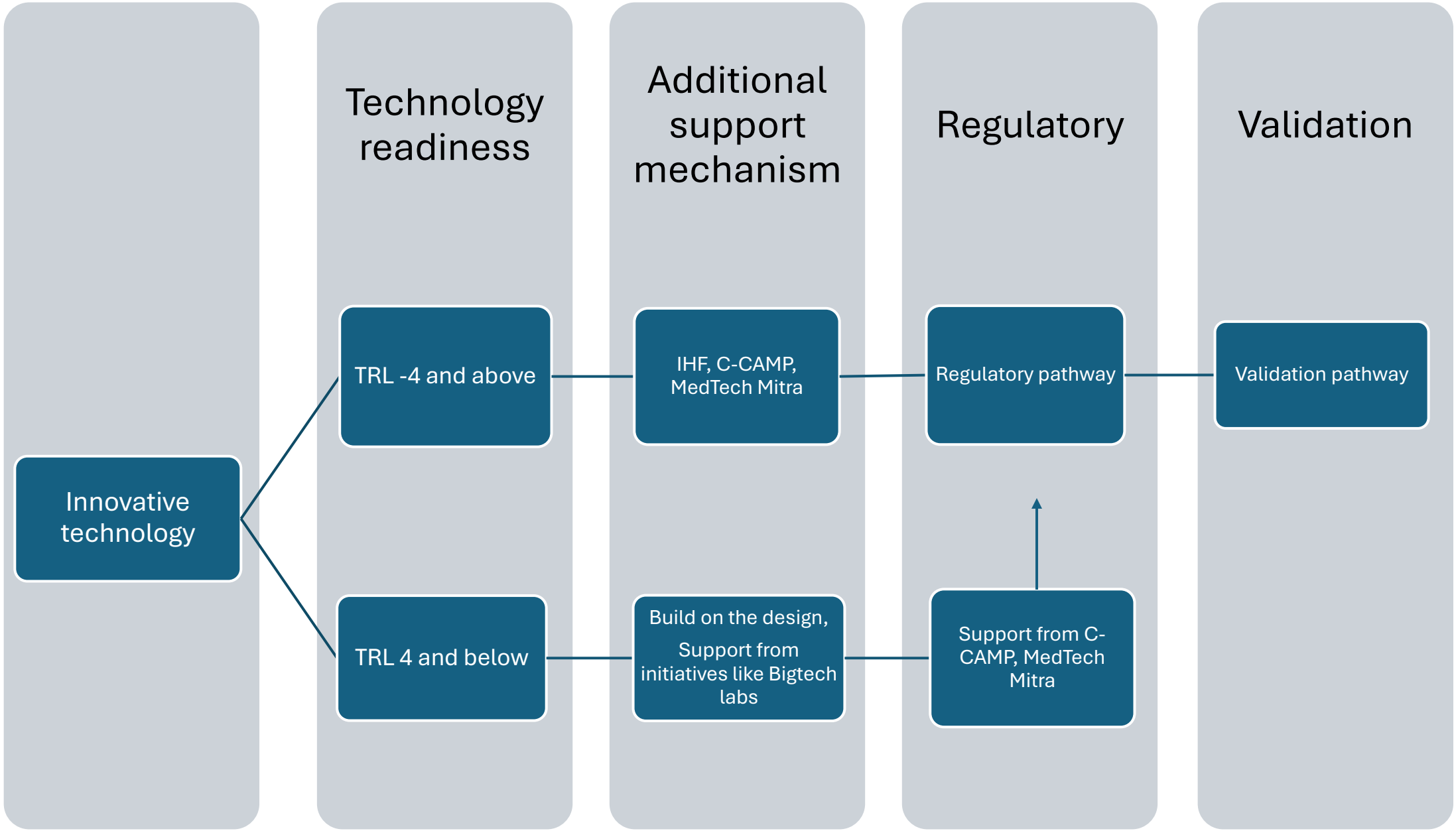
Methodology

- Review of existing literature and national documents
- Interviews of relevant stakeholders:
  - Representatives from ICMR
  - Representatives from CDSCO and ICMR approved labs
  - Manufacturers: Indian and imported technologies

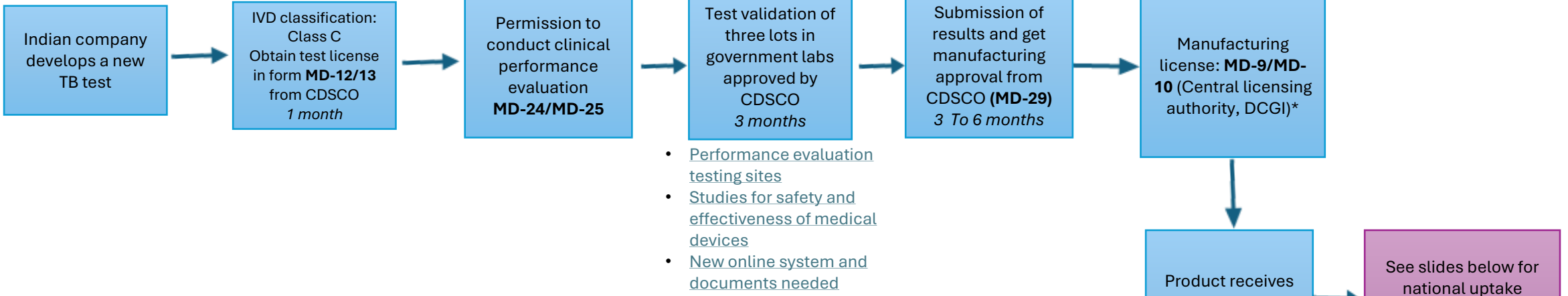
Big picture view

Technology readiness




Technology readiness
Additional support mechanism
Regulatory
Validation
Innovative technology
TRL -4 and above
TRL 4 and below
IHF, C-CAMP, MedTech Mitra
Build on the design,
Support from initiatives like Bigtech labs
Regulatory pathway
Support from C-CAMP, MedTech Mitra
Validation pathway

Regulatory pathway from CDSCO, indigenous company



Enablers:

a. Platforms like MedTech Mitra and Manthan

b. Initiatives from companies like Molbio and C-CAMP

c. CDSCO FAQs and revised new transparent pathways

Barriers:

a. Unavailability of clinical specimens for test validation

b. No standard protocol for CDSCO test validation (but ICMR is working on it)

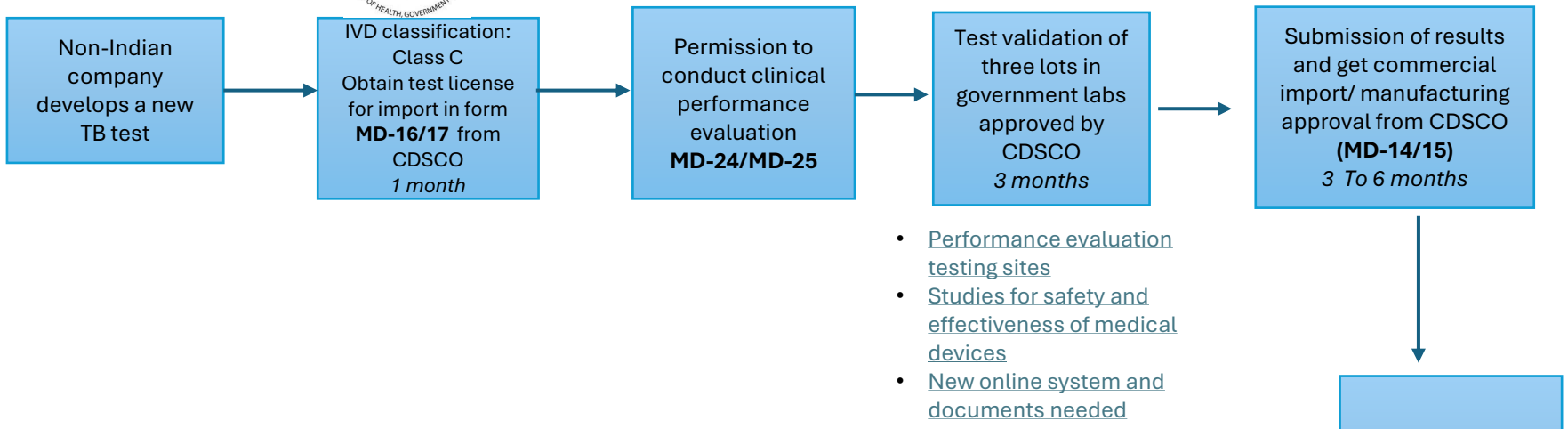
c. Inaccessibility of CDSCO sites, especially from remote areas of the country

d. Funding gap after the seed funding to take the technology forward

e. Innovators need handholding to assess public health needs, evidence generation requirements and market shaping strategies.

f. There are no current assessment standards for AI based technologies

Regulatory pathway from CDSCO, imported company



Enablers:

a. Platforms like MedTech Mitra and Manthan

b. Initiatives from companies like Molbio and C-CAMP

c. CDSCO FAQs and revised new transparent pathways

d. Many seed funding initiatives from Government

Barriers:

a. Unavailability of clinical specimens for test validation

b. No standard protocol for CDSCO test validation

c. Inaccessibility of CDSCO sites, especially from remote areas of the country

d. The company importing test kits may not always be fully aware of the quality and lot release criteria

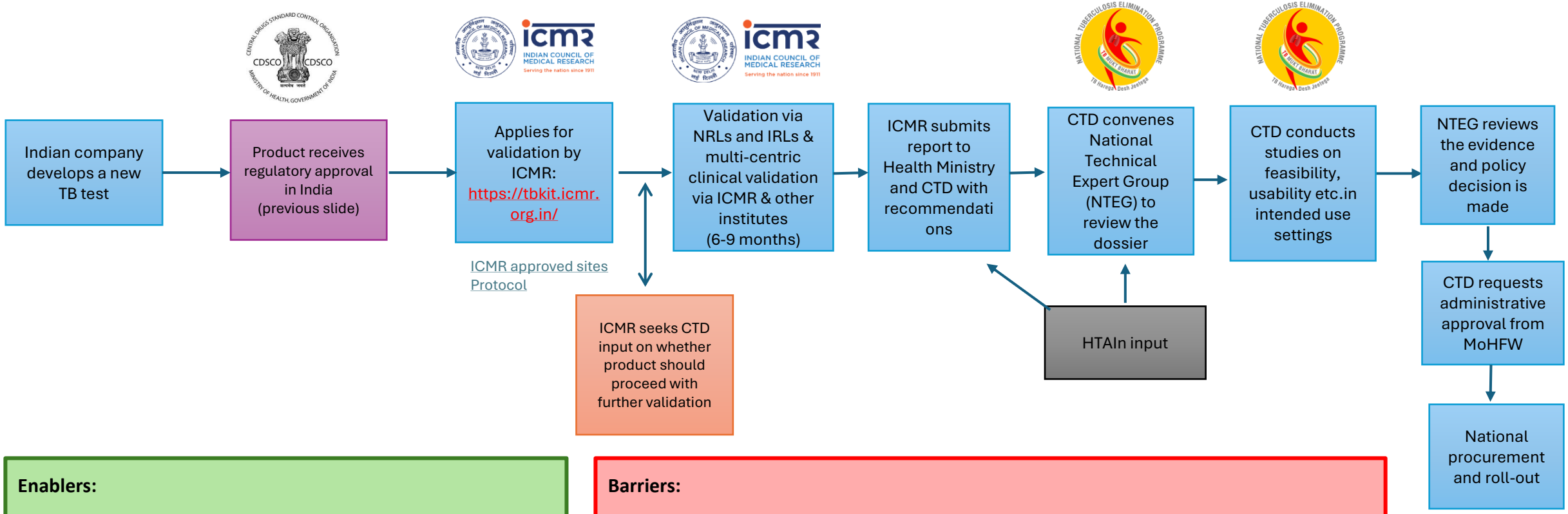
e. Issues with transportations, storage of kits when importing

f. Funding gap after the seed funding to take the technology forward

g. Innovators need handholding to assess public health needs, evidence generation requirements and market shaping strategies.

h. There are no current assessment standards for AI based technologies

Critical path for public sector in India



Enablers:

a. Standardized protocols for independent ICMR evaluation
b. More streamlined mechanism
c. ICMR portal allows easy upload and access to documentation
d. Transparency for results of the validation via: https://www.icmr.gov.in/information-on-tuberculosis-tb
e. Regular ICMR-CDSCO workshops

Barriers:

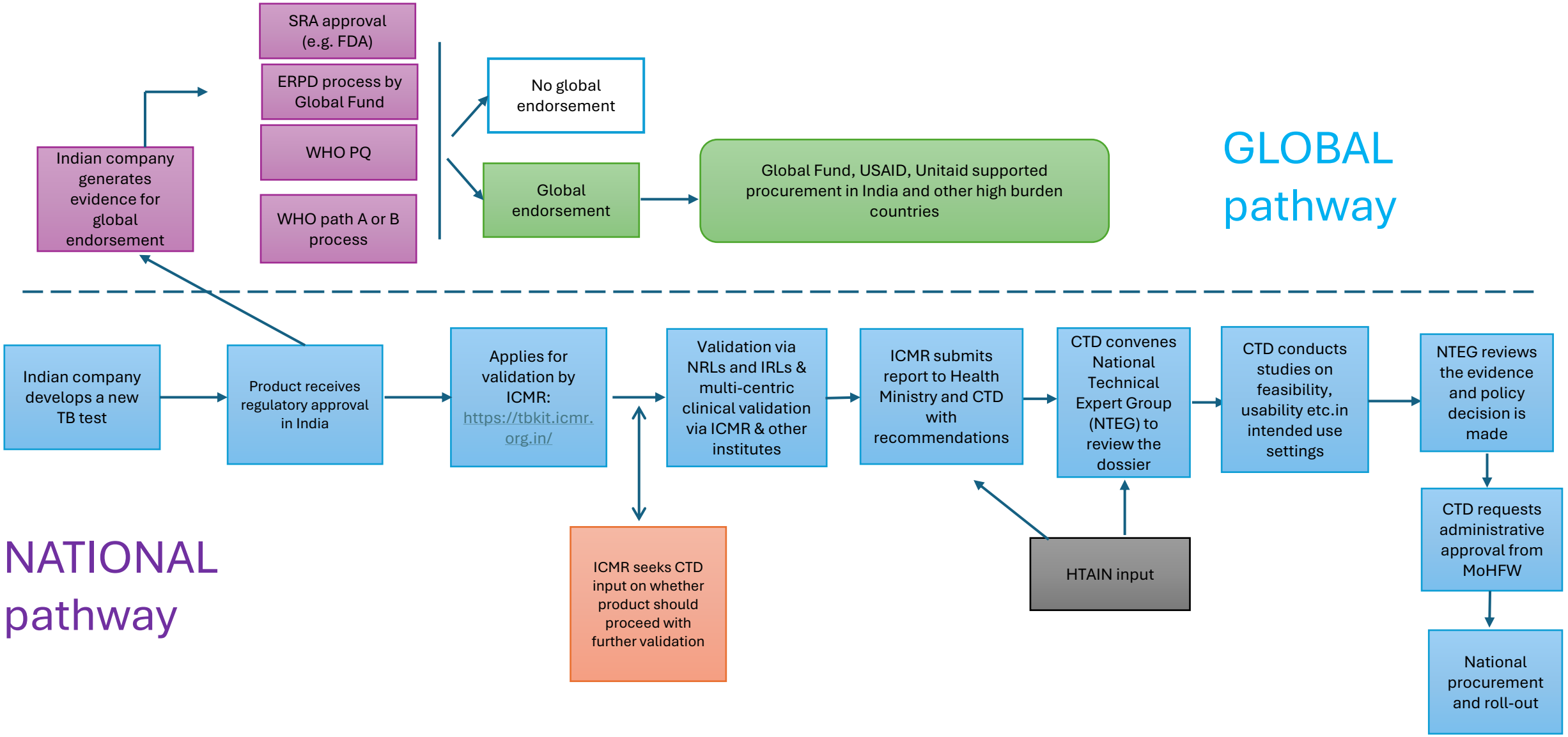
a. Cadence of NTEG meetings is not known; no published protocol for added feasibility and usability studies by CTD
b. Validation process in labs could take time depending on the availability of fresh specimens
c. Innovators do not know what to prioritize as no guidelines are provided by ICMR or NTP for screening tools or diagnostic tools
d. There are no current assessment standards for AI based technologies

HTAIn

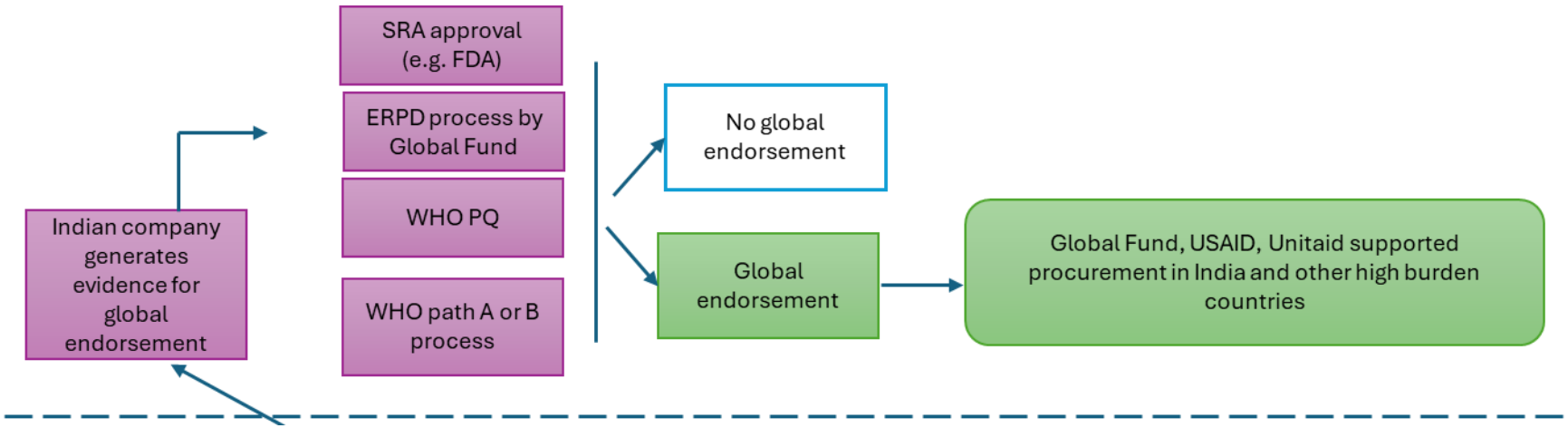
- Provides systematic evaluation of properties, effects and/or impacts of health technologies or interventions
- The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies
- Four divisions:
  - Clinical-effectiveness assessment Division
  - Economic assessment Division
  - Technology Integration in Public Health programs Division
  - Coordination, Communication and Administration Division

Health Technology Assessment in India (HTAIn) - Health Technology Assessment in India (HTAIn)

Critical path for indigenous test, for public sector in India & globally



What do Indian Innovators Need to Do, to Access The Global Pathway



Enablers:

a. The pathway allows for accessing other markets

b. Open timelines to apply for TB technologies through ERPD- providing flexibilities

Barriers:

a. Indian Innovators are not always sure about the requirements for global evidence needs such as sample size, reference standards etc.

b. The pathway and point of contact for the global endorsement is not clear/ streamlined

c. Not clear when to apply for ERPD, PQ or TB programme

What do Indian Innovators Need to Do, to Access The Global Pathway

WHO class A

First-In-Class Technologies

Multi-country, well-designed studies in PICO format

Evidence includes accuracy, people important outcomes, cost-effectiveness, acceptability and feasibility

WHO class B

Within class technologies

Multi-country, well-designed studies in PICO format

Evidence is reviewed by TAG and primarily includes accuracy

WHO PQ

For WHO recommended technology class

Evidence is reviewed by the WHO PQ team and needs to cater to the Technical Specification series: TSS -17; TSS 23

Evidence includes analytical and clinical accuracy, safety, labelling, quality assurance etc.

ERPD

For new technologies which have submitted or has intent to apply for PQ

Evidence is reviewed by the Expert review panel using a diagnostics product questionnaire.

It primarily includes accuracy (interim or final), regulatory status

Manufacturer independent evidence

- Manufacturer submits data based on TSS and questionnaire checklist
- Independent evaluation

Advice to manufacturers

- Assess the technology readiness
- Seek support from initiatives like MedTech Mitra, C-CAMP, Bigtech labs
- Engage in early conversations with these platforms to ensure the product meets the need of public health needs
- If it is a technology transfer, a stringent quality assessment framework is needed
- If tests are imported, it is critical to have all relevant documents to ensure optimal quality of the tests/reagents imported

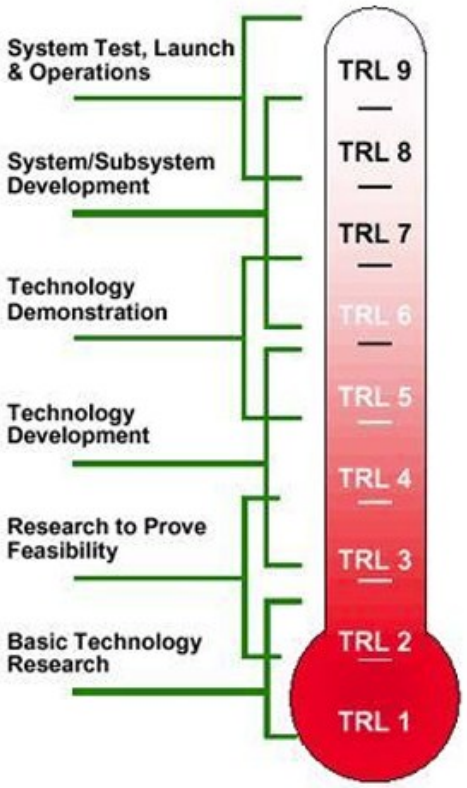
Thank you!

Additional slides

C-CAMP

- Supporting companies on TRL-4 and above
- Supporting initial testing before moving to CDSCO
- Support companies with analytical testing and clinical evaluation
- Have standards of MTB testing to enable analytical testing of molecular tests

Other considerations



1. Technologies at TRL 4 and above: C-CAMP can support
2. What happens to anything below TRL 4?

Barriers

1. Specimens are not available for initial product design
2. No handholding available at this stage
3. If the innovation is new and not a regular molecular test, it is difficult to assess its possibility of uptake

Available resources for AI based technologies

- Ethical considerations for use of AI: ICMR
- MIDAS: a platform to create India-centric datasets for AI-powered healthcare

Additional comments

- Innovators to think outside of the box: move away from sputum-based testing
- To have equivalency data on fresh and decontaminated frozen specimens to ensure easy testing at labs sites
- ICMR coming up with more easier platforms to have all information in one dashboard
- Upcoming: Atlas of innovations
- CDSCO planning to come up with a standardized protocol for innovators- mostly analytical testing