Critical Pathway Analysis:

A part of Evaluation and Demonstration of New Tuberculosis Diagnostics for Indonesia (EVIDENT Indonesia)

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Context

- There has been a commitment by the Government of Indonesia to open up for innovative TB diagnostics to be used in Indonesia (Nov 2024).
- From January to May 2025, the Ministry of Health has been revising a standard related to the **pre-market clinical validation of medical devices** for obtaining regulatory approval for **Tuberculosis (Co-creation 1)**.
- In the same time, MoH also develop a framework for simplified **Health Technology Assessment (sandbox)** procedure for general digital and treatment technology (not only for Tuberculosis) **(Co-creation 2).**

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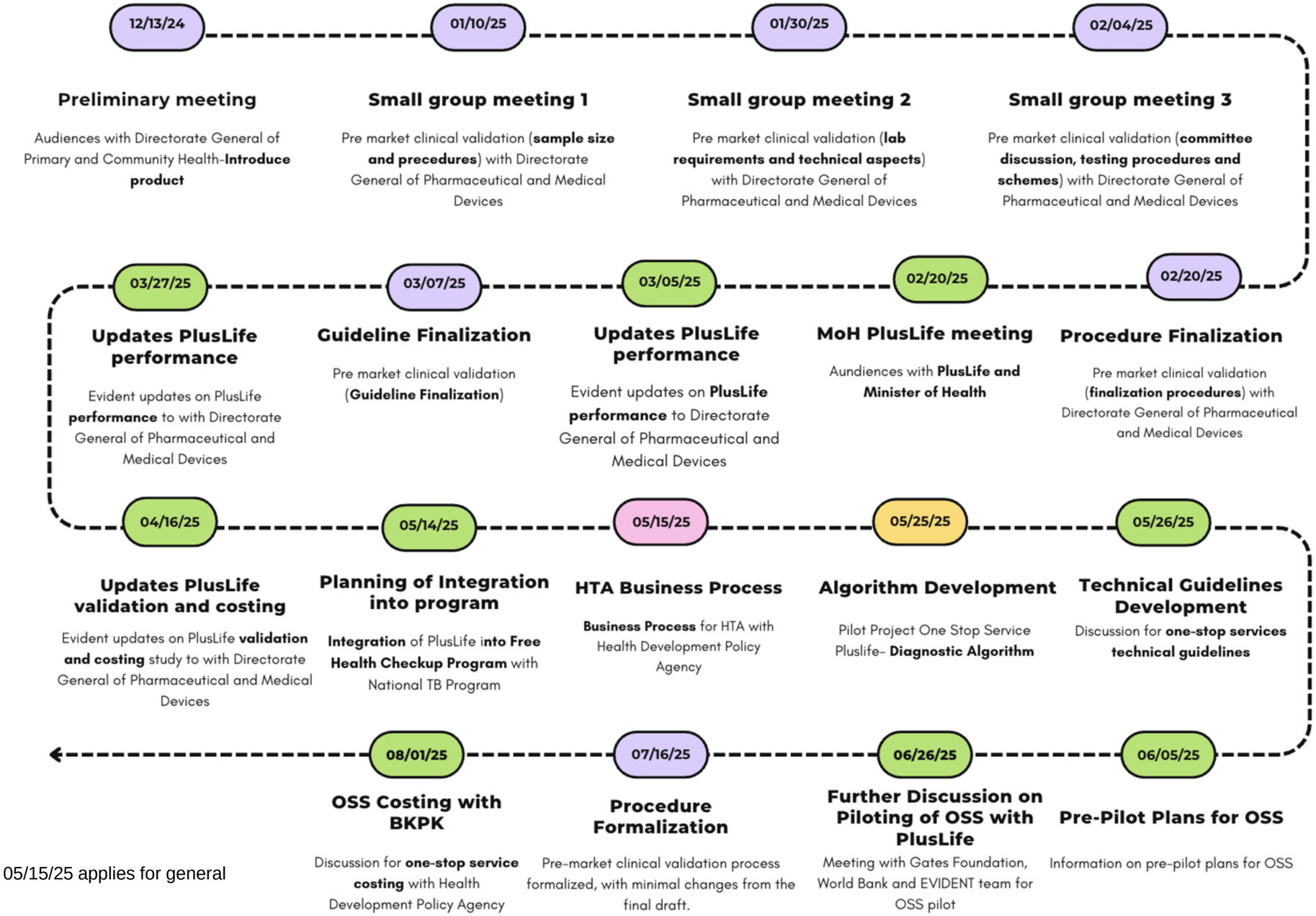
Data collection

Qualitative data (up to July 2025) :

- Document reviews: regulations, meeting notes with MoH and other stakeholders
- Interviews: 8 vendors, 2 MoH units, one provincial health office, and one association of distributor representatives.
- Participatory in 13 co-creation meetings with MoH and other stakeholders
- More co-creation meetings are planned

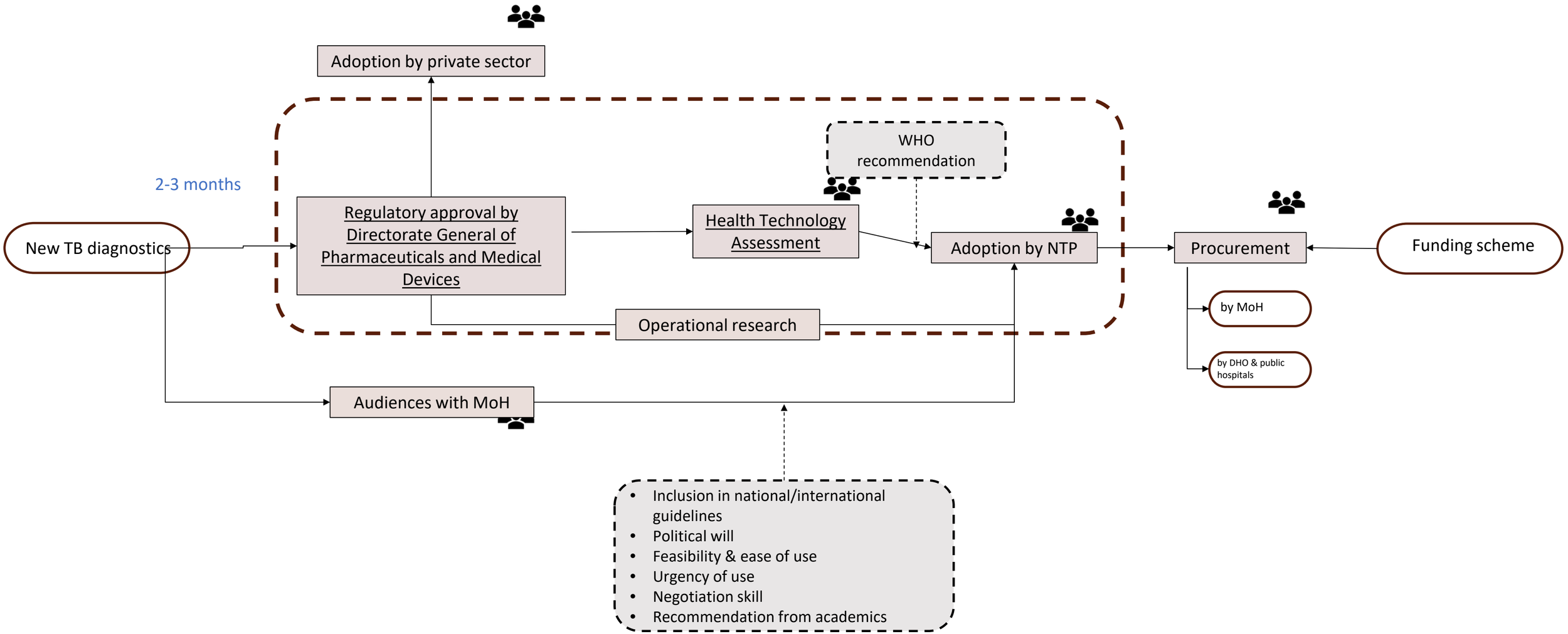
Pathway Co-creation Timeline



*Business process meeting on 05/15/25 applies for general HTA, not specific to TB.

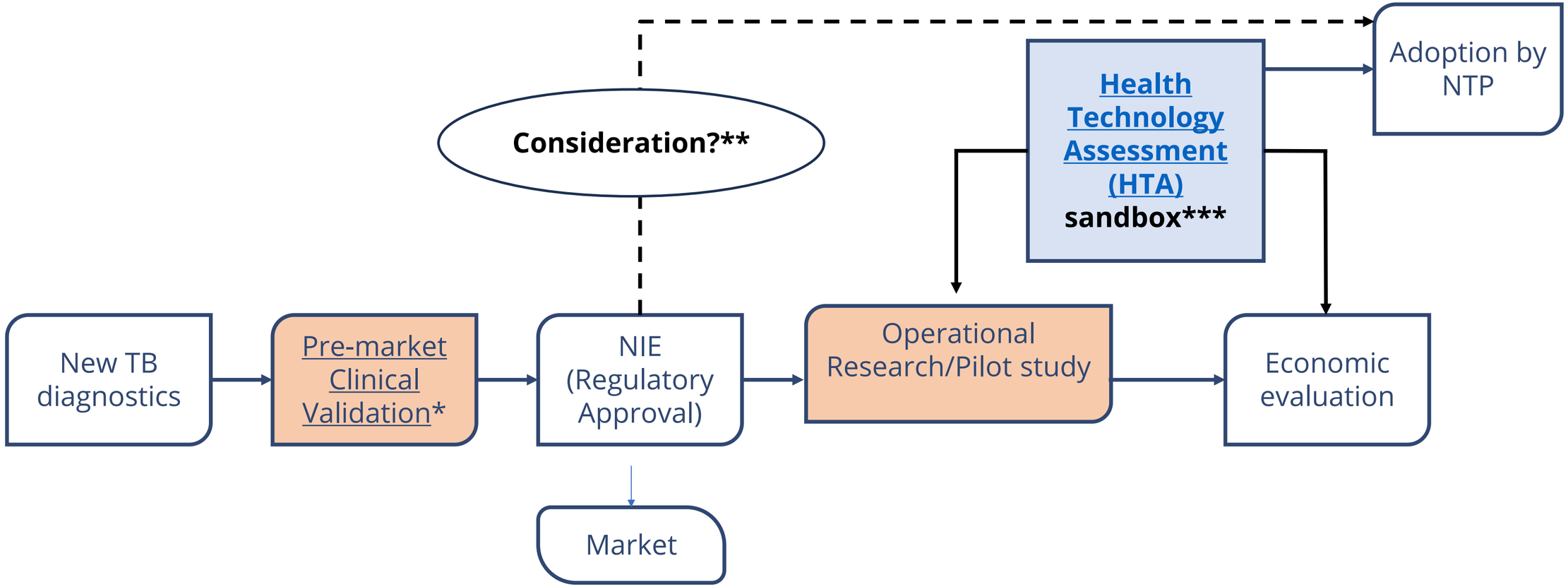
Pathway before Nov 2024

(finalized 16 Dec 2024)



Co-creation: Pathway for Tuberculosis Diagnostics

(preliminary finding up to July 2025)



*) The guideline of pre-market clinical validation is being finalized (July 2025). Consideration of fast track adoption without HTA is now being discussed, and can be the urgency of new diagnostic test for TB

**) Perceived urgency by the MoH

***) The HTA Sandbox is still general, and HTA for diagnostic tests has not been incorporated in the “new framework” of HTA (sandbox)

Mechanism for Validation Testing of Diagnostic Tools and Reagents for TB Testing (July 2025)

Manufacturers
Conducts validation testing at designated laboratories

Testing at 2 (Two) Different Laboratories
Laboratory A tests the reagen kit with a different *lot* number than Laboratory B

Test Results

Meets Requirements

Reviewed by Expert Team

Proceed with Licensing Application Process

Discordant

Retested at a Different Laboratory

Reviewed by Expert Team

Meet Requirements

Yes

No

Does Not Meet Requirement

Registrant Conducts Evaluation and Product Improvement

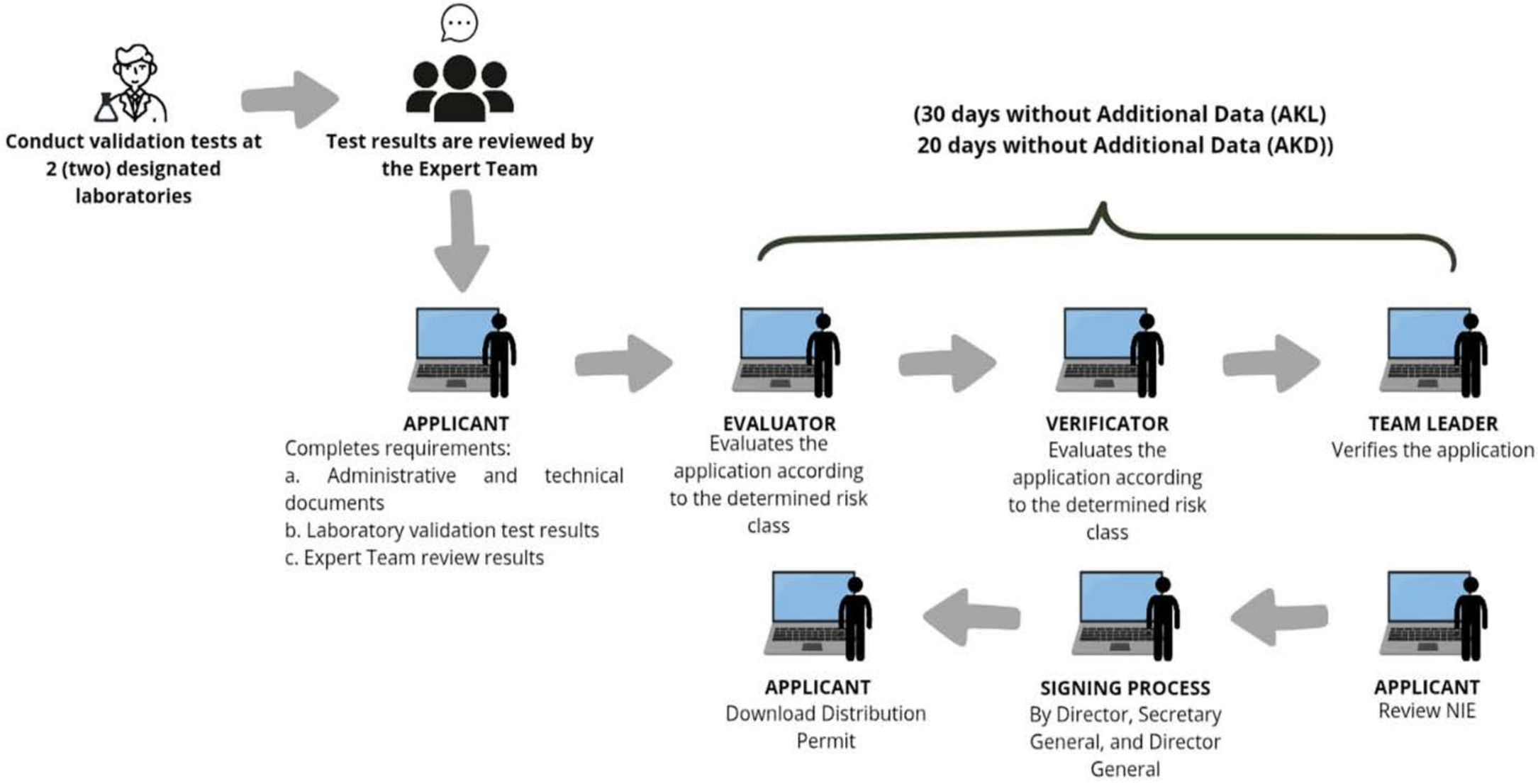
Co-creation 1: Stakeholder Identification

Pre-market Clinical Validation	Health Technology Assessment	Adoption	Procurement	Roll-out and Scale-up
▪ Directorate General of Pharmaceutical and Medical Devices ▪ TB Expert Committee ▪ TB Working Group Lab	▪ Health Development Policy Agency ▪ TB Expert Committee ▪ TB Working Group Lab	▪ Directorate General of Community and Primary Healthcare ▪ National TB Program	▪ Directorate General of Pharmaceutical and Medical Devices ▪ National TB Program ▪ Secretary General of MoH ▪ District Health Office	▪ Directorate General of Pharmaceutical and Medical Devices ▪ National TB Program ▪ Directorate General of Community and Primary Healthcare ▪ District Health Office

Example of co-creation 1: Pre-Market Clinical Validation Process

Before 2025	2025 - onward
➢ **Imported products** go through a document-based validation, whereas **indigenous products** go through a lab-based validation. ➢ Process on average **3-6 months**. ➢ **Unclear lab standards** for validations, perceived difficulty by local manufacturers.	➢ **Both imported and indigenous products** will go through a lab-based validation process. ➢ The process will take at most **4 months**. ➢ Clear regulations on lab standards for validation. ▪ Labs must: 1) **have access to clinical specimens**, 2) **capability for culture** (gold standard), **sensitivity, and molecular testing, 3) be accredited with SNI ISO/IEC 17025 and SNI ISO 15189**. ▪ Approx**. 200-400 samples are** needed with an absolute deviation of 7% (variation due to prevalence). ▪ Criteria for sputum sample storage: 1) **room temperature (3 days)**, 2) **2-8 Celsius (7 days),** 3) **-80 Celsius (1-2 years).** ➢ Validation will be conducted by **two accredited labs**, with a third one for ambiguous results.

Example of Co-creation 1:
Pre-market Clinical Validation Process for TB diagnostics



Source : Ministry of Health Indonesia

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Co-creation 2: Recent Developments of HTA

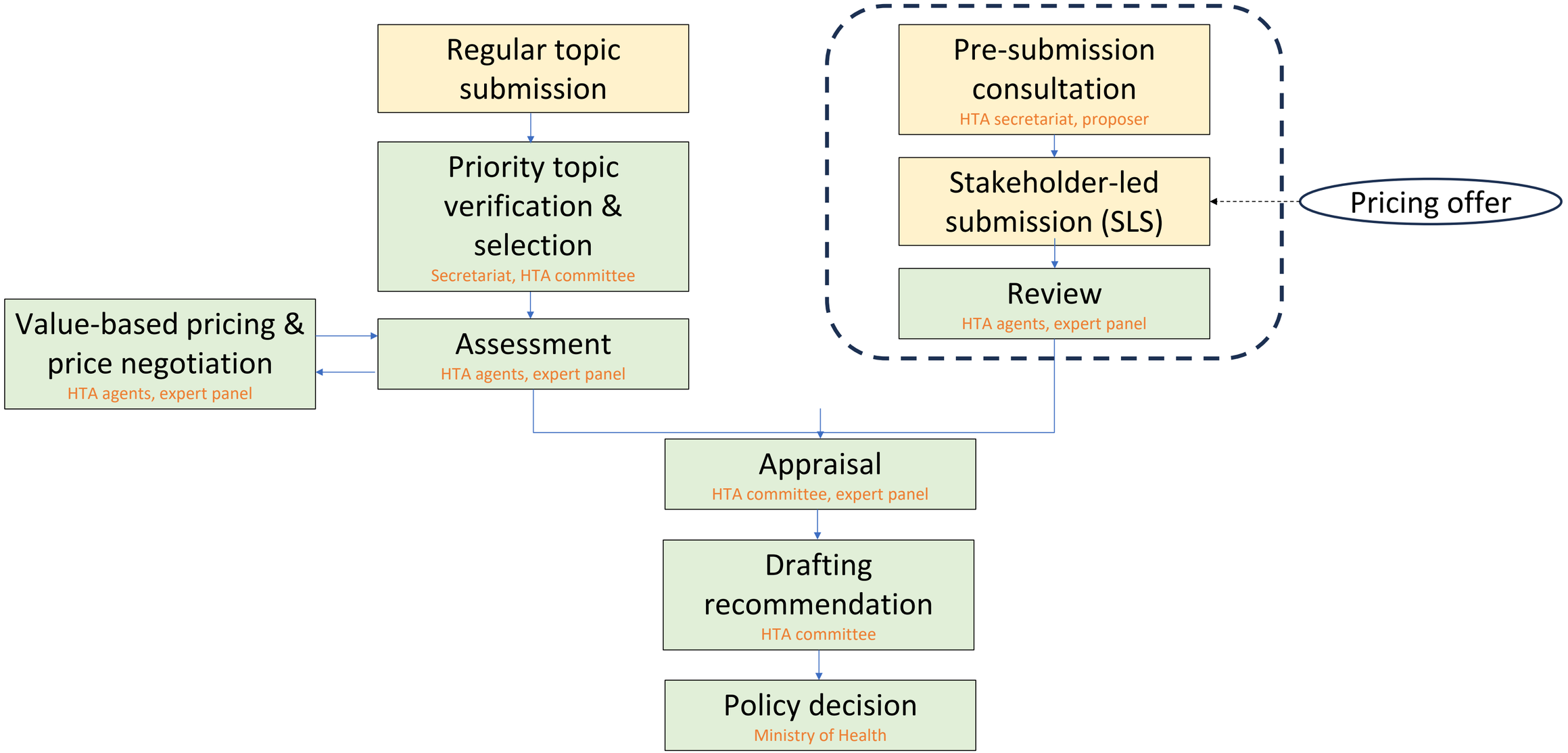
- As of 04/06/25, the HTA process is yet to be finalized and significant changes are still taking place.
- As of 14/05/25, the stakeholder-led submission scheme is being piloted.
- Several important developments include a clear criteria selection for priority topics, sandboxing as a proposed business plan for HTA, and a clear framework for evaluation.
- Discussion and co-creation is still ongoing, with several members of the EVIDENT team as authors.

Co-creation 2: Stakeholder Identification for HTA Process

Stakeholder	Topic Proposal	Verification of Topic Proposal	Priority Topic Selection	Data and/or HTA Provider	Assessment	Appraisal	Policy Recommendation	Implementer	Monitoring
Health Technology Assessment Committee	√		√	√	√	√	√		
Ministry of Health	√	√		√	√		√	√	√
BPJS (National Health Insurance)	√			√				√	
Professional Organization/Expert Panel (TB Expert Committee, TB Working Group, etc)	√			√	√	√		√	
Other Expert Panel (health economics, sociocultural, public health, etc)	√			√	√	√			
Hospitals	√			√	√			√	
Universities	√			√	√				
Patient and/or Patient Organizations	√			√	√	√			
Pharmaceutical and Health Technology Industry	√			√	√			√	√

*last updated on May 2025

Co-creation 2: Health Technology Assessment (HTA) for general health technology



*** Based on MoH Regulation, for general health technology, not only for TB**

Co-creation 2: Regular vs Stakeholder-led Submission

Regular Submission	Stakeholder-led Submission
HTA assessments are conducted **in-house** by the Ministry of Health in collaboration with **HTA Agents** (Universities, Research Centers).	HTA assessments are conducted **independently by HTA stakeholders**, and the results are submitted to the Ministry of Health for review.
Proposers are **not charged** a fee; the technologies assessed through HTA are selected based on a topic prioritization mechanism.	Proposers are **charged a fee** to request a review of the HTA assessment results they have conducted.

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Co-creation 2: HTA topic criteria selection

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6 Priority Topic Criteria			Weight
1	Impact of technology on health	(+) Efficacy & QoL (-) Harm, misuse risk	26%
2	Alignment with priority policies	Consistency of technology with policies/development program	20%
3	Cost-saving potential	Efficiency potential in national health insurance program expenditure	13%
4	Volume	Utilization Prevalence, Incidence	14%
5	Technology cost	Unit cost, cost per service, screening/test cost	11%
6	Acceptance	Acceptance according to community values/needs	16%

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Co-creation 2: Assessment Framework

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MRC Framework (UK Medical Research Council)	RE-AIM Framework	AAAQ Framework	Cost-effectiveness
1. **Implementability :** Can the action be carried out? 2. **Mechanism of impact** How does the technology lead to change? 3. **Contextual Influence** System and contextual factors that influence implementation Reference : MRC Guidance on Developing and Evaluating Complex Interventions	**Reach** : Who is intended to be affected by the technology ? **Effectiveness** : Does the technology achieve intended impact ? **Adoption** : Are relevant organizations able and willing to implement it	**Availability** : Is the technology available **Accessibility** : Can the technology be accessed without excessive burden? **Acceptability** : Is it well received by the public ? **Quality** : is it effective for its intended use	Cost-effectiveness analysis Cost-utility analysis Budget impact analysis

Proposed Innovation Assesment Business Process: Sandbox

Co-creation 2: Sandbox for HTA Business Process

- Accept applications to enter the Sandbox
- Conduct horizon scanning for emerging technologies (e.g., via hackathons)
- Conduct TRL assessment
- Issue temporary authorization for certain technologies to be tested in the Sandbox
- Coordinate monitoring and evaluation of Sandbox results

Solution #2

Sandbox as an Innovation Process for Testing and Accelerating Health Technology

1. Accelerates the adoption of new technologies that do not yet have a complete regulatory framework
2. Reduces market entry barriers for local or frontier technologies
3. Encourages cross-sector collaboration among developers, regulators, service providers, and patients
4. Provides real-world evidence (RWE) to support evidence-based decision-making (e.g., Health Technology Assessment/HTA)

Submission of Health Technology Proposal

Technology Profile Review

Innovative Technology Evaluation Committee

Solution #1

Implemented One Stop by one work unit in the Ministry of Health

Solution #5

Formation of a Special Committee for the Evaluation of Innovative Technologies, with tasks:

1. Select and conduct early evaluation of technologies
2. Set evaluation criteria and protocols
3. Monitor and supervise implementation
4. Final evaluation and policy recommendations
5. Cross-sector coordination and collaboration
6. Capacity building and governance development

Implementation of Limited-Scale Testing (Sandbox): Digital

Criteria to be eligible for Sandbox license:

- Technology Readiness Level (TRL) ≥ 4 for digital
- TRL ≥ 7 for therapy

Implementation of Limited-Scale Testing (Sandbox): Therapy

Sandbox Results Evaluation

Solution #3

Sandbox results can be evaluated using:

a. MRC Framework (UK Medical Research Council)
b. RE-AIM Framework
c. AAAQ (Availability, Accessibility, Acceptability, Quality)
d. Cost-effectiveness

Notes for use:

- MRC + RE-AIM for complex clinical interventions
- AAAQ for digital and health rights technologies
- Cost-effectiveness when intended as evidence for national adoption

Recommendation / Decision

Solution #4

Decision categories:

- ✅ **Accelerated Adoption / Approval**
- 🟡 **Conditional Approval**
- 🔁 **Re-testing**
- ❌ **Not Recommended**
- ⏸ **Deferred Decision**

Co-creation 2: HTA Mechanism Based on TRL (Technology Readiness Level)

Submission Health Technology

Technology Readiness Level Assessment (TRL)

Proposal #1
Implemented through a Single Window by one unit in the Ministry of Health to direct the follow-up of an innovation in the health sector

Proposal #2
TRL is used as a measurement tool to plan follow-up actions for innovations

Proposal #3

Implementation of Sandbox to support **the formation of regulations or funding decisions (HTA)**
The implementation of the Sandbox is carried out for technologies **that are ready to be tested in a limited environment,** with the aim of observing real-world performance in a limited way.

TRL 1-3

1. **Ethical and Conceptual Screening**
2. **Prototype Testing and Validation**

TRL 4-8

3. **Limited Scale Testing (Sandbox)**
5. **Regulatory and Licensing Assessment**
4. **Health Technology Assessment (HTA)**

TRL 9

6. **Implementation and System Integration Assessment**
7. **Post-Market Monitoring and Evaluation**
3. **Limited Scale Testing (Sandbox)**
4. **Health Technology Assessment (HTA)**

dashed lines depict process innovation

Solution #4
HTA **can be conducted in parallel** with Regulatory and Licensing Assessment to obtain marketing authorization.
The Sandbox can serve as a means **to obtain local evidence** in generating HTA studies.

Solution #4
The Sandbox can be conducted after obtaining marketing authorization, where one of its purposes is **to obtain local evidence** in generating HTA studies as well as for specific funding schemes.

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A Case study of PlusLife

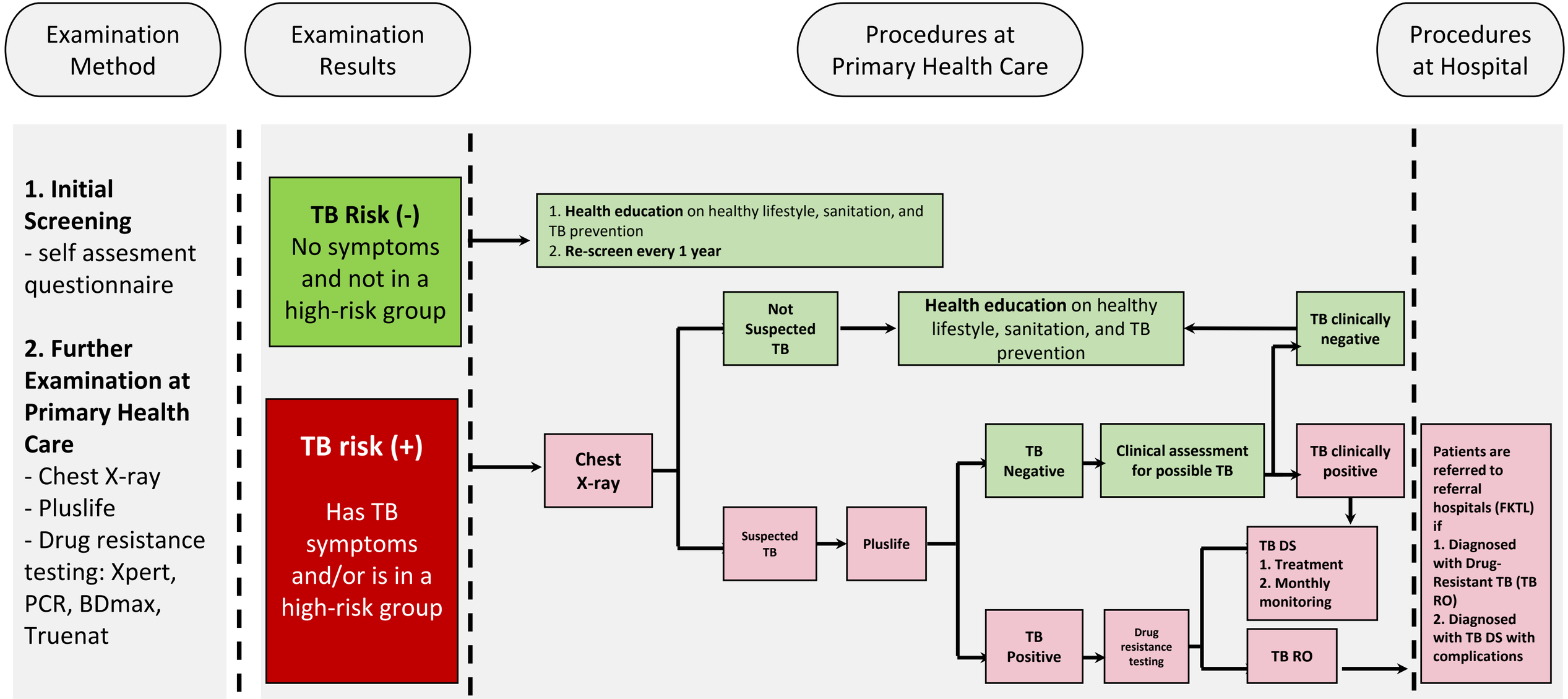
- There were regular updates by EVIDENT team regarding PlusLife performance to the Directorate General of Pharmaceuticals and Medical Devices.
- On 25/02/25, there was a meeting between PlusLife and PT Kirana Jaya Lestari team with the Minister of Health. Highlights included the importance of the Indonesian validation study, pricing, and double testing mechanism to offset false negatives.
- Further discussions were held between the EVIDENT team with Directorate of Pharmaceuticals and Medical Devices, Directorate of Prevention and Control of Infectious Diseases, and the National TB Program manager.
- On 14/05/25, the EVIDENT team was asked to participate in the free healthcare check-up (CKG) program by utilizing existing PlusLife machines.
- Two meetings were held in June to further discuss the piloting of the One Stop Service program within CKG, and is currently being piloted with the attached algorithm.
- This marks an interesting development in the CPA, as **PlusLife is adopted into a government program without a formal HTA process.**

Algorithm of Integration of PlusLife

High-risk groups (close contacts, household contacts, DM, HIV, malnutrition)

Pre-Pilot Project Flow of One Stop Service

Utilizing Chest X-ray with AI and Pluslife



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Summary

- Pathway to adoption for TB diagnostics is a dynamic process which is still being developed and finalized in Indonesia through co-creation process between researchers, experts, and policy makers (MoH)
- There are two on-going process:
  1) Validation and procedure for Tuberculosis diagnostics adoption
  2) HTA for general health technology
- Additionally, there is also a case study of TB diagnostics integration into existing government program (free health check-up)

Thank you

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Evident
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New TB Diagnostics for Indonesia

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