FIND

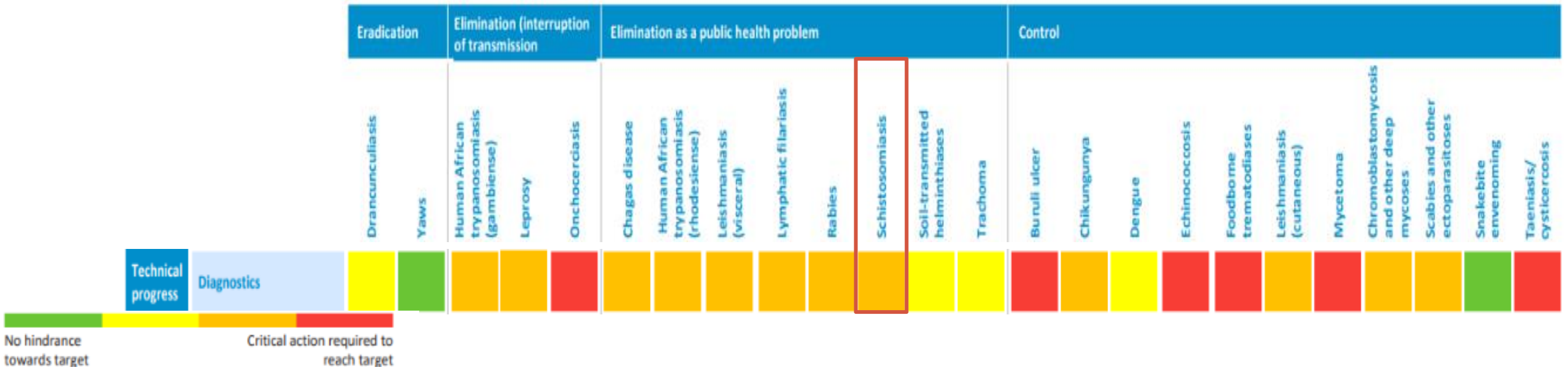
CLOSING THE DIAGNOSTIC GAP FOR SCHISTOSOMIASIS

SCH CAA RDT

18th October 2023, Project team

TO MEET THE 2030 TARGETS

NTD TESTING GAPS MUST BE URGENTLY ADDRESSED



WHO 2021–2030 NTD Roadmap places increased emphasis on diagnostics

6 diseases are missing any diagnostic tool

16 diseases have tools, but they must be improved to help reach the 2030 targets

2 diseases have no diagnostic needs

NTD diagnostic gaps have many root causes

Lack of data to guide interventions and investments

Few diagnostic development partners

No deliberate effort to establish an information mechanism that can avoid duplication of effort

New treatments need improved diagnostic tools

VISION FOR FIND'S SCHISTOSOMIASIS EFFORT

FROM….

Complex, costly and timely diagnosis process

- Multi-day sampling, lab transfer, skilled reader to interpret results etc

Over- or under treatment of affected communities

- Without precise mapping enabling strategic targeting, MDA campaigns are sub-optimal

Treatment exclusion of at-risk groups

- Although they are contributing to transmission, current MDA approach excludes adults and pre-school age children

Poor diagnosis and sub-optimal treatment strategy slow down efforts to reach goal

…TO

Rapid diagnostic testing

- For immediate assessment of prevalence in communities

Improved efficiency and costs of MDA campaigns

- Targeted MDAs for a focal disease

Expanded access to testing through better integration

- SCH screening and treatment integrated into non-NTD health programs
- SCH diagnosis integrated into PHC care in high-burden countries

Easy-to-use test allows precision mapping and more effective interventions paving the way to sustainability

CURRENT METHOD OF DETECTION AS RECOMMENDED BY WHO

CURRENT TECHNOLOGIES

	Microscopy	Dipstick	Antigen methods*
Sample type			
Method			 POC-CCA

WHO DTAG TPPs

1 M&E

Intended use:

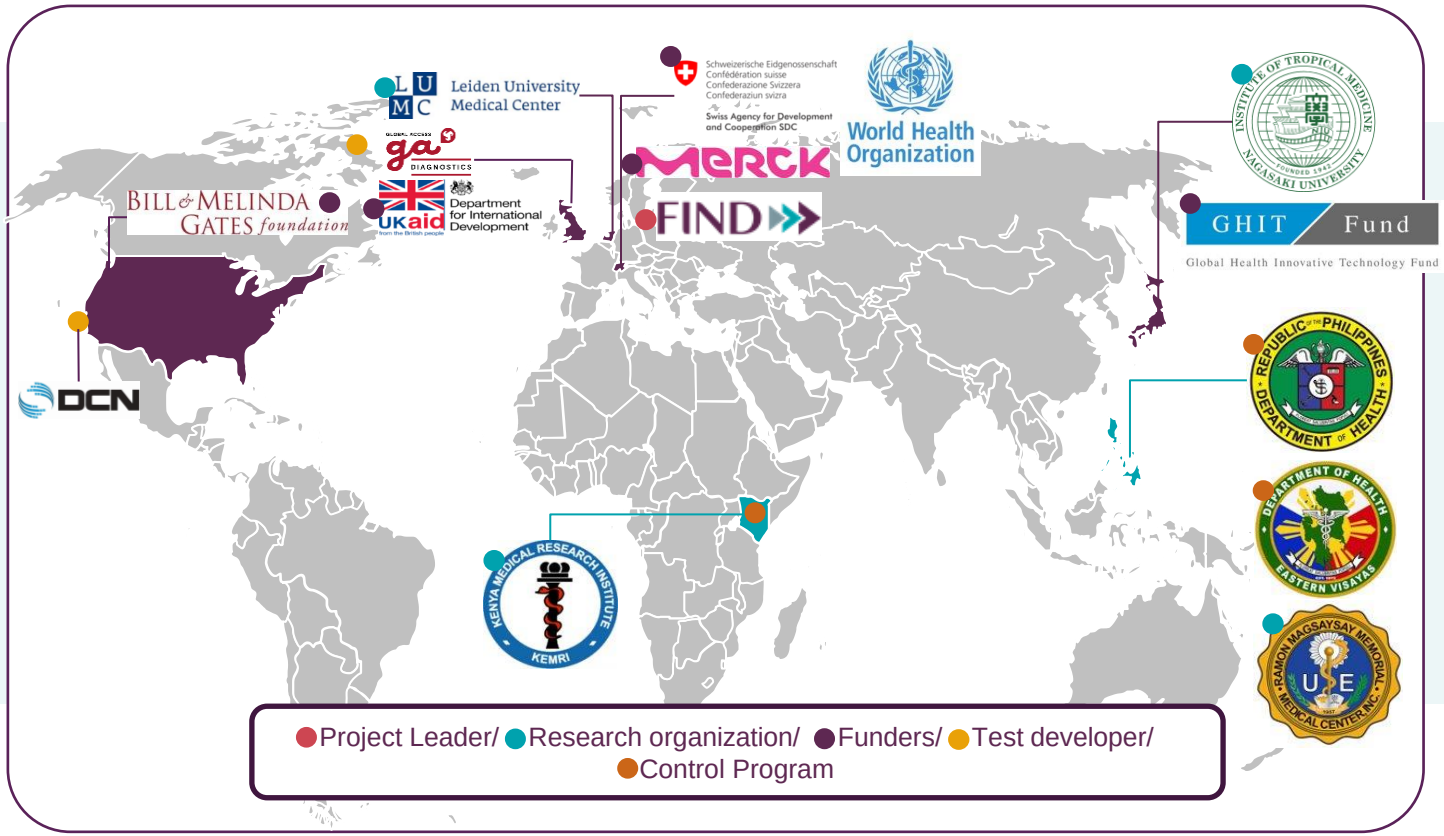
An in vitro point-of care test for the detection of analyte specific to S.*m* or S.*h* to aid in M&E of SCH control efforts.

	Min.	Ideal
Sensitivity	>60%	>75%
Specificity	>95%	>96.5%

*only works for S.*m* and at high-moderate intensity infections

SCH CAA RDT PROJECT

BACKGROUND, PARTNERS AND DONORS



Project started in 2018

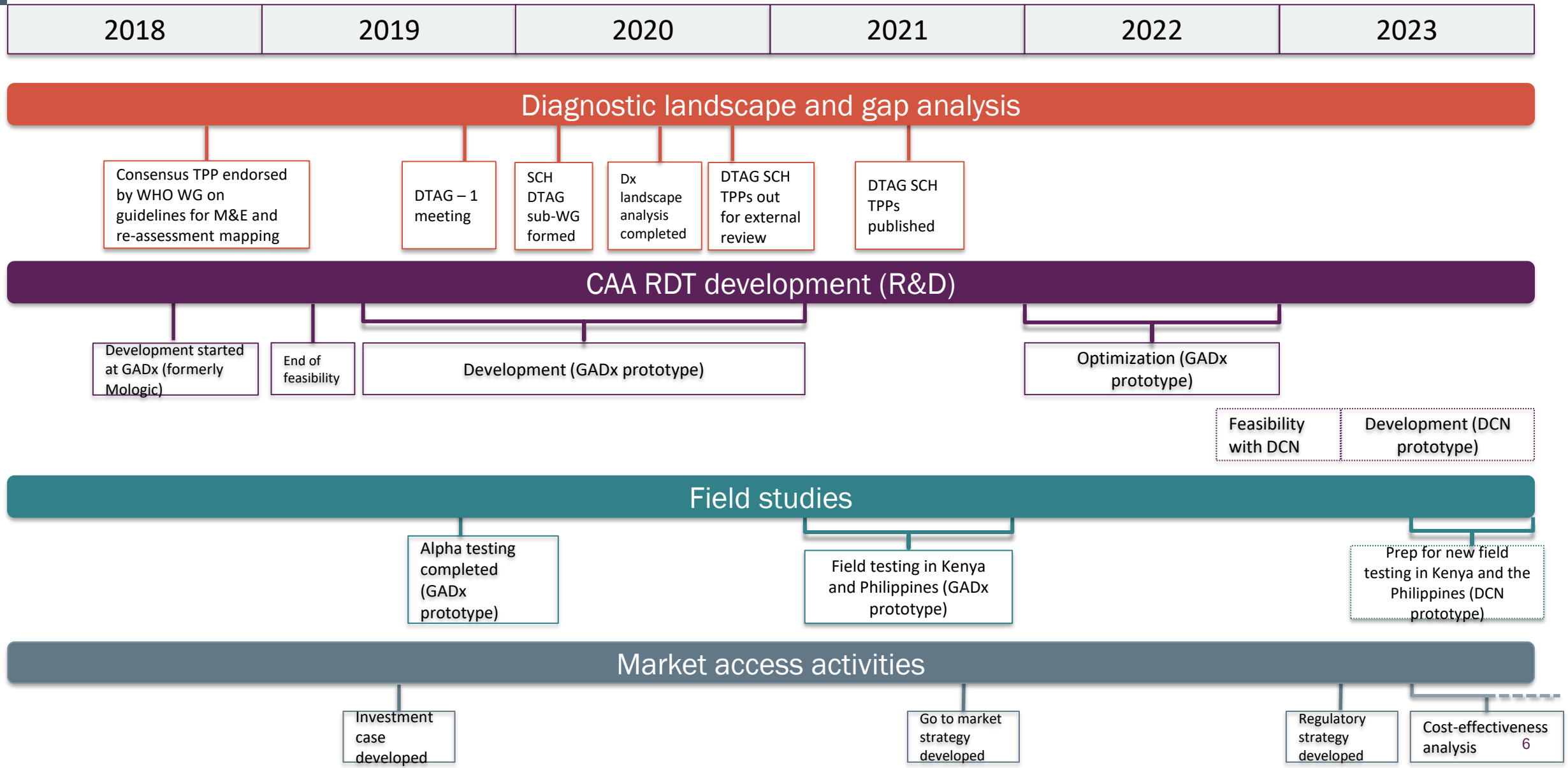
Consortium of partners

Background

- FIND and its partners are developing an easy-to-use, accurate and affordable **SCH rapid diagnostic test (RDT)** that detects circulating anodic antigen (CAA)
- CAA is secreted continuously by living schistosomes.
- The RDT will not require sample prep nor reader for detection
- Intended use: support mass drug administration campaigns and reassessment mapping

Circulating anodic antigens (CAA) are secreted by all species of schistosomes that are of public health importance, making it a particularly suitable target for schistosomiasis diagnostics. A laboratory-based test for CAA is available; however, in order to achieve optimal sensitivity, the test requires complex sample processing steps and a reader for detection. This project aims to bring CAA testing out of the laboratory and into community settings, by developing it into an RDT.

OVERALL WORK CONDUCTED SO FAR



PERFORMANCE OF THE RDT IN THE LAB

Meeting TPP requirements	Clinical Sensitivity	Clinical Specificity
S.mansoni	☑	☑
S.haematobium	☑	☑
S.japonicum	☒	☑

WHO DTAG SCH subgroup TPP:

TPP requirements	Minimum	Ideal
Clinical Se	60%	75%
Clinical Sp	95%	96.5%

Conclusions:

- Clinical sensitivity is met for S.*mansoni* (exceeds ideal requirements*)* and for S.*haematobium* however, more optimization needs to be done for S.*japonicum*

- Clinical specificity is met for all three SCH species.

KENYA AND THE PHILIPPINES

Implementers

KENYA MEDICAL RESEARCH INSTITUTE – KEMRI

REPUBLIC OF KENYA – HARAMBEE – MINISTRY OF HEALTH

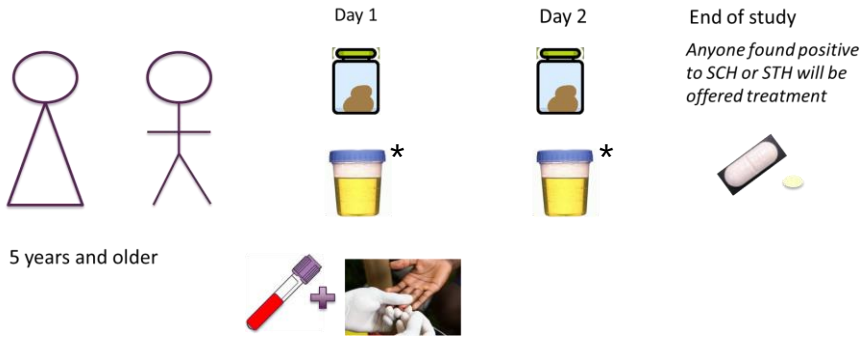
RAMON MAGSAYSAY MEMORIAL MEDICAL CENTER, INC.

DEPARTMENT OF HEALTH – EASTERN VISAYAS

INSTITUTE OF TROPICAL MEDICINE – NAGASAKI UNIVERSITY – FOUNDED 1942

High-level description

- 3 sites (2 SCH endemic, 1 non-endemic site)
- 396 individuals enrolled in each endemic site
- 184 individuals enrolled in the non-endemic site



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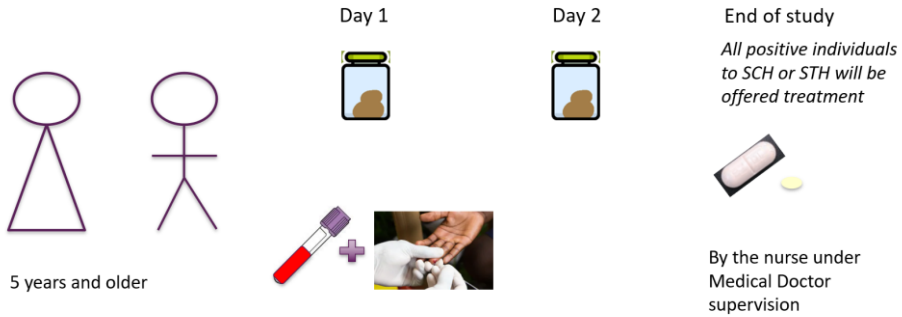


*collected only in the non-endemic and S.*haematobium* sites

BIRD'S EYE VIEW OF THE SCH ACCESS STRATEGY

USING A TRANSFORMATIVE SCH RDT – 2 APPROACHES

★Public health approach

Initial focus

Using RDTs for precision mapping and to monitor the impact of MDA

Reduce drugs wastage

Redirect drugs to where they are needed (incl. for adults– policy change required)

Reduce MDA fatigue

Reduce risk of drug resistance

Personalized treatment

Secondary focus

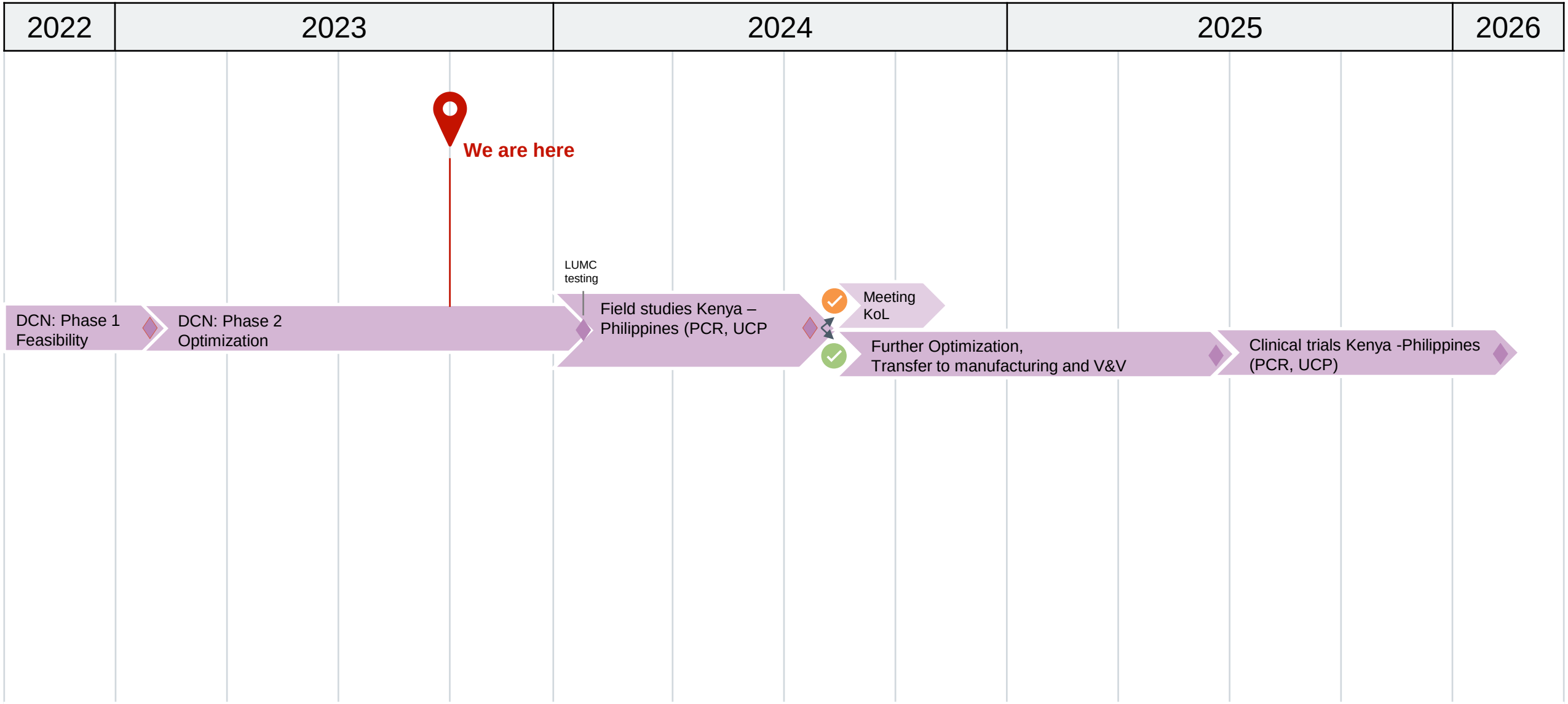
Using RDTs to enable existing health programmes to screen for SCH sustainably*

PHC

- EDL + package of care –e.g. hard-to-reach
- HIV, HPV, cervical cancer screening programmes
- Include in routine testing algorithm

*SCH CAA RDT is not aimed at elimination – doesn't meet the sens and spec requirements today.

CURRENT TIMELINE



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THANK YOU