

VivAccess & VivAction: Accelerating access to better radical cure for vivax

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Yangon, November 2019

What are VivAction & VivAction?

Joint partnership

Medicines for Malaria Venture (MMV) & PATH

VivAccess – Gates Foundation

VivAction - UNITAID

Goal

To accelerate better radical cure for vivax malaria

How

Work at global and national levels to accelerate **policy change** and scale-up of better treatments for **vivax**

Why now?

- Increasing dominance of vivax malaria across region
- Increasing evidence for lack of PQ14 efficacy
- Suite of new tools becoming available
- Elimination goals
- Variation in vivax elimination after falciparum 1 – 20 years

New radical cure tools on the way...



Improved malaria Diagnostic



G6PD Diagnostics:

- Qualitative RDT
- Quantitative G6PD tests

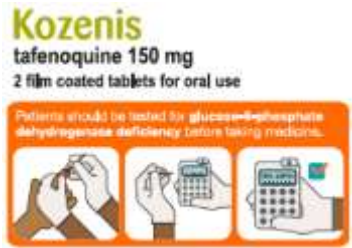


Radical cure treatments:

- PQ 7 day,
- Single-dose Tafenoquine,
- Paediatric formulation PQ & TQ

Shorter course 8-aminoquinolines that eliminate dormant stage of vivax

Tafenoquine single dose



- Single-dose, 2 x 150 mg tablets taken at the same time as blood- stage
- Requires quantitative G6PD test prior to use
- >16 years only
- NOT for use in pregnant or breastfeeding women

Primaquine 7 – day

- 7- day course 1 mg/kg/day
- As effective as PQ14 0.5 mg/kg/day
- Probably requires G6PD test prior to use

Status of single dose Tafenoquine

Kozenis

tafenoquine 150 mg

2 film coated tablets for oral use



Stringent regulatory authority approvals

- US FDA : Jul 2018
- AU TGA: Sep 2018

**WHO abbreviated process for prequalification:
Estimated c Q2 2021**

Revised vivax treatment guidelines estimated Q2 2021

Regulatory Status of G6PD Diagnostic Tests

CareStart qualitative test

- Broadly approved and distributed in region
- Interim ERPD approval i.e. can be procured by GF

SBD quantitative G6PD Test

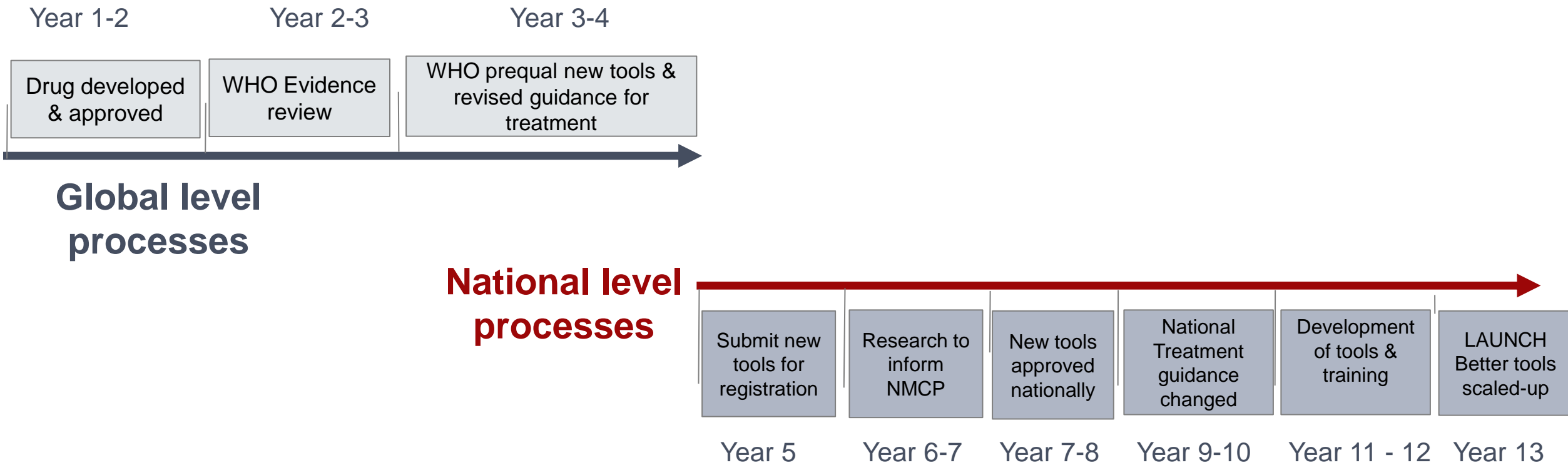


- **Stringent regulatory 2020**
- **Prequalification WHO c. Q2 2021**
- **Interim WHO (ERPD) approval i.e. can be procured by Global Funds**

Why try to accelerate new tools?

What normally happens...

On average time from development of new tools to implementation is 10-15 years



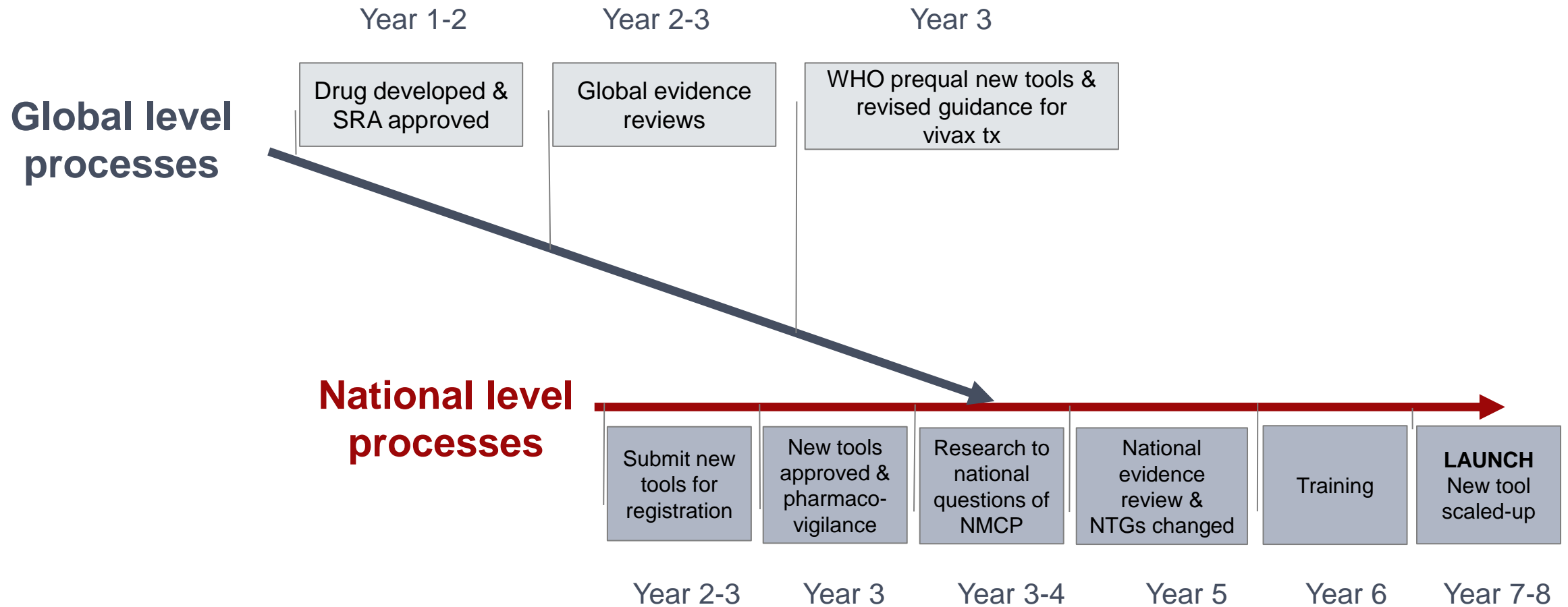
Why try to accelerate new tools?

Getting ready for WHO prequalification & revised guidance

- Identify activities that take the longest time and start to work on them now
- For example
 - Drug registration
 - Health system (pharmacovigilance) strengthening
 - Implementation research on new tools

How to accelerate?

Be ready....



What are MMV & PATH doing to accelerate access to better radical cure?

Globally

- Facilitate dossier preparation and submissions
- Collate evidence & works with WHO on policy guidance

Regionally

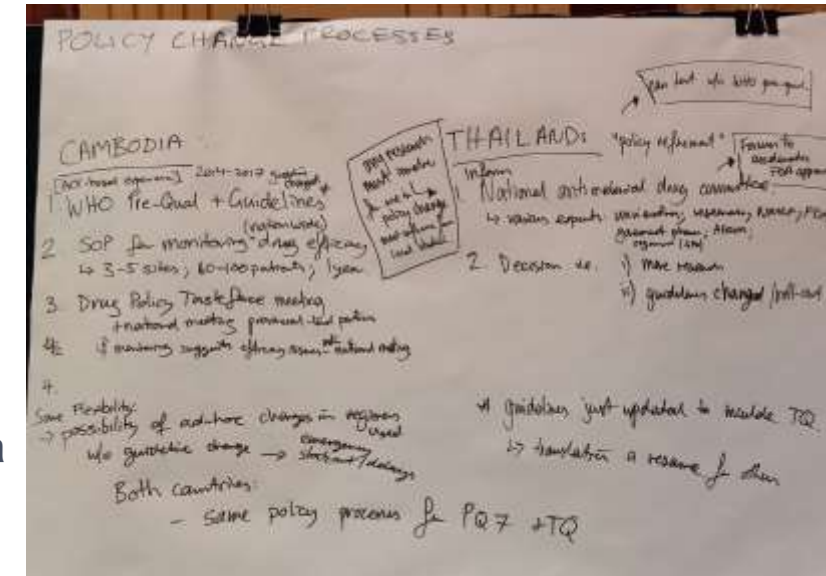
- Share experiences across countries
- Maintains operational research database
- Creating repository of study protocols, training materials, job aids, pharmacovigilance tools

What are MMV & PATH doing to accelerate access to better radical cure?

Nationally, working with NMCPs

- Determine options to be considered for better vivax radical cure
- Identify key questions that need to be answered nationally before policy change
- Determine Health Systems processes that need to be strengthened
- Map policy processes to identifying potential delays & ways to minimize them
- **VivAction in Myanmar – resources to undertake feasibility studies**

Figure: APMEN Vivax working group (Oct 2019) - Mapping policy processes & identifying potential delays in Cambodia & Thailand



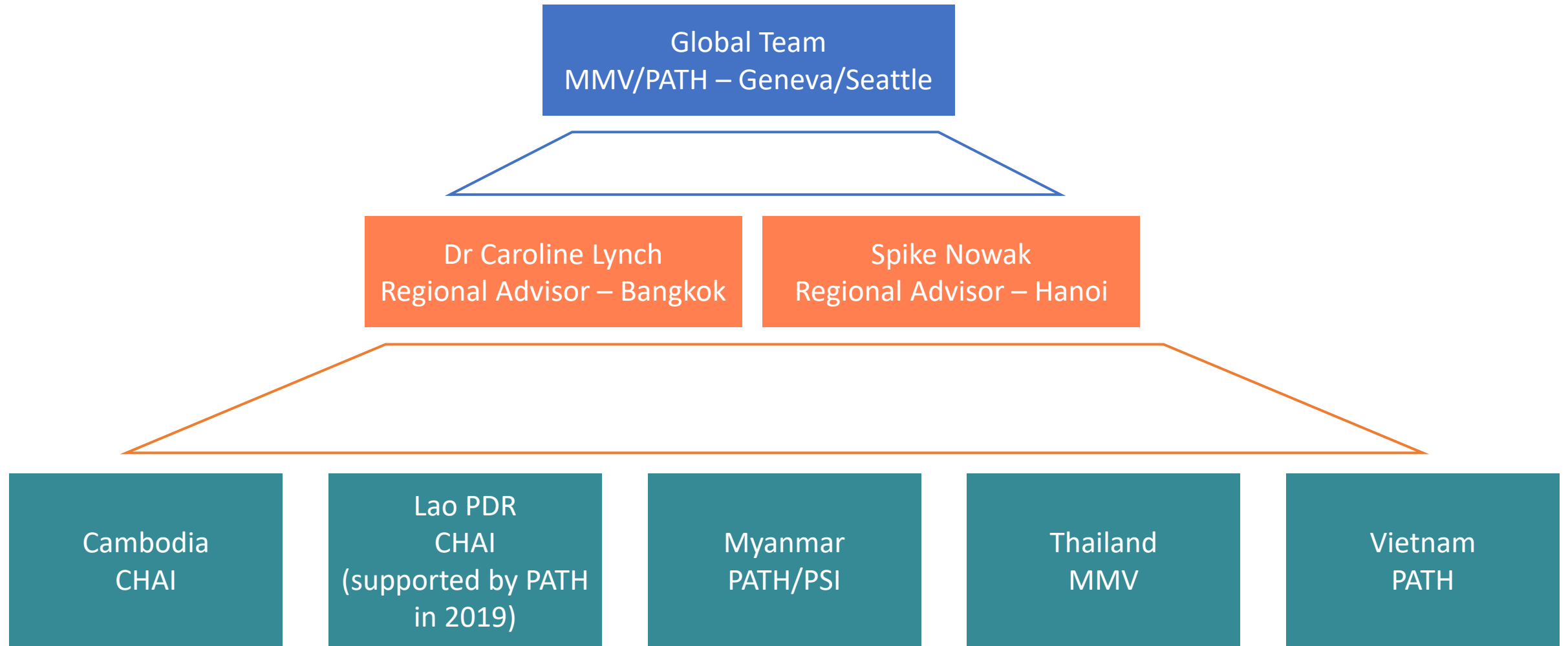
Thank you

#beready

Vivaxmalaria.org



Who are we?



Country coordinators