

# Vaccine Introduction & Uptake Timing Benchmark Project

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# Agenda

## Part 1: Main study: VPD, Vaccine & Country timelines

- Project overview & results
- Questions

## Part 2: Country case studies

- Overview
- Questions

# Project Objectives

- Identify timelines for vaccine introduction and uptake in Gavi-eligible countries for vaccines that address 6 vaccine-preventable disease (VPD) areas:
  - *Haemophilus influenzae* type b (pentavalent vaccines)
  - pneumococcal disease (pneumococcal conjugate vaccines, PCV)
  - rotavirus diarrhea (rotavirus vaccines, RVV),
  - cervical cancer (Human papillomavirus vaccines, HPV)
  - polio (inactivated polio vaccines, IPV) (*country-level analysis only*)
  - meningococcal A (MenA vaccines)
- Describe common bottlenecks in introduction timelines via country case studies

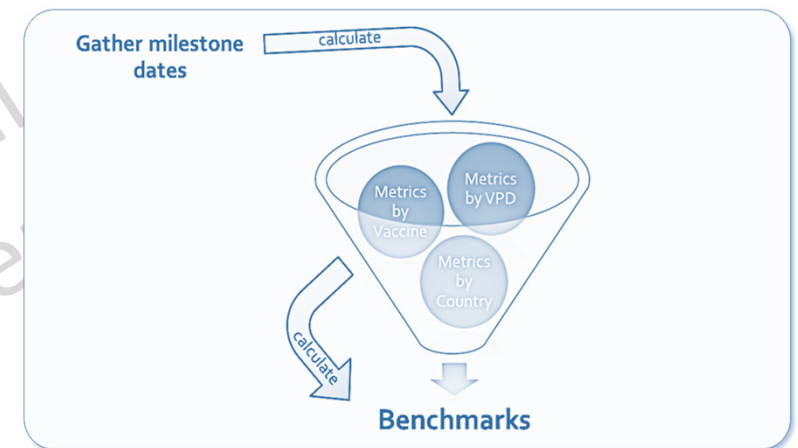
# Process & Scope

**Benchmark:** Median of metrics (with ranges) across all vaccine preventable disease (VPD) areas, vaccine products or countries

Analysis of milestone dates, metrics and benchmarks by:

- 1. VPD (vaccines): 6\*** VPD areas
- 2. Vaccine Product: 42** prequalified vaccine products within 6 VPDs
- 3. Country: 73** Gavi-eligible and graduating Gavi countries

*\* IPV included in country-level analysis only*

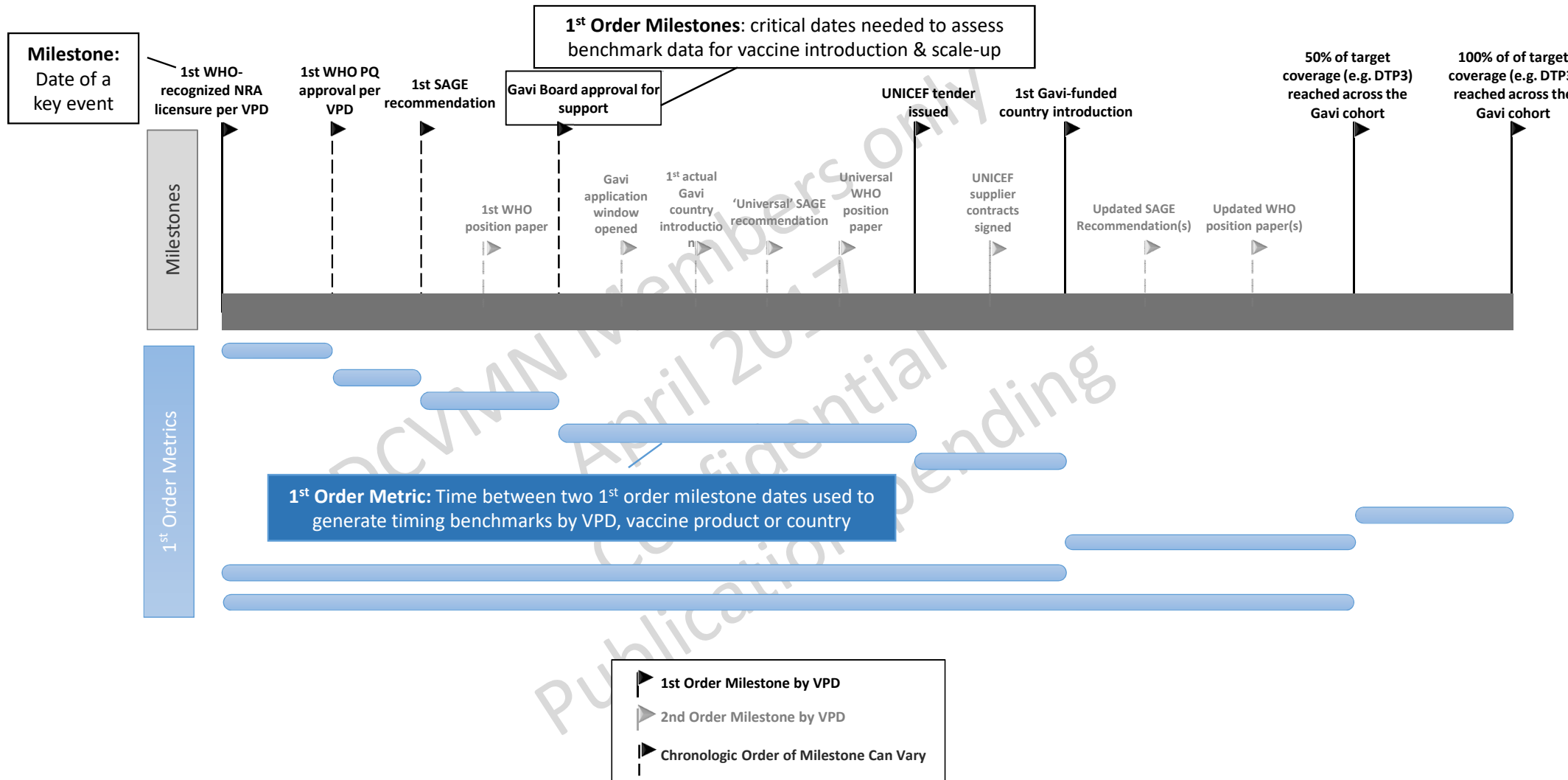


# Milestone dates (first order) by VPD and across VPDs

- First WHO-recognized NRA licensure
- First WHO PQ approval
- First SAGE recommendation
- First Gavi board approval
- Unicef tender issued
- First Gavi introduction
- 50% target coverage across the Gavi cohort
- 100% target coverage across the Gavi cohort

“universal” or “strong” SAGE recommendation also reviewed

# Output by Vaccine Preventable Disease (VPD) & Across VPDs



# Milestone dates (first order) by vaccine and country

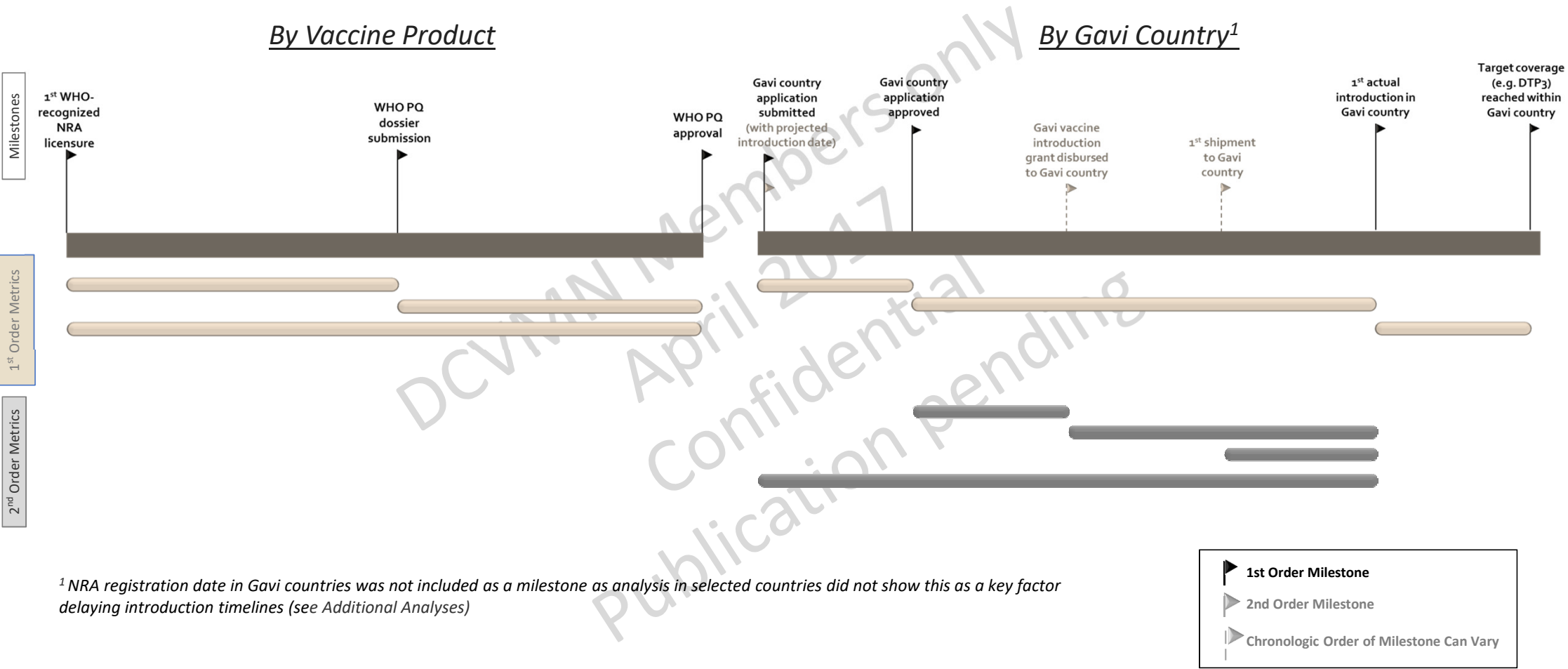
## Vaccine

- First WHO-recognized NRA licensure
- First WHO PQ dossier submission
- First WHO PQ approval

## Country

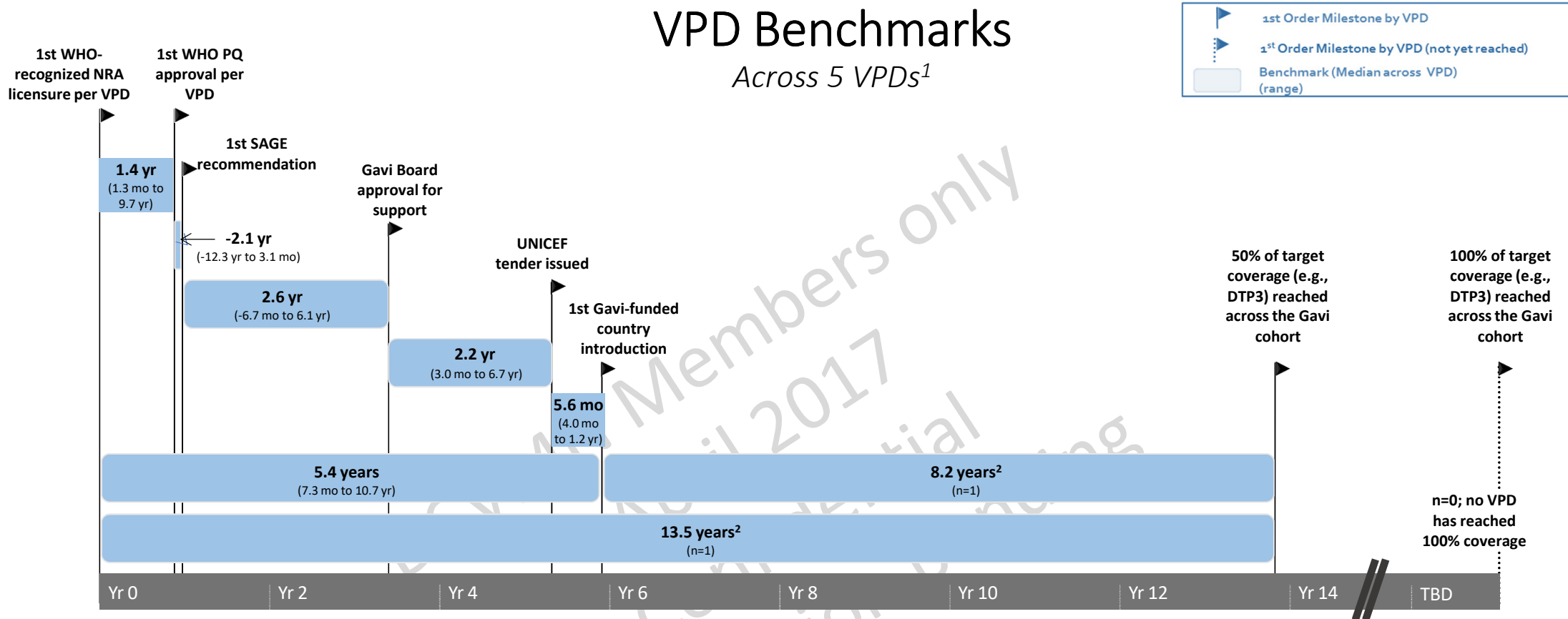
- Gavi country application submitted
- Gavi country application approved
- Gavi country introduction
- Target coverage achieved in the Gavi country

# Output by Vaccine Product & By Country





# VPD Benchmarks Across 5 VPDs<sup>1</sup>



- Not all milestones occurred in the expected order, thus resulting in negative metrics

<sup>1</sup>Pentavalent, PCV, Rota, Mena (RI & C), HPV

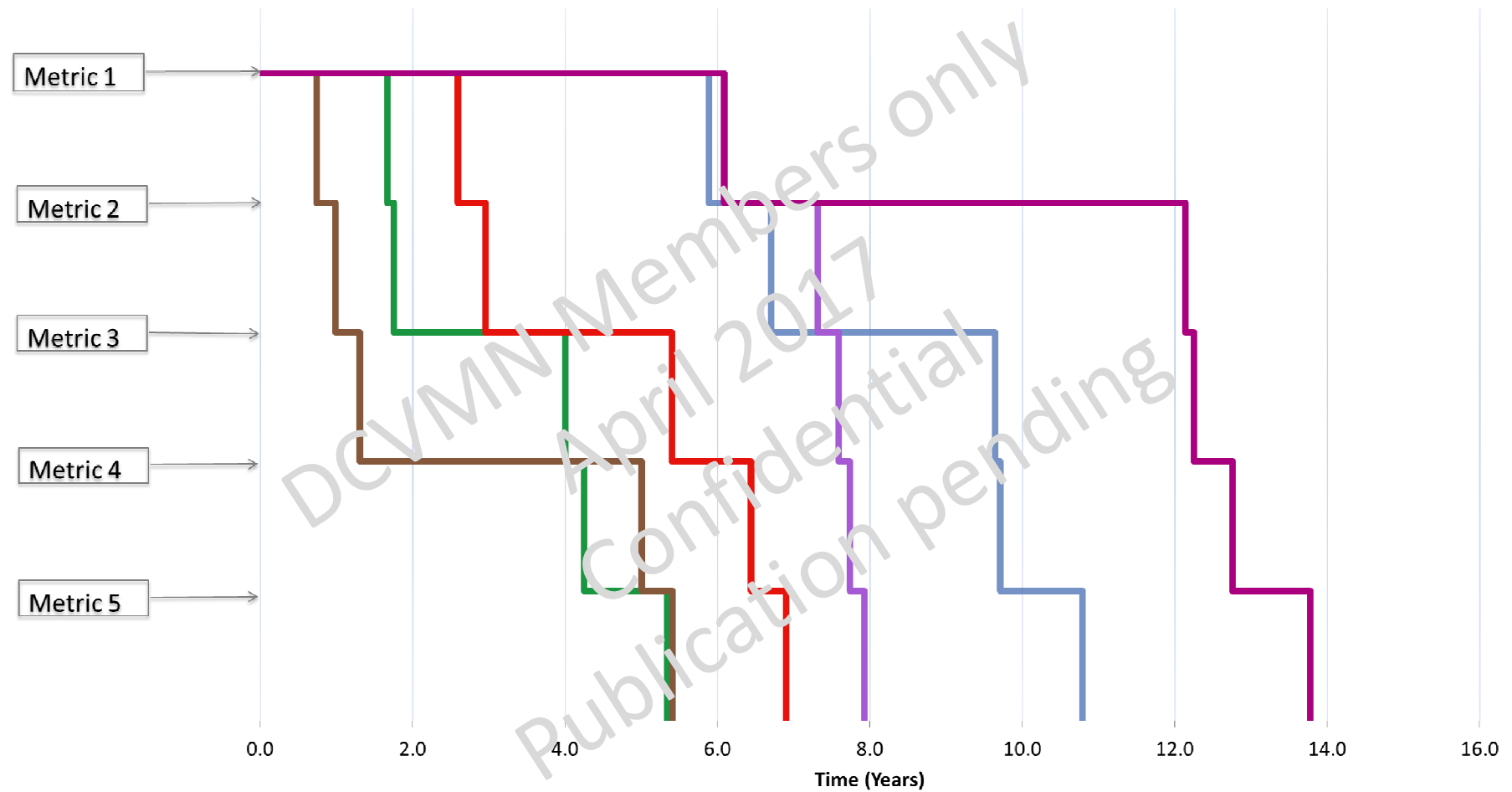
# No common pathway, different bottlenecks

Longest metric(s) by VPD in **bold**

VPD <sup>1</sup>	Metric 1	Metric 2	Metric 3	Metric 4	Metric 5
MenA (RI)	<u>SAGE to Gavi</u>	<u>Gavi to Licensure</u>	Licensure to PQ	PQ to UNICEF	UNICEF to Intro
PCV	<u>Licensure to SAGE</u>	SAGE to Gavi	Gavi to UNICEF	UNICEF to PQ	PQ to Intro
MenA (C)	<u>SAGE to Gavi</u>	Gavi to Licensure	Licensure to UNICEF	UNICEF to PQ	PQ to Intro
HPV	<u>Licensure to SAGE</u>	SAGE to PQ	PQ to Gavi	Gavi to UNICEF	UNICEF to Intro
Rota	Licensure to Gavi	Gavi to PQ	PQ to SAGE	<u>SAGE to UNICEF</u>	UNICEF to Intro
Penta	Licensure to SAGE	SAGE to PQ	<u>PQ to Gavi</u>	Gavi to UNICEF	UNICEF to SAGE/Intro

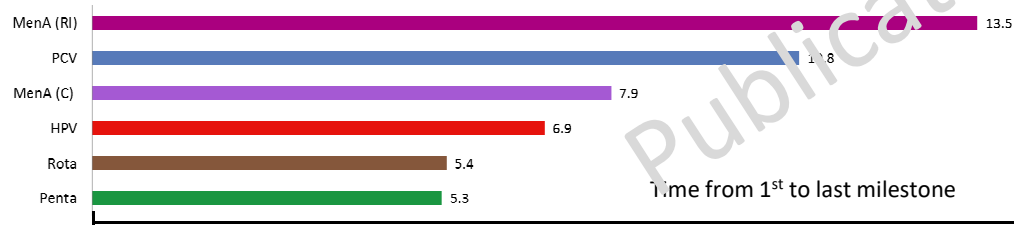
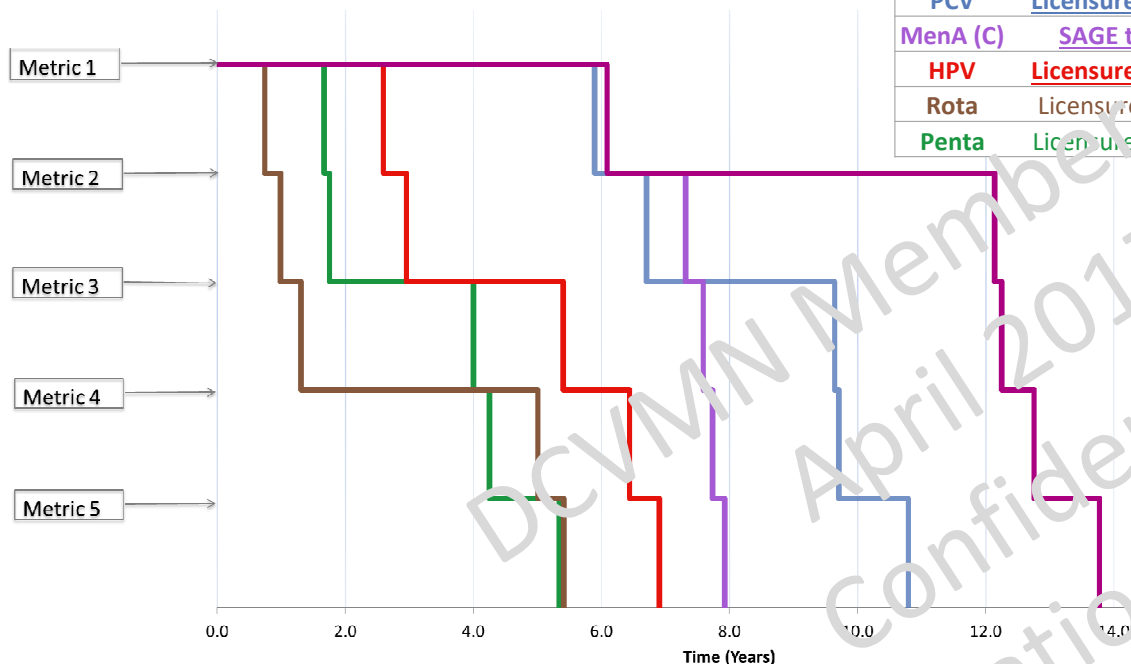
<sup>1</sup> VPDs listed in order of longest introduction timeline to shortest introduction timeline

## Variability in time to introduction



# VPDs don't take the same pathway to introduction

VPD	Metric 1	Metric 2	Metric 3	Metric 4	Metric 5
MenA (RI)	<u>SAGE to Gavi</u>	<u>Gavi to Licensure</u>	Licensure to PQ	PQ to UNICEF	UNICEF to Intro
PCV	<u>Licensure to SAGE</u>	SAGE to Gavi	Gavi to UNICEF	UNICEF to PQ	PQ to Intro
MenA (C)	<u>SAGE to Gavi</u>	Gavi to Licensure	Licensure to UNICEF	UNICEF to PQ	PQ to Intro
HPV	<b>Licensure to SAGE</b>	SAGE to PQ	PQ to Gavi	Gavi to UNICEF	UNICEF to Intro
Rota	Licensure to Gavi	Gavi to PQ	PQ to SAGE	<b>SAGE to UNICEF</b>	UNICEF to Intro
Penta	Licensure to SAGE	SAGE to PQ	<b>PQ to Gavi</b>	Gavi to UNICEF	UNICEF to SAGE

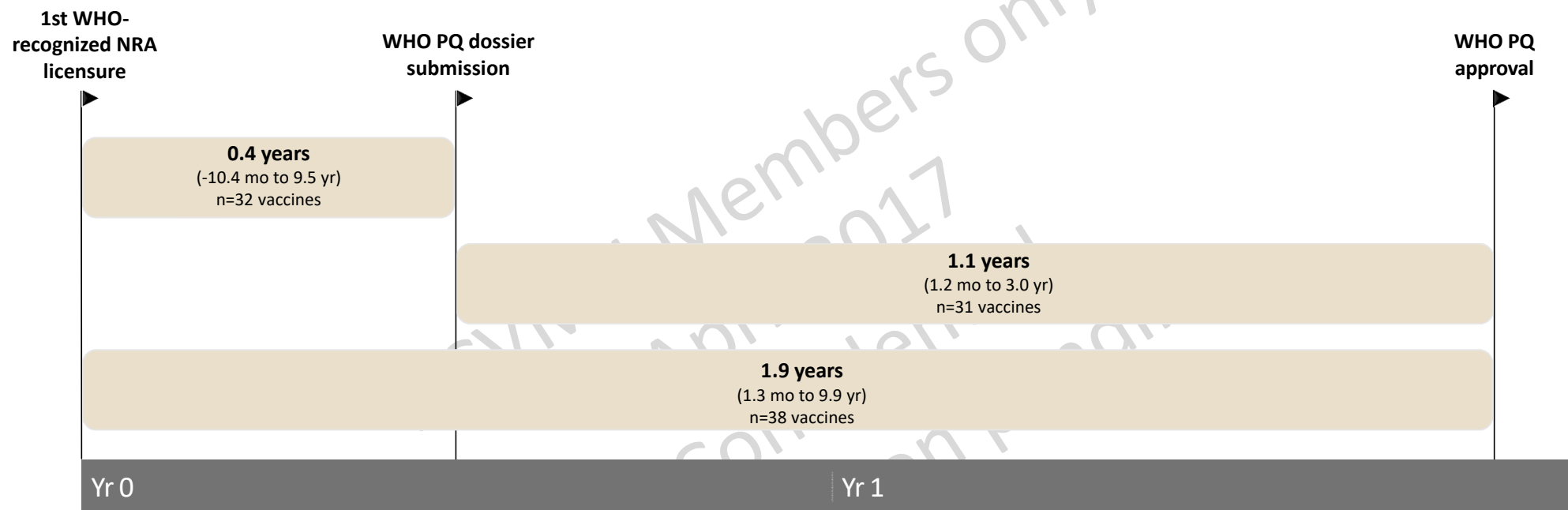
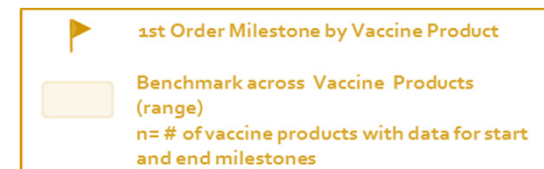


- Bottlenecks most often occurred towards the beginning of the process, with some exceptions

<sup>1</sup> Licensure = 1<sup>st</sup> WHO-approved NRA licensure per VPD; SAGE = 1<sup>st</sup> SAGE recommendation; Gavi = Gavi Board approval; PQ = 1<sup>st</sup> WHO prequalified vaccine by VPD; UNICEF = UNICEF tender issued; Intro = 1<sup>st</sup> Gavi-funded country introduction; excludes time to target coverage (DTP3) rate reached because only Penta reached 50% target coverage (DTP3) rate milestone:

# Vaccine-Specific Benchmarks

Across 39 vaccines, 5<sup>1</sup> VPDs

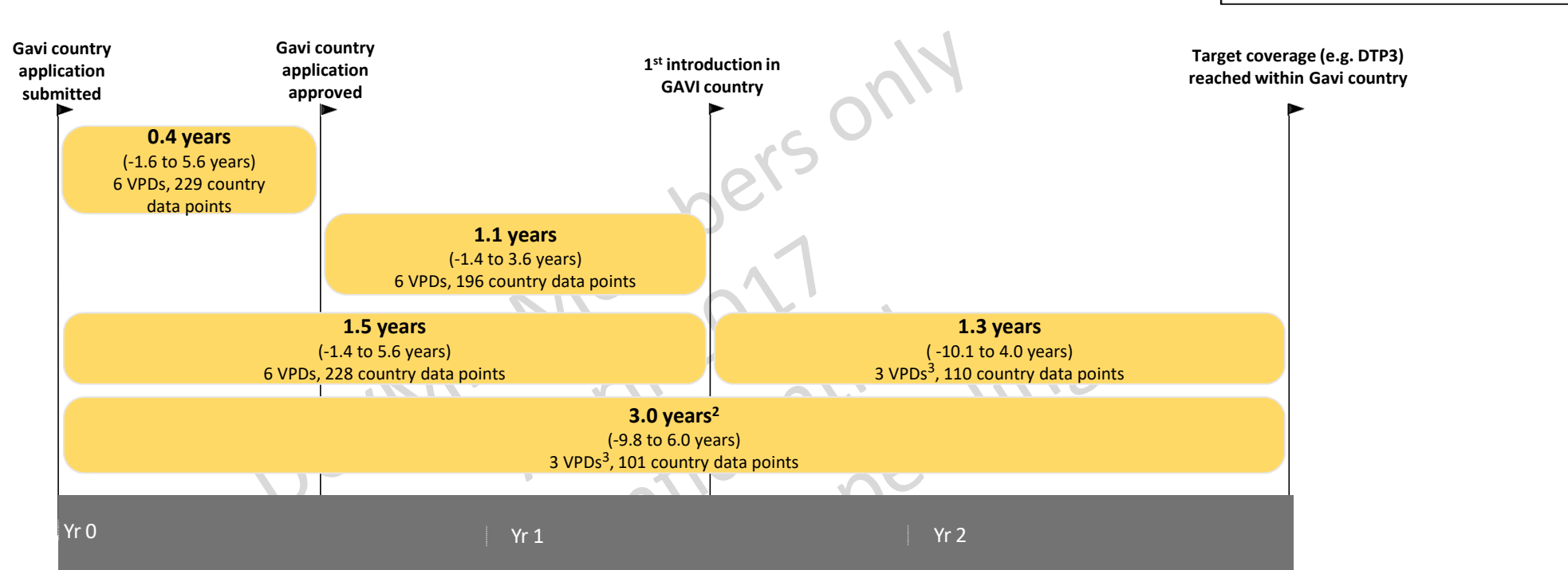


- For half of the vaccines (n=15), the manufacturers applied for WHO PQ in less than 5 months from time of 1<sup>st</sup> licensure
- The median time from WHO PQ dossier submission to WHO PQ approval was just over a year (1.1 years) with an overall median of nearly two years from 1<sup>st</sup> licensure to WHO PQ approval

<sup>1</sup>Includes vaccines on the UNICEF Price List for Gavi procurement from 2001-2016 (Pentavalent, PCV, Rotavirus, HPV, MenA)

# Country-Specific Benchmarks

Across 6<sup>1</sup> VPDs, 73 countries

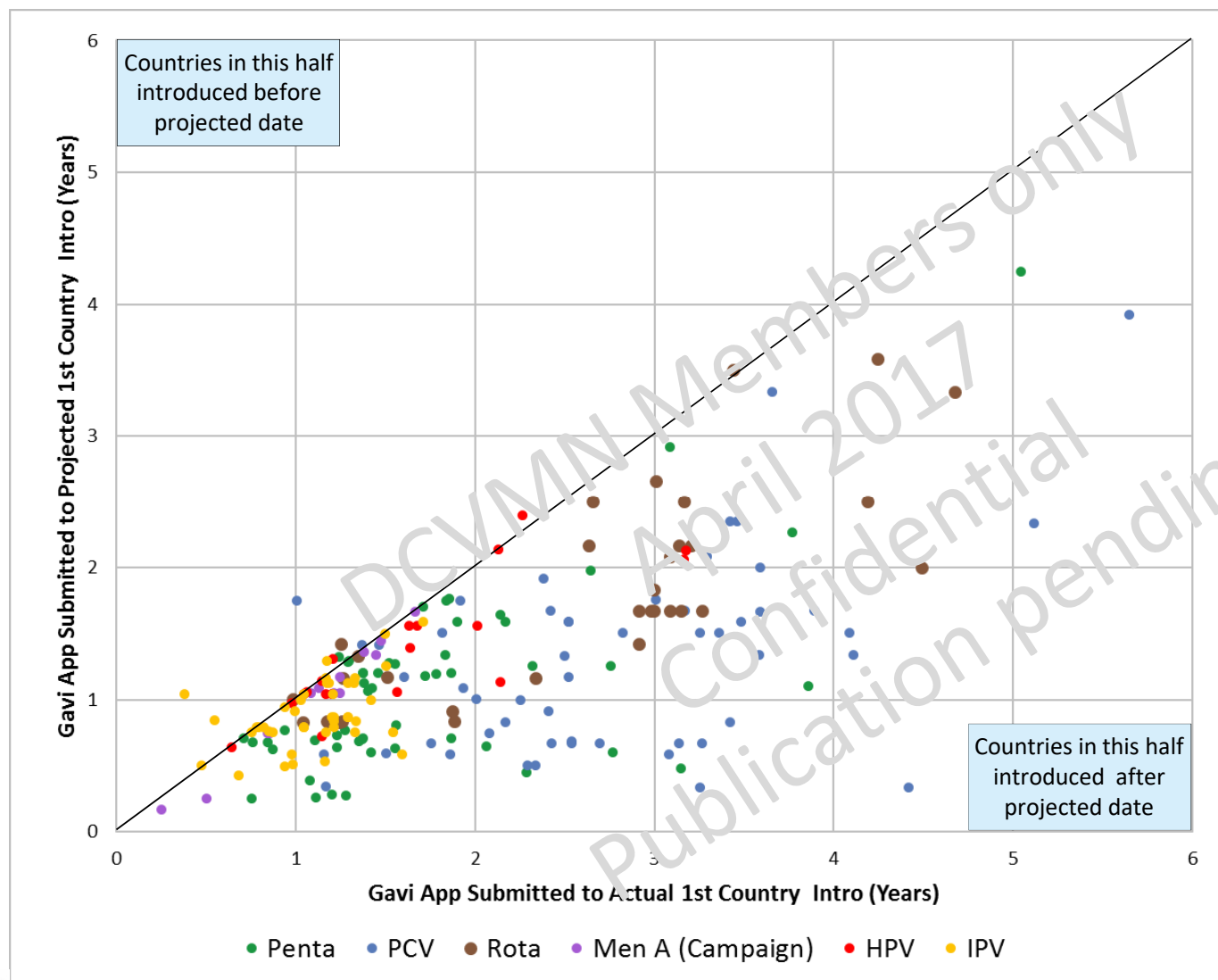


- Half of the countries received Gavi application approval within 0.4 years of their Gavi application submission and introduced a vaccine within 1.5 years from application submission
- The median time to reach target coverage rate was 1.3 years following introduction

<sup>1</sup> VPDs include Penta, PCV, Rotavirus, IPV, HPV, Men A (Campaign); <sup>2</sup> Median longer than sum of metrics due to different number of counties included; <sup>3</sup> VPDs include Penta, PCV and Rotavirus;

<sup>4</sup> Target coverage in Gavi country defined as 1<sup>st</sup> year when VPD coverage / DTP3 coverage  $\geq 90\%$

# Projected vs. Actual Country Introduction Timelines



- 16% of countries<sup>1</sup> (n=35) introduced on or before their projected introduction dates
- The majority of countries (84%, n=183) introduced after their projected introduction dates
  - PCV is the most frequently delayed VPD (96% delayed, n=51) and varies from < 1 month to almost 5 years
  - HPV had the most on-time or early (42%, n=8) introductions
  - Even with the global focus on polio eradication, IPV intros were also frequently delayed, but in general, these delays were shorter as compared to PCV

<sup>1</sup> 218 country data points analyzed across 6 VPDs; Countries with negative introduction or projected introduction timelines excluded

# Summary

- The order of milestones varies by both VPD and country
- Once the first vaccine was licensed, it took as little as 7 months to nearly 7 years for introduction in Gavi countries for each VPD (median of 5.4 years)<sup>1</sup>
  - Only pentavalent vaccine surpassed 50% of target (DTP<sub>3</sub>) coverage across the entire Gavi cohort, taking 13.5 years (21 years from the 1<sup>st</sup> Hib-containing vaccine) from 1<sup>st</sup> WHO-recognized NRA licensure
- The median time from earliest VPD milestone to Gavi-funded introduction was shortest for pentavalent (5.3 years) and longest for MenA routine (13.6 years)<sup>2</sup>
- PCV and RVV vaccines had longest delays in country introduction, likely due to a variety of reasons such as:
  - Supply constraints/misalignment of demand and desired formulation
  - Cold chain storage limitations
  - Pricing issues
  - Political considerations

<sup>1</sup> IPV included in country-level analysis only <sup>2</sup> Reflects that first Men A (routine) introduction occurred in Sudan July 27, 2016 after conclusion of this study

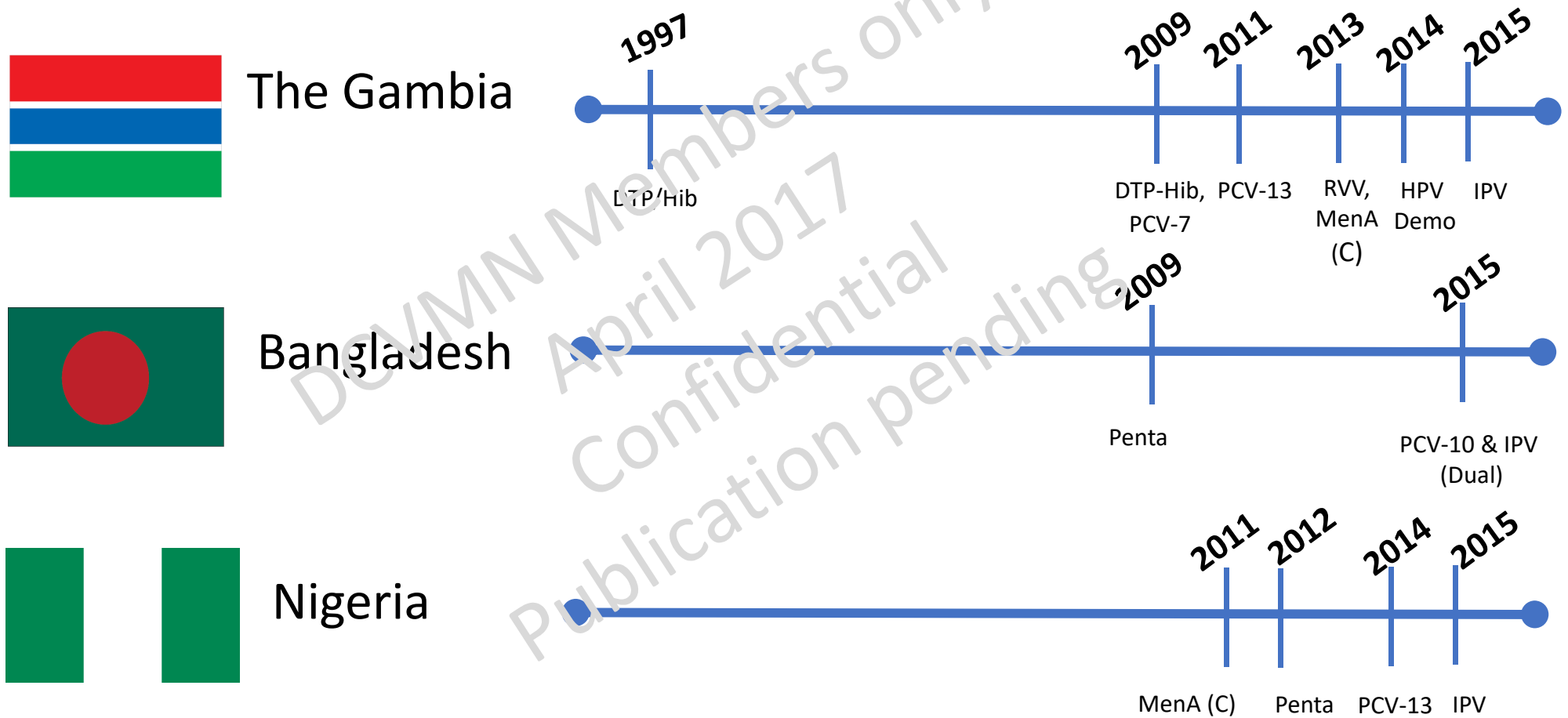




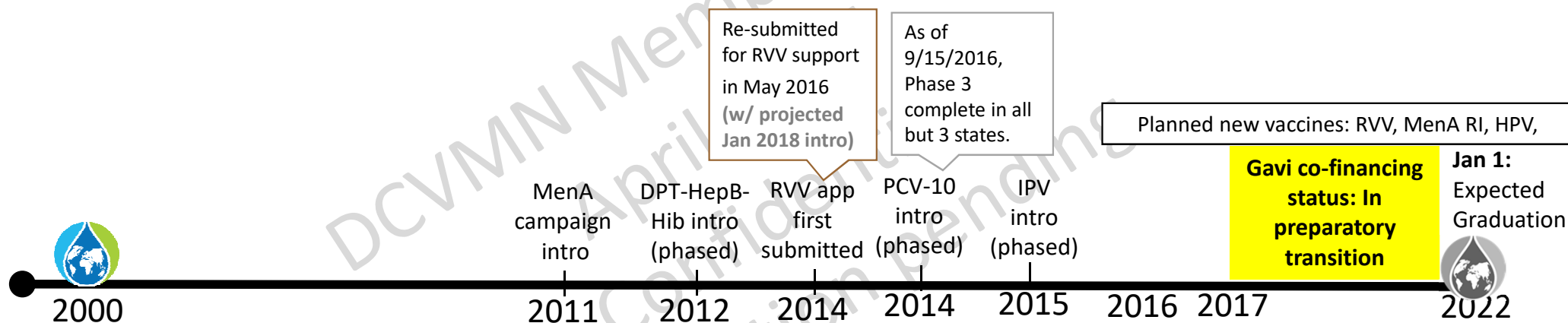
# Stories behind the Data

*Case Studies from the Benchmarking Project*

## Case countries & their introduction timelines



# Nigeria: new vaccine introductions

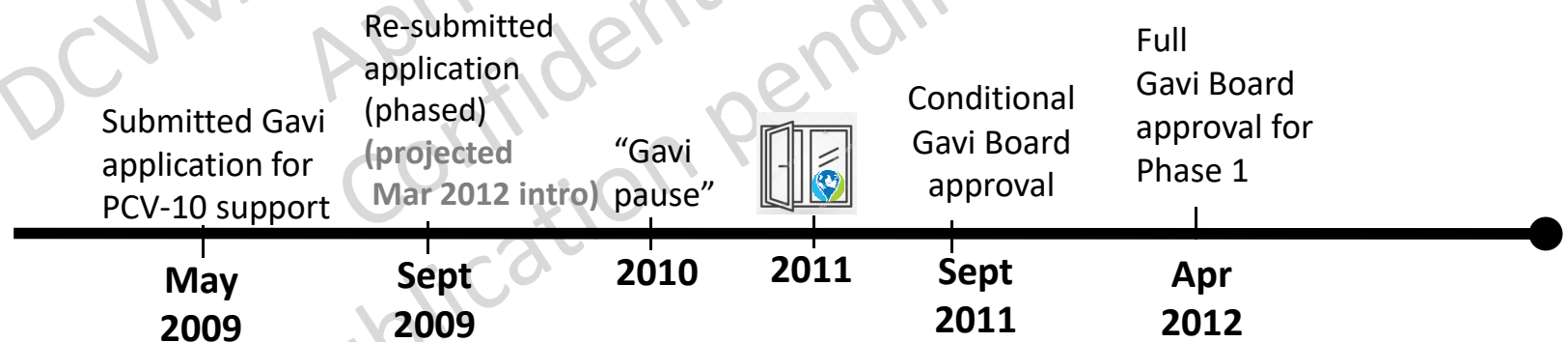


# Product trade-offs complicate The PCV Experience



## *From Gavi application submission to Gavi Board Approval*

- 2 years from submission to approval
- Cold chain constraints helped with 2 dose vial, but readiness requirements due to lack of preservative caused further delays

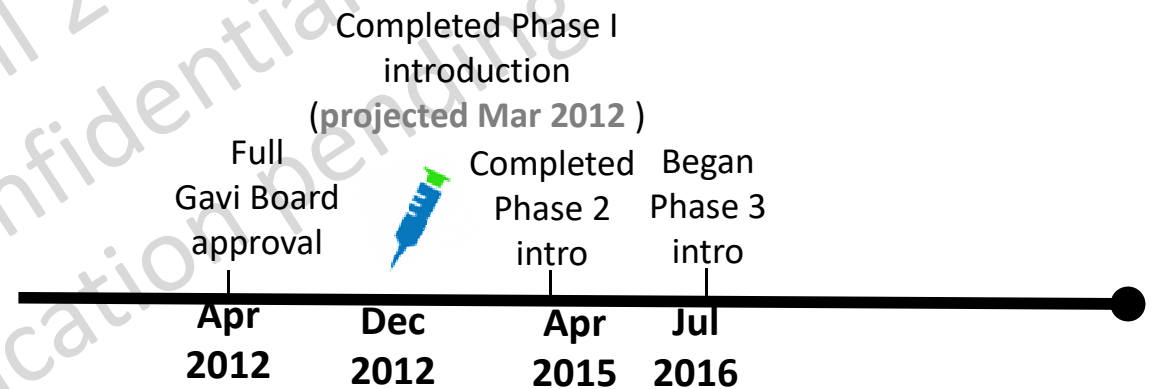


# Many factors delay intro The PCV Experience



## *From Gavi Board Approval to Country Introduction*

- Strikes, global supply, programmatic constraints, and financing (phase 1)
- VIG disbursed not disbursed until Sept 2013
- Phase 3 start uncertain due to supply. But, Bangladesh's delays helped free up global supply.



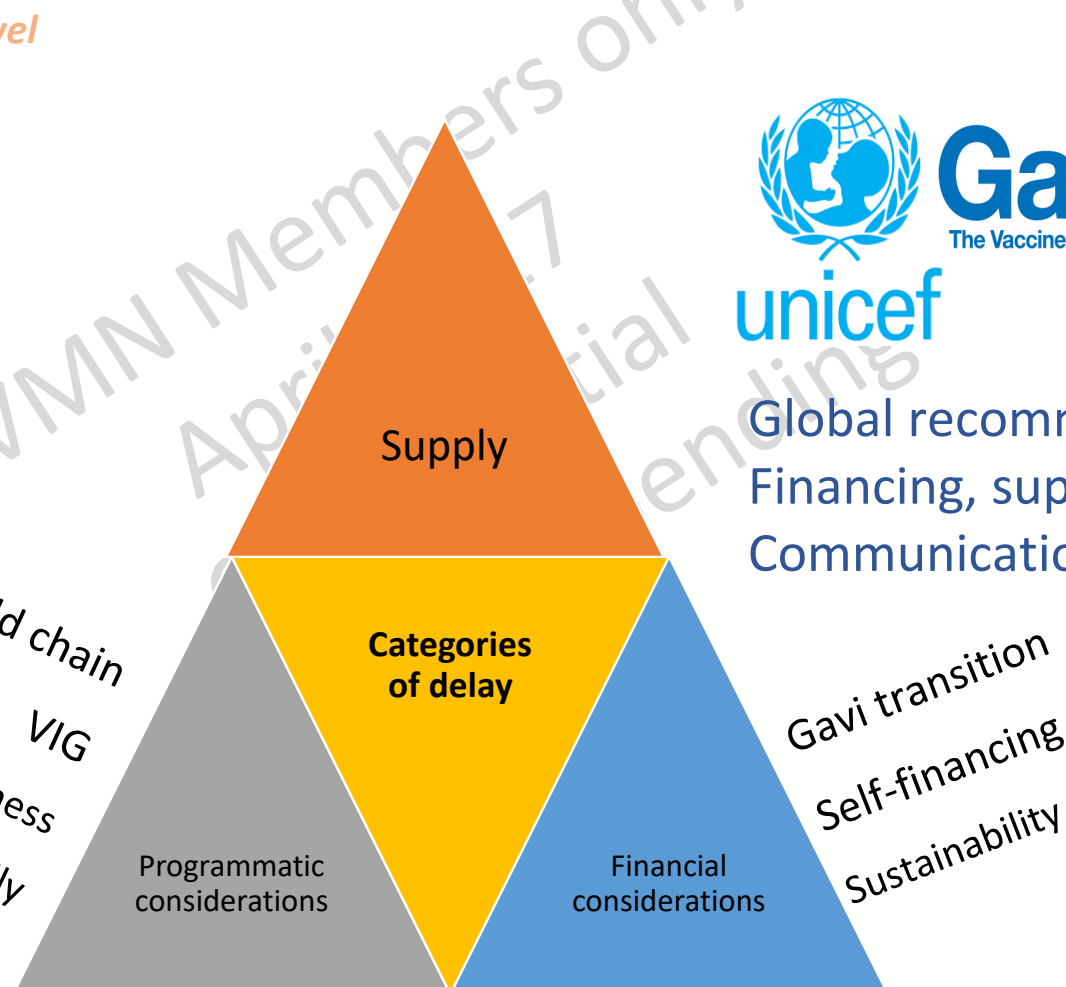
# Conclusions

*Reviewing Common Themes and Future Learnings*

# Causes of vaccine intro delay fall under common categories and occur at multiple levels



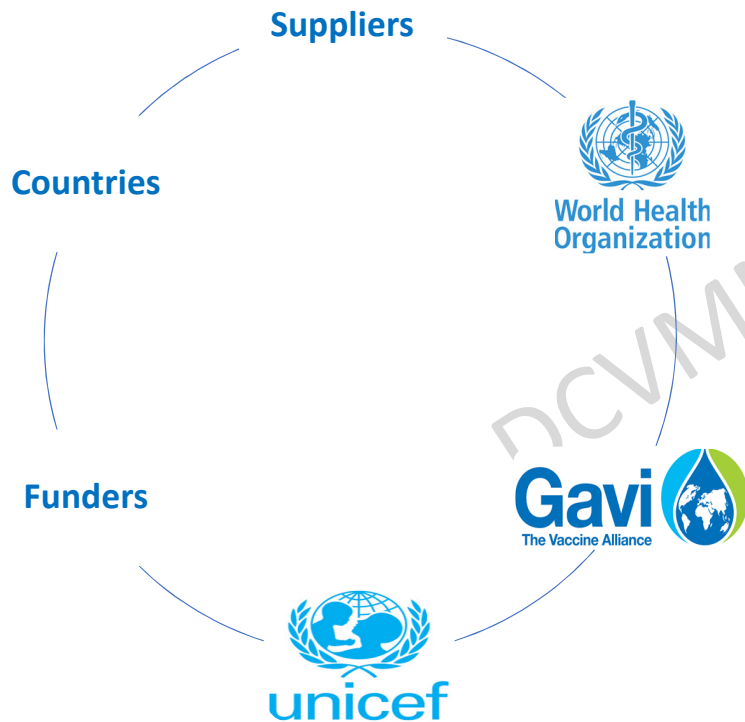
Readiness and political will  
Evidence of disease burden  
Public perceptions



Global recommendation  
Financing, supply of affordable vx  
Communication with countries

# What's needed

1. Programmatically suitable products
2. Awareness around disease & need for vaccine
3. A strong initial SAGE recommendation
4. A strong evidence base & identifying strategies for addressing data which may not be conclusive
5. Parallel processes (e.g. WHO prequalification & licensure)
6. Plan for supply needs
7. Plan for financing
8. Multi-partner collaboration & dialogue with countries





# Acknowledgements

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# Vaccine Introductions in Bangladesh



*a regional leader for vaccine intros*

- Overall, among all Gavi countries, a slow vaccine introducer
- However, historically disease burden in Asia has been unclear
- Thus, regionally an early introducer—amongst the first in Asia to introduce penta & PCV



# Vaccine Introductions in Bangladesh

