Strep A Vaccine Global Consortium
https://savac.ivi.int/

CONTEXT AND RATIONALE

- Quantifying the potential demand and market for a Strep A vaccine is important to inform industry investment decisions, particularly as Strep A vaccine development has yet to garner significant funding and activity from biopharmaceutical companies.

- The current study provides an estimate for:
  - The potential **demand** for a hypothetical Strep A vaccine **globally**
  - Associated **revenue and profit forecasts**
  - A **net-present value (NPV) analysis** of return on investments required for the development, licensure and manufacturing of a Strep A vaccine.

It is hoped that the results of this study will help to inform industry decision-making and drive increased prioritization of Strep A vaccine development as a viable commercial opportunity for industry.

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INPUTS AND ASSUMPTIONS: VACCINE PROFILE

- Hypothetical Strep A vaccine Target Product Profile (TPP) based on WHO Preferred Product Characteristics for a Strep A vaccine
- Additional assumptions required for model derived from literature review, expert interviews, proxy vaccine information and discussions with SAVAC FVVA Working Group and Technical Advisory Committee members

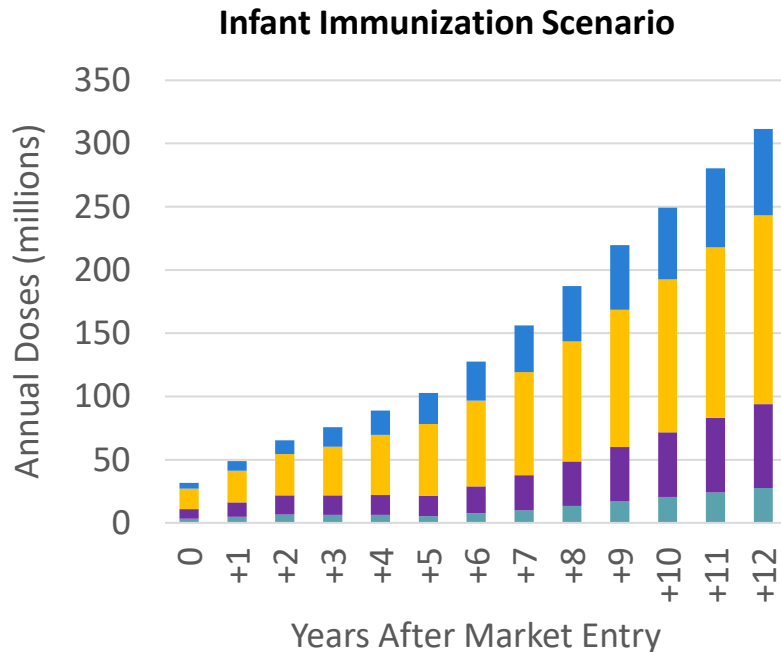| Parameter	Characteristics
Vaccine Type	Multivalent adjuvanted vaccine
Indication	Prevention of pharyngitis and superficial skin infections
Target Population	**Infants** (<1 year) or young **children** (~4-7 years)
Regimen	3 doses; no booster
Presentation	Single-dose vial (LIC, LMIC, UMIC-Public) or pre-filled syringe (UMIC-Private, HIC)
Price Per Dose	Range from $3.40 (LIC) to $54 (HIC)
COGS	~$3 per dose
Wastage Rate	5%

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INPUTS AND ASSUMPTIONS: MARKET DYNAMICS

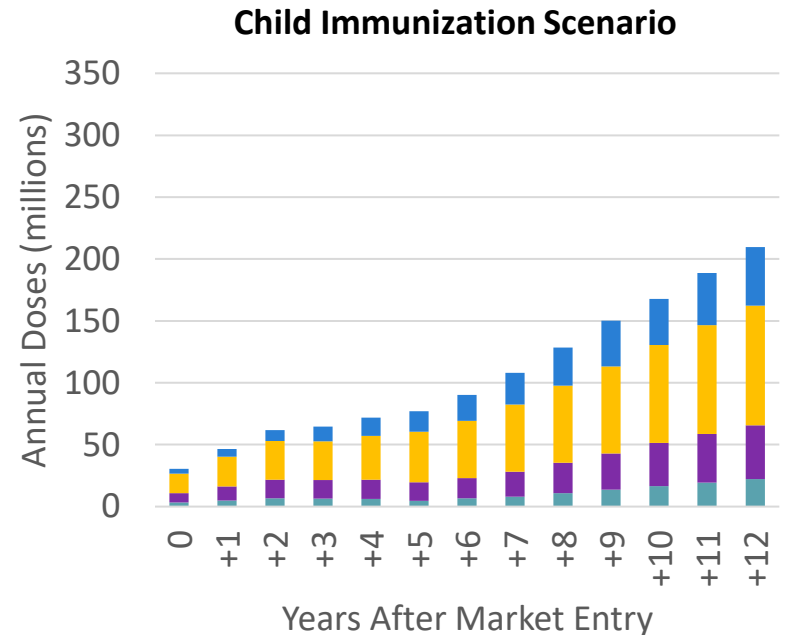| Parameter	Characteristics
Timing of Country-Specific Introduction	• 2035-2047 based on: • Strep A burden (RHD incidence) • Vaccine adoption history (PCV, Rota, Hib) • Vaccine delivery infrastructure (2019 DTP3 coverage rate) • Manual adjustment based on interviews with in-country vaccine decision-makers • Private market: available immediately upon vaccine launch in 2035
Market Segments	• Private market size: 5% in LIC, 10% in LMIC, 20% in UMIC, 35% in HIC • Post introduction in public market, private market sizes drop to 5% in LIC/LMIC, 10% in UMIC, 0% in HIC
Peak Vaccine Coverage Rate	• Public market: Equivalent to a country's 2019 DTP3 (infant) or MCV2 (child) coverage[1]; linear increase from 0% to peak rate 10 years after introduction • Private market: 30% for LIC and LMIC, 15% for UMIC, 10% for HIC; linear increase from 0% to peak rate 3 years after introduction

[1] For countries without an MCV childhood immunization program, a maximum coverage rate of 50% is assumed.

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RESULTS: DEMAND FORECAST

- **Total annual demand at year 12 is estimated at 312M doses for the infant immunization program scenario and 210M doses for the child immunization program scenario**
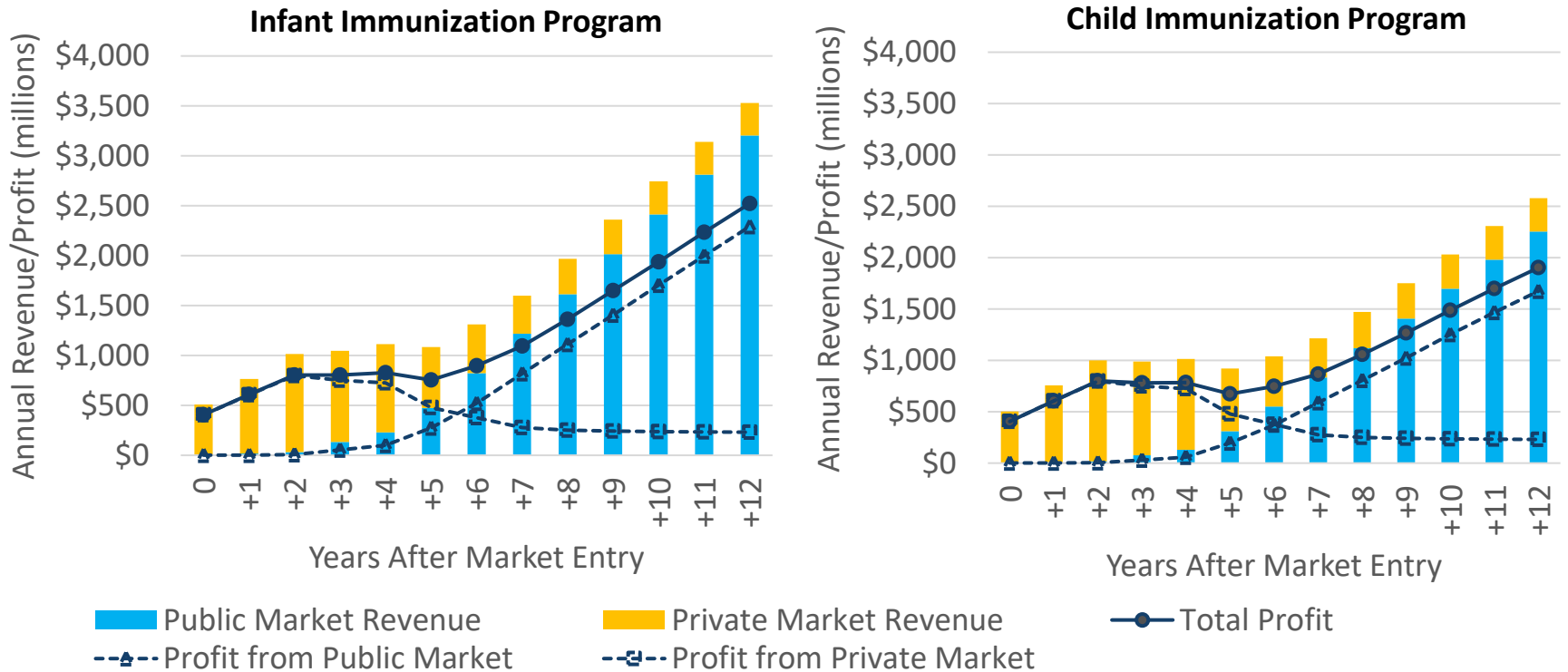- **~50% of demand is from LMICs, driven by large population and RHD burden**

Infant Immunization Scenario — Child Immunization Scenario. Annual Doses (millions) vs. Years After Market Entry (0 to +12). Legend: Low-income countries, Lower middle-income countries, Upper middle-income countries, High-income countries.

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RESULTS: REVENUE AND PROFIT FORECAST

- **Private market serves as the major driver of revenue and profit until year 5 (infant) or 6 (child) programs**

- **Average profit margin across all country income levels is ~70% at year 12, when the public market contributes ~90% of the total annual profit.**

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INPUTS AND ASSUMPTIONS: R&D COSTS

Parameter	Characteristics

Investment Costs	• Assumes full development activities including clinical trials, process development, regulatory activities, capacity building and post-marketing activities
	 • Two developer scenarios modelled:
	    • **Multinational Pharmaceutical Company (MPC)**
	      • Full global target market
	      • $502M (or $700M attrition-adjusted) investment
	    • **Developing Country Vaccine Manufacturer (DCVM)**
	      • Target market: LIC, LMIC, UMIC
	      • $127M (or $196M attrition-adjusted) investment
	 • Net present value (NPV) was calculated from 12 years of annual operating profits
	    • *NPV analyses are used to estimate profitability of a capital investment project and can enable comparison between investment alternatives. A discount rate is applied to future annual cash flows over a set time period in order to estimate the value of the project in today's dollars.*
	 • Discount rate of 10% for MPC and 20% for DCVM

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RESULTS: NET PRESENT VALUE (NPV) ANALYSIS

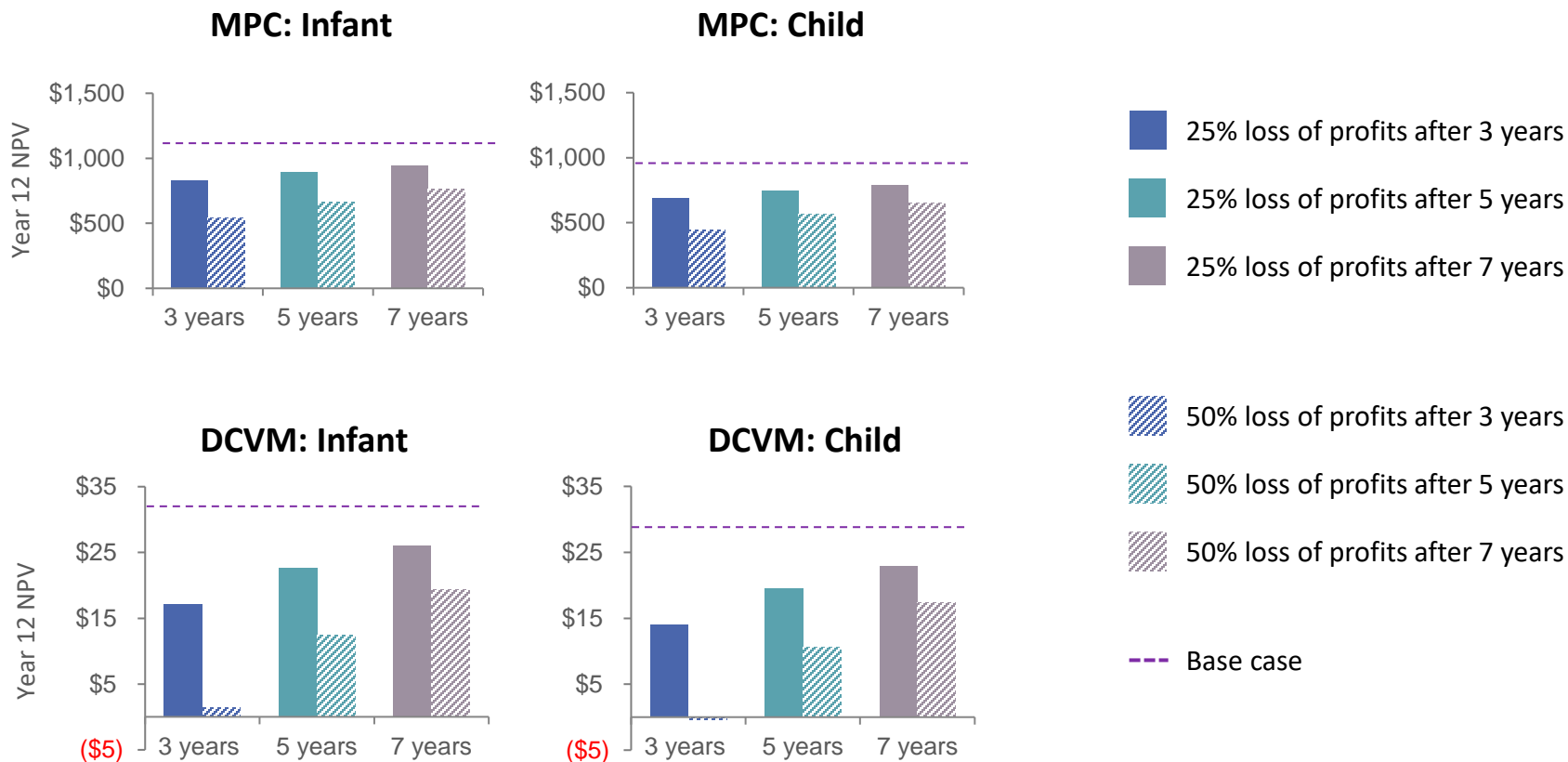- **NPV is positive for the MPC and DCVM investment scenarios for both the infant and child program scenarios assuming the developer bears full cost of development, from Phase 1 through manufacturing, regulatory activities, capacity building and post-market activities**

- **NPV is higher if earlier development stages are subsidized through global health funding**

Investment Scenario	Target Markets	Development Costs (millions USD)	Infant Program Scenario		Child Program Scenario	
			Average Profit Margin	NPV (millions USD)	Average Profit Margin	NPV (millions USD)
MPC	All markets	$700	71%	$1,120	74%	$930
DCVM	UMIC, LMIC, LIC markets	$196	55%	$33	60%	$28

NPV analyses are used to estimate profitability of a capital investment project and can enable comparison between investment alternatives. A discount rate is applied to future annual cash flows over a set time period in order to estimate the value of the project in today's dollars.

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- **NPV remains positive in all but the most extreme split-market scenario (i.e. entry of competitor Strep A vaccine)**

MPC: Infant

MPC: Child

DCVM: Infant

DCVM: Child

Legend:
- 25% loss of profits after 3 years
- 25% loss of profits after 5 years
- 25% loss of profits after 7 years
- 50% loss of profits after 3 years
- 50% loss of profits after 5 years
- 50% loss of profits after 7 years
- --- Base case

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CONCLUSIONS

- Return on investment analysis found a positive NPV for investment in Strep A vaccine development across multiple scenarios, including:

  - Different types of vaccine developer (i.e. MPC targeting all countries, DCVM targeting LICs, LMICs and UMICs)

  - Different target populations for the vaccine (i.e. infant or child immunization program scenarios)

  - Most split-market / competitive event scenarios modeled

- Primary limitation of this study is the uncertainty associated with forecasting demand of a vaccine 10+ years from market.

- Key assumption that work like that of SAVAC and others will continue to: 1) quantify and raise awareness of the burden of Strep A diseases; 2) illuminate the multifaceted health, economic and social impacts of Strep A vaccination; and 3) define appropriate regulatory pathways for a Strep A vaccine.

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ACKNOWLEDGEMENTS

- Meghan Wright, Marni Williams, Anne Mullin, Ryan Wiley

- SAVAC Executive Committee, FVVA Working Group, FVVA Technical Advisory Committee, IVI, Wellcome Trust

- Interviewees:

Category	Stakeholders
Global vaccine groups	Alejandro Cravioto (WHO SAGE), Alexa Reynolds (Gavi), Carmen Tull (USAID), Deepali Patel (Gavi), Folake Olayinka (USAID), Lois Privor-Dumm (IVAC, JHSPH)
In-country vaccine decision-makers	Ana Mocumbi (INS, Mozambique), Anne von Gottberg (NAGI, South Africa), Chowdhury Kawser (NCIP, Bangladesh), Chris Blyth (ATAGI, Australia), David Salisbury (DHSC, UK), Edward Waramin (NDOH, Papua New Guinea), Jhalak Gautam (MoHP, Nepal), Judith Mueller (CTV, France), Litiana Volavola (EPI, Fuji), Mathias Bauri (NDOH, Papua New Guinea), Nakorn Premsri (NVI, Thailand), Ole Wichmann (RKI, Germany), Satinder Aneja (NTAGI, India), Sibongile Walaza (NICD, South Africa), Tony Walls (PTAG, New Zealand), Vanessa Rouzier (GHESKIO, Haiti)
Industry	Andrew Wong (Walvax), Danilo Gomes Moriel (GVGH), Jim Wassil (Vaxcyte), Jin S. Park (SK Bioscience), Krishna Mohan (Bharat Biotech), Madhu Kapoor (SII), Patrick Tippoo (Biovac), Rachel Park (EuBiologics), Wendy Huang (Innovax)

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THANK YOU