# DCVM Meeting
# Vaccines Market Outlook
# Key Success Factors and Opportunities

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Dr E. Monfardini, Expert Life Sciences and Pharma Practice

J.B. Le Caron, Manager

L. Probst, Partner and Pharma Leader

Sujay Shetty, Director and Pharma Leader

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# Agenda

Vaccines market outlook
M&A and Licensing activities
Key Success Factors
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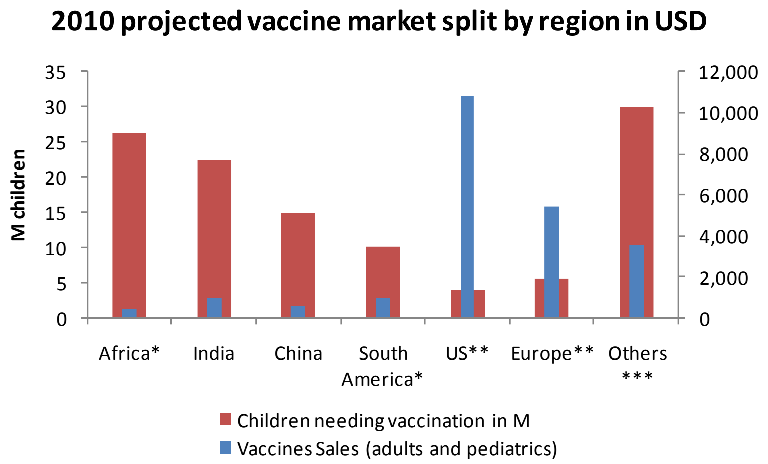
Annexes:
Case study: the Rotavirus vaccine

# A paradigm shift in the market place is needed to support immunization goals set for LMIC




*GAVI and non-GAVI

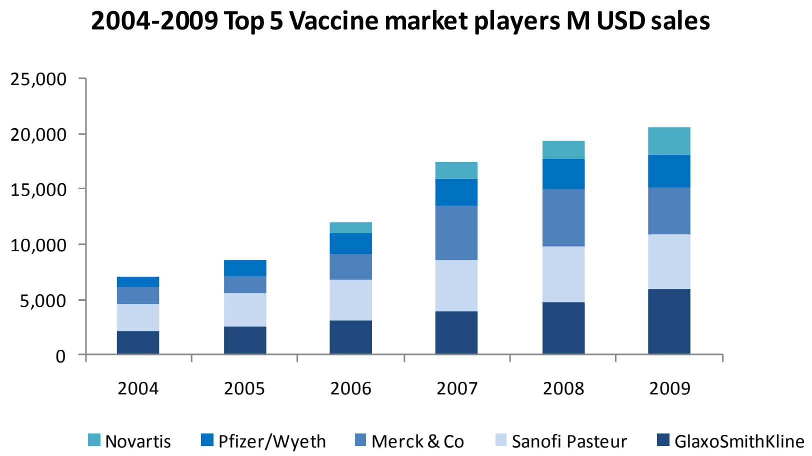
** Excludes seasonal flu and H1N1

*** Russia, Middle East, South East Asia, West Pacific

- HIC and GAVI/LMIC do not longer use the same vaccines
- HIC focus on new vaccines sales at high prices (Pneumo, Rota, H1N1)
- No longer HIC manufacturers maintain excess production capacity, which equals to the market demand, and drives prices up
- LMIC market penetration could drive future DCVM growth

Sources: www.unicef.org for supply and procurement vaccines projections; www.unicef.org /morocco; www.ecoliers-berberes.info; www.jeunesdumaroc.com; UN census bureau; National Advisory Group on immunisation (NAGI) of South Africa, April 2010; www.biofarminternational.com, April 2007; www.paho.org, Immunization Newsletter 2009; www.globalactionforchildren.org; www.ncbi.hlm.nih.gov; www.busines.mapsofindia.com/pharmaceutical; Datamonitor, March 2010, Vaccines in Emerging markets, Latin America; Datamonitor 2007, Pipeline Commercial insights, pediatrics and Adolescents vaccines; Freedonia reports: Focus on Vaccines February 2009; Datamonitor 2009: Seasonal influenza Vaccines market forecast; http://www.marketwire.com/press-release/Global-Vaccine-Market-Exceeds-20-Billion-Kalorama-1304184.htm; http://www.marketresearch.com/product/display.asp?productid=2621517; http://www.thefreelibrary.com/Research+and+Markets%3A+The+Global+Veterinary+Vaccines+Market+Is...-a0181359890; State of the world's vaccine and immunization, 3rd edition.

# Vaccine market sales growth is driven by big majors in HIC.




- 5 major peaked to 20.5 Bi USD in 2009
- Prevnar with 3.1 Bi USD, and Gardasil with 1.1 Bi USD are the blockbusters
- Big majors hold the complete vaccines IP: besides some limited cases, non-exclusive voluntary licensing has still to become a trend

Sources: http://en.sanofi-aventis.com/investors/key_facts_figures/key_facts_figures.asp#s4 ; Pfizer inc. 2009 financial report; GSK 2009 annual report; Novartis annual report 2009; Merck & co annual report 2009

USD/EUR exchange rate 0.70872 average of last 372 days – source: Oanda.com ; GBP/USD exchange rate 1.56 of last 366 days – source: Oanda.com

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# Licensing and M&A : emerging countries start to matter majors

## Our survey of reported deals between January 2008 and August 2010 shows that few deals involved emerging countries' manufacturers:

- 108 M&A or licensing deals were reported in the vaccines industry for this period.
- 52 Deals involved 5 major vaccines players:
  - GSK, Pfizer(Wyeth), Novartis, Sanofi, Merck.
- 9 Deals involved a Chinese or Indian companies.
- 2 Deals were true licensing agreements.

## M&A Activity: only one significant deal took place in 2.5 years time

| Deal Date | Short Deal Summary | Country | Buyer Name | Seller Name | Deal Type | Reporterd Deal Value in USD m |
|---|---|---|---|---|---|---|
| 01-May-2010 | **Swine vaccines business disvestment** | China | Harbin | Pfizer | Acquisition | n.a |
| 01-Jul-2009 | **Sanofi Pasteur acquired Shantha Biotechnics** | India | Sanofi | Shanta | Acquisition | 784 |
| 01-Nov-2009 | $125mm for an **85% stake** in **Zhejiang** Tianyuan Bio-Pharmaceutical Co. Ltd. (vaccines) | China | Novartis | Zhejiang Tianyuan Bio-Pharmaceutical Co. Ltd. | Acquisition | 125 |
| 01-Nov-2009 | Global CRO **PPD has bought** private large Chinese CRO **Excel PharmaStudies** | China | PPD | Excel PharmaStudies | Acquisition | n.a |

Sources: Windhover database, 2010

# Licensing: despite market potential, major players show little interest in closing deals with emerging potential rivals.

## Scarce licensing agreements underscore potential opportunities lack of awareness

| Deal Date | Short Deal Summary | Country | Licensor | Licensee | Deal Type | Reporterd Deal Value in USD m |
|---|---|---|---|---|---|---|
| 01-Oct-2009 | Long-term joint venture focused on **pediatric vaccines for the Chinese market** | China | Jiangsu Walvax JV | GSK | Joint Venture | 66 |
| 01-Nov-2008 | **joint venture for developing flu vaccines** targeting local viruses | China | GlaxoSmith Kline | Shenzhen Neptunus Interlong Bio-Technique Co. Ltd. | Joint Venture | 92 |
| 01-Mar-2009 | Develop and market Novavax's **seasonal influenza vaccine candidate** and **Cadila's product pipeline**. | India | CPL Biologicals | Cadila Pharmaceuticals Ltd., Novavax Inc. | Joint Venture | 19 |
| 01-Jul-2010 | Potential commercialization of **Merck's human papillomavirus (HPV) vaccine Gardasil and potential** additional **Merck products**. | China | Sinopharm Group Co. | Merck & Co. Inc. | Licensing | n.a |
| 01-Jan-2010 | **Biological E. will have rights** to develop, manufacture, and commercialize recombinant **H1N1** vaccine in India and South Asia | India | Biological E Ltd | VaxInnate Inc. | Licensing | n.a |

Sources: Windhover database, 2010

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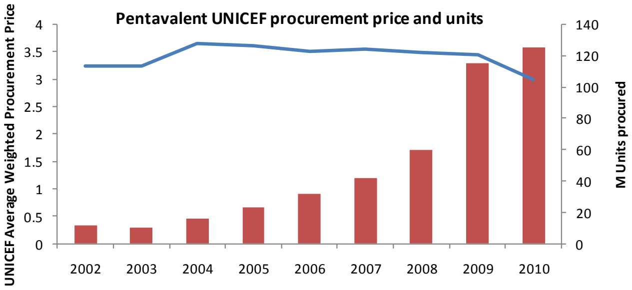
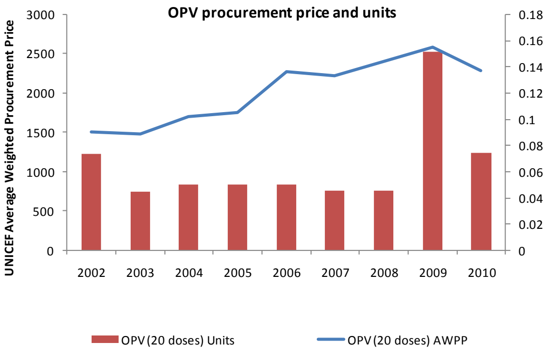
# Increased penetration of developing countries vaccines manufacturers leads to a more sustainable and affordable supply

| Prequalified Vaccine | manufacturers |
|---|---|
| Pentavalent (all doses) | Crucell<br>GSK<br>Panacea<br>Serum Institute |
| OPV all strains (20 doses) | Biofarma<br>Haffikim Bio Ph<br>Novartis<br>Panacea<br>Sanofi<br>GSK |
| Pnemococcal | GSk<br>Wyeth |
| Rotavirus | Merck<br>GSK |

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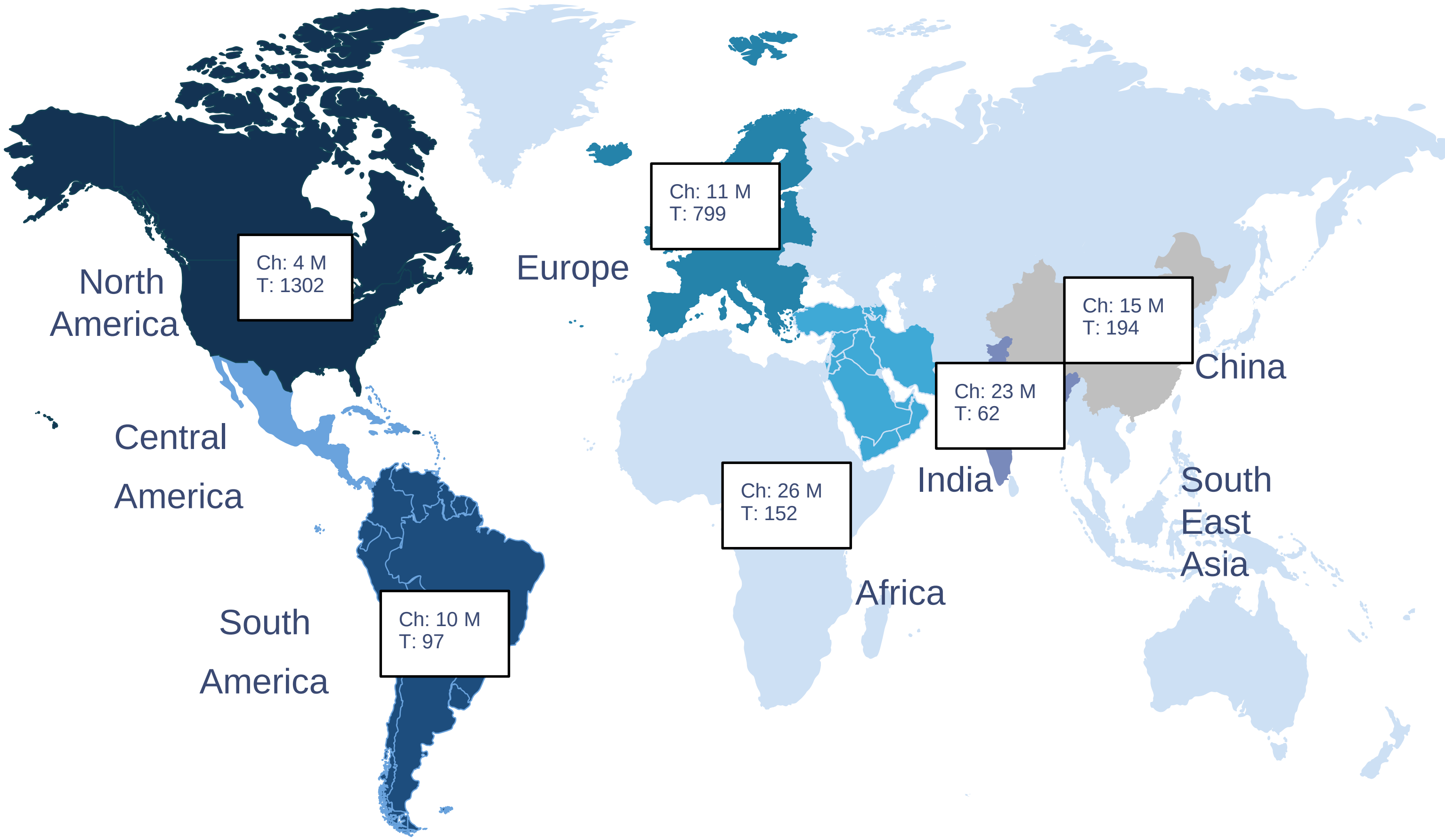
Sources: www.unicef.org for supply and procurement vaccines projections; www.WHO.int for list of prequalified vaccines

# A true industry commitment is needed to concentrate clinical trials where medical need is urgent

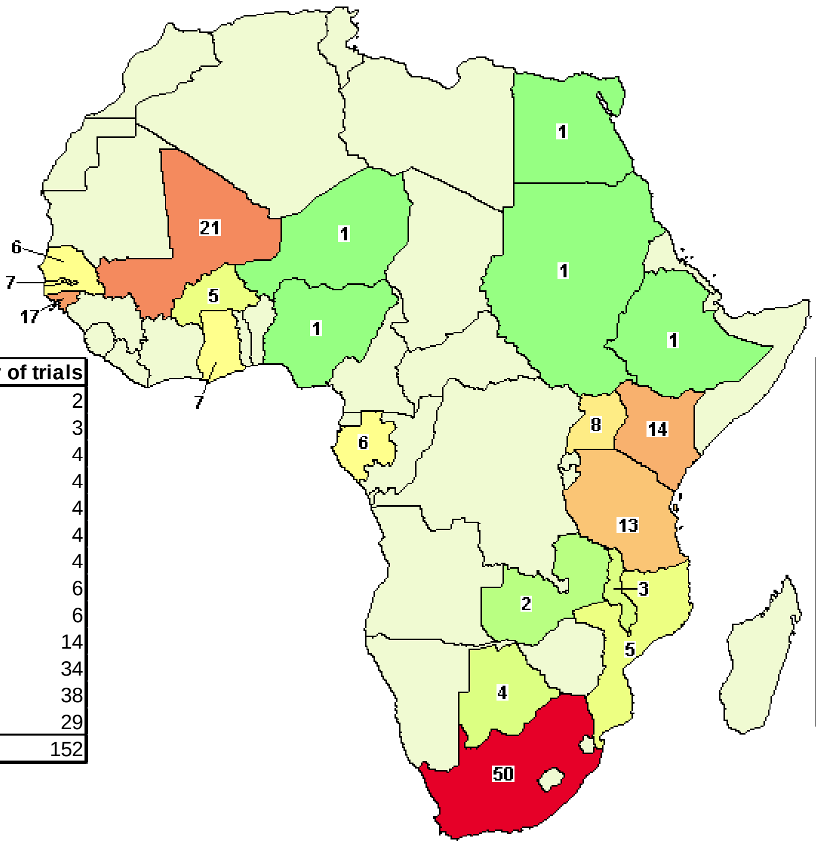



Ch: Nr of children needing vaccination
T: vaccines clinical trials

Sources: www.clinicaltrails.gov, WHO database, UN census Bureau

# GSK commitment in clinical trials in Africa as an example for the other big majors

Nr of infants to be vaccinated: 26 M




| Sponsors | Nr of trials |
|---|---|
| Novartis | 2 |
| Merck | 3 |
| Gates Malaria Partnership | 4 |
| Wyeth | 4 |
| Aeras Global TB vaccine foundation | 4 |
| International AIDS Vaccine Initiative | 4 |
| University of Witwatersrand, South Africa | 4 |
| African Malaria Network Trust | 6 |
| Sanofi-Aventis | 6 |
| University of Oxford | 14 |
| GlaxoSmithKline | 34 |
| Nat. Inst. of Allergy and Inf. Dis. (NIAID) | 38 |
| Others | 29 |
| Total | 152 |

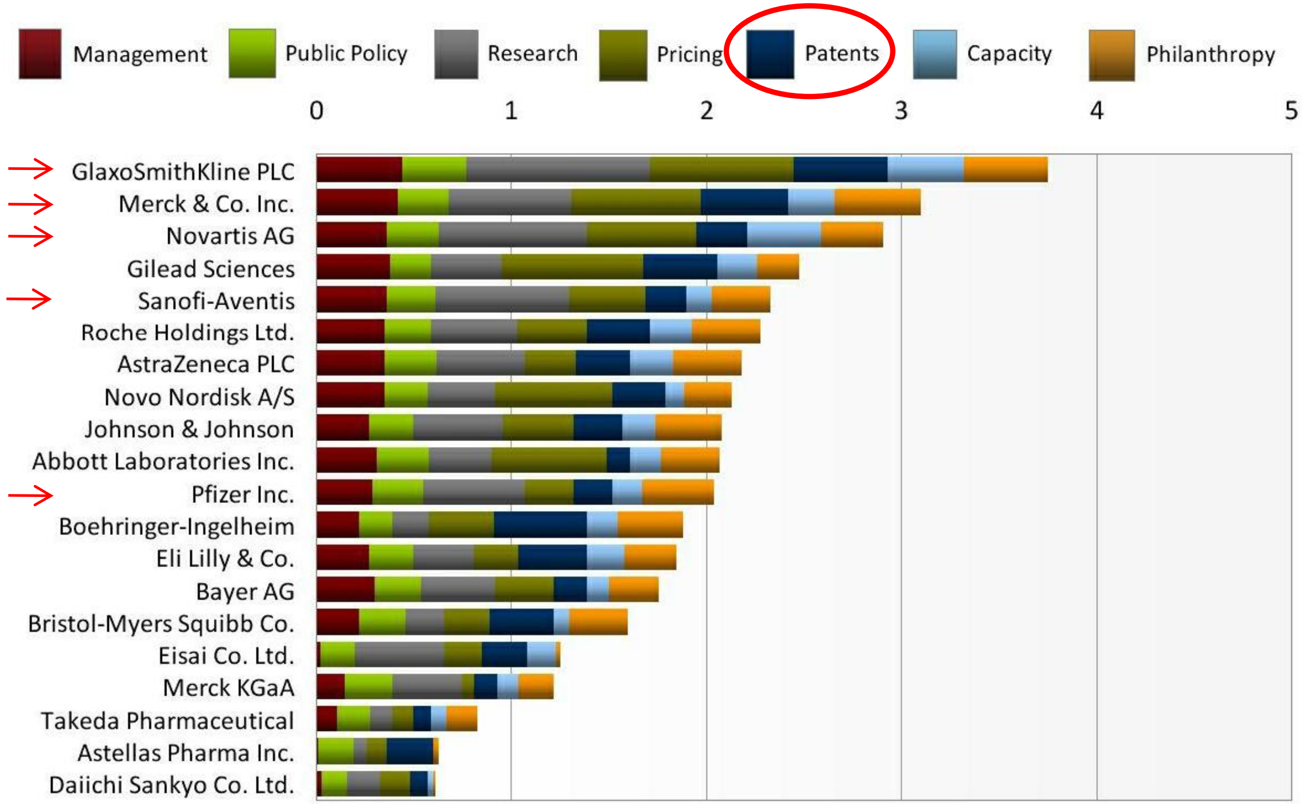
| Disease | Nr of trials |
|---|---|
| HIV Infections; Pneumococcal Infections | 1 |
| HIV Infections; Influenza; | 1 |
| Tuberculosis; HIV Infections | 4 |
| Pneumo | 7 |
| Rota | 10 |
| Influenza | 10 |
| TBC | 22 |
| Malaria | 31 |
| HIV | 44 |
| Others | 22 |
| Total | 152 |

**152** Nr of clinical tri

Source = www.clinicaltrails.gov

# Advocacy raises the awareness of donors and investors, and brings the big 5 on the light spot

## ATM Foundation was invited by the WHO to present the 2010 index results




IP as KSF:
Companies are ranked against their willingness to go for non-exclusive, voluntary licensing to other manufacturers

Sources: http://www.accesstomedicineindex.org/content/index-2010-0

# Financing DCVM growth and global expansion

- The presence of an active, innovative risk- sharing policy: alternative tools for financing clinical trials through joint ventures or out licensing agreements could increase DCVM global access

- DVCM technological performance, and compliance to cGMP procedures and standards is appealing to the big 5 and represents a unique added value

- The in house innovation of developing countries manufacturers and the value of its IP could serve as springboard for future revenues: this model is already applying to other businesses (eg: Indian companies actives in the oncology market)

- The AMC program represents a unique opportunity for new candidate Pneumo vaccine producers: all internal efforts should be focused and prioritized to meet this objective

- Work with other stakeholders to invest into programs aiming to develop local economy: this will increase the buying power of your customers

# WHO, UNICEF and PATH activities are key to boost growth of DCVM

- Assist local governments develop to processes for national vaccines registration complying to international standards, for an increased prequalification success rate

- Ensure resources for vaccines quality and continuous supply following the increased complexity of the vaccines produced and their continuously growing number

- Work with other stakeholders to increase reach in remote rural areas by leveraging on other existing health programs

- Interconnect local immunization programs with existing agro-food related strategies, to increase rate of success of local economic growth

- Work with governments to put in place sustainable and reliable surveillance and monitoring systems to measure success of immunization programs and create demand for vaccines

- Work with manufacturers to develop novel heat-stable formulations

- Advice manufacturers on clinical trials design and feasibility studies

Sources: www.unicef.org; Developments in Unicef Vaccine Procurement, Global Immunizaiton meeting, 2010; State of the world's vaccines and immunization, 3rd edition, 2009; Alliance for a Green Revolution in Africa website; PATH website; PwC internal analysis.

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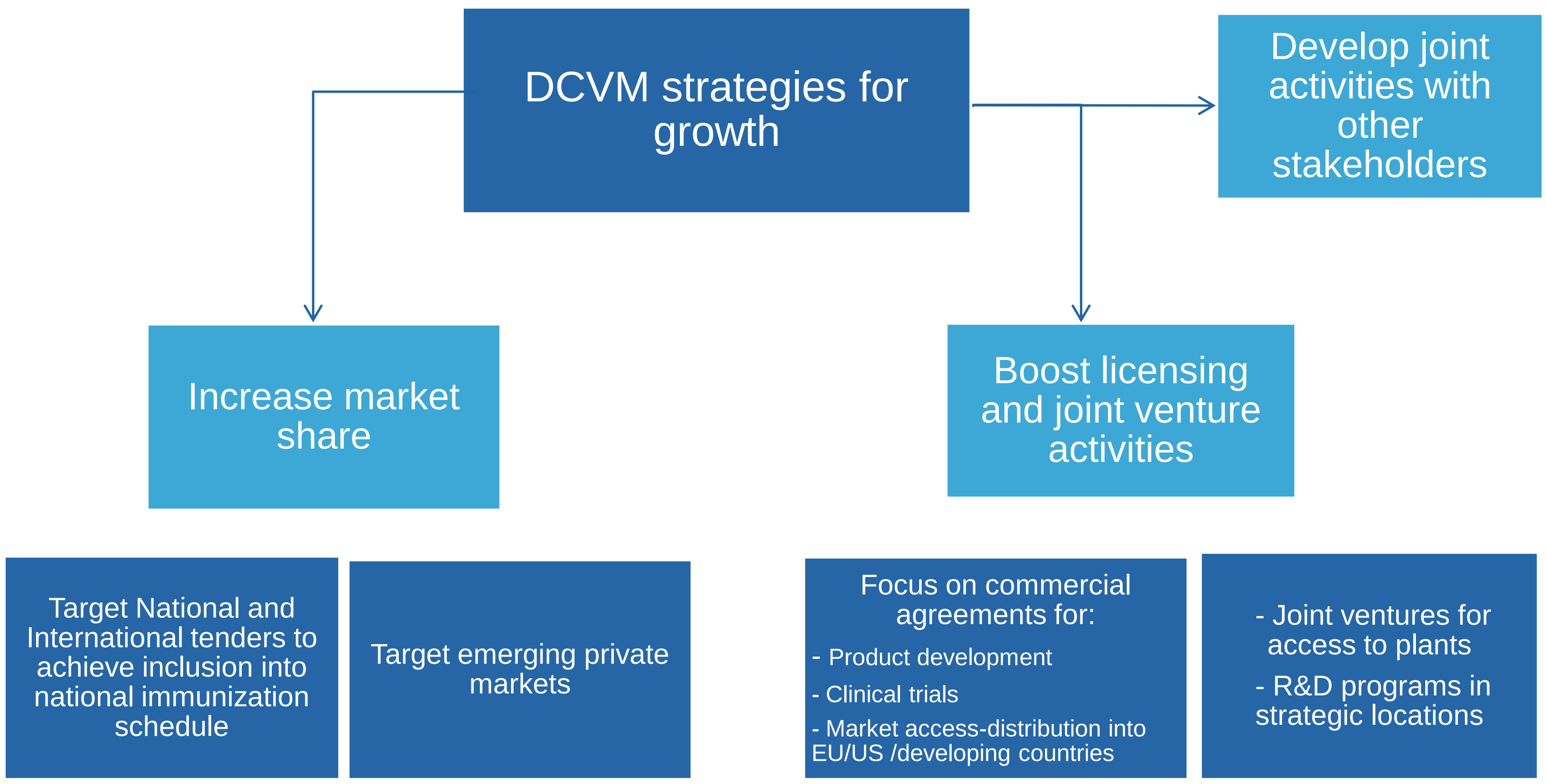
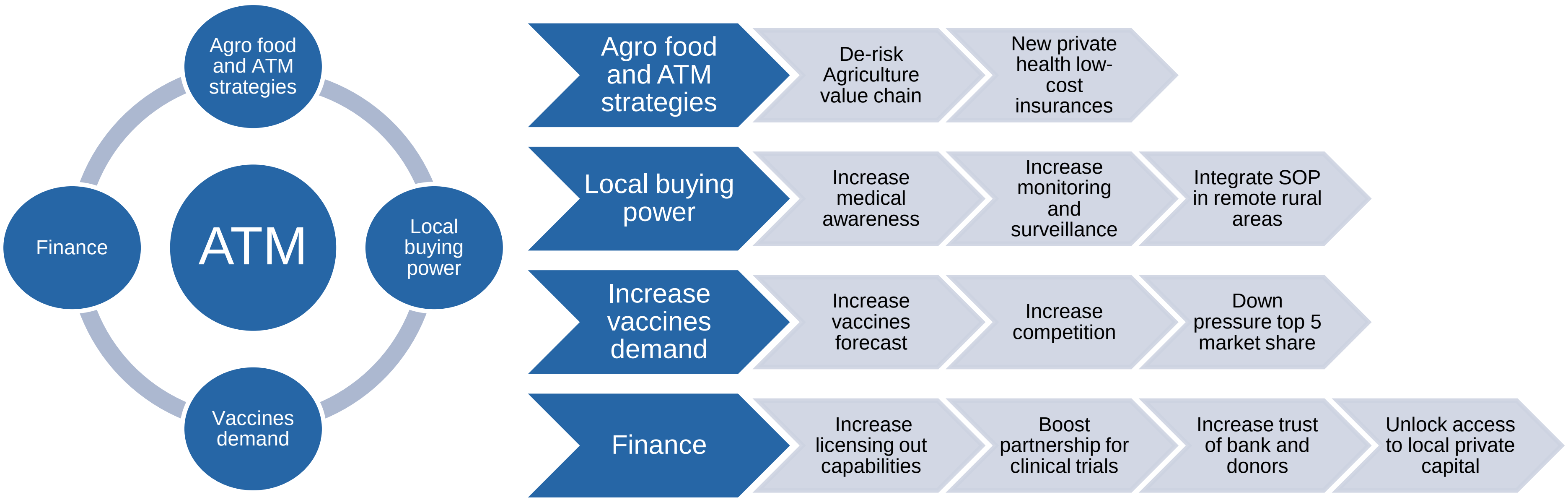
# DCVM: increase market penetration and boost licensing and joint venture activities



# All stakeholders: interlink economic development (agriculture and health) to unlock access to medicine, increase local buying power, and boost DVCM growth




Consider access to medicine and agriculture performance as interdependent, and invest in a de-risking strategy

Sources: PwC internal analysis

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# Stakeholders set sustainability as main priority (1/2):

UNICEF:

- *Ensuring an uninterrupted, sustainable supply of affordable vaccines of assured quality*

WHO:

- *Ensure a sustainable vaccines prequalification process and advice to NFDA agencies*

GAVI:

- *Support sustainable immunization programs for a sustainable health in critical areas*

NGOs:

- *Ensure an adequate and sustainable technical and strategic support to purchasing agencies, governments, and manufacturers*

ATM foundation:

- *redirect corporate efforts of big 5 towards a more sustainable market environment*

# Stakeholders set sustainability as main priority (2/2):

## Donors:

- *Donations invested to generate return for ensuring a more sustainable and long lasting impact on immunization programs*

## Investors:

- *Invest into a de-risked value chain, and not on a single program, to obtain low but sustainable return on investment*

## Manufacturers:

- *Put knowledgeable resources for setting new strategies to develop licensing activities, and for increasing market penetration by leveraging on the promising technological advancement brought by DCVM*

# Vaccines Market Outlook
# Key Success Factors and Opportunities

## PwC Luxembourg:

## A dedicated team focused on sustaining immunisation programs

Laurent Probst
Partner
+352-494848 2564

Erica Monfardini
Expert
+352-494848 2566

Sujay Shetty
Director
+91-22-6669 1305
(India)

Jean Baptiste le Caron
Manager
+352 – 494848 2527



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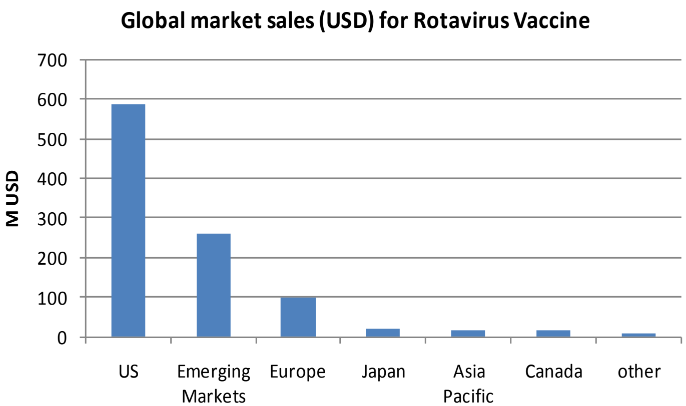
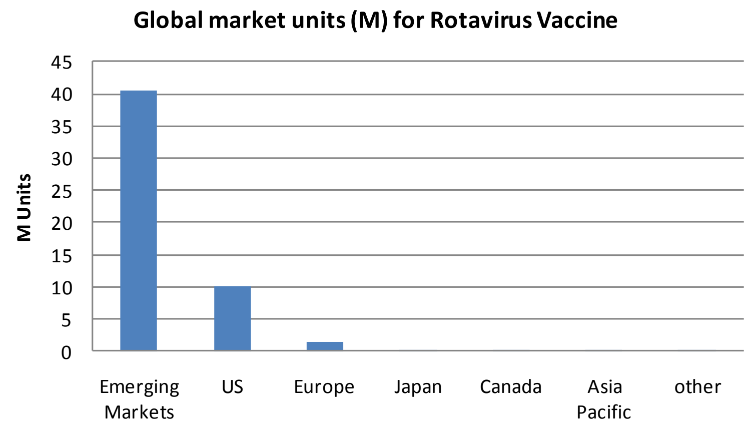
# Global Rotavirus vaccine Market Outlook: current sales estimates



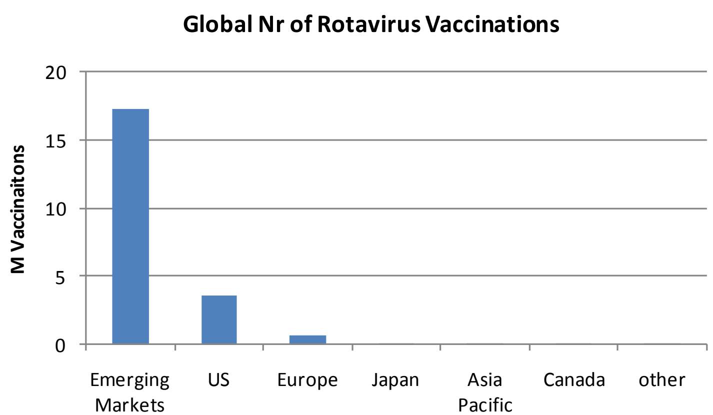

| Global Sales | |
|---|---|
| Merck | 56% |
| GSK | 44% |

| Emerging Markets Sales | |
|---|---|
| Merck | 34% |
| GSK | 66% |



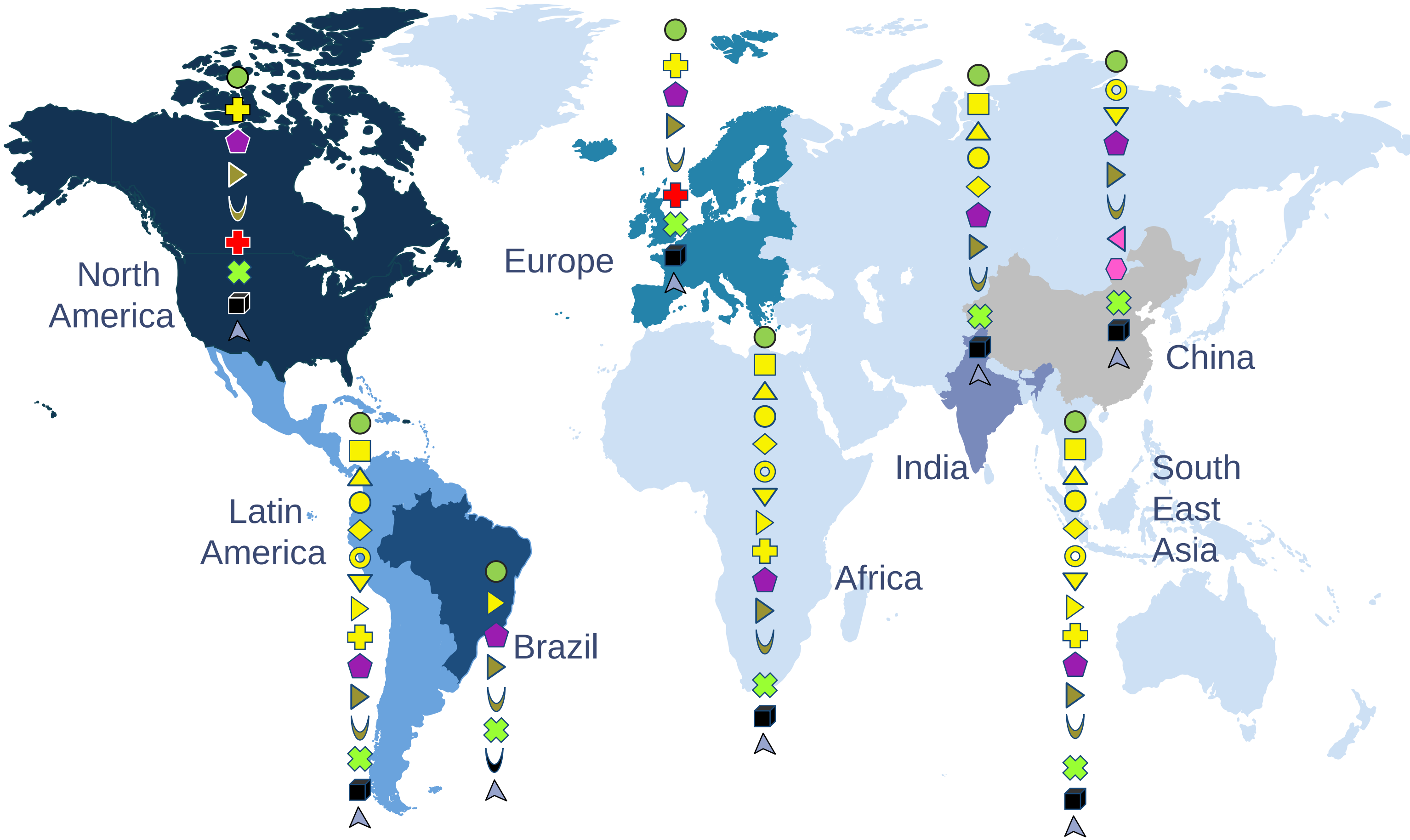

| Global Units | |
|---|---|
| Merck | 50% |
| GSK | 50% |

| Emerging Markets Units | |
|---|---|
| Merck | 43% |
| GSK | 57% |




Sources: GSK and Merck annual report 2009, other publicly available information

# Rota vaccine: future outlook for IP availability




116E
- Bharat Biotech Int Ltd

BRV-TV
- Shantha Biotechnics
- Serum Institute of India
- Bharat Biotech Int Ltd
- Biological E Ltd
- Wuhan Institute
- Chengdu Institute
- Butantan Institute
- Aridis Pharmaceuticals

RV3
- Meridian/BioFarma

Brazilian pentavalent
- Butantan Institute
- Fiocruz/BioManguinhos

Lanzhou Lamb LLR
- Lanzhou Biologicals
- Xinkexian Biological Tech

Rotavax
- Aridis Pharmaceuticals*

Rotashield
- BIOVIRx and IDT

Rotarix
- GSK
- Fiocruz/Manguinhos

Rotateq
- Merck & Co

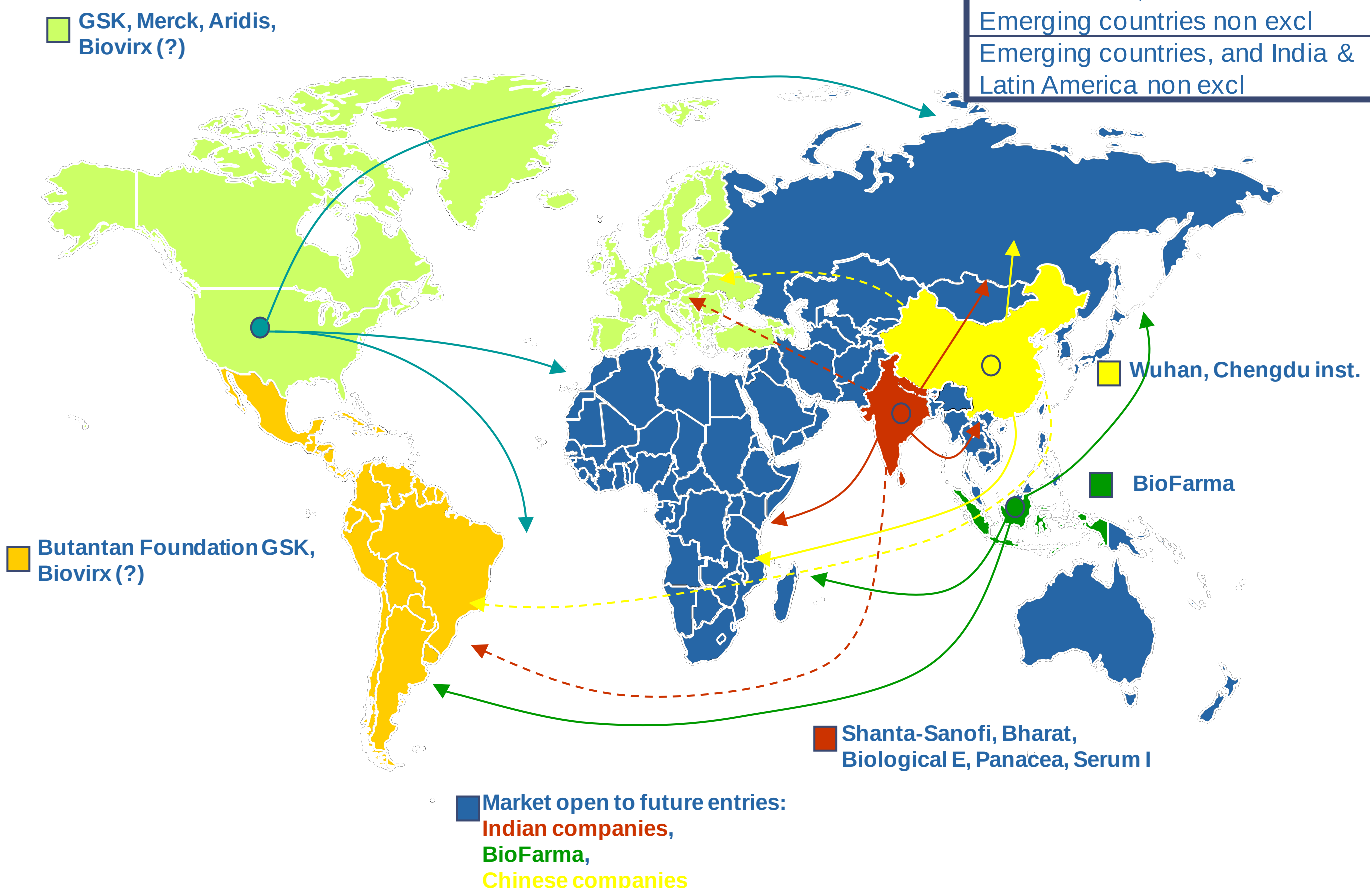
NOTE: Even though the Indian manufacturer Panacea doesn't own any IP for a Rotavirus vaccine, it has the capabilities, resources, and know-how to develop it or buy.

Source: Rotavirus Vaccine:NIH Office of Technology Transfer. 2007 and other publicly available information

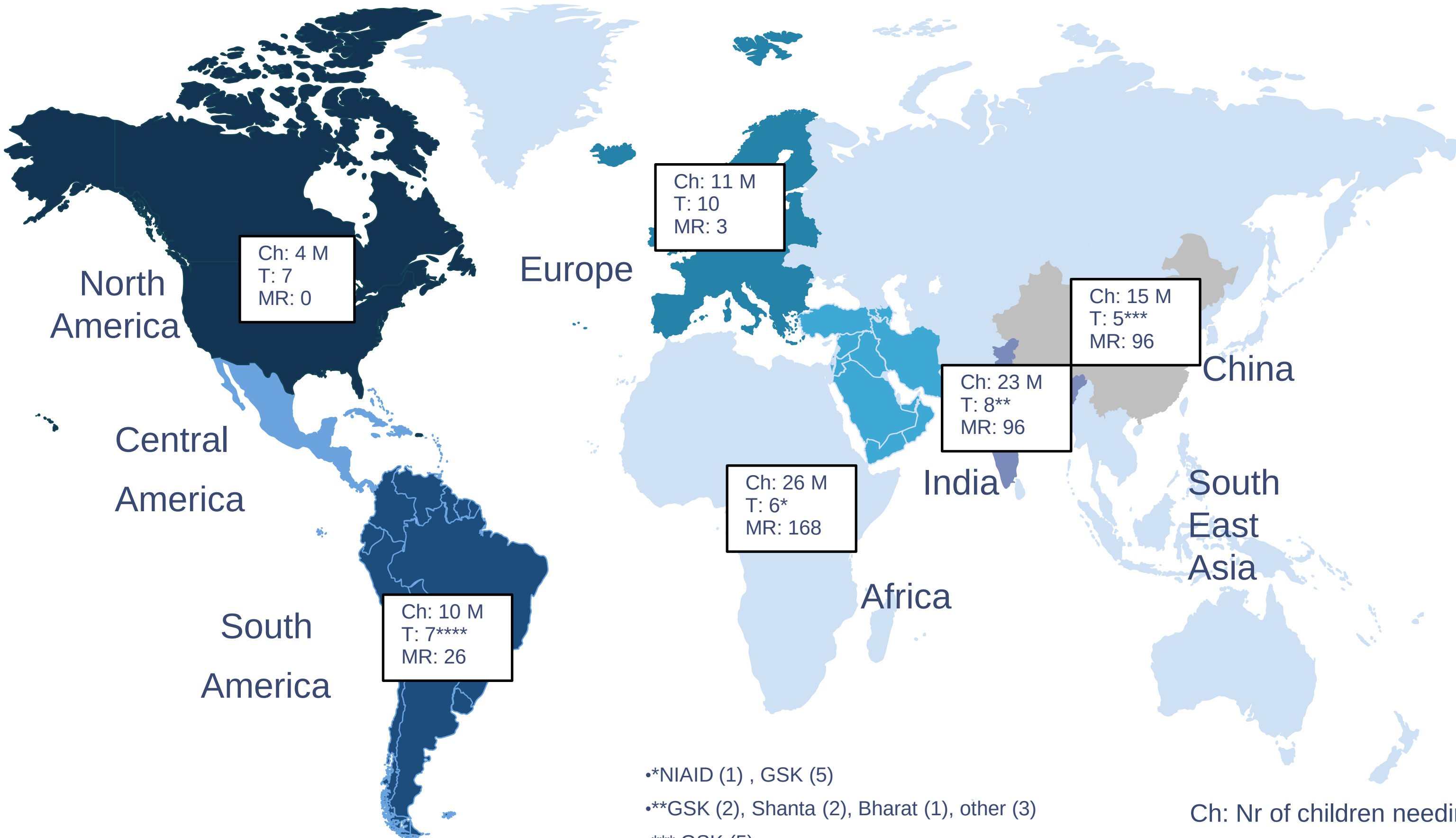
# India, China, and Indonesia: take off regions for global expansion?

**Licenses geographic coverage:**

| | |
|---|---|
| All countries | GSK, Merck, BIOVIRx, Bharat, BioFarma |
| Emerging countries, and China & Latin America non excl | Shanta, Biological E, Serum I. |
| Europe, Canada, US | Aridis |
| Latin America, and other Emerging countries non excl | Butantan |
| Emerging countries, and India & Latin America non excl | Wuhan, Chengdu |



# Rota vaccine IP: clinical trials do not support market need




- *NIAID (1) , GSK (5)
- **GSK (2), Shanta (2), Bharat (1), other (3)
- *** GSK (5)
- **** SGK (%), Merck (1), Butantan (1)

Ch: Nr of children needing vaccination
T: clinical trials
MR: Mortality rate

Sources: www.clinicaltrails.gov, WHO database, UN census Bureau, *Global illness and deaths caused by rotavirus disease in children, 2004,* CDC publication .