

VACFA 2014



	Pharma	Vaccines	Diagnostics
Manufacturers	Multinats and small and medium players	Small number of large producers >90% of value held by <15 manufacturers	Some multinats, large number of small & medium players
Role of regulatory agency	Mandatory except for complimentary	mandatory	Largely absent
WHO PQ	Mandatory for purchase by global initiatives	Mandatory for purchase by UN agencies	Mandatory for global purchases but only 2 products listed in 2011
Product pricing at source in relation to access	Moderate ;most end user prices are related to taxes and mark-ups	High; often mediated through national purchasing or global initiatives (GAVI)	High; plus additional costs of purchase and maintenance of test equipment and service
Intellectual Property	Integral to new products; generic production possible and more likely to be produced	Integral to new products, most EPI products no longer have patents Barrier is know-how rather than patents	New technology and constituents components often patent protected
Market competition	Limited therapeutic competition during patent life; generics play major role in reducing price	New vaccines produced by limited large producers; older vaccines have competing producers	High for some products; lower for some neglected diseases
Route of market	Mixed centralized; local OTC	Centralised purchasing by govts or purchasing entities	High product based segmentation ;limited central purchasing

In SADC

**Countries UNICEF
procures on
behalf of**

Part of the Vaccines

Based on 2008 Forecasts received by UNICEF

Tiered market

Western Markets	W Europe, USA, Japan	Self Purchasing
Upper Middle Income Countries	Brazil, Russia, South Africa, Turkey, Middle East Countries	Self Purchasing
Lower Middle Income Countries	Congo (brazzaville), Angola, Ghana etc.	Graduating
Low Income Countries	Lesotho, Tanzania, Kenya, DRC etc.	GAVI/UNICEF

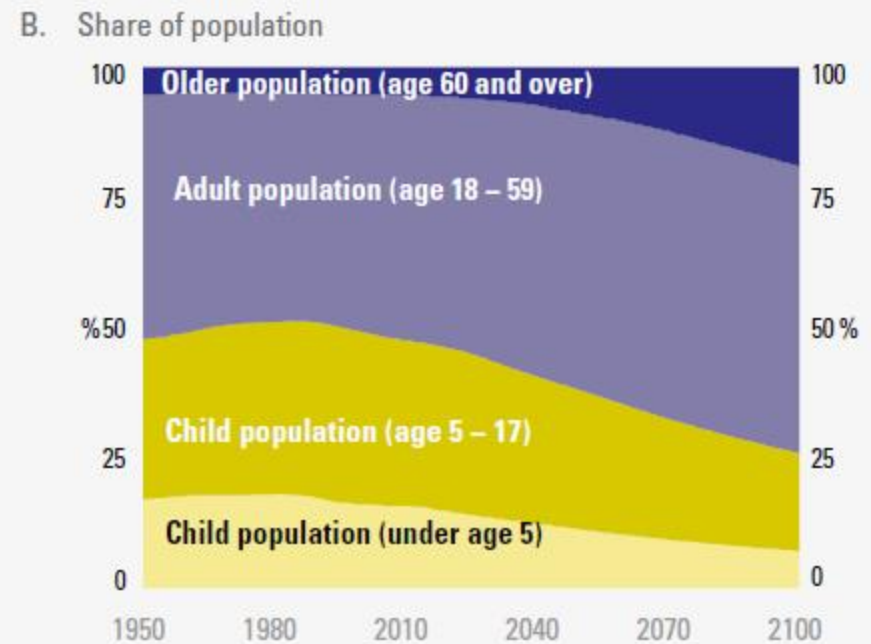
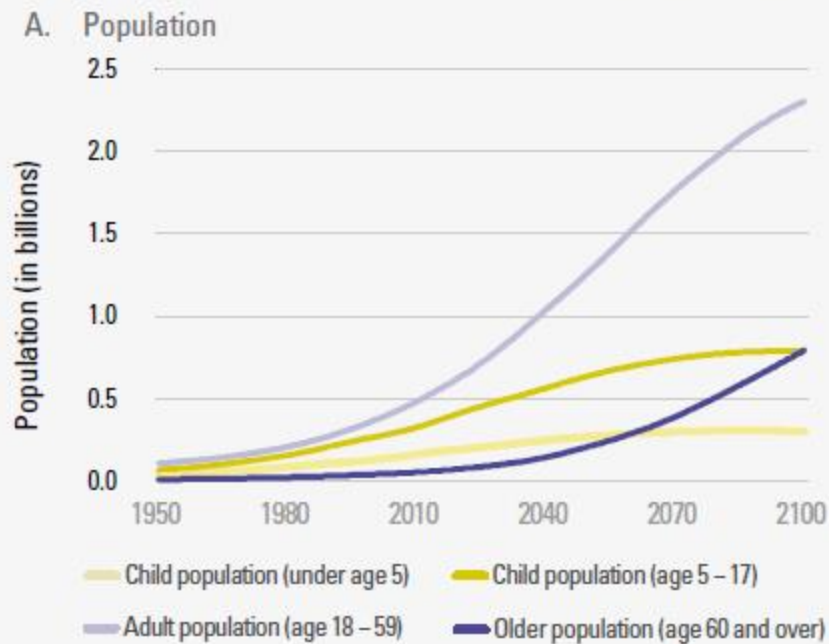
Developing Regions birth cohort and the proportion of vaccine manufacturers

Region	Birth cohort	No of Vaccine manufacturers
Africa	47m	? 3
Asia	61m	>20
Latin America	10,7m	4



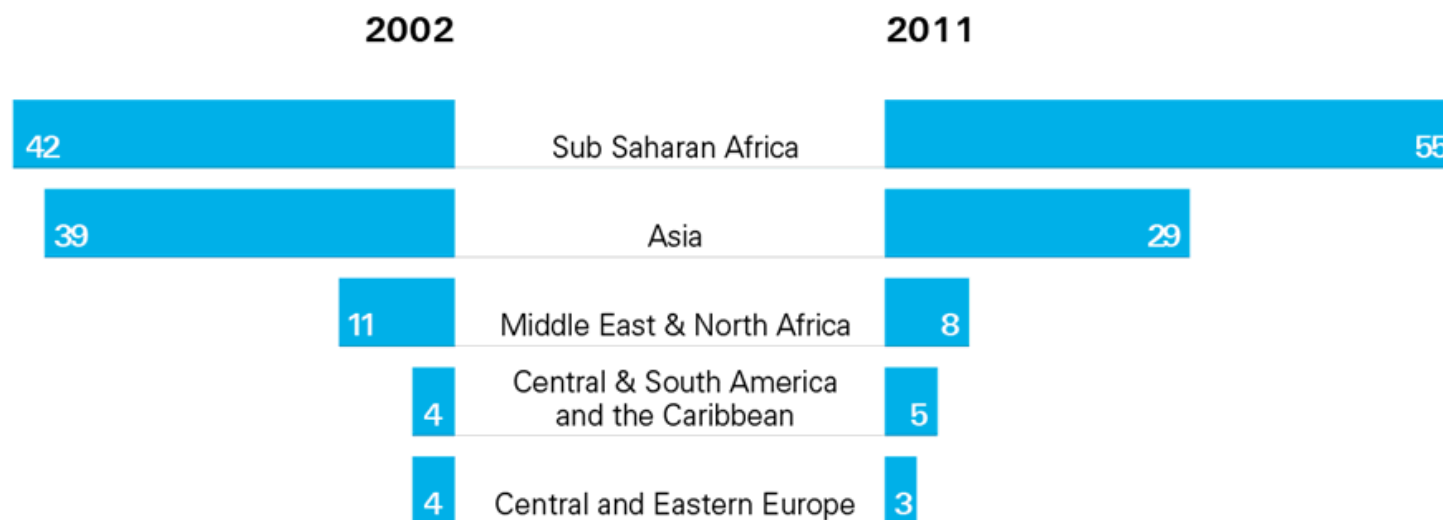
The absolute number of children in Africa will increase, while their share among the total population in Africa will decline to almost 40% in 2050

Population in Africa by age group, 1950–2100



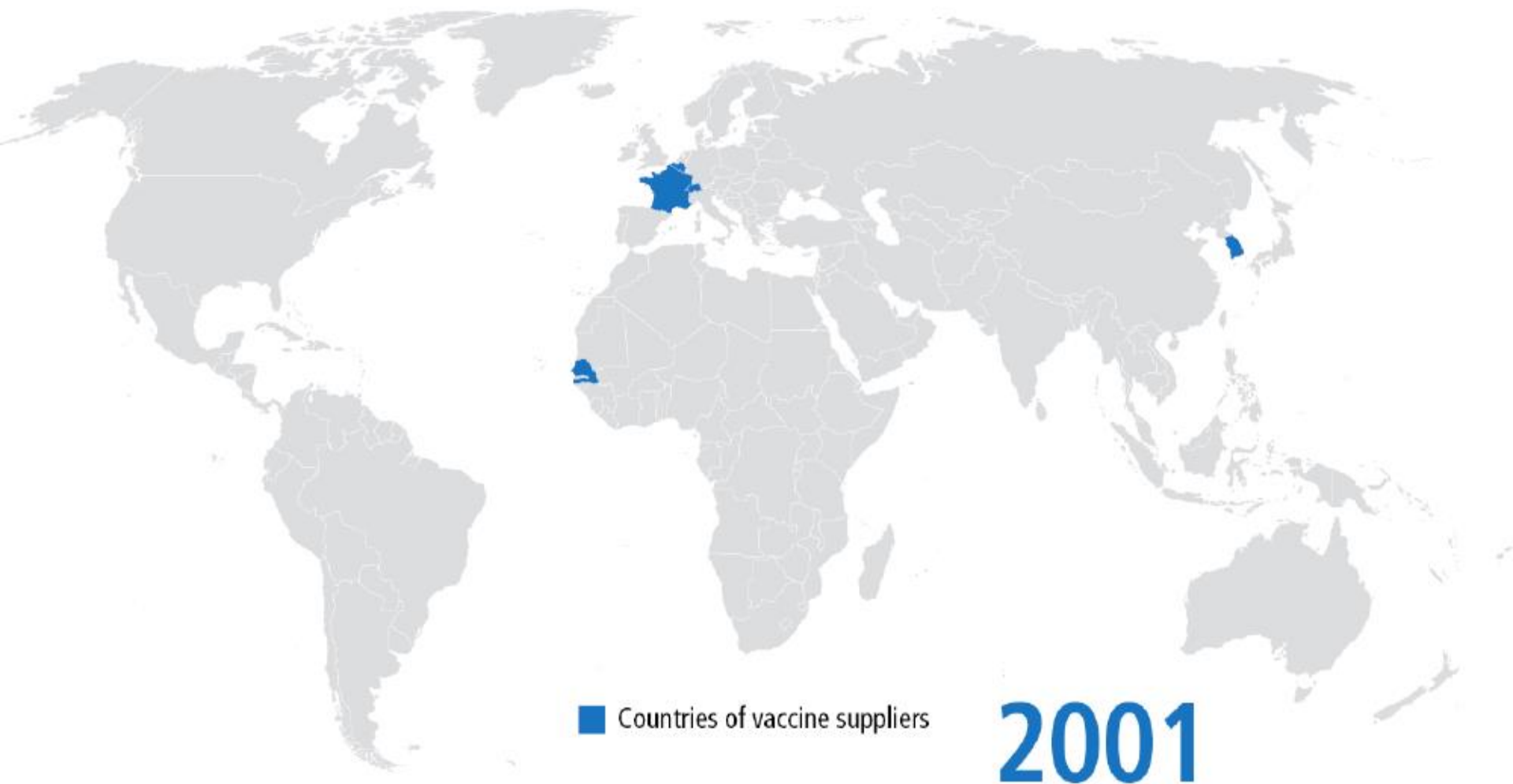
Source: UNICEF analysis based on UN WPP 2012 Revision.

Where UNICEF supplies are used



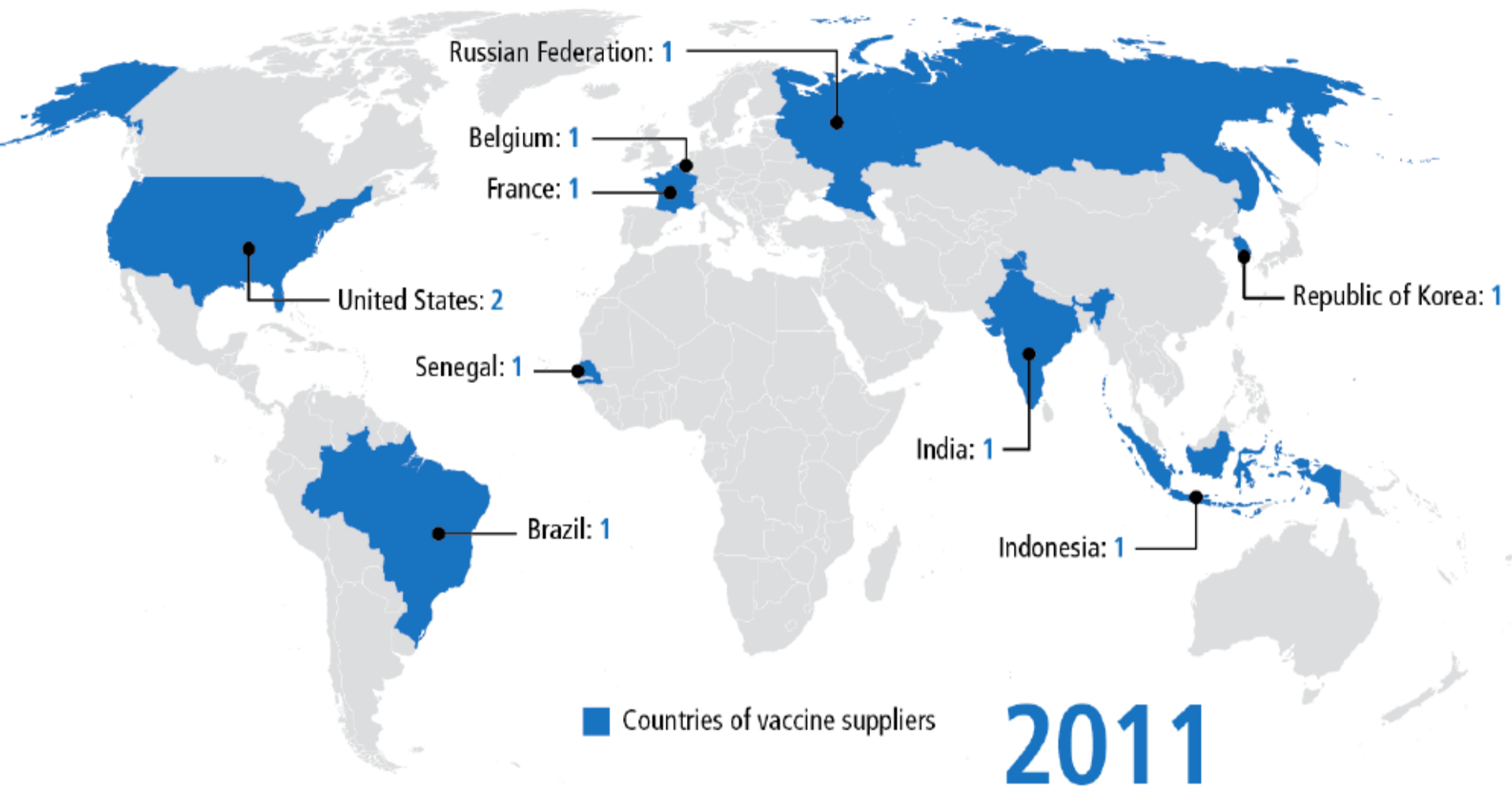
GAVI Supply

2001 – Vaccine supply:
5 suppliers from 5 countries



GAVI Supply

2012 – Vaccine supply:
10 suppliers from 9 countries





THE BIOVAC INSTITUTE
The science of protecting life



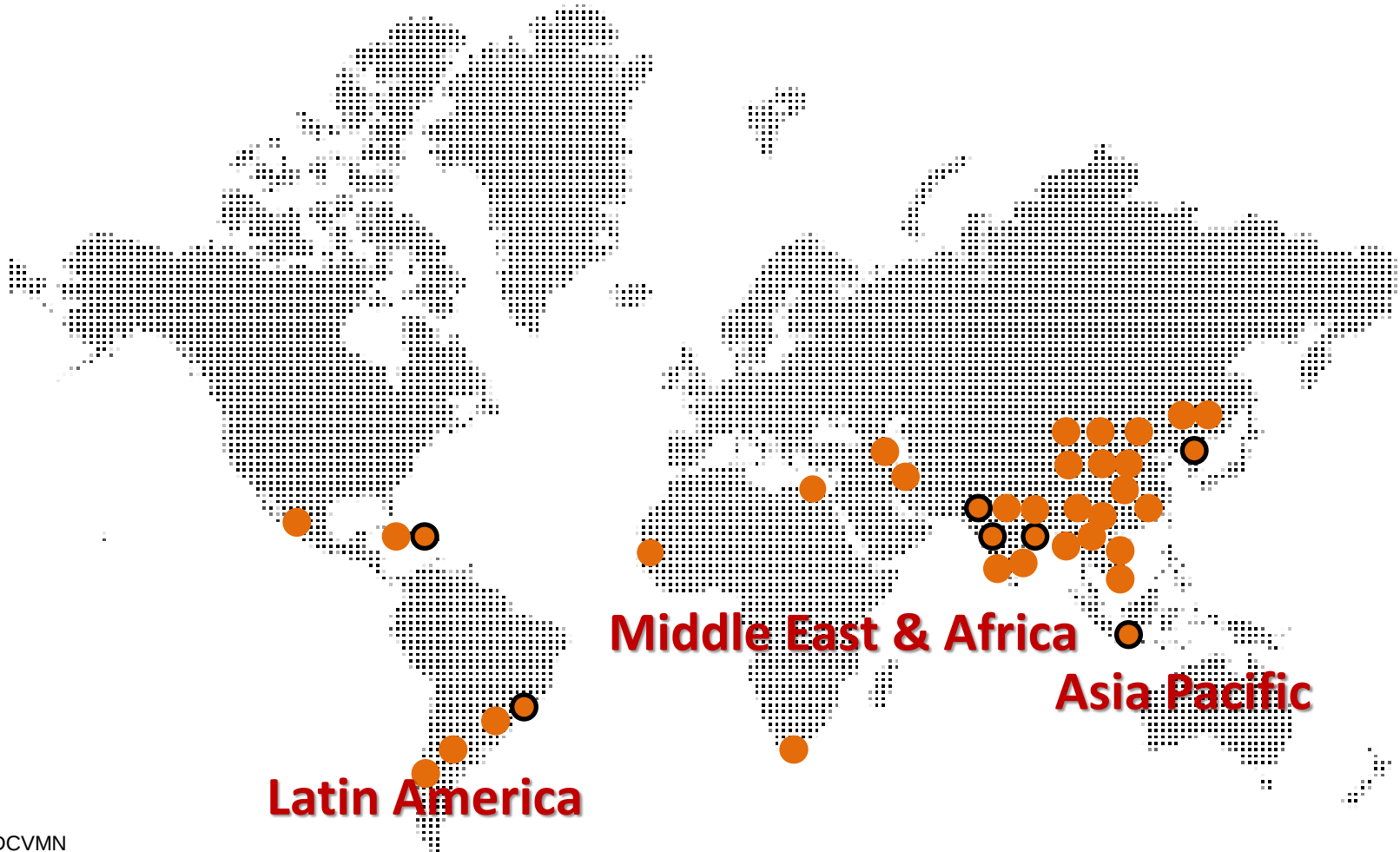
2014

Sources: UNICEF Supply Division and
WHO list of pre-qualified vaccines, 2014

*GAVI Alliance Board meeting
18–19 June 2014*



Developing Country Manufacturers



Industrialised countries

Developing countries

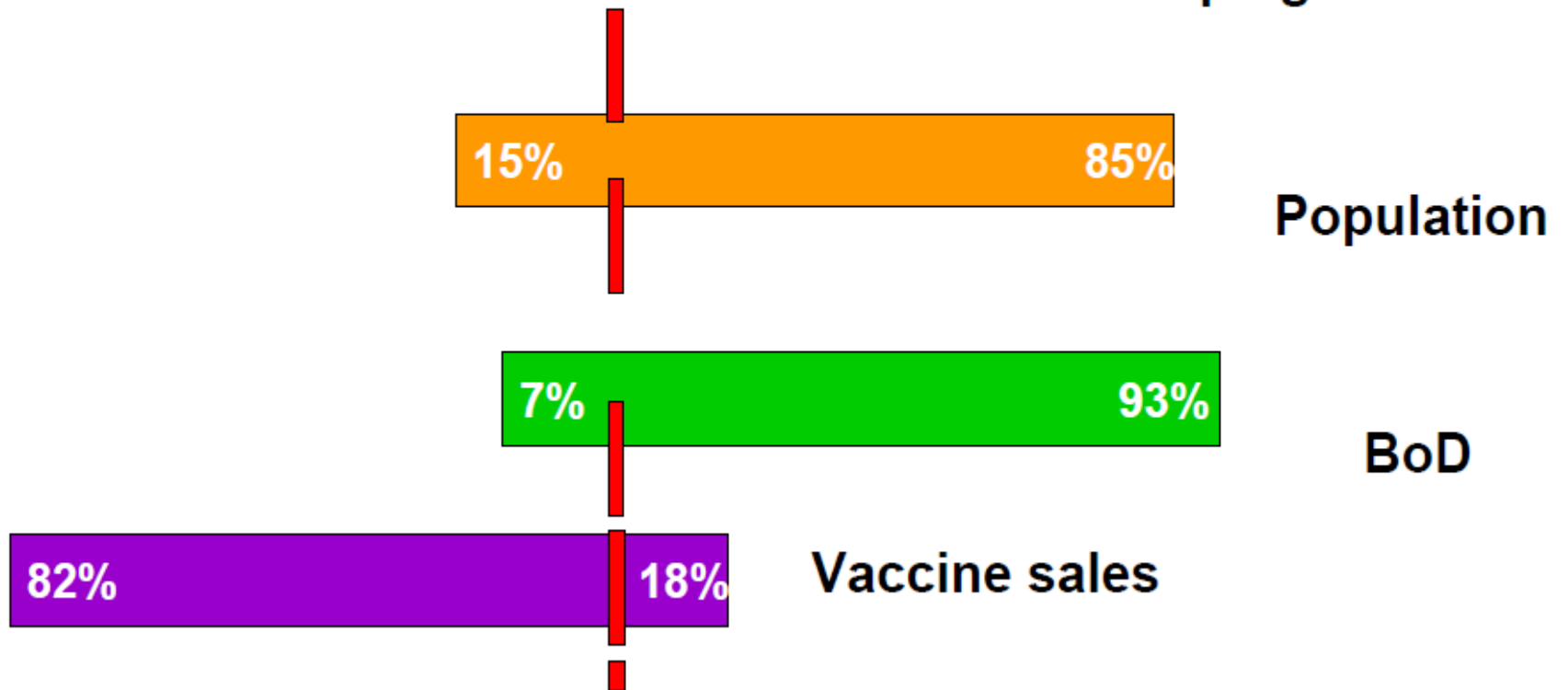
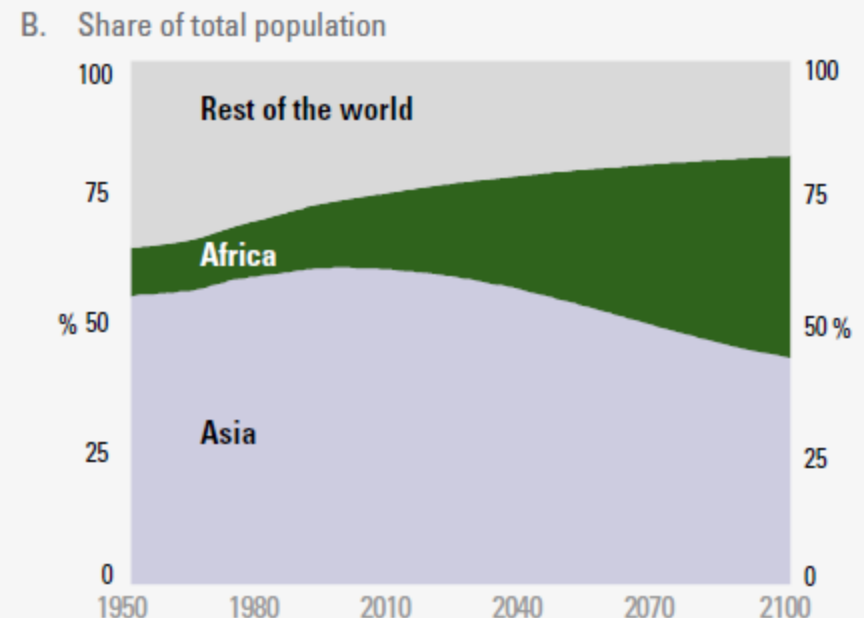
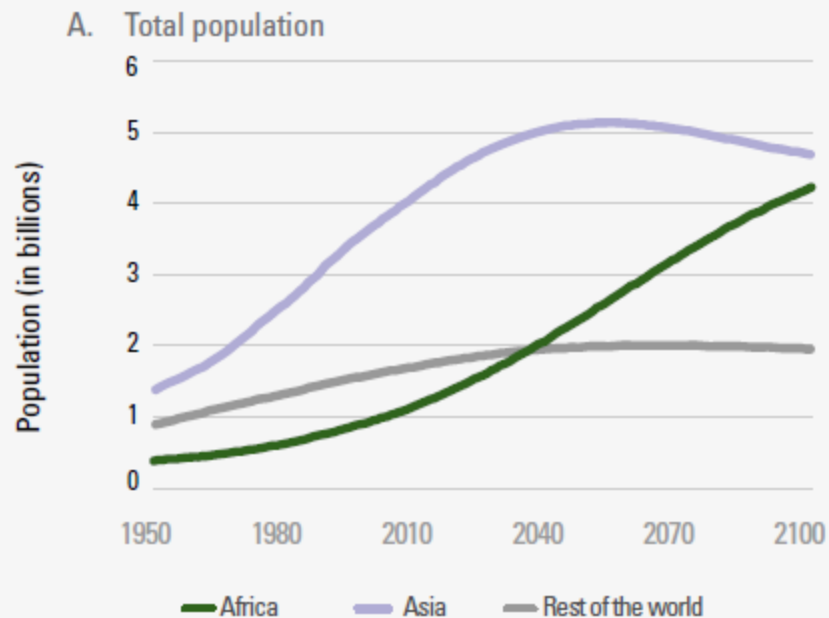




FIG. 1

Africa's population will double from 2015 to 2050

Total population by region, 1950–2100



Source: UNICEF analysis based on United Nations, Department of Economic and Social Affairs, Population Division, World Population Prospects: The 2012 Revision (UN WPP), United Nations, New York, 2013.

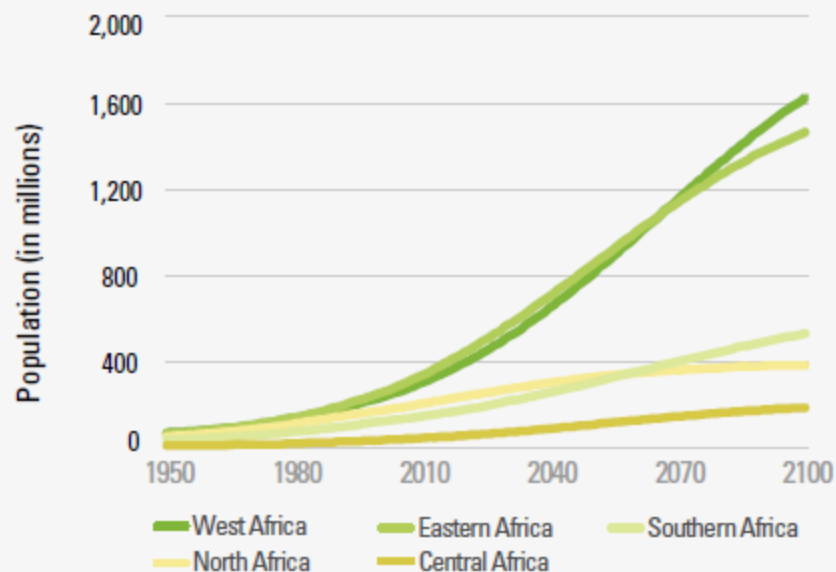


FIG. 2

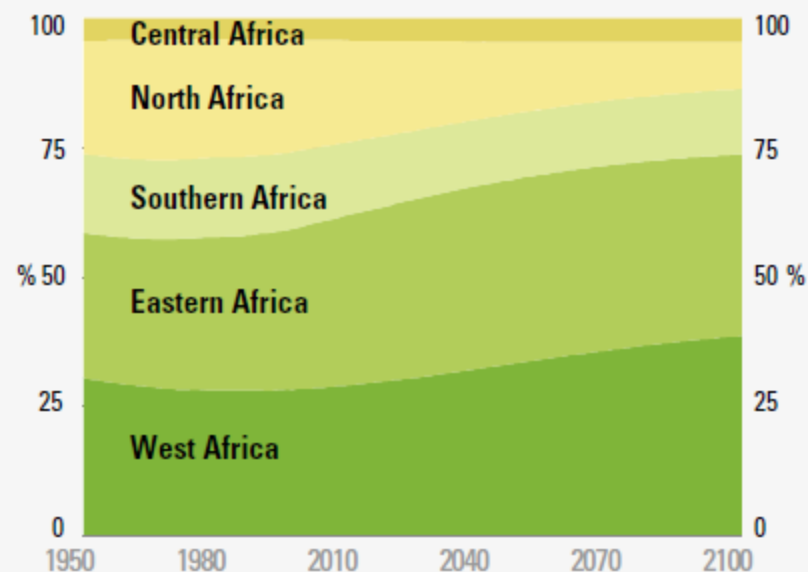
West and Eastern Africa will be the main drivers of population growth, with West Africa becoming the most populous region in Africa by 2067

Population in Africa by UNECA region, 1950–2100

A. Total population



B. Share of total population

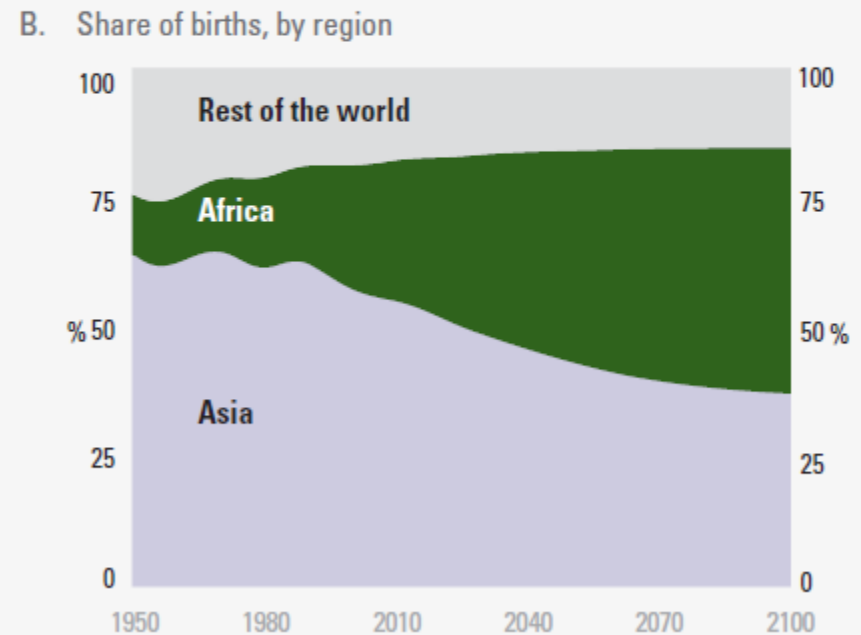
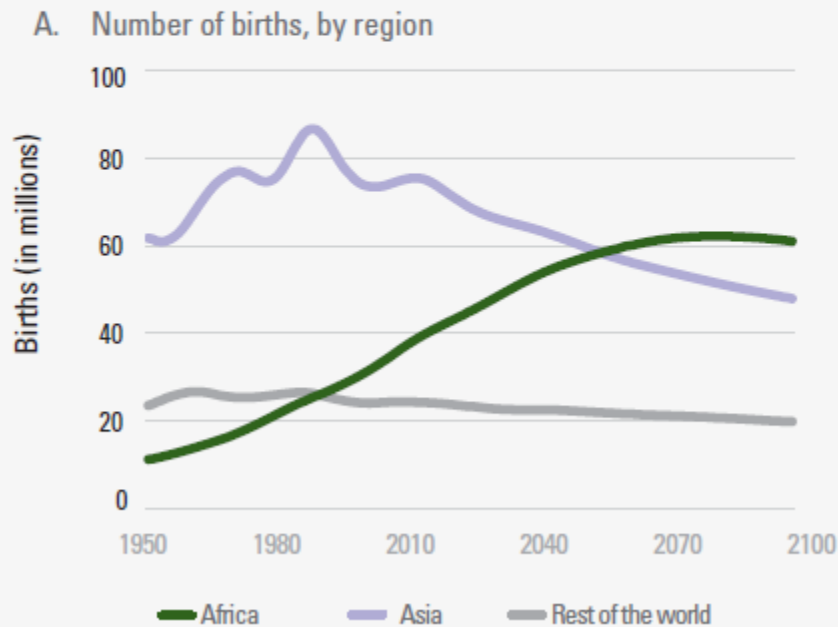


Note: The regional aggregates follow the United Nations Economic Commission for Africa (UNECA) regions. The detailed classification can be found at <http://www.uneca.org/node/2798/>.

Source: UNICEF analysis based on UN WPP 2012 Revision.

**The number of births will continue to grow in Africa but decline in the rest of the world;
Four in 10 of the world's babies will be born in Africa by mid-century**

Births, 1950–2100



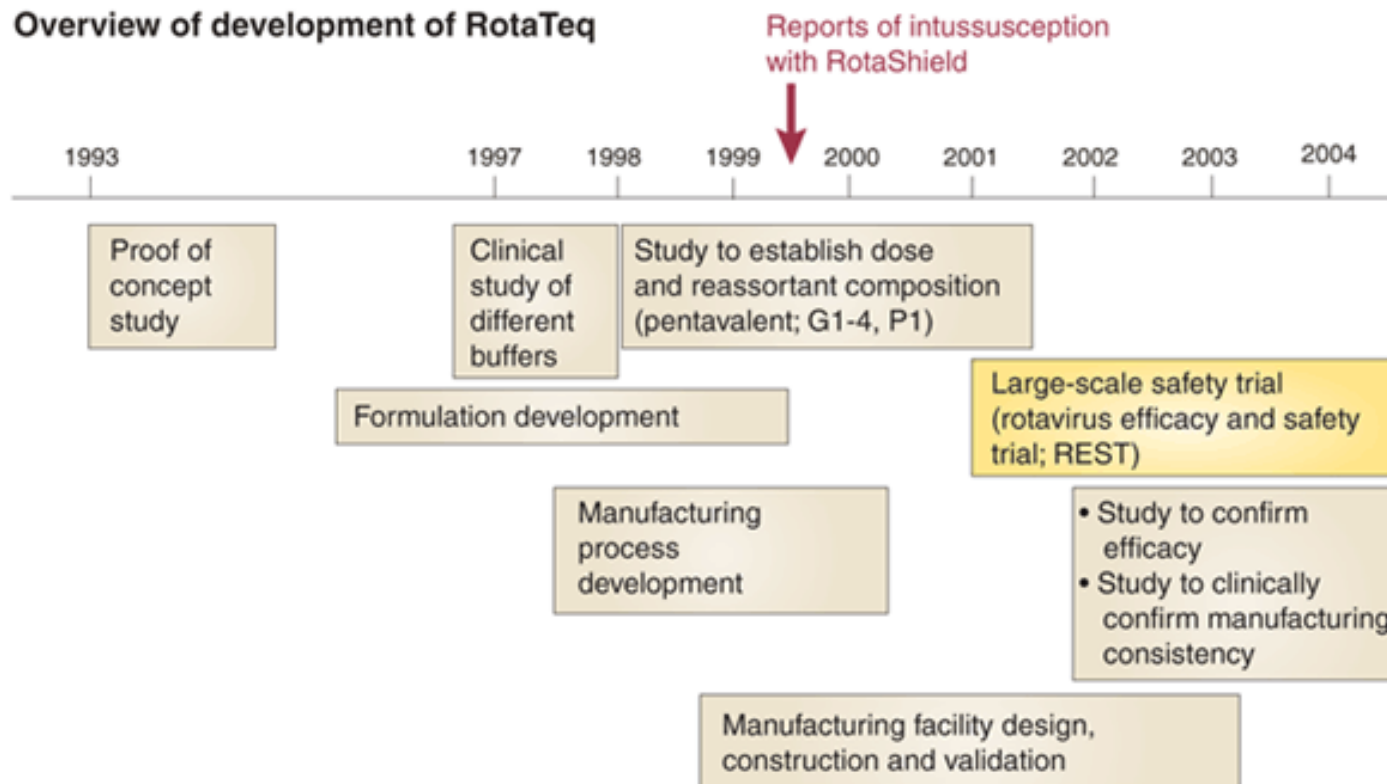
Journey is Long

2013	Launched Oral Polio Vaccine (OPV), Live
2012	Made first overseas acquisition Bilthoven Biologicals, Netherlands Launched Trivalent seasonal influenza vaccine, live (NASOVAC-S),
2011	Launched injectable inactivated polio vaccine (POLIOVAC PFS)
2010	Launched H1N1 Influenza Vaccine live (NASOVAC), H1N1 Influenza Vaccine inactivated (ENZAVAC), Meningococcal A conjugate vaccine (MenAfriVac) and r-HuEPO (REPOITIN)
2009	Launched liquid Pentavalent Vaccine (DTP-HepB-Hib) (PENTAVAC SD/PFS)
2008	Launched combi-pack of Pentavalent Vaccine (DTP-HepB+Hib) (PENTAVAC) and Quadrivalent Vaccine (DTP+Hib) (QUADROVAX)
2007	Launched Hib Vaccine (HIB PRO) and BCG Vaccine for Bladder Cancer (ONCO-BCG)
2005	Launched DTP-HepB Combination Vaccine (Q-VAC)
2004	Launched the world's only adsorbed liquid HDC Rabies Vaccine (Sii RABIVAX)
2002	Launched BCG Vaccine (Sii TUBERVAC)
2001	Launched Hepatitis B Vaccine (rDNA) (GENEVAC B)
1993	Launched MMR Vaccine (TRESIVAC)
1991	Launched Polyvalent Anti-Snake Venom Serum (Africa)
1989	Launched Measles Vaccine (M-VAC)
1981	Launched Polyvalent Anti-Snake Venom Serum (Asia)
1974	Commenced production of DTP Vaccine
1967	Operations began with manufacture of Tetanus Antitoxin followed by Tetanus Toxoid

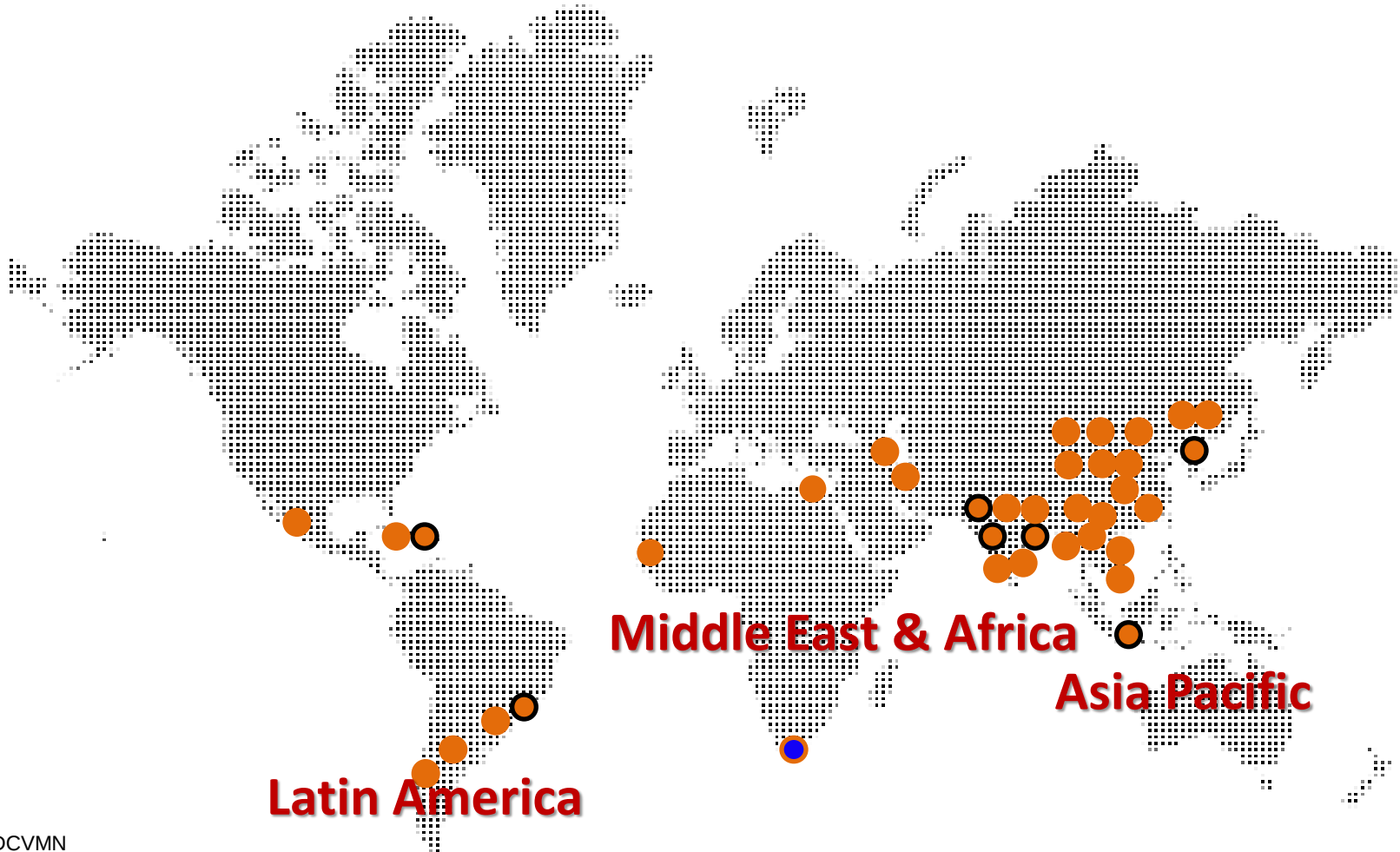


Challenges in Vaccine Development

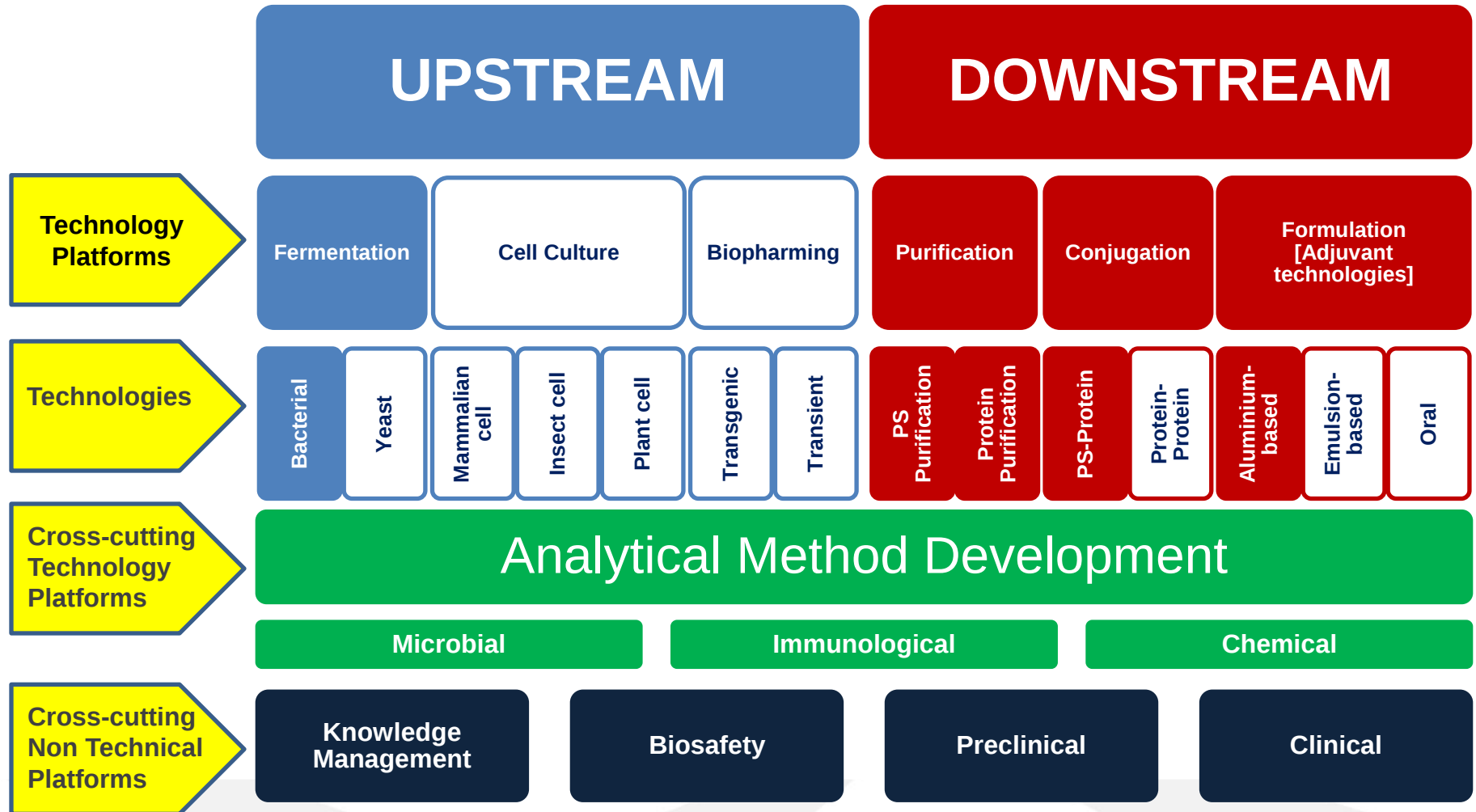
Overview of development of RotaTeq



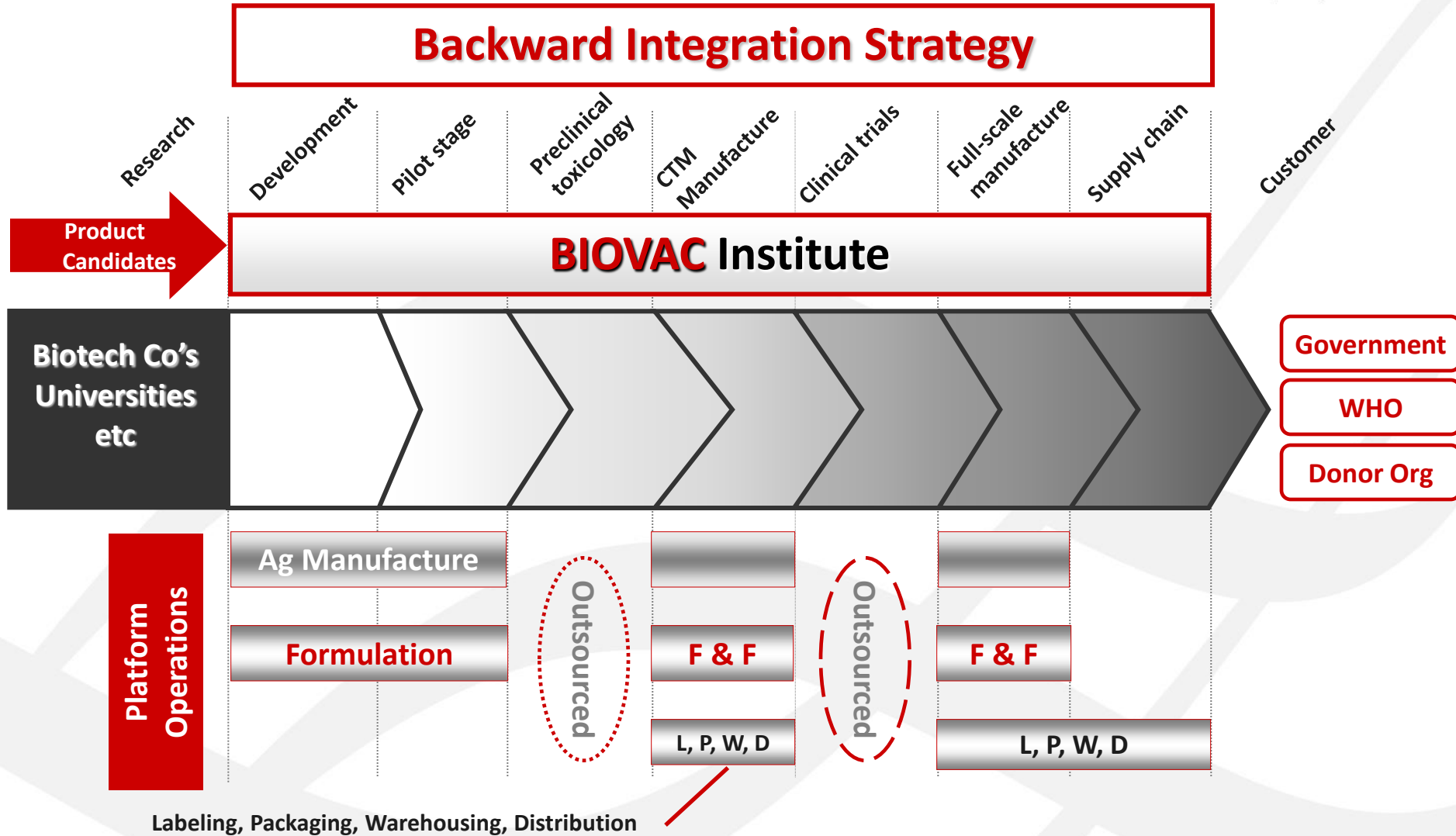
Overview of the development of a vaccine against rotavirus developed by Wyeth.



Platforms and Technologies



Vaccine Value Chain



API Production



Formulation



Filling



Packaging







Conclusion

- **Vaccine Manufacturing Capability**

- takes long to develop (patience!)
- Takes deep pockets
- Has risks

But.....

- Is absolutely essential where
 - there is the largest burden of vaccine preventable diseases (Africa!)
 - biggest population growth (africa!)

However needs a direct link with sound, long term procurement practises