# IPV USE & CHALLENGES

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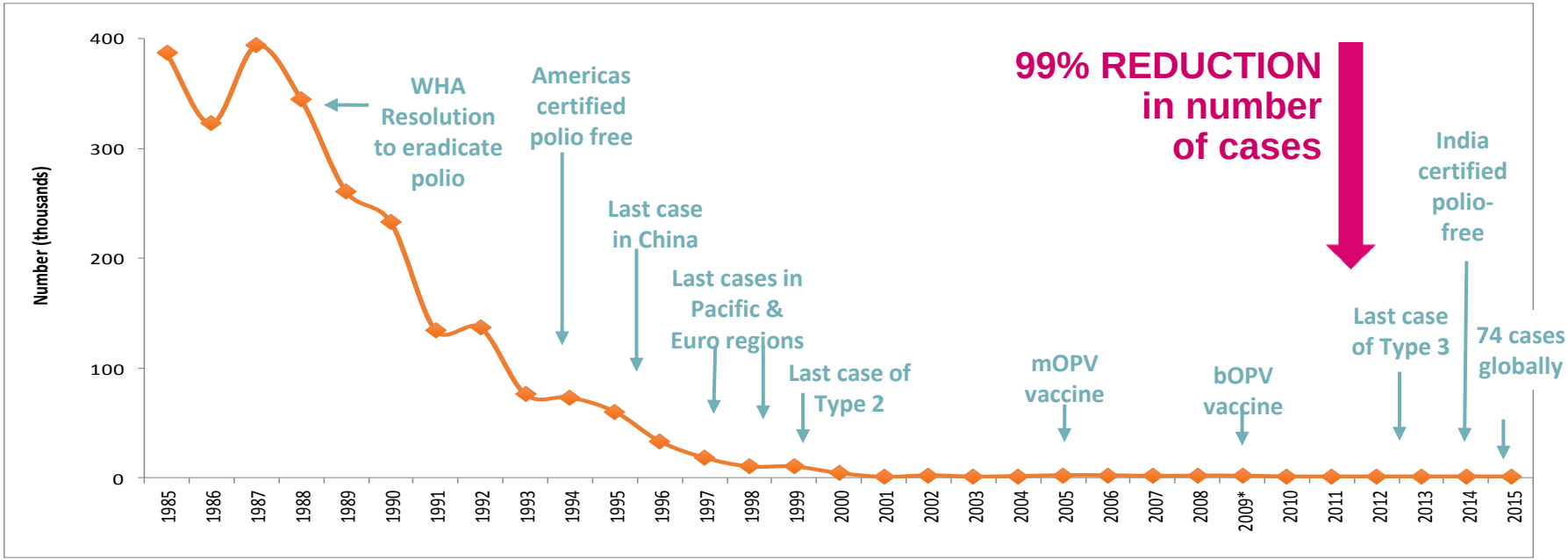
Child receiving IPV with tOPV during NID in Kano City, March 2015

# RATIONALE FOR OPV CESSATION

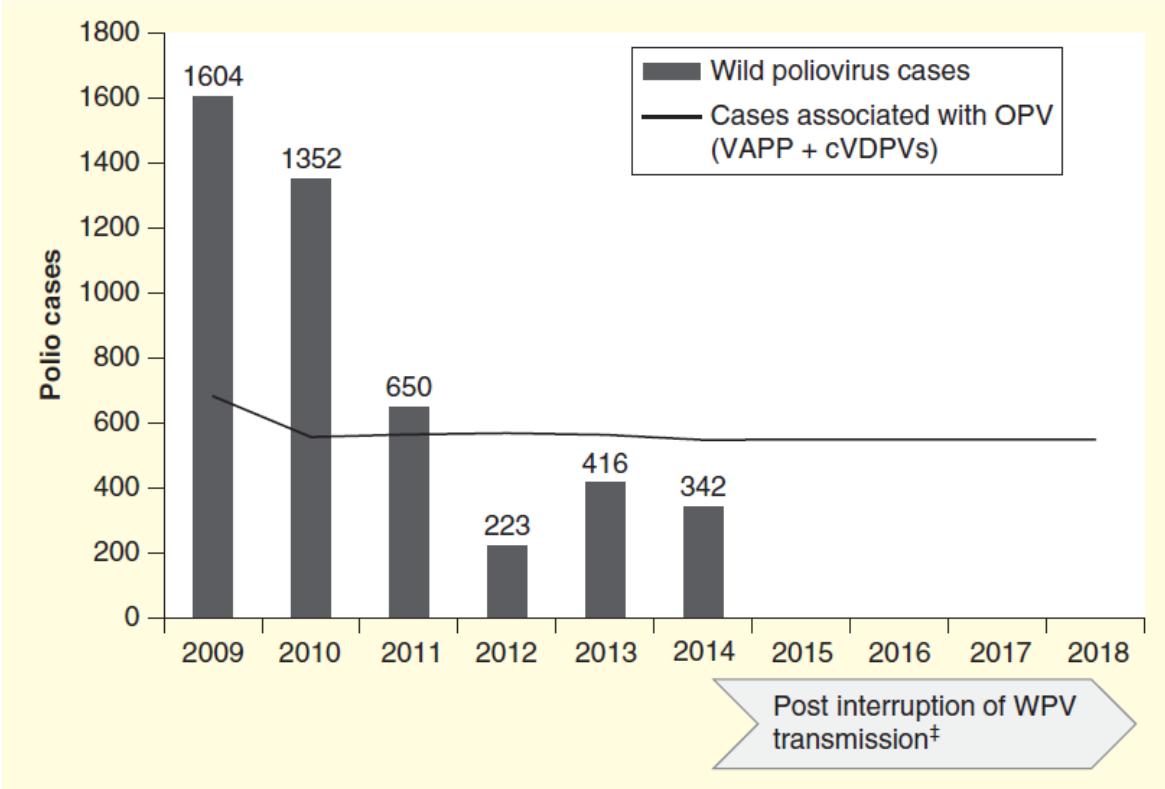
 

# DRAMATIC PROGRESS:
# ANNUAL GLOBAL POLIO CASE BURDEN




Source: WHO/Polio database

# NUMBER OF CASES RELATED TO VACCINE-DERIVED POLIOVIRUSES IN COMPARISON TO WILD POLIOVIRUS




Patel, et al. Expert Rev. Vaccines 2015 .1.online

# RATIONALE FOR SWITCHING FROM TRIVALENT OPV TO BIVALENT OPV

Currently, the risk associated with the type 2 component of tOPV outweigh the benefits

- Since 1999, indigenous transmission of type 2 wild poliovirus has not been detected
- **The type 2 component of tOPV:**
  - Causes more than 90% of vaccine-derived polio viruses (VDPVs)
  - Causes approx. 40% of vaccine-associated paralytic polio (VAPP) cases
  - Interferes with immune response to types 1 and types 3
- **IPV introduction** will help to boost immunity to all three types, prior to the switch

# OPV AND IPV HAVE THEIR OWN ADVANTAGES AND CHALLENGES

## Oral poliovirus vaccine (OPV)

- **Utilized to achieve eradication**
- **Generally safe**
- **Low Cost**
- **Easy delivery**
- **Reduction of efficacy**
- **In rare cases OPV has been associated with vaccine-associated polio (VAPP) and circulating vaccine-derived polioviruses (cVDPVs)**

## Inactivated poliovirus vaccine (IPV)

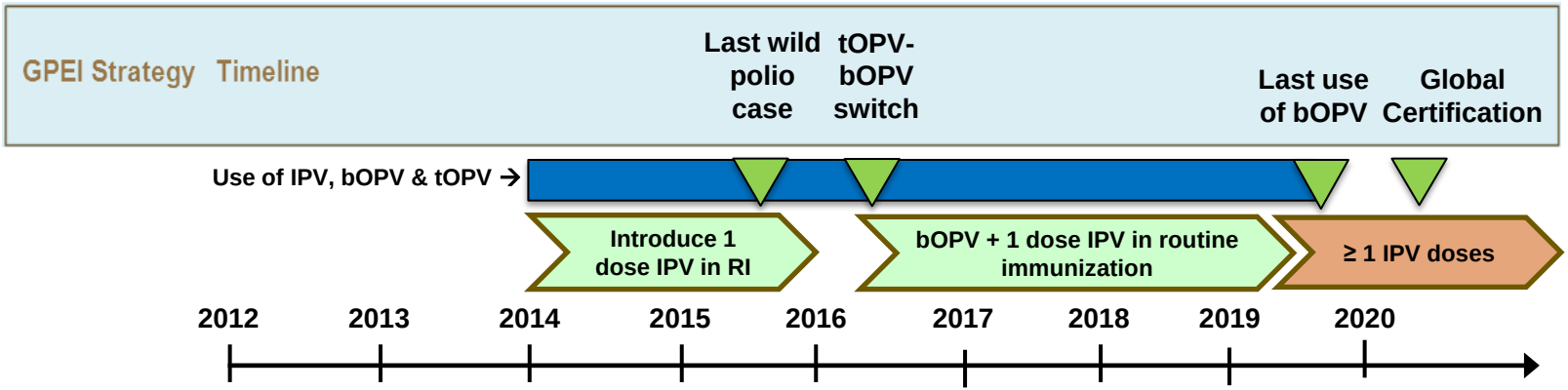
- **Safe (inactivated virus: non-infectious and genetic stable)**
- **Efficacious vaccine**
- **Has been sufficient to “maintain” eradication in regions with good sanitation and high vaccine coverage**
- **Intestinal immunity modest in comparison with OPV**
- **Protects individual but WT virus shed**
- **Less easy to deliver**
- **Expensive in comparison to OPV**

# VACCINE CHOICE IN THE ERADICATION ENDGAME

LATEST GPEI STRATEGIC PLAN OBJECTIVE

**"complete the eradication and containment of all *wild*, *vaccine-related*, and *Sabin polioviruses* such that no child ever again suffers paralytic poliomyelitis."**




**Current WHO IPV Recommendation**

- For IPV only -using countries: 3 doses of IPV
- For OPV-using countries: at least 1 dose of IPV at 14 weeks

# CURRENT IPV USE – ROUTINE IMMUNIZATION AND CAMPAIGN

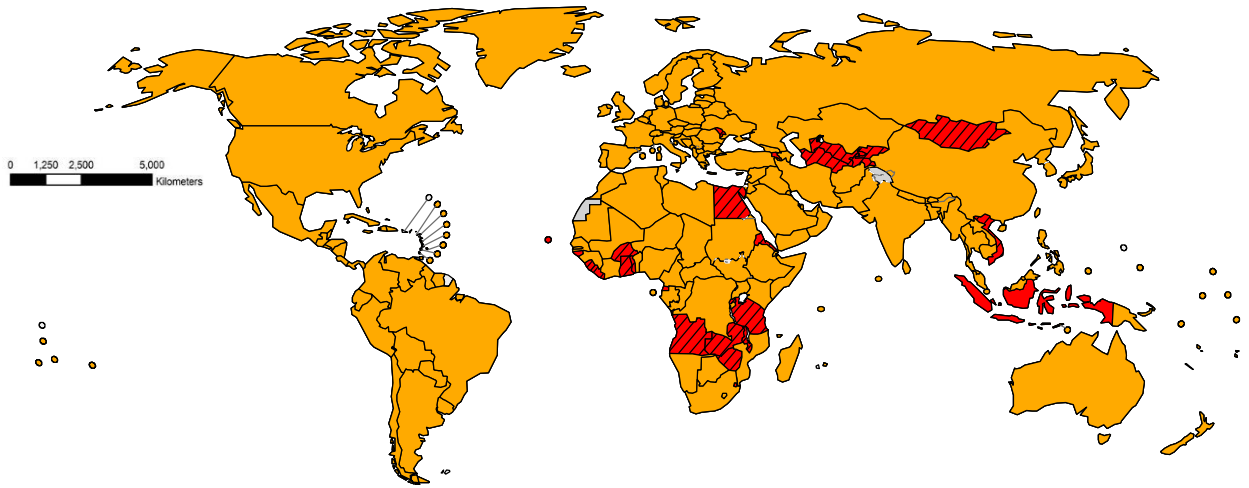
# POLIO ERADICATION STRATEGY

- Routine Immunization
- National Immunization Days (NIDs)
  - Vaccinating all children <5 years of age regardless of vaccination status
    - Also known as Mass Campaigns or Supplemental Immunization Activities (SIAs)
- Careful surveillance
- Mop-up campaigns


*Global Polio Eradication Initiative*

*From "Introduction to Poliomyelitis". Training of STOP Team 34, Atlanta, May 2010*

# COUNTRIES USING IPV VACCINE TO DATE AND FORMAL DECISION TO INTRODUCE




- Introduced to date* *(168 countries or 87%)*
- Formal commitment to introduce in 2016 *(6 countries or 3%)*
- Introduction delayed in 2017 *(20 countries or 10%)*
- Not available
- Not applicable

* *Including partial introduction in India*

- 100/126 countries have introduced since 2013
- 6 more countries plan to introduce in 2016
- 20 countries will introduce in 2017 due to IPV supply shortages

Data source: WHO/IVB Database, as of 03 May 2016
Map production Immunization Vaccines and Biologicals (IVB), World Health Organization

# bOPV AND IPV IN EPI (6-10-14 WEEK) SCHEDULE

- Good immunogenicity with ≥ 2 doses of **bOPV** for type 1 and type 3 polioviruses

- High rates of seroconversion to type 2 poliovirus have been seen
  - with **one** dose of **IPV** at 14 weeks
  - with **two** doses of **IPV** (seroconversion is near 100% depending on the age of administration)

- Evidence of a high rate of immune **priming** for type 2 antibody following one dose of IPV

# ROLE OF FRACTIONAL DOSE IPV

# FRACTIONAL DOSING OF IPV

- Due to IPV supply shortage, 40+ countries are not able to use IPV.
- WHO has recommended, and SAGE recently endorsed, that countries consider fractional dosing of IPV (fIPV) delivered intradermally (ID).
  - Recommendation is based on clinical data in comparison to 1 IM dose of IPV.
  - Routine immunization: **Two** doses fIPV delivered ID at six and 14 weeks, along with bOPV.
  - Campaign immunization: One dose fIPV delivered ID to be given along with mOPV or bOPV.
- Routine immunization:
  - fIPV is currently being implemented in all states in India.
  - Under consideration for introduction in additional countries including Sri Lanka and possibly Bangladesh.
- Campaign immunization:
  - fIPV campaign completed in Hyderabad, India area in July 2016 in response to VDPV2 detection in sewage (~300,000 children).
- Outstanding country uptake and operational questions remain

*Adapted from a slide by PATH*

# IPV SUPPLY – CURRENT AND PROJECTED

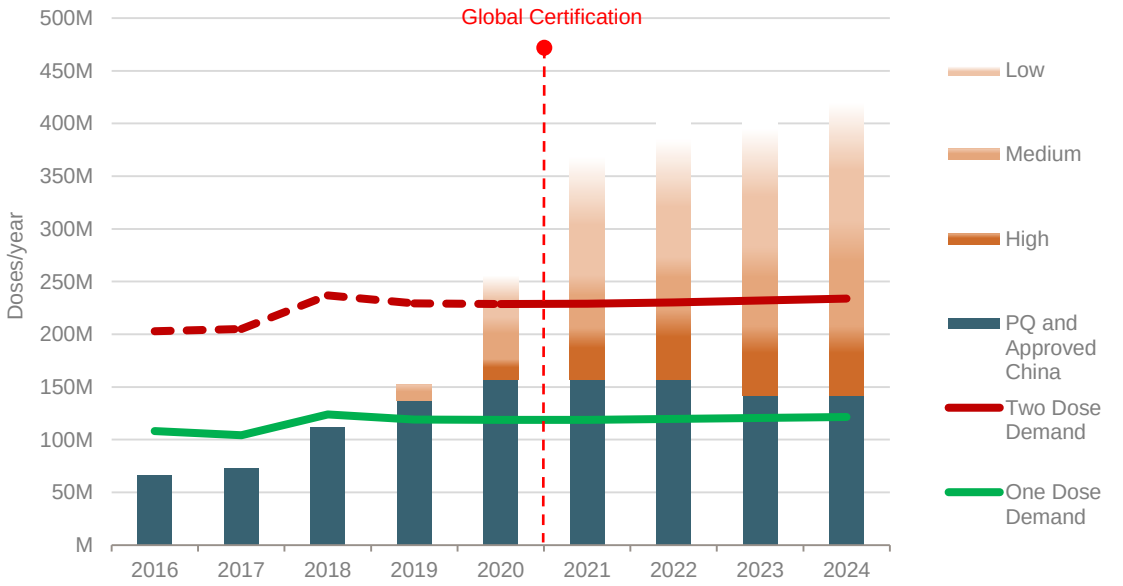
# IPV SUPPLY CONSTRAINTS: BACKGROUND

- Challenges due to problems with scale-up and manufacturing processes
- About **40% less IPV available than what was awarded through the initial UNICEF tender in 2014**
- **Severely reduced supply available: approximately 45 Tier 3 and Tier 4 countries negatively affected**
- The **IPV supply constraints are expected to remain dynamic until at least 2018** and will continue to be closely monitored by UNICEF and WHO

Adapted from GPEI

# ESTIMATED IPV DEMAND AND SUPPLY

Under realistic supply assumptions, some countries may be able to introduce a 2nd dose of IPV in 2020, but there is greater likelihood to meet total global demand for a 2-dose schedule from 2021.




***Notes:*** *Demand represents all 124 IPV introduced or introducing countries, including China and India; public market and RI only (not outbreak or catch-up demand). Factors in wastage by presentation. Demand does not account for fIPV usage, assumes a full dose vaccine*

***Source:*** *GVMM, IPV supply update, 2016, BMGF analysis, October 2016*

**Demand**

- Significant demand uncertainty still exists around future IPV dosage recommendations and duration of use post-certification
- A SAGE 2-dose recommendation would likely require at least 80M additional IPV doses to meet demand from 2020.
- Some countries included in the forecast may choose to use combination vaccines and move to a 3-dose schedule

**Supply**

- The 2020+ IPV market will likely be competitive
- Supply includes standalone IPV only (not combination vaccines or fractional intradermal).
- High, Medium, and Low refers to confidence in that supply capacity being NRA approved or PQed, available, and affordable for public markets.

# MANAGING THE CONSTRAINED IPV SUPPLY

*The Polio Oversight Board, which is made up of the heads of agencies of GPEI partners agreed to the following:*

1. Ensure adequate IPV supply to meet current and future needs of Afghanistan, Pakistan to ensure interruption of WPV transmission
2. Sustain use of IPV in routine immunization programme in highest risk (tier 1 and Tier 2) countries
3. Ensure sufficient quantities are available for outbreak response post-Switch.
4. Provide clarity to tier 3 and 4 countries regarding supply availability so they can plan, avoiding ad-hoc delays

Adapted from GPEI

# BMGF SUPPLY PRIORITIES

**1. Ensure Reliable Supply of OPV**

- A reliable supply of significant quantities of affordable OPV is essential to achieving polio eradication
- bOPV and mOPV have roles in SIAs including use as outbreak control and vaccine stockpiling

**2. Introduce and Maintain IPV in RI**

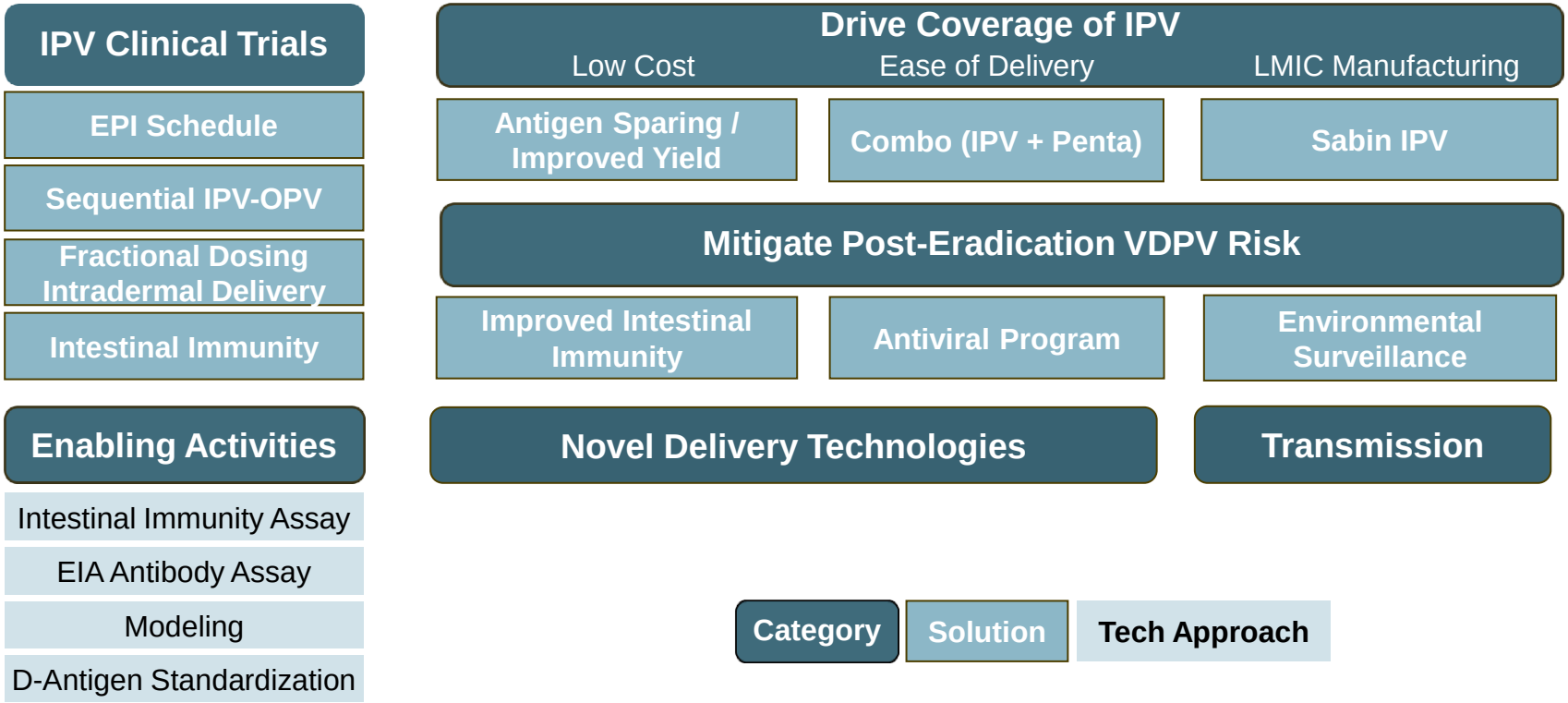
- A reliable supply of significant quantities of affordable IPV is also essential to polio eradication
- Standalone full-dose Salk IPV will enabled the tOPV to bOPV switch and will enable bOPV cessation
- Use of IPV in SIA campaigns and outbreak control demonstrates additional value of IPV to interrupt transmission

**3. Investigate Novel Products**

- Long-term needs may include larger commercial-scaled Salk or Sabin-based IPVs, potential dose-sparing IPVs, IPV-containing combinations, microarray patches and other novel presentations
- Potential for new adjuvants (e.g. DMLT) may have enhanced mucosal immunity impact
- More genetically stable OPVs to lower VAPP or VDPV risk

# THE FOUNDATION'S EFFORTS TO SUPPORT DEVELOPMENT OF BETTER VACCINES



# IPV POST OPV CESSATION

# SUMMARY AND LOOKING AHEAD

- Remarkable **progress** in 2016:
  - Lowest number of cases in lowest number of geographies
  - **Risks** remain primarily due to **inaccessibility** / civil unrest in both Afghanistan/Pakistan and Nigeria
- **Strategic Priorities:**
  - Surveillance
  - Vaccine Supply
  - Response Capacity (i.e. Outbreak response)
- Impact of future **vaccine policy**
- **Innovations** around vaccination schedules and **delivery** systems and their programmatic adaptation will be key in achieving and sustaining success in the coming years

# THANK YOU