ZIKV Vaccine
an Innovation
Project in Supply
Division
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UNICEF’s unique position to influence developers to innovate

**Identification of Bottlenecks**
- Program inputs (CO/RO/HQ)
- Feedback from partners
- End-user feedback

**Define and Communicate Potential Solutions**
- User research
- Target Product Profile (TPP)
- Expression of Interest, Request for Proposals

**Product Development & Testing**
- Field trials in UNICEF context
- Convening of partners/advisory committees for feedback

**Promote Market uptake and Scale up**
- Advance market commitment
- Subsidies/cost-sharing for new products
- Communication to Country Offices
Process for Product Innovation at Supply Division applied to ZIKV vaccine

Gate 0
Phase 0: Explore Desk research & light user analysis

Gate 1
Phase 1: Concept Heavy analysis of concepts & testing against users

Gate 2
Phase 2: Field trial Physical prototype development and field trial

Gate 3
Phase 3: Scale up Procurement and closely monitored implementation
Health Emergency Preparedness Initiative R&D Scope: Prioritization Framework

- UNICEF’s Need to Engage
  - Comparative Advantage
  - Synergies

- Uncertainties
  - Technology Maturity
  - Technical Feasibility

- Impact
  - Evidence
  - Scalability

- Demand
  - Caseload and disease trend
  - Demand predictability
  - Economic maturity of impacted countries
  - Severity of disease
  - Beachhead demand
How are we doing it?

• **Collaboration**
  - Partners such as WHO, PAHO, BARDA...
  - Industry and academia
  - Ensure alignment

• **Open and transparent communication with all**
  - Industry consultations and webinars
  - Demand forecasts
  - R+D pipelines
  - Tender calendars
  - Sharing of new information as soon as it is learned

• **Target Product Profiles**
  - Again – collaboration with partners and and communication of needs
  - Followed up with appropriate, and as needed pull mechanisms such as APCs
ZIKA: What is UNICEF doing?

**Control the spread** via vector control measures

**Mitigate the impact** on children and their families, in particular in the most disadvantaged communities through care and support

**Influence the market** to help drive the development of rapid diagnostics and vaccines

- Promote individual, family and community based vector control measures (including personal protection, breeding sites reduction, etc.) via mass, social and digital media communication campaign at national and local level
- Support capacity building on standard guidelines, case definitions and clinical care and case management with a strong family support focus
- Mobilize capacities for early childhood development (ECD), education, disability, psychosocial support and social protection to contribute to multidisciplinary support to families with newborns and children with complications
- Provide appropriate messages to dispel fears and stigma, promote inclusion, and ensure/enhance the reproductive rights of women and their partners
- Help drive rapid development and availability of Zika diagnostics and vaccines, including for emergency use
Zika in context of Health Emergency Preparedness Initiative (HEPI)

- Enabling preparedness for health emergencies
- A key component is R&D which is about defining those areas where there is a need for R&D to be undertaken for development of products (e.g. vaccines, diagnostics, medicines)
- Once a need has been identified for UNICEF to engage, we establish a PIP, create a TPP and pull mechanisms.
- Close collaboration with partners and stakeholders, - WHO, PAHO, BARDA and donors - for effective product development is essential.
- Ideal model is to have the regulator (WHO/PAHO), the funder of R&D (e.g. BARDA and BMGF) as well as the scaler (UNICEF and possibly others, such as PAHO).
Zika Vaccine Landscape

**Phase 0: Explore**
Desk research & light user analysis

- **Technology/Platform**
  - Recombinant or Subunit
    - NOVAVAX
    - HANNAH BIOTECH
    - INSTITUTO BUTantan
    - Institut Pasteur
    - Bharat Biotech
  - Live Attenuated
    - Dengue/Zika Chimera
    - sanofi pasteur
  - Whole Inactivated
    - Instituto Butantan
    - Invirx-BioChem
    - Inovio Biomedical
    - WRAIR
    - Instituto Butantan
    - National Institute of Allergy and Infectious Diseases
  - Nucleic Acid
    - mRNA + partner
    - DARUS Biologicals
    - INSTITUTO BUTantan
    - Valneva
    - DNA-VRC
    - Novocea
    - Institut Pasteur
  - Viral Vector
    - VSV with Harvard
    - GeoVax
    - PaxVax
    - TREMIS
    - Instituto Butantan
    - IMV
    - Institut Pasteur
    - VAAXART
  - Other
    - Gamaleya
    - Bharat Biotech
    - Takeda
    - Leidos

(slide from BARDA)
Reducing Lead-Times For Research, Development & Availability

Objectives:

- Right products available
- Reduce lead-time for development
- Identify bottlenecks
- Risk sharing
- Addressing the ‘gap’ between research and availability
ZIKV—In search of Appropriate Vaccines

Activities To Date

- Zika Diagnostics and Vaccine Industry Consultation May 2016
- TPP vaccine developed in collaboration with WHO, PAHO, PATH and industry
- Continued collaboration with WHO, PAHO, US FDA and BARDA on several areas (R+D landscape, regulatory approvals, demand forecasting, etc)
- Procurement Forecast shared with WHO + PAHO
- Development of financial mechanisms such as APC for accelerating R+D
- Continued follow-up on industry developments
Advance Purchase Commitment

- In discussions to secure committed funding (potentially > $10 million) to be used for procurement to guarantee funded off-take starting in 2017/18

- Exploring the role of an Advance Purchase Commitment (APC) to accelerate and de-risk suppliers’ entry into the market – elaboration of specific commercial terms for UNICEF and global community

- UNICEF, WHO and PAHO in conversations on how we can explore / potentially collaborate on this opportunity
Thank you!