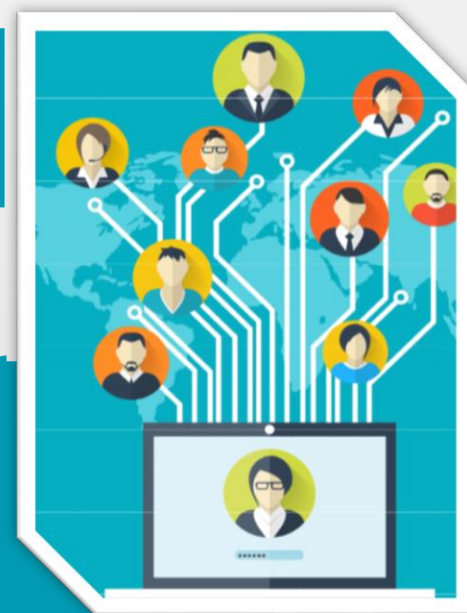




POLIO VACCINE STOCKPILE

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OUTLINE

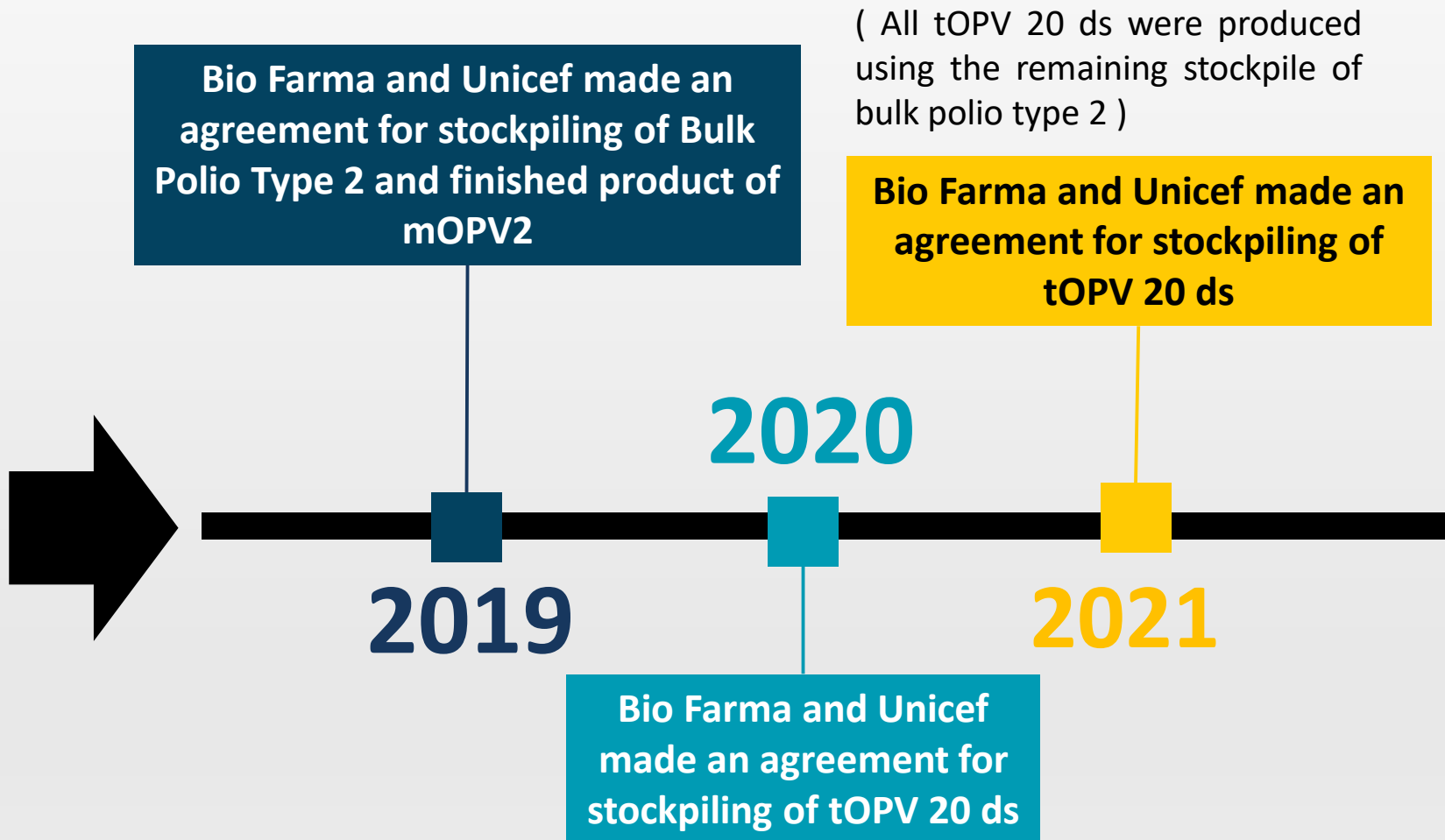
- **OPV TYPE 2 STOCKPILE ROADMAP AGREEMENT**
- **CONTRACTUAL ARRANGEMENTS FOR KEEPING THE STOCKPILE**
- **VACCINE SHIPMENT SCHEDULE**
- **STORAGE REQUIREMENTS OF THE STOCKPILE**
- **FIXED AND OPERATIONAL COSTS**
- **CHALLENGES**
- **STOCKPILE MANAGEMENT**



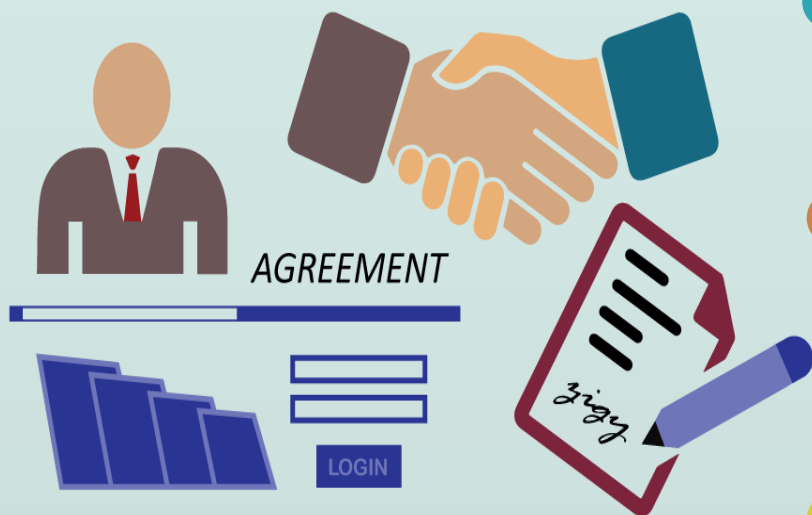
OPV Type 2 stockpile Roadmap Agreement



- **Government Support**
(Ministry of Health, NRA, NAC)
- **WHO support**



CONTRACTUAL ARRANGEMENTS FOR KEEPING THE STOCKPILE



Bio Farma keeps the product until its expiration date.

If there is any damaged product, Bio Farma has the obligation to replace all the product and report to UNICEF.

Any expired product has to be reported to UNICEF and the process of destruction is according to UNICEF's notification.



VACCINE SHIPMENT SCHEDULE



Monthly

Bio Farma informs UNICEF the product outputs monthly.



3 days

The lead time process is **3 days** from order receipt.



STORAGE REQUIREMENTS OF THE STOCKPILE

(BULK / FINISHED PRODUCT)



The storage for bulk and finished product have to comply with GAP 3 requirement.

The storage must have stringent biosecurity and biosafety system (which includes but not limited to):

- Procedure of emergency and contingency plan must be available,
- Spill Kits,
- CCTV and Access Control (as well as the record and backup system) along the path to the containment area,
- Security breach alarm system in the containment area.



FIXED AND OPERATIONAL COSTS

Direct and indirect Cost (Production)

- Labor
- Raw Material
- Overhead



COSTS

Other Operational Cost

- Insurance
- cost of storage
- Etc..

CHALLENGES

- 1 Bio Farma needs to establish a stringent Biorisk Management System (BMS) that covers all aspect related to handling of Type 2 Polio.
- 2 Bio Farma should follow Containment Certification Scheme (CCS) from Global Containment Certification (GCC)
- 3 Goverment should have an established National Authority for Containment (NAC) that is ready with the knowledge and procedures for certification of PEF
- 4 Bio Farma has to upgrade manufacturing and storage facility to meet GAP III requirements



- 5 Audit for QMS, BMS, and facility by NRA, WHO, also by NAC (National Authority for Containment)
- 6 Bio Farma has to prepare dedicated facility for the storage
- 7 Product Distribution and Transport procedure need to improve to comply with GAP III requirements
- 8 Bio Farma needs to establish Procedure for emergency handling in the event of a process failure (contingency plan)

STOCKPILE MANAGEMENT

Keeping an intensive communication with UNICEF to share any updates related to the stockpile.

i.e. production, stock, forecast, and monthly output



Through an effective communication, we can manage inventory and procurement process more efficient.





THANK YOU