Update on NEW VVMs in support of SARS-COV2 vaccine delivery

(including Ultra Cold Chain)

Ted Prusik
Agenda

- COVID-19 Target Product Profile
- Vaccine platforms with widely varying stability
- Current VVM types and new types for less stable formulations
- Temptime preparedness to supply VVMs on pandemic scale
- A call to manufacturers to provide stability information
Tremendous response from Private & Public sponsors…

COVID-19 vaccines development landscape
Situation as of 5 Oct 2020, total 248 candidate vaccines of which 49 in clinical trials

- Moderna
- AstraZeneca
- Gamaleya
- Jansen
- CanSino
- Sinovac
- Sinopharm
- Novavax
- Anhui Zhifei Longcom Biopharmaceuticals
### WHO COVID-19 Vaccine Target Product Profile (March 2020)


<table>
<thead>
<tr>
<th>#</th>
<th>Vaccine characteristic</th>
<th>Preferred</th>
<th>Critical or Minimal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Safety</td>
<td>Highly favourable benefit/risk profile with only mild, transient adverse events</td>
<td>Safety and reactogenicity whereby vaccine benefits outweigh risks</td>
</tr>
<tr>
<td>2</td>
<td>Efficacy</td>
<td>70%</td>
<td>50%</td>
</tr>
<tr>
<td>3</td>
<td>Duration of protection</td>
<td>1 year min.</td>
<td>6 months min.</td>
</tr>
<tr>
<td>4</td>
<td>Number of Doses</td>
<td>Single-dose</td>
<td>Two dose</td>
</tr>
<tr>
<td>5</td>
<td>Route of Administration</td>
<td>Oral / Nasal</td>
<td>Any route</td>
</tr>
<tr>
<td>6</td>
<td>Presentation (doses / vial)</td>
<td>Multi-dose for campaigns</td>
<td>Multi- or mono-dose acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multi-dose formulated, managed and discarded in compliance with WHO’s multi-dose vial policy</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Stability and Storage</td>
<td>Higher storage temperatures and high thermostability</td>
<td>Shelf life: at least 6-12 months. Storage: as low as -60 -70°C (Long term: -20°C or higher) at least 2-weeks stability at 2-8°C</td>
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| 7  | Stability and Storage           | Higher storage temperatures and high thermostability | Shelf life: at least 6-12 months  
                              |                                                 | Storage: as low as -60 -70°C  
                              |                                                 | (Long term: -20°C or higher)  
                              |                                                 | At least 2-weeks stability at 2-8°C  
                                                                                       |
|    |                                 | VVM, proof of feasibility and intent to apply to the primary container |                                                                                     |
COVID vaccines present extreme distribution challenges
Challenging cold chain to point of administration**

Distribution

On-site Storage

Ultra Cold Chain

Ultra Cold Chain

-20°C

5 days*

14 days*

90 days**


The J&J vaccine will be shipped frozen, but can be stored in liquid form at refrigerator temperatures for three months, whereas two of the front-runner candidates must be frozen or kept at ultracold temperatures until shortly before use.
Current six VVM types
7 months at refrigerated temperature to years at room temperature
Less stable novel platforms
Requiring Ultra cold chain, frozen distribution with short shelf life
New VVM types for short shelf life vaccines at 2 - 8°C
VVM PQS Specification revised to include VVM1 and VVM1/2

Stability information and programme need required to set the future VVM plan
New VVM types for short shelf life vaccines at 2 - 8°C
VVM PQS Specification revised to include VVM1 and VVM1/2

- VVM1 and VVM½ included in latest revision of WHO PQS specification
- VVM1 to be conditionally prequalified in December 2020

Stability information and programme need required to set the future VVM plan
New VVM types for short shelf life vaccines at 2 - 8°C

VVM PQS Specification revised to include VVM1 and VVM1/2

- **VVM1** and **VVM½** included in latest revision of WHO PQS specification
- **VVM1** to be conditionally prequalified in December 2020
- **VVM¼** formulation ready for qualification
  - possible conditional prequalification in 3 months

Stability information and programme need required to set the future VVM plan
For vaccines that require Ultra Cold Chain or limited stability in 2-8°C

VVM 1.0

HEATmarker® VVM 1.0

VVM 0.5 and

HEATmarker® VVM 0.5

VVM 0.25

HEATmarker® VVM 0.25

-80°C
Is VVM4 needed to fill the gap between VVM2 and VVM7?
There is still time to act but guidance is required.
Is VVM4 needed to fill the gap between VVM2 and VVM7?
There is still time to act but guidance is required.
Healthcare workers in LMICs rely on VVMs
Vaccine stability data is needed to define the supply chain
Call to research institutions, developer and manufacturers

- VVMs warn users not to use vaccines that have been damaged any stage of distribution from manufacture until the vaccine is used
- An appropriate VVM attached to the SARS-CoV-2 vaccine permits evaluation of the effect of time and temperature at all levels to ensure quality
- VVM will prevent wastage and facilitate outreach to remote populations
Temptime preparedness for VVM supply in pandemic
Capability, capacity and business continuity plan

**Business Continuity Plan**
- Contingent inventory of VVM dot types equal to 6 months of historical demand
- 3-year inventory of critical active chemistry
- Inventories stored at two different locations
- Two manufacturing machines and related equipment areas separated by firewalls
- Generator back-up and other risk mitigation measures in place

**Capability and Capacity**
- 5 billion doses in a 10 dose presentation requires 500 million VVMs
- Current demand is approximately 600 million VVMs each year
- Capacity is not a constraint BUT would require appropriate lead time for scheduling
DCVMN members are critical for pandemic response

Congratulations for all your efforts !!!

- Research and Development Efforts and Vaccine Technology Platforms
- Rapid scale up and large-scale manufacturing
- Fill-finish and distribution capabilities
- Many DCVMN members already comply with the Gavi/UNICEF requirements of adhering to GS1 barcoding traceability standards
- Maintaining supply of other essential vaccines
Thank You!

Questions?

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