Innovations in VVM Technology:

VVM 250
VVM+
2D Bar Code with embedded VVMs
Temptime product Innovations on top of VVM classic

1. **New categories - VVM250 stable vaccine Rotasil from SII**

2. **VVM+™**
   (a combined VVM classic with a peak threshold indicator to facilitate use of vaccines in Controlled Temperature Conditions CTC)

3. **Bar Codes with embedded VVM**
   miniature VVM active area integrated inside 2D Bar code: anti-counterfeiting/track & trace and serialization requirements
VVM Challenge  Highly Stable Rotavirus Vaccine
– 540 days at 37°C

Stability of heat stable, live attenuated Rotavirus vaccine (ROTAIII®)
Sameer P. Naik, Jagdish K. Zade*, Rajendra N. Sabale, Sambhaji S. Pisal, Ravi Menon, Subhash G. Bankar, Sunil Gairola, Rajeev M. Dhore
Sera Institute of India Pvt. LTD. 212/2, Magarpur, Pune 411024, India

The thermo-stability of ROTAIII®, ironically, has thrown up a new challenge in terms of vaccine vial monitors (VVM). The presently available VVM portfolio (Max VVM30: 30 days at 37 °C) does not begin to cover the extreme thermo stability of ROTAIII which is 18 months (540 days) at 37 °C. Efforts to develop a more appropriate VVM are on-going.

It has been already noted that there is remarkable reduction in mortality from diarrheal disease after vaccine introduction in
Controlled Temperature Chain

- CTC experiences: MenA (6); HPV (2); OCV (planned)
- OCC experiences: Indonesia (HepB) Chad (TT)
- Licensure progress – several vaccines
- WHO PQ – MenA, HPV, OCV
- The 4 main vaccine type opportunities:
  - TT/Td
  - HepB,
  - HPV,
  - OCV
- Considerable advocacy efforts
  - 3 WHO videos, 1 Ewan McGregor
  - 2017 – 2020 Strategic Roadmap
  - CTC Working Group
  - CTC Publications and Guidance
    French & English
  - Infographic
**WHY IS CTC USEFUL?**

**INCREASED COVERAGE**

Number of days that health workers can remain in the field to reach more remote communities.

**FEWER RESOURCES**

- **80**
  Number of ice packs needed daily to vaccinate 1,000 people.

- **22%**
  Percentage of health facilities in surveyed countries that have no refrigerators.

- **1.6 kg**
  Weight of vaccine carrier without ice packs.

- **5**
  Number of freezers needed to freeze 80 ice packs in 24 hours.

- **12%**
  Percentage of cold chain equipment in surveyed countries that is non-functional.

- **4.0 kg**
  Weight of carrier loaded with conditioned ice packs.

**EASIER OUTREACH**

- **98.7%**
  Percentage of vaccinators in Benin who agreed that CTC was useful or very useful in allowing them to vaccinate more persons.
Controlled Temperature Chain - Cost saving

An economic benefits study in Chad showed potential for campaign cost savings of up to 50% due to CTC.

Potential savings per dose U$0.03 – 0.103
Not all vaccines can be used in a CTC. To be used in a CTC, four conditions should be met:

1. **LAB**
   The vaccine must undergo and pass stability testing.

2. **NATIONAL REGULATORY AUTHORITY**
   Appropriate regulatory authorities must license the vaccine for CTC use with a label that specifies the conditions of use.

3. **WHO**
   The vaccine must be prequalified by the World Health Organization.

4. **COUNTRY**
   The government of the country where the vaccine will be used must give its consent in advance.

- **THERMOSTABLE**
- **LICENSED**
- **PRE-QUALIFIED**
- **APPROVED**
HEATmarker VVM+
Combined VVM and Peak Threshold Indicator in Same Device

- VVM+ reacts like a VVM up to 37°C
- At 40°C, VVM+ reaches the end point rapidly to show exposure to critical peak temperature
VVM+® - Combined VVM and Threshold Indicator Addresses High Temperature Excursions and CTC Requirements

- Combined VVM response and high temperature threshold in a single indicator
- No additional training required for field personnel
Launch of VVM+250 on Rotasil in Early 2019

VVM+250 Includes Both Innovations: Room Temperature Stable Vaccine and Peak Threshold

VVM+ addresses the risk that vaccines stored at room temperature may be subjected to high temperature excursions which can cause rapid vaccine degradation.
Next Generation Supply Chain with Digital VVM

2D Barcode with Embedded Temperature Sensor

- No additional space needed for vial-level use
Enhance the value of 2D barcodes (for stock management, patient safety and anti-counterfeiting) by incorporating temperature integrity:

- Specific area has cumulative (VVM) and/or threshold ink printed as part of barcode
- Rapid reading with phone or scanner
- Connect with cloud based data set of other sensors

Tests Passed

- Monitor Category: VVM7
- Remaining Life: 80%
- Expiration Date: 2019-12-31
- Product Authenticity: ✓ OK
- GTIN: 10123451234512
- Batch Number: 16R00150
- Serial Number: 1234

Tests Failed

- Monitor Category: VVM7
- Remaining Life: 0%
- Expiration Date: 2019-12-31
- Product Authenticity: ✓ OK
- GTIN: 10123451234512
- Batch Number: 16R00150
- Serial Number: 1234
GS1 2D Data Matrix with Vaccine Vial Monitor (VVM)

- **VVM** – gradual, irreversible color change from light to dark develops with cumulative time and temperature exposure.

Before heat exposure

After excessive heat

Time and temperature exposure
Demo of 2D Barcode with Temperature Sensor

Customized app decodes barcode information and checks sensor status

Heat Applied
Continuous End-to-End Temperature Monitoring with Dynamic 2D Barcode Indicator

Serialized barcodes on individual saleable units are a key enabling technology of global identification and tracking regulations.

The OneScan™ System
- Merges unit serialization and temperature monitoring in a single scan
- Improves stock management
- Enhances product integrity, patient safety, supply security and temperature compliance without inference

End-to-end unique identifier and unique temperature monitor
Digitization of Immunization Card linked to Mobile phones

Scan Uniquely Identified Immunization Card

Link each infant with the vaccines they receive

HMIS – Health Management Info System
2 D Bar code on primary packaging

Scan Uniquely Identified Immunization Card

Link each infant with the vaccines they receive

Scan Uniquely Identified Vial

Logistics Management Info System
Indonesian COVID-19 Pilot: Demonstrate RDT Tests are Accurate

Link the COVID-19 RDT Antibody Test to the Patient and COVID-19 Swab Test Results

COVID-19 RDT Antibody Test Kit with 2D barcode & temperature sensor  The Patient  Barcoded COVID-19 Test Swab Kit
2D Barcode with Temperature Sensor for COVID-19 RDT

Temperature Assured Traceability of Each Rapid Diagnostic Test (RDT)

High temperature exposure can compromise RDT test results
Serialized 2D barcode contains an embedded threshold temperature sensor
If sensor is triggered, do not use RDT
Serialization helps identify falsified and substandard RDTs
Scanned information becomes part of patient’s medical record
Over 200 COVID Vaccines developments

Most are exploratory

Some are in Phase I/II

Several new as well as established technologies

Temptime ready to work with all developers and manufacturers, when vaccines destined for developing countries

Over 70 developing countries “expect” VVM for all vaccines in their program

VVM is a critical characteristic but is not mandated

Policy set at Country level (e.g. India, Indonesia) as well as WHO
Thank you!!!