

# Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI)

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Comparator: VVM on primary containers used with stand-alone TI

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## Section 1: Summary of innovation

### 1.1 Example of innovation types:

Combined VVM-TI on vaccine primary containers



Image source: <sup>a</sup>

### 1.2. Description of innovation:

- A combined VVM and TI (VVM-TI) functions as a single indicator and can be directly attached to a vaccine primary container (e.g., vial, tube, ampoule – see section 1.1) and one version of the combined VVM-TI looks identical to existing VVMs. The purpose of a VVM-TI is to address high/peak temperature excursions of vaccine products – especially for vaccines used in a controlled temperature chain (CTC) – in addition to providing the standard functions of the VVM. Heat-stable and CTC-qualified vaccine formulations will be assessed in more detail in their respective technical notes. WHO recommends that a TI be used with vaccines that are kept in a CTC. At present stand-alone TIs are kept with vaccines in a CTC.

Stand alone TI



Image source: <sup>b</sup>

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<sup>a</sup>

[https://apps.who.int/iris/bitstream/handle/10665/192741/WHO\\_IVB\\_15.08\\_eng.pdf;jsessionid=A224999E6854225E8A5822E864FB67DF?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/192741/WHO_IVB_15.08_eng.pdf;jsessionid=A224999E6854225E8A5822E864FB67DF?sequence=1)

<sup>b</sup> [https://www.who.int/immunization/programmes\\_systems/supply\\_chain/ctc\\_vaccine\\_carrier\\_2.JPG](https://www.who.int/immunization/programmes_systems/supply_chain/ctc_vaccine_carrier_2.JPG)

Category: Labelling

Innovation: Combined VVM and TIs

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VVM labels contain heat sensitive material that changes colour irreversibly in response to cumulative heat exposure over time<sup>c</sup>. There is a direct relationship between the rate of VVM colour change and temperature, whereby lower temperatures result in slower colour change and higher temperatures result in faster colour change. (2,3)

- The colour of the central square on the VVM label indicates the cumulative level of heat exposure status of the vaccine. When the colour matches or is darker than the outer reference ring (refer to diagram below), this indicates that the vaccine has exceeded a pre-set limit beyond which it should not be used (5).
- There are five types of VVM labels, and the numbers correspond to the upper limit in days at 37°C for at least 95% of VVMs to reach the end point (6):
  - VVM 30 – high stability and used on the least heat sensitive vaccines
  - VVM 14 – Medium stability
  - VVM 11 – Intermediate stability
  - VVM 7 – Moderate stability
  - VVM 2 – Least stable, used on the most heat sensitive vaccines.
- Because the VVM reaction rates are not sufficiently rapid enough for exposures at higher temperatures, e.g., above 37°C or 40°C (1), standalone threshold temperature indicators (TIs) are used in addition to VVMs when vaccines are kept in a controlled temperature chain (CTC)<sup>d</sup>. These TIs must be purchased and distributed separately from the vaccine and kept at temperatures below their threshold. They are placed in vaccine carriers and cold boxes (without icepacks) during CTC storage and transport.
- The VVM-TI innovation integrates the TI with the VVM on individual vaccine vials. A VVM-TI reacts normally up to the specified peak threshold temperature (e.g., 37°C or 40°C) and rapidly reacts if exposed at or above the threshold temperature (4).
- There are two types of combined indicators, one where the VVM and TI are together on the same label or another where the TI is integrated into the VVM (5). The latter VVM-TI type has the advantages of minimizing space on the label and requiring no or minimal training because it is interpreted identically to the existing VVM.
- Combined VVM-TI labels could be used on all vaccine primary containers or just with vaccines that are qualified for use in a CTC. In the latter case, the combined indicator label would include a VVM30 since vaccines used in a CTC are highly heat stable.
- The WHO PQ specification and verification protocol has been developed and published for the combined VVM -TI label<sup>e</sup>.

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<sup>c</sup> What is VVM and how does it work, World Health Organization.

[https://www.who.int/immunization\\_standards/vaccine\\_quality/What%20is%20VVM%20and%20how%20does%20it%20work.pdf?ua=1](https://www.who.int/immunization_standards/vaccine_quality/What%20is%20VVM%20and%20how%20does%20it%20work.pdf?ua=1)

<sup>d</sup> Controlled temperature chain (CTC), World Health Organization. [https://www.who.int/immunization/programmes\\_systems/supply\\_chain/ctc/en/](https://www.who.int/immunization/programmes_systems/supply_chain/ctc/en/)

<sup>e</sup> [http://apps.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_catalogue/catdocumentation.aspx?id\\_cat=35](http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=35)

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### 1.3 Examples of innovations and developers:

Table 1.

Product name; Image	Developer (place); website	Brief description, notes
<p>Temptime combined and integrated VVM-TI</p> <p>Reading of integrated VVM-TI<sup>f</sup>:</p> <p>Reading of integrated VVM alone:</p>	<p><b>Temptime Corporation</b></p> <p>116 The American Road Morris Plains, NJ 07950 973.630.6000</p> <p><a href="http://temptimecorp.com/">http://temptimecorp.com/</a></p>	<p>The integrated VVM-TI is interpreted identically to the existing VVM: When the inner square of the VVM or VVM-TI matches or is darker than the surrounding reference ring, the vaccine has been exposed to too much heat and should not be used.</p> <p>When the vaccine is exposed to temperatures below the threshold, the VVM-TI undergoes a gradual colour change of the inner square from light to dark. When exposed to temperatures at or above the threshold, it rapidly changes to a colour that is darker than the reference ring.</p>

## SECTION 2: Summary of assessment for prioritisation

### 2.1 Key benefits:

- Ability to more accurately assess the heat exposure status of a vaccine than with the existing VVM and standalone TI because the combined VVM-TI is located on individual vaccine primary containers while the standalone TI is only distributed with vaccines used in a controlled temperature chain (CTC) and can become separated from the vaccines.
- An assessment of a prototype of the Temptime VVM-TI was conducted in Uganda and Nepal and found that the indicators were highly acceptable to health workers, logisticians, and immunization programme managers. Feedback obtained during the study indicated that the introduction of the VVM-TI would be acceptable by users due to the immediate colour change of the indicator due to the TI component and that this would have a positive impact on the vigilance of cold chain management practices and in ensuring the quality of vaccines administered to recipients (8).

<sup>f</sup> Photo provided by Temptime

Category: *Labelling*

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Comparator: *VVM on primary containers used with stand-alone TI*

## 2.2 Key challenges

- There are certain challenges related to the innovation, however they do not impact the assessment of innovation in phase I. Please refer to 2.3 (below) for challenges which will be assessed in the phase II, when they are applicable.

## 2.3 Additional important information

- As the application of the Temptime VVM-TI is identical to the application of the current VVM to primary vaccine containers, vaccine manufacturers would not require new labelling equipment to switch to the VVM-TI.
- The Temptime integrated VVM-TI is interpreted identically to the existing VVMs which have been used in countries for decades. This removes the burden of needing to train health workers and logisticians on interpretation and use of a separate TI in addition to using the regular VVMs.
- Individual vaccines can be assigned a combined VVM-TI that reflects the heat stability of that vaccine. The addition of the TI means that the indicator more accurately reflects the heat stability of the vaccine at higher temperatures – a useful feature should cold chain breaks occur or if the vaccine is exposed to temperatures at or above the peak threshold temperature.
- WHO has already developed prequalification specifications for the combined VVM-TI.
- At present, only prototypes are available and the innovation will require further development, testing and passing of regulatory and WHO prequalification approvals.
- Manufacturers providing vaccines with VVM-TIs would need to replace the existing VVM type used with the VVM-TI and adjust their quality assurance/quality control procedures to accommodate the additional TI function.
- PATH conducted an analysis comparing the projected costs for vaccines to be procured from 2017-2022 in four scenarios: using (i) VVMs on all vaccines, (ii) combined VVM-TI on all vaccines, (iii) combined VVM-TI on CTC vaccines and VVMs on other vaccines, and (iv) VVMs on all vaccines and use of separate TI for CTC vaccines. Given the assumed higher price of a combined VVM-TI indicator, the combined indicator is expected to cost considerably more when applied to all vaccines compared to VVM alone, whilst the incremental cost was smaller if the innovation was only applied to CTC qualified vaccines (personal communication, PATH).

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## SECTION 3: Evaluation criteria

### 3.1 Health impact criteria

Legend: **Green**: **Better** than the comparator: The innovation includes features that may increase heat stability; **White**: **Neutral**, no difference with the comparator; **Red**: **Worse** than the comparator: The innovation includes features that may decrease heat stability, **N/A**: the indicator measured is **not applicable** for the innovation; **Grey**: **no data** available to measure the indicator.

Table 2.

Ability of the vaccine presentation to withstand heat exposure	Parameters to measure against a comparator	Score	Assessment
	Does the innovation have features that may improve heat stability?	Neutral	The combined VVM-TI monitors heat exposure, but does not improve the heat stability of vaccines (6), which is no different to the comparator.

<b><u>No difference</u></b> to the comparator
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#### Indicator: Ability of the vaccine presentation to withstand freeze exposure

Legend: **Green**: **Better** than the comparator: The innovation includes features that may increase freeze resistance; **White**: **Neutral**, no difference with the comparator; **Red**: **Worse** than the comparator: The innovation includes features that may decrease freeze resistance, **N/A**: the indicator measured is **not applicable** for the innovation; **Grey**: **no data** available to measure the indicator.

Table 3.

Ability of the vaccine presentation to withstand freeze exposure	Parameters to measure against a comparator	Score	Assessment
	Does the innovation have features that may improve freeze resistance?	Neutral	The combined VVM-TI has no impact on the freeze sensitivity of vaccines, which is no different to the comparator.

<b><u>No difference</u></b> to the comparator
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## 3.2 Coverage and equity criteria

### Indicator: Ease of use<sup>9</sup>

Legend: **Dark Green:** **Considerably better** than the comparator: *Better for all* applicable parameters; **Green:** **Better** than the comparator: *Better for some* of the applicable parameters **AND no difference** for the rest of the parameters; **White:** **Neutral**, no difference with the comparator; **Yellow:** **Mixed:** *Better than the comparator for some* of the applicable parameters **AND worse than the comparator for the rest** of the parameters; **Red:** **Worse** than the comparator: *Worse for some* of the applicable parameters **AND no difference for the rest** of the parameters; **Dark Red:** **Considerably worse** than the comparator: *Worse for all* applicable parameters; **N/A:** the indicator measured is **not applicable** for the innovation; **Grey:** **no data** available to measure the indicator.

Table 4.

Ease of use	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Assessment of the potential for incorrect preparation based on usability data from field studies (or based on design of innovation if field studies not available)</li> <li>Assessment of the potential for incorrect administration based on usability data from field studies (or based on design of innovation if field studies not available)</li> </ul>	Does the innovation avoid reconstitution and is that an improvement?	Neutral	The use of the combined VVM-TI does not involve reconstitution of a vaccine, similar to the comparator.
	Does the innovation require fewer vaccine product components?	Better	The combined VVM-TI is a single indicator attached to vaccine primary packaging, whereas the comparator is composed of 2 separate components – a VVM and a standalone TI. A VVM-TI is interpreted the same as a standalone VVM without needing to interpret a TI.
	<sup>h</sup> Does the innovation require additional components or equipment (such as scanners or label readers)?	N/A	
	Does the innovation require fewer preparation steps and less complex preparation steps?	Better	The combined VVM-TI is reviewed in a single step, whereas a VVM and separate TI requires review of two indicators.
	Does the innovation improve dose control?	Neutral	Neither the combined VVM-TI nor the comparator are associated with dose control.
	Does the innovation improve targeting the right route of administration?	Neutral	Neither the combined VVM-TI nor the comparator are associated with route of administration.

<sup>9</sup> Ease of use can prevent missed opportunities resulting from the complexity of preparation and administration procedures. It could also impact the ability for lesser trained personnel to administer the vaccine (incl. self-administration). It can be assessed based on usability data from field studies (or based on design of innovation if field studies not available).

<sup>h</sup> This parameter is only assessed for RFID/barcodes, for all other innovations it is not applicable (N/A).

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**Better** than the comparator

### Indicator: Potential to reduce stock outs based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities

Legend: **Green**: **Better** than the comparator for one of the parameters; **White**: **Neutral**, no difference with the comparator; **Red**: **Worse** than the comparator for one of the parameters, **N/A**: the indicator measured is **not applicable** for the innovation; **Grey**: **no data** available to measure the indicator.

Table 5.

Potential to reduce stock outs based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Assessment of the potential to reduce stock outs based on the innovation's features</li> </ul>	Does the innovation require fewer components?	Better	The combined VVM-TI is a single indicator that is part of the vaccine primary container, whereas the comparator requires purchase, distribution and tracking of separate TIs. The separate TIs can be reused if they have not been exposed to excessive heat. Such reuse would require further inventory tracking. This has been captured under ease of use.
	Or does the innovation include labelling that facilitates product tracking and is it better than the comparator?	Neutral	The innovation has no features that would facilitate labelling or product tracking, similar to the comparator.

**Better** than the comparator

### Indicator: Acceptability of the vaccine presentation and schedule to patients/caregivers

Legend: **Dark Green**: **Considerably better** than the comparator: **Better for all** applicable parameters; **Green**: **Better** than the comparator: **Better for some** of the applicable parameters **AND no difference** for the rest of the parameters; **White**: **Neutral**, no difference with the comparator; **Yellow**: **Mixed**: **Better than the comparator for some** of the applicable parameters **AND worse than the comparator for the rest** of the parameters; **Red**: **Worse** than the comparator: **Worse for some** of the applicable parameters **AND no difference for the rest** of the parameters; **Dark Red**: **Considerably worse** than the comparator: **Worse for all** applicable parameters, **N/A**: the indicator measured is **not applicable** for the innovation; **Grey**: **no data** available to measure the indicator.

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Table 6.

Acceptability of the vaccine presentation to patients/ caregivers	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Does the innovation include features that may improve acceptability of vaccinees and caregivers</li> </ul>	Painful or not painful	Neutral	Both the combined VVM-TI and the comparator do not have attributes that impact pain.
	Perception of ease of administration (i.e. convenience for the vaccinees/caregivers)	Neutral	Vaccinees/caregivers do not interact with the innovation and it is expected to not impact their perception of ease of administration, which is similar with the comparator.
	Any other tangible benefit to improve/impact acceptability to vaccinees/caregivers		

**No difference** to the comparator

### 3.3 Safety criteria

#### Indicator: Likelihood of contamination

Legend: **Dark Green:** **Considerably better** than the comparator: *Better for all applicable parameters*; **Green:** **Better** than the comparator: *Better for some of the applicable parameters AND no difference for the rest of the parameters*; **White:** **Neutral**, no difference with the comparator; **Yellow:** **Mixed:** *Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters*; **Red:** **Worse** than the comparator: *Worse for some of the applicable parameters AND no difference for the rest of the parameters*; **Dark Red:** **Considerably worse** than the comparator: *Worse for all applicable parameters*, **N/A:** the indicator measured is **not applicable** for the innovation; **Grey:** **no data** available to measure the indicator.

Table 7.

Likelihood of contamination	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Risk assessment of potential for contamination based on design of innovation and on usability data from field studies</li> </ul>	Does the innovation reduce the risk of contamination while reconstituting the dry vaccine?	Neutral	Neither the combined VVM-TI nor the comparator have any attributes that can improve or have a direct impact on contamination.



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Likelihood of contamination	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Risk assessment of potential for contamination based on design of innovation and on usability data from field studies</li> </ul>	Does the innovation reduce the risk of contamination while filling the delivery device?	Neutral	Neither the combined VVM-TI nor the comparator have any attributes that can improve or have a direct impact on contamination.
	Does the innovation require fewer preparation steps and less complex preparation steps?	Neutral	
	Does the innovation reduce the potential risk of reuse of delivery technology?	Neutral	
	Does the innovation reduce the risk of use of nonsterile components?	Neutral	

**No difference** to the comparator

### Indicator: Likelihood of needle stick injury

Legend: **Dark Green: Considerably better** than the comparator: *Better for all applicable parameters*; **Green: Better** than the comparator: *Better for some of the applicable parameters AND no difference for the rest of the parameters*; **White: Neutral**, no difference with the comparator; **Yellow: Mixed**: *Better than the comparator for some of the applicable parameters AND worse than the comparator for the rest of the parameters*; **Red: Worse** than the comparator: *Worse for some of the applicable parameters AND no difference for the rest of the parameters*; **Dark Red: Considerably worse** than the comparator: *Worse for all applicable parameters*, **N/A**: the indicator measured is **not applicable** for the innovation; **Grey: no data** available to measure the indicator.

Table 8.

Likelihood of needle stick injury	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Risk assessment of the presence of sharps during the process of preparing and administering the vaccine</li> </ul>	Does the innovation contain fewer sharps?	Neutral	Neither the combined VVM-TI nor the comparator have any attributes that can improve or have a direct impact on needlestick injury.
	Does the innovation use sharps for preparing and/or administering the vaccine and is that better than the comparator?	Neutral	

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Likelihood of needle stick injury	Parameters to measure against a comparator	Score	Assessment
<ul style="list-style-type: none"> <li>Risk assessment of the presence of sharps during the process of preparing and administering the vaccine</li> </ul>	Does the innovation include an auto disable feature and is that better than the comparator?	Neutral	Neither the combined VVM-TI nor the comparator have any attributes that can improve or have a direct impact on needlestick injury.
	If the innovation uses sharps, does it include a sharps injury prevention feature and is that better than the comparator?	Neutral	
	Does the innovation reduce the risk of injury after vaccine administration?	Neutral	

**No difference** to the comparator

### 3.4 Economic costs criteria

#### Indicator: Total economic cost of storage and transportation of commodities per dose<sup>i</sup>

Legend: **Dark Green:** **Considerably better** than the comparator: *Reduces the volume per dose for applicable parameters;* **Green:** **Better** than the comparator: *Reduces the volume per dose for either of the applicable parameter, and there is no difference for the other;* **White:** **Neutral**, no difference with the comparator; **Yellow:** **Mixed:** *Reduces the volume for one of the parameter, and increases the volume for the other parameter compared to the comparator;* **Red:** **Worse** than the comparator: *Increases the volume per dose for either of the applicable parameters, and there is no difference for the other;* **Dark Red:** **Considerably worse** than the comparator: *Increases the volume per dose for both parameters;* **N/A:** the indicator measured is **not applicable** for the innovation; **Grey:** **no data** available to measure the indicator.

Table 9.

Total economic cost of storage and transportation of commodities per dose	Parameters to measure against a comparator	Score	Assessment
	Does the innovation reduce the volume per dose stored and transported in the cold chain?	Neutral	<p>No difference.</p> <p>The combined VVM-TI is a single indicator that is part of the vaccine primary container and does not change the volume of the vaccine. For the comparator, one separate TI is placed in each cold box or vaccine carrier. The additional volume from the separate TI indicator is negligible.</p>

<sup>i</sup> The assessment of the indicator is volume-related and builds upon PATH’s VTIA analysis. A directional estimation is made at this stage, and a better evaluation will be done in Phase II with more antigen-specific data.

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Total economic cost of storage and transportation of commodities per dose	Parameters to measure against a comparator	Score	Assessment
	Does the innovation reduce the volume per dose stored and transported out of the cold chain?	Neutral	The separate TI would be stored in a cool dark place and this adds a very small volume to the commodities that are stored out of the cold chain. However, this volume is very small since one TI is shared by several vials and can be reused.

**No difference** to the comparator

### Indicator: Total economic cost of the time spent by staff per dose

Legend: **Dark Green**: **Considerably better** than the comparator: *Reduces time for all applicable parameters*; **Green**: **Better** than the comparator: *Reduces time for either, and there is no difference for the other one*; **White**: **Neutral**, no difference with the comparator; **Yellow**: **Mixed**: *Reduces the time for one of the parameters, and increases the time for the other parameter*; **Red**: **Worse** than the comparator: *Increases the time for either of the applicable parameters; and there is no difference for the other one*; **Dark Red**: **Considerably worse** than the comparator: *Increases time for all applicable parameters*; **N/A**: the indicator measured is **not applicable** for the innovation; **Grey**: **no data** available to measure the indicator.

Table 10.

Total economic cost of the time spent by staff per dose	Parameters to measure against a comparator	Score	Assessment
	Does the innovation have attributes that can save time for the vaccinator in preparing and administering the vaccine?	Better	With a combined VVM-TI indicator, the vaccinator only has to review one indicator to determine if excessive heat exposure has occurred, whereas with a VVM and a separate TI the vaccinator has to review two indicators.
	<sup>j</sup> Does the innovation have attributes that save time for staff involved in stock management?	Neutral	The innovation does not have any attributes that save time for staff involved in stock management.

<sup>j</sup> This parameter only applies to barcodes and RFID to capture the benefits for stock management processes, not based on the number of components, but the specific features of the innovation.

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**Better** than the comparator

**Indicator: Total economic cost of one-time/upfront purchases or investments required to introduce the vaccine presentation and of recurrent costs associated with the vaccine presentation (not otherwise accounted for)**

Legend: **Neutral**: *NO* there are no one-time/upfront or recurrent costs and this is not different than the comparator; **Worse** than the comparator: *YES* there are one-time/upfront or recurrent costs.

Table 11.

Total economic cost of one-time/upfront purchases or investments required to introduce the vaccine presentation and of recurrent costs associated with the vaccine presentation (not otherwise accounted for)	Parameters to measure against a comparator	Score	Assessment
	Are there one-time upfront costs that will be incurred for use of this innovation or recurrent costs that will be incurred for use of this innovation?	Neutral	No. Similar to the comparator, there are no upfront or recurrent costs required with this innovation (other than training costs which would be required with any innovation).

**No difference** to the comparator

### 3.5 Secondary criteria on potential breadth of innovation use

**Indicator: Applicability of innovation to one or several types of vaccines**

Table 12.

Applicability of innovation to one or several types of vaccines	Assessment
<ul style="list-style-type: none"> <li>What vaccines/antigens does the innovation apply to, based on technical feasibility?</li> </ul>	The innovation could be applied to all vaccines, but is likely to be most useful for vaccines prequalified for use in a CTC. WHO CTC priorities on the VIPS priority antigen list include hepatitis B and HPV vaccines.

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### Indicator: Ability of the technology to facilitate vaccine combination

Table 13.

Ability of the technology to facilitate novel vaccine combination	Assessment
<ul style="list-style-type: none"> <li>Does the innovation facilitate novel combination vaccine products?</li> </ul>	The innovation has no impact on the ability to combine vaccine products.

## SECTION 4

### 4.1 Robustness of data:

Table 14.

Category	Assessment
<b>Type of study</b>	One field study was conducted in Uganda and Nepal assessing the acceptability of the combined VVM-TI and ability to interpret the indicator labels on mock vaccine vials following exposure to different temperatures (8).  Information provided by Temptime.
<b>Inconsistency of results</b>	
<b>Indirectness of comparison</b> <ul style="list-style-type: none"> <li>Indicate the setting in which the study was conducted (low, middle or high income setting);</li> <li>Comment if the data is on non-vaccine application of the innovation</li> </ul>	Data is vaccine specific and field data was used from Uganda and Nepal, therefore highly relevant to the assessment.

<b>Overall assessment:</b>	<i>Low to moderate</i>	Only one field study available on the usability, feasibility and applicability of the combined VVM-TI.  Data obtained from manufacturer, PATH and technical experts, as well as studies on VVM alone.
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### 4.2 List of technical experts, manufacturers and/or technology developers interviewed for inputs:

Table 15.

Expert/type	Organisation/contact details	Notes
Ted Prusik Senior Vice President  Jonathan Pearman Executive consultant	Temptime Corporation The American Rd Morris Plains, NJ 07950 Office: +1 973-630-6002 Mobile: +41 763996071 <a href="mailto:jonpearman@temptimecorp.com">jonpearman@temptimecorp.com</a> <a href="http://www.temptimecorp.com">www.temptimecorp.com</a>	Made contact via email to request data on the combined VVM-TI.  They provided some information on the innovation.

### 4.3 List of technical experts, manufacturers and/or technology developers that have reviewed and provided feedback/input to the technical notes (TN):

Table 16.

Reviewers	Organisation/contact details	Notes
Fatema Kazi	GAVI, the Vaccine Alliance <a href="mailto:fkazi-external-consultant@Gavi.org">fkazi-external-consultant@Gavi.org</a>	Developed and reviewed TN
PATH Medical Device and Health Technology Team Debra Kristensen Courtney Jarrahan Mercy Mvundura Collrane Frivold	PATH Debra Kristensen <a href="mailto:dkristensen@path.org">dkristensen@path.org</a>	Reviewed TN
Ted Prusik	<a href="mailto:TedP@temptimecorp.com">TedP@temptimecorp.com</a>	Sent for review by developer
Julian Hickling	Working in Tandem Ltd <a href="mailto:julian@workingintandem.co.uk">julian@workingintandem.co.uk</a>	Reviewed TN

Category: *Labelling*

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#### 4.4 References:

1. World Health Organization. Controlled temperature chain: Strategic roadmap for priority vaccines 2017-2020 [Internet]. Available from: [http://www.who.int/immunization/programmes\\_systems/supply\\_chain/ctc\\_strategic\\_roadmap\\_priority\\_vaccines.pdf?ua=1](http://www.who.int/immunization/programmes_systems/supply_chain/ctc_strategic_roadmap_priority_vaccines.pdf?ua=1)
2. Getting started with vaccine vial monitors. 2002;(March).
3. Watch F. Temperature monitors for vaccines and the cold chain Cold-chain monitor Vaccine vial monitor Stop ! Watch TM DT and TT shipping indicator DEPARTMENT OF VACCINES AND. 1999;
4. Pagliusi S, Dennehy M, Kim H. Vaccines, inspiring innovation in health. Vaccine [Internet]. 2018;36(48):7430–7. Available from: <http://www.sciencedirect.com/science/article/pii/S0264410X18306558>
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