

**Participants:**

Lingjiang Yang (LY) - Chair, Analia Acebal (AA), Berniece Warley (BW), Ganapathi Indukuri (GI), Huilin (Linda) Yu (HY), KR Krisnamurthy (KR), Rajinder Suri (RS), Ryan Myburgh (RM), Taufik Wilmansyah (TW), Vishnu Rayapeddi (VR), Yudha Bramanti (YB), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Sonia Villaseñor (SV).

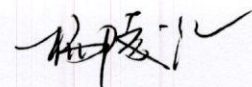
**Meeting** started at 12h05 and finished at 13h45.

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LY opened the meeting welcoming the consortium members as well as vaccine supply chain working group (WG) members attending as observers. SJ gave background to the meeting, indicating that this followed the priority of the WG on traceability going back to the assessments made in June 2019 and the Hanoi 2019 WG discussion where Bio Farma had first presented its traceability work in Indonesia. This is a requirement from UNICEF and GAVI in terms of the secondary packaging, but the project is looking also for primary packaging barcoding. Two calls for Expression of Interest had been issued by the DCVMN Secretariat for members to apply for DCVMN support for traceability pilots for barcoding of primary and/or secondary packaging. Three projects had been submitted and eventually approved by an independent assessment group from the donor community for support from DCVMN specifically for covering consultancy services. Four companies have signed the consortium agreement – Bharat Biotech, Biological E and Xiamen Innovax, in addition to Bio Farma. The consortium is an open information and experience exchange aimed at promoting best practices as well as sharing challenges in the tracking and tracing of vaccines. Companies join on a voluntary basis to share any information, with their discretion as to any proprietary data. It was indicated that additional members may be interested in developing traceability pilots and joining the consortium.

KR indicated that Bharat Biotech had initiated its traceability work on secondary and tertiary packaging some years back given the Indian national requirement of 2015 and WHO/UNICEF preferred product profiles with the same requirement. They have worked on 2D barcoding at the secondary level and 1D barcoding at the tertiary level with serialization which facilitates track and trace from factory to field and directly mitigates against counterfeiting. They have an internal working group on this project and a GS1-certified consulting service. Their barcoding system has undergone IQ and OQ; PQ should be completed by end-July and implemented thereafter, with a focus on vaccines they sell to UNICEF and later for all their vaccines. Challenges have included barcode creation, software development/upgrading and staff training. The COVID-19 pandemic has caused delays in implementing this work. They are currently assessing the feasibility of barcoding on primary packaging, which could be implemented later, with extended labeling being one option given the lack of space on the current label. While GS1 is an increasingly global standard, they also have to take account of different countries' regulatory requirements (e.g. Russian cryptocodes, US national drug codes). They are working on developing a downloadable app to read the information in different countries.

GI described the work of Biological E in traceability which started in 2012 with barcoding including serialization at the secondary and tertiary levels. This is fully implemented with no issues being faced to date, although the company has upgraded its data portal. Through an internal stakeholders' group which has already met, they are currently, on phase I, examining how to implement 2D/ 1D barcode packaging at the primary level but will not have serialization at this level. A main challenge is the label size, even more so for combination vaccines which have increased data and VVM requirements. Initially they will focus on larger vial sizes. They are looking at how to change the artwork to accommodate barcodes. Phase II will include reviewing the equipment and integration/aggregation software to include serialization on primary level packaging. The COVID-19 pandemic has also caused delays for them but they hope to move forward in July. It may be that barcoding of primary packaging for COVID-19 vaccines may take priority. Country requirements other than GS1 standards have to be taken into account as they are scoping both the US, European, Brazil, China and Russia markets. They indicated that they could provide examples of other country requirements so this aspect is taken into account in this work, although they insisted on the importance of GS1 becoming the global standard.



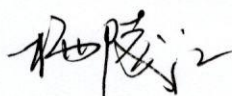


HY for Xiamen Inovax indicated the focus on their HPV bi-valent vaccine for the introduction of barcoding on secondary packaging with serialization. They initiated the work in May and expect to conclude in November although some delays may occur due to the COVID-19 pandemic especially in terms of the receipt of equipment if imported. They have organized an inter-departmental team and identified a GS1 consultancy service. They are familiarizing themselves with the GS1 standards and staff training is planned for the current month of June. One of the issues they are facing at the moment, although this is still early in the planning stages, is how to transfer traceability data to L4 platform and then to the receiving country according to their requirements.

YB provided an update on the on-going work of Bio Farma, now focused on the tracking and tracing of COVID-19 vaccines which they import in Bulk and fill/finish in their manufacturing plant. They are well developed in their traceability work which has not only followed the Gavi/UNICEF requirements but also the national requirement regulated in 2018 to mitigate against counterfeits. They selected the GS1 data matrix as their preferred option for barcoding allowing for nationwide scanning using mobile devices through applications they have developed. This way they can track and trace every product delivered in the country. They illustrated their method of aggregation from primary to secondary to tertiary packaging, at the moment (Phase 1) through manual cartoning which will be fully automated (Phase 2) by August after completion of PQ of the lines. One consequence of barcoding at the primary packaging level is a reduction of the speed of the line by up to 30% in order to scan and verify the barcode on each vial. This can have an impact on the vaccine production capacity. YB said that in order to ensure the proper transfer of data to the recipient country, the first thing is to ensure data follows properly the GS1 standard; then it is easier to integrate to external systems (for import or export of vaccines). If the recipient country follows GS1 configuration, they will be able to read the data without any issue. But in case they don't follow GS1, the manufacturer needs to transfer the data for them to upload it into their external system and be able to read it.

SJ summarized the meeting by saying that there was increasing interest in traceability (since January 2019, as expressed at the Shenzhen workshop), and varied experiences of DCVMN members. In each case, an inter-departmental team had been formed to address the various facets needed for barcoding, its aggregation across packaging levels and required software development. GS1 consulting services are crucial for establishing implementable plans. There are challenges to consider including label size due to the amount of data required to be on labels especially for smaller vials and for combination vaccines. Extended labels may be one option to consider but these would need to be tested closely for ease of scanning. Software development, aggregation/integration and proper staff training are all aspects that require close attention. Country-specific requirements not according to GS1 standards also need to be closely monitored and understood in order to see how they may impact of traceability systems. LY added that an important challenge to keep in mind is that all companies are having a delay in the implementation of barcoding in secondary package due to COVID-19 pandemic, but WHO/UNICEF deadline is by the end of this year. Trainings can be promoted within DCVMN and inviting more members to join. RS said that for COVID vaccines there will not likely be any issue, but for all the rest of vaccines it will be mandatory.

LY closed the meeting thanking consortium members for their inputs and agreeing to the next meeting of the consortium to be held mid-August.



Lingjiang Yang  
Chair  
14 June 2021

Notes by Steve Jarrett, Sonia Villaseñor and Sonia Pagliusi