

Participants:

Lingjiang Yang (LY) - Chair, Analia Acebal (AA), Ben Pierce (BP), Claudio Guzzo (CG), Ganapathi Raju (GR), Huilin Yu (HY), Juan Jose Dominguez (JJD) Kelvin Lee (KL), KR Krisnamurthy (KR), Lingjiang Yang (LY), PV Raju (PVR), Rajinder Suri (RS), Taufik Wilmansyah (TW), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Ulrike Kreysa (UK), Yudha Bramanti (YB), Sonia Villaseñor (SV).

Meeting started at 13h05 and finished at 14h32.

LY welcomed the 3 member companies invited to present their project on the vaccines' traceability. We aim to support our members to implement traceability on primary and secondary packages on their vaccines, if desired.

SP reminded that our goal in DCVMN is to remove the constraints of supply chain by supporting the members in implementing solutions. We believe that openly-available traceability systems, like GS1, may allow a level playing field so all manufacturers can benefit and implement reading systems that are compatible in countries and recognized by NRA's. It is voluntary, although UNICEF and Gavi do require this type of barcoding on secondary packaging for their specific tenders.

KR presented the project of Bharat. Following guidelines from the Indian Govt. and WHO recommendation to use GS1 barcodes, this project started one year ago, but it got delayed due to Covid. The project is planned for the PQ products starting by Polio 1/3 and then Rotavac and Typbar TCV. Secondary & tertiary packaging barcoding and serialization are priorities. Propix Technologies supports the project, with a cost of approx. USD 270,000. Thereafter, they may upgrade to the primary packaging level with a proposed start in April 2021. However, the constraint is the size of the label. IQ, OQ are completed and PQ is pending. They will discuss internally and revert if there is any specific support required. SP asked if they have a plan for field validation. KR said once PQ is completed some trial runs are planned and a pilot project on primary packaging would start with with polio vaccine. They will shortly send a detailed plan. LY asked if they will use the public system for reading the barcode information. KR said they will discuss and get back how to address this.

PVR presented the project from Bio E. They have implemented secondary and tertiary package GS1 barcoding since 2012, data being uploaded to the public domain. Now they plan to implement 2D codes on primary packaging. The challenge is the space available on the primary labels. The expected cost is around \$100,000. The Data matrix will include GS1 Barcode, GTN 14, expiry date, batch number and unique serial number. The vaccine pilot project will be with Td 20 dose, because of the bigger vial size. The project time frame will be April 2021 – Mar 2022. A Phase II would consider the use of multilayer labels for single dose vials.

HY presented the project for Innovax. The project was initiated because GS1 barcoding is required by UNICEF/GAVI with the exception of primary packaging. The pilot vaccine will be their HPV 16/18 bivalent vaccine. Currently they use the traceability AliHealth system, which however cannot be read internationally. They plan to start piloting GS1 barcoding by June 2021 with 3 stages, planning to contract a vendor for assistance in the implementation. The average cost is ca. 225,000 USD. They identified the needed support from DCVMN as sharing experience from other companies that have implemented GS1 barcoding system, communicating with the NRA to endorse the GS1 barcoding system and reviewing the design and protocol of the project. BP referred to HY's slide indicating that GS1 barcoding system was mandated to China by Gavi, so he asked if this would not apply for China, as a donor. LY clarified that China requires the vaccines to be traceable but did not define which coding standards should be followed, though AliHealth is followed in whole country. UK clarified that the Chinese Govt are now open to other traceability systems and other manufacturers in China have managed the switch from AliHealth to GS1. Some large hospitals and Sinopharm are ready for the switch. She added that Gavi and UNICEF have included this requirement for their public tenders. UK added that Innovax as supplier interested in UNICEF/ Gavi supply, is the motivation to implement GS1 standard, as a tender requirement, not as regulation.

SJ summarized 2 discussion aspects for discussion:

1. The main DCVMN objective is to establish a consortium of interested members (including Biofarma, Biovac and others) to look at the issues around barcoding across Tertiary, Secondary and Primary packaging; to exchange ideas, discuss technical issues, learn more about GS1 coding requirements, identify challenges and how to effectively verify the barcodes in the packaging line, etc. Specific consortium meetings would be scheduled to identify topics to discuss.
2. Specifically, there is ca. 2 months before members plan to start the pilot (April and June) and further discussions are needed with each of 3 proponents about specific project plans and the specific DCVMN support needed, either for general consultancy on designing the project plan, or about software development. More information will be collected and shared with reviewers as to a decision point on specific DCVMN support required.

To form the consortium: plan for meetings every 2 months (or more often if required). We have to reflect and plan for the meetings around specific issues e.g. software, hardware verification of barcoding. SP suggested to formalize the consortium through a brief MoU that lays out the goal of having the consortium as to openly share experiences on traceability, best practices and articulate on the needs and plans and how to accelerate the progress in traceability implementation (without disclosing business strategies and plans). The companies can engage, committing to this open communication over the next 10- 12 months. A Traceability consortium website will be created, to acknowledge participants. DCVMN will organize the meetings and organize consultations with experts.

LY reminded that DCVMN secretariat sent a second call for application with a deadline of 15th March 2021, to consider additional applicants for traceability pilots. At the beginning of the project companies may need support to help them to a quick start and to plan for implementation, step by step. DCVMN can also provide technical training or webinars to support advanced understanding of traceability.

SP suggested that other companies may join the consortium on a rolling basis. Although it may be difficult if they join in a stage in which conversations are well advanced. KL said the plan discussed makes good sense. He wishes we could move faster, but offered that it is also important to be thoughtful and inclusive to get maximum benefit.

Next steps.

1. Draft the MoU to share with consortium participants to formalize the consortium.
2. Manufacturers may benefit by having an expert consultant to help them articulate their needs and communicate within the consortium in the next presentations; this is something DCVMN can offer. This could happen in the next 2 months after signing the MoU. The consultants will work with the manufacturers over a period of a month before the meeting in April to try to align our communication and speed up the timelines. Steve will help identify expert consultants in the countries where manufacturers are based.

SP will send the new applications to the review group by email. The next meeting could be early April and be divided in 2 parts: One part only with the review group and then with consortium members (or vice-versa).

Nyon, February 10, 2021

Notes by SV, edited by SP and SJ

Approved: Lingjiang Yang, Chair
CNBG



Feb. 22, 2021