

Participants:

Lingjiang Yang (LY) - Chair, Analia Acebal (AA), Berniece Warley (BW), Brian Taliesin (BT), Catie Hou (CH), Claudio Guzzo (CG), Hong Hang (HH), Huilin (Linda) Yu (HY), Ira Shan (IS), Kamesh Chimalakonda (KC), Rajinder Suri (RS), Taufik Wilmansyah (TW), Kelvin Lee (KL), Narendar-Bharat (N), Rachel Park (RP), Ulrike Kreysa (UK), Vishnucharan Datta (VD), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Sonia Villaseñor (SV), Sophia-Sinovac; **Excused:** KR Krishnamurthy (KR).

Meeting started at 12h00 and finished at 13h15.

LY opened the meeting welcoming the consortium members, the supply chain group members and independent advisers attending.

KC introduced the work being carried out at BiologicalE. The traceability pilot is implementing GS1 barcoding on **primary packaging**, having selected their largest 15ml, 20-dose, COVID-19 vaccine to include the GTIN, batch number and expiry date on a label 62x26mm in size. Based on a question from BT, it was confirmed that serialization is not currently being implemented at this level. A coding machine has been installed and an auto-winder and printing machine have been ordered. Their consultants, URL, supported by DCVMN, are fully engaged in the pilot, artwork having already been developed. At this stage, the pilot is due for completion by end-February. Once this pilot is complete, BiologicalE will plan to replicate the work on other size vials and other vaccines.

TW briefly indicated that Bio Farma had fully implemented barcoding on **primary packaging** for the imported COVID-19 vaccines it packages, as presented in earlier consortium meetings. The next stage will be to replicate this process on other vaccines, specifically those procured by UNICEF and shipped internationally.

HY updated the meeting on progress with the Inovax barcoding of **secondary packaging** of its WHO-prequalified bivalent HPV vaccine, which includes serialization. Due to delays because of the pandemic, the pilot completion date has been shifted to 15 February. Equipment qualification is underway as is the drafting of SOPs. It is expected that validation exercises and a test run will take place this month. Their consultants, Acctruie, also supported by DCVMN, have already carried out two trainings as part of their services. Acctruie's support has been affected by COVID-19 travel restrictions which has caused the mentioned delay in implementation. HY indicated that maintaining close contact with the consultants and ensuring Inovax personnel were well trained enhanced the quality of pilot implementation. Once the pilot on secondary packaging is complete, Inovax will consider moving to the barcoding of primary packaging. UK stated she was pleased to see Inovax progress of the pilot going very well.

LY introduced the work of the Chengdu Institute of Biological Products (CNBG-Sinopharm) on the traceability pilot for its WHO-prequalified 2ml Japanese Encephalitis (JE) vaccine, packed in 10 vials to a box, which it sells to UNICEF. The pilot is implementing the barcoding of **secondary packaging** with the GS1 Datamatrix barcode and a linear 128 code on tertiary packaging, in accordance with UNICEF/Gavi requirements. The barcode will include GTIN, batch number, expiry date and serial number. One packaging line for sales to the international market is being upgraded with a target completion date of 31 March. The pilot is a multi-departmental effort led by the Production Department. A consulting company, Shanghai Minze Technology, has been selected to support the pilot, having already visited the site and developed a procedure flow for the upgrade. Guidance has been received from UNICEF although there are questions as to the expiry date designation. One equipment being imported is due to arrive mid- to late-February. The consultants will be on site at that time developing SOPs, working on the IQ, OQ and PQ, as well as conducting training. SJ indicated that he had just received from Shanghai Minze the training plan they had put together after consultation with GS1 China, which was a recommendation of the independent advisers to DCVMN. He will immediately review and revert with any clarifications. UK referred to the questions as to the expiry date

designation and asked LY to provide her the name of the UNICEF contact so she could follow up. On the imported equipment, SJ noted that China was introducing restrictions on imports having allegedly found the COVID virus variant omicron on some imported materials. LY indicated that the consultants would follow this import closely for any further delays. VD felt the timeline to be too tight and the pilot should include some contingencies, especially as equipment for example often has some teething problems. LY accepted this point but indicated that the first orders for its vaccine from UNICEF would not be until August so there was a sufficient time buffer.

AA updated the participants on the traceability project being undertaken by Sinergium Biotech. They are following the national regulatory agency (ANMAT) requirement in place since 2011 of implementing a traceability system for the domestic market which in the case of vaccines has recently been applied to new products being introduced into the country. The pilot is focused on the barcoding of **secondary packaging** of their quadrivalent flu vaccine, which is packaged in pre-filled syringes. The pilot uses Verifarma software which is standard in Argentina and linked to ANMAT. A printer has been installed and is functional. There have been some delays with installation, training and validation support from the vendor due to COVID-19 travel restrictions. Verifarma is currently scheduled to validate the software application by May. As the flu is in pre-filled syringes, the barcode will be applied to the immediate packaging containing the syringe. Due to the delays and the start of the flu season in the southern hemisphere, final implementation of the barcoding will only be on vaccine packaging for next year's flu season. UK noted a discrepancy in the written expiry date format on the test label, which again she would clarify after talking to UNICEF. BT also noted that the application identifiers on the 1D label were not according to standard. AA indicated that they would look into these points.

N confirmed that Bharat Biotech had fully implemented the barcoding of secondary packaging as required by the Government of India for exports and in order to meet the UNICEF/Gavi deadline of end-2021. He indicated that UNICEF was in agreement with the barcoding being applied. The company is now exploring with its consultants (Propix) an assessment of requirements for the barcoding of **primary packaging**. SJ acknowledged that he had just received from Propix an amended proposal for DCVMN support to the pilot and indicated that he would revert with any clarifications soonest.

SJ in summary highlighted that there had been progress in the pilots, with 3 pilots focused on the barcoding of primary packaging and 3 on the barcoding of secondary packaging. Clearly, there were still some delays due to the pandemic but all the pilots should be completed within the timeframe set, mid-year. It was likely that Innovax would be the first to complete its pilot of those receiving DCVMN support. Reporting from Innovax would be the start of amassing evidence on the pilots with a view to sharing widely the lessons and eventually leading to a peer-reviewed article. SJ also indicated that a space for the consortium had been added to the DCVMN website to heighten the visibility of the work being done (Cf. <https://www.dcvmn.org/-expert-working-groups>; and [Traceability Consortium Members list - DCVMN](#)). UK, BT and KL all highlighted the very good progress of the pilots. LY thanked them and looked forward to their continued support.

LY closed the meeting thanking consortium members for their inputs and noting the overall progress albeit with some delays due to the pandemic. It was agreed that the next meeting of the consortium will be scheduled for mid-March. Meanwhile a supply chain WG meeting shall be scheduled in February.

Notes by Steve Jarrett
18 January 2022



Lingjiang Yang

Chair of the Supply Chain Working Group