

Participants: Rachel Park (RP), Brian Taliesin (BT), Lingjiang Yang (LY), Taufik Wilmansyah (TW), Yudha Bramanti (YB), Sonia Pagliusi (SP), Yongsung Park (YP), Myeong Gyu Song (MGS), SUENG HYO Hong (SHH), Sonia Villasenor (SV), Prerna Kumar (PK), Rajinder Kumar Suri (RKS).

By Zoom: Linda Huilin (LH), Vishnu Rayapeddi (VR), Monica Soler (MS), GANAPATHI Indukuri (GI), Krishnamurthy Komarapuram (KK), Vishal Lobo (VL), Analia Acebal (AA), Risca Botha (RB), Youqing Ai (YA), Xingwen Zhang (XZ), Claudio Guzzo (CG), Craig Alan Repec (CAR).

### Day 1. Traceability projects

Rachel Park (EuBiologics) Chaired the meeting, welcomed participants and invited all to introduce themselves.

This Working Group (WG) meeting aimed to summarize and conclude activities conducted in the past three years, particularly on traceability, and to discuss any area to focus in the future. RP provided a brief update starting on the expressed intent to focus on supply chain raised at AGM 2017 in Seoul, when GS1 presented their tools (cf. <a href="https://pubmed.ncbi.nlm.nih.gov/29789241/">https://pubmed.ncbi.nlm.nih.gov/29789241/</a>) and the workshop on Supply Chain Best Practices and Traceability provided to members in January 2019 (cf. <a href="https://www.dcvmn.org/Advanced-Workshop-Vaccines-Supply-Chain-Best-Practices-Traceability-and">https://www.dcvmn.org/Advanced-Workshop-Vaccines-Supply-Chain-Best-Practices-Traceability-and</a>).

She provided a brief background to the Supply Chain Working Group roadmap and priorities, identified by a survey and focus on traceability, stockpiling and new packaging technologies as three priority areas, selected by members in 2019 (cf. <a href="https://pubmed.ncbi.nlm.nih.gov/32775997/">https://pubmed.ncbi.nlm.nih.gov/32775997/</a>). The traceability consortium started in 2020 after a workshop in Hanoi, where inspired by a traceability project being implemented in Indonesia (cf. <a href="https://pubmed.ncbi.nlm.nih.gov/33199075/">https://pubmed.ncbi.nlm.nih.gov/33199075/</a>). DCVMN members agreed to support projects by creating a platform for members, to sharing knowledge and learnings, on how to implement traceability on secondary and primary packaging. Six member companies engaged in pilot studies (cf. <a href="https://www.dcvmn.org/Traceability-Consortium-Members-list">https://www.dcvmn.org/Traceability-Consortium-Members-list</a>), four of them with some support of DCVMN donors, to sponsor technical assistance and training. The learnings were presented and discussed in this meeting.

Traceability is the ability to track vaccines through the supply chain from manufacturer to end users, with key information items included on the Global Trade Item Number (GTIN), such as lot number and expiry date, to improve ordering and inventory control, supply chain management, safety monitoring including adverse event following immunization, minimizing stock-outs, and preventing counterfeit. GS1¹ has a portfolio of standards based on symbols in one dimension, two dimensions or 3 dimensions (including RFID), from numbers to automatically captured data matrix, as well as additional information that can be captured and integrated, based on software. These standards can contain product specific information, but also location of product, invoicing stats, or other. In 2020, triggered by the announcement that traceability would be a requirement for UNICEF/Gavi procured and financed vaccines (cf. <a href="https://www.unicef.org/supply/stories/gavi-announcement-vaccine-manufacturer-gs1-compliance">https://www.unicef.org/supply/stories/gavi-announcement-vaccine-manufacturer-gs1-compliance</a>), EuBiologics voluntarily initiated and completed the implementation of GS1 traceability standards, before the launch of the consortium, hence did not join it. (see below)

In 2020, on 06<sup>th</sup> November, after consultation with the Donor Advisory Committee, a DCVMN call for expression of interest to all members, to set up traceability pilots, on primary and secondary

<sup>1</sup> https://www.gs1.org/





packaging was circulated. Upon positive response from manufacturers, an independent group met virtually on 10 February 2021 to review proposals and Memorandum of Understanding (MOUs) were shared with four favourably reviewed proposals (on 21st February 2021) to form a traceability consortium, established with those interested. The first Traceability Consortium meeting was held on 09th June 2021 (cf. <a href="https://www.dcvmn.org/Past-meetings-dates-672">https://www.dcvmn.org/Past-meetings-dates-672</a>). Six DCVMN member companies wished to implement traceability pilots, either self-funded (BioFarma & Sinergium), or partially funded by DCVMN donor (Bharat, Biological E, CNBG and Innovax). From those, 3 pilots focused on barcoding of primary packaging and other 3 on secondary packaging. Most traceability projects reported here were implemented over the period of June 2021 to June 2022. They shared their experiences in a series of working group meetings, in August and November 2021, and in January and March 2022 (cf. <a href="https://www.dcvmn.org/Past-meetings-dates-672">https://www.dcvmn.org/Past-meetings-dates-672</a>).

This meeting is aimed to be a wrap up of the implementation of GS1 traceability standards with DCVMN donor's support, and discuss the lessons learnt.

The Supply Chain WG also agreed to foster the integration of warehouse management systems (WMS), as a track-and-trace tool to the vaccine production process, from the entry of raw materials to the dispatch of finished product, with the goal of increasing efficiency, inventory management, and batch records, complementing the vaccine traceability from end-to-end: from raw materials to end-user. A call for proposals to support manufactures willing to establish or upgrade the WMS traceability of all supplies required to produce vaccines was circulated to members on 18<sup>th</sup> March 2022, and two favourably reviewed proposals, from four received, were prioritized to be discussed at this meeting (see below).

In 2021, 30-31<sup>st</sup> March, a DCVMN coordinated vaccine stockpiling workshop was held online<sup>2</sup>, to share experiences of manufacturers on holding static and rotating stockpiles. Member companies shared their experiences and challenges on stockpiling: EuBiologics on oral cholera vaccine, Bio-Manguinhos/Fiocruz in Brazil on yellow fever, Serum institute of India on Meningitis A conjugate, PT BioFarma on poliovirus vaccines, Bharat Biotech on buffer stockpiling. UNICEF was also invited to present their position on stockpiling. The meeting summary and recommendations were published in a peer reviewed open access article in 2021. (cf. https://pubmed.ncbi.nlm.nih.gov/34934942/)

In 2022, another DCVMN coordinated workshop on innovative packaging technologies to facilitate vaccine delivery to reach poorest populations in remote areas was held<sup>3</sup>. Implementation of liquid plastic containers' technology was reported by EuBiologics for oral cholera vaccine, and Serum Institute of India for rotavirus vaccine. BioFarma shared experiences with cPAD, compact plastic auto-disable devices. PATH was invited to share their new packaging development project, including cPAD and dual chamber devices, and discussed the final recommendation of Vaccine Innovation Prioritization Strategy (VIPS). These included microarray patches, heat-stable/controlled temperature chain qualified liquid formulations, and barcoding on primary packaging, reiterating the value of open dialogue between industry and policy agencies on projects implemented by manufacturers, to accelerate access to suitable vaccines to all people, as needed. Participants discussed how DCVMN could support the member companies on new packaging technology development, as a project to be further explored in 2023.

<sup>&</sup>lt;sup>2</sup> https://www.dcvmn.org/Supply-Chain-Stockpile-workshop

<sup>&</sup>lt;sup>3</sup> https://www.dcvmn.org/Workshop-on-new-packaging-technologies



### Rachel Park invited participants to present the respective traceability studies results.

EuBiologics shared that they implemented the GS1 traceability tools on secondary packaging of oral cholera vaccines, for export to UNICEF and other countries, as to the requirements. Their project started in 2020 and completed in 2021, using own funds and own expertise, in consultation with GS1 local representative. In the future, EuBiologics hopes to learn more from the consortium dialogue to perform primary packaging.

Innovax (Linda Huilin) provided information based on requirements of WHO prequalification (PQ) and UNICEF procurement, that triggered their decision to implement GS1 standards on secondary package of HPV vaccines, preparing for future serialization. Innovax build a team of professionals from several departments, applied for GS1 GTIN registration and assembled the list of documents required to implement product traceability standards. They contracted GS1 qualified provider to train the team, help in technical validation of equipment, code assignment server, hand scanner and drafting relevant Standard Operating Procedures (SOPs). With the support of a GS1 expert service, the staff was trained on how to apply barcode, and how to initiate change control and regulatory filling, both for National Regulatory Authorities (NRAs) and WHO. Main challenges included the lack of previous experience and the COVID-19 pandemic period in 2021, that delayed some project steps, i.e. progress of the qualification of equipment has been postponed twice, still online training could be provided. HPV vaccine with serialization 2D code is now ready for pilot run and export, depending on future tenders and orders. Total project cost was USD 200,000, with about 25% sponsored by DCVMN donor towards technical assistance by local a contractor for training and planning.

CNBG (Lingjiang Yang) reported on traceability of the WHO prequalified vaccine, live attenuated Japanese Encephalitis (JE), due to the mandatory requirements by UNICEF from January 2022 on. The team studied the UNICEF guideline in July 2021 and decided to pursue preferred characteristics by adding the serial number to the 2 ml/10 dose vial. They developed the implementation plan for the GS1 2D code matrix on secondary packaging, using the GS1-128 compatible China barcode, that aggregates information in each level of package, used since 2008. The multidisciplinary team was composed of professionals from seven departments, led by the manager of production department. The work started in September 2021, by vendor selection, followed by installation/qualification of equipment, process validation, and SOP generation and training. Upgrade of existing equipment by adding control panels, cameras and printers, as well as re-configuration of software, in consultation with GS1 experts, was needed to comply with requirements. Liaising with GS1 office in China and UNICEF for advice and confirmation was very helpful. Regulatory actions were implemented, and submitted to the local NRA and to WHO PQ services as post-approval changes (PACs), which has been accepted. Packaging of vaccines for 2022 orders has now started. Challenges included delays due to equipment delivery and the COVID-19 pandemic lockdowns. Understanding the coding logic and integration of information into the warehouse management system was another challenge. Furthermore, readability of the print-out was also a challenge, and vendor support was critical to finetune the printing equipment and validate it onsite, and field validation is coming next. Regular meetings with the DCVMN traceability consortium provided inspiration for the team to advance. The budget for the needed equipment was approximately USD 150,000 and software costs were around USD 50,000. The local contractor was sponsored by DCVMN donor, with USD 50,000 for planning and training activities.

BioFarma (Yudha Bramanti & Taufik Wilmansyah) is an Indonesian holding company, with 132 years of history. It now integrates vaccines, medicines, diagnostics manufacturing (upstream), with



distribution, clinics, pharmacies and other services (downstream). With 15 WHO prequalified vaccines, BioFarma collaborates internationally with OIC, PATH, BMGF, IVI, UNICEF and WHO<sup>4</sup>. Products are supplied 40% to domestic markets and 60% for export (mostly UNICEF). In 2016, an issue of counterfeit vaccines was identified locally, hence in 2017 planning for product track-andtrace was initiated, and piloted in 2018-19, implementing GS1 barcode and 2D code (data matrix) for serialization, with improvements in 2020 and implementation in the field in 2021. Some countries require GS1 data matrix (Egypt, Ecuador, Brazil, Argentina, South Africa, Saudi Arabia, Australia, EU, US). (see slide 10 of BioFarma presentation day 1) As most vaccines are in multi-dose vials, it was decided to introduce GS1 in primary packaging as well. The COVID-19 pandemic further stressed the need to strengthen traceability and prevent counterfeiting activity, using the "Internet of Things" tools, to ensure authenticity of health products. The goal of this project was the digitalization of product distribution, including temperature monitoring and GPS sensors. The conceptual design of the project was made in-house in consultation with local GS1 experts, however not with any external service provider involvement. The pilot project started in 2019, and serialization and aggregation were implemented since 2021, on primary, secondary, and tertiary packaging. Technical challenges included the integration of the new system into existing hardware and software, that has been implemented many years ago. Research to understand which system can be integrated with the old version and gap analysis was useful to make needed modifications. Positive outcomes of the project include the support to the government in fighting counterfeit, improved coordination of health services and increased vaccine confidence among the general public. With capacity for 100 million doses for COVID-19 vaccine, and up to 250 million in the future, aggregation process for automatic readability was based on helper code on the cap of vials, with the same data on the labels. Next steps are to implement the traceability to customers abroad by using the GS1 Electronic Product Code Information Services (EPCIS)<sup>5</sup> tool as a solution to share data with other countries broadly. BioFarma project was self-funded. (See slides).

Bharat Biotech (Krishnamurthy) shared the views of their team. The company has successfully completed 25 years of existence in 2022, with 3 billion doses of 25 vaccines, supplying over 125 countries worldwide. India requirements to meet authentication of vaccines led to mandatory implementation of GS1 barcoding on the secondary packaging years ago. Traceability will also protect reputation and prevent the use of expired products. The project team formed by professionals from 10 different departments (product, IT, packaging, QA, QC, regulatory, engineering, exports, dispatch department), has engaged with GS1 qualified technical assistance firm, for planning and training. Supported by the vendor, codes were generated and SOPs for IQ/OQ/PQ were prepared. New barcodes were approved by NRA, WHO and UNICEF. Strategies for secondary and tertiary level barcoding was to label multipack with 2D code containing the GTIN (batch number, serial number, manufacturing/expiry date). At tertiary packaging level, the code incorporated the shipper GTIN, expiry date, and batch number. The scope of work was on WHO PQed vaccines, starting with typhoid conjugate, polio and Rotavirus vaccines. After engaging with GS1 local organization and allocation of GTINs, the team developed the international software application, followed training and education on how to handle the packaging lines, before implementation. Vendor helped with SOPs preparation, and pilots are taken for each product with

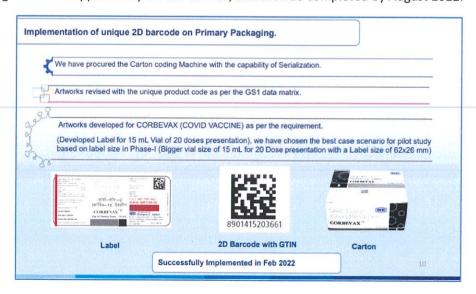
<sup>&</sup>lt;sup>4</sup> OIC=Organization of Islamic Cooperation; PATH; BMGF=Bill and Melinda Gates Foundation; IVI=International Vaccine Institute; UNICEF=United Nations International Children's and Education Fund; WHO=World Health Organization.

<sup>&</sup>lt;sup>5</sup> https://www.gs1.org/standards/epcis



presentation and packaging configuration. Challenges included printing bar code-2D matrix with human readable details on multi-carton, scanning barcode, reject multi-carton packs with barcode defects, the loose vials packaging with multi-cartons, one batch with different loose box in dispatch. The vendor helped in the resolution of the issues, by designing software and hardware layout, consultancy and guidance for artwork modification, documentation and preparation of SOPs. Carton artwork change was also required. The system is now in operation for commercial batches. The total budget was USD 270,000. Next phase is to implement barcoding on primary packaging for a pilot study, with DCVMN donor support, to be completed soon. Further integration of primary and secondary packaging is scheduled for implementation in January 2023.

Biological E (Ganapati Indukuri), incorporated in India since 1953, is the largest manufacturer of tetanus vaccines globally. GS1 tools and GTIN have been in use domestically since 2012, for secondary and tertiary packaging levels, and in 2021 DCVMN enabled the primary level serialization as an exercise for 2D code for all packaging levels, strengthening supply chain transparency across the various distribution channels. Redesign of label artwork, and training has been supported by a GS1 local contractor, sponsored by DCVMN donor. This was helpful to understanding the traceability systems and for accuracy of execution. The project team formed by professionals from six different departments, in consultation with service provider, implemented the pilot. The key activities encompassed printing technology selection, visual inspection system selection, preparing the User Requirements Specification (URS) and related documents, harmonization of product GTINs across the company, integration of serialization database, training for integrating new requirements, new labels design and printing. The challenges included the limited space of the primary package (vials) and curved surface, to fulfil requirements of various NRAs for export. Multilayer labels may be an option, but require additional regulatory approvals, while the 2D data matrix code can include product identification information, as well as expiration date and lot number. Biological E submitted the dossier for COVID-19 vaccine primary package to local NRAS and for WHO prequalification. (cf. figure below, slide BioE 10) The project costs were about 250 thousand dollars, and the primary packaging level was supported by DCVMN donor, and shall be completed by August 2022.



Sinergium Biotech (Analia Acebal), as all drug manufacturers in Argentina, must implement a traceability system that ensures their control and monitoring, from the production or import of the product until its delivery to the user, according to the regulatory authority resolution No. 435/11 of



ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia), since 2011, for secondary packaging only. Hence, the project was designed and planned to implement secondary packaging level. Sinergium invested in the software and equipment necessary to implement the traceability, from IQ/OQ/PQ6, to validation. Consultants and external suppliers included Verifarma®, a software provider qualified for GS1 standards, and LIXIS-Marchesini group, hardware solution for track-and-trace automation in packaging lines. The principal challenges encountered were the COVID-19 pandemic, leading to delays in equipment delivery, travel restrictions (technicians for installation and qualification). The project was rescheduled twice, and due to technical issues of printing with different formats for cartons and syringes' box. Operational training is being conducted now for full implementation and supply of first traceable batch of a vaccine planned for January 2023. The overall investment was around USD 300,000 (including technical support) and was fully covered by Synergium, while keeping a dialogue with DCVMN traceability consortium, to exchange knowledge and experiences.

### Discussion

Brian Taliesin summarized that the requirements for traceability of vaccines started at different times in different countries, for different reasons, and in general the concept of traceability contributes to enhancing trust in vaccines. Overall, vaccine manufacturers responded to the need for traceability due to counterfeit activities, regulatory requirements, support to healthcare services, strengthening safety and reputation of manufacturers. Six manufacturers agreed to move forward together, by sharing knowledge and experiences, to facilitate the understanding of traceability standards and enabling faster implementation, as possible. DCVMN supported them by convening regular group meetings, facilitating communication on technical, non-competitive topics, and supporting local technical assistance for planning and training for four of the six manufacturers that voluntarily chose to join the consortium. Since the first meeting in Hanoi in November 2019, despite the COVID-10 pandemic, lockdowns, and travel restrictions, the consortium moved forward in 2020 and 2021 on a virtual platform.

Rachel Park added that this consortium of six manufacturers fostered a "learning by doing" approach, and participating members have achieved the goals set by each company in the implementation of traceability standards on primary or secondary vaccine packaging, enabling advancements, despite limitations. The work shared by BioFarma in 2019 has served as inspiration to all other participants. All seven manufacturers went beyond the set goals of implementing barcode, and achieved the traceability of secondary packaging using 2D code (Innovax, Chengdu, Sinergium, BioFarma, Bharat, Biological E, EuBiologics) and one manufacturer (BioFarma) achieved implementation of traceability 2D code on primary package (vials), while two manufacturers (Bharat, Biological E) are completing the primary package labels with 2D codes, in the third quarter of 2022. One manufacturer is also implementing 2D code on primary package/syringes, for the private market in Argentina (Sinergium). It was felt, particularly for manufacturers located in in the south of Asia or South America, that the consortium provided a platform to learn what is happening in other countries and in other companies.

Lingjiang Zang concluded that the aim to learn from each other, sharing experiences and best practices has been achieved successfully. Taufik mentioned that implementing traceability requires internal and external coordination, and the support from many stakeholders: MoHs, NRAs,

<sup>&</sup>lt;sup>6</sup> IQ = Installation Qualification, OQ = Operational Qualification, PQ = Performance Qualification.

healthcare facilities, distributors, and field health workers, as they have to verify the product authenticity. The COVID-19 vaccine distribution using this system showed no such counterfeit product found or reported in Indonesia. However, this needs to be consistently monitored over time and for other products as well.

The next challenge is now increasing the awareness, communication, training and compliance of all these actors to ensure that vaccines are tracked and traceable, not only in the country of manufacturing, but also globally. Notably, the traceability of products across borders is a challenge that will need careful coordination, potentially through procurement agencies, such as PAHO Revolving Fund or UNICEF.

Brian Taliesin suggested to perhaps classify the challenges, as related to the parts of the packaging line (see figure below, slide 5 Sinergium)<sup>7</sup>. Lingjiang encouraged all manufacturers to continue traceability to the primary packaging level for all products, and to integrate it into the warehouse management system, to achieve end-to-end traceability: the traceability from raw materials to final product, then from final product to the end-user, and so to protect lives worldwide.

# Components required for the project, hardware and software 1 PVS-T equipment installation (GTIN number printing and reading on the case) 2 PVS-Mi equipment installation (Reading GTIN numbers associated carton box) 3 PVS-P equipment installation (Pallet label printing associated cartons boxes)

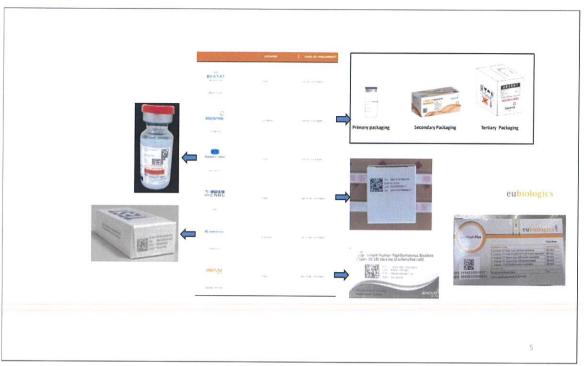
Examples of 2D codes developed and implemented over the period 2020-2022, shared by seven DCVMN members: six who joined the Traceability consortium<sup>8</sup> and one who implemented traceability before the launch of the consortium (EuBiologics). Four manufacturers implemented GS1 barcodes on secondary packaging to comply with UNICEF/Gavi requirements. Three manufacturers voluntarily implemented GS1 barcodes also on primary packaging (Biological E, BioFarma, Bharat),

<sup>&</sup>lt;sup>7</sup> https://www.dcvmn.org/IMG/pdf/6 drug traceability system project- sinergium biotech-june 2022.pdf

<sup>&</sup>lt;sup>8</sup> https://www.dcvmn.org/Traceability-Consortium-Members-list



on COVID-19 vaccines, going beyond requirements and preparing for future challenges in traceability.



Illustrations of 2D codes on primary and secondary vaccine packages implemented by the consortium members between June 2021 and June 2022.

# Day 2. Warehouse management systems

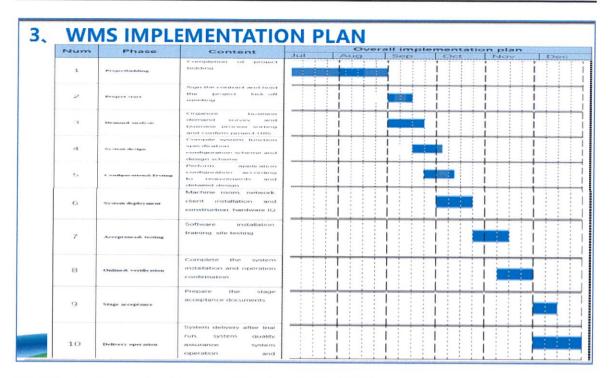
Lingjiang provided a brief overview of the WMS, as a software-based system that allows for visibility of the continuum from supplies to products. It is a data driven system, including inventory, and allows to interpret data as to process from start materials to final product release, and availability. It considers and integrates requirements and validity of data. Such WMS has been implemented at Chengdu Institute for Biological Products within around 12 months, including construction of new warehouse. (cf. slide 5 of Lingjiang presentation, day 2)

Innovax (Linda Huilin) summarized the company intend to implement a project for real-time control of inventory, aimed to minimize human errors, and increase product quality, through compliance with traceability markers. The first phase would focus on defining user requirements specifications (URS), the second phase focus on validation, third phase is installation of equipment and software, and fourth phase is the document drafting and review. A working team has been selected to drive the project; roles and responsibilities have been defined. While having gained experience with the GS1 system, the challenge now is the integration of various codes and the control system.

BioFarma (Taufik Wilmansyah) shared the implementation of Radio Frequency Identification (RFID) technology in warehouse inventory management to minimize errors (quantity/quality/expiry date of raw materials) and working time of employees, storage space utilization, increasing security and efficiency in business processes, from receipt of goods to quarantine and release. Despite high costs of equipment, the RFID investments depend on the size of the project, and tags enable attribution of products to final users, and are reusable. To integrate data, BioFarma is considering the use of EPCIS, and is willing to share insights into vaccine distribution management system, to fight against counterfeit products locally and globally.

Virogin Biotech (Benjiao Qiao) an affiliated company from CNBG, has shared their implementation plan for WMS. The project aims to achieve collaborative innovation for using viral vectors as a platform, and introduce a new generation of oncolytic viruses, mRNA vaccines, and vectored vaccines, also based on RFID schemes. The team has been configured in March 2022, and planning phases include 10 steps next (Cf. figure below) with selection of contractor, develop and confirm URS, software configuration, design of system integration, system installation and qualification of hardware and software (license for software installation), training of operators up to 31<sup>st</sup> October 2022, followed by system operation, documentation drafting and review, validation and delivery to the field before December 2022. NRA audit and approval is expected in August 2022.





### Discussion on Expected outcomes and timelines for the WMS

Four manufactures applied by end April for warehouse management systems support, and from proposals favourably reviewed by three independent experts, two were prioritized. DCVMN secretariat communicated that due to donor no-cost extension timelines, the WMS projects commitments would have to be wrapped up by 31st October 2022, at least to the agreed phases to be performed with DCVMN support. Reviewers were not aware of funding time limitation to end October 2022, which was notified to DCVMN secretariat on 16th June. Still, the support could be considered for the project phases that can be conducted until end October. Linda, from Innovax, mentioned that the warehouse project should be integrated into WMS system, however it was decided by Innovax management to temporarily stop WMS work this year, thus not compatible with timelines for this grant support for 2022. Nevertheless, a third proposal was favourably reviewed, and already agreed by reviewers: in the event of drop-out DCVMN secretariat would contact the third proponent, for support in case they can complete the project by the end of Oct 2022. Rajinder Suri asked present speakers if their companies would be willing to take up this challenge and comply with timelines by October 31st. Biological E and Bharat representatives confirmed their interest and availability, as to reviewers' recommendations. Virogin colleagues mentioned that they would be able to complete the steps 1 to 6 of the project plan, including the software installation, testing and training by end October 2022, with DCVMN support, while completing the installation/validation and documentation would be finalized by November /December 2022, without DCVMN support. Secretariat to follow up on process and MOUs. Brian Taliesin thanked the Virogin team for their reactivity and willingness to compress some project phases to advance faster than planned.

So far 6 companies kept meeting and reporting on a regular basis during 2021-22, discussing with each other irrespective of funding: BioFarma, Sinergium, Innovax, CNBG, Bharat, Biological E, sharing their knowledge and experiences. DCVMN International secretariat highlighted that all DCVMN members are welcomed to join the upcoming supply chain WG meetings (every six weeks) and discuss their traceability projects (with/without funding). Biovac (Risca Botha) commented to have



also experienced some challenges in integrating the scanning of packaging codes between systems, and offered to share their experience at the next Supply Chain WG meeting. Rajinder Suri invited suggestions/inputs/innovative thoughts ideas from all towards a 5-year plan.

GS1 (Craig Alan Repec) provided a brief overview of the EPCIS open tool, used for supply chain visibility to identify, capture, and share product information globally. EPCIS stands for Electronic Product Code Information System, and is designed to serve as "share point" for information on commissioning, packaging, unpacking, dispensing and movement of products. It interfaces with other tools in the supply chain for transaction information, such as ordering, invoicing, payment. It has also been published as ISO/IEC 19987 standard. Business process steps are captured as "events", which indicate what objects are the subject of an event; when did this event take place; where did the event occur, and follow ups; why did the event take place; how (warm, humid, fast, radioactive, etc.) are the objects. EPCIS 2.0 (cf. <a href="https://ref.gs1.org/standards/epcis/">https://ref.gs1.org/standards/epcis/</a>) provides a major update for deployments gaining momentum in 2022-2023, with pandemic supply chain security, inventory management of vaccines & PPE, as well as for pharmaceutical chain-of-custody. It was suggested by DCVMN secretariat to organize a GS1 webinar for all members to learn more about EPCIS in the near future. GS1 confirms its commitment to further share explanations on EPCIS.

Secretariat suggested to draft a report of this meeting, and further format it as a publication, using some of the slides as illustration, to facilitate and enhance access to the information to all those unable to join this meeting. It will be prepared and circulated in the next few weeks.

Rachel Park appreciated the willingness of DCVMN members to share their experiences, challenges and lessons learnt in the area of supply chain traceability. She reminded all of the first DCVMN workshop on supply chain best-practices and traceability, organized in Shenzhen, China, for learning about GS1 standards<sup>9</sup>. UNICEF requirements announced in September 2019 further strengthened the importance of this topic and triggered manufacturers to introduce traceability in secondary packaging. Manufacturers went beyond the requirements, by using 2D codes for data matrix and started implementing traceability in primary packaging as well. It was a joint learning process for all, and the collaborative spirit among different teams is highly appreciated.

Next meeting possibly by early August (tbc). The meeting was adjourned.

PS. Meeting slide presentations are available at <a href="https://www.dcvmn.org/Traceability-Consortium-Supply-Chain-WG-meeting">https://www.dcvmn.org/Traceability-Consortium-Supply-Chain-WG-meeting</a>

Report drafted by S.Pagliusi, based on notes by R.Park, B. Taliesin & own.

Reviewed & acknowledged by

1st n

Seoul South Korea, (144 July 2022

Ms. Rachel Park

Location, date

 $<sup>^9\,\</sup>underline{\text{https://www.dcvmn.org/Advanced-Workshop-Vaccines-Supply-Chain-Best-Practices-Traceability-and}}\\$