Participants: Steve Jarrett (SJ), Brian Tailesin (BT), S.Villasenor (SV) and Sonia Pagliusi (SP).

Excused: Geraldine Bonnet (GB) and Kelvin Lee (KL). Started at 4 pm CET; adjourned at 4:45 pm CET.

SJ welcomed all. BT asked about the expectations on the warehouse mngt project call for proposals: as to whether it is pursuing traceability through the warehouse management, rather than warehouse management in general. SJ clarified that this is indeed the case, as so far the traceability projects focused from final product from the factory onwards to the point of delivery; now the innovative concept is to ensure traceability from raw materials through the final product, within the "production area". Currently this is done through several modular systems of inventories of raw materials, of intermediary products, supplies and equipment. The working hypothesis is to integrate both systems to have a rapid and transparent data management, reducing human resources, human errors, in a systems' integration process, and ultimately perhaps reducing cost of production. There are two main questions: 1) should the internal manufacturer supply chain, be a concern of DCVMN, to get involved and support this part? 2) are the 4 applications proposing real substantial improvements to contribute to lower cost of production? BT asked if the traceability of internal supply chain management is associated to quality of supply, towards serialization and batch management, e.g. to facilitate internal recalls? SJ agreed that it may help with regulatory assessment of production processes. At that level of rigor associated with warehouse/internal supply chain management, for track-and-trace components of vaccines, it was agreed that this is an added value.

BT added that two proposals for automatic storage retrieval system, based on SAP, appear to fall outside the scope on quality, as not aligned with track-trace on quality management. It is also appreciated that transitioning from manual systems to automatic ones is needed, but one proposal is missing the validation, because "green-yellow-red" stickers may be a better alert to errors than black-white barcodes. On another proposal, is appreciated the realtime scanning, perhaps using bins tracing? It seems they seek support to start this area of work, to learn what is needed in a warehouse management system with RFIDs. One issue is that RFIDs are quite expensive, unless they use returned blaster identifiers, that works well for internal supply management, as lean manufacturing approaches. It may require different equipment.

BT mentioned that helping them understanding the requirements to advance seems a good approach and goal, to mature in manufacturing. Sharing their learnings through DCVMN meetings with others could also create greater good for the community. SJ asked if local consultants would be able to support these projects or should it be global consultants? BT said that vaccines have special/specific components related to supply chain, and ideally service providers with previous knowledge would be helpful. Overall conclusion, is that it is an area of interest, and potential cost savings justify the support of DCVMN, to put them in "par" with other vaccine manufacturers, as requirements are increasing. Fostering current manufacturing capabilities as additional vaccines are needed, in his view, to creating greater quality. BT proposed to rank applications and SJ suggested DCVMN should start with supporting two best applications. BT agreed to starting with 2 as a good approach and asked about funding. SP commented that currently, DCVMN has potential awarded funding from PATH, of 300K USD, which (minus 15% indirect costs) comes to 255K for the actual projects, though this budget is for any DCVMN activities, such as training, etc. to be discussed at the donors advisory committee on 15th June. Another point to consider is that the same companies that submitted the proposals are the companies that participated at the traceability pilots: on one hand it shows continuation of projects to a higher level. It is noted that one of the companies did not advance yet with the traceability project, while two companies already submitted the final reports. One company did not submit the final report yet, but could come in anytime. Finally, having 4 applications may call for a selective process to invest on the best two, supporting clear plans in scope, rather than try to support any application, signalling the need to improve the quality of applications in the future. BT supported the concept that manufacturers should complete the initially funded projects, before receiving additional funding. The rationale and recommendation should come from the reviewers to the donors' advisory committee (DAC). BT agreed to recommend two projects for support, that meet the considerations, while keeping one alternative project in case of "drop out". SJ also shared the inputs

from GS1, where the ranking of the applications was proposed; reviewers agreed that the "fourth" proposal was unclear and out of scope (see below).

Proposal 1:
+ Clear on the phases of the project
+ Good analysis of the potential risks
+ Complete and consistent

Proposal 2:
- The current process as described is open to many errors and lack of efficiency. Automation would be highly beneficial both for efficiency and safety.
+ It is the only project mentioning the need for training in order to use the IWMS at it best.
+ SAP is a well-recognised and experience solution provider in this area

Proposal 3:
+ Very clear on the deadlines and costs
+ The risk assessment is detailed and fair
+ The division of the process in 5 modules makes it easier to implement
+ The integration with other existing systems/processes is well taken into account
- RFID are exceptionally used in Healthcare. Regulations are requiring the use of a DataMatrix as the data carrier on vaccines. The use of RFID will increase cost, not only to apply the tag on vaccines but also to read the tag.
- The benefit in regards to reduction of management cost is only true if first the relevant staff is properly trained on how to manage the process and integration with other process effectively
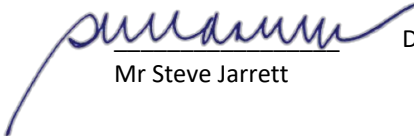
Proposal 4:
- Difficult to assess as the explanations are very high level and the flow chart is challenging to read.
- Nothing related to existing system and the interoperability
- Nothing on process efficiency and product safety

BT appreciated and agreed on the key comments listed, and added that quality management was clearly articulated on the first proposal, adding a strong point to it, aligned to the goal of improving vaccines' quality. He added that switch over from manual to automatic systems, on proposal 2, may risk to generate more errors. There was agreement to ask for clarification on RFDI usage. SJ to clarify on that. It was agreed that applicants ranking would be shared at DAC anonymously. The below list ranking reflects comments of one reviewer, and the other reviewer has suggested to swap rank proposal 2 and 3, as proposal 3 has more positive points, provided the RFID is clarified. It was agreed to put forward proposal 1 first and proposal 3. SJ commented that as proposal 2 uses SAP, they may already receive support from SAP services, and thus not need DCVMN support.

SJ acknowledged the comments of BT, and assuming budget is available, to support for 2 applications as the way forward. BT acknowledged the support of Steve and secretariat; SP acknowledged SJ role of guiding, knowledge sharing, very proactive and active in facilitation, writing reports for open access, he has been the source of success for this area of work and advancements for the DCVMN members. She clarified that this is a support to motivating manufacturers, through training and technical knowledge, for them to learn how to advance this area. DCVMN, as an association is not an investor, and 50K is the largest support value ever made, from agreed donors funds, that rather go to service providers, not to manufacturers. SP clarified that DCVMN is not in a position to use own "members" funds to support members projects themselves, and acknowledge the generous PATH support. SP will draft and circulate minutes to Geraldine, and Steve would focus on drafting recommendations to DAC.

Notes taken by S.Pagliusi.

Acknowledged by Reviewers

_____ Date 14 June 2022_____
Mr Steve Jarrett