KICK-OFF MEETING OF THE OIE VIRTUAL BIOBANK PROJECT

Paris, 15–17 October 2019

The kick-off meeting of the OIE Virtual Biobank project was held at the OIE Headquarters in Paris from 15 to 17 October 2019.

1. Opening

Dr Matthew Stone, OIE Deputy Director General, International Standards and Science, welcomed the participants on the first day of the meeting and explained the OIE’s interest in developing an OIE-Virtual Biobank (henceforth, OIE-VB).

He underlined that the creation of an OIE-VB would facilitate searches for biological resources collected and preserved in OIE Reference Centres and National Reference Laboratories. These resources include reference materials, such as antisera for use as reference reagents, which are important tools for the development and standardisation of tests for the diagnosis and control of OIE listed diseases.

He also explained that this initiative represents an opportunity to harmonize procedures and systems implemented for similar projects, and that it creates a chance to strengthen the cooperation and sharing among laboratories.

Finally, he reminded the participants that the main objectives of the meeting were to discuss the IT solution described in the business plan of the project, which was jointly drafted by the Istituto Zooprofilattico Sperimentale della Lombardia e dell’Emilia-Romagna (henceforth, IZSLER) and the OIE, and describe the metadata and quality requirements schemas before moving to the implementation of the project.

2. Adoption of the agenda, appointment of a chair and rapporteur

The meeting was chaired by Dr Maria Laura Boschiroli. Dr James Watson acted as rapporteur.

The agenda, including the project background, the Terms of Reference (ToR), and the list of participants are presented in Appendices I and II, respectively.

3. Review of the IT solution proposed by IZSLER

Dr Antonino Caminiti, chargé de mission at the Science Department of the OIE, explained that the main aim of the OIE-VB project is to create a web-based virtual biobank system for users to search and for suppliers to share biological materials. These materials would be well characterised and locally managed according to a quality management system that meets the requirements of internationally recognised standards, such as the ISO 9001 on quality management systems and the ISO 20387 biotechnology, biobanking and general requirements for biobanking.

Dr Domenico Nilo Mazza, Head of the IT Department of the Istituto Zooprofilattico Sperimentale della IZSLER, presented the system architecture described in the business plan. The architecture includes the OIE-VB web portal, the biobank protocol and the biobank management system (henceforth, BMS) for local biobanks.

1 Note: This ad hoc Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the February 2020 report of the Biological Standards Commission because this report provides its considerations and comments. It is available at: http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/laboratories-commission-reports/meetings-reports/
Following the presentation, the Group discussed the architecture and made the following conclusions:

- For local biobanks without an existing BMS, an option would be to provide the biobank with a ready-to-use pre-configured management system, while another option would be to download software for the local management of biological materials (e.g. for the registration of metadata associated with biological material, the charge and discharge of items from the inventory, etc.) to be installed.

- For local biobanks with an existing BMS, the biobank protocol will allow the connection and communication between local biobanks and the OIE-VB through an interface. There could be extensive customisation needed for the interface to correctly map the metadata between the local biobanks and the OIE-VB. This would have to be worked on by the local biobanks.

The Group noted that performing queries according to the proposed architecture has the potential to be slow and miss the information of local biobanks, if the query is made when the local biobanks’ internet services are down. Therefore, the Group proposed to consider maintaining a centralised catalogue in the OIE-VB. Participating local biobanks will ensure that information on materials is regularly updated through the BMS. This would ensure that users have access to the complete catalogue, regardless potential connectivity issues with local biobanks.

Regardless of whether the local biobanks have a BMS in place, option is also available for local biobanks to upload the data without being connected with the OIE-VB (e.g. via spreadsheet or web-based form). However, this would not be desirable for large number of records. For these suppliers, the Group proposed to create a mechanism to alert them on the need to keep the data up to date (e.g. through emails submitted to local biobanks by the OIE-VB).

Concerns were raised on the proposal to have a cloud-based management system for local biobanks as not all laboratories would have access to stable internet connection. Other options including a hybrid management system, e.g. a system to provide updates to BMS either online (through cloud) or offline, could also be considered as an alternative for the future.

The Group noted that there are several open source biobank management systems available, such as Baobab LIMS, Open LIMS, SENAITE and Open Specimen, all of which have different advantages and disadvantages. A small working group could be setup by IZLSER to select the most suitable option.

Dr Boniotti, manager of the biobank operated by IZLSER, presented a proposed structure and interface for the OIE-VB web portal to the Group.

The Group suggested that the web portal could include a dashboard that would provide regular update of the activities of individual local biobanks (e.g. metrics such as what materials were distributed and to which parties, if confidentiality issues do not arise, etc.). This would provide incentive for local biobanks to actively participate in the OIE-VB and maintain the data up to date.

The OIE-VB could allow the centralised approach to manage transaction of materials between the local biobanks and the recipient. However, the Group recognised that this may bring up additional level of complexity that would be beyond the scope of this project.

Finally, the Group suggested the project team and the OIE to carefully consider the legal and security issues related to local biobanks granting information system access to an external entity, such as the OIE-VB, as well as any potential confidentiality concerns.

4. **Review of the minimum set of metadata to be associated with biobank materials**

The Group extensively discussed the minimum set of metadata to be associated with biological resources that were originally drafted by the experts during the *ad hoc* Group meeting on Veterinary Biobanking in 2017.

The Group suggested that the implementation of the metadata should maintain flexibility. For instance, mandatory fields should be carefully considered and based on the type of material.

The Group also proposed to use the OIE nomenclature for animal species, diagnostic tests, animal diseases or other appropriate ontologies, when available, for the metadata schema.
The Group revised the original metadata schema drafted in 2017, which has now been organised into different tables according to the object type (e.g. materials, batch, contact information, quality attributes, etc.). The revised version of the metadata is available online on the OIE website at this [link](#).

The Group noted that while all the metadata would be needed for managing materials stored in individual biobanks, only a subset of metadata will be actually required by the OIE-VB. For this reason, the Group proposed to restructure the metadata scheme to clearly distinguish the metadata required for the BMS and the OIE-VB. For instance, the Group proposed that the metadata could be individually associated with the attributes for “Biobank Management System” and/or “OIE Virtual Biobank”, when required, to identify these subsets of metadata.

The Group suggested the revised metadata schema be reviewed by a small selected panel of experts consisting of OIE reference laboratories, the Italian network of biobanks and the three laboratories to be selected as user cases (see section 6 of this report). This should be done in the early phases of the project to arrive at a best agreement of the metadata schema and better facilitate the development of the IT system.

To this end, the Group proposed to make an electronic consultation requesting the OIE Reference Centers to submit an expression of interest to participate in this process of revision. IZSLER, in partnership with the OIE would select a representative group among those that express interest. The Biological Standard Commission will be consulted regarding this proposal.

5. **Review of quality standards to be satisfied by biobank materials**

Dr Boniotti presented a scoring system developed by IZSLER in collaboration with the network of Italian biobanks to rank biological materials according to quality control criteria, such as identity, purity, stability and potency.

The Group discussed advantages and disadvantages of attempting to rank materials according to these quality control criteria. An advantage of a scoring system would be to ensure that only high-quality materials would be provided to the OIE-VB, as suggested by the expert group on Veterinary Biobanking in 2017. However, from a practical viewpoint, possible disadvantages would include the technical complexity behind having to establish the scoring system, reluctance to accept the system by the OIE Reference Laboratories, and the risk that it would discourage participation of potential suppliers in the OIE-VB.

Based on the discussion, the Group suggested a more pragmatic approach of presenting information on the required quality control criteria, which will only be provided by the suppliers in the form of technical data (e.g. free text description, upload of documentation, etc.). The quality may then be independently assessed by the users. This would avoid most of the disadvantages of a ranking method, while maximizing the advantage of having the relevant information provided for the applicant to assess quality.

However, given that the information to assess the quality according to the scoring system proposed by IZSLER would be provided through the minimum set of metadata, the Group suggested to assess the feasibility of such system and carry out a pilot study involving the Italian network of biobanks. The quality score for biological materials would not initially be shown or applied within the OIE-VB deployed to the three user cases (see section 6). The results of this exercise could be presented for review by the Group for possible application to the whole network of biobanks participating in the OIE-VB project in the future.

The Group placed emphasis on the fact that OIE-approved international standard reagents should be differentiated and clearly distinguished from non-OIE-approved reagents in the OIE-VB, regardless of the information on the quality level provided by suppliers. This is because OIE-approved international standard reagents are designated by the Biological Standards Commissions. The Group discussed the opportunity to include pathological materials and samples from experimental studies among the types of biological resources that can be provided through the OIE-VB. However, as the current listing schema of the metadata was developed for other kinds of materials, such as cell lines, antigens, antibodies, fixed tissues, viruses, bacteria, parasites and fungi, the Group recognised the need for further evaluation to improve compatibility for pathological materials, samples from experimental studies or vaccines.
6. **Next steps for implementation and strategies to initiate and sustain sharing of materials (short-term strategies)**

To maximise the success of the project in the short-term (*i.e.* during the implementation phase), the Group proposed to create three different user cases to represent laboratories from different regions and characteristics that could be used as pilot study to fine tune the system.

This may include: i) a laboratory with good IT support with an existing BMS; ii) a laboratory with good IT support without an existing BMS; and iii) laboratory with limited IT support and without an existing BMS.

This approach would provide valuable experience before expanding the biobank to larger number of laboratories in the following phase.

On-site visits would be required to setup the system locally. The Group suggested that the roll-out implementation of the pilot study be done by IZSLER to contain the costs, although this would require additional funding. The DG of IZSLER concorded with the proposal and will consider additional funding for these on-site missions.

The selection of the candidates for the three user cases from among the respondents could be done through the electronic consultation that will be carried out to receive expression of interest for the review of the metadata schema (see section 4 of this report). IZSLER in partnership with the OIE would select the user cases.

7. **Propose strategies to support active engagement within the network of OIE Reference Centres (long-term strategies)**

To maximise the success of the project in the long-term (*i.e.* after the implementation phase of the project and during the run-phase), and support active engagement within the network of the OIE Reference Laboratories, there is the need to clearly define the benefits, incentives and justification for local biobanks to join and actively participate in the project, such as providing the metadata to the OIE-VB and supplying materials.

For OIE Reference Laboratories, this could include provisions that define participation as being in alignment with their mandate and related activities (*e.g.* distributing diagnostic reagents). This would provide positive representation of the organisations carrying out their expected roles. Other incentives for suppliers would include international recognition by the scientific community and access to a free working open source system for managing materials with continued support.

To ensure buy-in from stakeholders, this system would also (i) provide increased visibility for laboratories through the OIE-VB web portal and OIE communication channels, such as the OIE webpage and OIE Bulletin, (ii) promote research and collaboration, and (iii) advance the aims of the OIE to minimise the economic impact of animal diseases and safeguard animal welfare by facilitating the search for diagnostic materials.

The Group was informed of the Material Transfer Agreement (MTA) that was developed by the OIE to facilitate the exchange of materials. The Group noted that the OIE MTA may not be exhaustive and additional documentation could be requested by local biobanks for the provision of materials. When possible, this could be built into the OIE-VB to provide automated documentation, adding additional incentive for participating in the project.

8. **Final remark**

As a future direction, the Group suggested that consideration could be given for the amendment of the Guidelines for applicants for OIE Reference Laboratory status to require participation in the OIE-VB.
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Background

Following the Recommendation of the 2014 Third Global Conference of OIE Reference Centres to establish an international-VB, the OIE convened an ad hoc Group of experts at the OIE Headquarters in Paris in 2017. The Group discussed the steps that were needed for the implementation of the OIE-VB (OIE-VB), which is a web-based system to promote the development and distribution of biological resources, especially diagnostic reagents, worldwide.

The expert Group drafted a list of metadata to be attached to biobank materials, proposed rules to define acceptability and quality level of biobank materials, recommended the use of controlled terminologies for describing biobank materials, and suggested a set of high-level key requirements for the IT system.

Based on the work of this ad hoc expert Group, IZLSER - OIE Collaborating Centre for Veterinary Biologicals Biobank, drafted the business plan of the OIE-VB project in partnership with the OIE. The business plan was approved by the director General of the OIE in 2019.

The project governance described in the business plan establishes that the Steering Committee and the External Advisory Committee meet regularly to discuss challenges and developments relating to the project. Hence, the OIE is convening the kick-off meeting of the project, which will be held at the OIE headquarters in Paris and will include members of the Steering Committee and the External Advisory Committee.

The objective of the meeting is to provide guidance, expert advice and concrete recommendations in matters related to (i) the IT solution for the OIE-VB described in the business plan, (ii) the minimum set of metadata to be associated with biobank materials and (iii) the quality requirements to be satisfied by biobank materials for inclusion in the OIE-VB.

Terms of Reference

Meeting participants are expected to:

1. Review the minimum set of metadata to be associated with biobank materials
2. Review the quality standards to be satisfied by biobank materials
3. Review the IT solution proposed by IZSLER by single component:
   a. The OIE-VB Portal
   b. The Biobank Protocol
   c. The Biobank Management System
4. Evaluate next steps for implementation and provide expert advice
5. Propose short and long-term strategies to initiate, promote and sustain sharing of biobank materials among laboratories and across countries
6. Propose strategies to support active engagement within the network of OIE Reference Centres

Agenda

1. Opening of the kick-off meeting
2. Designation of the chair and rapporteur
3. Adoption of the agenda
4. Consideration of Terms of Reference
5. Other business
6. Adoption of the report
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List of participants

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