Data and Sample Sharing Procedure for the management of the VALUE-DX database and biobank

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1. Introduction

The purpose of this Data and Sample Sharing Procedure (DSSP) is to enable effective, secure, and responsible sharing of data and samples of the VALUE-DX database and biobank. Procedures in this document are compliant with:

- H2020 guidelines on open access to data
- Procedures described in the Data Management Plan (VALUE-DX Deliverable 3.1)
- The 2017 International Committee of Medical Journal Editors (ICMJE) requirements on data sharing statements for clinical trials

The VALUE-DX database and biobank belongs to the VALUE-DX Consortium and is managed by the VALUE-DX Database and Biobank Management Board.

2. Terminology, Acronyms and Abbreviations

- *VALUE-DX Consortium*: all partners and subcontractors within the VALUE-DX project.
- *VALUE-DX Database and Biobank Management Board*: all work package co-leaders of the VALUE-DX project involved in the request, chaired by the VALUE-DX Coordinator(s) (Annex II: list of the VALUE-DX work package co-leaders)
- *VALUE-DX database*: all clinical and lab data collected and analysed by the VALUE-DX consortium within the VALUE-DX project, stored in the central database in Utrecht.
- *VALUE-DX biobank*: all patient samples and clinical isolates collected by the VALUE-DX consortium within the VALUE-DX project, stored in the central laboratory in Antwerp.
- *VALUE-DX Database Management Unit*: Academic work package 3 co-leader and the staff members of the Julius Center Data Management Unit who are responsible for maintenance of the VALUE-DX database, inserting new data and giving out data (Annex III: list of members of the VALUE-DX Database Management Unit).
- *VALUE-DX Biobank Management Unit*: Academic work package 2 co-leader and the staff members of the Laboratory of Medical Microbiology of the University of Antwerp who are responsible for maintenance of the VALUE-DX biobank, giving out samples and isolates (Annex IV: list of members of the VALUE-DX Biobank Management Unit).

3. Data and sample sharing procedure for VALUE-Dx partners

Each partner of VALUE-DX can request a subset of data or clinical samples for further analyses and publication from the VALUE-DX database and biobank (as mentioned in section 8.3 of the Consortium Agreement of VALUE-Dx). Preferably, while doing so, the already existing publication schemes per work package should be followed.

Data/sample requests should be addressed to the WP co-leaders concerned and should be accompanied with a clear description of which data and/or clinical samples are needed. For data requests, a data dictionary and a dedicated data request spreadsheet is available. Using the data request spreadsheet, the desired data should be specified.

After approval of the request by the WP co-leader concerned, data will be made available by the VALUE-DX Database Management Unit, using the Digital Research Environment (DRE). The DRE offers a high level of safety and security. The platform implements robust security measures to ensure the integrity and confidentiality of data. DRE utilises Azure, a trusted and highly secure cloud computing platform, which employs advanced encryption algorithms and strict access controls to safeguard data at rest and in transit. The platform also adheres to industry-standard best practices for security, regularly updating and patching its systems to mitigate potential vulnerabilities. Additionally, DRE implements strong user authentication mechanisms, such as multi-factor authentication, to prevent unauthorized access to user accounts. Users of the VALUE-Dx Database Management unit with the 'Owner' role are admins of the workspace and can add any users with the 'Member' role. Control over data stays with the Owner. Members have limited rights on the DRE and can only download data to their own environment after requesting approval from the Owner.

Clinical samples will be made available by the VALUE-Dx Biobank Management Unit.

4. Data and sample sharing procedure for Third parties

a. Principles

VALUE-DX will facilitate and support access to data and samples to third parties based on the following principles:

- The data/samples remain under the management of VALUE-DX, unless otherwise specified under a separate agreement.
- The quality of data and biological samples shall be ensured by VALUE-DX.
- Requests for access to samples/data issued by requesters will be required to follow the request procedure for samples/data as outlined in this Data and Sample Sharing Procedure.

- The VALUE-DX Database and Biobank management Board must approve all access requests prior to access being granted.
- The VALUE-DX Database and Biobank management Board shall treat all access requests confidentially and will not use them for any other purpose than assessing the request for access to samples and/or data.
- The contribution of the requesters research must be consistent with the VALUE-DX publishing policy.
- Where a VALUE-DX Database and Biobank management Board member puts forward or is part of a team that puts forward an Access Request, they will recuse themselves from the review and approval process.
- Requesters who follow the procedures as laid out in this document will be granted access based on fair and non-discriminatory terms and as per the prioritisation policy.
- All researchers are expected to act in an honest, transparent, equitable manner and uphold the highest standards of quality in research.
- Access to the finite samples may be prioritised as per the expertise and insight of the VALUE-DX Database and Biobank management Board.
- The requester needs to confirm that the samples provided are stored in a secure storage and operational facility accompanied by an appropriate access policy.
- Samples/data can be used for academic or industrial research purposes. The usage and limitations need to be specified in an MTA between the Requester and VALUE-DX.
- To maximise the value of the biobank, all provenance data as well as data derived from samples/data are transferred back to VALUE-DX free of charge ('return of data').
- All analyses will be subject to the overarching principle that they must also be evaluated by an appropriate and legitimate ethical review board.
- VALUE-DX shall explicitly document any restriction of use or obligation applicable to these biological samples or data.
- It may be that VALUE-DX requires the requesters to partially or fully cover the costs incurred in providing samples and/or data. Potential costs may include data preparation, sample handling costs, shipping costs, fees per aliquot etc. Cost aspects will be specified in the Access Agreement between the requester and VALUE-DX.
- All individual level data will be de-identified/pseudonymised prior to sharing. Under no circumstances will identifiable information be provided at an individual level.
- Researchers are expected to take the necessary precautions and safeguards to avoid subjects' privacy breaches.
- It is the responsibility of the Requester to ensure that they have read and understood the relevant VALUE-DX policies and procedures and that they act in accordance with them.
- Requesters are expected to make their research results accessible for academic purposes in a timely manner. This could be part of the Access Agreement. The VALUE-DX consortium should be acknowledged in any research results according to the VALUE-DX publication policy.

b. Procedure

Investigators outside the VALUE-DX consortium can request VALUE-DX data and/or clinical samples for additional analyses following article publication of the results. Each request, should be accompanied with a rationale, aim and analysis plan, and with a clear description of which data and/or clinical samples are needed, using the applicable parts A, B, C, D and E of the 'VALUE-Dx data/sample access request form' (Annex 1). For data requests, a data dictionary is available.

The completed request form should be sent to the VALUE-DX Coordinator(s) and/or to the WP co-leaders concerned. Subsequently, the request will be forwarded to all WP co-leaders who are involved in the request. In case of a sample request, also the WP2 co-leaders will be included. All involved WP co-leaders and coordinator(s) will jointly form the VALUE-DX Database and Biobank Management Board for the applicable data/sample request.

The request will be assessed as soon as possible by the members of the VALUE-DX Database and Biobank Management Board. Members not responding within 2 weeks of sending the request automatically agree with this request. The outcome of the request review will be documented in Part F of 'VALUE-Dx data/sample access request form' by the main WP-(co)Leader involved in the request an sent to the applicant.

When approved, preferably by consensus, and if not by at least two third of the members of the VALUE-DX Database and Biobank Management Board, the requested datasets and/or clinical samples can be provided by the VALUE-DX Data Management Unit and/or VALUE-DX Biobank Management Unit. However, access requests approved, require additional permission from a research ethics committee before access to data or samples is finally given.

Research organisations who have passed both of these application steps must then sign and adhere to the conditions set out in access agreements and disposal policies that outline how the biobank samples and/or data are to be used, stored and protected. This ensures that researchers use the samples and associated data only in line with received consent. A single standardised approach governing all biobank samples will be applied.

The whole procedure should preferably not take more than three weeks.

Accountability is provided at three levels:

- the VALUE-Dx Database and Biobank management Board,
- the relevant local research ethics committee,
- the legal agreement that outlines terms of use of the data/samples

5. Annex I: VALUE-DX data/sample access request form

Date of Application: **DD/MM/YYYY**

Part A - General Information		
Principal Applicant		
Name		
Position		
Organisation		
Mailing Address		
Contact Information	**Telephone**	
	Email	
Funding Source for Project		
In addition, please attach the following: • If the applicant is a student, please provide contact details for the academic advisor. • If Academic staff, provide the contact information for the relevant responsible individual within site. • If there are co-investigators, please include their names and contact information.		
Co-Investigators	**1.** Name 1, Location, Contact Information. **2.** Name 2, Location, Contact Information. **3.** Name 3, Location, Contact Information. **4.** Name 4, Location, Contact Information. **5.** Name 5, Location, Contact Information.	
Have you obtained ethical approval for this Study? Please attach the letter of ethical approval to this form. (Approval does not mean that no extra ethical approval by the biobank is needed)	☐ Yes	☐ No

Part B - Description of Research Project	
B.1. Project Title	
B.2. Research Question and Hypothesis	
B.3. Study Rationale	
(If samples are required, specify details on what is being measured)	

B.4. Detailed Proposed Methodology
B.5. Lay Summary

Part C - Description of Data
C.1. Please provide a justified detailed description of the data you are requesting.
Please use the data dictionary for the description of requested data. Also indicate where the data will be processed (stored and analysed).
C.2. Provide the sample size required for the study and the justification

C.3. Specify in detail the statistical analysis plan
C.4. Provide any time scheduling requirements

C.5. List any collaborators that will have access to the data (will all samples be analysed on a single site, if not should be described in extra agreement since other partners are also obliged to adhere to the conditions)

Part D - Description of Samples
D.1. Sample number and types requested (sample type, management, storage conditions, …).

D.2. Sample volume(s) requested.

Part E - Signatory	
E.1. Name	
E.2. Position	
E.3. Address	
E.4. Email	
E.5. Phone	

Part F - Application Review	
F.1. Meeting Date	
F.2. Reviewers	
F.3. Review Outcome	

6. Annex II: VALUE-DX Database and Biobank Management Board:

a. VALUE-Dx coordinators

Herman Goossens; Univ. of Antwerp; E-mail: herman.goossens@uza.be
Jean-Louis Tissier; bioMérieux; E-mail: jean-louis.tissier@biomerieux.com
Tim Jinks; Welcome E-Mail: t.jinks@wellcome.org

b. VALUE-Dx work package co-leaders

WP2: LAB

Surbhi Malhotra; Univ. of Antwerp; E-mail: surbhi.malhotra@uantwerpen.be
Carine Malcus; bioMérieux; E-mail: carine.malcus@biomerieux.com

WP3: data

Frank Leus; Univ. of Utrecht; E-mail: F.R.Leus@umcutrecht.nl
Jean-François Gorse; bioMérieux; E-mail: jean-francois.gorse@biomerieux.com

WP4a: PRUDENCE

Chris Butler; Univ. of Oxford; E-mail: christopher.butler@phc.ox.ac.uk
Susanne Emmerich; Abbot; E-mail: susanne.emmerich@abbott.com
Adam Zerda; BD; E-mail: adam_zerda@bd.com

WP4b ADEQUATE

Julia Bielicki; UKBB (Basel); E-mail: juliaanna.bielicki@ukbb.ch
Florence Allantaz; bioMérieux; E-mail: florence.allantaz@biomerieux.com

7. Annex III: VALUE-DX Database Management Unit

Frank Leus (WP3 co-leader); E-mail: F.R.Leus@umcutrecht.nl
Lisanne Vintcent E-Mail: L.E.M.Vintcent@umcutrecht.nl

Julius Center for Health Sciences and Primary Care
Universitair Medisch Centrum Utrecht
Universiteitsweg 100, Postbus 85060
NL-3584 CG Utrecht,
The Netherlands

8. Annex IV: VALUE-Dx Biobank Management Unit

Surbhi Malhotra (WP2 co-leader); E-mail: surbhi.malhotra@uantwerpen.be
Leen Timbermont E-mail: Leen.Timbermont@uantwerpen.be

Medical Microbiology
Universiteit Antwerpen- Campus Drie Eiken
Universiteitsplein 1 S6
B-2610 Wilrijk
Belgium