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D2.5 Biobank

VALUE-Dx

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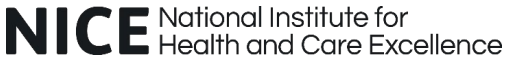
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1. Introduction

A biobank of clinical samples and DNA derivates from CA-ARTI patients was created within VALUE-Dx and will be maintained. Dedicated and leftover samples of PRUDENCE (WP4a) and ADEQUATE (WP4b) were stored at the decentralised hub of the “Biobank Antwerpen” hosted at the Laboratory of Medical Microbiology, University of Antwerp, Belgium.

2. Analysis report

In Belgium, all samples with human body materials, including all derivatives, need to be registered in an official biobank (registered at the Belgian Federal Agency for Medicines and Health Products - FAGG). Accompanying patient data can be collected and can be accessed in compliance with the rules fixed by the General Data Protection Regulation (GDPR) and the informed consent form.

The University of Antwerp and the University Hospital Antwerp teamed up and established the “Biobank Antwerpen” (BB190007). A biobank hub was set-up at the Laboratory of Medical Microbiology with full monitoring and a back-up system, operated by local staff trained on the biobank protocols and on sample shipment legislation according to IAATA guidelines. All specimens are registered using the data management system SLIMS (Agilent). SLIMS is a web-based laboratory information system (LIMS) with electronic laboratory notebook (ELN) and full audit trail.

Within VALUE-Dx, samples from a subset of participants in PRUDENCE (WP4a) and ADEQUATE (WP4b) were collected. These samples were shipped to the Laboratory of Medical Microbiology for research purposes and biobanking.

For ADEQUATE, all sites had to store the leftover of the BioFire nasopharyngeal swab (NP Swab) from participants that were randomized in the diagnostic intervention arm and gave consent for future use. Participants could also consent for the microbiology study. In this case, sites had to collect oropharyngeal swabs (OP Swabs) at Randomisation and at Day 30.

A total of 523 subjects were enrolled in the study of which 196 were enrolled in the diagnostic intervention arm and gave consent for future use. A total of 194 NP Swabs were received and stored as such in the biobank.

Of the 49 participants that consented for the microbiology study, 49 Randomisation OP Swabs and 37 Day 30 OP Swabs were received. Upon arrival at the central lab, samples were thawed, and dedicated aliquots were made for biobanking along with processing the sample for study objectives. DNA extracts remaining after laboratory analysis were also added to the biobank. A total of 140 aliquots and 100 DNA derivates are biobanked.

Also in PRUDENCE, participants could consent for a microbiology-biomarker study. The following samples were collected from participants that consented for this substudy:

- Three types of blood samples, EDTA plasma, Heparin plasma, and PAXgene (whole blood), were collected at four distinct time-points: on Day 1, Day 3, Day 7 and Day 28.
- Nasopharygeal swabs in Bacterial Storage Medium and in DNA/RNA Shield medium were collected at three time-points: on Day 1, Day 7 and Day 28.
- Stool samples in Glycerol and in DNA/RNA Shield medium were collected at four time-points: on Day 1, Day 7, Day 28 and Day 90.

Of the 115 participants that consented for the microbiology-biomarker study, the Laboratory of Medical Microbiology received 406 EDTA plasma samples, 401 Heparin plasma samples, and 406 PAXgene samples. These samples were forwarded to the research partner, Laboratory of Cell Biology & Histology, University of Antwerp, to evaluate host status and response (immune profile and biochemical markers) for host biomarker based diagnostic interventions and screenings. Leftover samples and derivatives are registered in the “Biobank Antwerpen”.

The received stool samples and NP Swabs in DNA/RNA Shield, 330 and 314 respectively, were thawed, aliquoted, and processed for study research purposes. Of the stool samples in DNA/RNA Shield, 1301 aliquots and 330 DNA derivates were biobanked. While of the NP Swabs in DNA/RNA Shield, there are 600 aliquots and 359 DNA derivates available.

The 314 NP Swabs in BSM and 332 stool samples in glycerol were stored as such in the biobank.

3. Conclusion

The VALUE-Dx Biobank consists of a comprehensive collection of clinical samples with high quality standards obtained from the WP4 studies. The specimens can be linked to pseudonymized patient information. Samples are available for future use according to the obtained patient consent and applicable legal and ethical considerations.

This biobank supports the sustainability of the VALUE-DX project and paves the way for future collaborations within the consortium.

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