WORKSHOP: Elements of Secure Processing Environments

19/20 June 2023, Brussels/online

Aim of the Workshop

HealthyCloud, B1MG, PHIRI, HRIC, EOSC-Life, EUCAIM, *inter alia*, are EU projects where BioMedical Science Research Infrastructures (BMS RIs) together with other consortium partners are tasked to providing input and recommendations to policy makers for shaping the future data landscape in the field of health research. In parallel, the EU Commission driven by DG Sante is building a European Health Data Space with numerous implications for research and realised with projects such as EHDS2-pilot.

Many projects and the European law such as the Data Governance Act and the draft EHDS Regulation are built on the assumption, that personal data should only be processed in a "Secure Processing Environment" defined as "the physical or virtual environment and organisational means to provide the opportunity to re-use data in a manner that allows for the operator of the secure processing environment to determine and supervise all data processing actions, including to display, storage, download, export of the data and calculation of derivative data through computational algorithms" in Art. 2 (14) DGA.

This workshop will present already existing SPEs as best practices and to extract and discuss the basic technical and organisational requirements to build such an SPE in particular in compliance with the GDA and the EHDS along the lines of the following questions:

- Is there consensus on technical and organisational measures on TREs/SPEs? Nationally and/or internationally and/or domain-specific? (We already know internationally there is close to none at the moment)?

- What certifications are used (also where) to demonstrate the compliance? Nationally and/or internationally and/or domain-specific?

- What are the approval mechanisms in different countries?

Following a *Setting the Scene* introduction, best practice examples presentations from countries such as Finland, Norway, the Czech Republic, the Netherlands, Spain or Germany (e.g., SensitiveCloud, TSD, Findata, HUNTCloud, OPENVRE, de.NBI cloud) and the industry will allow for in-depth discussions. As participants we aim for researchers from industry and academia, EU Commission representatives across DGs, EDBP, EDPS and national DPAs and policy makers as well as patient representatives.

The result will be a report on minimum requirements for the establishment of a compliant SPE being fit for the processing of personal health data.

Venue:
NH Collection Brussels Centre
Boulevard Adolphe Max – Adolphe Maxlaan 7
1000 Brussels, Belgium

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AGENDA V2.0

Place: NH Hotel Brussels Centre
Boulevard Adolphe Max – Adolphe Maxlaan 7
1000 Brussels, Belgium

Day 1: 13:00-17:00 CEST

Welcome (15 min) – Juan González-García & Michaela Th Mayrhofer

Setting the scene (30 min) – Irene Schlünder & Juan González-García

Putting Secure Processing Environments (SPEs) and EHDS into context - about terminology & results of HealthyCloud and EOSC-Life

Q&A – (15 mins)

Best practice examples: Session I (1,5 hrs) – Chair: Petr Holub

1. Presentation: Kaisa Silander, THL (Finland) and Heikki Lanu, Findata (Finland)
2. Presentation: Gard Thomassen, TSD, IT-Director University of Oslo (Norway)
3. Presentation: Ludek Matyska, MUNI, SensitiveCloud (Czech Republic)

Coffee break (30 min)

Best practice examples: Session II (1 hour) – Chair: Michaela Th Mayrhofer

4. Presentation: Laia Codó, OpenVRE vs. SecureVRE (Spain)
5. Presentation: Morris Swertz, UMCG, Molgenis (The Netherlands)

Day 2: 9-00-13:00 CEST

Wrap-up of day 1: Salvador Capella
Best practice examples III (1 hour) Chair: Salvador Capella

6. Presentation: Lionel Grondin, Health Data Hub (France)
7. Presentation: Nils Hoffmann, de.NBI Cloud (Germany)

The industry perspective (30min) – Chair: Petr Holub

8. Presentation: Dalibor Kačmář, National Technology Officer, Microsoft

Coffee break (30 min)

Panel discussion (1 hour) – Chair Juan González-García & Irene Schlünder
Is there any consensus on:

- Technical security (including the use of clouds)
- Organisational measures such as roles (e.g., controller, processor)
- Certification

Open discussion on best practices & recommendations (45 min)
Petr Holub & Salvador Capella

Closing remarks (15 min)
Petr Holub & Salvador Capella