

Biomedical Research Training Workshop Week

Implementing Biomedical Research Projects: The Complete Workflow from Concept, ELSI and Privacy Considerations to High-Quality Biobanking

11 - 15 May 2020, Medical University of Graz

Graz, Austria

Jointly organised by

EJP RD, BBMRI-ERIC, EASI-Genomics



with support from

Medical University Graz, BBMRI.at, CBmed GmbH and QIAGEN GmbH



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ABOUT THE TRAINING WORKSHOP

This workshop is aimed at biomedical researchers, medical professionals and biobank managers who want to organise biomedical research projects on human biological samples. We welcome the participation of representatives from patient organisations, as well.

In two modules we will use several use-cases to address the key issues in biomedical research involving human subjects, human biological samples and associated medical data: ethics, legal issues, privacy and data protection, data standardisation and the implementation of sample workflows in a clinical context that are compatible with the *In Vitro* Diagnostic Regulation.

In the *first module* we will show participants how to obtain ethical, legal and regulatory counsel for their projects, since regulations vary widely between European countries. In addition, we will provide practical guidelines on how to manage genetic data from human samples. The goal is to arrive at a logically organised checklist that prevents us from overlooking important issues that may be particularly challenging, e.g. in transnational collaboration. The *second module* will deal with procurement of samples and data in a workflow in a clinical context aligned with current CEN/ISO standards for pre-analytical procedures.

PRELIMINARY PROGRAM

Module 1 (May 11 – May 13) and Module 2 (May 13 – May 15)

Monday 11 May 2020

Morning: Tour of the Graz Biobank (optional)

12:00 - 13:00 Lunch & registration

13:00 – 13:10 **Welcome address** Peter M. Abuja (MUG, EASI-Genomics), Michaela Th. Mayrhofer (BBMRI-ERIC, EJPRD)

13:10 – 13:30 **Opening and introductions to the workshop** Mary Wang (FTELE, EJPRD), Peter M. Abuja

Brief presentation on respective projects: EJPRD and EASI-Genomics

Goals of the training workshop & modules

13:30 – 14:00 **Biobanking in diverse working fields (RD, Cancer, Population/cohorts)** Petr Holub (BBMRI-ERIC, EJPRD)

14:00 – 14:30 **Genomics in health research** Lennart Johansson (TBC, UMCG)



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14:30 – 15:00 Presentation of the Problem Cases: Introduction to Problem-Based Learning *Mary Wang*

15:00 – 15:45 Breakout session: Problem Analysis (45') Group discussions on the problem case, identification of knowledge gaps and questions. Discussions are facilitated by speaker/experts.

15:45 – 16:15 Coffee break

ELSI Considerations

16:15 – 16:45 Lecture: An overview of ELSI in biobanking and privacy management *Michaela Th. Mayrhofer*

16:45 – 17:15 Lecture and examples of biobank societal engagement *Lorena Casareto (TNGB, EJPRD)*

17:15 – 17:45 Lecture on GDPR *Irene Schlünder (BBMRI-ERIC ELSI Services & Research)*

17:45 End of day 1

Tuesday 12 May 2020

09:00 – 09:10 Recap of day 1, aims of day 2 *Michaela Th. Mayrhofer*

09:10 – 10:30 Breakout sessions: Solution Part I Participants work in groups to come up with solutions on the problem case on *ELSI* aspects, using the information material provided by the lectures on day 1.

10:30 – 11:00 Coffee break

Data Management Considerations

11:00 – 11:30 Data management of samples/biobank, BIMs, Catalogue, data mapping *Esther van Enckevort (UMCG, EJPRD)*

11:30 – 12:00 Genomic data management considerations; existing standards and resources *Carles Garcia Linares (CRG-CNAG, EJPRD)*

12:00 – 13:30 Lunch & Networking

13:30 – 14:00 Lecture on coding unstructured data using ontologies *Nancy Mah (Charité, EJPRD)*

14:00 – 15:30 Breakout session: Solution Part II (1h30) Participants work in groups to come up with solutions on the problem case on *data* aspects, using the information material provided by the lectures.

15:30 – 16:00 Coffee break



16:00 - 17:00 **Tool demos** *Esther van Enckevort, Petr Holub*

17:00 End of day 2

Wednesday 13 May 2020 (joint day for Modules 1 & 2)

09:00 – 10:00 **Presentation from participant groups** on the developed solutions, feedback from experts

10:00 – 10:45 **The role of ethics committees in biomedical research** *Josef Haas (Ethics board of the Med Uni Graz)*

10:45 – 11:15 Coffee break

11:15 – 11:45 **The Study Protocol – key elements and a description of the whole workflow** (ethics, data management, privacy protection, patient selection, sample management and analysis) *Peter M. Abuja*

11:45 – 12:15 **Reflections on Module 1** *Michaela Th. Mayrhofer, Mary Wang*

12:15 – 12:30 **Group Photo** (for participants in either module)

12:30 – 13:30 **Lunch & end of Module 1**

13:30 – 14:00 **Outlook on Module 2** *Peter M. Abuja (MUG, EASI-Genomics)*

14:00 - 15:00 **Rationale for defining standardized pre-analytical workflows in light of the requirements of the IVDR** *Uwe Oelmüller (QIAGEN GmbH)*

15:00 – 15:30 **Significance of standards, implementation in clinical collaborations** *Peter M. Abuja*

15:30 – 16:00 Coffee break

16:00 – 16:30 **Presentation of the use-case based on actual collaborative research with clinical departments** *Amin El-Heliebi (MUG, CBmed GmbH), Peter M. Abuja*



16:30 – 17:00 **State-of-the-art in standardized biobanking at the Graz Biobank** *Christian Güllly*
(MUG, Biobank Graz)

17:00 – 17:30 and 17:30 – 18:00 **Optional tours of the Graz Biobank**

17:00 End of Day 3

Thursday 14 May 2020

09:00 – 9:10 **Aims of day 4** *Peter M. Abuja*

09:10 – 09:40 **The CEN/ISO standards' common structure and tool for self-assessing whether a workflow is compliant with a particular standard** *Conny Stumptner (MUG, BBMRI.at)*

09:40 – 10:30 **Outline of the process of setting up a standard-compliant sample procurement scheme for biological sample** *Peter M. Abuja*

10:30 – 11:00 Coffee break

11:00 – 11:30 **Clinical implications of tissue sampling during surgery** *Prisca Pondorfer-Schaefer*
(Otorhinolaryngology MUG)

11:30 – 12:00 **Viewpoint of a clinical oncologist regarding liquid biopsy sampling** *Thomas Bauernhofer (Oncology, MUG)*

12:00 – 13:00 Lunch break

13:00 – 13:30 **Outside the laboratory: Implementation of the workflow in the clinics – preparations for patient inclusion and sample collection:** Use of flow diagrams, process slips *Peter M. Abuja*

13:30 – 13:45 **Outline of the use-case exercise** *Peter M. Abuja*

13:45 – 15:00 **Group exercise - Outside the laboratory: organizing the collection of samples at the clinic, transfer and storage of samples** *Peter M. Abuja, Lisa Oberauner-Wappis (CBmed), Christina Skofler (CBmed), Christine Ulz (CBmed)*

15:00 – 15:30 Coffee break



15:30 – 16:30 Discussion of exercise and summary of afternoon programme *Peter M. Abuja, Lisa Oberauner-Wappis, Christina Skofler, Christine Ulz*

16:30 – 17:00 Standardized workflow and documentation for the use-case *Peter M. Abuja, Lisa Oberauner-Wappis, Christina Skofler, Christine Ulz*

17:00 End of Day 4

Friday 15 May 2020

09:00 – 09:10 Recap of day 4 and aims of day 5 *Peter M. Abuja*

09:10 – 10:00 Recommendations for working with archived formalin-fixed paraffin embedded samples from clinical routine and quality control of nucleic acids prepared for NGS from fresh-frozen and fixed, paraffin embedded material *Daniela Pabst (MUG, EASI-Genomics) & Peter M. Abuja*

10:00 – 10:30 Coffee break

10:30 – 12:00 (Relocation to laboratory - 2 groups alternating)

Group demonstration - Inside the Laboratory: Demonstration of blood collection and sample workup for ccfDNA for NGS *Peter M. Abuja, Christine Ulz, Christina Skofler*

Group demonstration - Inside the Laboratory: Snap-freezing, documentation and storage of samples *Peter M. Abuja, Christine Ulz, Christina Skofler*

12:00 – 13:00 Lunch break

13:00 – 14:00 Discussion and open questions

14:00 End of workshop

