**IMI2 821520 - ConcePTION**

**ConcePTION**

**WP4 – Establishment of a non-commercial, Europe-wide breast milk biobank and analytical centre**

# D4.2 List with names and expertise of expert delegates group for BBMRI Technical committee

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| | Mikaela Magnusson (3 - Uppsala Biobank / UPPS) |
| | Peggy Gandia (21 – University Hospital of Toulousse / CHUT) |
| | Sara A. Paciga (43 – Pfizer Limited / Pfizer) |
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| | Matylda Czosnykowska-Lukacka (3rd party involved - Wroclaw Medical University) |
| | Ronny Baber (3rd party involved - University of Leipzig) |

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## Document History

| Version | Date | Description |
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| V final | 31 Mar 2020 | Final version |

## Abstract

As part of ConcePTION WP4, D4.1, standard operating procedures (SOPs) for sample handling of breast milk, serum and plasma were collected from the project partners and compared with specifications from the state-of-the-art literature. After the assessment of the workflows, a first version of a harmonised procedure for breastmilk collection was developed.

The generic document for sampling and processing breast milk and plasma samples (Collecting and processing milk samples_Draft1.0_dkaw09182019) covers the main processing steps at the clinical site, with the focus on the standardization of the pre-analytical and analytical management of breast milk, based on collection, processing steps, processing times, storage temperature, freeze-thaw-cycles and analytical method for the defined intended use.

A Technical committee will be established with the aim, to review, develop and finalize the standard documents (Standard Operating Procedures (SOPs), work instructions, templates, checklists, forms) with the focus on the standardized pre-analytical and analytical management of human breast milk and blood (see Figure 1). Regular committee meetings will be initiated and hosted and will take place via web-conferences and / or f2f project meetings.

The next step will be the further development of the generic document (Collecting and processing milk samples_Draft1.0_dkaw09182019). This document will be adapted to the intended use (e.g. clinical study and/or breast milk collection for biobanking purposes), defined by the project partner experts. Additional standardized documents will be drafted, reviewed and finalized, and they will be included in the Quality Management handbook for the breast milk biobank management system according to ISO 20387:2018 “General requirements for biobanking”.

## Expert delegates group for the BBMRI Technical committee consists of:

- Alice Panchaud Monnat, University of Lausanne (ULAUS);
- Hedvig Nordeng, University of Oslo (UOLS);
- John Jakubczak, Pfizer Limited (Pfizer);
- Matylda Czosnykowska-Lukacka, Wroclaw Medical University;
- Mikaela Magnusson, Uppsala Biobank (UPPS);
- Peggy Gandia, University Hospital of Toulousse (CHUT);
- Ronny Baber, University of Leipzig;
- Sara A. Paciga, Pfizer Limited (Pfizer);

- External expert(s):
    - Kerri Bertrand, UC San Diego

**Dr. Alice Panchaud**, PhD, is a **certified clinical pharmacist specializing in drug optimization during pregnancy and breastfeeding**[1], and a lecturer at various universities of Swiss Romandie. Her research interests focus primarily on the safety and efficacy of drugs during pregnancy and lactation using pharmacoepidemiologic and pharmacometric approaches. She is the initiator of the innovative concept of population pharmacokinetic modeling and simulation to assess the exposure of infants to drugs, which was awarded the Presidential Trainee Award and the David Goldstein Award by the American Society of Pharmacology and Therapeutics in 2009. This led to an ongoing multicenter observational study in Europe using this approach to assess breast milk antidepressant exposure and explain the variability associated with it. She is currently PD-MERclin at the University Hospital in Lausanne.

**Prof. Hedvig Nordeng's** expertise lies in **pharmacoepidemiology and pharmacotherapy for pregnant and nursing women[1].** She came to the School of Pharmacy at the University of Oslo in 2006 as an associate professor. In 2011 she became a professor of pharmacoepidemiology as area of expertise. Since 2005 she holds a position as a researcher at the Department of Child Health and Development at the Norwegian National Institute for Public Health. Dr. Nordeng is responsible for evaluating all drugs on the Norwegian marked with respect to breast milk transfer and recommendations about breast feeding in the Norwegian National Formulary. She has authored over 100 scientific articles, book chapters and national guidelines on drug use in pregnancy and lactation.

**Dr John Jakubczak**, is currently the director of the Pfizer Tissue Bank and Reagent Characterisation Group. In his current role, he leads a team responsible for **supporting the needs of research and development colleagues across Pfizer for human tissue access, human tissue biospecimen management, and for expertise in developing and characterizing the quality, function and specificity of reagent antibodies[1]**. Prior to his current role, Dr. Jakubczak served as a Translational Oncology lead on a number of clinical oncology teams at Pfizer, responsible for the development and execution of clinical biomarker studies for a number of Pfizer oncology medicines.

**Matylda Czosnykowska-Łukacka,** PhD, is currently an Assistant Professor at the Neonatology Department of the Wroclaw Medical University Regional and works as **a Human Milk Bank Coordinator in the University Hospital in Wroclaw in Neonatal Intensive Care Unit (NICU)[1].** The Regional Human Milk Bank in University Hospital in Wroclaw is a member of the Polish Biobanking Network. She has authored a number of publications on human breast milk as material for scientific purposes. Her expertise and experience in human milk and plasma collection at the polish biobank in Wroclaw Medical University will be an important input for ConcePTION.

**Mikaela Magnusson**, M.Sc., is currently working as a **project coordinator at the Uppsala Biobank**[1]. She has more than ten years of experience in various fields within the human health care sector, e. g. in biotech research, instrument development, project management within CRO and biotechnology. Over the past few years, she deepened her knowledge as a bioprocess scientist and research engineer at well-known companies in Sweden. Her contribution to ConcePTION lies in the development of documents for the sampling, transport and storage of blood and breast milk samples and in the development of the documents for the Quality Management System for the Breastmilk Biobank Analysis Centre in Uppsala.

**Prof. Dr Peggy Gandia**, PhD, is **specialized in pharmacokinetics and modelling (POP PK)[1]**. After being a resident pharmacist from 1997 to 2002 at Toulouse hospital, she obtained a PhD in Pharmacokinetics in Toulouse III University in 2003. From 2004 to 2011, she was both a Resident Doctor to the Laboratory of Pharmacokinetics and Toxicology (Toulouse Hospital), and Assistant Professor in the Department of Pharmacology (Faculty of Pharmacy, Toulouse). In 2011, she was both Hospital Practitioner and Assistant Professor. Since 2014, she has joined the UMR1436-INTHERES research team, whose theme focuses on all issues related to anti-infectious therapeutics (kinetic profiles, pharmacokinetic-pharmacodynamic relationships, dosage adjustments, resistances). Currently she is a professor in the department of Pharmacology at the Faculty of Pharmacy (Toulouse, France)

**Dr Ronny Baber**, M.Sc., is an expert at **DIN for ISO TC276 (Biobanking and Biotechnology) and an expert from the German accreditation body for ISO 20387: 2018[1].** Currently, he is head of the Leipzig Medical Biobank of the Medical Faculty of the University of Leipzig. Since 2017 he is the head of the LIFE-Biobank and Preanalytical Laboratory, which host a breastmilk collection from more than 1000 women. For ConcePTION he is involved in the drafting, reviewing and finalising of the

standardized documents describing the of pre-analytical workflows for the sampling and processing of human breast milk and blood.

**Sara Paciga**, MA, is currently the Head of Clinical Genetics & Biospecimens at Pfizer, a group whose remit includes oversight and accountability for the Pfizer biofluids BioBank. Both in the current role, and her prior role as Director of Clinical Genetics, she has focused on driving strategic utilisation of human biospecimens and providing access to clinical and genetic data to advance Pfizer's portfolios, including **contributing a key understanding of the policy, compliance, operational and scientific principles involved in biospecimen collection, storage and use**[1]. Since joining Pfizer in 2002, she held roles progressively increasing in scope in Pharmacogenomics, Genetics, and human biospecimen management.

**Kerri Bertrand,** MPH, is a Research Manager at UC San Diego, Department of Pediatrics, Division of Dysmorphology and Teratology. **She manages two large cohort studies focusing on pregnancy and lactation research**[1]**.** MotherToBaby CA is a large observational research study that focuses on the safety of medications and substances in pregnancy in relation to birth defects and neurodevelopment. Mommy's Milk is the first biorepository for human milk research in the United States. Mommy's Milk focuses on many aspects of human milk, including medication and substances during lactation. In addition, one of her research interests lies in marijuana use during lactation, specifically, if cannabinoids pass into breast milk and if these have an impact on the child development.

[1]Expertise of BBMRI Technical Committee

The BBMRI Technical Committee is an expert group that covers various areas of expertise of the ConcePTION consortium. Its aim is to develop standardized documents (Standard Operating Procedures (SOPs), work instructions, templates, checklists, forms) for the pre-examination processes for collecting and processing of samples (blood and breast milk) for the Breastmilk Biobank Analysis Centre in Uppsala.

The work of the BBMRI Technical committee can be summarized as following:

- Participation in meetings on a regular basis
- Review of literature to verify key processes and methods
- Sharing expertise in human breast milk and plasma collection and processing
- Review, development, and completion of standardized documents for the pre-analytical and analytical management of breast milk and blood processing, based on collection methods, processing steps, processing times, storage temperature, freeze-thaw-cycles and analytical methods for the defined intended use
- Review, development and completion of the documentation of the Quality Management System (QMS) for the Breastmilk Biobank Analysis Centre in Uppsala
- Complete tasks according to the workflow of the BBMRI Technical Committee (see Figure 1)

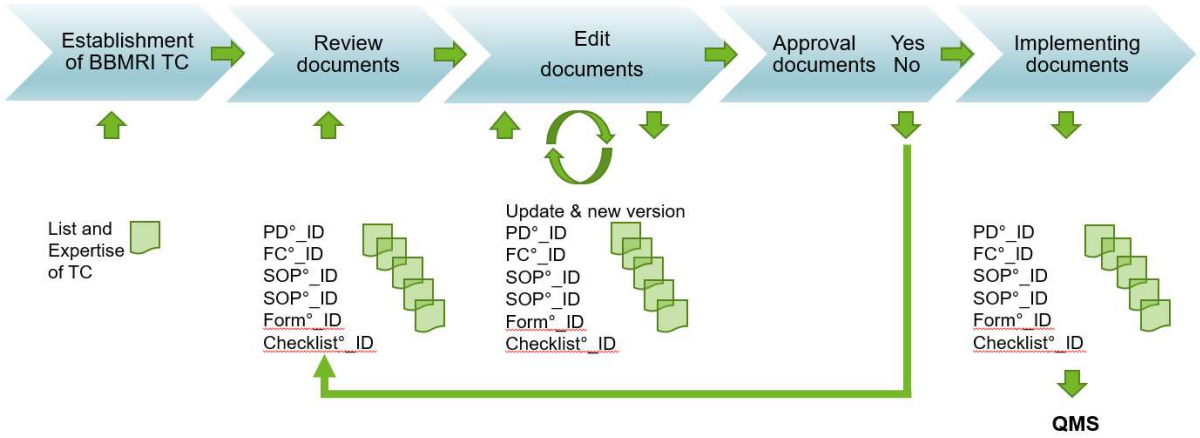


Figure 1: Workflow of the BBMRI Technical Committee

Legend:
TC = Technical Committee
PD = Process description
FC = Flowchart
SOP = Standard Operating Procedure
ID = Identification number
QMS = Quality Management System of Breastmilk Biobank Analysis Centre in Uppsala