AMENDMENT OF THE CORE WORK PROGRAMME 2017

Version 1.1

Prepared for the consideration of the AoM#9

11 April 2017

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This document is concerned with amendments to the Core Work Programme 2017. It contains European Commission approved H2020 projects and a new Workstream on the Code of Conduct.

Graz, 11 April 2017

Prof. Jan-Eric Litton, PhD

BBMRI-ERIC Director General
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INTRODUCTION

Since the approval of the Core Work Programme 2017 during the AoM’s 8th Session in November 2016 the European Commission has approved one COST Action which allows BBMRI-ERIC to join the consortium, namely CLINIMARK. Additionally, the work on the Code of Conduct advanced and requires specifications in a dedicated workstream. According to the Statutes Art 5 point 2 (c) and Art. 10 point 6 the AoM needs to approve income and as in the previous year herewith an Amendment to the Work Programme 2017 is put forward to the AoM for approval:
AMENDMENT TO ITEM 10 – PROJECTS ACTIVE

CLINIMARK: ‘Good biomarker practice’ to increase the number of clinically validated biomarkers

**Topic:** COST Action OC-2016-1  **Type of Action:** n.a.  **Duration:** 48 months

**Start Date:** 26/10/2016  **Grant Agreement Nr:** CA16113

**Website:** tbd

**Total requested Grant by Consortium:** € n.a.

**Total requested Grant by BBMRI-ERIC:** € no

**Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement:** none

**Benefit/tasks for BBMRI-ERIC: Coordinator** Erasmus MC, NL, (Theo M Luider)

BBMRI-ERIC participates in the Management Committee and will evaluate the inclusion of Expert Centres from the Biomarker field

**Abstract:** Thousands of circulating proteins have been shown to be hallmarks of emerging disease, response to treatment, or a patients’ prognosis. The identification of these small molecule biomarkers holds a great promise for significant improvement of personalized medicine based on simple blood tests. For instance, diagnosis and prognosis with biomarkers (e.g. carcinoembryonic antigen (CEA)) has significantly improved patient survival and decreased healthcare costs in colorectal cancer patients. Unfortunately, despite significant investments to increase the number of biomarker studies, only ~150 out of thousands of identified biomarkers have currently been implemented in clinical practice. This is mainly caused by the time-consuming process of reliably detecting biomarkers, the irreproducibility of studies that determine a biomarkers’ clinical value, and by a mismatch in studies that are performed by academia and what is required for regulatory and market approval. To increase the number of clinically validated biomarkers, rather than further increasing the number of biomarker discovery studies, CliniMARK will improve the quality and reproducibility of studies and establish a coherent biomarker development pipeline from discovery to market introduction.

CliniMARK aims to achieve said goal by creating a Best Biomarker Practice (BBP) community, which will provide guidance to:

1. Classify biomarkers according to their characteristics, anticipated clinical use, and their phase of development,

2. Select and validate appropriate research-grade biomarker detection tests,

3. Select appropriately designed studies and biological samples to reliably and reproducibly validate biomarkers clinically, and

4. Select and report on appropriate clinical data storage, biomarker data storage, data analysis protocols, privacy concerns, ethical issues, and statistical analysis methods.
List of Participants: BBMRI-ERIC, Ghent University, BE, University of Alberta, CA, Actelion Pharmaceuticals Ltd, Switzerland, Palacky University, Olomouc, CZ, Eberhard-Karls-Universität Tübingen, DE, Mosaiqes-Diagnostics, DE, Zellkraftwerk GmbH, DE, Center for Applied Medical Research, University of Navarra, SP, University of Tartu, ES, CEA Paris, FR, Firalis SAS, FR, LGC, UK, Biomedical Research Foundation Academy of Athens, GR, Biosystems International Kft, HU, Radbound University MC, NL, University of Groningen, NL, National Institute of Health Dr. Ricardo Jorge, PO, “Juliu Hatieganu” University of Medicine & Pharmacy, RU, Caprion Proteomics LLC, USA, Eurofins Central Laboratory, USA, The Cyprus Institute of Neurology and Genetics, CY
AMENDMENT TO ITEM 7 – OUTREACH

7.4. Workstream: Code of Conduct

As legal texts are not easily accessible to non-lawyers, the Code of Conduct on Processing of Personal Data for Purposes of Scientific Research in the Area of Health shall provide a practical means for implementing and complying to the GDPR. By developing codes of conduct that are as understandable as possible, we can help to guide researchers and administrative staff, reduce unnecessary fear about compliance and enhance data sharing for the sake of progress in research.¹ This requires the inclusion of relevant stakeholders in the drafting process (e.g., EFPIA, EMA, patient advocacy groups, DG Justice, etc.). The Code of Conduct shall apply to data controllers who process personal data for purposes of scientific research in the area of health, e.g. researchers and research institutions, biobanks, health databases/registries. Supported by the National Node Directors (Management Committee Meeting #16 in Trondheim), parting Director General Jan-Eric Litton shall continue as the leading person until the Code of Conduct is validated by the Commission in 2018.

7.4.1. Objectives

Purpose of the Code of Conduct:

- To contribute to the proper application of this Regulation, taking account of the specific features of processing personal data in the area of health;
- To clarify and specify certain rules of the GDPR for controllers who process personal data for purposes of scientific research in the area of health;
- To help demonstrate compliance by controllers and processors with the Regulation;
- To help foster transparency and trust in the use of personal data in the area of health research.

Building on excellent existing codes (e.g., RD-Connect or IMI Code of Practice), which were set up by research consortia and in the context of projects, thus having a limited reach and life-span. BBMRI-ERIC aims for consensus with other BMS RIs and stakeholders from academia, patient advocacy groups and academia to contribute to a code that is useful and widely supported in the field of health research. This would be an important step towards simplifying data exchange across Europe.

7.4.2. Expected Outcomes and Time Plan

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<th>Expected outcome</th>
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<td>3. Code of Conduct</td>
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7.4.3. Responsible Parties

- Headquarters: Director General (lead), Chief Policy Officer, Engagement Officer, Common Service ELSI (Task Force GDPR and Task Force Code of Conduct)
- National or Organisational Nodes: experts
- Projects: ADOPT BBMRI-ERIC (page 36), CORBEL (page 45), RD-Connect (page 70)
