European Network on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (*EUROMENE*)

COST action CA15111

Deliverable 4

Guidelines on ME/CFS biobank management and maintenance, catalogue synchronisation and integration with healthcare management systems (continuous updated)

In order to determine the current situation, the working group on epidemiology (WG1) designed a survey on the availability of biological sample collections on the European population with ME/CFS. This survey was filled out by members of EUROMENE reporting the availability of such samples in their countries. Table 1 presents a summary of such a survey. The main conclusions were:

1. The availability of biological sample collections on the European population with ME/CFS is scarce. Available samples are located in France, Germany, Italy, Norway, Spain, and the United Kingdom. *Further information available in Table 1 of the present deliverable and Minutes from the meeting in Riga (Latvia) in September 2016.*

2. When available, biological sample collections on the European population with ME/CFS lack of a standardised and synchronised approach (Table 1). *Further information available in Table 1 of the present deliverable and Minutes from the meeting in Riga (Latvia) in September 2016.*

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Table 1. Existing disease-specific biological sample collections within EUROMENE

Bio-resources features	Countries with collaborating institutions					
	Germany	Italy	Spain	Norway	France	UK
Number of donors with ME/CFS	500	100	1640	120	150	286
Number of donors in control groups	100	40	400 (FMS) 300 (Chronic pain) 300 (RA) 300 (MDD) 1250 (HC)	160 (healthy)	none	135 (healthy) 46 (multiple sclerosis) 46 (chronic fatigue non-ME/CFS)
Sample types	Blood	Blood Plasma FTA® DNA	Blood, urine, saliva	Blood, urine, saliva	Blood derivatives, CSF, urine	Blood derivatives
Data attached	Clinical data	Participation category (diagnosis)	>800 clinical, laboratory test results, and other variables	~700 clinical, laboratory test results and other variables	Diagnostic category	780 clinical laboratory test results and other variables at 2 time-points
Representativeness (care level)	Secondary care	Community	Community, primary, and tertiary outpatient care	Secondary care	Secondary care	Community, primary, secondary care
Representativeness Geography	Berlin Brandenburg	Lombardy/ North Italy	Barcelona, Granada and Valencia, Spain	Oslo	France	Greater London, East of England
Location	Berlin, Charité	Pavia University Laboratory	VHIR/Salamanca Hospital Valencia IBSP-CV Biobank Granada University	Oslo University Hospital	Henry Mondor University Hospital, Cretéil	Royal Free Hospital Biobank, London
Expertise of participating institution	Immunology	Molecular biology, genetics immunology	Genetics, Immunology, Mitochondrial metabolism, transcriptomic and proteomic biomarkers, epidemiology/ clinical research, database	Genetics, autoimmunity/ immunology	Genetics, Immunology, Clinical imaging	Immunology, genetics, epidemiology, clinical research
Sources of funding	Various	Patients Association	Local associations of affected patients, private donations, Spanish Biobank Networking (ISC-III, Madrid, Spain)	Oslo University Hospital	University, Patients Association, private donations	NIH, various NGOs, private donations
Charities and other institutions supporting the bioresource	Lost voices, MERUK	AMCFS	ESTEVE Foundation	No	PICRI program	MEA, MERUK, ME Trust

Note. Data and samples from the bioresources have been mainly used by the hosting research groups. The UK group have opened the UK ME/CFS Biobank to external researchers, and samples and data are available to be used in ethically and peer-reviewed approved studies, fees for cost-recovery applies.

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In addition to the survey, issues related to biobanking on ME/CFS have been discussed in three meetings of the management committee (MC) and the working group on epidemiology (WG1); Riga (Latvia) in September 2016, Barcelona in April 2017, and Belgrade in September 2017.

The main conclusions of these meetings were:

1. Biobanking on ME/CFS in Europe is of interest for addressing new questions. For instance, Elisa Oltra (Spain) has started a pilot study to assess differences on miRNAs between people with severe ME/CFS (n=15; i.e., cases) and non-ME/CFS people (n=15; i.e., controls) using a biological sample collection from the UK Cure-ME Biobank. *Further information is available in Minutes from the meeting in Barcelona (Spain), April 2017.*

2. Biobanking on ME/CFS in Europe ideally involves a specific donor program coupled with rapid collection and processing of biological sample collections, supplemented by comprehensive prospectively collected clinical, laboratory and self-assessment data from cases and matched controls. *Further information is available in Minutes from the meeting in Riga (Latvia), September 2016.*

3. Biobanking on ME/CFS in Europe is most efficient and cost-effective if it is incorporated into an existing biobank. *Further information is available in Minutes from the meeting in Riga (Latvia), September 2016.*

4. Successfully biobanking on ME/CFS in Europe requires careful consideration of logistic and technical issues, continuous consultation with patients and the donor population. *Further information is available in Minutes from the meeting in Riga (Latvia), September 2016.*

5. For biobanking on ME/CFS in Europe, a sustainable model of funding is required; ideally involving research councils, health services, and patient charities. *Further information is available in Minutes from the meeting in Riga (Latvia), September 2016.*

6. Given that biobanking on ME/CFS in Europe involves the exchange of human samples among the research teams, taking into account ethical, legal, and societal issues (ELSI) at both pan-European and national levels. *Further information is available in Minutes from the meeting in Belgrade (Serbia), September 2017.*

In line with our conclusions, **the agenda for the next meeting** of the management committee (MC) and the working group on epidemiology (WG1), which is planned for **September 2018 in London (UK)**, is as follows:

1. To show examples of good practices in biobanking. For instance, the Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium (BBMRI-ERIC). Website: http://www.bbmri-eric.eu/BBMRI-ERIC/about-us/

2. To define the vision of EUROMENE regarding biobanking on ME/CFS in Europe. Particular attention will be payed to biobank management and maintenance, catalogue synchronisation and integration with healthcare management systems.

3. According to the EUROMENE vision on biobanking, to design a chronogram to develop the stepped procedure to elaborate the EUROMENE guidelines on ME/CFS biobank management and maintenance, catalogue synchronisation and integration with healthcare management systems within the next 12 months.