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European Prevention of Alzheimer's Dementia Consortium

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D3.1 Inventory of Parent Cohorts as potential participants in EPAD

WP3 – Parent Cohorts and EPAD Register

V1.3

Final

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Description of the deliverable	This WP3 deliverable describes the existing Parent Cohorts that will be initially considered for inclusion into EPAD activities.
Key words	Parent Cohorts, National Leads, Fingerprinting, Catalogue, Inventory.

DOCUMENT HISTORY

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DEFINITIONS

- Partners of the EPAD Consortium are referred to herein according to the following codes:
  - **Janssen**. Janssen Pharmaceutica NV (Belgium)
  - **UEDIN**. The University of Edinburgh (United Kingdom)
  - **UOXF.** Masters and Scholars of the University of Oxford (United Kingdom)
  - **BBRC.** Barcelona Beta Brain Research Center (Spain)
  - **SYNAPSE.** Synapse Research Management Partners S.L (Spain)
  - **KI.** Karolinska Institutet (Sweden)
  - **VU-VUMC.** Stichting VU-VUmc (Netherlands)
  - **UCAM.** Masters and Scholars of the University of Cambridge (United Kingdom)
  - **MRC.** Medical Research Council (United Kingdom)
  - **BERRY.** Berry Consultants LLP (United Kingdom)
  - **UNIGE.** Université de Genève (Switzerland)
  - **RUMC.** Stichting Katholieke Universiteit (Netherlands)
  - **CU.** Cardiff University (United Kingdom)
  - **CHUT.** Centre Hospitalier Universitaire de Toulouse (France)
  - **QUINTILES.** Quintiles, Ltd (United Kingdom)
  - **AE.** Alzheimer Europe (Luxemburg)
  - **EMC.** Erasmus Universitair Medisch Centrum Rotterdam (Netherlands)
  - **APHP.** Hôpital de la Salpêtrière (France)
  - **INSERM.** Institut National de la Santé et de la Recherche Médicale (France)
  - **ULEIC.** University of Leicester (United Kingdom)
  - **IXICO.** IXICO Technologies Ltd (United Kingdom)
  - **ARACLON.** Araclon Biotech S.L (Spain)
  - **FRAUNHOFER.** Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e.V. (Germany)
  - **Eisai.** Eisai Inc (United States)
  - **SARD.** Sanofi-Aventis Recherche & Développement (France)
  - **NOV.** Novartis Pharma AG (Switzerland)
  - **BI.** Boehriger Ingelheim International GmbH (Germany)
  - **Eli Lilly.** Eli Lilly and Company Ltd (United Kingdom)
  - **HLU.** H. Lundbeck A/S (Denmark)
  - **Takeda EU.** Takeda Development Centre Europe Ltd (United Kingdom)
  - **AC Immune.** AC Immune SA (Switzerland)
  - **Biogen**. Biogen Idec, Inc (United States)
  - **Amgen.** Amgen NV (Belgium)
  - **Pfizer.** Pfizer Limited (United Kingdom)
  - **UCB.** UCB Biopharma SPRL (Belgium)
- **Grant Agreement.** The agreement signed between the beneficiaries and the IMI JU for the undertaking of the EPAD project (115736).
- **Project.** The sum of all activities carried out in the framework of the Grant Agreement.
- **Work plan.** Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- **Consortium.** The EPAD Consortium, comprising the above-mentioned legal entities.

- **Project Agreement.** Agreement concluded amongst EPAD participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **EMIF Project.** The EMIF project aims to develop a common information framework of patient-level data that will link up and facilitate access to diverse medical and research data sources, opening up new avenues of research for scientists. To provide a focus and guidance for the development of the framework, the project will focus initially on questions relating to obesity and Alzheimer's disease.
- **Fingerprint.** A set of Data Descriptors that characterize a database. These are created through responses to a questionnaire.
- **Catalogue.** Most precisely: the "EMIF Catalogue" is the central repository and user interface for publication, edition and consultation of Databases available in the EMIF Platform.

EXECUTIVE SUMMARY

The present document aims at describing the existing Parent Cohorts that will be initially considered for inclusion into EPAD activities. The EPAD National leads were contacted to provide the details of their Parent Cohorts within their region.

This deliverable belongs to activity 3.1 "Parent Cohorts identification, characterisation and selection", which aims at identifying those parent cohorts and registers (PCs) from which subjects can be selected for inclusion in the EPAD Virtual Register and potentially EPAD cohort and trial.

In a first step, Parent Cohorts closely linked to EPAD partners will be approached. Especially those already involved in EMIF-AD or the Dementia Platform UK (DPUK) will be leveraged[1]. In a concurrent step, additional Parent Cohorts not part of these studies from partners in EPAD will be used to identify subjects and supplement the EPAD Register as needed. These cohorts will be continuously identified by EPAD participants. Spontaneous proposals are also expected as EPAD reputation grows.

Fingerprint data will be accessed via the already existing EMIF Catalogue, which will be updated to meet EPAD fingerprint needs since not all variables needed are currently included in this catalogue. Both EMIF-AD and EMIF-Platform coordinators are partners in EPAD, facilitating access to the Catalogue and use for EPAD purposes.

WP3 will expand in the upcoming deliverables on the legal agreement templates to engage with Parent Cohorts (D3.2), cohort fingerprinting activities (D3.3) and the development of data discovery software to facilitate EPAD Cohort recruitment (D3.4).

[1] DPUK Cohort Characterization is an on-going process led by WP1 of DPUK and will be complete by end 2015. Collaboration with EPAD is not requested in this DPUK Work Package specifically, rather Cohorts are asked for their attitude to re-contact and access to any research in principle.

1. Introduction

The overall aim of WP3 "Parent Cohort and EPAD Register" is to screen subjects from ongoing Parent-Cohort (PC) studies for inclusion in the EPAD Register, which will be the source for selection into the EPAD Longitudinal Cohort Study (LCS) and the EPAD PoC Trial.

WP3 will integrate existing information from the numerous pre-existing PCs from across Europe in two steps. Step 1 involves the identification and profiling/fingerprinting of Parent Cohorts and step 2 consists of linking de-identified subject level data from within these cohorts to a data discovery software tool leading to a virtual register of ~24,000 subjects. Based on different access rights to the data discovery software tool, EPAD participants will remain blinded to subject IDs whereas Parent Cohort Research Teams will have access to their subject IDs. By doing so, EPAD will only know the number of potential subjects for the EPAD LCS and the Parent Cohort Research Team will have access to lists of subjects to invite for selection into the EPAD-LCS at the aligned Trial Delivery Centre.

2. Building of the potential Parent Cohort list

This deliverable 3.1 is the first list of Parent Cohorts proposed for inclusion into EPAD activities. National Leads who are WP3 members were asked to provide name and details of potential cohorts within their region. The information on PCs was provided in the excel template which included a list of first variables for the characterization of the PCs, the template used is accessible at TeamworkPM https://epadpm.teamwork.com/files/1680035.

This list will eventually be supplemented with new cohorts or cohorts not yet ready to participate at this stage. Thirty-one parent cohorts were identified from 11 countries (see Annex 1).

We have collected high-level information on the study design in order to pre-screen the cohort for eligibility for the EPAD Register. The inclusion criteria to continue to the fingerprinting at this stage are:

- Active cohorts with non-demented subjects aged 50+
- Willingness of cohort PI to provide subjects for EPAD
- Consent from subjects for re-contact or possibility to obtain consent to re-contact

3. Next steps: Legal agreements, Fingerprinting and Data discovery

In the next step we will collect detailed information on the cohorts using the tool developed in the EMIF Project[2] to create a catalogue of database fingerprints, called EMIF Catalogue.

The structure of the EMIF Catalogue will be updated to respond to the specific EPAD fingerprint needs, since not all the variables needed are currently included in this catalogue and some are redundant for EPAD's needs. A temporary adaptation for the EPAD project within the EMIF Catalogue will be ready in July and a final version is expected by end of September.

On the basis of this information cohorts will be selected for the registry. The results will be reported in D3.3 "Report on fingerprinting and selection of suitable Parent Cohorts" and thereafter deployed to all PCs.

[2] http://emif.eu/

Templates for legal agreements to facilitate Parent Cohort engagement have been also developed, which will be reported in deliverable D3.2.

Finally, data discovery software is under development in WP3 in order to facilitate detection of suitable subjects in Parent Cohorts that can be of interest for recruitment into the EPAD Cohort. A first report on such software will be reported in deliverable D3.4.

As an aid to the whole process, WP3 has been developing a 'FAQ' document that explains the different engagement steps with Parent Cohorts, and that is intended to be used by National Leads and WP3 representatives in order to initiate and develop transparent, mutually trusting relationships with Parent Cohorts.

The first cohorts to be considered will be [Country, Parent Cohort name, EPAD Nat. Lead][3]:

- Sweden Memory clinic Stockholm Miia Kivipelto
- UK PREVENT Craig Ritchie
- NL Amsterdam Philip Scheltens*
- Belgium Antwerp Sebastian Engelborghs*
- Spain ALFA (BBRC) José Luis Molinuevo
- France Toulouse see below* Bruno Vellas

* Already in EMIF catalogue

[3] The list may be updated as engagement with PCs proceeds, and it will be also reported in D3.3 "Report on fingerprinting selection of suitable Parent Cohorts"

ANNEXES

Annex I. List of Potential Parent Cohorts

Country	Name or site of Cohort	Principal investigator	Type of cohort	Age range	Interested in EPAD	Consent to recontact
Sweden	Memory Clinic Stockholm	Miia Kivipelto/ Laura Fratiglioni	Memory clinic based	50+	Yes	Yes
Finland	FINGER	Miia Kivipelto	Prevention trial	60-77	Yes	Yes
Finland	CAIDE	Miia Kivipelto	Observational study with subjects from the general population	70+	Unknown	Unknown
Denmark	DDRC	Steen Hasselbach	Memory clinic based	50-90	Yes	Yes
Norway	Register Oslo cohort	Nenad Bogdanovic	Memory clinic based	50+	Yes	Yes
UK	PREVENT	Craig Richie	Observational study with subjects from the general population	40-59	Yes	Yes
UK	Generation Scotland	David Porteous	Observational study with subjects from the general population	28-98	Unknown	Unknown
UK	UK Biobank - Lothian part and other parts	Cathie Sudlow/Rory Collins	Observational study with subjects from the general population	40-69	Yes	Yes
UK	DCR	Simon Lovestone	Memory clinic based	18+	Unknown	Unknown

Country	Name or site of Cohort	Principal investigator	Type of cohort	Age range	Interested in EPAD	Consent to recontact
UK	Whitehall II	Mika Kivimaki	Observational study with subjects from the general population	62-89	Unknown	Yes
UK	ELSA	Andrew Steptoe	Observational study with subjects from the general population	50+	Unknown	Unknown
UK	CFAS 2	Carol Brayne	Observational study with subjects from the general population	65-84	Unknown	Unknown
UK	CFAS	Carol Brayne	Observational study with subjects from the general population	65+	Unknown	Unknown
UK	CamCAN	Lorraine K Tyler	Observational study with subjects from the general population	18+	Unknown	Yes
UK	Brains for Dementia Research (Control Group)	Paul Francis	Observational study with subjects from the general population	Healthy 65+. MCI any age.	Unknown	Yes
Netherlands	Amsterdam	Philip Scheltens	Memory clinic based	18+	Yes	Yes
Belgium	Antwerp	Sebastian Engelborghs	Memory clinic based	18+	Yes	Yes

Country	Name or site of Cohort	Principal investigator	Type of cohort	Age range	Interested in EPAD	Consent to recontact
Spain	ALFA (BBRC)	José Luis Molinuevo	Observational study with subjects from the general population	45-75	Yes	Yes
Spain	CITA	Pablo Martínez-Lage	Observational study with subjects from the general population	45-75	Yes	Yes
Spain	Fundacion Reina Sofia	Miguel Medina	Observational study with subjects from the general population	70-85	Yes	Yes
Spain	Sant Pau	Alberto Lleó	Memory clinic based	45-80	Yes	Yes
Portugal	Coimbra	Catarina Oliveira	Memory clinic based	50-90	Unknown	Unknown
Portugal	Lisbon	Alexandre de Mendonça	Memory clinic based	70-85	Unknown	Unknown
Switzerland	Geneva	Panteleimon Giannakopoulos	Memory clinic based	50-90	Yes	Unknown
Switzerland	Zurich	Christoph Hock/Anton Gietl	Population Based	55-80	Yes	Unknown
Switzerland	Lausanne cohort 65+	Brigitte Santos-Eggimann	Observational study with subjects from the general population	65-81	Yes	Unknown
Switzerland	Bus Sante	Idris Guessous	Observational study with subjects from	30-75	Yes	Unknown

Country	Name or site of Cohort	Principal investigator	Type of cohort	Age range	Interested in EPAD	Consent to recontact
			the general population			
Switzerland	MentDis_ICF65+	Alessandra Canuto	Observational study with subjects from the general population	65-84	Yes	Unknown
Switzerland	Colaus/PsyCoLaus	Martin Preisig	Population Based	35-85	Yes	Unknown
France	Toulouse and related network **	Bruno Vellas	Prescreening memory clinic	50+	Yes	Yes

**Other partners in the French network are: Bordeaux, Dijon, Lille, Limoges, Lyon, Marseille, Montpellier, Nancy, Nantes, Paris –Broca, Paris Sud, Paris Nord, Rennes, and Strasbourg