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European Prevention of Alzheimer's Dementia Consortium
Grant Agreement n°115736

D4.10 - Start of quarterly EPAD Cohort recruitment update on EPAD website

WP4 – EPAD Cohort and EPAD Trials

V2.0

Final

Lead beneficiary: *Part.1 JPNV*
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DOCUMENT INFORMATION

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IMI Project officer	Elisabetta Vaudano (elisabetta.vaudano@imi.europa.eu)		

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Work package	WP4	Title	EPAD Cohort and EPAD Trials

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Authors (Partner)	Part.1 JPNV, Part.2 UEDIN & Part.5 Synapse		
Responsible Author	L. Steukers		Email lsteuker@its.jnj.com
	Partner	Part.1 JPNV	Phone +32 (0) 14 60 56 62

Description of the deliverable	This deliverable will report on how EPAD Cohort recruitment numbers are being disseminated to various stakeholders including the general public.
Key words	EPAD cohort; recruitment; website; general public; dissemination

Confidential Information (please indicate here if any sections contain confidential information and should NOT be made publically available)

Relevant Section(s)	N/A
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Does the Executive Summary contain confidential information	No
Can the Executive Summary be published online	Yes

¹ If "Other" type of dissemination level, please inform the PMO team (mgt@ep-ad.org) accordingly.

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NAME	DATE	VERSION	DESCRIPTION
L. Steukers	07/12/2016	1.0	First draft
PMO members	20/12/2016	1.1	Internal review
L. Steukers	02/01/2017	1.2	Review and changes
L. Ford/J. Georges/R. Milne	16/01/2017	1.3	Review and comments
L. Steukers	23/01/2017	1.4	Review and changes
L. Steukers	16/02/2017	2.0	Final version

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DEFINITIONS²

- 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.** BarcelonaBeta 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.** Boehringer 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 Limited (United Kingdom)
 - **Amgen.** Amgen NV (Belgium)
 - **Pfizer.** Pfizer Limited (United Kingdom)
 - **UCB.** UCB Biopharma SPRL (Belgium)
 - **ARIDHIA.** Aridhia Informatics Ltd (United Kingdom)
 - **ROCHE.** F. Hoffmann - La Roche (Switzerland)

² To be completed with terms and abbreviations related to the actual content of the document

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- **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.

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EXECUTIVE SUMMARY³

The European Prevention of Alzheimer's Dementia (EPAD) is a project to develop an environment for and then test multiple different interventions for the secondary prevention of Alzheimer's dementia. The EPAD project brings together 37 partners from academia, NGOs and the commercial sector. The EPAD Longitudinal Cohort Study (LCS) is a key component of the overall EPAD Project. Thousands of research participants will be recruited via the EPAD Register from Parent Cohorts across Europe into the EPAD LCS. Eligible research participants will be dementia free but showing risk factors for developing Alzheimer's dementia at the time of recruitment into EPAD LCS. The current vision is that the EPAD LCS will, after initial recruitment, maintain a constant sample size indefinitely. Research participants may leave the EPAD LCS due to withdrawn consent, entry into the EPAD Proof-of-Concept (PoC) Trial, entry into another clinical trial or whenever LCS research participant exclusion criteria are met. The current report describes how LCS enrolment numbers and information on overall progress is disseminated to various stakeholders. In order to adequately inform the public on overall progress, the EPAD website (<http://ep-ad.org/>) includes counters for active clinical sites and screened LCS research participants which are updated on a weekly basis.

³ Maximum 2,000 characters (including spaces).

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1. Introduction

The European Prevention of Alzheimer's Dementia (EPAD) is a project to develop an environment for and then test multiple different interventions for the secondary prevention of Alzheimer's dementia. The flow of research participants from the population at large to the trial is divided into 4 stages. Firstly EPAD will engage parent cohorts from across Europe who may have eligible research participants for secondary prevention studies. Second, approximately 24,000 individuals from these parent cohorts will be invited to join the EPAD register. These research participants may or may not have evidence of abnormal biomarkers. The third step is drawing research participants from the EPAD register into the EPAD Cohort (ie, the EPAD Longitudinal Cohort Study or EPAD LCS) to maintain a suitable cohort population of approximately 6,000 research participants for the longitudinal follow up. These research participants will have demonstrated positive evidence of abnormal biomarkers. Finally, research participants in the EPAD LCS, who satisfy inclusion and exclusion criteria, may be invited to enter the EPAD Proof of Concept trial for evaluation of treatments for the secondary prevention of Alzheimer's dementia. After initial screening, research participants will undergo yearly follow-up assessments.

The EPAD-LCS has four aims:

1. To be a readiness cohort for the EPAD Proof of Concept Trial
2. To provide biomarker, cognitive, clinical and risk factor data (including genetic data) for disease modelling work in a pre-dementia population.
3. To use disease models for risk stratification and thereafter research participant selection for the EPAD PoC Trial.
4. To provide run in, pre-randomisation data for the EPAD-PoC analysis at an individual level to allow for more powerful analyses of change following intervention with various agents in the EPAD PoC trial

2. EPAD Cohort recruitment numbers

2.1. Recruitment Reports from Quintiles database

Enrollment reports can be obtained through the imedidata (Medidata Rave) system. Partner Quintiles is making this tool available for the EPAD LCS. Different reports with adapted views/filters can be established depending on the needs of the stakeholder. The EPAD PMO identified the following 'customers' (in order of increasing level of detail in the reports):

- **EPAD Consortium/General Public/External Stakeholders** – Summary LCS recruitment report (see Figure 1) providing anonymized data on the number of research participants screened, the site and region and also the current status (screen failure, screened & participating, early termination). Individual EPAD partners can however request more details at any given stage about the LCS enrollment progress in EPAD.
- **EPAD Executive Committee (ExCom)** – Overall LCS Recruitment progress updates.
- **EPAD National Leads** – LCS Recruitment progress, recruitment/site, etc.

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- **EPAD Balancing Committee** – Fully detailed report on expected/current LCS recruitment, balance preclinical/prodromal, etc. to be used as planning tool.

Enrollment Report for EPAD_UoE_001 - Prod

02 Dec 2016

Site	Site Group	Status	# Subjects
BBRC	Spain/Portugal	Screen Failure	1
BBRC	Spain/Portugal	Screened	33
CHUT	France	Screened	7
UEDIN	Scotland/ROI	Early Termination	1
UEDIN	Scotland/ROI	Screen Failure	1
UEDIN	Scotland/ROI	Screened	22
VUMC	Benelux	Early Termination	1
VUMC	Benelux	Screen Failure	1
VUMC	Benelux	Screened	3

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Figure 1. Summary LCS Recruitment report

2.2. Website updates

The EPAD website was launched in September 2015 (<http://ep-ad.org/>). For more information, please read the section about the website in D6.2 Initial Report on communication tools and material (available in TeamworkPM at: <https://epadpm.teamwork.com/files/2288856?v=1>). The main aim of a website is to make information available in an easily accessible manner ('click and go'). Since initiation of the sites, clear visible counters on the home page have been included to provide information on the amount of Partner Institutions participating in EPAD but also on the amount of activated EPAD TDCs/clinical sites and screened EPAD LCS research participants. Since October 2016, weekly updates based on the enrollment numbers provided in the reports are included on the website by the EPAD Project Management Office (Figure 2).

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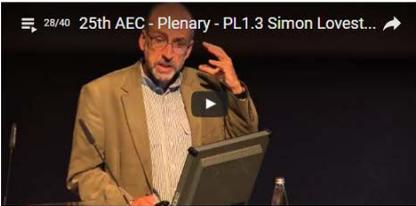


Welcome to EPAD

Collaborative research to better understand the early stages of Alzheimer's disease and prevent dementia before symptoms occur.

The EPAD project is part of a global effort in the fight against Alzheimer's disease and is a major European initiative to create a novel environment for testing numerous interventions targeted at the prevention of Alzheimer's dementia.

Watch Dr. Simon Lovestone explaining the IMI-EPAD project.




37
 Partnering Organizations


6
 Study Sites


122
 Research Participants

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Figure 2. Weekly updated counters on the EPAD public website

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PUBLIC SUMMARY⁴

The European Prevention of Alzheimer’s Dementia (EPAD) is a project to develop an environment for and then test multiple different interventions for the secondary prevention of Alzheimer’s dementia. The EPAD project brings together 37 partners from academia, NGOs and the commercial sector. The EPAD Longitudinal Cohort Study (LCS) is a key component of the overall EPAD Project. Thousands of research participants will be recruited via the EPAD Register from Parent Cohorts across Europe into the EPAD LCS. Eligible research participants will be dementia free but showing risk factors for developing Alzheimer’s dementia at the time of recruitment into EPAD LCS. The current vision is that the EPAD LCS will, after initial recruitment, maintain a constant sample size indefinitely. Research participants may leave the EPAD LCS due to withdrawn consent, entry into the EPAD Proof-of-Concept (PoC) Trial, entry into another clinical trial or whenever LCS research participant exclusion criteria are met. The current report describes how LCS enrolment numbers and information on overall progress is disseminated to various stakeholders. In order to adequately inform the public on overall progress, the EPAD website (<http://ep-ad.org/>) includes counters for active clinical sites and screened LCS research participants which are updated on a weekly basis.

⁴ This summary will be published on the EPAD website in case the Executive Summary cannot be published. In case the Executive Summary can be made publically available, you can simply copy/paste for the Public Summary.