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European Prevention of Alzheimer's Dementia Consortium

Grant Agreement nº115736

D7.1 Establishment of a Business Leadership Committee

WP7 – Business Model and Sustainability

Final-v.2

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1. DOCUMENT INFORMATION

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Description of the deliverable	The EPAD Business Leadership Committee (BLC), created in WP7, will work closely together with the ExCom and WP7 leads to advise on issues pertaining to engagement terms, intellectual property (IP), data use, regulatory strategy, sustainability models and other business matters. With respect to IP handling and regulatory matters, the BLC and WP7 members will work together with the respective committees to provide support.

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

2. DOCUMENT HISTORY

NAME	DATE	VERSION	DESCRIPTION
S. Ramasastry, J.L. Molinuevo, E. Molero, C. Díaz, F. Tennigkeit, B. Cooke	18/03/2015	1.0	First draft
S. van der Geyten	18/03/2015	1.0	Internal review
E. Molero	31/03/2015	2.0	Final Draft
Consortium review	09/04/2015	2.0	Final version

3. 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.** 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.** 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 (Grant Agreement n° 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.
- **ExCom.** Executive Committee
- **PMO.** Project Management Office

4. THE BUSINESS LEADERSHIP COMMITTEE

4.1. OVERVIEW

Summary
The mission of WP7 is to create an independent and sustainable plan for EPAD beyond the scope of the initial project. Additionally, WP7 will help configure a pre-competitive space for intellectual property rights coordination and associated business workflows to enable the consideration of Investigational Medicinal Products coming from different companies within the EPAD trial, including provisions for trial undertaking and other business matters.

Overview of the EPAD Business Leadership Committee
The EPAD Business Leadership Committee (BLC), created in WP7, will work closely together with the ExCom and WP7 leads to advise on issues pertaining to engagement terms, intellectual property (IP), data use, regulatory strategy, sustainability models and other business matters. With respect to IP handling and regulatory matters, the BLC and WP7 members will work together with the respective committees to provide support.

The BLC members are part of the internal EPAD community and belong to partner organizations. The BLC members are selected and appointed on an individual basis, based on their personal area of expertise. In that regard, they are not acting as representatives of their professional organizations.

The BLC is anticipated to be a flexible group that will evolve in membership and composition. As WP7 focuses on its initial deliverables (PPP benchmarking analysis and stakeholder analysis), the BLC will be a disciplined group of approximately 3 to 4 experts. As WP7 begins to focus on a formal business plan for sustainability, the BLC is envisioned to include 5 to 8 officers who are leaders in various disciplines including industry, academic projects, business development, clinical/scientific and legal. The BLC members will be asked to serve for one-year terms to allow for flexibility of the committee and diversity of perspectives.

Key Responsibilities of the BLC
- Serve as an expert advisory committee within WP7 in support of EPAD on business and sustainability issues that arise during the Project
- Help establish continuity throughout the Project and provide strategies that could be used after the initial term of the Project
- Engage and incorporate WP Leaders and other EPAD Participants into business discussions as appropriate
- Provide counsel and expertise in their respective fields to WP7 key deliverables
- Provide informal feedback on key WP7 deliverables
- Participate in annual workshops on business and sustainability topics (date TBD – potentially part of the General Assembly agenda)
- Time commitment: annual workshop and teleconferences as needed (estimated to be once per quarter).

Considerations
The BLC will serve as an advisory committee within WP7 that will aim to support EPAD leadership groups such as ExCom and the Legal & IP Committee. The BLC will not serve as

an autonomous decision making authority and nor will it be the primary resource for decision making within EPAD.

4.2. MEMBERS OF THE COMMITTEE

Calendar Year 2015

Analytics
Scott Berry (Berry Consultants)

Finance/Legal
Ben Cons (SVP, Strategic Planning, Quintiles)

Alliances/Foundation
Jean Georges (Alzheimer Europe)

Business/Industry
Andy Satlin (Eisai)

Clinical
Bruno Vellas (Universite de Paul Sabatier, Toulouse)

4.3. COMMITTEE BIOGRAPHIES

Scott Berry
Scott Berry is President and a Senior Statistical Scientist at Berry Consultants, LLC. He earned his MS and PhD in statistics from Carnegie Mellon University and was an Assistant Professor at Texas A&M University before co-founding Berry Consultants in 2000. He has led Berry Consultants to be widely regarded as the premier Bayesian consulting company in the world. Since 2000, he has been involved in the design of hundreds of Bayesian adaptive clinical trials of pharmaceuticals and medical devices and has become an opinion leader in the field of Bayesian adaptive clinical trials. Some of these trials have been groundbreaking trial designs, setting new standards for innovation and flexibility in trial design. These include the trials supporting the first fully Bayesian approval by the center for drug evaluation of the United States FDA (Pravastatin-Aspirin combination) and the statistical design for Time Magazine's #2 Medical Breakthrough of 2007 (Veridex's GeneSearch BLN Assay).

Ben Cons
Ben Cons, PhD, Senior Vice President Quintiles Corporate Development, structures and delivers managed partnerships with pharmaceutical and biotechnology industries. An innovative team leader, he is adept in developing partnership solutions between companies that realize value for all parties.

Dr. Cons joined Quintiles in 1996, bringing his expertise in pharmaceutical drug development and commercialization to drive corporate development goals.
Educated in the U.K., Dr. Cons acquired a bachelor's degree in biological sciences with honors from Portsmouth Polytechnic, and then continued his studies to earn a doctorate in molecular pharmacology within the physiology and pharmacology department of Southampton University.

Jean Georges
Jean Georges is the Executive Director of Alzheimer Europe. Before joining the organisation on 1 November 1996, he worked as a journalist and as a parliamentary assistant to members of the Luxembourg and European Parliament. His main duties in Alzheimer Europe include:

- support of the Board,
- liaison with the member organisations and other European umbrella organisations,
- personnel and financial issues,
- fundraising and
- overall project management of the various projects of the organisation.

In 2006, he was appointed as one of the two patient representatives on the Management Board of the European Medicines Agency and he is also a member of the Executive Committee of the European Patients' Forum.

Andy Satlin
Global Head of Clinical Development for Neuroscience and General Medicine Product Creation Unit at Eisai, responsible for clinical development plans, biomarker strategies, and operational excellence of all global drug development projects. Currently working on innovative amyloid-based approaches to Alzheimer's disease using a novel, Bayesian adaptive design to improve success and mitigate the risks of Phase 2 studies. Graduate of Yale University and Harvard Medical School, trained in psychiatry and geriatric psychiatry at McLean Hospital in Massachusetts. Board-certified in psychiatry by the American Board of Psychiatry and Neurology. Previous pharmaceutical industry experience running a company-wide Protocol Review Committee and serving as Global Head of Regulatory Affairs for Neuroscience at Novartis.

Bruno Vellas
Bruno Vellas, MD, PhD, is past President of the International Association of Gerontology and Geriatrics (a non-governmental organization recognised by the United Nations), president of the IAGG Global Aging Research Network, and founder of the European Alzheimer Disease Consortium (funded by the European Community). He coordinates numerous scientific responsibilities at both national and international level (i.e., research projects and scientific task forces) in the field of Alzheimer's disease. He is main associate Editor of the Journal of Prevention of Alzheimer's Disease (J.P.A.D)

4.4. APPOINTMENT PROCESS

- Immediately following EPAD's kickoff, the WP7 team convened to discuss potential candidates for the BLC in terms of contributing to the WP7 tasks and the overall consortium.
- WP7 created a short list of candidates across disciplines and expertise during January 2015.
- During February 2015, WP7 finalized the structure and short list of potential candidates. This was based on the immediate needs and deliverables for 2015.
- This plan and list was submitted to EPAD Steering Committee on February 17, 2015.
- EPAD Steering Committee approval and endorsement received on February 24, 2015.
- Invitations extended to BLC candidates immediately after approval.
- All candidates confirmed by March 1, 2015.

4.5. NEXT STEPS

The WP7 team will conduct an orientation teleconference for the BLC in early April 2015. The goals of the meeting will be to align expectations and initiate preliminary brainstorming on *D7.2 Study of Public Private Partnerships* and *D7.3 Stakeholder Analysis and Regulatory Challenges*. As a follow up to the initial session, a formal workshop to discuss the D7.2 and D7.3 will be conducted during the General Assembly in May 2015.