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

D1.4 Scientific report on compound inclusion for trial

WP1 – Scientific Challenges

V1.0

Final

Lead beneficiary: *UOXF*

Date: *12/07/2016*

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DOCUMENT INFORMATION


Grant Agreement Number	115736	Acronym	EPAD
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Project URL	www.ep-ad.org		
IMI Project officer	Elisabetta Vaudano (elisabetta.vaudano@imi.europa.eu)		

Deliverable	D1.4	Title	Scientific report on compound inclusion for trial
Work package	WP1	Title	Scientific Challenges

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Nature	Report <input checked="" type="checkbox"/> Prototype <input type="checkbox"/> Other <input type="checkbox"/>			
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Description of the deliverable	Report updating the CCSC process flow, progress made towards the development of the virtual pipeline, and an overview of the interventions that are under consideration by the Candidate Selection Committee.
Key words	EPAD, Clinical Candidate Selection Committee, Virtual Pipeline, PoC, Interventions

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DOCUMENT HISTORY

Name	Date	Version	Description
David Ruvolo & Sindhuja Musku	11/03/2016	0.1	Draft Completed
Andrew Satlin	16/03/2016	0.2	Revisions
David Ruvolo & Sindhuja Musku	17/03/2016	0.3	Incorporation of feedback & submission to EPAD PMO; Submission to EPAD PM for Review
EPAD Members	21/03/2016 to 12/04/2016	---	Independent Review Process
David Ruvolo & Sindhuja Musku	12/04/2016	0.4	Incorporation of feedback
Andrew Satlin	12/04/2016	0.4.1	Review v0.4.
David Ruvolo & Sindhuja Musku	13/04/2016	0.5	Further revisions (if applicable); submission to EPAD PMO for review
EPAD Members	01/07/2016	---	EPAD Open Review
David Ruvolo & Sindhuja Musku	11/07/2016	0.6	Incorporation of feedback.
Andrew Satlin	11/07/2016	---	Review of v0.6
David Ruvolo & Sindhuja Musku	11/07/2016	1.0	Further revisions (if applicable); publish and submit final document to EPAD PMO

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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.** 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 (Luxembourg)
 - **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)
- **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.


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- **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.

ABBREVIATIONS

Abbreviations used throughout the document are listed in the table below.

- **CCSC.** Clinical Candidate Selection Committee
- **CDG.** Clinical Development Group
- **CSC.** Candidate Selection Criteria committee
- **EFPIA.** European Federation of Pharmaceutical Industries and Associations
- **LCS.** Longitudinal Cohort Study
- **PoC.** Proof of Concept
- **SAG(s).** Scientific Advisory Group(s)
- **VP.** Virtual Pipeline Committee
- **WPx.** Work Package *number* (ex: WP1, WP2, etc.)

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EXECUTIVE SUMMARY

The objective of this document is to present deliverable 1.4 (D1.4)— “Scientific report on compound inclusion for trial” — developed by the Clinical Candidate Selection Committee. The purpose of this document is to report on the work done by the Virtual Pipeline (VP) and Candidate Selection Criteria (CSC) subcommittees of the Clinical Candidate Selection Committee (CCSC), and to describe the composition, and list the members, of the CCSC group that will perform the actual evaluation and selection of interventions nominated for inclusion in the EPAD PoC. The time range of this report is from the beginning of the preliminary solicitation process in December 2015 through March 2016. It should be noted that interventions listed in this report are subject to change as information regarding the interventions (i.e., suitability, intervention review using the scoring guide, discussion with CCSC selection committee, etc.) occur.

D1.4 is an extension of D1.2. In D1.2¹, the CCSC presented the guidelines (CCSC compound selection criteria) and the process for selecting potential interventions for use in the Proof of Concept (PoC) trial (CCSC process flow), which will utilize the evaluative measures presented in D1.1² and more recently modified in D1.3³.

This document comprises three sections:

1. The first section presents an update on the CCSC process flow.
2. Section two lists Candidate Selection Committee members who will perform the actual evaluations and selections.
3. The last section reports on the progress made toward the development of the virtual pipeline.

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1. Update on the CCSC Process Flow

The purpose of the Process Flow, originally presented in D1.2, is to ensure a procedure for the solicitation, nomination, and the selection of interventions for use in the PoC.

Table 1. Update on the Process Flow by Item as of March 2016

No.	Description	Status	Notes
1	Solicitation for Potential Interventions	In progress	First wave of materials were sent in December 2015*
2	Review of Preliminary Interventions (Solicited)	In progress	Review of returned questionnaires (total of 7) and discussions with nominators of suitable interventions are scheduled
3	Review of Potential Interventions (Unsolicited)	In progress	1 company expressed interest in nominating an intervention. CCSC materials were sent and awaiting further information
4	CCSC Meets with Owners of Potential Interventions	In progress	Several meetings have occurred with interested companies to further discuss the EPAD project and suitability of their intervention
5	Notification of the EPAD CDG	-----	-----
6	Confidentiality Agreements in Place	In progress	For those companies who are expected to go for CCSC review, CDAs are being prepared and signed by committee members
7	Development of the Virtual Pipeline	In progress	Tracking database developed, which will be updated as companies express interest
8	Submission of Nomination Form	-----	-----
9	CCSC Preliminary Review	-----	-----
10	CCSC Full Review	-----	-----
11	EPAD Appendix/Amendment Reviewed and Approved	-----	-----
12	Appendix & Amendment Drafted	-----	-----
13	PoC Trial Begins	-----	Sep/Oct 2017 (as per DoW)

*See table 3 for current status of the Virtual Pipeline

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2. Members of the CCSC

As stated in D1.2, “The actual evaluation and selection of nominated interventions, which comprises the ongoing executive function of the group, will be conducted by the formally constituted CCSC with membership as prescribed in the Project Agreement” (see note 1). The group is responsible for the actual evaluations and selection of potential interventions. This group consists of six members: 2 from non-EFPIA EPAD partners; one representing EFPIA (as an industry representative but not as a member of an EFPIA company); one EMA observer (non-voting role); one external independent observer (non-voting role); and one representing the owner of the nominated intervention. The current composition of the group is listed in the following table. These members are committed to serving for one year; subsequently, they may elect to continue, or other representatives of the prescribed groups will be selected. In its first official meeting, the group will select a chairperson. To the extent that a discussion will take place or decision will be made concerning a non-IMP related matter, the Clinical Candidate Selection Committee will also consist of one representative with voting rights from an EFPIA Participant (currently designated as Andrew Satlin, Eisai, member of the EPAD Executive Committee).

*Table 2. Core Members of the Nomination Committee**

No.	Name	Role
1.	Philip Scheltens	EPAD Member
2.	Craig Ritchie	EPAD Member
3.	Richard Bergstrom	EFPIA Director General (i.e., industry representative)
4.	Maria Isaac	EMA Representative (non-voting)
5.	Chas Bountra	Independent Observer, Academia (non-voting)


*Note: The sixth member of the committee will always be a representative of the nominating company.

3. Development of the Virtual Pipeline

Preliminary Solicitation materials (i.e., CCSC FAQ document, EPAD Value Proposition Slides, and CCSC Process Flow) were sent to potential nominators in December 2015. Table 3 presents a snapshot of the current progress of the development of the Virtual Pipeline (VP) as of March 2016. Currently, there are five interventions being discussed as potential nominations.

Table 3. Status of the Virtual Pipeline

Category	Cases
General Interest & In Further Discussion	5
No Plans to Submit or No Available Intervention	4

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Notes

¹ Deliverable 1.2 – <https://epadpm.teamwork.com/files/2141396>

² Deliverable 1.1 – <https://epadpm.teamwork.com/files/1885537>

³ Deliverable 1.3 – <https://epadpm.teamwork.com/files/2243376>