Models of Patient Engagement for Alzheimer’s Disease (MOPEAD): a European project to move Alzheimer’s disease towards an early diagnosis

Laura Campo, MOPEAD Project Leader
Eli Lilly and Company Ltd (EFPIA)

Mercè Boada, MD, PhD. MOPEAD Project
Chief Medical Officer, Fundació ACE, Barcelona, Spain
What is its reason for MOPEAD being?

To better understand the obstacles to engagement patients for early diagnosis and treatment.

To establish successful strategies to overcome them.

To propose recommendations and guidelines.
Our aim: develop a path towards remaining normal

Improving **timely diagnosis** through citizens’ participation

Raising awareness of **HIDDEN** persons with cognitive decline

Provide strategies to plan actions aimed at **early detection**
MOPEAD: Generate data & share knowledge

Optimal phenotype diagnosis of AD

Optimal etiological diagnosis of AD

Figure 1: Alzheimer’s disease-type dementia survival probability by the IWG-1, IWG-2 and NIA-AA criteria. The graphs represent the Alzheimer’s disease-type dementia survival probability according to the IWG-1 (left), IWG-2 (middle), and NIA-AA (right criteria), adjusted for age, gender, education and center. IWG-1: The group without presodal Alzheimer’s disease represents subjects without memory

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<table>
<thead>
<tr>
<th>Partner</th>
<th>Country</th>
<th>Type of institution</th>
<th>Leader</th>
<th>Activities</th>
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<td>Fundació ACE</td>
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<td>Academic and clinical center</td>
<td>Mercè Boada</td>
<td>Management, clinical core, analysis, and dissemination</td>
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<td>Laura Campo</td>
<td>Management, clinical core, analysis, and dissemination</td>
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<td>Frank Jessen</td>
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<td>Vall d’Hebron Research Institute</td>
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<td>Clinical core (Run 4)</td>
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<td>Luxembourg</td>
<td>Patient organization</td>
<td>Jean Georges</td>
<td>Management and dissemination</td>
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4 different scenarios to engage citizens at risk of Alzheimer’s disease (pre-screening)

- Neuropsychological online test
- Neuropsychological test conducted at a memory clinic
- Neuropsychological test carried out by a general practitioner
- Neuropsychological test given to patients diagnosed with type 2 diabetes by a specialist

Kick-off: October 2016
End: December 2019

3 years

2,000 participants (65-85 years old)
MOPEAD works like a funnel

PRE-SCREENING
2000 participants

SCREENING
660 participants

Common protocol for evaluation CSF profiles, MRI and APOE, besides clinical diagnosis

WP3

Run 1
Open House Initiative
Open House campaigns

Run 2
Primary care-based patient engagement
GPs/Health Centers

Run 3
Tertiary care-based patient engagement
Type 2 diabetic patients

Run 4
Face-to-face Models

Dissemination (WP5)

Online Models
AD Citizen Science
Public engagement
online forms and documentation

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Screening models for recruitment
- Online citizen science platform
- Open house initiative @ memory clinics
- Primary care physician
- Diabetologist clinic

Common diagnostic protocol
- Establish diagnosis according to international criteria and validate previous screening stage

Data analysis
- Build models of effectiveness and cost efficiency of each patient engagement strategy and compare across centers and countries

Dissemination
- Distribute and advocate patient engagement models for their broader application

IMI-EFPIA
MOPEAD
Cronogram & Activities

2018
May
Recruitment
10 months

Common diagnostic protocol
11 months

2019
Jan
March
May
Oct.
Dec.

Data analysis
8 months

Dissemination
3 months

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WP2: Pre-screening process (2000 participants)

Four different protocols. Each Run has its own specific protocol.

AD Citizen Science
- Inform consent
- Demographics
- CANTAB-sub test
- Total: 500 subjects
  - 100 per country

Open House Initiative
- Inform consent
- Demographics, MMSE, SCD/3 Questions
- FCSRT
- HAD scale
- Total: 500 subjects
  - 100 per country

Primary Care Campaign
- Inform consent
- Demographics, Clinical anamnesis
- MMSE, SCD/3 Questions
- CAIDE Risk Score
- Total: 500 subjects
  - 100 per country

T2DM Campaign
- Inform consent
- Demographics
- Clinical anamnesis
- MMSE, SCD/3 Questions
- Diabetes-specific Dementia Risk Score (DSDRS)
- Total: 500 subjects
  - 100 per country

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**WP3: Screening process (660 participants)**

Using established full diagnostic protocol to **detect patients at risk of AD**

**Neurological assessment**
- Anamnesis (reliable informant)
- Physical examination & **CDR-SB**

**Neuropsychological assessment**
- Comprehensive neuropsychological battery & **R-BANS**

**Consensus clinical diagnosis: Optimal phenotype diagnosis**
- Dementia
- **Mild cognitive impairment**
- No cognitive impairment

**Biomarker: Optimal etiological diagnosis**
- Dementia due to/not due to AD
- **MCI due to/not due to AD**
- Control or SCD due to/not due to preclinical AD

**MRI**
- Blood test
- Genetic

**CSF (IC)**
Strategies to evaluate efficiency of MOPEAD (WP4)

Data Management Plan Overview

- **Input:**
  - data from individuals

- **Output:**
  - results of the project

Roles, responsibilities and purpose of data collection

- Data Owner
- Data Custodian
- Data Processors
- Purpose of data collection
  - Data transfer
  - Data access
  - Data storage and preservation

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Subjects included up to today

<table>
<thead>
<tr>
<th></th>
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<th>Total WP3</th>
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<td>87</td>
</tr>
<tr>
<td>RUN2</td>
<td>661</td>
<td>155</td>
</tr>
<tr>
<td>RUN 3</td>
<td>435</td>
<td>94</td>
</tr>
<tr>
<td>RUN 4</td>
<td>264</td>
<td>56</td>
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<tr>
<td>Total</td>
<td>2,847</td>
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29%
### MRI final status

**MRI: Expected (660) and Performed (400/60%)**

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<th></th>
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<th>Netherlands</th>
<th>Slovenia</th>
<th>Spain</th>
<th>Sweden</th>
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<td>1</td>
<td>15</td>
<td>33</td>
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<td>55</td>
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<td>46</td>
<td>61</td>
<td>95</td>
<td>129</td>
<td>69</td>
<td>400</td>
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### CSF final status

**CSF: Expected (396/660/60%) and performed (144/660/22%)**

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<th>Slovenia</th>
<th>Spain</th>
<th>Sweden</th>
<th>ALL SITES</th>
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<td>1 (6%)</td>
<td>23 (64.71%)</td>
<td>3 (9.7%)</td>
<td>12 (60%)</td>
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<tr>
<td>RUN2</td>
<td>4 (11.76%)</td>
<td>14 (45%)</td>
<td>18 (51.43%)</td>
<td>11 (33.3%)</td>
<td>18 (64.3%)</td>
<td>65</td>
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<tr>
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<td>6 (23%)</td>
<td>6 (35.30%)</td>
<td>6 (18.7%)</td>
<td>9 (47.4%)</td>
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<td>1 (100%)</td>
<td>8 (44.44%)</td>
<td>3 (9.1%)</td>
<td>0 (0%)</td>
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<td>Total</td>
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<td>55</td>
<td>23</td>
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# MOPEAD Participation RUN 1

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<th>Pre-screened Positive</th>
<th>Pre-screened Positive/%</th>
<th>Evaluated WP3</th>
<th>Evaluated WP3/%</th>
<th>Evaluated vs positive/%</th>
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<td>50.00%</td>
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<td>528</td>
<td>161</td>
<td>30.49%</td>
<td>31</td>
<td>5.87%</td>
<td>19.25%</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>140</td>
<td>63</td>
<td>45.00%</td>
<td>6</td>
<td>4.29%</td>
<td>9.52%</td>
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<tr>
<td>Slovenia</td>
<td>125</td>
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<td>32.00%</td>
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<td>32.50%</td>
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<tr>
<td>Sweden</td>
<td>653</td>
<td>140</td>
<td>21.44%</td>
<td>31</td>
<td>4.75%</td>
<td>22.14%</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>1487</strong></td>
<td><strong>416</strong></td>
<td><strong>27.98%</strong></td>
<td><strong>87</strong></td>
<td><strong>5.85%</strong></td>
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## MOPEAD Participation RUN 2

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<th>Evaluated WP3</th>
<th>% Evaluated WP3</th>
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<td>19.10%</td>
<td>70.83%</td>
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<tr>
<td>Spain</td>
<td>101</td>
<td>39</td>
<td>38.61%</td>
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<td>84.62%</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>181</td>
<td>54</td>
<td>29.83%</td>
<td>33</td>
<td>18.23%</td>
<td>61.11%</td>
</tr>
<tr>
<td>Slovenia</td>
<td>118</td>
<td>30</td>
<td>25.42%</td>
<td>22</td>
<td>18.64%</td>
<td>73.33%</td>
</tr>
<tr>
<td>Sweden</td>
<td>83</td>
<td>47</td>
<td>56.63%</td>
<td>33</td>
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<td>70.21%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>661</strong></td>
<td><strong>218</strong></td>
<td><strong>32.98%</strong></td>
<td><strong>155</strong></td>
<td><strong>23.45%</strong></td>
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### MOPEAD Participation RUN 3

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<td>51.95%</td>
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<td>57.50%</td>
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<td>Slovenia</td>
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<tr>
<td>Sweden</td>
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<td>55.38%</td>
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<td><strong>Total</strong></td>
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<td><strong>188</strong></td>
<td><strong>43.22%</strong></td>
<td><strong>94</strong></td>
<td><strong>21.61%</strong></td>
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### MOPEAD Participation RUN 4

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<th>Evaluated WP3</th>
<th>% Evaluated WP3</th>
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<tr>
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<tr>
<td><strong>Total</strong></td>
<td><strong>264</strong></td>
<td><strong>150</strong></td>
<td><strong>56.82%</strong></td>
<td><strong>56</strong></td>
<td><strong>21.21%</strong></td>
<td><strong>37.33%</strong></td>
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RUN 1

**Global statement:** Less harmonic run among the sites. Highly variable between countries. Ethic committees delayed their approval in some countries due to the complexity of citizen science keeping confidentiality of the personal data. The NPS tool seems to be appropriate to reach the clinical objective.
Run 2

**Global statement:** Run 2 was the easiest to implement and to deal with. The advertising campaign was useful to attract motivated participants. In our experience little effort was enough to attract participants.

**Feedback by the patients:** The majority of participants classified as positive in the pre-screening were willing to complete the diagnosis in WP3.

**Feedback from the memory unit professionals:** Methodology and logistics were easy to understand and fits quickly into daily practice. They could adapt it at their specific logistics in each site’s facilities.
RUN 3

**Global statement:** Differences were established by different public health systems, different cultures and the memory clinics organization.

**Feedback from the patients:** Diagnostic procedures such as cognitive testing, MRI or LP are rejected by a part of this population. They find this test too long or invasive.

**Feedback by the PCP/GP:** No time, no treatment available and are not interested in training.
MOPEAD Closing remarks

Run 4

**Global statement:** Different approaches to patients with T2DM and complex and diverse relations between memory clinics and tertiary endocrinology units.

**Feedback by the patients:** Pluripathologic patients with severe diseases, not wanting to be diagnosed with more diseases. They refuse lumbar punctions.

**Feedback from the endocrinologists:** Lack of information and training about cognitive decline, low motivation to manage both entities as a unique public health issue.
MOPEAD Closing remarks

✓ MOPEAD has been created to be an open access study to use its data bank for academics, researchers, stakeholders, patients associations and pharma industry.

✓ MOPEAD has as its fundamental objective to build synergies with other IMI projects in order to reduce time and cost for professionals and institutions.

✓ As a **proof concept** study
  ✓ it is a reproducible model through European countries.
  ✓ it has the flexibility to be applied and adapted to the specific characteristics of the public health system.
  ✓ it is a model that could settle educational plans addressed at health professionals and civil society.
See you in BCN-PIT 2020!
## RUN2-Open House

<table>
<thead>
<tr>
<th>RUN2</th>
<th>Pre-screened</th>
<th>Positive</th>
<th>%</th>
<th>Evaluated in WP3</th>
<th>%</th>
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<td>26.97%</td>
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<td>19.10%</td>
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<td>Boada</td>
<td>101</td>
<td>39</td>
<td>38.61%</td>
<td>33</td>
<td>32.67%</td>
</tr>
<tr>
<td>Visier</td>
<td>181</td>
<td>54</td>
<td>29.83%</td>
<td>33</td>
<td>18.23%</td>
</tr>
<tr>
<td>Kramberger</td>
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<tr>
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<td><strong>155</strong></td>
<td><strong>23.45%</strong></td>
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## RUN2- Open House

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<tr>
<th>RUN2</th>
<th>% evaluated vs positive</th>
<th>Diagnosed with MCI or Dementia</th>
<th>%</th>
<th>% Diagnosed with MCI or Dementia Vs Evaluated</th>
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<tbody>
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<td>70,83%</td>
<td>19</td>
<td>10,67%</td>
<td>55,88%</td>
</tr>
<tr>
<td>ES</td>
<td>84,62%</td>
<td>32</td>
<td>31,68%</td>
<td>96,97%</td>
</tr>
<tr>
<td>NL</td>
<td>61,11%</td>
<td>1</td>
<td>0,55%</td>
<td>3,03%</td>
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<td>73,33%</td>
<td>17</td>
<td>14,41%</td>
<td>77,27%</td>
</tr>
<tr>
<td>SI</td>
<td>70,21%</td>
<td>13</td>
<td>15,66%</td>
<td>39,39%</td>
</tr>
<tr>
<td>Total</td>
<td>71,10%</td>
<td>82</td>
<td>12,41%</td>
<td>52,90%</td>
</tr>
</tbody>
</table>
Demographics Information
Participation by gender and age RUN 1 - Global

Total pre-screened: 1487
Total evaluated: 87

Participation
MALE 40.69%
FEMALE 59.31%

Participants evaluated
Age group
Male Female
[85+] 0 0
[75-85] 20 10
[70-75] 10 20
[65-70] 0 0

48.91% FEMALE
1.09% MALE
Total pre-screened: 1487
Total evaluated: 87

Participation by gender and age RUN 1 - Global

Participation:
- MALE: 40.69%
- FEMALE: 59.31%

Participants evaluated:
- Age Group:
  - [75-85]: Male, Female
  - [70-75]: Male, Female
  - [65-70]: Male, Female

Gender distribution:
- MALE: 48.91%
- FEMALE: 51.09%
Participation by gender and age RUN 2 - Global

Total pre-screened: 661
Total evaluated: 155

Note: age of people with unknown gender was not taken into account.
Participation by gender and age RUN 3 - Global

Total pre-screened: 435

Total evaluated: 94

Note: age of people with unknown gender was not taken into account.
Participation by gender and age RUN 4 - Global

- Total pre-screened: 264
- Total evaluated: 56

Participation:
- Male: 56.06%
- Female: 43.94%

Participants evaluated by age group:
- [85+]: Male 10, Female 16
- [75-85]: Male 10, Female 16
- [65-75]: Male 10, Female 16
- [65-70]: Male 10, Female 16

Total evaluated:
- Male: 57.14%
- Female: 42.86%
The MOPEAD project: Advancing patient engagement for the detection of “hidden” undiagnosed cases of Alzheimer’s disease in the community

Octavio Rodríguez-Gómez, Adrián Rodrigo, Fátima Iradier, Miguel A. Santos-Santos, Hans Hundemer, Andreea Ciudin, Lena Sannemann, Marissa Zwan, Bridget Glaysher, Anders Wimo, Jaka Bonn, Gunilla Johansson, Isabel Rodriguez, Montse Alegret, Dianne Gove, Susana Pino, Paloma Trigueros, Mia Kivipelto, Brandy Mathews, Antonio Ciudad, Daniel Ferreira, Christophe Bintener, Miren Guruchaga, Eric Westman, Mark Belger, Sergi Valero, Peggy Maguire, David Krivec, Milica Kramberger, Rafael Simo, Inmaculada Pérez Garro, Pieter Jelle Visser, Annette Dumas, Jean Georges, Frank Jessen, Bengt Winblad, Craig Shering, Neil Stewart, Laura Campo, Mercè Boada, on behalf of the MOPEAD Consortium
Preliminary Conclusions I

• Delays in inclusions were as consequence of IRB’s approval focus on ethics issues in RUN1

• RUN2 in Spain has fulfilled the expectations due to F.ACE’s previous experience in conducting Open House pre-screenings. It seems to be the most efficient

• RUN3 works very low as a consequence of poor GP’s implications

• RUN4 seems to be efficient depending on public health systems
Preliminary Conclusions II

• Different inclusion rates in all RUNs and countries observed

• Once WP3 is finished, the correlation between pre-screening and screening will be assessed to check quality.

  ▪ Dissemination actions have been successfully