

Learning from experiments in public and participant involvement

Dr Richard Milne

Structure

- Background
- Motivations
- The involvement spectrum
- Challenges
- The EPAD experience
- Suggestions and proposals

Background

- Expanding scale, scope and depth of health data
- Challenges include consent, distribution of benefits, trust
- Governance
 - 'Adaptive', 'responsive',
 - Engaged – public/patient/participant
 - New models (data trusts, co-operatives, collaboratives etc. for diverse data)
 - Biobank experience

Participant involvement/engagement in governance (PEG)

- Alignment with societal expectations and collective goals of health research
- Legitimacy
- Build trust
- ‘Data subjects’ as stakeholders in *both inputs and outputs*
- Reciprocity
- Contribution to ethical considerations (cf Dresser)
- Role of participants in successful research (cf Morris and Balmer, Pols)

Publics, participants and 'subjects' in governance

Wave I

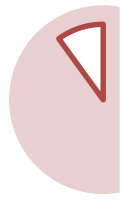
- From consultation to deliberation
- Upstream engagement



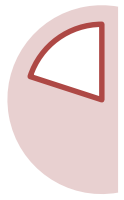
Wave II

- From community engagement to participant engagement and involvement in governance

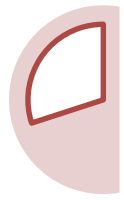




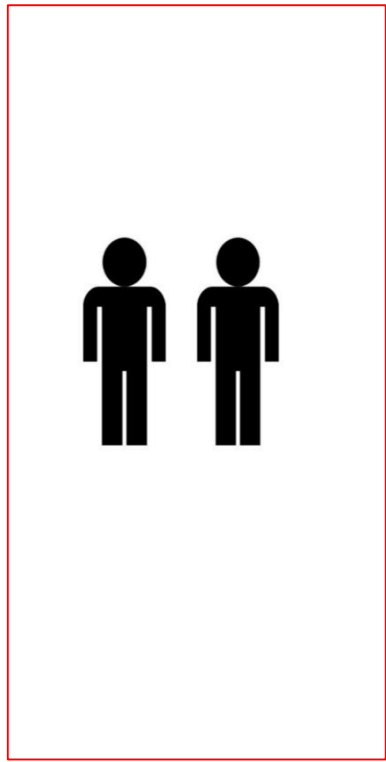
None



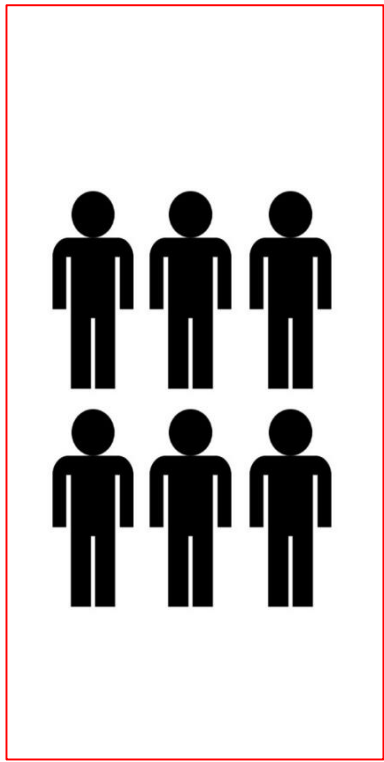
Ad-hoc



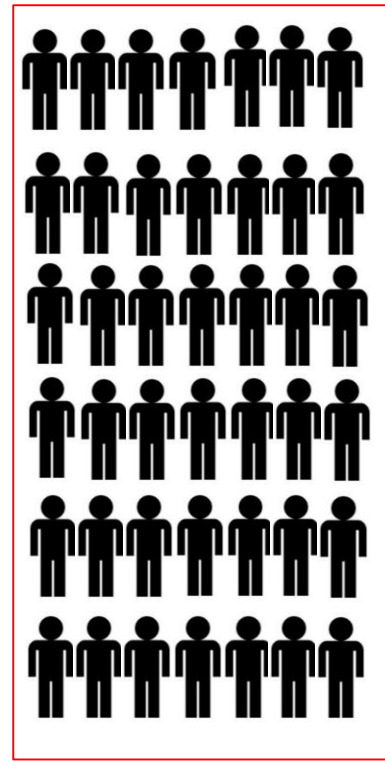
Individual



Group



Collective



METADAC



All of Us
RESEARCH PROGRAM

 MIDATA



 OPEN HUMANS

Challenges

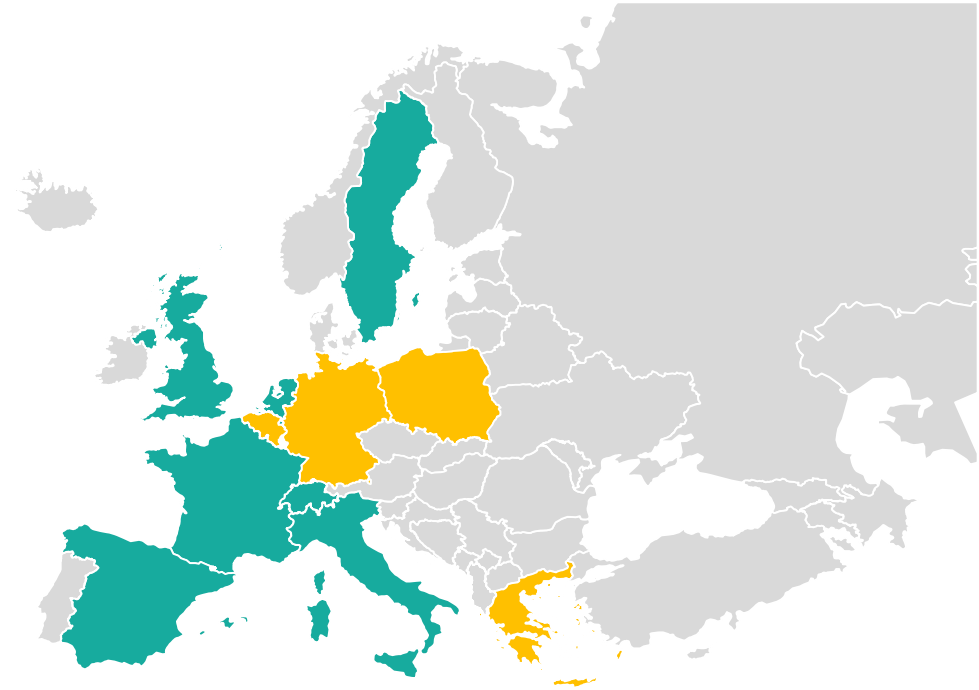
- Representation
- Authority/effectiveness
- Focus of issues
- Accountability (internal, external)
- Inclusion
- Implementation and adoption
- Practicalities
- Space for ‘amateurs and dilettantes’ (cf Weber, Hennion)

“The most important weakness is one common to all representational approaches: **how well the views of the representatives reflect those of the people they represent.**”
(Cohen and Mello 2019, *JAMA*, *emphasis added*)



The EPAD consortium 2015-2020

- Public/private consortium, funded €60m by the Innovative Medicines Initiative (IMI) for development of secondary prevention of Alzheimer disease.
- 11 European countries, 39 partners
- **Longitudinal cohort, adaptive clinical trial platform, bioresource**



Participant Panel

- Recommended by ELSI group
- **Locally** (Scotland, Spain, France, NL, England)
- Common ToR on recruitment, meeting rules
- **Centrally** (through feedback to PI, General Assembly)
- EPAD participant panel in study governance
 - Study experience, research design and documentation, logistics and retention, dissemination
 - Access for re-contact
 - Planning



Challenges

Representation

Challenges from both researchers and participants

Participants as 'delegates' or 'trustees'

Authority

Based on equal involvement with research community

Direct communication with project leadership

Importance of interpersonal relationships

Focus

Work directed by participants

Implementation and buy-in

Facilitated by *active involvement* of PI and study teams, but unevenly distributed (5 of 11 countries)



Inclusion

All participants eligible, 2 year term

But how to develop

Accountability

Discursive accountability to participants, to group

But – limited accountability to a) cohort and b) external publics

Practicalities

Language

Expectations

Ethics and regulatory considerations (esp. France)

Core funded but still requires time and commitment

Space for adaptation

Participant-led involvement

Adaptation and openness in governance

Commitment to discussion and refinement

Finding the 'right' PEG: experimentation and learning

- Core questions:
 - What do we want from PEG?
 - What do participants want?
 - How do the approaches we adopt reflect these?
 - How can they be incorporated in conventional research structures?
- Experimentation requires
 - Experimental Space
 - Documentation and sharing experience

Thanks to...

EPAD Research Participants Panel

EPAD ELSI group

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