

The European Commission's science and knowledge service

Joint Research Centre

Current JRC activities in the field of biomedical research, with a focus on indicators to monitor impact and innovation of funded biomedical research

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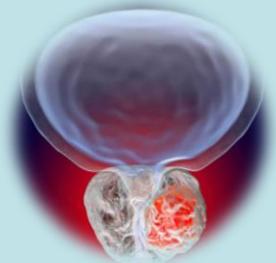
ECVAM

European Union Reference Laboratory
for Alternatives to Animal Testing



Non-communicable diseases

- increasingly prevalent in Western countries, > 86% of total premature deaths
- 9.9 million new cases of dementia every year, **Alzheimer's disease** (AD) accounting for 60-80% of cases
- **Breast cancer** (BC) and **prostate cancer** (PC) ranked as the 1st and 4th most common cancers in 2020
- result of a combination of genetic, physiological, and environmental factors (e.g., diet, exercise and smoking)



Translational failures in these fields of biomedical research

- basic/fundamental and pre-clinical research successes have not, in most cases, translated into effective therapeutic treatments for humans;
- **AD** → failure rate **>99%**, no disease-modifying therapies have been developed so far (*Alzheimers Dement (N Y)*. 2018; 4():330-343)
- **Cancer** → failure rate **97%** (*Sci Transl Med*. 2019 Sep 11; 11(509))
- Lack of efficacy and (off-target) toxicity represent the most common causes of trial failure

Translational failures in these fields of biomedical research

➤ Possible reasons behind drug development failure:

- ✓ **flaws in animal experimentation design**
- ✓ **inappropriate target selectivity**
- ✓ **neglecting efficacy, PK and PD properties of new compounds**
- ✓ **inappropriate selection of clinical trial participants**



Animal use in Europe

- ✓ Each year, more than 100 million animals are used in research worldwide
- ✓ According to the EC 2019 Report on the Statistics on the Use of Animals for Scientific Purposes in the Member States of the European Union in 2015–2017 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1581689520921&uri=CELEX:52020DC0016>):

Within applied/translational research, **human cancer (27%)** and **human nervous and mental disorders (14%)** accounted for the highest numbers of animals



Review

Alzheimer's Disease, and Breast and Prostate Cancer Research: Translational Failures and the Importance to Monitor Outputs and Impact of Funded Research

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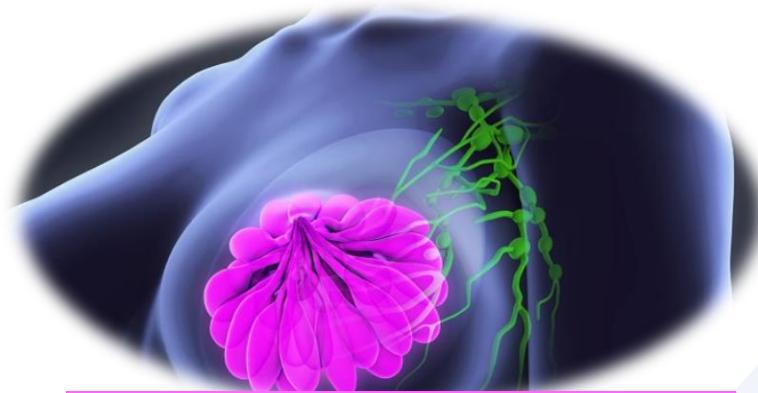


Are Animal Models Needed to Discover, Develop and Test Pharmaceutical Drugs for Humans in the 21st Century?

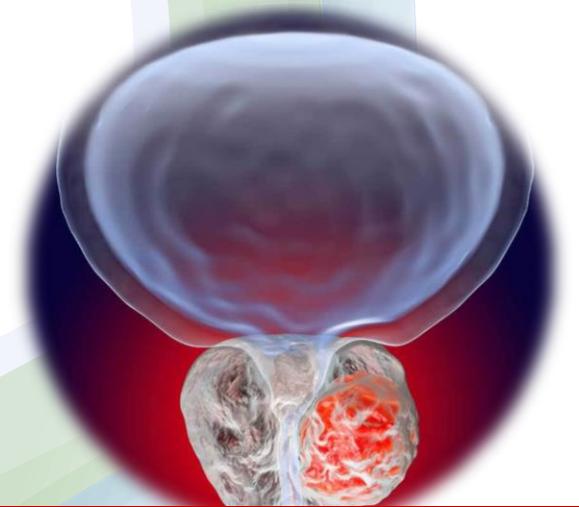
What is the impact of EU-funded research on AD, BC and PC ?



Alzheimer's Disease

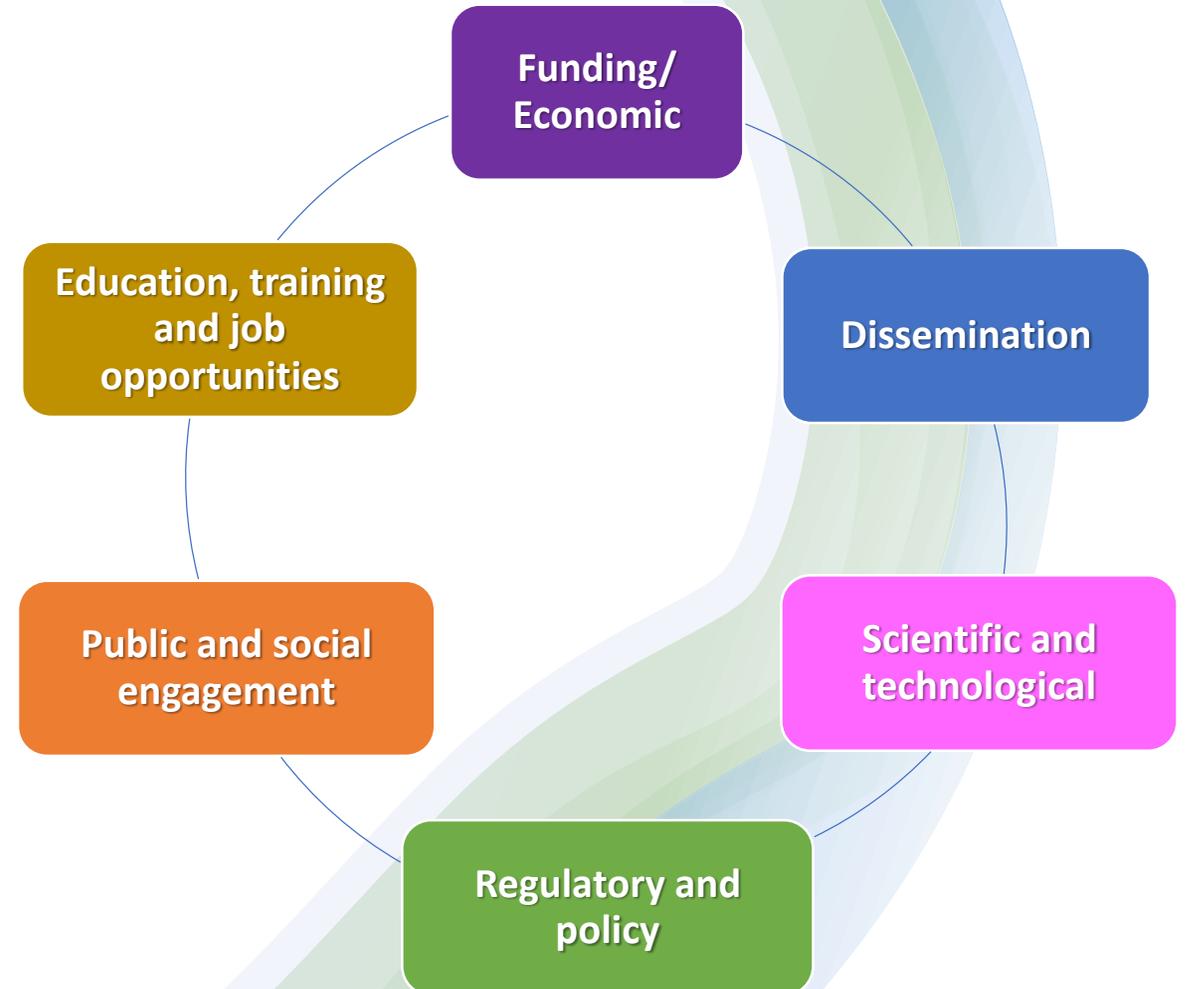


Breast Cancer



Prostate Cancer

Can we use indicators to retrospectively measure innovation and impact of funded research?



Indicators

Funding/ Economic

- Number of EU projects
- Value of EU projects
- Value of projects from non-EC funding bodies

Dissemination

- Number of publications on new scientific insights
- Number of publications on new methods, tools and approaches
- Number of citations

Scientific and technological

- Number of patents
- Number of new diagnostic tools
- Number of approved drugs, treatments or medical devices
- Number of clinical trials for new drugs
- Number of new preventive measures

Regulatory and policy

- Number of public health guidance values/options in regulatory medical-health sectors
- Number of new regulatory policy actions
- Number of new non-regulatory targeted policy actions

Public and social engagement

- Level of public/social engagement
- Global indicators: Public health trends

Education, training and job opportunities

- New job opportunities
- New learning opportunities

Main goals



Through these indicators we aim to gain insight and understanding:

- i. how EU-funded projects have contributed to innovation and major scientific breakthroughs;
- ii. how scientific results have translated into effective socioeconomic impacts;
- iii. what scientific methods and research approaches underpinned the advances made.

Survey

- Launched Feb. 14 2020
- Addressed to current and former participants of EC-funded research projects in the fields of Alzheimer's disease and other dementias, breast cancer or prostate cancer.

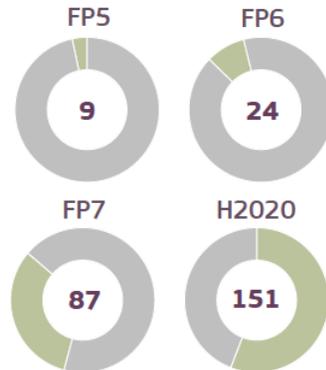


Survey Respondents

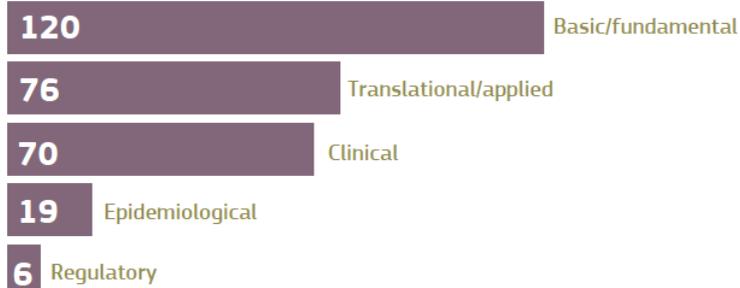
Survey on Innovation and Societal Impact of EU-funded Research



EU Framework Programmes*



Areas of research*



Type of organisation*



*Participants could select more than one answers

Primary country of the conducted research

Primary country of the conducted research	Answers
United Kingdom	34
Italy	20
Netherlands	20
Germany	18
Spain	18
France	14
Sweden	11
Belgium	9
Denmark	7
Norway	6
Switzerland	6
Austria	5
Czechia	5
United States of America	5
Other	24

Table 1: Geographical distribution of survey participants (primary country where they conducted their research activities)

Follow-up analysis of survey replies: Synopsis report



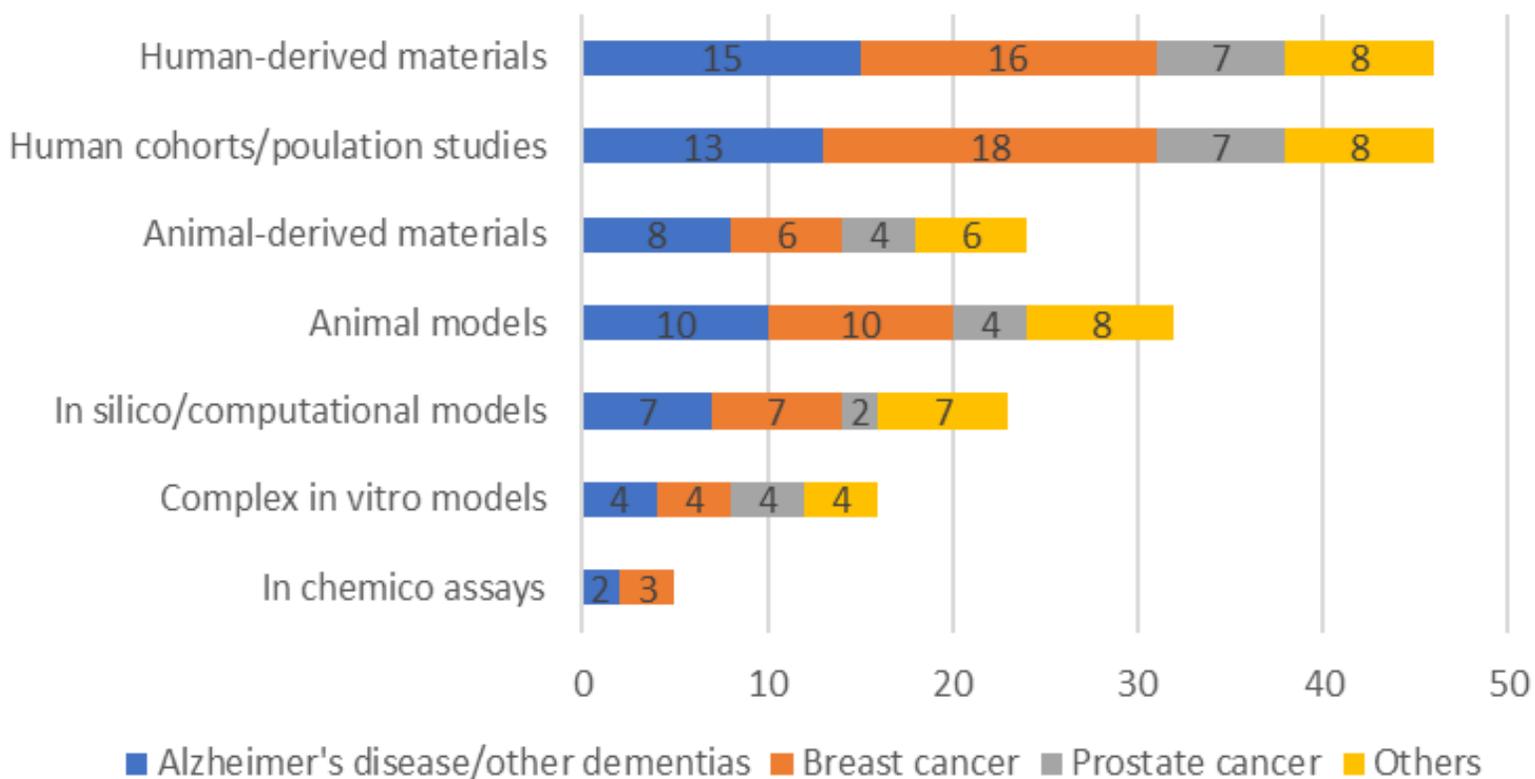
- the **type of impact** of EU-funded research concerning the EU FP, the area and field of research, and the **selection of the models**;
- the **challenges** encountered and the possible issues concerning **follow-up funding**;
- what **ingredients** have contributed to research **success** and the generation of impact;
- the importance of **public engagement**.



Selection of experimental models across fields of research



Highly relevant models across fields of research

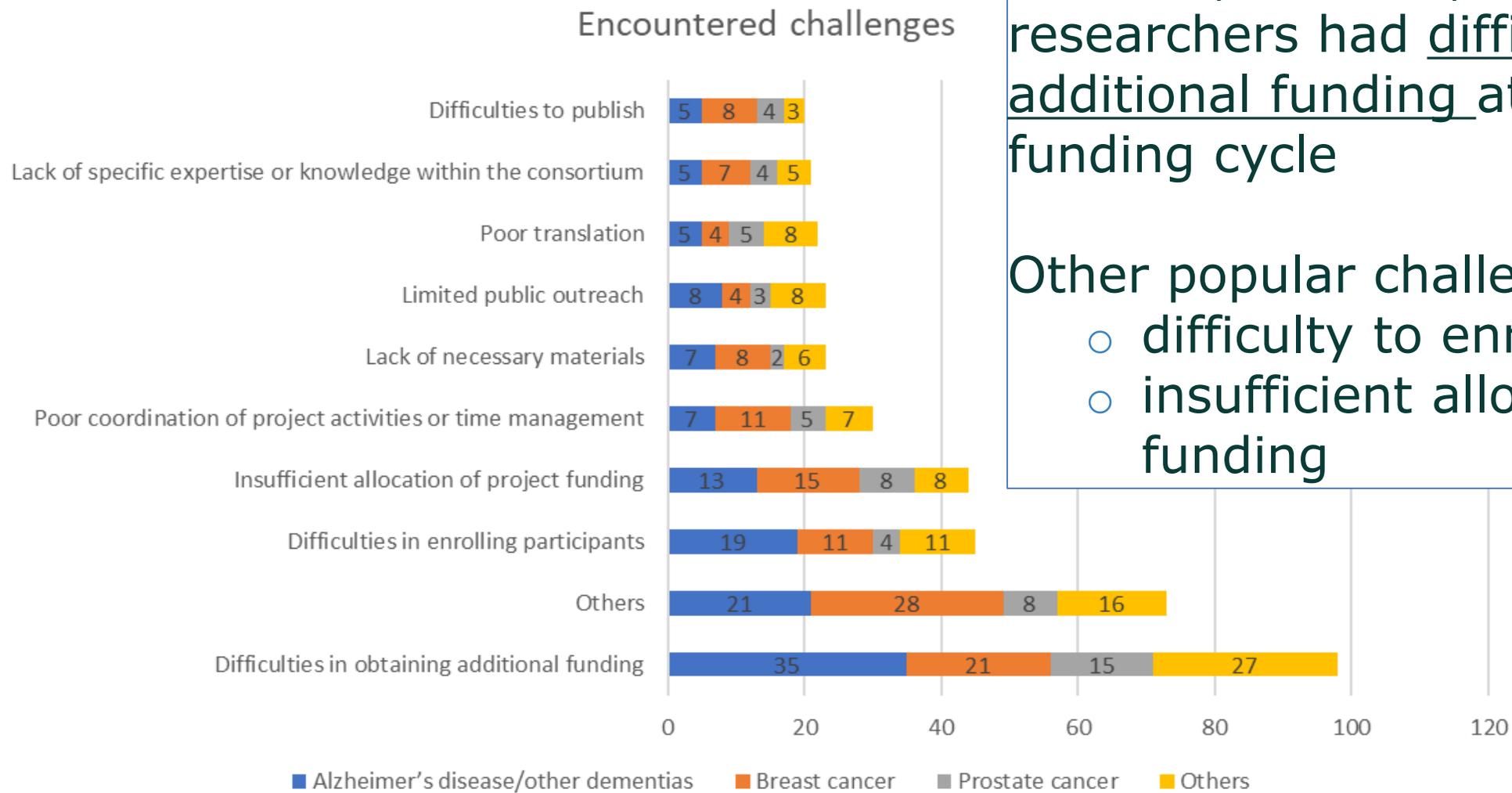


70% of users of **human-derived materials** considered them as highly relevant to their research questions

57% of users of **animal models** considered them as highly relevant to their research question:

- 63% of AD researchers
- 56% of BC researchers
- 50% of PC researchers

Encountered challenges across fields of research

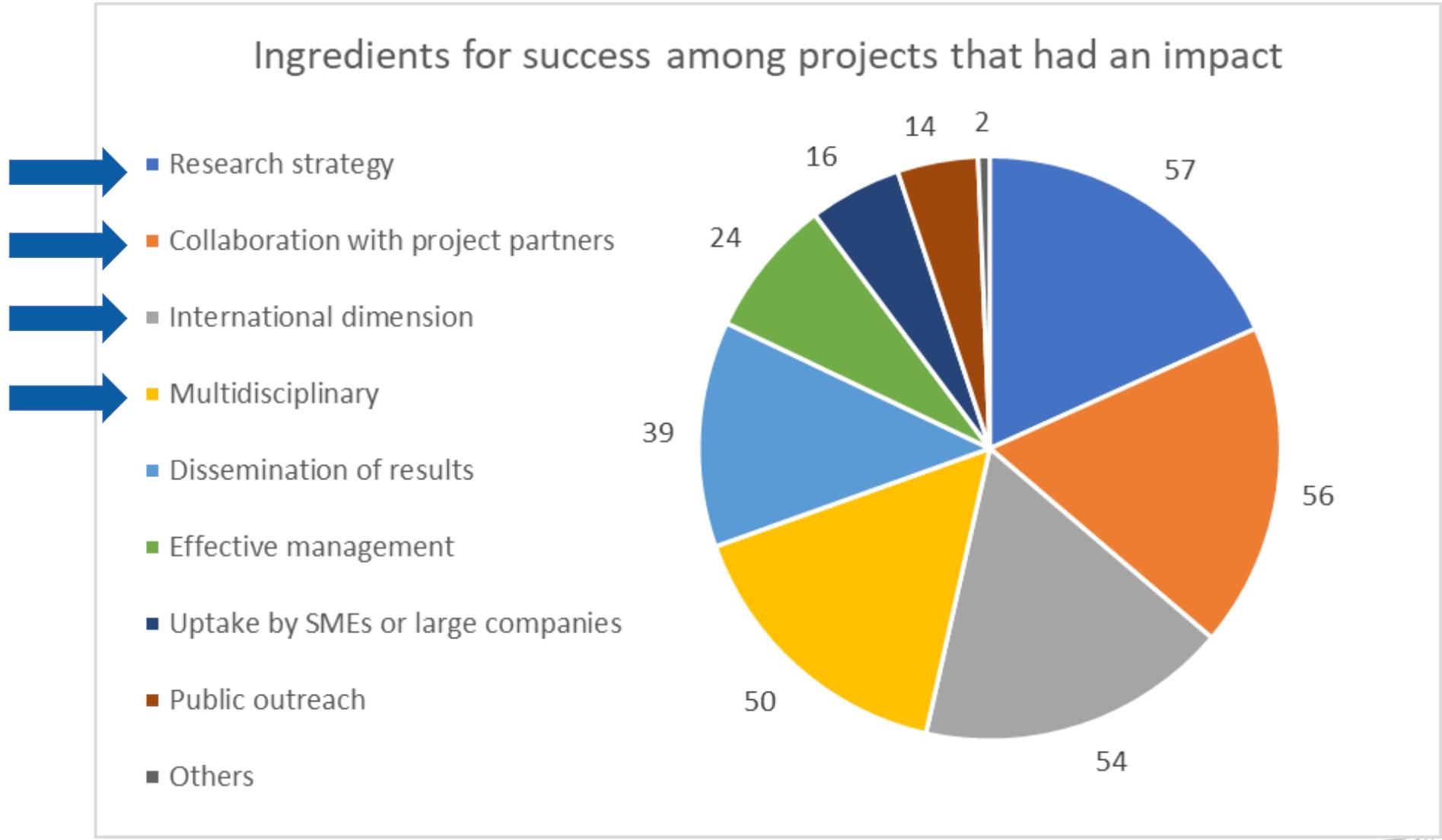


28% AD, 26% PC, and 18% BC researchers had difficulties in obtaining additional funding at the end of funding cycle

Other popular challenges:

- difficulty to enroll participants
- insufficient allocation of project funding

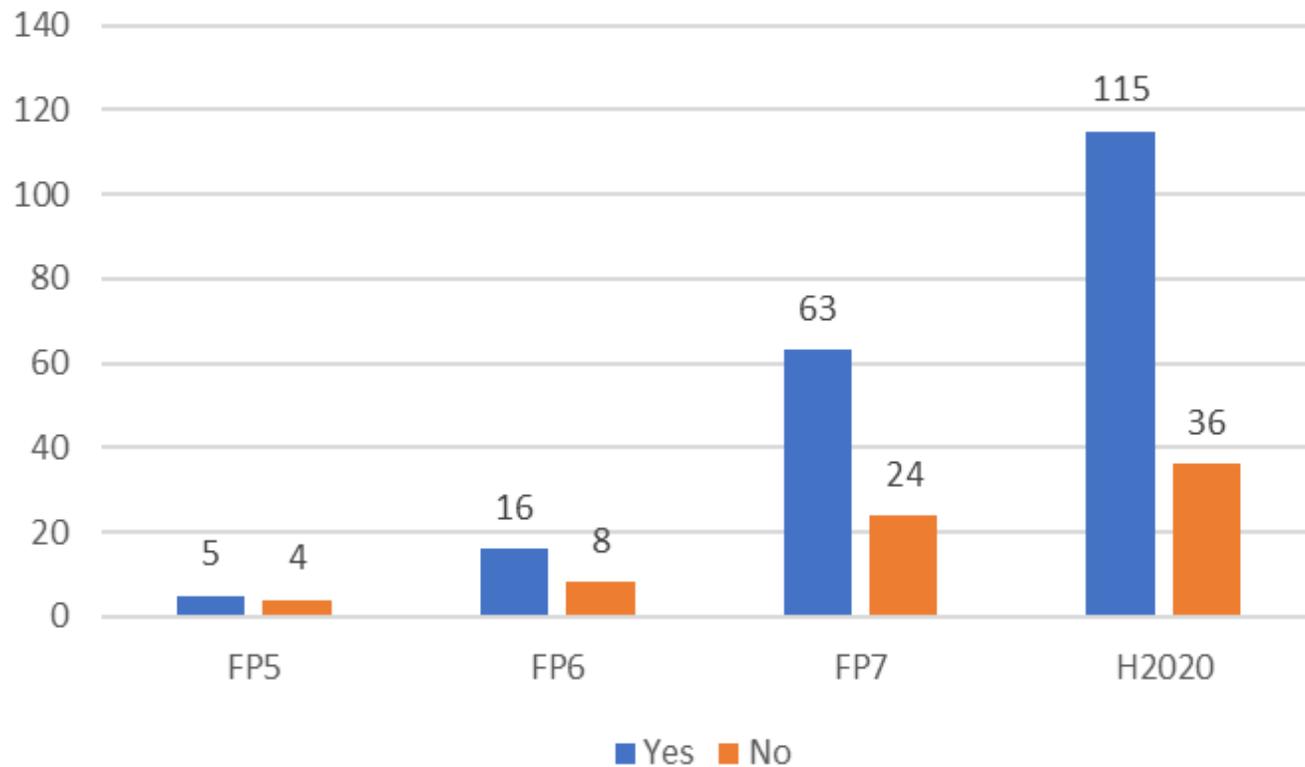
Ingredients for success in projects that claimed impact



Public engagement across FPs



Public engagement across EU FPs



- 76% H2020 participants
- 72% FP7 participants
- 67% FP6 participants
- 56% FP5 participants

→ indicated public engagement efforts

Interviews of Survey Respondents



- Conducted 29 in-depth interviews to seek further input in 4 main areas, each correlate to specific question(s) in the survey:
 1. Major research outcomes and their social impact
 2. Translatability issues
 3. Challenges obtaining funding
 4. Dissemination to the general public
- Coding analysis of interview transcripts (NVivo)



Main findings

1. Most respondents feel their research **will have an impact**
2. **Time is an important factor** in the generation of societal impact
3. Obtaining **follow-up funding** to continue research is often an issue
4. The design of the overall research strategy, positive collaboration with project partners, the international dimension and the multidisciplinary nature of the project are considered as the **major ingredients for success**
5. **Epidemiology-based research** has significant potential to generate relevant results
6. Research aimed at designing **novel diagnostic or prognostic tools** often leads to more immediate impact
7. The impact of **sophisticated in vitro and computational models** is increasing with time
8. Use of **animal models** is still considered unavoidable by many, despite associated translational failures
9. **Human cohorts and population studies** and the use of **human specimens** are highly relevant
10. It is very **difficult to enrol participants** in clinical studies, especially in the field of AD
11. **Disseminating science to the public** is important but needs to be done properly



