# Patients as research participants: how to meet ethics standards?

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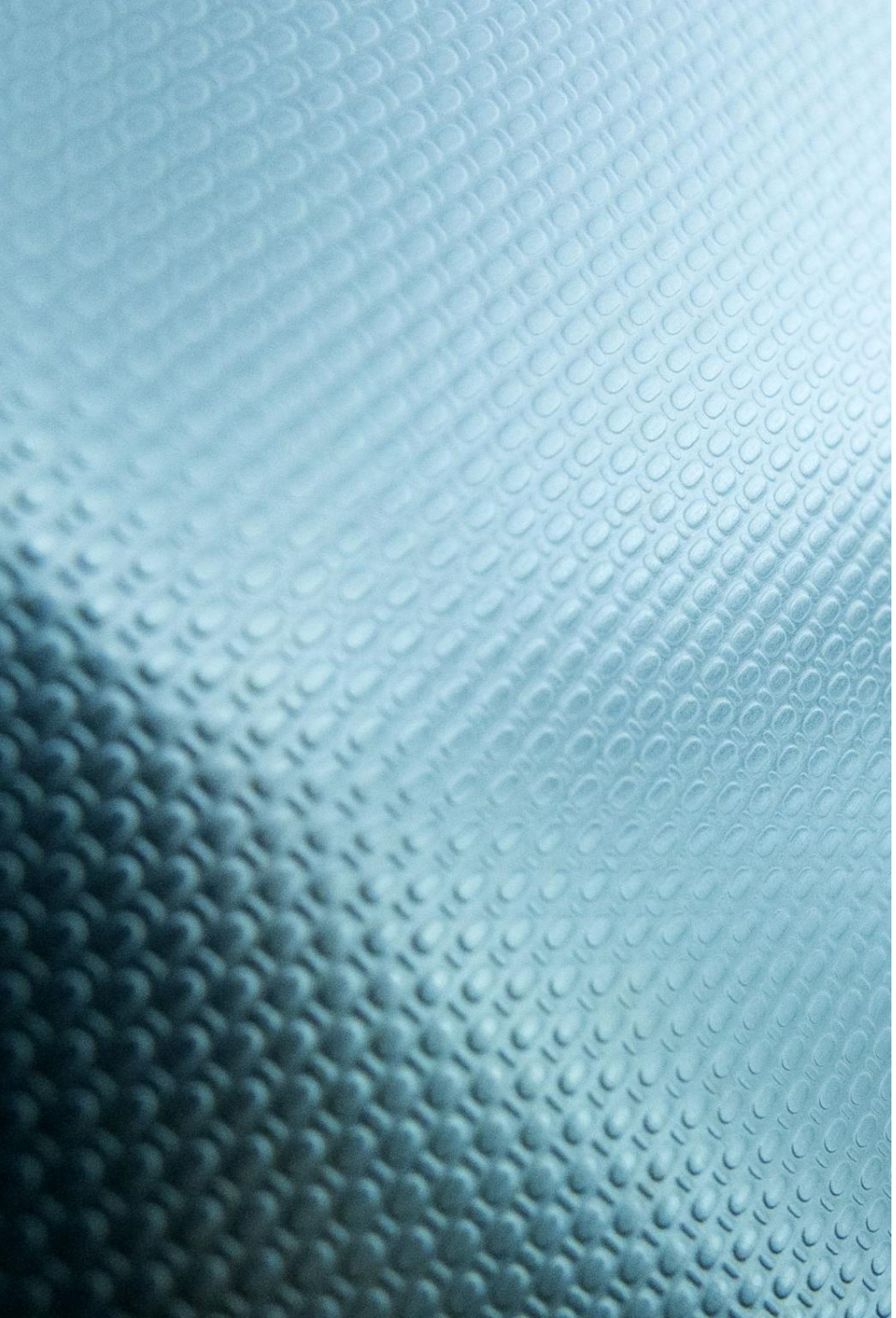
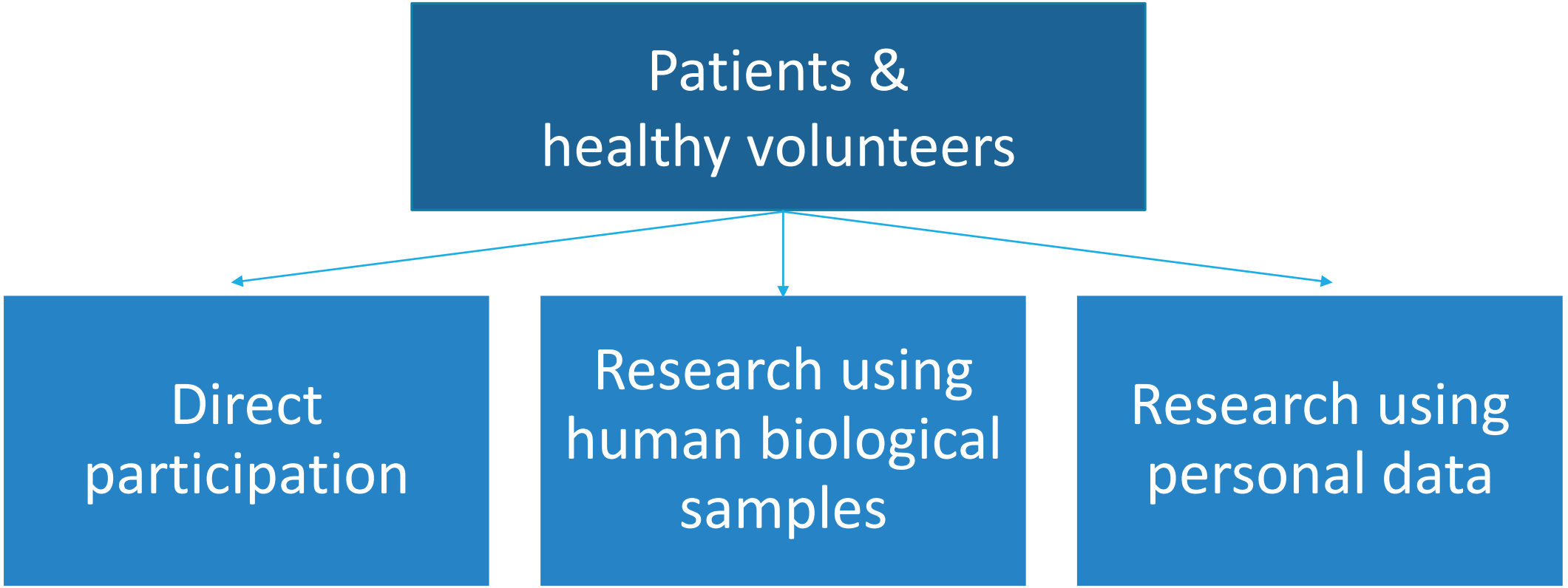
# Outline

- Background
- Quality of informed consent
- Therapeutic misconception
- Research participant involvement



# Background

# Patient involvement in medical research (human subject research)

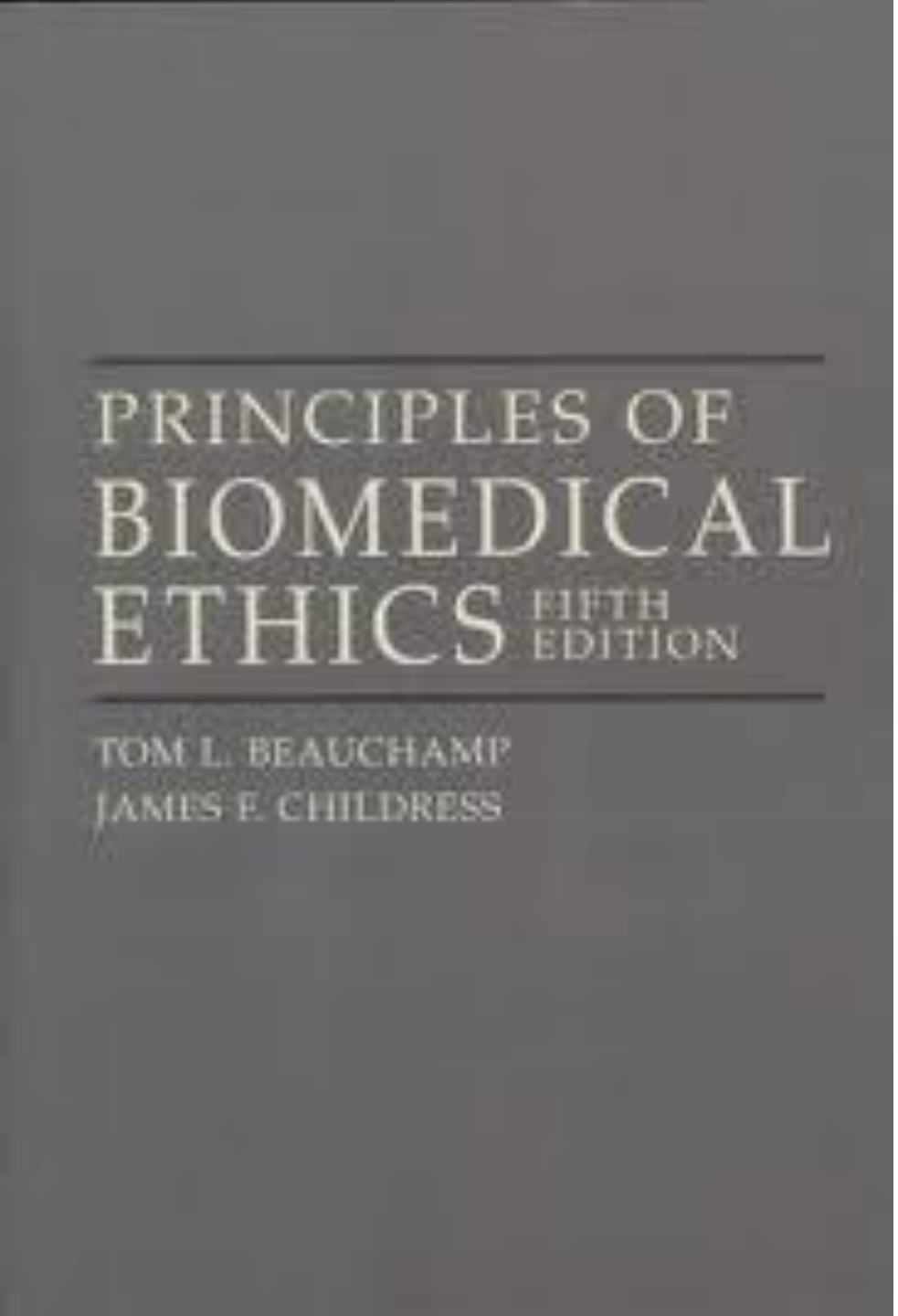


# Biomedical research vs. clinical practice

| Human subject research | Clinical practice |
| --- | --- |
| Purpose - to benefit future patients | Purpose - to benefit an individual patient by prevention, diagnostics and treatment |
| Contributes to generalizable knowledge | Provides direct benefit to the patient |
| Uncertainty about the results | Reasonably foreseeable results |
| Often - deviation from standard practice: innovative (additional) treatment procedures | Usually, no deviation from the standard practice (clinical guidelines) |

# Normative and legal framework

- Nuremberg Code
- Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (WMA)
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
- WHO Standards
- Declaration of Taipei Ethical Considerations regarding Health Databases and Biobanks (WMA)
- CoE Convention on Human Rights and Biomedicine




# Principles of biomedical ethics

## Autonomy

- Informed consent

## Beneficence

- Public (and individual) benefits

## Non-maleficence

- Risk-benefit ratio

## Justice

- Fair recruitment and non-discrimination


# Quality of informed consent

# Elements of consent

## Capacity

- Is a person competent to understand, evaluate, and make a decision on whether to participate or not?

## Information

- Is it complete, comprehensive and fully understood?

## Voluntariness

- Do research participants have a choice to refuse participation or withdraw and are they aware of this choice?

# Different types of consent

- Informed consent for a research study
- Open consent
- Broad consent
- Dynamic consent
- Opt-in/opt-out

# Quality of informed consent

- Research participant has to understand potential risks, benefits, conditions of participation, study design and his/her right to withdraw without penalty
- If consent is not informed, it can be as bad as (or worse than) not getting consent at all

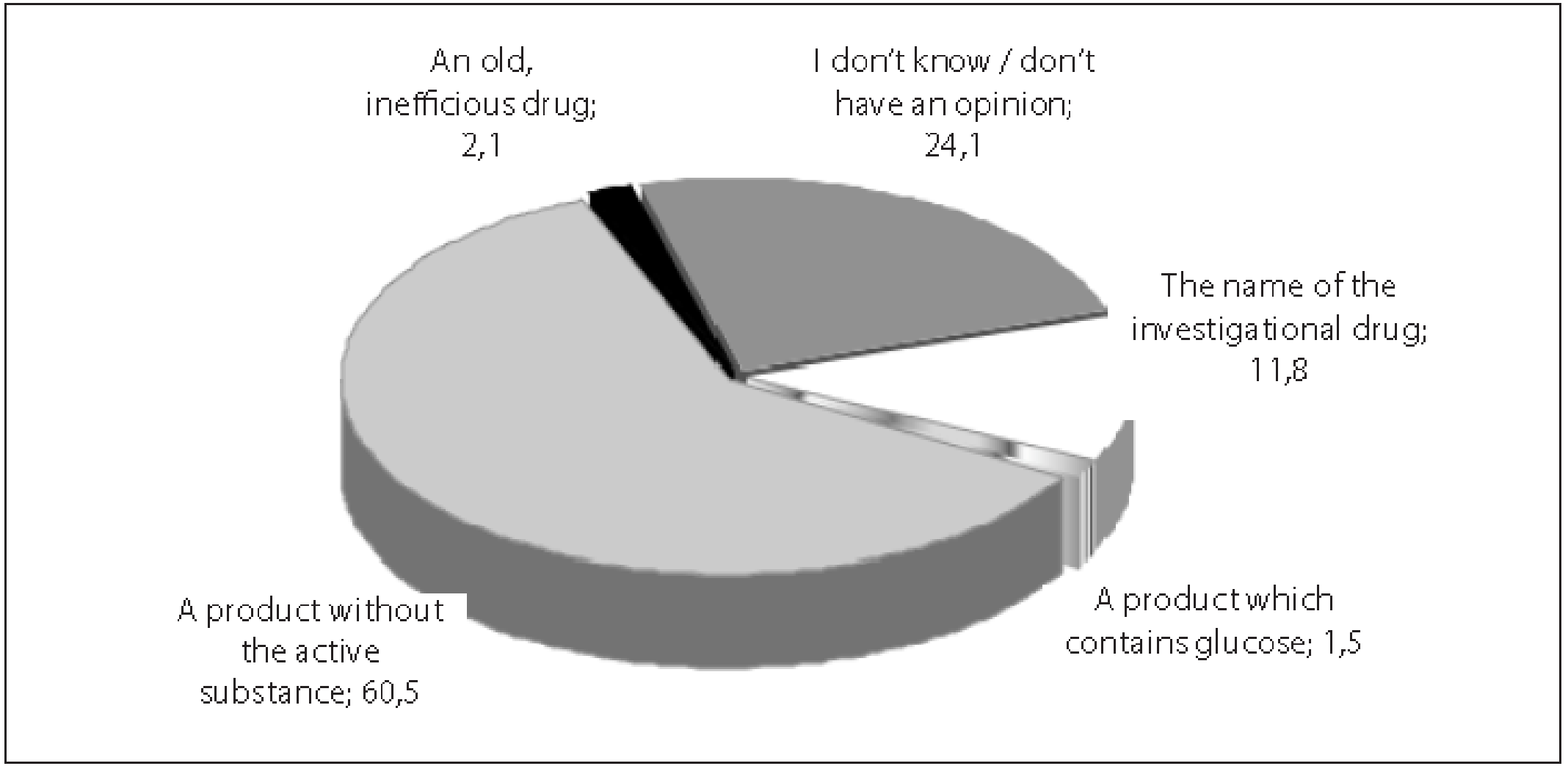



**Fig. 3: Distribution of answers to the question, "What, in your opinion, is a placebo? (percentage)**

Čekanauskaitė, A. (2013). Informedness about clinical trials of patients participating in placebo-controlled clinical trials in Lithuania. https://epublications.vu.lt/object/elaba:1925159/

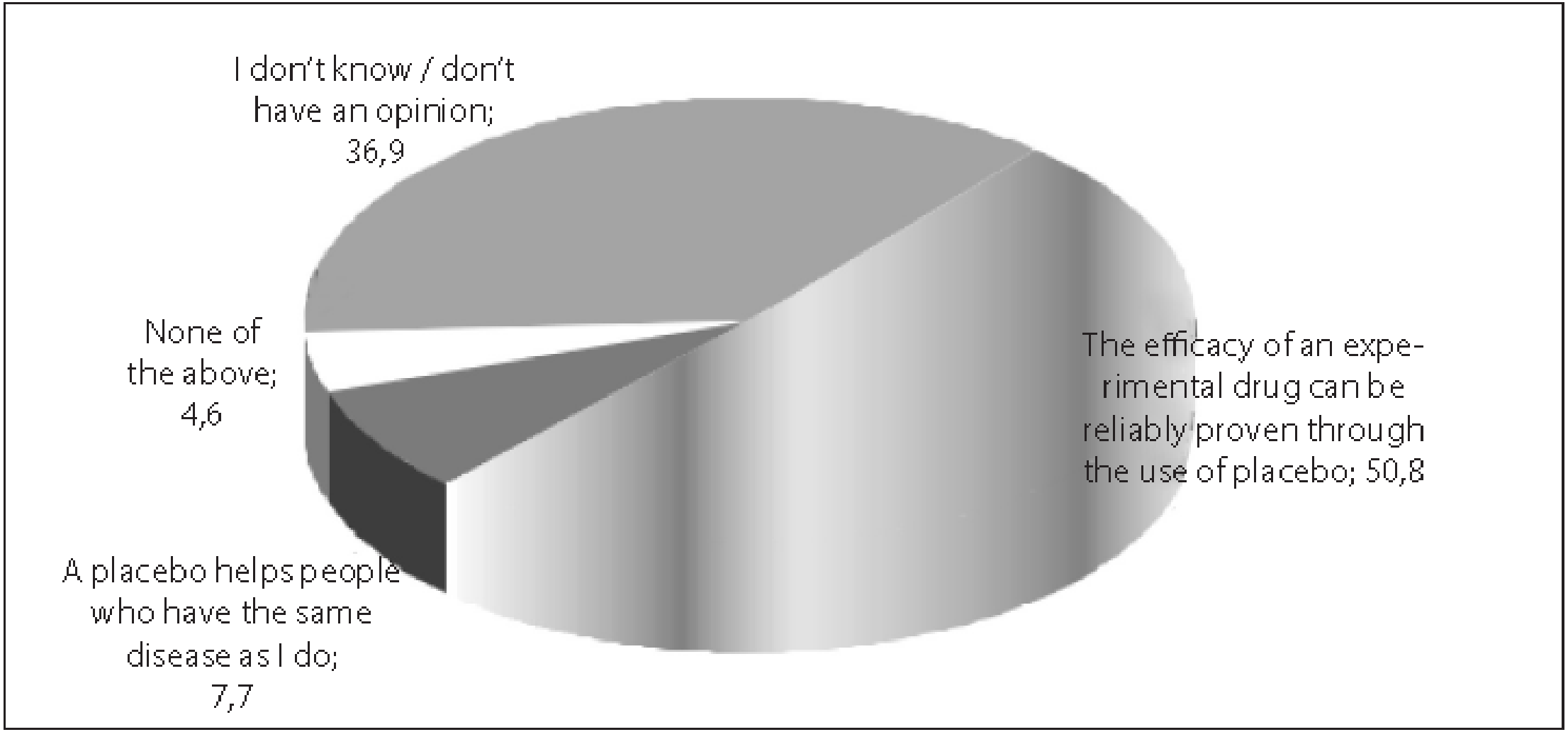



**Fig. 4: Distribution of respondents' answers to the question, "Why, in your opinion, is a placebo used in clinical trials?" (percentage)**

Čekanauskaitė, A. (2013). Informedness about clinical trials of patients participating in placebo-controlled clinical trials in Lithuania. https://epublications.vu.lt/object/elaba:1925159/

«The results of the study reveal that the legal framework sets the basis for adequate informedness about clinical trials of clinical trial participants, however, patients participating in placebo-controlled clinical trials are insufficiently informed about clinical trials. Patients participating in placebo-controlled clinical trials are better informed about the rights of clinical trial participants than about clinical trial design, however, informedness about design is a more important condition for overall informedness. The majority of placebo-controlled clinical trial participants do not understand at least one of the three key elements of clinical trials design and they tend to interpret the scientific methods used in clinical trials therapeutically.»

Čekanauskaitė, A. (2013). Informedness about clinical trials of patients participating in placebo-controlled clinical trials in Lithuania. https://epublications.vu.lt/object/elaba:1925159/

«We concluded that there are significant discrepancies in research participants' understanding of voluntary participation, blinding, and freedom to withdraw. Only rarely did all participants respond correctly to questionnaire items, indicating that they actually comprehended what they consented to. We found that participants presented the highest level of understanding (over 50%) about voluntary participation, blinding (excluding knowledge about investigators' blinding), and freedom to withdraw at any time. Further, our results suggest that only a small minority of patients had a clear and accurate understanding of all aspects of their consent. In particular, patients presented significant difficulties in grasping the concept of placebo randomisation, safety, risks, and side effects. [..] Additionally, some patients had very limited comprehension of the research benefits.»

Pietrzykowski, T., Smilowska, K. The reality of informed consent: empirical studies on patient comprehension—systematic review. *Trials* **22,** 57 (2021). https://doi.org/10.1186/s13063-020-04969-w

# Therapeutic misconception

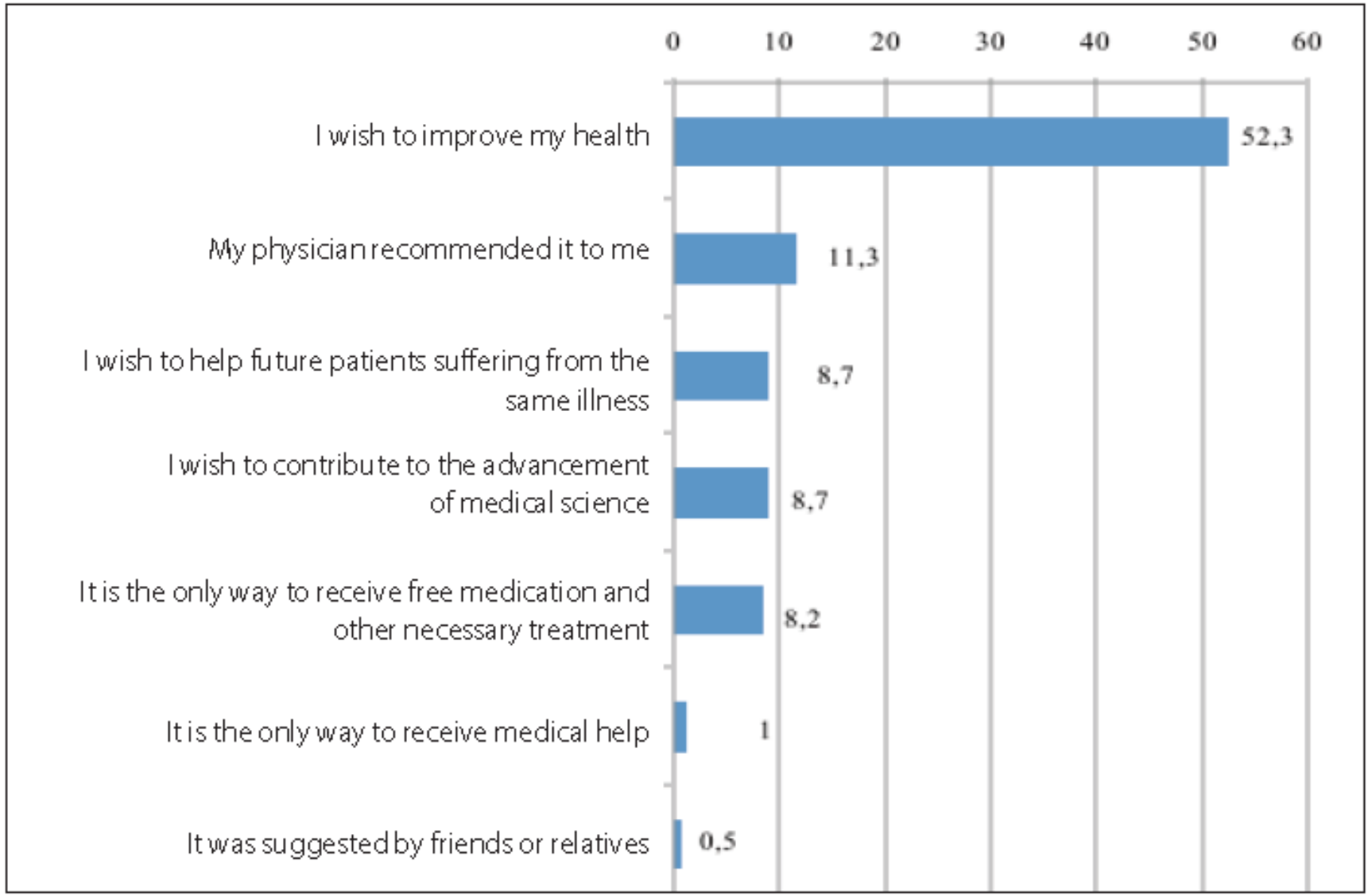



**Fig. 7: The distribution of answers to the question, "Why did you agree to participate in the trial?" (percentage)**

Čekanauskaitė, A. (2013). Informedness about clinical trials of patients participating in placebo-congrolled clinical trials in Lithuania. https://epublications.vu.lt/object/elaba:1925159/

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# Therapeutic misconception

Research subjects may enter research studies because they think they will individually benefit from the research intervention

Causes:

- Human nature – we hear only what we want to hear
- Confusion of roles of physician and researcher
- The confusing methods of science (placebo, randomization etc.)

«A body of evidence identifies the various vulnerabilities associated with the process of informed consent. Commonly misconceptions about the nature of research, especially those that mistake research for treatment, the ‘therapeutic misconception’, can occur. Serious misconceptions about research potentially undermine the validity of consent. Various factors increase the likelihood of therapeutic and other serious misconceptions, which include the complexity of the research, the timing and context of decisions. Researchers may also contribute to misconceptions, for example by being too optimistic about the benefits of research. Wider factors such as the ‘promissory’ hyperbole that accompanies public discussion of bioscience research also encourage inflated expectations of research.»

Woods, S. (2018). Therapeutic and Other Misconceptions in Clinical Trials for Paediatric Genetic Disorders. *eLS*, 1-9.

# Therapeutic misconception

- Potential participants should not be excluded from participating in research just because a therapeutic misconception is present
- Researchers are responsible for dispelling unrealistic hopes
- Researchers have a duty to ensure that the decision to participate is well-informed and voluntary
- Some guidelines advise to avoid situation where treating physician is the person who recruites the patient for research

# Research participant involvement

# Participation

Research ethics committees

Community based participatory research

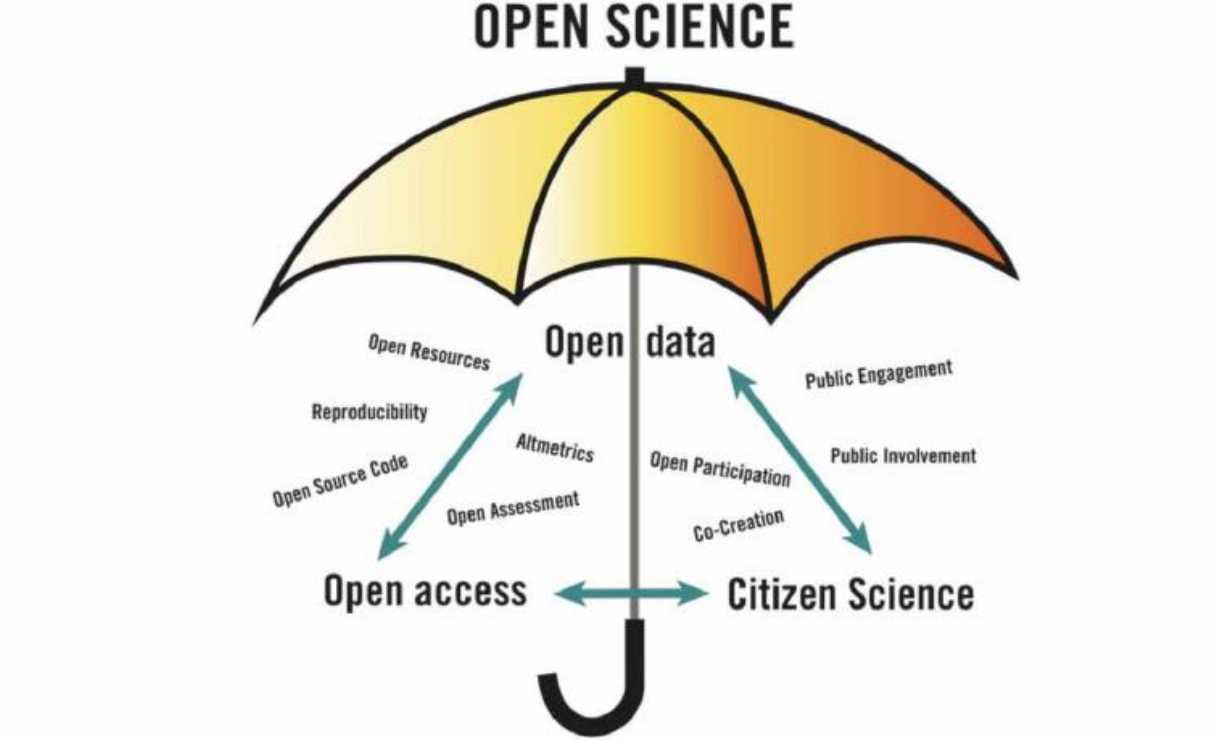
Citizen science

# Community based participatory research

«Community-based participatory research (CBPR) is an approach to research that involves collective, reflective and systematic inquiry in which researchers and community stakeholders engage as equal partners in all steps of the research process with the goals of educating, improving practice or bringing about social change »

Tremblay, MC., Martin, D.H., McComber, A.M. *et al.* Understanding community-based participatory research through a social movement framework: a case study of the Kahnawake Schools Diabetes Prevention Project. *BMC Public Health* **18,** 487 (2018).

# Citizen science

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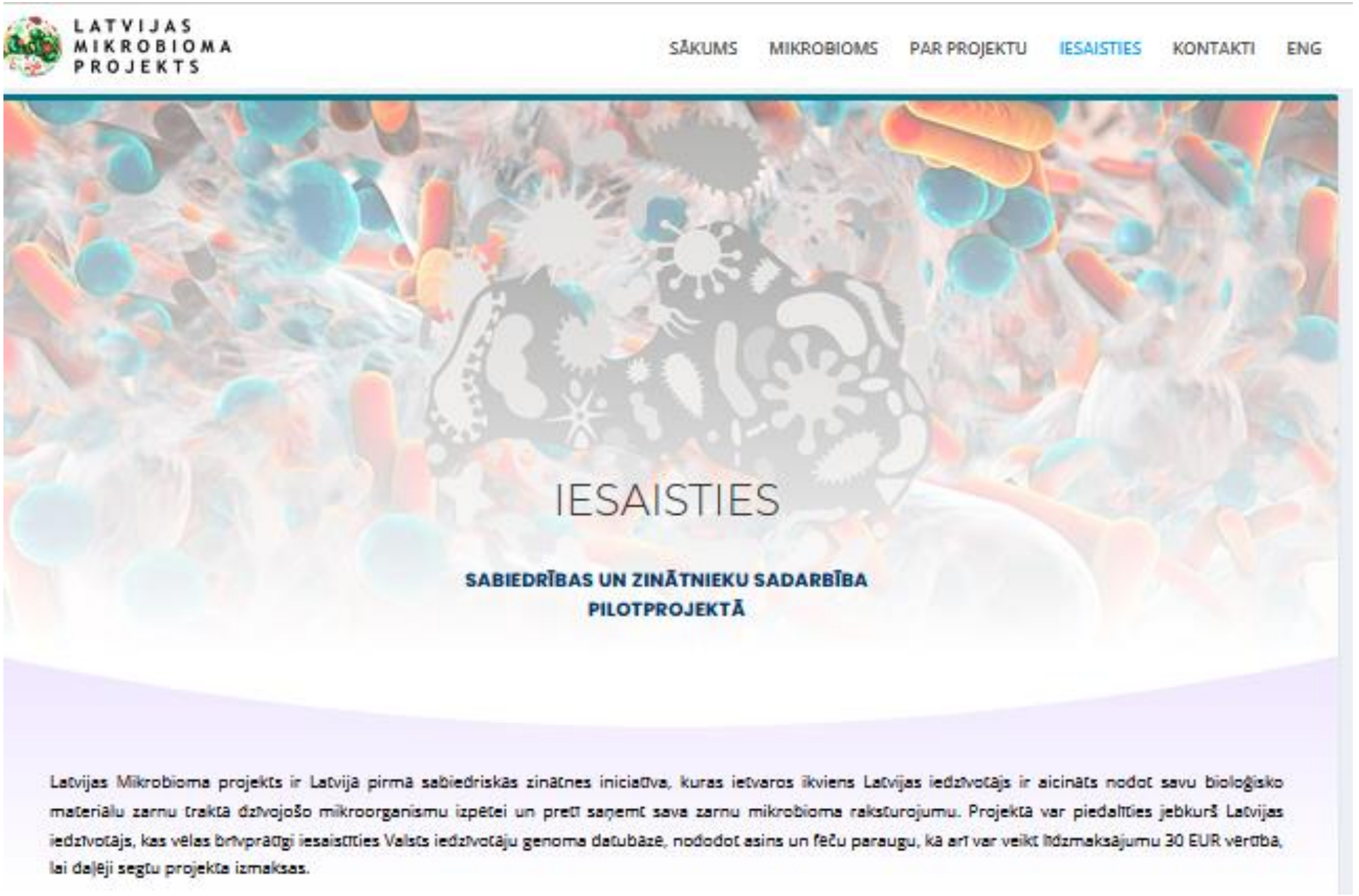
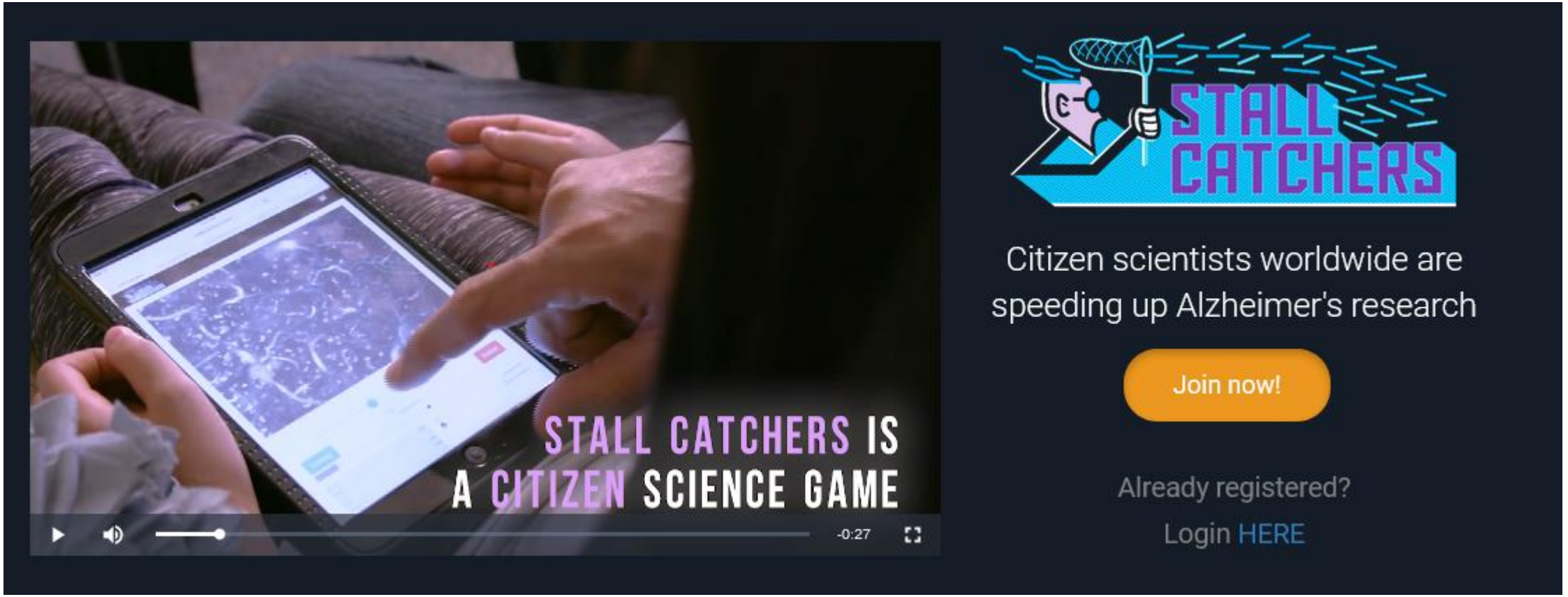
Responsible open science in Europe

RoSiE

https://rosie-project.eu/




https://latvijasmikrobioms.lv




https://stallcatchers.com

# Questions?