

4th EUFEMED CONFERENCE
25-26 May 2023, Berlin

Session 2

*Challenges in healthy volunteers and patient recruitment for human pharmacology trials -
Experiences and Suggestions*

„Why I took part in a clinical trial“

Results from a survey on motivation among Polish healthy volunteers

Agnieszka Kulesza
Ewa Urbańczyk



Introduction

The Purpose of the Survey

to learn about the volunteers' motivation factors, perceived benefits/values, and concerns related to participation in clinical trials.

Participants

healthy volunteers who signed an Informed Consent and underwent at least one study visit.

Non-Participants

healthy volunteers registered in the volunteers' database but not yet participated in a clinical trial.

Target group

Healthy volunteers registered in the database of Biokinetica Phase 1 Unit (POLFEMED supporting member).

Methodology

Online questionnaire sent via e-mail to 15 000 healthy volunteers (participants and non-participants), April-May 2023.

Questions

The respondents rated each of the response options in the cafeteria on a scale from 1 to 10 (ranging from irrelevant to very significant).

Confidentiality and anonymity was assured – anonymized responses were aggregated and sent to POLFEMED for collective analysis.

Respondents' Profile

Demographics



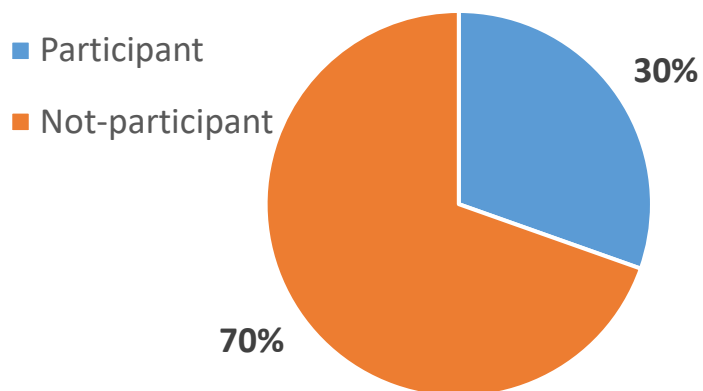
1

2 RESPONDENTS PROFILE

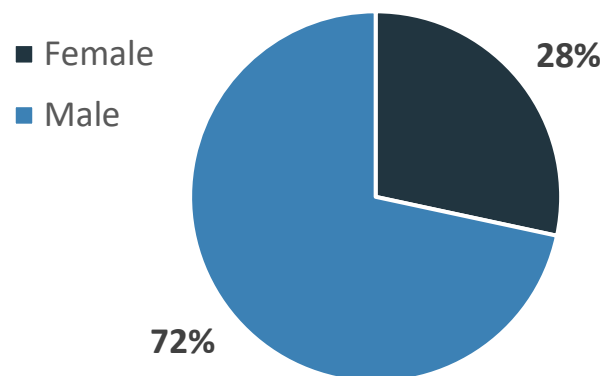
3

4

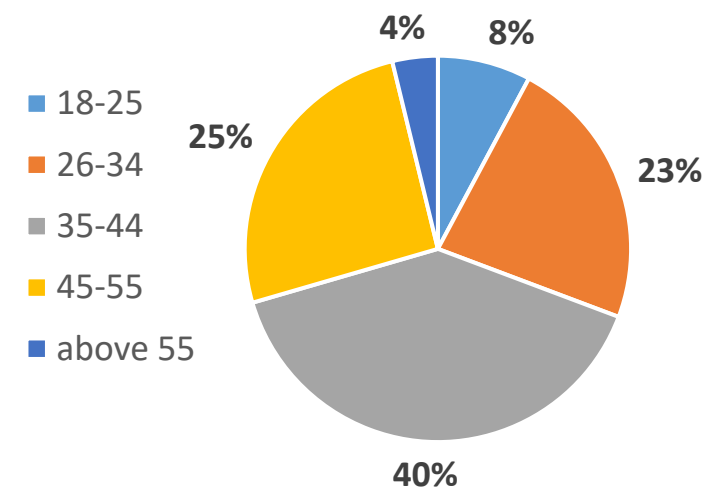
Status



Gender



Age



| No of questionnaires sent | 15.000 |
|---------------------------|--------|
| Received answers | 974 |
| Valid answers | 973 |
| Participants | 296 |
| Non-participants | 677 |
| Females | 276 |
| Males | 697 |

Observations

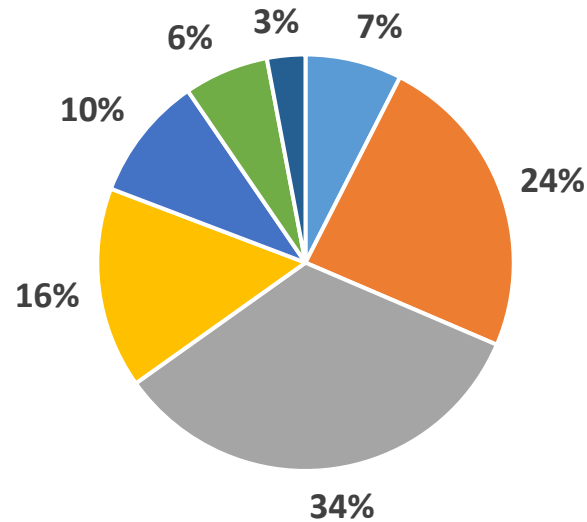
- 65 % of respondents were between 35-55 y.o.
- 27% of survey respondents have a chronically ill person among their family or close friends.

Socioeconomic Data

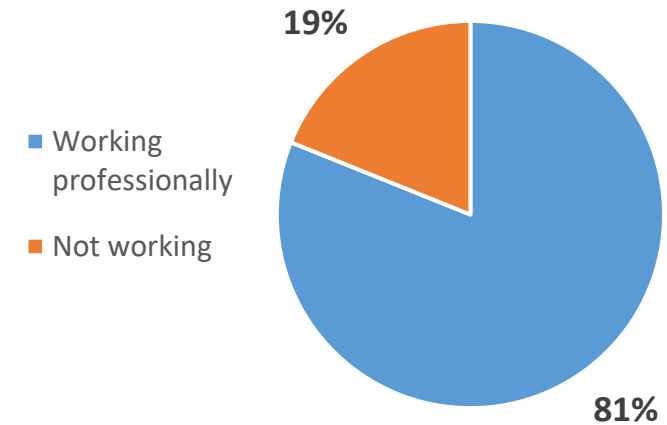
- 1
- 2 RESPONDENTS PROFILE
- 3
- 4

Income

- below 2000 (below 445 €)
- 2000-4000 (445-891 €)
- 4000-6000 (891-1336 €)
- 6000-8000 (1336-1782 €)
- 8000-10000 (1782-2227 €)
- 10000-15000 (2227-3341 €)
- above 15000 (above 3341 €)

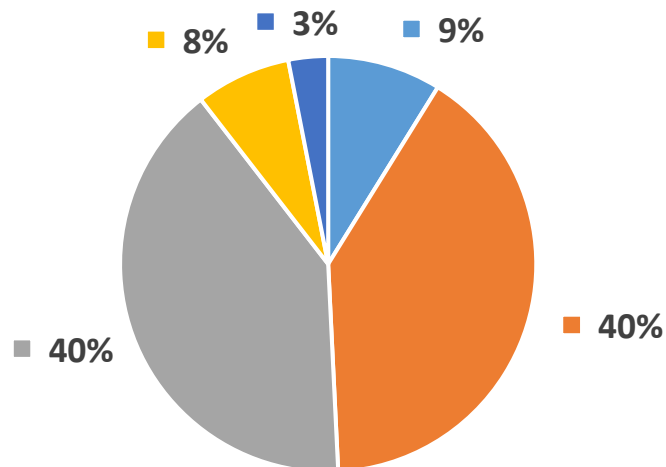


Employment status



Education

- Postgraduate
- Higher education
- Secondary
- Vocational
- Basic



Observations

- 81% are professionally active.
- 49% have at least a higher level of education.
- Only 3% have a basic level of education.
- 35% have monthly income above the national monthly average: 7 500 PLN ≈ 1 670 € (EU 2021: 2 800 €).

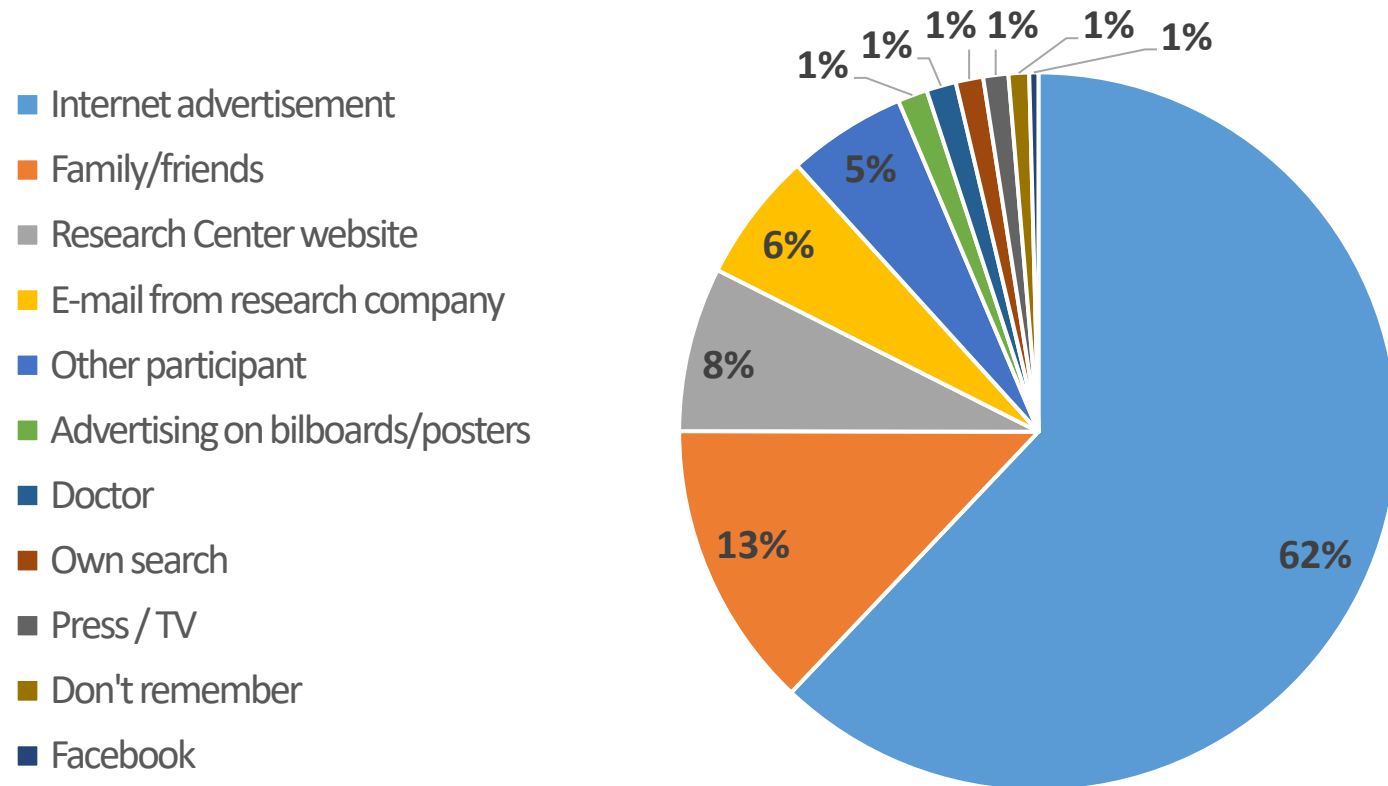
Source of Information about Clinical Trials

1

2 RESPONDENTS PROFILE

3

4



Observations

- Internet advertisements dominate as a primary source of information.
- Only 1 % of respondents declared they gain knowledge about clinical trials from healthcare professionals.

Status in Clinical Trials

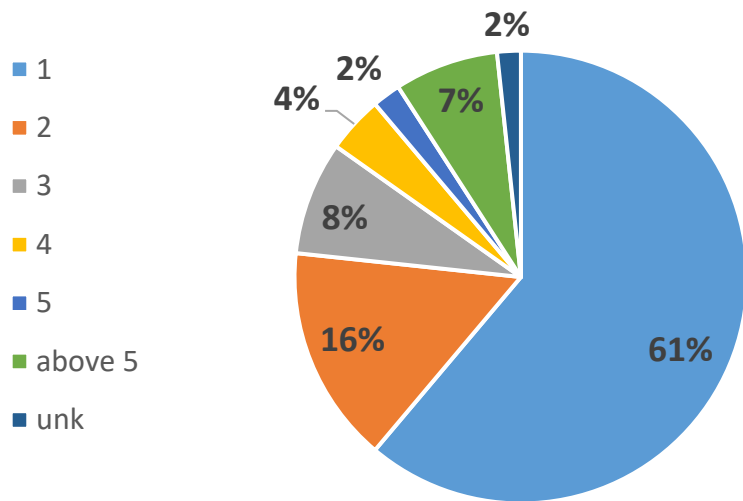
1

2 RESPONDENTS PROFILE

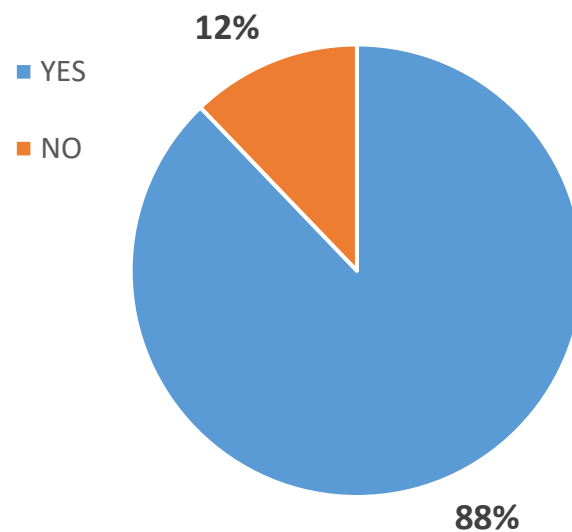
3

4

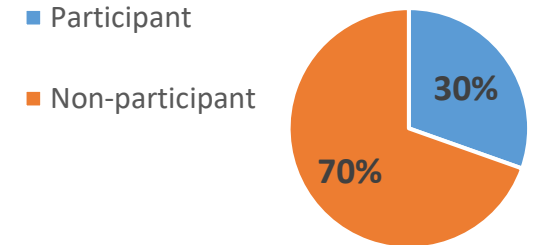
No. of trials per participant



Completed study?



Participation



Observations

- A majority of participants (61%) have taken part in a single clinical trial.
- 7% of participants participated in more than 5 clinical trials.
- 88% of respondents completed their last study.

Results

Motivation



Respondents were asked to assess each factor on a scale from 1 (insignificant) to 10 (most significant). The numerical values associated with each factor represent the arithmetic mean of all the responses.

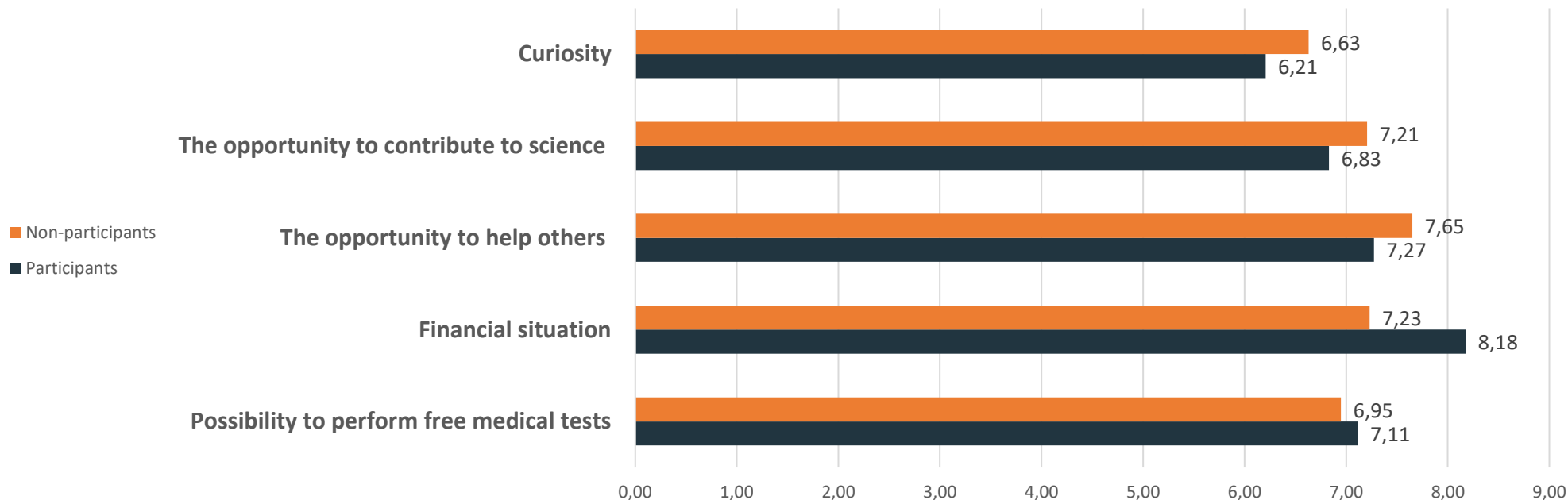
1

2

3 RESULTS

4

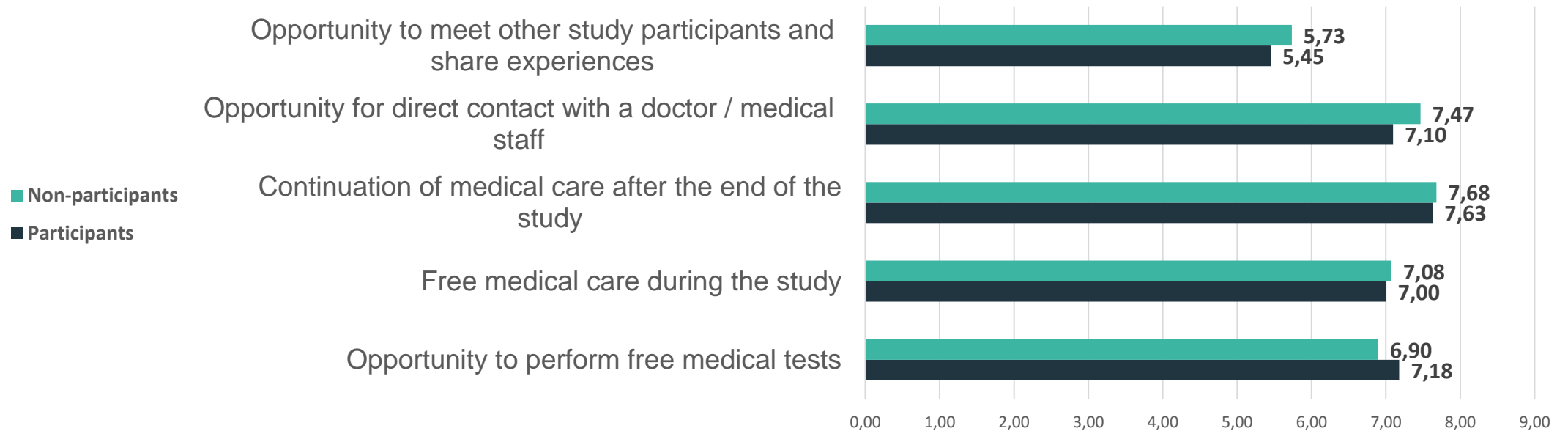
What made you participate in the study?



Observations

- In the participant group, the highest average score (8,18 points) was given to the opportunity to improve own financial situation.
- In the non-participant group, the highest average score (7,65 points) was given to the opportunity to help others.
- Both groups placed as second the „possibility to perform free medical tests” which may reflect poor access to public medical services in Poland.

What aspects of your participation in the study do you value the most?



Observations

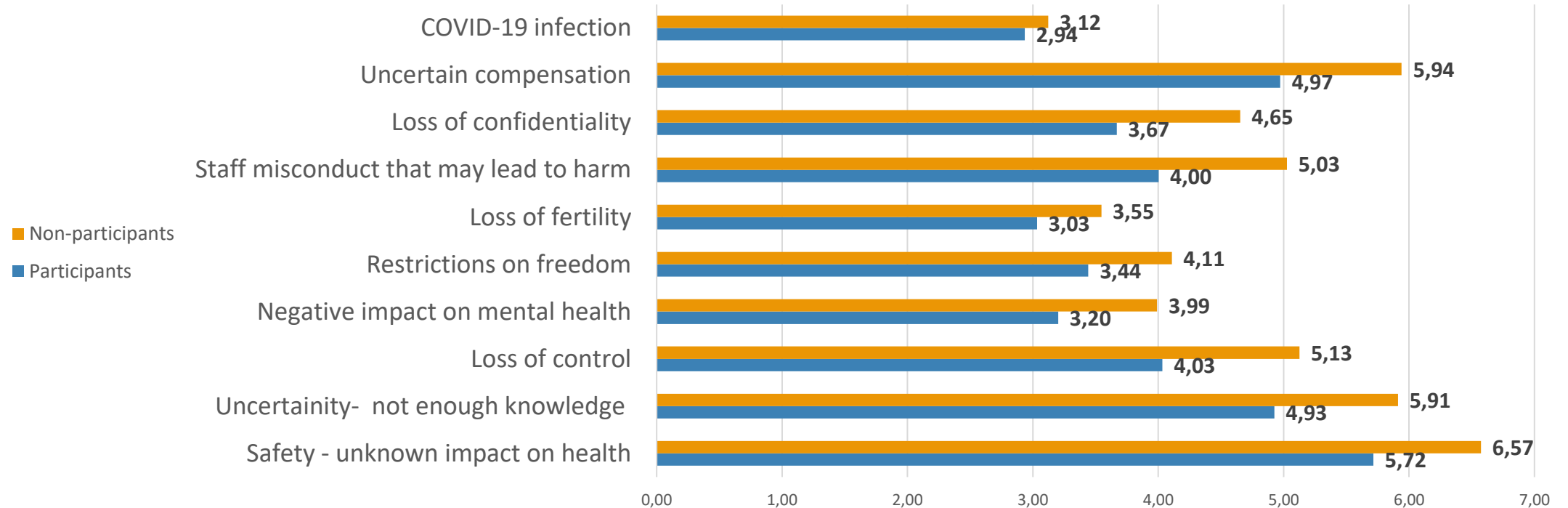
The most important aspect of study participation for respondents is the continuation of medical care after the end of the study, followed by the possibility of direct contact with medical professionals and the opportunity to perform free medical tests during te study.

What were you most afraid of when deciding to participate in a clinical trial?

Rate on a scale of 1-10 with 1 being the least significant and 10 being the most significant

- **Safety** - you are concerned that the unknown effect of the study drug or treatment may lead to serious adverse effects in the future.
- **Uncertainty** - you do not have enough knowledge about what awaits you in the study and you are afraid of unknown consequences.
- **Loss of control** - you are concerned that participation in clinical trials may lead to loss of control over your own treatment you may need.
- **Negative impact on mental health** - you are afraid that participation in clinical trials may have a negative impact on your mental health - you are afraid of feeling isolated, stressed or depressed.
- **Restriction of freedom** - you are afraid that when taking part in a clinical trial you will have to follow strict rules and restrictions regarding lifestyle, e.g., eat certain foods at certain times or refrain from eating for some time, use contraception or refrain from having sex , give up your favorite stimulants, e.g., coffee or caffeinated drinks, for the duration of the test which may be bothersome for you.
- You are concerned that participation in a clinical trial will result in **loss of fertility**
- **Staff misconduct** - you are concerned that a clinical trial may be conducted incorrectly or unethically, and this may lead to your harm.
- **Loss of confidentiality** - you are afraid that your personal data may be disclosed to third parties, you are afraid that your participation in a clinical trial will be publicly disclosed.
- **Uncertain financial compensation** - you are concerned that the possible compensation for participation in the study and possible compensation for adverse reactions is too small in relation to your costs related to participation in the study or the cost of treatment.

What were/you most concerned about when deciding to participate in a clinical trial?



Observations

- In both groups the major concern related to participation in clinical trial is safety - that the unknown effect of the study drug or treatment may lead to serious adverse reactions.
- Significant differences between volunteers who already participated in clinical trials and those who have not participated – participants present lower level of concerns in all investigated factors.

Satisfaction & Willingness To Participate



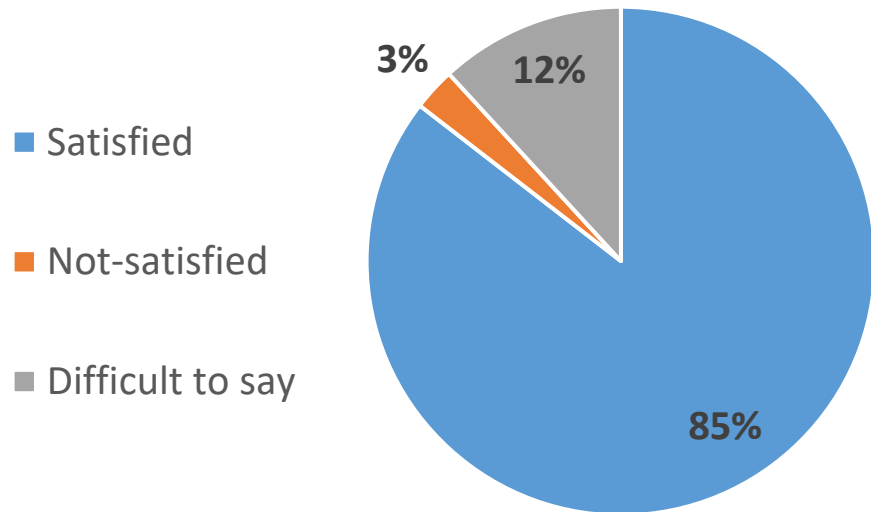
1

2

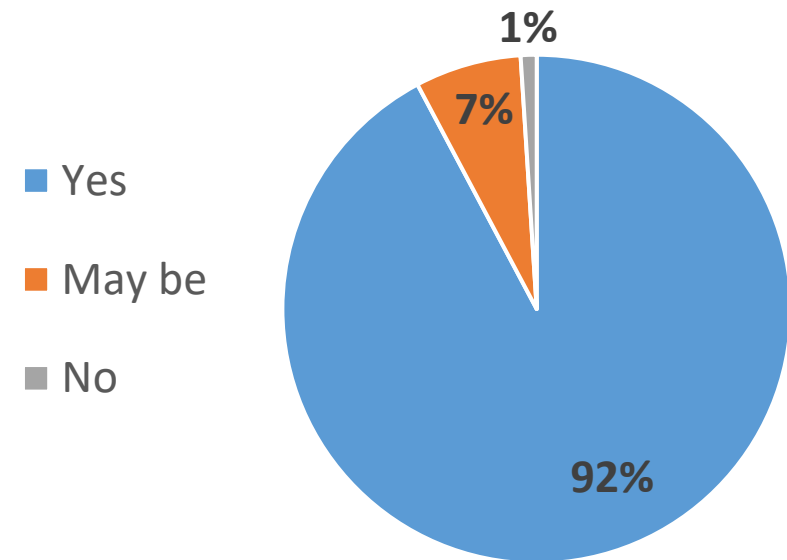
3 RESULTS

4

Are you satisfied with your participation in the clinical trial?



Would you take part in a clinical trial in the future?



Observations

- 85% of participants are satisfied with their participation in the clinical trial.
- 92% of participants declared an interest to take part in a clinical trial in the future.

Conclusions

Loyalty

Survey results show a high level of **positive attitude toward participation in clinical trials** – **92%** of participants want to take part in a clinical trial again.

Trust

Former participants present a higher level of confidence in clinical trials, as shown by significantly lower average scores in all categories of concerns as compared to non-participants.

Incentives

The **financial aspect is a very important motivator** in both analysed groups – but was indicated as a key motivator by the group of participants – whereas non-participants emphasized their willingness to help others.

Care

Both analysed groups highly rated the possibility to perform **free medical tests and direct, unlimited contact with medical professionals** (also after the study) to discuss health issues which may reflect an unmet medical need in Polish society.

THANK YOU

DANKE

ANY QUESTIONS?

