# Patient preferences on decentralized clinical trial approaches

## Focus group study to identify attributes

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# Conflict-of-interest statement

**I have no personal conflict of interest to declare.**


## Funding

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- "www.imi.europa.eu"


## Disclaimer

- The research leading to these results was conducted as part of the Trials@Home consortium. This paper only reflects the personal view of the stated authors and neither IMI nor the European Union, EFPIA, or any Associated Partners are responsible for any use that may be made of the information contained herein.

# Background - What is decentralization of clinical trials?

" trials that make use of digital innovations and other related methods to make them more accessible to participants"

"moving trial activities to the participant's home or to other local settings"

"minimising or eliminating physical visits to a clinical trial centre"

Adapted from: https://trialsathome.com/trialshome-glossary/

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# Objective

## What are the drivers for participation in clinical trials?

**Research gap:** little knowledge about how changes in decentralization of a trial effect preferences for participation.

**Aim:** determine the drivers (attributes) for participation in clinical trials with different decentralization levels in persons with type-2-diabetes mellitus (T2DM).

The findings will be used to elicit preferences in a discrete-choice-experiment.

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# Methods

## Step 1: Literature search

- Identification of attributes
- Iterative discussion rounds with researchers

## Step 2: Focus groups

- Focus groups in three countries: The Netherlands, Austria and Germany
- 1 Focus group consists of 4-6 participants
- Duration: 3-4 h
- Nominal group technique

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# Methods

## Structure of the focus group

**Part 1: Informed Consent**

**Part 2: Background questionnaire**

**Part 3: Focus group session**

A. Introduction

B. Silent generation and round-robin

C. Clarification

D. Ranking

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# Results from literature

## Attributes for clinical trial participation:

**30 identified attributes**

**condensed to nine attributes**

- Travel time per visit
- Location of trial activities
- Study measurement complexity
- Type of contact with health care professionals
- Frequency of study visits
- Use of digital technology
- Entire duration of the trial
- Data collection
- Risk and safety IMP

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# Preliminary results focus group session

## Pilot focus group session with 3 participants: 15 identified attributes

| (Changed) attributes from the literature |
| --- |
| Risk and safety of the trial product |
| Location |
| Time spent |
| Flexibility-timing |
| Actual tasks (TODOs) |
| Training |
| Innovation |
| Data collection |
| Type of contact with health care professionals |

| Completely new attributes |
| --- |
| Referral |
| Support network system |
| Trial security |
| After trial treatment |
| Remuneration |
| Personal and community benefits |

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# Preliminary results focus group session

## Ranking of the top 5 most important attributes in the pilot focus group session

| Ranking of the attributes | |
|---|---|
| 1 | Location |
| 2 | Time spent |
| 3 | Flexibility – timing |
| 4 | Actual tasks (TODOs) |
| 5 | Personal and community benefits |

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# Conclusion

- Focus groups are essential to identify relevant attributes
- Transparent process is important
- Drivers for participation in clinical trials are important, e.g.:
  - To increase participation in clinical trials
  - To design future patient-centric clinical trials

## Next steps

- Finalize focus group sessions in three countries
- Define a final set of attributes and levels
- Elicitation of preferences within a discrete choice experiment

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# Thank you!

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