

Trials@Home Webinar

Digital Literacy in DCTs. What is asked of trial participants?



Disclaimer

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Agenda

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- Who are we?
- T@H and participant diversity
- DigiPACT
 - Introduction
 - Results
 - Discussion
 - Future applications

Today's presenters





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T@H consortium

TRIALS @HOME

Trials@Home project

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The aim

Provide recommendations on and drive the adoption of...

Project start September 1, 2019, due to end August 31, 2024

Decentralised Clinical Trials (DCTs), a disruptive approach, enabled by emerging digital technology, setting the trial around the patient rather than a centralised trial setting

The consortium





T@H and participant diversity



Participant Diversity in Decentralised clinical Trials

- Conventional clinical trials often fail to include a diverse participant population^{1,2}
- Decentralised clinical trials are more diverse?
 - 1. Promises High
 - Accessibility, Patient centricity, ...
 - 2. Evidence Low
 - 3. Challenges ?
- We at T@H think it's important to understand what the effect is of a decentralised trail approach on participant diversity
 - 1. Knepper et al. Nature (2018)
 - 2. <u>Under-served groups</u> Witham et al. Trials (2020)

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The why of the T@H RADIAL proof-of-concept study



aims to assess the scientific and operational quality of a fully decentralised and hybrid trial approach compared to a conventional trial approach



Evaluate the <u>acceptability</u> of DCTs in terms of safety, data quality and medical endpoints

(i.e., can we responsibly move to decentralised clinical trial approach?)

Explore <u>potential benefits</u> of DCTs, in terms of subject retention, recruitment, diversity, cost, and site and patient satisfaction

The how of the T@H RADIAL proof-of-concept study





Objectives and Endpoints

Potential benefits

To compare **recruitment and retention rates** between the site-based arms (Part A) vs decentralised arm (Part B)

To compare participants characteristics (**Diversity**) between the site-based arms (Part A) vs decentralised arm (Part B) (on various diversity aspects such as race, ethnicity, socioeconomic status, digital literacy, distance to health care professional, mobility etc.)

To compare the **site staff and participant satisfaction** regarding their experience with the operational approach (Conventional, hybrid or remote)

Evaluate the acceptability

Acceptable treatment compliance?

Acceptable AE/SAE time to reporting and reporting rate

Acceptable rate of missing data and reasons for missing data (data quality)

Acceptable clinical endpoints (HbA1c, hypoglycaemias)

+ more





Participant Diversity in Decentralised clinical Trials

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Participant diversity in Decentralised clinical Trials - Challenges?



DigiPACT







Background

- During the COVID-19 pandemic, many healthcare services had to be carried out remotely^{1,2}.
- This limited the access of vulnerable groups in the population to healthcare due to a lack of access to technology or low digital literacy, known as the **digital divide**^{1,2}.
- Although decentralised clinical trials (DCTs) offer to remove some barriers, increased digital tool use may limit access of some groups to clinical trials^{3,4}.
- Currently, the digital skill requirement of DCTs are **not known**, limiting further research on the impact of digital literacy requirements on clinical trial diversity.

1. Watts G., COVID-19 and the digital divide in UK, 2022

- 2. Ramsetty A. and Adams C., Impact of the digital divide in the age of COVID-19, 2020
- 3. Kozin S. and Coravos A., Decentralised trials in the age of real-world evidence and inclusivity in clinical investigations
- 4. Dorsey ER. et al., The new normal in clinical trials: decentralized studies, 2020





Research Question

What are the digital literacy competencies required from participants for effective participation in decentralised clinical trials?



Digital Competencies

- Applicable when digital methods are used
- Tools with same purpose may have different digital competence requirements

Decentralised Clinical Trials

- Every clinical trial is unique
 - Different measurement needs
 - Different tool needs
- Decentralisation ≠ digitalisation
- Decentralision is a continuum

= We can't make a list of digital competencies that is applicable to every clinical trial







Objectives

- Identify fundamental skills required for effective participation in decentralised clinical trials.
- Construct lists of skills that may be required for 5 identified decentralised elements.



Methods

- 1. Semi-structured interviews
- 2. Delphi study (3 rounds of survey and a panel meeting)
- 3. Mapping of identified skills on the European Digital Competence Framework for Citizens (DigComp)



Delphi Structure







- Demographic questions
 - Initial skill lists formed through interviews and literature research listed under 5 decentralised elements

- Skills were listed under 5 decentralised elements.
- Skills were further grouped under 4 main titles:
 - 1) Skills that reached consensus (no action needed)
 - 2) Skills that didn't reach consensus
 - 3) Skills subjected to changes in wording
 - 4) Newly added skills
- All skills in the study listed
- Panel members were asked to choose 5 most important digital skills for effective participation in DCTs.
- Skills that reached consensus and skills that weren't chosen by any panel member in R2 were excluded.
- Panel members were asked again to choose 5 skills.

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N/A

2 Section

Section

Consensus Criteria - Section 1

• All skills rated on a 5-point Likert scale

Absolutely not required	Not required	Neutral	Required	Absolutely Required	l don't know
1	2	3	4	5	excluded

- Consensus criteria
 - Median = 4-5 and IQR <1.5 = positive consensus "critical skill";
 - Median = 3 and IQR <1.5 = positive consensus, "not critical skill"
 - Median = 1-2, and IQR <1.5 = negative consensus, "not required skill";
 - IQR ≥1.5 = no consensus, or the skill was newly added = the skill was included in the subsequent Delphi round for another rating.

IQR: interquartile range





Consensus Criteria - Section 2

- Round 2
 - Skills that were chosen by the majority (>50%) reached consensus on the importance of the skills
- Round 3
 - The skills that weren't chosen in round 2 by any participant were excluded.
 - 2 cut-off points were included: 50% and 25%









Demographics

Occupation (n=25)

9	Biopharmaceutical company	
5	Technology vendor	
4	Academia	
3	Healthcare provider	
2	CRO	
2	Consultant	

Experience

Experience with selecting technologies to be used in DCTs
Experience with participant diversity in clinical trials
Setting up and/or running DCTs
Experience running DCTs, with knowledge of patient/site feedback regarding remote clinical trial elements
Experience with developing technologies for DCTs



Lists per Decentralised Element

Remote Consent		
	Ability to download a file from an application or website	
	Ability to download and open attachments from emails	
	Ability to electronically sign a document	
Critical skills	Ability to navigate webpages	
	Ability to recognise and engage with links (in forms of text, graphic, etc.)	
	Ability to use two-factor authentication technologies	
	Ability to use video conferencing tools	
Not oritical skills	Ability to attach and send documents by e-mail	
	Ability to sign on a touch screen with finger	
Not required skills	Ability to save files on a computer or mobile device.	
Not required skills	Ability to upload files on a website	



Fundamental Skills for DCTs

Votes (% over 23 participants)	Most important digital skills for effective participation in DCTs
15 65.2%	Ability to create and sign-in to an account in a mobile device application or computer software*
15 65.2%	Ability to fill out online forms. *
14 60.9%	Ability to share information through applications (e.g., entering data, filling in an e-diary) *
12 52.2%	Ability to connect a device to the internet*
13 56.5%	Ability to recognise lack of internet connection
12 52.2%	Ability to connect one or more Bluetooth devices to a mobile device
10 43.5%	Ability to download and set up an application via application-store on a mobile device
9 39.1%	Ability to recognise and engage with links (in forms of text, graphic, etc.)
7 30.4%	Ability to use email service (e.g., receive, send emails)
7 30.4%	Ability to recognise pending notifications in a mobile application when the application is not open
6 26.1%	Ability to navigate webpages
6 26.1%	Ability to turn on video and microphone on video conferencing tools

* Skills that were distinctively rated higher in round 2. These skills were excluded in round 3.







Highlights

DigComp Framework Mapping

- Three main competence areas:
 - 1) Devices and software operations
 - 2) Information and data literacy
 - 3) Communication and collaboration.
- General proficiency level: foundation

- First published in 2013 to identify the digital skill requirements in different sectors and guide the development of assessment tools and training modules.
- six main competence areas
- Four broad proficiency levels describing
 - The acquisition of knowledge of the competence
 - The complexity of the tasks they can handle
 - Their autonomy in completing the task
- An exception is online recruitment and screening skills. Proficiency level: foundation intermediate

Fundamental Skill List

- Similarly, all critical skills for online recruitment and screening were listed in the list of fundamental digital skills.
- Other skills listed in fundamental digital skills were mostly related to data integrity.

Highlights

Not required skills

- All the skills in the study were taken from real life examples. Therefore, rating as "not required" was not expected.
- Several reasons were observed in the feedback:
 - Overburdening participants when not necessary
 - Importance of using available technology to minimise the digital skill requirement
 - Maintaining trust towards clinical trials
 - Maintaining data integrity

Skill (decentralised element) Ability to use video conferencing tools (online recruitment and screening) Ability to save files on a computer or mobile device (remote consent) Ability to upload files on a website (remote consent)

- Ability to change security settings on a mobile device (telemedicine)
- Ability to manage a digital personal calendar (telemedicine)

Ability to download applications through sources other than application-store (trial applications)

Ability to put in the correct date and time on a device (during setup or after reset) (remote measurement devices)

Navigating Available Statistical Data and Literature

- Poor diversity in clinical trials limit the applicability of the results to the general population⁶.
- Although digital tools are expected to lift some of the barriers such as travel burden, they carry the risk of
 introducing a new barrier by requiring digital literacy^{3,4}.
- Older adults are perceived as the vulnerable group for increased digital literacy requirements⁷.
- Currently, it is unknown if and which groups in the populations will be excluded from clinical trials due to digital divide.
- However, skills identified in this study can be used to navigate the existing data.

Kozin S. and Coravos A., Decentralised trials in the age of real-world evidence and inclusivity in clinical investigations
 Dorsey ER. et al., The new normal in clinical trials: decentralized studies, 2020
 Clark LT et al. Increasing diversity in clinical trials: overcoming critical barriers, current problems in cardiology, 2019
 Van Rijssel TI et al., Ethics review of dcts: results of a mock ethics review, 2022





Older adults – Eurostat 2021 Individuals' Level of Digital Skills⁸

Eurostat assessment categories	Skills levels according to the study results
Information and data literacy	Above basic
Communication and collaboration	Above basic
Digital content creation	Basic
Safety	No skills - basic
Problem solving skills	No skills - basic
Overall skills	Above "limited"

- 65% of the population in European Union, meet the skill requirements in DCTs.
- 20% of the population lacks the required digital skills or their skills level couldn't be assessed due to lack of internet use in past 3 months.

Age group (years)	Number of individuals lacking skills (%)	Stratification according to education level
64-74	49%	Low education: 59%
55-64	27%	High education: 9%

8. Eurostat, Individuals' level of digital skills (from 2021 onwards), 2021



Older adults – Literature and OECD

- Technology ownership is an important criteria in adoption of new digital tools by the older adults (<u>approx</u>. <u>50% of the population</u>)⁹.
- OECD dataset: more than half of the older adults aged 55-74 used internet on a daily basis in 25 countries (out of 31 reported countries)¹⁰.
- **Design** of the digital tool, **instructions** and **meaningfulness** to the patient group was found important^{11,12}.

9. Van Houwelingen CT. et al., Understanding olde rpeople's readiness for receviving telehealth: mized – method study, 2018

10. OECD, ICT access and usage by households and individuals, 2021

- 11. Terp R et al., Older patients' competence, preferences and attitudes towards digital technology use: explorative study, 2021
- 12. Vaportzis E. et al., Age differences in the use of health information technology among adults in the United States: An analusis of the health information national trends survey, 2021





Other populations - Eurostat

- Individuals;
 - With lower formal education
 - Living in low income households
 - Living in rural areas

	Meeting skill criteria	Not enough overall skills
No - low formal education	45%	39%
High formal education	86%	5%

- have insufficient digital skills and/or no internet use in the past 3 months prior assessment⁸.
- Some socio-economic factors can act as risk factor in some disease areas (e.g.,cardiovascular diseases)¹³.
- This may amplify digital divide in some clinical trials.

8. Eurostat, Individuals' level of digital skills (from 2021 onwards), 2021

13. Dalstra JA et al., Socioeconomic differences in the prevalence of common chronic diseases: An overview of eight european countries, 2005

Strengths and Limitations

- + First research to our knowledge to identify and map the digital competence requirements of DCTs according to DigComp.
- + Modular lists that can be tailored to specific trials.
- + Delphi panel representative of different stakeholder groups.
- Soft digital literacy skills are not included.
- Rapidly evolving landscape may require update of the lists.
- Approximately half of the panel members (44-50%) were members of Trials@Home Consortium.



Conclusions and Future Research

With only the results from this study, it is not possible to make definitive conclusions on the effect of a decentralised approach on the participant diversity.

However, it is beneficial for:



Early identification of potential vulnerable groups



Bridging a possible digital divide during the planning of the clinical trial



An awareness tool to minimize the digital literacy requirements by design



Development and wide adoption of standard tools is critical for future research on relationship between digital literacy requirements and clinical trial diversity



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