

What are digital literacy requirements for Decentralised Clinical Trials?

A Delphi study to reach expert consensus

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Purpose

Identify required digital literacy for effective participation in decentralised clinical trials by

- Identifying top digital skills required for effective participation in all DCTs
- Constructing exhaustive lists of skills that may be required for each of the following decentralised elements:



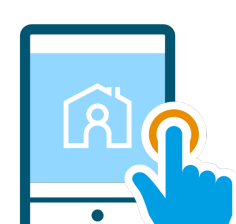
Online recruitment and screening



Remote consent



Telemedicine



Clinical trial applications

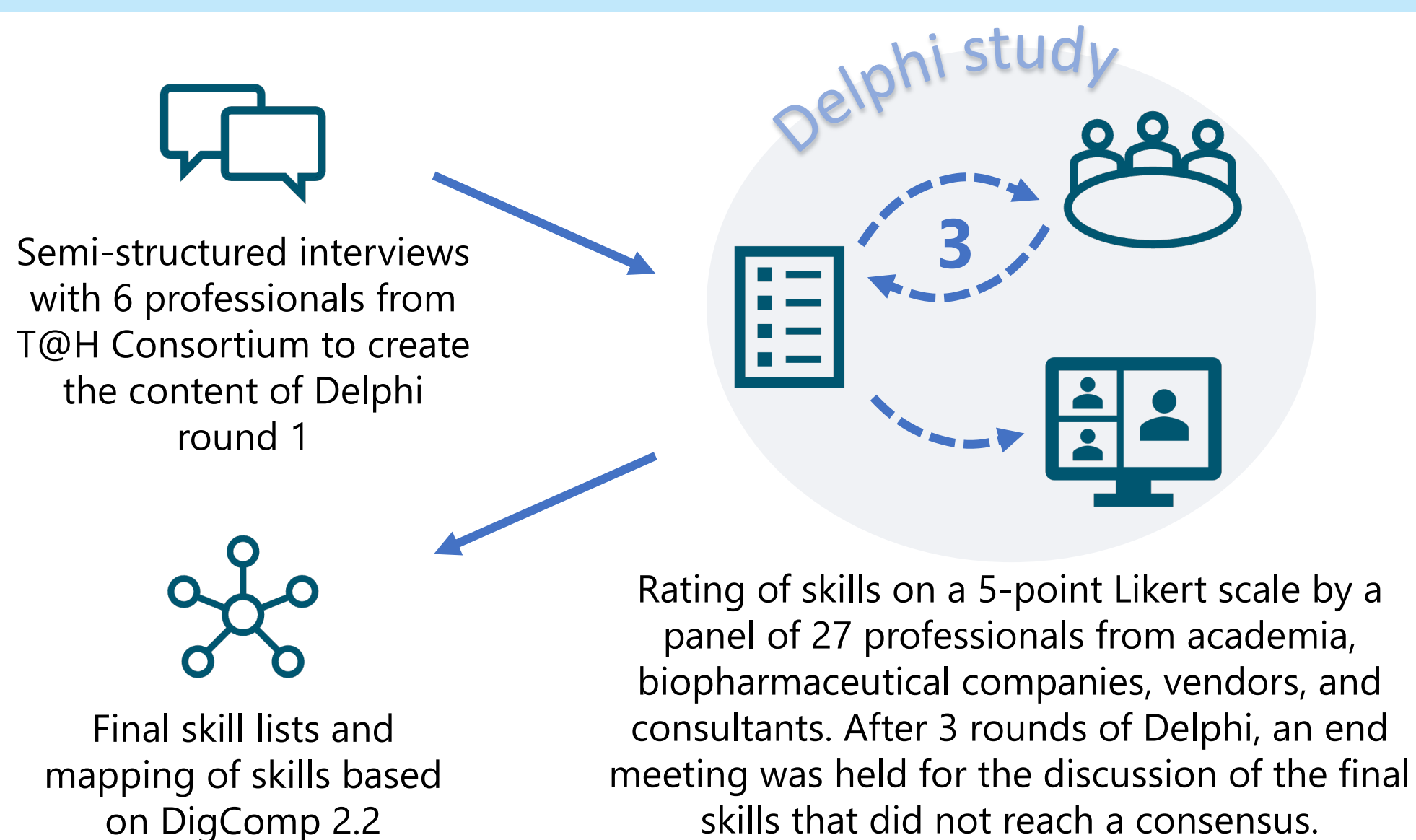


Remote measurement devices

Background

- Decentralised clinical trials (DCTs) are clinical trials in which trial activities are centered around participants by use of technology and other operational innovations.
- The digital skills required for effectively participating in DCTs may be distributed unequally in the population, possibly affecting the participant diversity.

Methods



Results

Top skills required for effective participation

Ability to...

1. create and sign-in to an account in a mobile device application or computer software
2. fill out online forms.
3. share information through applications
4. connect a device to the internet.
5. recognize lack of internet connection
6. connect one or more Bluetooth devices to a mobile device
7. download and set up an application via application-store on a mobile device
8. recognize and engage with links (in forms of text, graphic, etc.)
9. use email service (e.g., receive, send emails)
10. recognize pending notifications in a mobile application when the application is not open

Exhaustive list for skills for remote consent

Ability to...

- download and open attachments from emails
- use video conferencing tools
- recognize and engage with links (in forms of text, graphic, etc.)
- navigate webpages
- download a file from an application or website
- use two-factor authentication technologies
- electronically sign a document
- attach and send documents by e-mail
- sign on a touch screen with finger
- ◆ upload files on a website
- ◆ save files on a computer or mobile device

• Required (median 4-5) ○ Neutral (median 3) ◆ Not required (median 1-2)

Potential application areas



Designing new tools

What are the most skill-intensive points in our current remote consent process, and how can we make it more user friendly?

Instead of requiring participants to sign by hand, we can utilize eSignature system where signing is click based.



Selecting tools

Does remote consent tool A require more digital skills than remote consent tool B?

Tool B is preferred because it offers a click-based signing process that also automatically e-mails a signed copy to the participant.



Assessment of the potential impact of required digital skills on participant diversity

In a clinical trial conducted in US, some participants may have difficulty to join a video conference meeting due to a lack of internet at their home (approximately 18% of the households in US doesn't have internet)^{1,2}.



Determine digital literacy burden of a study

Which skills from this list do we check? In which ways is this clinical trial more digital skill intensive than the other clinical trial?



Creating assessment tools & training modules

Based on the top 10 skills required for DCTs, we can create a training module that can be used in every DCT. We can assess participants abilities with an assessment tool covering these skills.

Conclusion

- ✓ Top skills reflects the importance of digital skills in reaching potential clinical trial participants and data integrity & safety.
- ✓ Eliminated skills reflects what processes to avoid for better patient centricity and data integrity.
- ✓ Lists of digital skills for decentralized elements form a base for designing and selecting tools, assessing potential impact on diversity, determining digital literacy burden of a study, and creating assessment tools & training modules.
- ✓ List of top10 digital skills for DCTs is a good foundation for creating training modules that can be reusable across different DCTs.

1. Ramsetty, A., & Adams, C. (2020). Impact of the digital divide in the age of COVID-19. *Journal of the American Medical Informatics Association*, 27(7), 1147-1148.

2. Data, O. E. C. D. ICT access and Usage by Households and Individuals 2021.