831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP5 – CODE

D5.3 Report on the mapping of paradigm changes in the relationships between HCPs and patients

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Document History

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V1.0	27 Jan 2023	First draft (PN)
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V4.0	15 Jun 2023	Fourth draft for PMO and CODE review (AB)
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Summary of the task

Widespread adoption of Decentralised Clinical Trials (DCTs) means changing roles and responsibilities within healthcare and patient spaces. Training and education tools may be required, depending on the current level of knowledge and comfort with DCT approaches across stakeholder groups. As such, stakeholder market research needs to be conducted in order to measure and quantify the current level of familiarity and reception of DCTs among stakeholders. The goal is then to identify which groups might require training and education.

The present report details how Work Package CODE of Trials@Home met with stakeholders through virtual roundtables as part of Task 5.2 (Implementation of Stakeholder Roundtables), then identified key stakeholder groups and developed targeted surveys to probe these groups as part of Task 5.3 (Stakeholder Market Research on Opinions on DCTs), leading to deliverable 5.3 (D5.3). Three relevant stakeholder groups were identified: Principal Investigators (PIs), General Practitioners (GPs) and patients, leading to the development of three distinct surveys to probe them. Report D5.4 will describe how the surveys were administered and highlight findings on how moving to DCTs would impact the identified stakeholders. These insights will help to measure and quantify the paradigm change inherent in a move from traditional trial methodology towards DCTs. This will then serve as input for the development of training and education activities (D5.5, Education and Training Sessions).

Methods

Work Package CODE focuses on the communication and dissemination component of Trials@Home, as well as on stakeholder engagement. The Training & Education working groups consist of several CODE members, each with a specific area of expertise, such as clinical practice and patient care, clinical trial implementation, patient engagement, patient advocacy, statistical analysis, and communication.

CODE members were allocated to two different working groups dedicated to training and education, as outlined in the project plan. The first Training & Education working group, WG1, was the brainstorming group, responsible for defining which stakeholders would require training and education with the adoption of a decentralised trial approach. Task 5.2, Implementation Stakeholder Roundtables, was meant to be a series of face-to-face roundtables with stakeholders, for the purposes of consulting for this task. This nicely aligned with the establishment of the Trials@Home External Stakeholder Platform (ESP). When establishing the ESP, the consortium made suggestions of key stakeholders that could be invited. The list was then reviewed and vetted by the Trials@Home Executive Board and each selected stakeholder was invited to become an ESP member. Because the COVID-19 lockdowns in 2020 did not allow traveling for face-to-face meetings, these roundtables mainly took place digitally. Where needed, additional consortium members were also consulted. The Training & Education working groups also consulted with EAGLE, the Trials@Home work package that focuses on the legal and regulatory aspects of DCTs, when considering whether to approach certain groups.

A smaller working group, WG2, was then derived from WG1, dedicated to creating materials to probe the perspectives of these relevant stakeholders. Throughout tri-weekly meetings, this group first discussed the best format for conducting the market research, then wrote the questions for the survey.

Results

Defining Stakeholder Groups to Probe

During brainstorming sessions, the WG1 team agreed that patients, site study teams, General Practitioners (GPs), regulators, ethics committee representatives and technology providers were the stakeholders most impacted by a shift from traditional trials to full DCTs. WG1 decided to survey three of these groups: patients, PIs/study teams, and GPs. Patients were chosen as they will be the ones participating in DCTs, and it is important to determine whether they may need training and education in order to fully participate. PIs, study coordinators and study nurses, in other words, the site study team, were also selected as highly relevant because they will be the ones carrying out clinical trials, whether DCTs or conventional. Finally, GPs were chosen because they are always informed if their patient is recruited for a clinical trial. As such, they can be a valuable support to any patient considering a trial, as well as a source of referral for recruitment.

Not all relevant stakeholders were selected to survey, as not all groups were defined as potentially benefitting

from training and education. In discussions with EAGLE, it was decided not to approach regulators and ethics committee representatives, as they were already approached as part of EAGLE work in an interview study with regulators and focus groups with ethics committee members (See the Trials@Home website for links to these papers and others). WG1 also agreed that the technology stakeholders would not be approached. These stakeholders either develop a technology that is already implementable within DCTs (and thus would need little adaptation and no need for high DCT awareness) or they are developing technologies specifically for DCTs and are thus already educated on DCTs. Similarly, pharmaceutical companies and CROs were not probed as they have historically been early adopters of DCTs. Since the purpose of this market research is to determine which groups require further training and education, it would not be necessary to approach these groups who are expected to have familiarity with DCTs already.

Survey Development

During a series of work sessions in 2021, WG2 developed three surveys: one for study teams at clinical sites, one for patients and one for GPs. See Annexes 1, 2 and 3 for the full question sets of all three surveys. These surveys included mainly multiple-choice questions, offering several predefined answers. Most of the questions were also supplemented with a free text field for other or more detailed answers to gain more insights. All three surveys were reviewed and approved by the Trials@Home Executive Board. Note that the survey refers to remote decentralised clinical trials (RDCTs) instead of DCTs because at the time the survey was conducted, RDCT was the standard term within the Trials@Home project. Meanwhile the project has changed its terminology and is now using the term 'decentralised clinical trials' (DCTs).

➤ PI Survey. The first survey that was developed was designed to probe all investigators, study coordinators and study nurses. This study will be referred to as the PI survey for brevity, even though not all those surveyed were expected to be PIs. The goal was to reach out to European university hospitals, general hospitals, private practices and site management organisations to determine their current knowledge of DCTs, what they think the burden will be and what education or training they could benefit from.

The survey first asked about respondents' role, what type of organisation they work for, their therapeutic area, and their country. The rest of the questions were split into three main categories. The first was awareness, where questions were focused on whether PIs have heard of remote or decentralised clinical trials, whether they have heard of IMI and Trials@Home, and how comprehensive they perceive their knowledge to be. The next category was readiness, where questions were focused on the PIs' interest in new clinical trial models, and on getting insights on any expectations, opportunities and concerns they see in the implementation of those models. The third question category was experience, where questions were designed to find out if and what experiences the respondents themselves had had with (partly) remote or decentralised types of clinical trials. The full list of questions can be found in Annex 1.

➤ Patient Survey. The second survey was aimed at patients living in Europe, not restricted to a specific therapeutic area. As the concept of DCTs is expected to be more familiar to PIs than patients, the survey was adapted from the PI survey to first include a range of questions on patients' knowledge of clinical trials in general. They were then asked about their current knowledge of DCTs and about potential obstacles or difficulties they expected to encounter. The survey inquired about previous DCT participation, their experience with DCTs and if they had dropped out of the trial. This survey focused on the valuable aspects for patients, but also on the barriers they had encountered and the concerns they had. The survey ended with questions on the type of training and education they anticipate they would benefit from. The question set can be found in Annex 2.

➤ GP Survey. This stakeholder group was also expected to be less familiar with DCTs than the PIs. As such the survey was designed to probe GP knowledge of traditional trials as well as DCTs. They were also asked what they see as obstacles and opportunities and what their training and education needs might be. See Annex 3 for the full question set.

Conclusion

WP CODE identified stakeholder groups who would be most affected by a transition to more DCT approaches in clinical trials as part of the Trials@Home deliverable D5.3. They then identified which of these groups might benefit from training and education materials, settling on patients, clinical site staff and GPs. Three separate surveys were then developed through working group discussions and brainstorming. The content of the three surveys focused on probing respondents' opinions on what kinds of obstacles they might experience with DCTs, however for the patient and GP surveys there were also questions asking about their experience and knowledge of clinical trials in general. These surveys were all approved by the project's Executive Board. The report for D5.4 will detail how these surveys were administered as well as the results, which will be used to inform future training and education needs.

Annexes

ANNEX 1 PI Survey question set
ANNEX 2 Patient Survey question set
ANNEX 3 GP Survey question set