Impact of mobilising collective intelligence in clinical research planning

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor in Philosophy

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November 2020

Abstract

New methods of conducting research have been emerging outside clinical research. For example, worldwide game players helped to construct protein molecular which scientists had been struggling with for 15 years. In these examples, researchers leveraged collective intelligence of people who were not usually involved in research. My research aims to investigate whether and how mobilising collective intelligence could be used in the planning of a randomised controlled trial.

To achieve this aim, I first conducted a scoping review to describe the methods of mobilising collective intelligence across different research fields. From this scoping review, I proposed a framework for implementing a research project using these new methods.

Second, I conducted a qualitative study involving online survey and semi-structured interviews to investigators, researchers or coordinators of research projects mobilising collective intelligence. Drawing on their experience, I provided good practice advice for the governance, planning, and conducting of research involving collective intelligence.

Finally, I developed a proof-of-concept study using case vignettes to leverage patients' collective intelligence to improve trial organisation. Patients proposed several suggestions to improve the logistical organisation of trials. They also highlighted the importance of changing one-size-fits-all approach of trial organisation.

In conclusion, the work in this thesis provides the first comprehensive accounts of methods used to mobilise collective intelligence across different research disciplines. The proof-of-concept study provided an example of leveraging patients' collective intelligence to explore ideas and perspectives to improve clinical trial planning.

Acknowledgement

I would like to express my deep and sincere gratitude to my supervisor, Professor Isabelle Boutron, for giving me the opportunity to work with her and providing invaluable guidance throughout this research. Her dynamism, vision and motivation have deeply inspired me. She has taught me the methodology to carry out the research and to present the research works as clearly as possible. I have special respect and sincere thanks to my co-supervisor, Professor Bridget Young, for her continued support and guidance. Her empathy, patience and immense knowledge were a source of my professional and personal growth.

I would also like to thank Professor Philippe Ravaud for accepting me to work with his team and for his valuable advice to my projects. I sincerely thank Elise Diard, Isabelle Pane, Viet-Thi Tran, Mehdi Benchoufi, Lina Ghosn, Linda Nyanchoka and Nivantha Naidoo for their support in my research. I would like to thank Laura De Nale and Audrey Conjaud for their kind help with administrative work. I would like to thank members and ex-members of the METHODS team Anna C., Theodora O., Theodoros E., Alexandre V., Justine J., Michail K. and Ignacio A. for their friendship and support.

I would also like to thank my colleagues within the MiRoR Project for their unwavering encouragement and friendship. I am grateful to the EU Horizon 2020 Marie Sklodowska Curie Actions (Grant agreement number 676207) for funding this PhD.

Last but not the least, I would like to thank my family: my parents, my sister and my partner for supporting me spiritually throughout writing this thesis and my life in general.

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Publications and Presentations

Publications

1. **Van Thu Nguyen**, Bridget Young, Philippe Ravaud, Nivantha Naidoo, Mehdi Benchoufi, Isabelle Boutron (2019), *Overcoming Barriers to Mobilizing Collective Intelligence in Research: Qualitative Study of Researchers With Experience of Collective Intelligence*, J Med Internet Res. 21(7):e13792.
2. **Van Thu Nguyen**, Mehdi Benchoufi, Bridget Young, Lina Ghosn, Philippe Ravaud, Isabelle Boutron (2019), *A scoping review provided a framework for new ways of doing research through mobilizing collective intelligence*, Journal of Clinical Epidemiology. 110: 1-11.

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3. Nivantha Naidoo, **Van Thu Nguyen**, Philippe Ravaud, Bridget Young, Philippe Amiel, Daniel Schanté, Mike Clarke, Isabelle Boutron, *The research burden of randomized controlled trial participation: a systematic thematic synthesis of qualitative evidence*, BMC Medicine 18, 6 (2020).
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5. **Van Thu Nguyen**, Cecilia Superchi, Isabelle Boutron (2018), *2-Year outcome from two parallel randomized controlled trials. Reporting considerations*, Osteoarthritis and Cartilage. 27(3): e3-e4.
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Presentations

Methods to mobilize collective intelligence: A Scoping Review, Evidence Live Conference, Oxford (UK), June 2018 (Poster)

Methods to mobilize collective intelligence: A Scoping Review, Cochrane Colloquium, Edinburgh (UK), September 2018 (Poster)

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Chapter I. Introduction

1.1. Rationale for the thesis

Evidence based medicine is defined as the integration of clinical expertise and patients' values with the best available external evidence obtained from systematic research. However, the quality of clinical research used to generate evidence has been increasingly questioned. It has been estimated that billions of dollars of investment in clinical research had been wasted due to avoidable problems in clinical trial planning. This includes the pursuit of research questions which do not address the priorities of patients and clinicians and the inappropriate design of clinical research, with "unrepresentative samples, small samples, incorrect methods of analysis, and faulty interpretation" (1). These issues could be prevented if clinicians, patients, methodologists and biostatisticians were involved in setting research agendas and designing clinical research. Meanwhile, mobilising collective intelligence through crowdsourcing is an emerging method which has been used to solicit the contributions to research, not only of researchers across different research disciplines, but also public members. This innovative method could be used to involve diverse stakeholders in clinical trial planning to contribute to tackling research waste.

1.2. Aims and objectives of this thesis

The central aim of this thesis was to investigate whether and how mobilising collective intelligence could be used in clinical trial planning. The research was guided by three main objectives which were to:

1. Identify and describe methods of mobilising collective intelligence through crowdsourcing in different research fields and propose a framework to implement them. This involved a scoping review of research projects which used methods of mobilising collective intelligence (Study One).
2. Identify barriers to mobilising collective intelligence, strategies to overcome these barriers and provide good practice advice for planning and conducting research using collective intelligence. This was undertaken using a qualitative approach with an online survey and semi-structured interviews (Study Two).
3. Evaluate the impact of mobilising collective intelligence on the planning of clinical trials. This was addressed through a proof of concept study using case vignettes to mobilising collective intelligence of patients and public members in clinical trial design (Study Three).

1.3. Thesis structure

The thesis is structured in six chapters. Chapter 1 introduces the aims and objectives of the thesis. Chapter 2 provides a review of background literature to describe the context of this thesis.

Chapters 3 presents the scoping review which described research using methods of collective intelligence across different research disciplines and developed a framework for implementation of collective intelligence projects.

Chapter 4 presents the qualitative study which aimed to identify barriers to mobilising collective intelligence, solutions to overcome these barriers and seek for good practice advice from researchers experienced with collective intelligence.

Chapter 5 describes the proof of concept study which applied the methods of collective intelligence to solicit contributions from patients and members of the public to improve clinical trial design.

Chapter 6 concludes the thesis by summarising the results, discussing the strengths and limitations of the thesis overall, and providing suggestions for future work.

Chapter 2. Background literature

2.1. Evidence-based medicine and randomised controlled trial

2.1.1. What is evidence-based medicine?

Evidence-based medicine was first coined by David Sackett and Gordon Guyatt in the 1990s to encourage clinicians to integrate external evidence obtained from systematic research into their clinical practice to provide optimal care for patients (2, 3). Although the term evidence-based medicine was first defined in the 1990s, the development of evidence-based medicine well predated the 1990s. Historical literature shows the work of clinicians and researchers who used evidence to inform their patient care. For example, James Lind conducted the first clinical trial to provide evidence of the cause and treatment for scurvy in the eighteenth century, while John Snow used evidence from observational data to identify causes of transmission of cholera in the nineteenth century.

In 1962, the US Food and Drug Administration (FDA) issued a legal regulatory framework requiring rigorous testing of clinical trials in human beings to provide evidence of efficacy of new drugs. This regulatory requirement led to a tremendous increase in the number of clinical trials, thus created a large amount of medical literature (Figure 1).

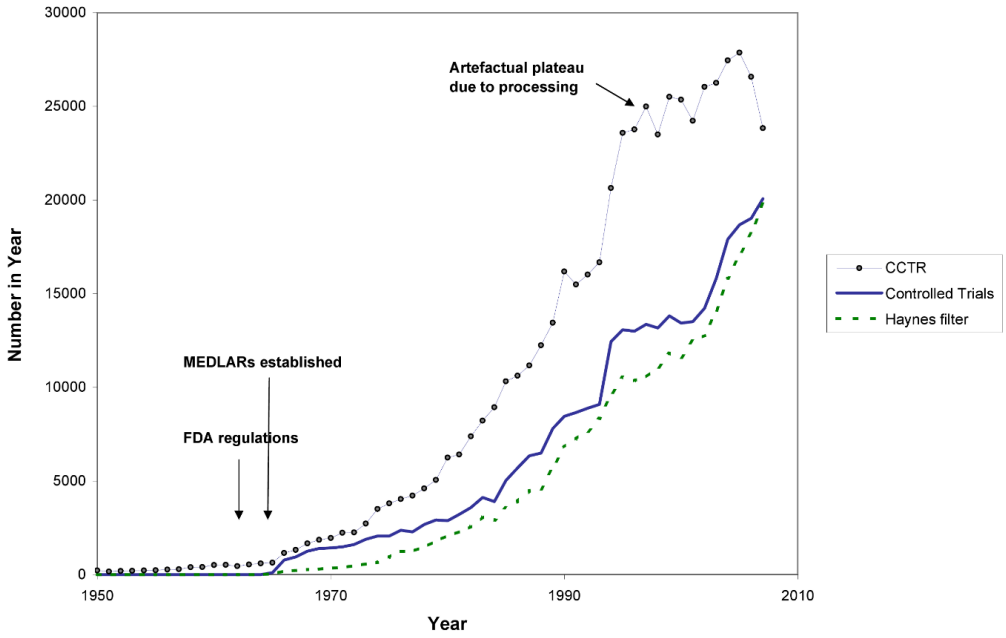

Figure 1. The number of published trials from 1950 to 2010 (reproduced from Bastian et al, 2010, (4))

However, unsystematic clinical experience with intuitive reasoning based on physiological knowledge remained dominant in practice. For example, it took ten years after evidence of benefits was established before practitioners started to use thrombolytic therapy for treating myocardial infarction (5). A recent systematic review showed that the proportion of recommendations supported by high-quality evidence in clinical guidelines released by American College of Cardiology/American Heart Association has not increased overtime despite the increased efforts in conducting clinical research (6, 7). As such, evidence-based medicine should be reinforced to ensure that clinical practice is based on scientifically trustworthy empirical evidence.

2.1.2. How to practice evidence-based medicine?

Evidence-based medicine consists of five main components: asking an answerable question, searching for the best evidence, critically appraising the evidence, integrating the evidence with clinical expertise and patients' values, and evaluating performance (*Table 1*).

Table 1. The five basic components of evidence-based medicine (reproduced from Swanson et al, 2010 (8).

Step 1	Converting the need for information (about prevention, diagnosis, prognosis, therapy, causation, etc.) into an answerable question
Step 2	Tracking down the best evidence with which to answer that question
Step 3	Critically appraising that evidence for its validity (closeness to the truth), impact (size of effect), and applicability (usefulness in our clinical practice)
Step 4	Integrating the critical appraisal with our clinical expertise and with knowledge of a patient's unique biology, values, and circumstances
Step 5	Evaluating effectiveness and efficiency in executing steps 1-4 and seeking ways to improve for next time

The main difference between evidence-based medicine and traditional medicine is that evidence-based medicine considers the best evidence and critically appraising validity of the evidence, while traditional medicine corporates evidence in the practices without verifying its trustworthy. A simple

hierarchy of evidence was proposed to support practitioners in evaluating the evidence (9). The randomised controlled trial is considered as the clinical study design providing the most valid evidence, certainly in comparison with observational studies. However, researchers soon recognised that randomised controlled trials were also subject to bias and that more critical tools should be used to assess methodological issues that could influence the quality of evidence. As such, the GRADE classification of the quality of evidence was developed to provide a structured and transparent system for assessing the quality of evidence (10, 11). *Table 2* presents criteria to assess the quality of evidence.

Table 2 Quality of evidence assessment (reproduced from Guyatt et al, 2011 (12)).

<table>
<tr><th>Study design</th><th>Quality of evidence</th><th>Lower if</th><th>Higher if</th></tr>
<tr><td>Randomised trial →</td><td>High</td><td rowspan="3">Risk of bias
-1 Serious
-2 Very serious
Inconsistency
-1 Serious
-2 Very serious
Indirectness
-1 Serious
-2 Very serious</td><td rowspan="3">Large effect
+1 Large
+2 Very large
Dose response
+ 1 Evidence of a gradient
All plausible confounding</td></tr>
<tr><td></td><td>Moderate</td></tr>
<tr><td>Observational study→</td><td>Low</td></tr>
</table>

	Very Low	**Imprecision** -1 Serious -2 Very serious **Publication bias** -1 Likely -2 Very likely	+1 Would reduce a demonstrated effect or +1 Would suggest a spurious effect when results show no effect

2.1.3. Randomised controlled trial

The randomised controlled trial is a clinical research design in which sample are randomly assigned to one or several intervention groups to compare these interventions with a control group receiving a placebo or conventional treatment. *Table 3* describes main features of a well-designed randomised controlled trial. Participants, clinicians and researchers might be blinded to treatment group to avoid the influence of their treatment preference on outcome assessment. Although observational studies such as case control studies, cohort studies can provide evidence of association between intervention and outcomes, they cannot rule out other factors that might interfere this association. By using a comparison group, randomisation and blinding, randomised controlled trials can minimise the effect of these factors.

Table 3. Features of a well-designed randomised controlled trial (reproduced from Kendall et al, 2003 (13)).

• The sample to be studied will be appropriate to the hypothesis being tested so that any results are appropriately generalisable. The study will recruit sufficient patients to allow it to have a high probability of

detecting a clinically important difference between treatments if a difference truly exists.

- There will be effective (concealed) randomisation of the subjects to the intervention/control groups (to eliminate selection bias and minimise confounding variables).
- Both groups will be treated identically in all respects except for the intervention being tested and to this end patients and investigators will ideally be blinded to which group an individual is assigned.
- The investigator assessing outcome will be blinded to treatment allocation.
- Patients are analysed within the group to which they were allocated, irrespective of whether they received the intended intervention (intention to treat analysis).
- Analysis focuses on testing the research question that initially led to the trial (that is, according to the a priori hypothesis being tested), rather than "trawling" to find a significant difference.

The quality of a randomised controlled trial is assessed by two main indicators: internal and external validity. Internal validity is the extent to which the differences observed between control and intervention group are attributed to the intervention. Flaws in design, conducting and reporting of randomised controlled trials can lead to bias, whereby the results deviate from the truth. Cochrane Collaboration has developed a tool to assess risk of bias in five domains related to design and reports of trials: selection bias, performance bias, detection bias, attrition bias and reporting bias (14). External validity is

the ability to generalise the results of randomised controlled trial into general population (15). Although randomised trials are designed to eliminate bias and increase internal validity, it is uncertain to what extent the result of the trial can be translated into clinical practice. External validity depends on several factors such as the selection of clinical trial participants and patients' treatment preferences (15).

2.2. Avoidable waste in the production of research evidence

With the advent of the evidence-based medicine movement and increasing requirement from regulatory boards, global investment in clinical trials has risen rapidly. The number of clinical trials registered on clinicaltrial.gov in 2010 was about 83,000. By May 2019, there were more than 300,000 trials registered (16). It was estimated that US$ 44.2 billion was invested in clinical trials globally in 2018 and this number is expected to grow to US$ 65.2 billion in 2025 (17). However, a tremendous increase in the investment in clinical trials does not necessarily translate into producing more usable evidence. Research agendas are heavily shaped by industry with little attention to patients' needs. Ioannidis has recently stated that "evidence-based medicine has been hijacked" and "clinical evidence is becoming an industry advertisement tool" (18, 19). Chalmers and Glasziou estimated that 85% of investment in biomedical research is wasted (20). A recent series on Lancet identified waste in all stages of research including irrelevant research priority setting, inappropriate research design, and inaccessible and unusable research reports (21-25).

2.2.1. Research waste caused by ignorance of users' need

To provide evidence for decision making, research should answer questions which are important to patients and other stakeholders such as clinicians, funders and policy makers. However, patients and clinicians are not usually involved in research priorities setting which leads to the gaps between research and practice. A study showed that only 9% of surveyed patients with knee osteoarthritis indicated research on oral and injection treatment as their first priority, but 59% of published research on knee osteoarthritis were evaluation of oral and injected pharmaceutical treatment (26). The James Lind Alliance is an initiative aiming to engage patients and the public in all phases of clinical trials, particularly in setting research agenda through Priority Setting Partnerships (PSP). PSPs bring together patients, clinicians and researchers to identify the top 10 important research questions for a specific therapeutic area that future research should address (27). However, a recent scoping review showed that only 20% of clinical research in dialysis addressed top 10 research priorities identified by a PSP organised by the James Lind Alliance (28). Similarly, in the field of oncology research, two of the three highest priorities defined by patients, which were supportive and palliative care, early detection and prevention, were covered by less than 15% of research funded by UK cancer research institute (29). This persistent gap between patients' needs and research topics raises questions about the value of research, and whether research results can be translated into clinical practice and health policy to benefit patients and care providers.

2.2.2. Research waste caused by ignorance of trial participants' experience

Clinical trials are expensive to conduct, time consuming and burdensome for patients. A quarter of clinical trials are prematurely discontinued which is a substantial source of waste in research (30). A systematic review of discontinued trials listed 28 reasons for premature discontinuation. Of these, high burden trials with many visits, invasive procedures, long questionnaires, approaching patients in inconvenient situations were some of the reasons demotivating participants (31). Further, burdensome trials might also increase the frequency of missing data due to dropouts, which might bias the estimate of the treatment effect (32). These could have been prevented by pilot studies to estimate the burden to participants and identify strategies to improve participants' experience, thus increasing their motivation to participate in trials. Complex informed consent forms and language barriers are other reasons for difficulties in recruitment and retention of clinical trials. A review showed that nearly 50% of trial participants could not understand the information related to randomisation and placebo, and 45% were unable to name at least a risk of participation explained in consent forms (33). There is a lack of efforts to help patients have better informed choices. The meta-analysis showed that the understanding of patients on informed consent has not improved for the last 30 years. Even for patients who participated in a trial, one out of six still felt informed consent form complicated (33).

Further, follow up visits are often organised inconveniently for patients, which creates unnecessary barriers for patients to complete trials. Patients have to

travel in rush hours to clinics, look for parking places and wait for hours to finish an examination and fill out questionnaires. These inconveniences disrupt their daily life and have negative impacts on their work and income (34). Although patients spend time and efforts on answering study questionnaire, outcomes which are perceived as important by patients such as functionality, social and emotional wellbeing, and adverse reactions are not always measured in clinical trials (35). A systematic review of 112 clinical trials in critical ill patients identified only 27 trials assessing patient-important outcomes and only six of them measured outcomes related to quality of life and functional disability (36). Clinical trials are designed by clinical trialists, methodologists and statisticians, while patients whose daily lives are directly affected by the participation in the trial are less often involved in trial design. This waste of research due to ignorance of participants' experience when planning clinical trials could be ameliorated by involving patients early in the conception of trials.

2.3. Stakeholder involvement to increase research value

To ensure that clinical trials answer high priority questions, and evidence generated from clinical trials are aligned with information needs in healthcare practice, patients and other healthcare stakeholders should be involved in planning and conducting clinical trials. Stakeholder involvement in clinical research is defined as " an iterative process of actively soliciting the knowledge, experience, judgement and values of individuals selected to represent a broad range of direct interests in a particular issue, for the dual purposes of creating a shared understanding and making relevant, transparent and effective

decisions" (37). Stakeholders who can contribute to clinical research are "individuals, organisations or communities that have a direct interest in the process and outcomes of a project, research or policy endeavour". *Table 4* lists different categories of stakeholders who could contribute their experience and knowledge to planning and conducting clinical trials (38).

Table 4. Stakeholders who can engage in clinical trial planning and conducting (reproduced from Deverka et al, 2013 (37))

Category	Description
Patients and the public	Current and potential consumers of patient-centred health care and population-focused public health, their caregivers, families, and patient and consumer advocacy organizations.
Providers	Individuals (e.g., nurses, physicians, mental health counsellors, pharmacists, and other providers of care and support services) and organizations (e.g., hospitals, clinics, community health centres, community-based organizations, pharmacies, EMS agencies, skilled nursing facilities, schools) that provide care to patients and populations.
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of health care.
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for

	reimbursement for interventions and episodes of care.
Policy makers	Government, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities.
Product makers	Drug and device manufacturers.
Principal investigators	Other researchers and their funders.

This list of stakeholders is not exhaustive and does not require researchers to involve all these categories of stakeholders in their research. Researchers could decide the type of inputs and perspectives that would be the most beneficial for their research. Patients with their personal experience can provide their unique perspectives to ensure research questions are relevant to their healthcare needs and to make research designs more pragmatic. Inputs from other stakeholders such as payers, policy makers and clinicians, are also important to ensure that research is useful for decision making.

2.3.1. Conceptual model for stakeholder involvement in clinical research.

Patients and other stakeholders can be involved at several different stages of planning and conducting clinical research. *Table 5* describes the stages where stakeholders can contribute to clinical research and the types of input they can provide (39).

Table 5. Engagement activities in each stage of planning and conducting clinical research (reproduced from Forsythe et, 2016 (39))

Stage of the research process	Engagement activities
Topic solicitation, agenda setting and development of research questions	• Provide input on the research topic, prioritization/agenda setting and how to frame the research question • Selection of outcomes studied
Proposal development	• Provide input on lay/plain language summaries for funding applications • Solicit or amass funding • Identify and build partnerships with researchers • Provide support for IRB approval process
Method/study design	• Select study design • Select or develop data collection tools
Recruitment	• Recommend strategies for more successful recruitment
Data collection	• Deliver the research data instrument or conduct participant interviews • Develop and host biobanks or registries that serve as sources of data
Data analysis	• Participate in coding the data and data analysis • Suggest themes for qualitative analysis

Results review, interpretation, and translation	• Interpret research findings • Highlight most patient-relevant findings • Identify implications of results for health care delivery
Dissemination	• Communicate results to other patients, community, and researchers

To support researchers in engaging stakeholders in clinical research, Deverka et al developed a conceptual model for stakeholder involvement in clinical research (*Figure 2*) (37). This conceptual model describes a process starting with the inputs i.e. contribution of stakeholders which are processed by the use of both quantitative and qualitative techniques to generate outputs, which are the decisions related to research planning and conducting. It is important to note that the inputs of the model are not only evidence from literature, but also personal knowledge and experience of stakeholders. The method used to analyse information should be able to preserve the diversity of stakeholders' perspectives.

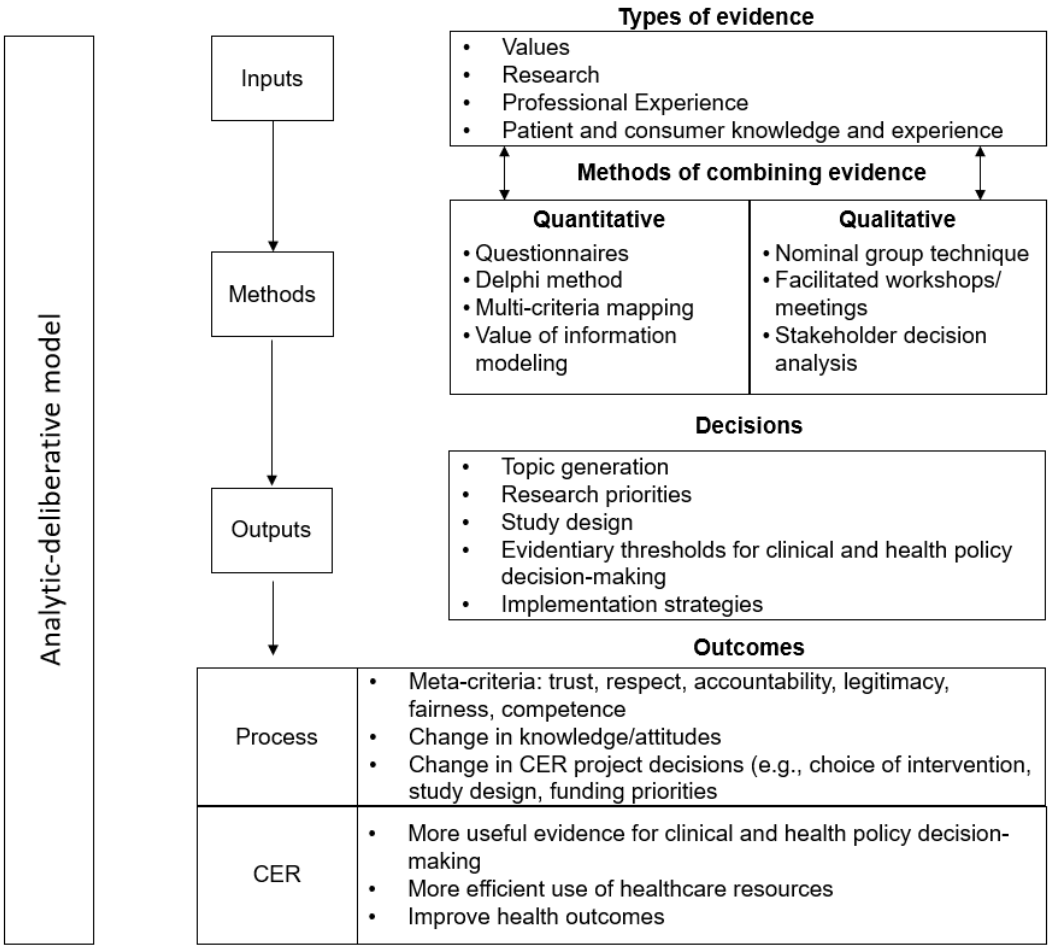

Figure 2. Conceptual model of stakeholder engagement in comparative effectiveness research (reproduced from Deverka et al, 2013 (37)).

This conceptual model describes three key components of involving stakeholders in clinical research, while enabling flexibility in the choice of methods to engage and process information contributed by stakeholders. In addition, by emphasising the value of personal experience, all stakeholders could see the role of their contribution in research.

2.3.2. Patient and public involvement in clinical research

The prevalence of patients and public member is uneven across countries and depends relatively on the policy of the funders. A systematic review of 23 clinical trials having patients and public involvement showed that nearly half

of them (10/23) came from the United States, 9 studies from the United Kingdom, and only three studies from other countries in Europe. (39). In Western Europe, the movement of patient and public involvement was quite active, however, it mainly happened in a small group of institution. In the United Kingdom, researchers involved patients and public members with the main reason to fulfil requirements from funders (40). As clinical trials have an important role to provide robust evidence to inform clinical practice, patients and public involvement should also be involved in the planning and conducting of clinical trials to ensure that trials are addressing questions relevant to patients, and the design of trials reflects patients' needs and preference. The value of patient and public involvement in the design and conduct of research is gaining wider recognition. Patient and public involvement is defined as research undertaken "with" or "by" patients or members of the public, rather than "to", "about" or "for" patients (41). This active involvement in research is different from passive participation in clinical trials as a study "subjects" with no or limited scope to contribute to designing and conducting research. Patient and public involvement is also different from public engagement activities, which aim to increase public awareness of research through communication activities of researchers to public. The aim of patient and public involvement is to increase research value by identifying relevant research questions and create appropriate research from patients' perspectives. Indeed, studies reported that public involvement helped to create a mutual respect between researchers and public members and consequently increase acceptability of research in community (42). Patients and public members contributed pragmatic suggestions, identified cultural issues to tailor

appropriate recruitment strategies and develop user-friendly data collection tools that should be considered when designing trials (43). They also collaborated with researchers to identify top research priorities to overcome challenges in trial recruitment and retention (44, 45). More research evaluating impacts of patient and public involvement on trial planning and conducting are needed (46). A study within a trial showed that advertisement of patient and public involvement in trial recruitment did not improve recruitment rate. However, a meta-analysis of 26 studies showed that patient and public involvement had a modest positive impact on trial recruitment and retention (47).

Funders in the UK, the USA and Europe have been encouraging public involvement in research. The Patient Centred Outcomes Research Institute (PCORI) in the USA is a research funder supporting research led by patient and public members (48). In the UK, NIHR stipulate that researchers must involve patient and public in the development of funding application, design and conduct of research (49). INVOLVE is an initiative funded by NIHR to support research with patient and public members. In Europe, EUPATI is a collaborative project connecting pharmaceutical industry, academia, not-for-profit, and patient organisations (50). The project focuses on educating and training patients to enhance their knowledge on medical research, and thus increase their confidence to effectively contribute to research.

Despite the increasing recognition of value of public involvement, there are still barriers to its implementation in research. As there is no one-size-fit-all approach for patients and public involvement, researchers have found it challenging to identify appropriate methods to effectively involve patients and

public members in making decision related to research (46, 51). Researchers have also found it difficult to integrate opinions of patients and public members, when patients and public members had contrasting ideas with researchers (42). Further, researchers are also concerned about how to select patients and public members and to involve in research to represent opinions of other patients and public members. Additionally, concerns about conflict of interest when patient organisations increasingly receive financial support from industry have raised questions about the transparency and independence of patients' contribution to research (52, 53). On the other hand, it is noted that public involvement might also be a negative experience for patient and public members who are involved, if the method used is inappropriate (54). For example, patient and public involved in research have reported instances when they have not been listened to, or their opinions were not considered seriously. Patients want more transparent processes for selecting who represents them, as they have noted that researchers sometimes tend to select patients who researchers feel comfortable with. Further, people who involved in research also shared concerns that their opinions could not represent the perspective of other patients (55). Patients and public members reported difficulties of communicating with researchers due to the use of scientific language and insensitivity of researchers when interacting with patients and public (56). Patients and public members who involved in research also commented on the burdensome procedures such as filling in complicated application forms and obtaining references to be able to contribute their opinions (57, 58). They also reported that involvement in research was time consuming, and they felt overburdened with tasks and limited time to read documents before going to

meetings. These issues highlight the need to explore different methods to access a diverse group of patients and public members and improve their experience with the process.

2.4. A new research method - Collective intelligence

2.4.1 Definition of collective intelligence.

New ways of planning and conducting research have emerged recently involving large numbers of diverse participants. For example, participants, who are usually not directly involved in research, now contribute their new research ideas, their skills and knowledge to the analyse clinical trial data. For example, an initiative mobilized 1636 patients contributing more than 3000 ideas to improve health care and the health system (59). These new methods of planning and conducting research are based on the concept of collective intelligence.

Collective intelligence is defined as "shared intelligence emerging when mobilising people who are usually not involved in the research process to work on a specific task (60). Two necessary conditions for collective intelligence to occur are: "1) A group has the capability to overcome challenges through shared or individual processing of information; 2) This capability allows the group to come to results superior to the results that could have been reached by conventional methods or by one member of the group alone" (61). These conditions allow individuals in a group to process information either collectively as a group, or separately as independent individuals, in ways that the aggregated results of their works have greater impacts than a mere sum of

individual works. Researchers often collaborate and interact with other researchers within or outside their team. However, with the development of web 2.0 application, they can connect to people from all walks of life and leverage their knowledge and skills to accelerate research. Three pillars of collective intelligence are outreaching to achieve diversity of opinions, an aggregation mechanism to synthesize information, and interaction among group members to synergize their ability.

With the rapid growth of research on collective intelligence, there are numerous literatures which propose different terms to describe collective intelligence. Although terms such as crowdsourcing, citizen science and open innovation all refer to organisational models which leverage collective intelligence, there are some distinctions between them. Crowdsourcing is a model in which the knowledge and skills of diverse individuals are leveraged to complete a specific task or solve a specific problem set by an organisation. It combines a bottom-up, open, creative process with top-down organisational goals (62). Amazon Mechanical Turk (MTurk) is an example of crowdsourcing where task givers offer distributed workers low per-task payment in exchange for completing discrete tasks. Citizen science is a subtype of crowdsourcing focusing on public involvement in research. In citizen science, public members voluntarily complete tasks such as collect data, code or label data to help scientists advance their research as well as increase public's understanding in science (63). Although crowdsourcing allows individuals to contribute to a specific task, not all crowdsourced tasks require participants to use their knowledge or "intelligence" to complete the tasks. For example, crowds share geolocation data through mobile devices, which does not require any

knowledge or skills. In such cases, crowdsourcing does not necessarily generate collective intelligence (64-67).

Open innovation is another organisational model of collective intelligence which recognizes that problem-solvers are unlikely to work in a single firm and "valuable ideas can come from inside or outside the organisation" (68). People from diverse backgrounds and diverse settings can work collaboratively to generate better outcomes. The difference between crowdsourcing and open innovation is that the tasks in the former are governed and pre-specified by the task givers, while the latter emphasizes the collaboration between individuals from different entities to create concepts and solutions. Open innovation is a strategic direction that private sectors have been undertaking to exchange technology and human resources for business development. Public sectors are also increasingly adopting this approach to collaborate with external parties.

2.4.2. Collective intelligence in research

Methods of collective intelligence have been increasingly used in research across different disciplines. Kaggle and Innocentive are platforms where individuals from all over the world can contribute to solve research problems in all disciplines such as computer science, technology development, health care (69, 70). Climatecolab is an online community with 120,000 participants who contribute research ideas to address the challenges of climate change (71). Game players on Foldit succeeded in constructing a protein model which scientists had been struggling with for 15 years (72). There are certain literatures summarising the application of collective intelligence in health research to solve empirical research problems, acquire and analyse data, and

boost medical education (73). For example, a competition on developing algorithms to monitor the progression of amyotrophic lateral sclerosis resulted in 37 algorithms developed by researchers worldwide. Two of these algorithms were shown to outperform the algorithm used by ALS physicians (74). SPRINT is another data challenge which attracted 200 teams and individuals all over the world participated to analyse data from Systolic Blood Pressure Intervention Trial (58). Clinical trials are facing complex challenges such as identifying research priorities and research questions relevant to patients, improving recruitment and retention, reducing burden of trial participation and implementation, enhancing transparency in clinical trial data analysis and data sharing (73). that require diverse perspectives of different stakeholders and patients and public members such as Collective intelligence could be a promising method for soliciting patients and public's contribution in clinical trials. For example, a collective intelligence project included nearly 500 participants contributing research ideas in maternal, new-born, child health and nutrition. Participants sent more than 4000 ideas which were then grouped into 373 research options ranked by priority. This exercise helped funders and the Indian government to understand which questions were important to health consumers to prioritize funding (75). An alliance for clinical trials in oncology created an online platform to welcome all general public members share their ideas and concepts for possible further study (76). Transparency Life Sciences, a private company, created a platform for trial protocol builder where researchers, clinicians, patients and public members can comment to improve a clinical trial protocol. The contribution of collective intelligence contributors led to several major changes in the eligibility, dose,

primary endpoints and statistical analysis plan (77). These promising examples of application of collective intelligence suggest that this method could be used to involve diverse stakeholders such as patients, public members and professionals in other fields to improve clinical trial planning, and thus reduce research waste.

2.5. Summary

New forms of planning and conducting research are needed to tackle the methodological challenges that clinical research is facing. Patients, public members and other professionals should be involved in clinical research to ensure that research addresses high priority questions, uses rigorous methods and improves experience of clinical trial participants. Methods of collective intelligence have been used in other fields to involve diverse individuals in research. In order to apply this emerging method in clinical research, it is important to understand the framework to implement this method; barriers to its implementation, good practice and solutions to overcome these barriers; and evaluate its impact on improving clinical research. In the next chapters, I describe the thesis methodology and three studies conducted to address these objectives.

Chapter 3 Developing a framework for mobilising collective intelligence

3.1. Background

In the previous Chapter, I explained the crucial role of evidence-based medicine in clinical practice. I also provided an overview of challenges that evidence-based medicine encounters due to the lack of diversity in the planning and conducting of research. These challenges highlight the need to identify new ways to integrate perspectives of diverse stakeholders in identifying research questions, choosing study designs and conducting research.

In other research fields, new ways of doing research based on the concept of collective intelligence with crowdsourcing have been successfully implemented. However, these methods are still relatively new in clinical research. To determine whether and how we can apply the methods of collective intelligence in clinical trial planning, it is important to have an in-depth understanding of how these methods have been used in other fields and develop a framework for implementation. To address this objective, we conducted a scoping review to describe methods used to mobilise collective intelligence across different research fields.

3.2. Method

3.2.1 Rationale

Methods of mobilising collective intelligence have been used in different research fields to involve large and diverse groups of participants in research. Although there have been some documents describing methods of collective intelligence, these literatures focused on one organisational model of collective intelligence in a specific research field such as crowdsourcing in health research (64). In order to support researchers in the choice of methods of collective intelligence, it is important to map the methods that have been used across research fields. While systematic reviews aim to synthesise evidence to answer a particular research question in a specific research field, scoping reviews enable researchers to identify and map available evidence on a broad topic (78, 79). In a scoping review, researchers are able to use evidence from research using heterogenous designs in different disciplines (79, 80). Another difference between a scoping review and a systematic review is that a systematic review aims to use only the best available evidence to answer a specific question. In contrast, a scoping review provides an overview of all available evidence related to the topic (78). Thus, a scoping review was considered to be the most suitable approach given the broad aim of this study.

3.2.2. Study design

Drawing on the framework proposed by Arksey and O'Malley and Joanna Briggs Institute (80, 81), we conducted the scoping review in four steps: 1) identifying relevant literature, 2) study selection, 3) data charting, 4) data analysis and reporting results.

3.2.2.1. Identify relevant literature

Definition of collective intelligence with crowdsourcing

In this study, we defined collective intelligence with crowdsourcing as shared intelligence emerging when people who are usually not involved in the research process are mobilised to work on a specific task (60).

Search strategy and information sources

We searched the English-language articles in the following standard databases: PubMed, Web of Science; Scopus; EBSCO Business Source Premier; EBSCO Academic Source Premier; publication resources of the Centre for Collective Intelligence, Massachusetts Institute of Technology (MIT) (search date December 03, 2016); and Google Scholar (January 11, 2017).

We also hand-searched databases of funders who support innovation in health research such as PCORI, NIHR, Robert Wood Johnson, Horizon 2020, FP7 and Laboratory for Innovation Science at Harvard (search date December 03, 2018). We searched Google Scholar for Wikimedia, Wikiproject Medicine, and Task Exchange by Cochrane (search date December 03, 2018).

Search terms were: collective intelligence, crowdsource/ crowdsourcing/ crowdsourced, open innovation, peer production. To increase the precision of the search, search terms were limited to the titles of articles. The search strategy for each database is presented in *Table 6* and *Table 7*. We did not restrict the search by publication date, study design, or study setting.

Table 6 Search strategy for PubMed, Web of science, EBSCO business source premier and EBSCO academic source premier

Search strategy

1. “Collective intelligence” (Title)
2. Crowdsourc* (Title)
3. “Open innovation” (Title)
4. “Peer production” (Title)
5. #1 OR #2 OR #3 OR #4

Table 7 Search strategy for Scopus, Google scholar

Search strategy
1. “Collective intelligence” (Title)
2. Crowdsourc* (Title)
3. “Open innovation” (Title)
4. “Peer production” (Title)
5. #1 OR #2 OR #3 OR #4
6. Methods (Title – Abstract – Keyword)
7. Components (Title – Abstract – Keyword)
8. Design (Title – Abstract – Keyword)
9. #6 OR #7 OR #8
10. #5 AND #9
11. #10 NOT (simulation) NOT (computational) NOT (study protocol)

3.2.2.2. Study selection

Eligibility criteria

We screened retrieved literature and selected relevant articles based on the following criteria;

Inclusion criteria:

- Collective intelligence was described clearly in the methodology section of the document, including how it was organised, who participated and governance rules for groups.
- Participants consciously acknowledged that they were involving in collective intelligence initiatives.
- Collective intelligence was used to make decision, solve problems and create innovation or new strategies.

Exclusion criteria

- We excluded citations without abstract. Articles, which were not original research (i.e. editorial, commentary, perspective), were excluded. Conference papers, and protocols without results were excluded.
- We excluded activities that involved crowdsourcing which only aimed to collect spatial data via mobile devices and where the activities involved sending information without judgement (e.g. uploading photos on social media).
- Due to the wide contextual differences, we excluded research on using collective intelligence to improve business strategy of firms.
- Literature reviews were excluded from this analysis, but we reviewed the reference list to identify eligible original studies.

– We excluded studies which used mathematical models to simulate different virtual scenarios of collective intelligence.

Identification process

One researcher (VN) screened the titles and abstracts of all retrieved citations and the full text of all relevant citations identified. A second reviewer checked 10% of excluded citations to ensure the quality of the process. Overall, 300 reports were double checked; disagreements were resolved after discussion (Cohen's kappa coefficient = 0.97 [95% confidence interval (CI) 0.954–0.986]).

3.2.2.3. Data charting process

We applied content analysis to inductively develop themes and categories for each domain. We classified the methods described in each article by answering the following questions: what the reasons for using collective intelligence were; who participated and what were their motivations; and what was the process of mobilising collective intelligence in terms of organization, communication, evaluation of participants' contributions and decision making. We also relied on the framework from Massachusetts Institute of Technology's Centre for Collective Intelligence and published work on crowdsourcing to ensure that our themes described essential domains to understand methods of collective intelligence (64, 82). First, two researchers (VN, IB) read a set of 20 articles to identify themes describing the methods used for each domain. The two researchers then met to reach consensus on the themes to be included in a data extraction form. Second, one researcher (VN) used this initial set of themes to extract data from another set of 20 articles. The second researcher (IB) cross-

checked the data collected and the themes to ensure that the themes covered the information needed. Then, two researchers (VN, LG) extracted data from a set of 33% of articles included, with consensus achieved in case of discrepancies (pooled Cohen's kappa coefficient = 0.63 [95% CI 0.42–0.83]), and one researcher (VN) extracted data from all remaining articles included. Any new themes identified during data extraction were recorded and discussed with the senior researcher (IB), thereby refining and enriching the list of themes.

Data items

We extracted the following data from the titles, abstracts, methods, results and conclusions of retrieved reports:

Publication characteristics: title, year of publication, author, type of article (reports of original research, methodological papers), field of study (computer science and technology, biomedicine and other fields including economics, finance and business; environmental science; education; media and communication; psychology and social science), and funding sources.

Methods of CI: To understand the methods of collective intelligence, we extracted information for seven domains: (1) reasons for using collective intelligence, (2) type of participants and methods of recruitment, (3) motivation, (4) type of participants' contribution, (5) type of interaction between participants, (6) methods to evaluate participants' contribution and decision-making on what ideas or solutions to use, and (7) challenges of collective intelligence reported by authors and authors' satisfaction with participants' contributions.

3.2.2.4. Data analysis

Data extracted from articles were coded by content analysis and inductively grouped to create categories. We used R v3.4.2 (the R Foundation Statistical Computing, Vienna, Austria) to compute frequencies and percentages for each method.

3.2.3. Ethical consideration and data sharing

The study used publicly available data. Thus, there is no risk of ethical violation and there is no restriction on data sharing. The data from this study are available on Zenodo, an open access repository, at https://doi.org/10.5281/zenodo.2577175.

3.3. Results

3.3.1. Study identification and general characteristics

We retrieved 3,780 citations from the electronic search and excluded 3,395 based on titles and abstracts. Two further articles were excluded as the full texts could not be found. After reviewing the reference lists of literature reviews retrieved from the search, we identified five more eligible articles. We assessed the full texts of 383 articles, and 145 articles from 145 projects were eligible for data extraction (Figure 3): 49 from biomedicine, 47 from computer science and technology, and 49 from other fields. Overall, 89 projects received funding from not-for-profit organizations (i.e., funding from academic institutions, non-governmental organizations, philanthropic and charity organizations, public funders) (83), 13 from for-profit organizations and 2 from crowdfunding; 41 articles did not report funding sources.

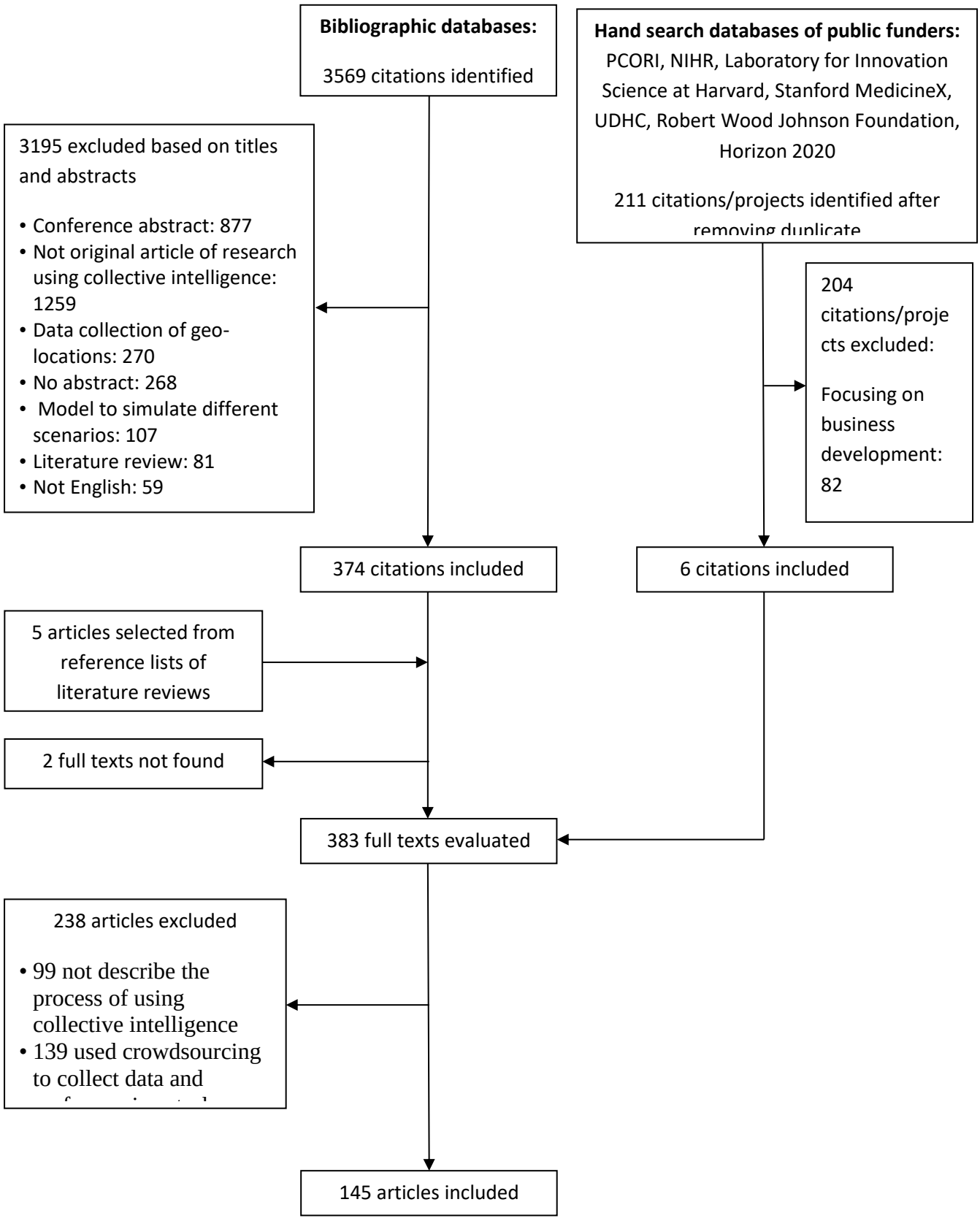

Figure 3 Study selection process

3.3.2. Reasons for using collective intelligence

From 145 included articles, we identified and classified the following four main reasons for using collective intelligence:

- Create intellectual outputs (n=65 projects, 45%): Participants contribute to the creation of health education materials, clinical trial protocols, prognostic models, software, articles, and policies.
- Generate ideas (n=38, 26%): Participants contribute to new ideas for research and development. For example, Harvard Medical School launched idea challenges to generate new research questions on type I diabetes (84).
- Conduct evaluations (n=10, 7%): Participants evaluate the quality of the ideas/work. Collective intelligence is mobilised to critically appraise research quality.
- Solve problems (n=25, 17%): Participants solve a practical problem and propose solutions to difficulties given by organizers. For example, collective intelligence of experts from 26 different European countries is being mobilised for the clinical diagnosis of very rare genetic syndromes of multiple congenital anomalies (85).

Six articles (4%) described mobilising collective intelligence for both generating ideas and conduct evaluations; one article (1%) aimed to create intellectual outputs and conduct evaluations. Table 8 provides examples for each reason for using collective intelligence in biomedicine.

Table 8 Examples of projects using collective intelligence by each reason

Reasons for using collective intelligence	Example
Create intellectual outputs	- DREAM challenge is an open science initiative. It leverages collective intelligence to use data from clinical trials to create predictive models (e.g., prognostic model of survival rate, prediction model of treatment response) (86, 87). - A project used crowdsourcing to mobilise 60 physicians/researchers and 42 patients/advocates to develop a protocol for a cancer trial (88). This pilot project led to the creation of an online community of doctors and patients to develop protocols of clinical trials called Transparency life sciences (89).
Generate ideas	- Harvard Medical School launched idea challenges to leverage collective intelligence from the community to generate new research ideas on type I diabetes (84). - Researchers used a creative contributory contest to ask community members to contribute new ideas for an HIV testing campaign (90).
Conduct evaluation	- CrowdCARE is an initiative that mobilises the knowledge and skills of the crowd to critically evaluate the evidence from health practice to facilitate evidence synthesis (91).
Solve problems	- DYSCERNE used crowdsourcing to create a network of clinicians in 26 different European countries for the

	clinical diagnosis of very rare genetic syndromes of multiple congenital anomalies (85). - Foldit and Phylo are online games that allow users to manipulate the structures of proteins to solve problems of the order and structure of nucleotides in proteins to help cure diseases (92, 93).

3.3.3. Type of participants and methods of recruitment

Participants could be classified into three categories: (1) open public (n=110, 76%) (everyone can contribute regardless of their background); (2) experts in the field (n=21, 14%); and (3) defined groups (n=14, 10%) (a specific population relevant to the research topic, such as students or patients). Participant demographic information (e.g., sex, education, economic status) was reported in only 16 articles (11%). The number of participants contributing to the projects was reported in 59 articles (41%). When reported, the median number of participants who contributed to the projects was 242 [Q1–Q3: 111–535].

The methods used to recruit participants were reported in 50 articles and included creating a Website or mobile phone applications, combined with an open call in social media platforms (60%) (88, 94-96), using personal networks and offline communities (22%) (97-99), targeting online communities (PatientsLikeMe, www.reddit.com) (6%) (100-102), contracting with crowdsourcing intermediary platforms (i.e., online platforms connecting organizations wishing to leverage collective intelligence with a readily available

community) (InnoCentive, Kaggle) (6%) (84, 86, 103), and recruiting on crowdsourcing marketplaces (Amazon Mechanical Turk) (6%) (104, 105).

3.3.4. Motivation

In total, 108 articles (74%) reported the incentives or intrinsic factors used to motivate participants to take part in the projects. Financial incentives were the most common (n= 42, 39%) (94, 103, 106, 107), followed by recognition from the network (n= 8, 7%) (85, 108) and access to data (n= 2, 2%) (109, 110).

Intrinsic motivation could sometimes have a role; for example, participation in a project could arise from individuals' sense of belonging to a network (n= 17, 16%) (90, 111), personal interest in the topic and gaining new knowledge (n= 17, 16%) (112, 113), fun (n= 12, 11%) (92, 114, 115), and altruism (n= 4, 4%) (98, 116). Six articles (6%) reported a combination of both incentives and intrinsic motivation.

3.3.5. How participants contributed to the projects

We identified four methods by which participants contributed to projects: independent contribution (collection) (i.e., participants work independently to complete small pieces of work) (n=50 projects, 34%) (88, 99, 101); competition (i.e., participants submit their work independently, only good solutions are selected and rewarded) (n= 33, 23%) (90, 94, 103); the use of a game to collect independent contributions from participants while creating fun and enjoyment (n= 16, 11%) (92, 114, 115); and collaboration (i.e., participants work interdependently and collaboratively to complete tasks together) (n=41, 28%)

(117, 118). One project (1%) combined competition with independent contribution (119). Participants joined the competition to generate ideas, then the community was involved in evaluating the ideas independently. Four projects (3%) combined competition with collaboration: the project first organized a competition, then held a workshop at which the leading teams collaborated to create better solutions (100, 120-122). *Table 9* provides examples of each type of contribution in biomedical projects.

Table 9 Main features of types of participants' contributions

	Examples	**Main features**
Independent contribution (collection)	- Transparency life science is a platform that mobilises clinicians and patients in clinical trial protocol development. A clinical trial protocol is divided into several items (i.e., inclusion, exclusion criteria, intervention, sample size). Clinicians, patients and relatives independently review and contribute to improve the items. Their contribution is aggregated to create a complete protocol that is reviewed again by community members for final approval (88).	- Work is divided into small pieces; participants can work independently. - There is a mechanism for aggregating contributions from all participants (e.g., averaging, voting)
Competition	- DREAM challenges (http://dreamchallenges.org/) are competitions in biomedical sciences that use open clinical trial data to	- Gives a well-defined problem to solve

	answer fundamental questions in biological science and human health. DREAM challenges last from 3 to 6 months. Anyone interested can join DREAM challenges. Teams who have the best-performing models will receive a reward (107). - Researchers in Guangzhou, China organized a creative competition whereby participants contributed their ideas to develop a campaign to increase the HIV testing rate. Overall, 96 submissions were received after 39 days. A photo gallery was organized to celebrate the top five submissions. Winners were invited to join a panel of experts in the field of sexual health as recognition for their skills and knowledge (90).	- Gives clear criteria for evaluation to recognize innovative ideas - Provides a strong communication plan for before, during and after the competition. Uses different channels to publicize the competition in advance and provide real-time updates. - Gives time to participants to understand the problem such as organizing an introduction workshop, providing a dataset, and tutorials for training. - Provides a forum for participants to exchange ideas and form their teams. - Rewards for winners.
Play games	- MalariaSpot (http://malariaspot.org/) is a Web-based game in which participants detect malaria parasites in digitized blood samples. By playing games, participants recognize which	- Web-based, mobile-based applications accessible to a wide range of participants - Provides tutorials to participants

	blood images contain parasites and the types of malaria parasites. The results from the games help researchers increase the accuracy of malaria diagnosis (115). - Phylo (http://phylo.cs.mcgill.ca/) and Foldit (http://fold.it/portal/) are Web-based citizen science games allowing participants without a significant background in biology to contribute to the development of protein structures. The games are designed as small tasks with different level of difficulties. By playing the games, participants actually solve a problem in protein structures (92, 93).	- Creates different levels of complexity - Real-time updates and leader boards are used to increase engagement from participants
Collaboration	- DocCHIRP is a crowdsourcing network of medical doctors that mobilises the collective intelligence of their members to search for solutions to their medical questions (123).	- Work is not able to be divided into independent pieces. - Provides a platform for discussion, a way to record ideas from all participants (i.e., Wikis), and a moderator who supports the discussion. - Provides tools to navigate ideas contributed by

		participants (i.e., text analysis) to identify patterns of ideas; automatic team matching

3.3.6. Interactions between participants and organizers

In 64 articles (44%), participants did not have any interaction with other participants or organisers (stand-alone). For 54 projects (37%), participants could receive feedback from other participants and for 20 (14%), from organisers. Other methods for interaction between participants and organisers included online focus group discussion (n=7, 5%).

3.3.7. Evaluation of participants' contribution and decision-making process

Although 98 (68%) articles claimed that authors were satisfied with participants' contributions, only 89 (61%) reported methods to evaluate the contribution and decision-making for selecting the best contributions. We identified two main categories: evaluation and decision by an independent panel (n=63, 43%) and evaluation and decision by end-users (target customers, community members) (n= 26, 18%). For example, Harvard Medical School launched an idea competition on diabetes and used a panel of 142 faculty members to review the 150 submissions and select the best one (84). In Dell's IdeaStorm, community members gave points to each idea (111); the evaluation was based on average points from all participants.

3.3.8. Challenges of mobilising collective intelligence

Among 145 articles reviewed, only 13 mentioned the challenges encountered when using collective intelligence. Most of the challenges concerned two main issues: (1) implementation of collective intelligence projects and (2) sustainability (*Table 10*).

Regarding challenges in implementation, two articles discussed difficulties in recruitment and participant retention (123, 124). Two articles described challenges in communicating with participants, including lack of a platform for exchanging ideas among participants, dominant voices in the discussion, unclear communication from organizers causing mistrust and a feeling of being exploited, and unclear idea expression from participants, which slowed the idea selection (111, 125). Two articles emphasised the importance of making the research questions understandable to participants and provided participants with adequate information to address the problems posed (94, 126). One article discussed the issues of selecting inappropriate comparison standards when evaluating participant contributions (127).

Seven articles highlighted the challenges in sustaining the integration of collective intelligence in traditional business models, including resources and changes in the organization's culture when integrating new ideas from participants (111, 121); increased workload for organizers to prepare tasks for participants, screen and select the best solutions (123, 128); and the need for policies on data sharing and how participants could access data contributed by other participants (123, 129).

Table 10 Challenges during the process of collective intelligence and proposed solutions

Challenges	Proposed solutions
Challenges in recruitment	
Attracting a large number of participants and keeping them motivated	Combine extrinsic motivation (i.e., financial rewards, recognition) with intrinsic motivation. There are different ways to trigger intrinsic motivation [i.e., using games to make taking part in tasks enjoyable for participants (115), encouraging participants to develop their knowledge, providing tutorials and giving participants opportunities to practice and develop new skills (94)].
Challenges in communication	
Feeling of disappointment when participant's ideas are not implemented, feeling of being exploited	Communicate clearly to participants the goals of organization, how the ideas will be used to contribute to the organization and community, and the implementation plan.
Lack of platform for idea sharing	Create an online platform for participants to share ideas. Combined with automatic text analysis to provide real-time feedback, create a classification to keep track of all ideas and eliminate redundancy.

Dominant voices in the discussion	Provide options for being anonymous in the discussion and a moderator to manage the platform, resolve conflicts, flag dominant voices, and arrange categories of ideas without intervening in the discussion.
Challenges in sustainability	
Difficulties in integrating ideas of participants in a business model	Communicate clearly the goals of the organization, what the organization is looking for.
Time and resources required for screening and selecting ideas of participants	Assign a dedicated staff member to moderate and manage the classification of ideas, and thereby accelerate the evaluation process.
Lack of policy for data sharing	Predefine terms of participation and communicate with participants for agreement on data sharing.

3.3.9. A framework to mobilise collective intelligence

Figure 4 presents types of participants, how participants contributed to projects, interactions among participants, and the evaluation of participants' contributions and decision making according to the different reasons for using collective intelligence. To generate evaluation and solve problems, independent contributions were used often, with mostly no interaction among

participants. In contrast, competition was often used to generate ideas, and participants were able to exchange ideas and receive feedback from each other. To create intellectual products, participants collaborated with each other and were able to receive feedback from other participants and organizers to improve their products.

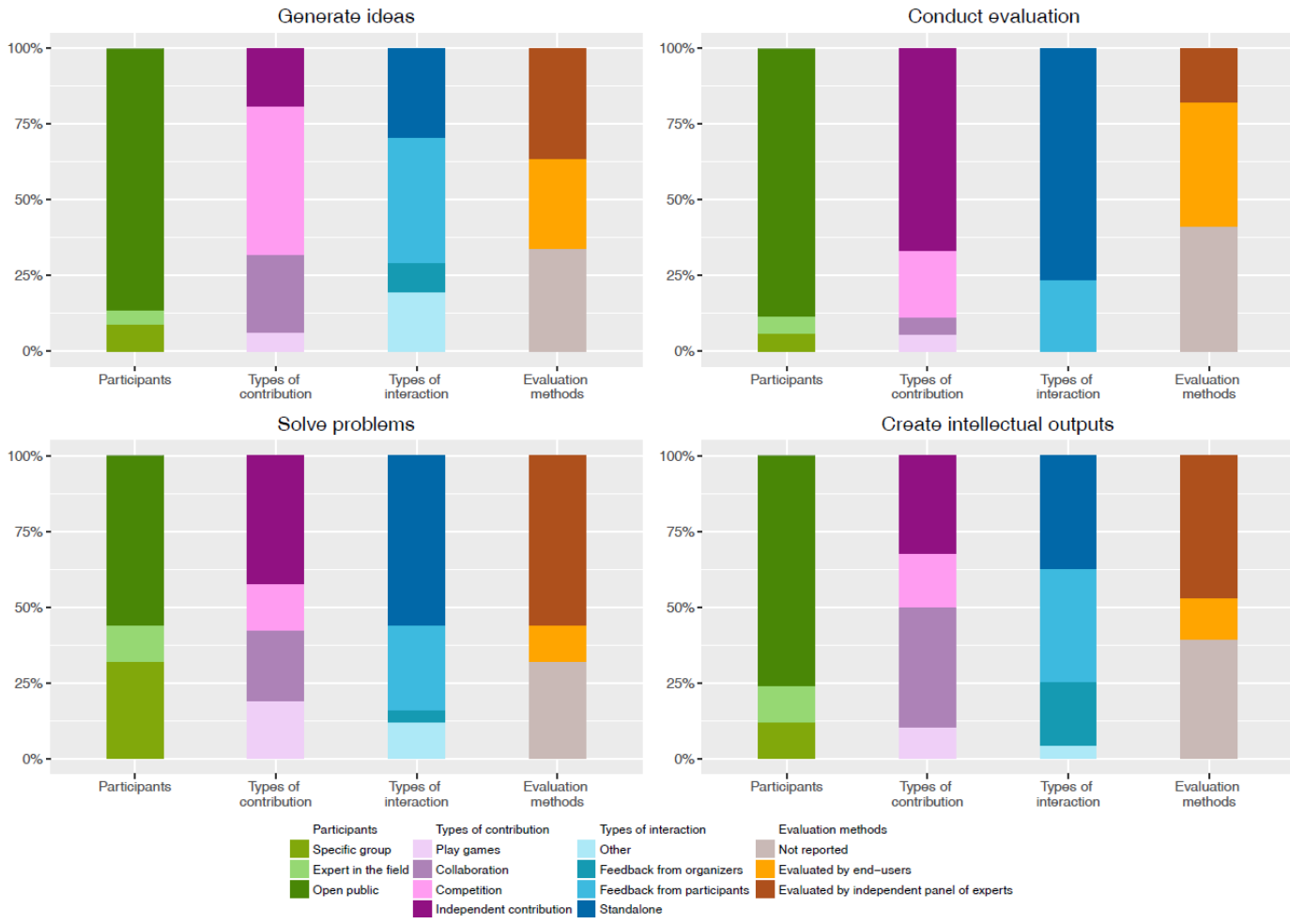

Figure 4 Differences in methods of mobilising collective intelligence by reasons for using collective intelligence

Considering all the information recorded, in Figure 5 we propose a framework of the process of mobilising collective intelligence. The framework describes seven steps in the process and the classification of methods for each step.

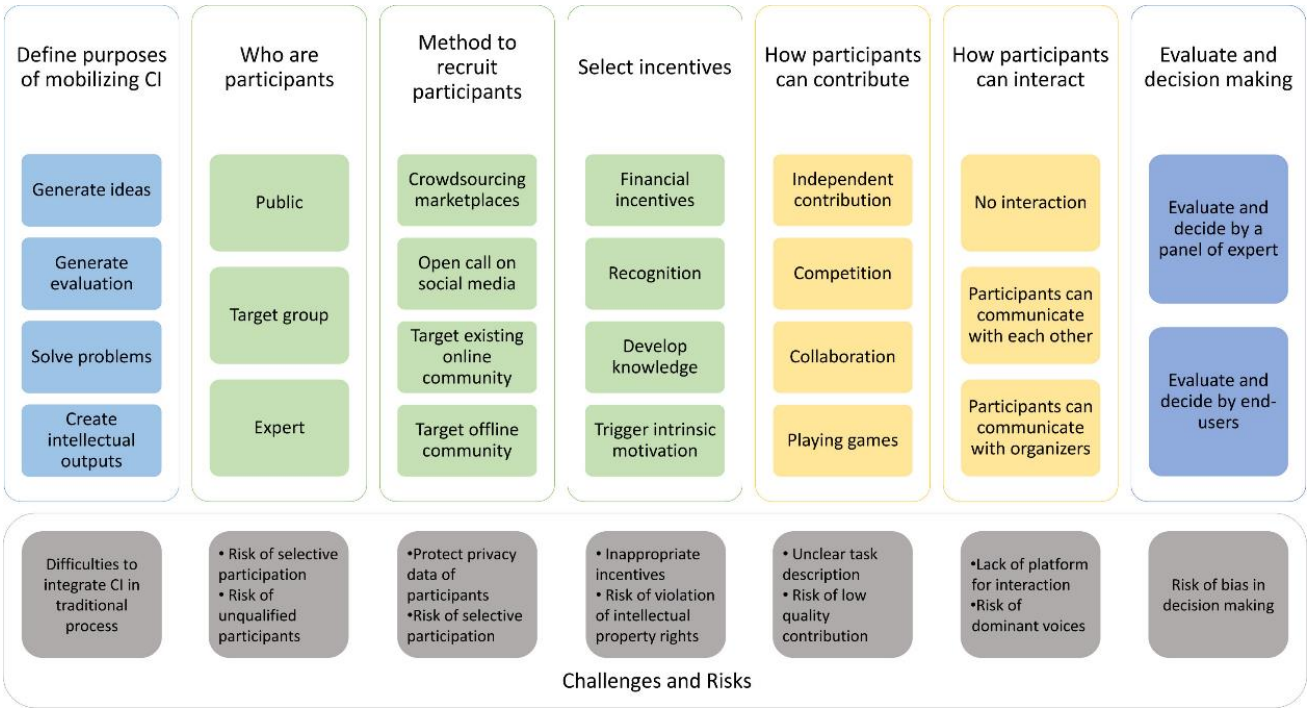

Figure 5 Framework of process of mobilising collective intelligence

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3.4. Discussion

This scoping review provides an in-depth description of methods mobilising collective intelligence with crowdsourcing and proposes a framework to implement these methods in research.

In this review we defined collective intelligence with crowdsourcing as shared intelligence that emerges when people who are usually not involved in research are mobilised to work on a specific task. Some literature considers crowdsourcing used to collect data and perform simple tasks as a kind of collective intelligence (82, 130). However, in this study, we focused on research

harnessing collective intelligence whereby participants contribute their intellectual abilities.

Collective intelligence relies on the principles of the wisdom of the crowd and "swarm" intelligence. The wisdom of the crowd theory states that decisions resulting from the aggregation of information from a large crowd of independent individuals are often better than those from any single member of the group (131). Wisdom of the crowd is particularly relevant to evaluation and decision making. Swarm intelligence emerges when the interaction of independent individuals produces better problem-solving abilities than a single individual (132, 133). Swarm intelligence is used to generate ideas, solve problems and create intellectual products.

By applying principles of collective intelligence and by using an online interface to crowdsource to a large population, clinical research might be accelerated and enriched by innovation. Collective intelligence can be applied to support different stages of clinical research (e.g., identify research questions, design interventions, develop research protocols, analyse data and appraise research quality). Examples include a Harvard Medical School challenge to leverage the wisdom of crowd to identify pioneering ideas for type I diabetes research (84). Similarly, the New England Journal of Medicine launched the SPRINT data challenge to give data scientists across the world the opportunity to access to and analyse clinical trial data (134). Cochrane crowd and CrowdCARE are initiatives that use the power of the crowd to reduce the research burden and accelerate the process of evidence synthesis (91, 135).

To our knowledge, this scoping review is the first study to systematically describe the methods of mobilising collective intelligence with crowdsourcing in published research across different fields. Our results show that some essential information is missing from reports of research involving collective intelligence. Half of the articles did not report the number of participants contributing to the project, and demographic information on participants was reported in just 10% of articles. This hinders verification of claims made about the diversity of participants and whether participants' backgrounds and experience were appropriate to tackle the research problem. There are several potential risks of bias related to mobilising collective intelligence that we discuss in *Table 11*.

Table 11 Potential risks of mobilising collective intelligence

- **Internal validity**

Because most of the projects are open to the public, participants might not have adequate skills and knowledge to contribute meaningfully to research. They might also have conflicts of interest that researchers cannot verify. This might have severe consequences if the contribution of unqualified participants influences decision making, especially when it leads to changes in healthcare practices. Some projects added an extra step to assess the ability of participants. For example, the SPRINT data challenge had a qualification round to ensure that participants had certain skills to tackle the research problem (134). This issue emphasizes the importance of an independent evaluation panel for objective assessment to adequately evaluate participants' contribution.

- **External validity**

Clear guidance is lacking on how many participants are needed to obtain relevant results. In our sample, the number of participants who actually contributed to the projects varied considerably, from 37 to 6200. This raised questions about the external validity of the contributions of participants, and whether ideas or solutions generated and voted for by participants would be applicable to the community.

- **Risks related to privacy and personal data**

There are certain risks for participants when joining collective intelligence projects. When registering to be a member on intermediary platforms, participants might have to disclose their knowledge, but the platforms can use this knowledge without proper acknowledgement (136). Similarly, ethical questions have been raised about online communities when data contributed voluntarily by patients has been sold for financial interests without informing patients (137).

- **Intellectual property**

Participants in projects funded by academic institutions were not required to transfer exclusive copyright to organizers, and their contributions could be publicly accessible (84), whereas in projects funded by for-profit organizations, participants were obligated to transfer the copyright to organizers in exchange for monetary rewards. The latter case might imply some ethical risks. Organizations offered monetary rewards for only the highest ranked

submissions, but in some cases, claimed ownership of all of submissions, which might cause a sense of mistrust in participants (138). Hence, organizations should ensure the transparency of the terms of intellectual property.

The literature on collective intelligence might entail risk of reporting bias. Overall, 68% (98/145) of articles stated positive outcomes from mobilising collective intelligence, but only 9% reported difficulties encountered. In all, 28% (40/145) did not report sources of funding. Most retrieved publications were funded by not-for-profit organizations (61%), indicating that projects using methods of collective intelligence funded by for-profit-organizations might be underreported. Hence, funders and researchers must be encouraged to publish their research to contribute to the knowledge base and thereby assist methodological improvement.

This scoping review has some limitations. First, I restricted the search to keywords in titles to reduce the number of irrelevant articles, so I might have missed some reports that contained keywords elsewhere in the text. However, the aim of the study was to provide a description of different methods of mobilising collective intelligence rather than exhaustively review all relevant articles or report multiple repetitions of the same methods. Second, I focused on published literature, and some projects involving collective intelligence may not result in a classical scientific publication. Third, because no validated tool for critical appraisal of collective intelligence was available, I did not assess the quality of research reports.

3.5. Summary

In this scoping review, 145 research articles have been identified to describe the methods of mobilising collective intelligence. The review shows that research involving collective intelligence have been developed in a range of ways. However, the reporting of these research is suboptimal as some key features of the methods used were not always reported in the published articles. This highlights a need to develop a reporting guideline for research involving collective intelligence to enable quality assessment and ensure reproducibility of research.

Furthermore, the rationale for the choice of mobilising collective intelligence, barriers to using these new methods and good practice advice for these projects were not documented in the published reports. This information is important to help us better understand why researchers decided to involve collective intelligence in their research, their experience with the new methods and what the best ways to mobilise collective intelligence. These important issues will be explored in Chapter 3.

Chapter 4 Good practice advice for mobilising collective intelligence

4.1. Background

In the Chapter 3, I described a scoping review of 145 research projects using methods of collective intelligence to involve diverse stakeholders in research. From the scoping review, I proposed a framework to mobilise collective intelligence in research which classified four organisation methods to solicit participants' contribution, types of participants and how to recruit them, and ways to evaluate participants' contribution. The framework also highlighted some risk factors that might impede the quality of research involving collective intelligence.

However, the publications on collective intelligence did not investigate the experience of researchers who used these new methods. In this Chapter, I present a qualitative study of researchers experienced with mobilising collective intelligence which aimed to identify the barriers to mobilising collective intelligence, ways to overcome these barriers and provide good practice advice for planning and conducting research mobilising collective intelligence across different disciplines.

4.2. Method

4.2.1. Reflexivity

It is noteworthy that researchers' social position, personal experience and beliefs can influence their choice of research method, interaction with research participants and the knowledge that ensues from research (139). Hence, being reflexive and transparent about researcher's identity and beliefs is crucial when describing the way data are collected and interpreted.

Before starting the PhD thesis, I was a pharmacist and working as a research coordinator managing the planning and conduct of clinical trials in a clinical trial unit in a low-middle income country. The work allowed me to interact with diverse stakeholders such as principle investigators, clinicians, nurses, patients and regulators. I highly valued the involvement of nurses and patients in the organisation of the trials to make trial procedures more convenient for patients and reduce unnecessary burdens. However, in that context, the involvement of nurses and patients happened at a fairly late stage when the trials had been approved and implemented. As a result, patients' and nurses' suggestions could only be adopted after a protocol amendment, which sometimes significantly delayed the benefits of better trial procedures reaching trial participants. Further, the rigid application of trial regulations from high income countries without taking into account the context of a low-middle income country also caused certain challenges for trial implementation. With this experience, I commenced the PhD work to look for new ways to involve diverse stakeholders in research planning, especially ones whose voices are less heard such as patients and practitioners.

4.2.2. Research paradigm and methodological approach

To answer a research question, researchers should consider which methods should be used to collect, analyse and interpret the data and how to justify the choice of these methods. Relevant here is the concept of research paradigm (140, 141). A research paradigm consists of three components:

- Ontology: the nature of the phenomena, what is the knowledge to be known;
- Epistemology: the relationship between the researcher and the knowledge, how researchers interpret the phenomena;
- Methodology: the procedures of acquiring information to explain the phenomena.

There are different research paradigms that researchers use to conduct their research such as positivism, critical realism, pragmatism, interpretivism as presented in *Table 12*).

Table 12 Research paradigms adapted from Guba and Lincoln (1994) (142), Denscombe (2008) (143) and Kivunja and Kuyini (2017) (144)

Research paradigm	**Ontology**	**Epistemology**	**Methodology**
Positivism	Reality is 'knowable' and driven by natural laws	The biases and values of the researcher must not influence outcomes.	Experimental; Quantitative approaches
Critical realism	Theories shape our inquiry into reality to identify causal mechanism of social events and	Scientific inquiry is driven by theories of the observer including the choice of research	Mixed methods approaches; combination of empirical investigation and

	propose solutions for social changes	question, paradigm selection, methods, analysis and interpretation	theory construction.
Pragmatism	Reality is the practical effect of ideas (no commitment to any one system of reality or philosophical system)	Individual researchers have the freedom of choice to select procedures that best meet their needs	Mixed methods approaches; action research
Interpretivism	Reality is created by individuals and groups	All scientific inquiry is related to the values of the observer including choice of research question, paradigm selection, methods, analysis and interpretation	Qualitative approaches

Given the practical aim of the study to understand the process of mobilising collective intelligence and to provide practical knowledge to researchers who want to apply these new methods, pragmatism is a suitable research paradigm for the work presented in this chapter. Pragmatism focuses on the impact of knowledge obtained from research in a given context. In contrast to positivism or interpretivism, which require researchers to make a discrete choice between quantitative and qualitative approaches, pragmatism welcomes the use of both quantitative and qualitative data to solve the research question (145).

The experiences of researchers who have used methods of mobilising collective intelligence across research disciplines is an important source of knowledge which can help us to better understand these new methods. A qualitative approach in which research participants can freely express their personal experience and practice will allow me to explore barriers and facilitators to mobilising collective intelligence and identify important but unanticipated issues. Thus, to address my research question, I conducted a qualitative study of researchers with experience of collective intelligence methods across different research disciplines. In order to approach a larger number of researchers who had experience with collective intelligence and located in different countries, I decided to use a pragmatic approach by combining both semi-structured interviews and an online survey with open-ended questions. When analysing qualitative data, researchers can use a deductive approach to confirm their assumptions or an inductive approach to explore new concepts which have not been determined. In this study, my approach was partly deductive guided by the framework synthesised in the Chapter 3, but also inductive to explore new themes relevant to collective intelligence.

4.2.3. Study design

To explore researchers' experience with collective intelligence, I conducted 1) a multinational online open-ended survey, which allowed me to access the perspectives of a diverse group of respondents involved in collective intelligence, and 2) semi-structured interviews, which allowed for more in-depth exploration of respondents' perspectives on this fairly new topic.

4.2.3.1. Sample and recruitment

I recruited principal investigators and project coordinators experienced in running collective intelligence projects. I purposively sampled these researchers, seeking diversity in terms of their experience of different collective intelligence methods and their disciplinary backgrounds. I identified i) authors of articles reporting a project using collective intelligence (146); ii) researchers in the network of European citizen science association (42); and iii) invited speakers from collective intelligence conferences (147, 148). I also used snowball sampling, asking respondents to send us email addresses of colleagues active in the field of collective intelligence.

An invitation email (Appendix 2) was sent via Mailjet (50) to researchers and project coordinators whose email addresses were available. The invitation contained a link to the first page of the survey, through which they indicated their consent (Appendix 3). Two reminder emails were sent to non-respondents.

I invited a purposive sample of 24 researchers to semi structured interviews via personalised emails. As researchers who responded to the survey were mainly from the field of computer science, for the semi-structured interviews, I purposively invited researchers who had used collective intelligence in biomedical research to increase the diversity of the sample and the relevance of their research context to our main aim of applying collective intelligence in clinical research. Additionally, I also contacted researchers who were recommended by survey respondents as experts in the field of collective intelligence to gain in-depth knowledge about these new methods.

4.2.3.2. Online open-ended questions survey

The survey was developed using the framework that resulted from the scoping review presented in Chapter 3 (146), after which it was piloted (Appendix 4). It comprised five closed-ended questions to identify respondents' background and expertise, and four open-ended questions exploring their motivation, and their experience with mobilising collective intelligence, particularly the barriers they encountered and their solutions (*Table 13*). Finally, respondents were asked to provide three pieces of advice to a colleague planning to use collective intelligence in a project for the first time.

To promote interaction between survey participants I also asked them to rate and comment on the advice that other respondents had entered. The advice shown to each respondent was randomly selected from the pool of advice provided by previous respondents.

Table 13 Open-ended questions in the online survey

- What are **the benefits of collective intelligence** that made you decide to use it in your project?
- What were the **most important factors** contributing to the success of mobilising collective intelligence in your project?
- What were the **most challenging issues** you had to face when using collective intelligence in your project and **your solutions for those challenges** (e.g. difficulties in identifying and motivating participants, designing tasks for participants, evaluate quality of participants' contribution, decision making)?

- What **three pieces of advice** would you give to a colleague who intends to use collective intelligence in a project for the first time?

  Please read the advice from another participant (an answer from another participant is displayed)

  What do you think of this advice?

4.2.3.3. Semi-structured interviews

I sent individuals who expressed an interest in being interviewed an information sheet about the study. Interviews were conducted according to participants' convenience (e.g. face-to-face, telephone, teleconference (gotomeeting.com) and oral informed consent was obtained before the interview started (Appendix 5:, Appendix 6:).

I used a conversational approach with a semi-structured interview guide to allow interviewees to freely describe their experience and share their insights on important issues that I might not have had anticipated (149). The interview topic guide covered key questions in the survey questionnaire and was used to guide the conversation with interviewees and ensure the consistency in data collected (Appendix 7) (150). Consistency does not mean that I asked questions in the same way to each interviewee but to ensure that the conversations with interviewees covered the general research topic. Prior to the interview, I read the publications of interviewees to tailor questions and prompts to their specific projects and the methods they had used to mobilise collective intelligence. During the interview, I tried to build rapport with interviewees, encouraging them to provide more details via prompts to gain in-

depth information about the planning and conduct of interviewees' research using collective intelligence. I also encouraged interviewees to discuss differences of opinion regarding the implementation of collective intelligence. For example, while one interviewee shared that it was expensive to organise a competition as a way to mobilise collective intelligence, another interviewee claimed that the use of competitions to mobilise collective intelligence was cost-effective. I also prompted each interviewee about the context of their research in order to understand factors that might lead to their differing opinions and experiences.

All interviews were conducted in English. These were audio recorded, transcribed verbatim by a native English-speaking transcriber and I anonymised the transcripts. Interviews lasted between 22 minutes to 1 hour (median: 34 minutes). After each interview, I wrote a summary of the interview to record reflections on the interview and initial thoughts for the analysis.

4.2.3.4. Analysis

Our analytical approach was pragmatic to provide insights on the methods of mobilising collective intelligence, but broadly interpretive in treating respondents' reports as subjective accounts of their experience when using these methods. Analysis of open-ended survey responses and interview transcripts was thematic, drawing on the framework analysis (151, 152). The analysis was partly deductive with some aspects being informed by the previous literature on collective intelligence, but also inductive to identify new themes and ensure that the analysis was grounded in the data. I led the

analysis. Two senior researchers BY and IB periodically reviewed transcripts and commented on the developing analysis.

Open codes and categories were developed by constant comparative approach, reading and re-reading data and considering it in the context of other data from the same respondent and in the context of the wider dataset (153). An initial framework of themes and sub-themes was developed based on the first eight interview transcripts, and then imported into NVivo to code the remaining transcripts and survey entries. The framework was further refined throughout the process of analysis.

Data saturation was examined by the theme accumulation curve which presented the number of distinct themes generated against a number of units of analysis used to generate those distinct themes (Appendix 8) (154).

Respondents' survey comments on the advice provided by other respondents were categorized as "agree" (i.e., positive comments), "disagree" (i.e., negative comments) and "neither agree nor disagree" (i.e., neutral comment or did not directly comment on the idea in the answer). I and another researcher (NN) independently assessed the content of each comment and discussed this to reach consensus. I received 129 pieces of advice. One hundred of these were commented upon by other respondents with 28 being commented on twice, resulting in 128 comments. Most comments (77%, 98/128) agreed with the advice provided by respondents and only 9% (12/128) disagreed. I summarize the advice which commentators disagreed with in (Appendix 9).

The themes described in the results section below are derived from both interviews and survey entries. I present excerpts from the interviews and

surveys to explicate the findings and our interpretation of the data. Interviewees are indicated by 'I' and survey respondents by 'S'; '[…]' denotes text removed for brevity. Research disciplines of interviewees and survey respondents are listed in (Appendix 10).

4.2.3.5. Securing study quality

Lincoln and Guba proposed four criteria to assess the trustworthiness of qualitative research: credibility, transferability, dependability and confirmability (155). Credibility corresponds to the concept of validity in quantitative research which presents the confidence in the findings of the study. In this study, credibility was assured by examining the consistency of the data between the survey and the interviews, and across respondents from different research disciplines. I involved different researchers in the data analysis process to constantly review the development of the coding framework (156).

Transferability corresponds to external validity in quantitative research which examines the extent to which qualitative findings can be applied to other contexts. To ensure transferability, I took into account the contextual information, survey and interview respondents' background when analysing the data as well as presenting the findings (157). The survey also allowed participants to express their opinion on the advice provided by other participants, which helped me ascertain that certain advice was applicable in different contexts.

Dependability corresponds to the concept of reliability in quantitative research and describes whether data are collected in a consistent, logical manner, and

research process is well-documented (158). Closely related to dependability, confirmability assess the accuracy of data interpretation and that the findings are grounded in the data (158). To ensure dependability and confirmability, senior researchers closely supervised the data collection process by reading the transcripts of the first five interviews for quality control. Senior researchers were also involved in data analysis process to ensure divergent interpretation of the data. We regularly discussed the data to identify new themes and refine the coding framework. The anonymised data of the survey is publicly available, and the anonymised transcripts of the interview will be provided upon request to ensure transparency of research process.

4.2.3.6. Ethical consideration and data sharing

The study received ethical approval (Ref: 17-386) from French National Institute of Health and Medical Research (INSERM) Ethic Committee (IRB00003888) (Appendix 11).

The anonymised data from the online survey is available on Zenodo, an open access research data repository at https://doi.org/10.5281/zenodo.3462583. Anonymised transcripts of interviews are kept electronically in a secure file store in laboratory of the METHODS team of CRESS-UMR1153. The transcripts will be provided upon request.

4.3. Results

4.3.1. Respondent characteristics

Of 157 people who clicked the survey link, 65 participated in the survey. Of the 24 people who were purposively invited for interview as they used collective intelligence in biomedicine research and were recommended as experts in the topics, 17 participated. Of those who were not interviewed, two were unable to schedule an interview within the time frame of the study, two advised the interviewer to contact another team member responsible for the projects, two did not respond, and one was unable to be interviewed in English. *Table 14* presents demographic characteristics of survey respondents and interviewees. Survey participants were mainly from the field of computer science (43%), while interviewees were mainly involved in biomedicine and healthcare (59%). They mostly mobilised collective intelligence to solve research problems (70%) and generate new ideas (46%).

Table 14 Respondent demographics

Demographic information	Survey respondents	Interviewees	Total
Age group	N = 65 (%) [a]	N = 17 (%)	N = 82 (%)
20 – 29	4 (6)	0 (0)	4 (5)
30 – 39	27 (42)	1 (6)	28 (34)
40 – 49	19 (30)	11 (65)	30 (37)
50 – 59	8 (12)	3 (18)	11 (13)
≥ 60	4 (6)	2 (12)	6 (7)
Location	N = 65 (%) [a]	N = 17 (%)	N = 82 (%)
Europe	42 (65)	11 (65)	53 (65)
North America	18 (28)	6 (35)	24 (29)
Asia	2 (3)	0 (0)	2 (2)

Research field [b]	N = 65 (%) [a]	N = 17 (%)	N = 82 (%)
Computer science	28 (43)	2 (12)	30 (37)
Biomedicine and healthcare	9 (14)	10 (59)	19 (23)
Engineering and technology development	9 (14)	0 (0)	9 (11)
Economics, commercial, business development	7 (11)	2 (12)	9 (11)
Education and information studies	7 (11)	0 (0)	7 (9)
Environmental science	5 (8)	2 (12)	7 (9)
Psychology and social science	5 (8)	0 (0)	5 (6)
Laws, politics, and governance	4 (6)	1 (6)	5 (6)
Other	10 (15)	0 (0)	10 (12)
Purpose of using collective intelligence in their projects [b]	N = 65 (%) [a]	N = 17 (%)	N = 82 (%)
Solve problems (i.e., participants propose solutions to difficulties given by organizers)	44 (68)	13 (76)	57 (70)
Generate ideas (i.e., participants contribute to new ideas for research and development)	32 (49)	6 (35)	38 (46)
Evaluate ideas (i.e., participants evaluate the quality of the ideas/work)	23 (35)	1 (6)	24 (29)
Create intellectual outputs (i.e., participants create health education materials, clinical trial protocols, prognostic models)	16 (25)	1 (6)	17 (21)
Other	10 (15)	0 (0)	10 (12)
a Two missing data b Respondents selected more than one option.			

4.3.2. Researchers' motivations for mobilising collective intelligence

Participants reported trying the methods of collective intelligence as a new way of doing research because traditional research methods no longer fitted their needs (*Table 15*). They commented that research questions were becoming very complex, unlikely to be solved within a single discipline, and traditional models of research, where each team worked in relative isolation impeded research efficiency.

Respondents also noted the personal "*pleasure"* they derived from working "*in teams with other people*" (I10). Collective intelligence helped make research more enjoyable and helped them *"to find some bridge, to… better understand each other, work closely together and this has some huge impact*." (I02)

Table 15 Reasons for mobilising collective intelligence

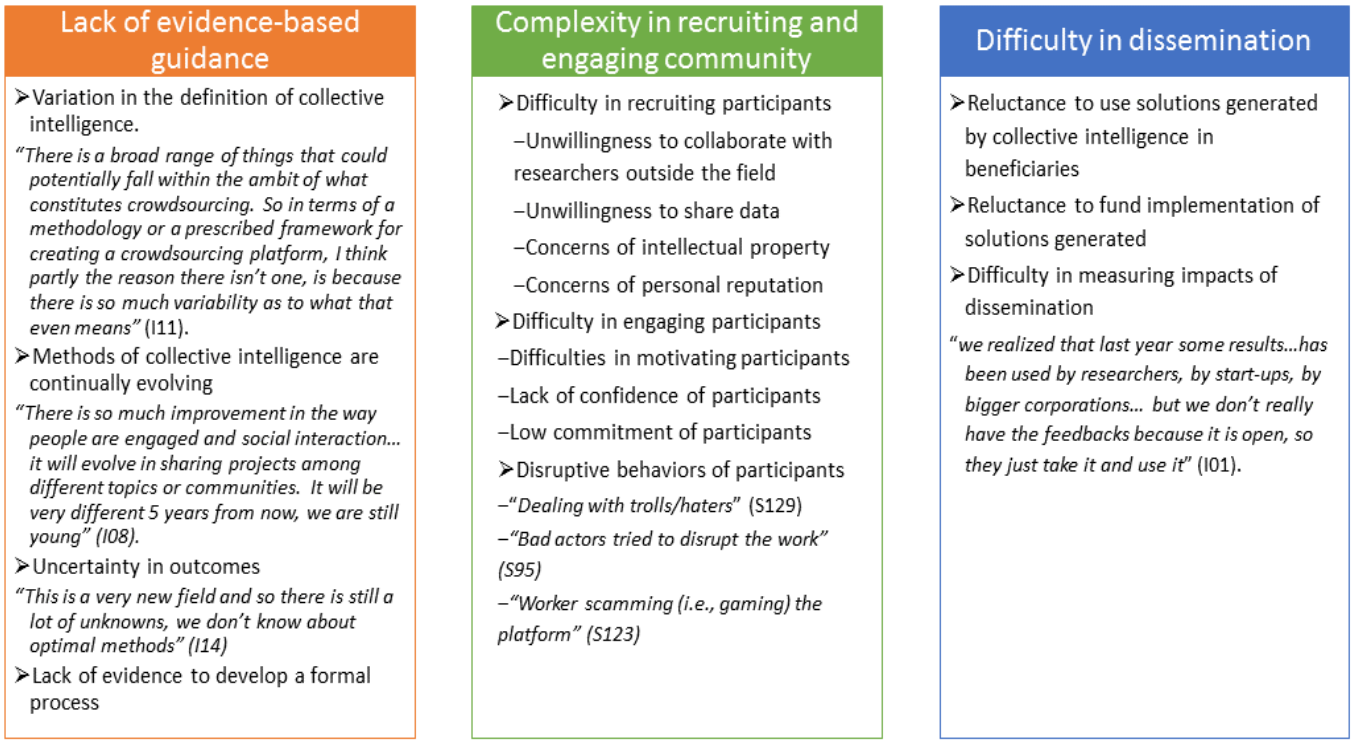
Issues with traditional research practice	**How collective intelligence can address the issue**
Research questions were becoming more complex and the answers could not be found from a single discipline.	Collective intelligence provided the opportunity to work with people with different types of expertise and integrate their skills to solve problems from different angles. *Knowledge is distributed in different domains and some 'wicked' questions cannot be answered within a single discipline or sector, i.e. we need both different science disciplines as well as expertise from the practice and policy sector. (S75)*
Current research was conducted inefficiently by "*repeating efforts*" (*I06*).	Collective intelligence allowed researchers to do research as collective efforts where different approaches to a research question could be collectively and thoroughly evaluated to avoid redundant efforts. *In science, often we are developing solutions independently and we are kind of repeating*

	erm… efforts, […] an alternative is to post a problem or a question to the research community and then just see what kind of solutions people come up with, and possibly combine these solutions and that you could call collective intelligence. (I06)
As research questions became more complex, conducting research required longer time. Researchers would not have enough time to investigate different aspects. "*It takes for hundreds of years… you will never [be able to] explore everything".* *(I08)*	With a large community contributing, researchers were able to finish work within shorter timescales. *Draw on the experiences and expertise of a varied group of people to advance and implement ideas that would take a significantly longer time to solve as an individual. (S104)*
It was more costly to work with experts in the field and took longer to engage them.	Mobilising contribution from a wide community was cheaper than working with experts in the field yet could achieve the same outcomes. *Our organization has done over 300 crowd-based challenges and has found success in 80-90% of those challenges with cost and schedule savings in the majority of them. (S49)*

4.3.3. Barriers to mobilising collective intelligence

While collective intelligence brought numerous benefits, respondents found aspects of collective intelligence challenging. These challenges in part arose from the novelty of the method and complexity in engaging the community (Figure 6).

Figure 6 Barriers to mobilising collective intelligence



<u>Lack of evidence-based guidelines on methods of mobilising collective intelligence</u>

Use of collective intelligence through crowdsourcing in research is relatively new. Some respondents reported that they had delved into this method before they had become fully aware of the concepts of collective intelligence, crowdsourcing or citizen science. Respondents also recounted challenges they

had faced in their projects due to lack of evidence for an "*optimal method*" (I14) and noted the absence of a methodological guide for them to follow.

Complexity in recruiting and engaging the community of participants

Respondents believed that some potential collective intelligence participants had "*a lot of prejudice*" (I03) towards collaborating with people from different fields and it was "*not easy to make them to participate*" (I02) in collective intelligence projects. Interviewee I06 working in the field of biomedicine spoke of the difficulties he had experienced in motivating industrial partners to work with academic institutions in his challenge contests. He commented that collective intelligence participants had concerns about the ownership of the research, intellectual property of the solutions created, and about the negative reputational consequences if their solutions performed poorly.

Respondents described difficulties in "*retaining all the people that sign up…to get them to actually participate*" (I09), as most participants joined collective intelligence as a side project or "*an unfunded kind of project*" (I12). They also believed that many potential collective intelligence participants were "*not confident enough*" (I07), which hindered their contribution.

Respondents reported situations when participants had tried to cheat or behaved aggressively which adversely influenced the community and demotivated other participants. Interviewee I04 shared his experience with this disruptive behaviour, when organising challenge contests for data analytics*: They will make different identities…and…submit hundreds [times]… [they] cheat the leader boards. [They] will discourage many people*

from [participating]…but [they] don't have the solution. He explained that this disruptive behaviour partly arose from the competitive nature of a contest, adding that participants might be under pressure from their organisations to win international contests to enhance the reputation of their organisations.

Difficulties in disseminating the solutions generated by collective intelligence

Respondents found it challenging to disseminate and implement the findings of their collective intelligence projects to the relevant communities, as funders and beneficiaries were unfamiliar with this emerging method. These challenges arose partly from the "*prejudice*" of researchers (I03) that people who were outside of the field might not have sufficient capacity to create solutions. Interviewee I15 spoke of his difficulty in persuading funders to sponsor the further development of solutions generated by collective intelligence participants in a challenge contest that he had organised.

The third challenge…was getting people to recognise that these solutions existed and were available…there is a reluctance to use crowdsource and open source solutions like this. (I15)

4.3.4. Good practice advice for planning and conducting collective intelligence projects

In describing their projects, respondents reflected on the solutions that they had considered or used to overcome these barriers. We also explicitly sought their advice on what they perceived to be good practice in planning and conducting collective intelligence projects. In the sections that follow, we

present respondents' advice and good practice recommendations for collective intelligence projects covering three main themes: project governance, planning and conduct of collective intelligence projects (Figure 7).

Figure 7 Good practice advice for planning and conducting research mobilising collective intelligence

The project governance

Establishing a coordination team

Respondents advised researchers to establish a coordination team dedicated to supporting projects mobilising collective intelligence. They suggested that the coordination team should include people with diverse expertise to bring more "*insights"* (I01) to the project and help with "*getting leadership and [funders] on board*" (S23). Respondents also encouraged researchers to involve stakeholders and representatives from potential collective intelligence participant groups in planning, designing and conducting collective intelligence projects. Respondent S62 suggested that "*Listen very carefully to your participants and work with them. Ensure mutual benefits in your design and co-create the project*". Respondents advised that the involvement of participants' representatives from early stage would help identify mutual research interests between participants and researchers, design appropriate tasks and develop effective communication strategies to engage potential participants. Respondents also emphasized the importance of including people with experience in communication in the team to support recruitment and engagement activities with collective intelligence participants.

Create a set of common rules

Respondents suggested that the coordination team should create a set of common rules for collective intelligence participants to encourage mutual respect and constructive contributions. They mentioned the use of "*diplomatic quality control*" (I03) to flag up aggressive or disruptive behaviour from participants and to try to create a participatory and friendly environment for

others to freely contribute their work. They also suggested preparing a resolution plan to resolve conflicts between collective intelligence participants.

Planning a collective intelligence project

Identify the research question

Respondents commented that an early step in research involving collective intelligence was to identify "*an interesting problem*" (I06) with "*high scientific value"* (I04) that would gain from the involvement of a large and diverse community.

It is number one that there is a problem out there worth solving […], a project that it makes sense to try and bring in… people outside of the normal kind of scope or expertise area for it. (I15 – biomedicine and healthcare)

They noted that identifying "*just difficult enough*" (I06) problems, and "*putting yourself in the participants' [positions]*" (I08) was crucial to create appropriate research problems to gain buy-in from target communities. Interviewee I15 working in the field of biomedicine and healthcare described how a dynamic process involving *"a lot of conversations"* was part of the process of establishing whether the community would be interested in the research problem.

"We knew there were a lot of people…working on it [the research topic] and no one had come up with an optimal solution and we felt like there were enough people who would be interested…, but that didn't come from us just sitting in a room alone. We actually reached out to many of the people… to see if they felt like there was a need and an ability to really take this further.

Identify communities of participants

The choice of the communities was also considered by respondents as a key factor in ensuring successful mobilising of collective intelligence. Respondents suggested identifying communities who "*have most contact with these problems*" (I05). They explained that "*you need to have champions of the cause… if you are doing something on Alzheimer's, finding a person … who has Alzheimer's, who their mother, father has Alzheimer's and who has a personal vested interest and a strong…passion for the cause"* (I14).

They emphasised two important characteristics of the community – diversity and independence. Diversity in participants was thought to be important in order to generate novel solutions to the research problem. Diversity could be achieved by involving a larger number of participants with various disciplines. "*The more participants you have, the more likely some of them will come with the new idea.*" (I04). Similarly, maintaining the independence of participants as they worked on the research problem was crucial to "*free the minds and let [participants] think freely*" (S104), allow "*outside of the box thinking*" (S146) and ensure that participants could voice ideas without being influenced by a dominant opinion.

Decide incentives to engage participants

Respondents suggested offering a combination of both extrinsic motivators such as authorship and access to the data, and intrinsic motivators such as making tasks enjoyable, offering participants the opportunity to gain new knowledge, and find meaningful outlets for their skills. They described some innovative activities to engage participants.

"Some of the things that we have done have been really fun, and really brought the community together…to create…a sense of community…like the 24-hour citation screening challenges. Where we have had hundreds of people, online at the same time, all with a specific target to try and reach within 24 hours… and those have been hugely exciting, really popular." (I17)

Interestingly, some respondents tried to "*avoid monetary prizes*" (I14) as they believed that *"the crowd may only be interested in the compensation and therefore, may take short-cuts or cheat if the task allows for that"* (S153). Instead, they suggested offering research partnership, mentorship or training as ways to benefit participants' professional development.

Determine methods to evaluate solutions created by collective intelligence and decision making

Respondents emphasized the need to "*set up objective methods to validate the results"* (S65), for example, by establishing a panel with diverse expertise to comprehensively evaluate contribution of participants. They also acknowledged the need to allow enough time for evaluation, given the large number of participants, and advised involving the crowd in the evaluation to increase the efficiency of the process. Automating screening of participants' contributions was also suggested to reduce workload for the panel when doing evaluation.

Conducting collective intelligence projects

Prepare tasks and interface

Respondents highlighted the need to design a user-friendly interface to *"make it really easy for people to contribute even if they have only got a minute free"* (I17). They explained that "*the design of the interfaces or platforms which people will use is often overlooked but can influence the results or the ease of data collection*" (S25).

They also advised researchers to prepare training materials and offer tutorials to explain the project to participants and equip them with essential skills. However, they noted that the training should avoid providing participants with examples which could hinder participants' creativity.

Respondents also recommended "*verifying if it [the task and interface] works on small scale*" (S16) and gradually scaling up. The pilot phase could help researchers to foresee any technical and ethical issues related to data collection and participants' identities, which could be addressed before a large number of collective intelligence participants enrolled.

Create a clear description of the research problem

"*Crafting"* (I14) a clear description of the problem in a language relevant to those communities was considered as a key step to help collective intelligence participants understand the project objectives and judge whether they had the relevant skills to participate.

"Good communication of a complex objective or complex data set…is not… always easy…if there is something that you don't even understand, …you won't put your time in that challenge." (I10)

Respondent S20 also suggested dividing the objectives into concrete deliverables with clear requirements for participants' contributions. *"In order for the collective to provide "intelligence" as opposed to noise, one must be very careful about what one measures… If the measures are ambiguous to the participants, or if there exists a short-cut for the participants to satisfy immediate goal without actually contributing to the overall big picture, many participants will find this short-cut and will explore it".*

Organize communication activities to recruit participants

Respondents described how they had organized various communication activities to recruit participants via advertisements on social media (e.g., Google, Facebook, websites), and announcements in scientific publications. Several saw working with an intermediary online platform which had a readily available online community as a practical approach for those who were new to collective intelligence. They advised researchers to partner with local organisations such as non-governmental organisations, universities and patient organisations and organise face-to-face meetings to connect directly with participants.

Engage participants through responsive communication

To engage participants effectively, respondents believed that communicating frequently with collective intelligence participants, even having someone available "*24/7*" to guide them and give feedback on their contributions. Respondents believed this would improve the quality of participants' contributions and increase their commitment. Further, through responsive communication with participants, researchers could understand what

resources participants needed to develop an implementable solution. Although virtual communication helped in ensuring responsive communication, respondents advised supplementing this with face-to-face engagement events to increase trust and create a sense of community among collective intelligence participants.

Disseminate solutions created by collective intelligence to beneficiaries and collective intelligence participants

Respondents advised researchers to diversify the dissemination of their project findings through multiple channels, and make the results open access to public through social media.

Respondents suggested involving leaders of organizations from the beginning of the projects to ensure their support for implementation of solutions generated by collective intelligence. They encouraged other researchers using collective intelligence to "*show their results*" (I02), "*evaluate"* (I13), and *"be transparent about mistakes"* (I17) and saw rigorous evaluation of collective intelligence as necessary to provide evidence of its usefulness to stakeholders, "*so that it gets recognised and funded properly"* (I13).

4.4. Discussion

My study has shown that researchers were interested in looking for efficient methods of conducting research, leading them to try collective intelligence. Researchers believed that by involving large numbers of participants with various disciplines, they could find more innovative solutions to research problems in shorter time with fewer costs compared with conventional

methods. They indicated that participants' contributions could be solicited to solve problems, generate new research ideas, evaluate ideas and create intellectual outputs. Researchers embarking on collective intelligence projects for the first time learnt through the process and gradually improved their methods. In the scoping review presented in Chapter 3, only 12/145 articles described challenges in mobilising collective intelligence mainly in recruiting and retaining participants, whereas researchers in this qualitative study often emphasized challenges, and noted previously undescribed challenges such as the disruptive behaviours of collective intelligence participants. They also highlighted the needs to develop evidence-based guidelines to standardise methods of mobilising collective intelligence. Drawing on the experiences of researchers across different fields and with experience of different collective intelligence methods, I have provided solutions and good practice advice to support researchers in the planning and implementation of their collective intelligence projects. This advice will help researchers to prepare structures and processes for their projects, plan essential steps in their research, and foresee and develop strategies to overcome the barriers.

Despite increasing recognition of value of collective intelligence in research (159, 160), there are still examples of inappropriate methods being used to mobilise collective intelligence (161). For example, a project involving crowdsourcing in Rwanda failed to recruit and engage participants because researchers mainly used social media for recruitment and requested participants to use a complicated tool to collect data (162). However, at the time the project took place, community members in Rwanda were not connected on social media and were unfamiliar with the data collection tool.

These issues could have been mitigated if representatives of the target communities had been involved from the outset as members of the project coordination team to advise on the conception and design of the collective intelligence project. A NASA competition to name a new node of the International Space Station was misled when an influential person called on the community to vote for his own name (163). These examples emphasised the necessity of sharing experiences of researchers who have implemented collective intelligence projects to help future collective intelligence projects avoid methodological mistakes and outputs that are biased by group thinking or lack of diversity in the project team.

Several efforts to define and standardise methods of collective intelligence in specific fields are available. These include a practical guide on using challenge contests to crowdsource ideas and solutions for health research from the World Health Organization, and a list of toolkits compiled by the European Association of Citizen Science for researchers carrying out citizen science activities whereby members of the public collect and classify data via independent contribution (164, 165). In this qualitative study, I explored the experience of researchers who used one or more of these four methods in diverse disciplines, rather than focusing on one specific method to identify the barriers that researchers might encounter in different contexts. Good practice advice from researchers across disciplines could benefit researchers in planning and conducting future collective intelligence projects using one of these four methods within and outside health research.

In the scoping review in Chapter 3, I mapped different methods used in mobilising collective intelligence. In this Chapter, I used a qualitative study to

explore researchers' motivations for using collective intelligence, their choice of methods and what considerations guided their planning and conduct of research involving collective intelligence. By using an online survey and semi-structured interviews with a purposive sample of international researchers who had experience of implementing a range of different collective intelligence methods, I gained a breadth of perspectives. Respondents to the survey and interviews came from diverse disciplines with some of them identifying themselves as multi-disciplinary researchers. The survey allowed a degree of interaction between researchers, which aided the analysis and interpretation of the results. By identifying areas that researchers agreed on, this helped us to ascertain what barriers and strategies were applicable across different disciplines. Additionally, the semi-structured interviews allowed researchers to explain about the context of their research and describe in-depth their ideas and methods for addressing problems in mobilising collective intelligence.

My study has some limitations. The online survey allowed participants to freely express their opinions, but I was unable to probe to clarify the information written and gain deeper understanding of their context. Furthermore, my survey and interview samples were mainly researchers who had published their collective intelligence projects. Therefore, I am uncertain about how far the findings are relevant to unpublished collective intelligence projects. Additionally, although I interviewed and surveyed researchers who had experience of running collective intelligence projects, I did not interview collective intelligence participants. Such data could provide further valuable insights on how to motivate and engage them.

4.5. Summary

In this qualitative study, 82 respondents participated in an online survey or semi-structured interviews about their experience with running collective intelligence projects. They suggested that mobilising collective intelligence could help to involve diverse stakeholders to answer complex questions which requires multidisciplinary efforts. Mobilising collective intelligence could also save time and cost when conducting research. They also shared several barriers to mobilising collective intelligence which mainly arose from the novelty of the methods. The good practice advice that we derived from respondents' accounts aims to support researchers to overcome these barriers when planning and conducting research involving collective intelligence effectively.

In the next chapter, I will present a proof of concept study which used these lessons from researchers experienced with collective intelligence and the framework developed in the Chapter 3 to mobilise collective intelligence in clinical trial planning.

Chapter 5 Mobilising collective intelligence in clinical trial planning

5.1. Background

There are several factors that can influence patients' decision to take part and remain in a trial. A survey of 12, 427 individuals who had participated in a clinical trial across 68 countries showed that patients' decision depended on not only potential benefits, risks of trials, and type of interventions, but also practical logistics and organisation of trials such as location of research centre, length of their participation and whether they would be informed of results at the end of trials (166). The informed consent process plays a key role in ensuring patients have a good understanding of the trial and can make an informed choice. Patients also expressed the importance of the way inform consent was managed by choosing an appropriate time, giving patients time to reflect and discuss with their relatives. (167, 168). Additionally, poorly organised follow-up visits also discouraged patients to remain in the trials. Nearly 50% of trial participants surveyed said that trial participation disrupted their daily life. Patients also expressed their disappointment due to inadequate feedback of trial results. Ninety percent of patients indicated that they wanted to receive summary of study results. However, only 50% of them received such a summary (166). Patients' contribution to research conception, design, conduct and dissemination could help to improve these aspects of trial organisation and conduct to improve patients' experience with trial participation (169-172). Funding agencies have acknowledged the benefits of patient involvement in research and increasingly encourage researchers to co-

produce research with patients (173). The question about patient involvement in research has changed from "why to involve patients in research" to "how to involve patients in research" (41). Several funding agencies have provided methodological guidance for patient involvement in different stages of research (172). Further, new ways of involving patients in the conception of clinical research based on the methods of mobilising collective intelligence have emerged. For example, an initiative collected inputs of 42 patients together with 60 doctors/ researchers to develop a trial protocol. The inputs from patients and doctors led to important modifications of eligibility, dose, and trial endpoints (174).

In this Chapter, I present a proof-of-concept study to leverage patients' collective intelligence to improve the organisation of clinical trials, with the ultimate aim of enhancing patients' experience of trial participation. There are a range of domains that can influence patients' experience with trial participation such as experience with intervention, experience with trial personnel (175). In this study, I focused on patients' experience with trial procedures, informed consent, follow-up visits and receiving trial results in particular, as the contribution from patients to improve these procedures could potentially be used in a wide range of trials without limitation on type of interventions or study personnel.

5.2. Method

5.2.1. Mobilising collective intelligence through crowdsourcing

To develop this proof-of-concept study, I followed the framework developed in Chapter 2 (*Figure 8*) and the good practice advice synthesised from researchers' accounts of their experience as reported in Chapter 3. This indicated that the people who are central to clinical trials - patients - should be asked for their preferences and opinions to improve the organisation of clinical trials. I anticipated that independent contribution (i.e. collecting participants' contributions individually and independently) would be the most suitable way to solicit patients' ideas, because this allows patients to contribute their ideas freely without feeling pressure from other stakeholders such as researchers or clinicians. A steering committee involving methodologists, clinical trialists and patient representatives was established to support the implementation of the study. Methodologists and clinical trialists were from Methods in Research on Research (MiRoR) training network. They have extensive experience in planning and conducting clinical trials. One patient representative in France and one in the UK also participated to support the development of the project. They had experience in research planning and reviewing research proposals.

In order to solicit patients' ideas to improve the organisation of clinical trials, I used an online vignette-based survey. Vignettes have traditionally been used in a number of areas, including in medical training to evaluate clinical practice, and have been increasingly used in research to address topics such as identifying the best trial designs for methodological questions (176-179). In this study, vignettes were case scenarios of real clinical trials that had assessed pharmacological treatments. These vignettes explained to patients what a clinical trial is and what patients are expected to do when participating in the clinical trial. Then participants were asked a set of directed questions to elicit

their preferences for different ways of organising trials. An online survey format allowed me access to a diverse group of patients who could contribute their opinions independently. Although patients were not able to interact with each other which might lead to important insights, this approach enhanced the independence of patients without influence from other participants to avoid group thinking.

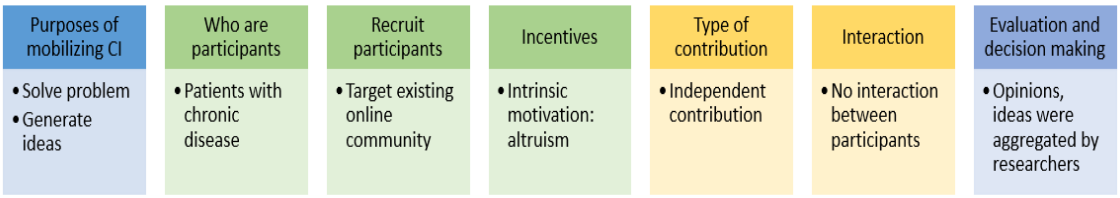


Figure 8 Planning of the proof of concept study according to framework of mobilising CI

5.2.2. Participants

Patients were recruited from an online community of patients, ComPare. ComPare is an e-cohort of nearly 36,000 patients with chronic diseases in France who contribute their information about their diseases, quality of life and treatment adherence. The e-cohort is coordinated by Dr. Tran Viet Thi and Professor Philippe Ravaud at the hospital Hotel Dieu, Paris, France. Participants in ComPare have contributed to research on burden of treatment and proposed new ideas to improve medical care (180). Dr. Tran Viet Thi and a team of administrators are responsible for the communication with patients in ComPare. When researchers want to conduct a research project with ComPare, they must submit a study protocol to the scientific committee of ComPare. After the project is approved, the administrators will help the

researcher to disseminate study materials to patients. Patients can also send their questions about the research project to the administrating team.

5.2.3. Vignette-based survey development

The vignette-based survey was developed in three steps: i) I performed a systematic search for protocols of real clinical trials testing pharmacologic treatment; ii) with the support from the steering committee, I developed vignettes based on these trials that summarised the main tasks that patients would be asked to complete when participating in the trials; iii) I worked together with an informatician from ComPare to create the questionnaire to deliver the vignettes. In the vignettes, I highlighted to patients that these were hypothetical trials and they were not being asked to take part in a trial.

Clinical trial protocol search

To develop case vignettes, I systematically searched for protocols of clinical trials which meet the following criteria: i) phase 3 randomised controlled trials; ii) on-going trials or recently completed (2017 onward); iii) evaluating pharmacological treatments; iv) targeting chronic diseases with high number of available patients in ComPare such as osteoporosis, osteoarthritis, asthma and cardiovascular diseases, diabetes and endometriosis; v) different routes of drug administration with the possibility of self-administered i.e. oral, subcutaneous injection, inhalation. I conducted the search on clinical trial registry www.clinicaltrials.gov. For asthma, diabetes and endometriosis, there was no suitable protocol available on www.clinicaltrials.gov; hence, I conducted a search on PubMed for recently published randomised controlled trials in New England Journal of Medicine (2016 onward) (*Table 16*).

Table 16. Protocol search strategy

Search strategy on clinicaltrials.gov	**Search date**
Osteoporosis, phase 3, study protocol	26 August 2019
Asthma, phase 3, study protocol	26 August 2019
Osteoarthritis, phase 3, study protocol	27 August 2019
Cardiovascular disease, phase 3, study protocol	27 August 2019
Search on PubMed	
((asthma AND NEJM AND randomised controlled trial)) AND ("2018/01/01"[Date - Publication]: "3000"[Date - Publication])	13 November 2019
((diabetes AND NEJM AND randomised controlled trial)) AND ("2016/01/01"[Date - Publication]: "3000"[Date - Publication])	27 February 2020
((endometriosis AND NEJM AND randomised controlled trial)) AND ("2016/01/01"[Date - Publication]: "3000"[Date - Publication])	27 February 2020

Selection criteria for the trials were:

- Parallel design
- Follow-up duration is at least one year
- Full protocol is available

Exclusion criteria:

- Clinical trials are exclusively on patients less than 18 years old
- Clinical trials testing treatments for secondary conditions (e.g. osteoporosis induced by using glucocorticoids)
- Trials conducted exclusively in Asia, Africa and Latin America
- Trials testing medical devices
- Trials recruiting exclusively from a specific population (e.g. Black, Hispanic, Asian population in the United States)

Six protocols targeting common diseases in ComPare were chosen for vignette development (*Table 17*).

Table 17. Protocols selected for vignettes development

Trial title	Route of administration of treatment
Study to Determine the Efficacy and Safety of Romosozumab in the Treatment of Postmenopausal Women With Osteoporosis	Subcutaneous injection
Study of the Analgesic Efficacy and Safety of Subcutaneous Tanezumab in Subjects With Osteoarthritis of the Hip or Knee.	Subcutaneous injection
RCT of the efficacy and safety of an ICS/ LABA reliever therapy regimen in asthma	Inhalation
REVEAL: Randomized EValuation of the Effects of Anacetrapib Through Lipid-modification	Oral
Empagliflozin and progression of kidney disease in type 2 diabetes	Oral

Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist.	Oral

Vignette conception

Each vignette was structured in two parts. The first part described the clinical trial, patient population recruited in the trial, and description of the new treatment. The second part described the procedure of the trial including three main steps: i) informed consent; ii) follow-up visits; iii) receiving results when trial completes. In each step, participants were able to indicate their preferences regarding how the clinical trial should be organised. We proposed three different ways to organise each step of the trial:

a) following the traditional organisation of trials with all procedures of informed consent, follow-up visits at research centres as described in the original protocols.

b) following a new organisation of trials where patients could participate in the trial from their home. They could sign informed consent electronically, answer follow-up questionnaires online, have video calls with study doctors, and do examination tests at a laboratory nearby.

c) combining both models with some on-site visits at research centres and some home-based visits. Patients can decide which visits take place at the research centre or at home.

d) participants could propose new ideas for organising the trial.

For each choice, we described what patients would be asked to do, how much travel would be involved, and how they would be able to communicate with trial investigators.

Previous literature on collective intelligence discussed the limitation of providing examples of solutions when soliciting participants' ideas, as it might decrease the diversity of their ideas (164). We nevertheless decided to allow patients to make choices, instead of asking open-ended questions. Each clinical trial is a specific context and patients might not have participated in several clinical trials or be in a position to put forward their ideas about different ways of organising clinical trials. An open-ended question to ask patients to suggest solutions might be too challenging for patients. Additionally, by providing examples, we aimed to facilitate patients to propose feasible ideas which trialists would be able to implement in clinical trials. Further, as there is no clear evidence of which way of organising clinical trial is best to reduce research burden, we believed there is no risk of influencing patients' opinions by providing examples.

Each participant completed one vignette (Appendix 13-19). After the participant indicated their preference for how the clinical trial should be organised, participants were asked about the likelihood that they would participate in a trial which was organised at the hospital, at their home or combination of both.

The survey was first developed in English, then translated in French and sent to patients' personal accounts on ComPare.

5.2.4. Motivation to engage participants

Although from the scoping review, financial incentives were often used in research projects mobilising collective intelligence, we decided to not provide monetary incentives to participants for several reasons. First, we did not collect any identifying data or IP addresses of participants, and so there might be a risk that individual participants would complete the survey several times, which would have biased the results.

Second, the literature has shown that patients are motivated to participate in research for altruistic reasons, their interest in the topic of their illness, their wish to bring patients' perspectives to research, and their interest in contributing to scientific knowledge (63, 181). In the invitation letter, we therefore emphasised the value of patients' contributions to the project, how it will help research and other patients in the future. When designing the task and the interface, we also tried to make sure that completing the task was not time consuming and onerous for patients.

Further, it is also important to engage participants and keep them updated about the progress of the project. Participants could therefore contact the team via a contact form on their personal account with ComPare.

5.2.4. Data analysis

Demographic information and quantitative analysis

In the end of the survey, participants answered several demographic questions which we anticipated might influence their decision making, such as area of residence (i.e. urban, rural), educational level, and familiarity with the internet.

Quantitative data on patients' preferences regarding the traditional or new models of trial organisation were aggregated to calculate proportion of each model. Chi-squared tests, or Fisher's exact tests when appropriate, were utilised to test the independence of categorical variables.

Qualitative data analysis

Analysis of participants' answers to open ended questions about their ideas for how clinical trials should organised were informed by thematic analysis. Data were imported into NVivo to facilitate the coding process. One researcher (VN) performed open coding and proposed initial themes. Senior researcher (IB) reviewed the analysis process and discussed to refine the themes identified.

5.2.5. Ethical considerations and data security

Ethical approval

ComPare received approval from the CCTIRS (Advisory Committee on Information Processing in Health Research) N° 16.395 date 07/07/2016 and was authorised by CNIL (Commission Nationale de l'Informatique et des Libertés: French independent administrative control authority for the protection of personal data) N° 916397 date 25/11/2016.

The protocol of this research received ethical approval from Inserm's Institutional Review Board (Comité d'Évaluation Éthique, IRB 00003888) reference 19-580 (Appendix 12) and was approved by the scientific committee of ComPare.

Informed consent

Patients in ComPare gave their consent to participate in research proposed by the platform. The administrator team first sent an email to eligible patients to ask if they wished to participate in this research project. We then sent the vignette-based survey to patients who indicated their agreement.

Confidentiality and data management

The database was managed by an IT engineer in the ComPare team. The databased was stored in a secure placed in INSERM METHODS team of Centre de Recherche Épidémiologie et Statistique Sorbonne Paris Cité (CRESS-UMR1153).

Patients' personal data were collected according to the research protocol of ComPare. In this project, we only accessed de-identified data of patients with the permission from the scientific committee of ComPare.

Data sharing

After the results of this study are published in a peer-reviewed journal, the de-identified data of this study will be available on request to academic researchers who have to submit a protocol to the scientific committee of ComPare and sign a data use agreement.

5.3. Results

5.3.1. Study population

We sent invitation emails to 2315 patients in the Compare e-cohort explaining the objectives and potential impact of this study. 834 patients responded positively to our invitations. We then sent to this group the survey containing the vignettes of trials corresponding to their conditions. A total of 628 patients

answered the vignette-based survey (*Table 18*). Respondents mainly lived in France (621/628, 99%) ranging from 21 to 84 years old (median: 55, IQR: 44 – 64). 68% of respondents lived in an urban area. Nearly 60% of respondents could reach a university hospital within one hour of driving from their place of residence.

Table 18. Characteristics of participants (n=628)

	Total (n=628)	Asthma (n=133)	Diabetes (n=83)	Endometriosis (n=59)	Hypercholesterolemia (n=76)	Osteoarthritis (n= 125)	Osteoporosis (n=152)
Gender							
Female	491 (78%)	107 (80%)	41 (49%)	59 (100%)	35 (46%)	97 (78%)	152 (100%)
Age	55 (IQR: 44-64) [21-84]	45 (IQR: 36-52) [22-84]	54 (IQR: 46-63) [26-81]	38 (IQR: 32-45) [21-60]	61 (IQR: 56-69) [25-80]	57 (IQR: 50-66) [26-80]	60 (IQR: 55-64) [23-83]
Employment *							
Unemployed	51 (8%)	18 (14%)	2 (2%)	7 (12%)	4 (5%)	10 (8%)	10 (7%)
Apprentice	21 (3%)	4 (3%)	3 (4%)	9 (15%)	0 (0%)	3 (2%)	2 (1%)
Employed	272 (44%)	71 (53%)	43 (52%)	39 (66%)	25 (33%)	41 (33%)	53 (35%)
Retired	169 (27%)	15 (11%)	24 (29%)	0 (0%)	37 (49%)	41 (33%)	52 (34%)
Disabled	102 (16%)	19 (14%)	10 (12%)	4 (7%)	10 (13%)	28 (22%)	31 (20%)
Other	12 (2%)	5 (4%)	1 (1%)	0 (0%)	0 (0%)	2 (2%)	4 (3%)
Highest level of education *							
No formal diploma	14 (2.2%)	4 (3%)	3 (4%)	1 (2%)	3 (4%)	2 (2%)	1 (1%)
Highschool diploma	99 (15.8%)	18 (13%)	18 (22%)	6 (10%)	13 (17%)	24 (19%)	20 (13%)
Higher education	225 (36%)	52 (39%)	27 (33%)	17 (59%)	32 (42%)	37 (30%)	60 (39%)
Undergraduate and postgraduate	150 (23.9%)	57 (43%)	33 (40%)	35 (59%)	28 (37%)	62 (50%)	70 (46%)
Other diplomas	4 (0.6%)	1 (1%)	2 (2%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Living area							
Rural area	201 (32%)	45 (34%)	33 (40%)	20 (34%)	20 (26%)	40 (32%)	43 (28%)

Urban area	427 (68%)	88 (66%)	50 (60%)	39 (66%)	56 (74%)	85 (68%)	109 (72%)
Distance to the university hospital							
Less than one hour	362 (58%)	74 (56%)	53 (64%)	35 (59%)	45 (59%)	80 (64%)	75 (49%)
From one to two hours	229 (36%)	51 (38%)	27 (33%)	20 (34%)	26 (34%)	37 (30%)	68 (45%)
From two to five hours	37 (6%)	8 (6%)	3 (3%)	4 (7%)	5 (7%)	8 (6%)	9 (6%)
Previous participation in a trial							
Yes	106 (17%)	26 (20%)	16 (19%)	4 (7%)	14 (18%)	19 (15%)	27 (18%)
* One missing data							

5.3.2. Patients' preferences regarding the way a trial is organised

Patients expressed their preference regarding the new trial model in which they could participate in a trial from their home (*Table 19*). For the informed consent process, 311 (50%) respondents indicated that they preferred to be given information about the trials and sign the consent form at home via the internet. 239 (38%) respondents preferred having information about the trial explained at the hospital and signing the consent form at home. Regarding follow-up visits, 251 (40%) wished to have all follow-up visits at home and 254 (41%) patients preferred the combination of both on-site visits at research centres and home-based visits with the possibility to arrange the visit according to their choices. Only 122 (19%) chose to have all follow-up visits at the hospital.

In contrast, most of respondents (44%) wished to have an in-person meeting with research investigators when receiving the results of the trials; 192 (36%) respondents chose to receive a summary of results by email (31%) or by post (5%), and 126 (20%) respondents would like to have a video call with research investigators.

Preferences for the way a trial was organised also varied by patients' conditions. For the informed consent process, although most patient groups preferred to sign informed consent at home, patients with endometriosis preferred to be explained about the trial at the hospital and sign the informed consent at home (56%). Patients with asthma, diabetes and hypercholesterolemia preferred to have home-based follow up visits. Patients with hypercholesterolemia were the only group for which most patients choose to receive trial results by mail (43%), the other groups wished to meet a research investigator in person.

Table 19. Patients' choices of trial organisation

	Total (n=628)	Asthma (n=133)	Diabetes (n=83)	Endometriosis (n=59)	Hypercholesterolemia (n=76)	Osteoarthritis (n=125)	Osteoporosis (n=152)
Informed consent							
At home	311 (50%)	73 (55%)	39 (47%)	19 (32%)	47 (62%)	58 (46%)	75 (49%)
At hospital and home	239 (38%)	32 (32%)	40 (48%)	33 (56%)	22 (29%)	40 (32%)	62 (41%)
At hospital	78 (12%)	18 (14%)	4 (5%)	7 (12%)	7 (9%)	27 (22%)	15 (10%)
Follow up visits *							
By choices	254 (41%)	51 (38%)	29 (35%)	28 (48%)	23 (30%)	61 (49%)	62 (41%)
At home	251 (40%)	58 (44%)	42 (51%)	19 (32%)	41 (54%)	30 (24%)	61 (40%)
At hospital	122 (19%)	23 (17%)	12 (15%)	12 (20%)	12 (16%)	34 (27%)	29 (19%)
Receive results							
Meeting a doctor at the hospital	275 (44%)	58 (44%)	39 (47%)	32 (54%)	24 (32%)	62 (50%)	60 (40%)
Video call with a doctor	126 (20%)	30 (23%)	19 (23%)	16 (27%)	16 (21%)	19 (15%)	26 (17%)
By mail	192 (31%)	38 (29%)	25 (30%)	9 (15%)	33 (43%)	38 (30%)	49 (32%)
By post	34 (5%)	7 (5%)	0 (0%)	2 (3%)	3 (4%)	6 (5%)	16 (11%)

Figure 9 illustrates the diversity of participants' choices for the trial as a whole. Among patients who wished to have informed consent process take place at home, 32% (100/311) preferred the combination of visits at research centre and home-based visits for follow-up and 11% (35/3110) selected all visits at the

hospital. Of 78 patients who chose informed consent at the hospital, 17% (13/78) would like to have all follow-up visits at home and 33% (26/78) chose the combination of both visits at home and at the hospital. Even for patients who wanted to have all procedures of informed consent and follow-up visits at home, they had different choices for receiving results.

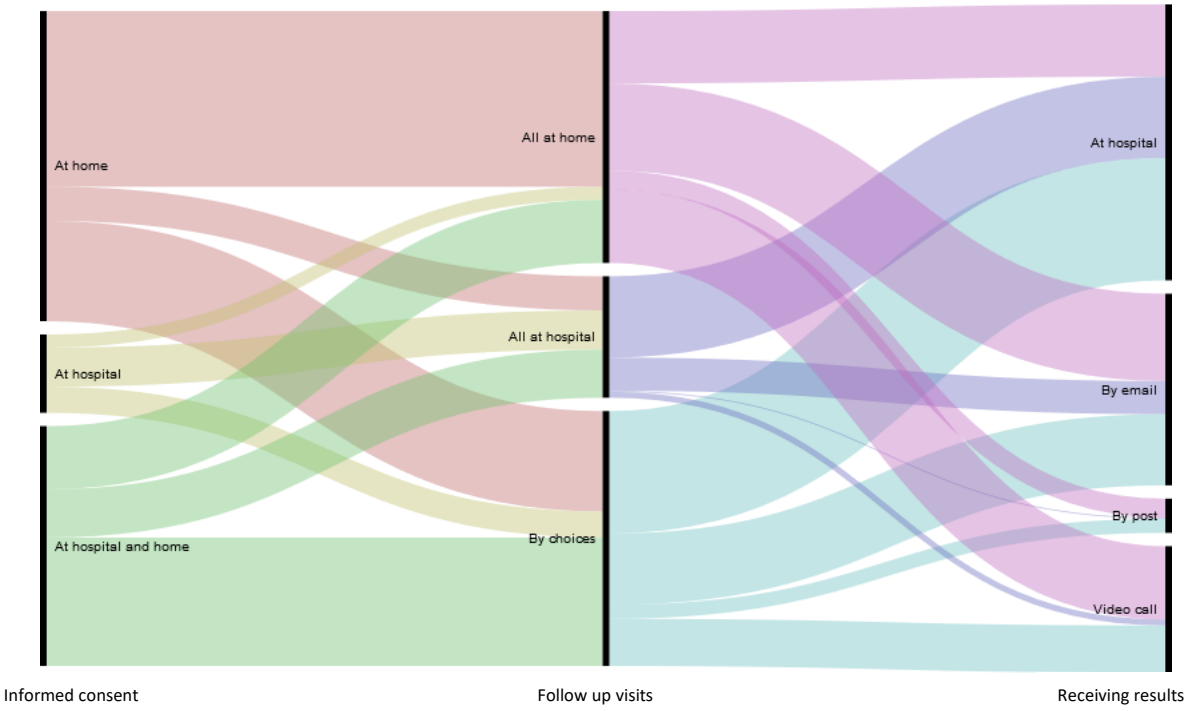


Figure 9. Diversity of patients' choices for the way a trial is organised

5.3.3. Patients' willingness to participate in clinical trials according to the way a trial is organised

The mean (SD) probability of participating in the trials when informed consent is signed at hospital was 53% (34%) versus 70% (31%) for informed consent at home (mean difference [95% CI] 17% [4 – 30]), and 64% (33%) for the combination of both (mean difference [95% CI] 11% [3 – 19]).

The mean (SD) probability of participating in the trials when all follow-up visits took place at the hospital was 54% (34%) versus 74% (29%) when there

were combination of research centre-based visits and home-based visits (mean difference [95% CI]: 20% [10 – 30]), and 70% (31%) when all follow-up visits took place at home (mean difference [95% CI]: 16% [2 – 30]).

Figure 10 shows the difference in probability of participating in the trials when trials were organised in a way that patients' preferred versus their non-preferred model. Mean (SD) of probability of participating in trials was 82% (24%) if trials were set up according to patients' preference, versus 55% (33%) if trials were set up according to patients' non-preferred model.

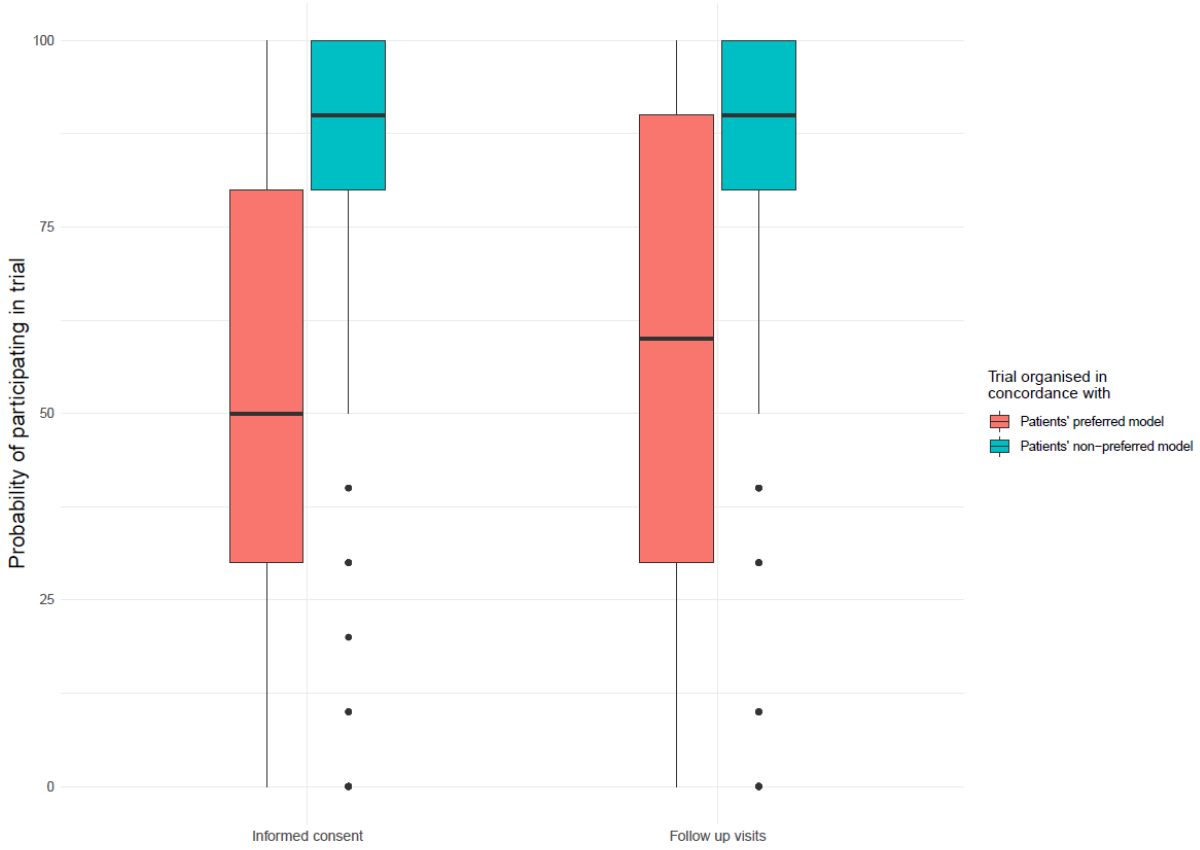


Figure 10. Probability of participating when a trial is performed in accordance with patients' preferences

5.3.4. Factors associated with patients' preferences regarding the way a trial is organised

People who lived in rural area and who lived from two to five hours driving from the university hospital were more likely to choose the informed consent process online at home (57% and 65% respectively). Patients who lived in rural area preferred home-based follow-up visits (47%), while patients who lived in urban area preferred follow-up visits both at home and at the hospital. Patients who were less confident with the internet were more likely to select informed consent and follow-up visits at the hospital (*Table 20*, *Table 21*, *Table 22*).

Table 20. Factors associated with patients' preferences of informed consent process organisation

	At home online	**At the hospital and at home**	**At the hospital**	**p-value**
All (n=628)	311 (50%)	239 (38%)	78 (12%)	
Living area				
Rural (n=201)	115 (57%)	71 (35%)	15 (8%)	0.00687
Urban (427)	196 (46%)	168 (39%)	63 (15%)	
Distance to the university hospital				
Less than one hour (n=362)	158 (44%)	147 (41%)	57 (16%)	0.00283
From one to two hours (n=229)	129 (56%)	82 (36%)	18 (8%)	
From two to five hours (n=37)	24 (65%)	10 (27%)	3 (8%)	
Confidence with internet				
Not confident (n=1)	1 (100%)	0 (0%)	0 (0%)	0.0471
Slightly confident (n=7)	1 (14%)	2 (29%)	4 (57%)	
Somewhat confident (n=44)	19 (43%)	18 (41%)	7 (16%)	
Fairly confident (n=218)	107 (49%)	85 (39%)	26 (12%)	
Completely confident (n=358)	183 (51%)	134 (37%)	41 (12%)	

Table 21. Factors associated with patients' preferences of follow-up visit organisation

	All follow up visits at home	**Follow up visits at home or at the hospital by choices**	**All follow up visits at the hospital**	**p-value**
All (n=627) *	251 (40%)	254 (41%)	122 (19%)	
Living area				
Rural area (n=200)	93 (47%)	81 (40%)	26 (13%)	0.00926
Urban area (n=427)	158 (37%)	173 (41%)	96 (22%)	
Distance to the university hospital				
Less than one hour (n=362)	128 (35%)	147 (41%)	87 (24%)	0.00474
From one to two hours (n=228)	108 (47%)	92 (40%)	28 (13%)	
From two to five hours (n=37)	15 (41%)	15 (41%)	7 (18%)	
Confidence with the internet				
Not confident (n=1)	1 (100%)	0 (0%)	0 (0%)	0.00503
Slightly confident (n=7)	1 (14%)	2 (29%)	4 (57%)	
Somewhat confident (n=44)	13 (30%)	14 (32%)	17 (39%)	
Fairly confident (n=218)	81 (37%)	95 (44%)	42 (19%)	
Completely confident (n=357)	155 (43%)	143 (40%)	59 (17%)	
* one missing data				

Table 22. Factors associated with patients' preferences of ways to receive trial results

	Receiving results by post	Receiving results by email	Meeting a doctor at the hospital who explains the results	Having a video call with a researcher who explains the results	p-value
All (n=627) *	34 (5%)	192 (31%)	275 (44%)	126 (20%)	
Living area					

Rural area (n=201)	14 (7%)	63 (31%)	71 (35%)	53 (26%)	0.0072
Urban area (426)	20 (5%)	129 (30%)	204 (48%)	73 (17%)	
Distance to the university hospital					
Less than one hour (n=362)	14 (4%)	104 (29%)	186 (51%)	58 (16%)	0.00265
From one to two hours (n=228)	17 (8%)	76 (33%)	74 (32%)	61 (27%)	
From two to five hours (n=37)	3 (8%)	12 (32%)	15 (41%)	7 (19%)	
Confidence with the internet					
Not confident (n=1)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0.1095
Slightly confident (n=7)	0 (0%)	0 (0%)	7 (100%)	0 (0%)	
Somewhat confident (n=43)	2 (5%)	13 (30%)	24 (56%)	4 (9%)	
Fairly confident (n=218)	16 (7%)	65 (30%)	93 (43%)	44 (20%)	
Very confident (n=358)	16 (4%)	113 (32%)	151 (42%)	78 (22%)	

5.3.5. Patients' suggestions to improve the way a trial is organised

256 patients responded to at least one open-ended questions expressing their opinions about the ways a trial is organised and providing suggestions for improvement.

Challenges to trial participation at the hospital

Respondents indicated that hospital visits as part of trial participation would be more practical in comparison with trial visits at home as they believed the tests and examinations would be completed on the same day and they wanted the feeling of reassurance from seeing a doctor. However, several barriers related to the visiting the hospital dissuaded them from this traditional model. Patients expressed their disappointment with long waiting time and lack of punctuality at the hospital.

What is terrible at the hospital is the waiting, sometimes hours for a blood test, then again a few hours to see an intern… and the impossibility to make the appointment by ourselves, which makes us dependent, useless, and does not make us responsible. (A patient with diabetes/24)

Further, as the appointments were mainly arranged during working time, many patients mentioned about their loss of income or that they had to use up annual leave to attend the visits at the hospital. Several respondents shared their perspectives about the distance to travel to the hospital. For some patients who suffered from chronic conditions, it required substantial physical effort for them to travel to the hospital. Another barrier related to the travel to the hospital was the cost of transportation.

Challenges to trial participation at home via the internet

Although patients considered participating in a trial from home via the internet as a solution to reduce travel and save time, their main concern was a lack of contact with research investigators. They indicated that an in-person conversation with research investigators would help reassure them when making decision related to the trial participation.

I prefer the hospital. In the context of a clinical trial, a contact with a real human is important. The internet does not transmit the emotion. Everything done at the hospital such as blood tests is more practical for me. […] It is reassuring at the hospital setting. They (doctors) can see my condition and I also feel that I am a stakeholder and an actor of my own decisions when having a human in front of me. (A patient with osteoarthritis/73)

Several respondents spoke about their concerns about accuracy of tests and data collected outside the context of the hospital which might influence the quality of research. Additionally, respondents expressed their concerns about new responsibilities if they had to arrange appointments at a nearby laboratory. Further, respondents also highlighted the likelihood that they would not have required equipment for video calls with doctors and that their internet connection might be unstable.

It is preferable that all patients are followed in the same hospital to avoid experimental bias. Same equipment, same follow-up staff. Only in-hospital follow-up makes this possible. At home, the deviations due to errors, for example in video cameras, should not be ignored. In remote consultation (video) no palpation and "organoleptic" examination (smell, sight, touch) of the patient is possible. The direct contact with the doctor at the hospital and the team involved in the trial seems to be the most efficient for the examination of the patient included in the study. It seems to me to be the best way to guarantee the confidentiality, the Internet does not allow it. The secured internet should be restricted to administrative aspects. If the security could be ensured, it could be used to collect the data (while limiting data manipulation) e.g. for monitoring symptoms, weight (but be careful with the error of patient's equipment), temperature, etc. (A patient with osteoporosis/68)

Interestingly, one patient explained her opposition to trial visits at home as she wanted to keep her home as a private place for "rest" and "recreation".

I do not use the webcam. I prefer the classic meeting. On the other hand, I use e-mail and telephone. The trial replaces the usual care. It seems important to me to have a familiar and reassuring context for the follow-up visits. My home is a place of conviviality, rest, or recreation. I do not want that my home to become a place of care. I already have auto injections. I prefer to go to the doctor, in a centre of care even if that seems more constraining. (A patient with asthma/4)

Suggestions to improve patients' experience of trial participation

Patients made several suggestions to improve their experience when participating in trials (*Table 23*). They emphasised that research investigators should consider patients as partners in the trials, not solely as participants. Research investigators should maintain regular communication with patients and take into account patients' opinions when planning their trial participation.

The patient must then become a partner (a member to be taken into account, to listen to, to share information and results with (by mail, appointment, internet), to be part of everything). (A patient with endometriosis/1)

It is important to have patient representation in scientific councils, trial organisation, etc. In my opinion, patients must be given more say in the running of the trial. (A patient with diabetes/60)

Further, patients also spoke of the necessity of tailoring the trial procedures to each patient as their conditions were unique depending on their distance, severity of the disease and employment status.

I think you cannot generalize, but for each clinical trial, the patient must be given a choice of how to participate. This depends mainly on the distance between home and hospital and of course whether the person has a professional activity or not. The way of participating could be proposed to the patient at the same time as the consent and the patient will then be in control of whether he or she can and wants to participate. (A patient with asthma/125)

Table 23. Patients' suggestions to improve their experience of trial participation

Suggestions	Quotes
General suggestion	
Improve information for patients	*It is important to have as much information as possible, both orally and in writing, and to have time for reflection whenever possible. (A patient with osteoarthritis/8)* *I like the idea of being able to see a video describing the study. It allows you to come up with more relevant questions in front of the doctor. (A patient with endometriosis/3)* *A video presenting the study and answering frequently asked questions prior to consent (A patient with osteoporosis/17)*
Create a patient group/forum to put questions about the trial to the investigators	*I don't know to what extent this proposal can affect the clinical effects, but perhaps the questioning phase could be done in a group setting? The questions could then be more varied than those asked individually, and this would free up time for the doctor. (A patient with endometriosis/3)* *A patient forum for patients who can ask questions I would not have thought of. (A patient with hypercholesterolemia/66)*
Improve visits at the hospital	
Keep to appointment times and reduce waiting time	*Make sure that appointments with doctors or ECG radiography departments are on time. (A patient with osteoarthritis/41)* *It all depends on the location of the hospital and how easy it is to get there by public transport (I don't drive). On the other hand, please respect the appointment times very strictly. (A patient with osteoporosis/5)*

Arrange a reception dedicated to trial participants	*Make sure that appointments with doctors or ECG radiography departments are on time, without going through the general reception of the hospital... In order for me to participate in a study, the "logistics" must be as fluid as possible and outside the traditional care circuit in terms of administration and waiting time. (A patient with osteoarthritis/41)*
Provide flexibility of appointment time	*Having the possibility to have intelligent appointments, to have all examination and tests in the morning or in the afternoon or from 10:00 to 15:00 for example, this allows fragile, sick and tired people to take time and take care of their health, when they come from far away or when they have difficulty to move. It is important to be able to organise according to our conditions. (A patient with diabetes/13)* *I would be willing to go to the hospital without any worries, but I do not want this to be done during my working hours as it should not be the concern of my employer. (A patient with asthma/65)* *If the date and time of the appointment are suitable with my schedule, I can attend the visits at the hospital. (A patient with endometriosis/46)*
Combine follow-up visits with routine care visits	*Should we combine the visit with the examination and radiography for osteoarthritis? (A patient with osteoarthritis/97)*
Reimburse transportation fees and provide free parking	*The fee of transportation and parking should be reimbursed for traveling to and parking at the research centre. (A patient with osteoarthritis/35)*
Suggestions to the home-based visits	
Involve local hospitals and healthcare providers for follow-up visits	*I participated in a clinical trial. The appointments with the doctor took place at the hospital. The biological tests between appointments at the hospital were done at a laboratory near my home. I appreciated this organisation. (A patient with asthma/56)* *To not wait too long at the hospital, and to be able to do the visits at a hospital nearby to reduce the travel time. (A patient with asthma/123)* *The visit at home gave me an idea that the patients can go to see a nurse. (A patient with asthma/76).*
Involve primary care doctors for informed consent and follow-up visits	*Another suggestion is to involve the primary care doctor as an intermediary to explain the study. (A patient with osteoarthritis/82)* *To involve the primary care doctor to avoid a part of the travel to the hospital? (A patient with endometriosis/51)*

	Follow-up of the trial by primary care doctor and nurse for usual blood examination in close contact with the research team of the university hospital. (A patient with hypercholesterolemia/37)
Apply technology to reduce burden of data collection	*Plan (or use an existing one) an application with file sending via email for patients already doing PeakFlow follow-ups if this can replace or complement the certain spirometry (to avoid sending an IDE at home). (A patient with asthma/115)*

5.4. Discussion

The study involved 628 patients with different conditions. 50% of patients would like to have informed consent completely at home, while 38% wanted to visit the hospital to have the trial explained by a doctor or research and have time to consider and sign consent form at home. 40% and 41% of patients would like to have follow up visits completely or partially home-based. About 60% of patients preferred to have a doctor inform them about the study results either in person or via a video call. The study also showed that if the trials were set up according to patients' preference, it could increase the probability of them participating in trials by nearly 30%.

Patients highlighted the importance of personalizing the trial processed according to patients' preference and desires. Patients provided useful suggestions to consider when planning a trial. To improve their experience with trial visits at the hospital, they proposed to set up a dedicated reception system specifically for trial participants at the hospital to reduce waiting time. Patients suggested involving local healthcare providers to not only minimise travel to research centres, but also improve their care during the trial participation. They also highlighted the important role of their primary care doctors to increase trust in the trial as well as support patients to complete trial tasks.

Implications

The development of clinical research has been focusing on investigators' research interests and the ease and feasibility for sponsors to conduct trials with insufficient consideration of patients' diverse preferences and desires. The patient and public involvement movement has strived to bring the voices of patients into research planning, conducting and dissemination. Literature shows that patient and public involvement in research could potentially improve research design, recruitment, and retention rate (41, 182). However, the issues of identifying patients and ensuring the representation of patients involved across demographic and socioeconomic dimensions remain a challenge to patient and public involvement (183). A systematic review showed that only a small number of patients ranging from two to 24 patients were involved in the planning stage of the trials (184). Researchers have been focusing on "choosing the right patients" to engage in research activities instead of seeking for diversity (185, 186). Our study provided a proof of concept of a method to leverage collective intelligence of a diverse group of patients (187-190). We used case-vignettes developed in collaboration with patient representatives to solicit patients' preferences and ideas to improve the organisation of trials. We recruited patients via an online patient community which was not resource intensive and achieved a sample of patients with different conditions, a wide range of age (median 55, [min-max:21-84]), levels of education, employment status and place of residence . The age range and levels of education of our sample reflect the general population in France. For example, around 80% of French population have at least high school diploma

which is similar to our sample. The median age of general population in France is 42 years old, however, we included only people over 18 years old in our sample (191). Additionally, to ensure the diversity of patients' perspectives, it is also important to create an environment that patients would be willing to share their opinions. By using vignette-based survey, patients could freely express their opinions and ideas without being influenced by other participants.

Further, our study could offer solutions to the problem of poor recruitment and retention in trials (192-194). Our results showed that researchers could increase patients' willingness to participate in trials by some modifications in the logistical organisation of trials without changing research questions or study design. Some of these modifications could be quite simple to implement such as respecting appointment times, minimising waiting times, involving local healthcare providers to reduce travel for patients. Patients showed their desire to discuss different choices during trial participation with investigators. Indeed, previous literature showed that research investigator rarely had this discussion with patients (195). Patients also expressed the need to be informed about trial results, preferably during a discussion with a doctor to have a chance to bring up questions and have their questions answered directly. This desire from patients is in line with efforts to enhance transparency of trial results that funders are striving for. Further, informing patients about trial results helps them understand the meaning of their contribution to science and may encourage them to participate in future studies (196).

Limitations

Our study has some limitations. We recruited patients from a patient e-cohort, thus patients in our sample had more experience with the use of the internet and participating in research. The majority of participants lived in France (98%), thus their experience with clinical trial participation might be different to patients living in other countries. Nevertheless, this proof of concept study could be adapted to other languages and disseminated to international patient communities. Additionally, a limitation of online survey was that we were not able to clarify responses or obtain further details of the context that patients were referring to. However, with an online survey, we were able to include a relative high number of patients, thus increasing the diversity of participants' opinions and ideas to improve trial organisation. Further, the use of case vignette-based online survey could be adopted easily by trialists to communicate the trial procedures to patients and solicit ideas for improvement at the early stage of trial planning. We used closed questions to solicit patients' opinions and ideas which might restrict their ability to express new ideas to improve trial organisation, thus we might not have limited the potential of collective intelligence to elicit new ideas and perspectives of patients. However, the closed questions were considered as appropriate in this context by the steering committee and patient representatives to provide simple and quantifiable data on patients' views regarding the complex concepts related to clinical trials as a prelude to open-ended questions regarding potential solutions. The results showed that patients' opinions and ideas were relatively diverse, and their answers to open-ended questions provided insights on both pros and cons of research centre-based and home-based trials. Another limitation of the study is that patients were not involved

in the final decision-making process to prioritise the solutions proposed. Patients' perspectives on the prioritisation of these solutions could help achieve a higher level of collective intelligence by translating their ideas into an actionable plan to guide changes in the conduct of clinical trials. Although this proof-of-concept study used hypothetical scenarios, trialists could adapt this method by using their real protocols to solicit patients' opinions and then use the feedback from patients to adapt trial organisation according to patients' preferences.

5.5. Summary

This study provided the proof of concept of leveraging patients' collective intelligence to improve patients' experience of trial participation. In this study, 628 patients with diverse characteristics contributed their opinion to improve clinical trial organisation. They indicated that the possibility to make decision about when and how trial visits took place would make them more willing to participate in the trials. Patients expressed the needs to transform the current one-size-fits-all approach of clinical trial participation.

The collective intelligence of different stakeholders could be leveraged to address other challenges in trial planning. This will be discussed in Chapter 6.

Chapter 6 Discussion

6.1. Introduction

Methods of mobilising collective intelligence have emerged outside the field of clinical research to enable thousands of experts and non-experts to contribute their personal experience, knowledge and skills to research (20, 63, 65, 197, 198). My principal aim in this thesis was to describe the methods of mobilising collective intelligence and determine if and how they can be used to transform clinical trial planning. In this Chapter, I summarise the key findings for each of the thesis objectives. I then discuss the implications of this work, what the work has contributed to knowledge about methods of mobilising collective intelligence and its application in clinical research planning. Lastly, I propose future areas for research on mobilising collective intelligence.

6.2. Key findings

6.2.1. Framework of mobilising collective intelligence

The first objective was to describe different methods to mobilise collective intelligence in various research disciplines, who participated in these research projects, their motivations and how they contributed to research projects. I conducted a scoping review to describe the methods used across research disciplines which is presented in Chapter 2. I identified 145 articles with 49 from the field of biomedicine, 47 from computer science and technology and 49 from other research fields. Most of these research projects (76%) involved members of the public who did not have expertise in research. They were involved in these research projects to create intellectual output, to generate

new ideas, to solve problems and to conduct evaluations. The methods used to collect contributions from collective intelligence participants varied depending on the reason for using collective intelligence. When collective intelligence participants contributed to conducting evaluation and solving problems, they often worked independently without interaction with other participants. In projects where participants generated new ideas, competitions were often used to motivate participants. Participants also received feedback from other participants to refine their ideas. In projects where participants contributed to creating intellectual products, collaborations between participants were encouraged. Participants also received feedback from other participants and organisers to improve their work.

This review also showed that the reporting of research mobilising collective intelligence is suboptimal. The numbers of participants who signed up and actually contributed, and their demographic information were not reported in sufficient detail to indicate the diversity of participants. Sources of funding were not mentioned in nearly a third of publications and about 40% of retrieved articles did not report the methods used to evaluate the contributions of participants. A framework was developed to guide the planning and implementation of research mobilising collective intelligence.

6.2.2. Practical advice on mobilising collective intelligence

The second objective of the thesis was to identify barriers to mobilising collective intelligence, strategies to overcome these barriers and provide good practice advice for planning and conducting research using collective intelligence. This objective was addressed by a qualitative study and survey of

researchers with experience with these new methods. This study comprised an online survey with open ended questions and semi-structured interviews. Researchers explained that they were motivated to try this new way of conducting research by the need to involve more diverse perspectives to tackle research questions which were becoming ever more interdisciplinary. Mobilising collective intelligence also helped them to save time and costs when conducting research.

Researchers reported having experienced disruptive behaviours from some of participants (i.e. cheating, "trolling", use of inappropriate language) which they feared might discourage other participants. They commented that participants had concerns about intellectual property of the solutions created and were worried that these concerns might hinder participants from taking part in collective intelligence projects. Researchers also spoke of encountering reluctance from funders and beneficiaries to adopt the solutions contributed by collective intelligence participants. To overcome these barriers, researchers highlighted the need for more transparency in reporting of the collective intelligence process to help decision makers understand the methods and the contributions of collective intelligence projects. Clear communication with participants on the terms of intellectual property from the beginning of the projects, and dissemination of results back to participants were proposed as ways to address the concern about intellectual property. Researchers shared practical advice on identifying research questions suitable for mobilising collective intelligence, identifying potential participants and ways to engage them. Although most of research involving collective intelligence engaged participants virtually via internet-based platforms, researchers advised to not

underestimating the value of face-to-face communication to build trust and strengthen the sense of belonging within a community of participants.

6.2.3. Proof of concept – mobilising patients' collective intelligence in research planning

The third objective was to evaluate the impact of mobilising collective intelligence on the planning of clinical trials. This objective was addressed by a proof-of-concept study to mobilise the collective intelligence of patients in clinical trial planning. The aim of this study was to involve a large number of patients to overcome the current challenges of patient involvement in research due to lack of diversity. I used case-vignettes to illustrate the context of a clinical trial to patients who might not have experience of taking part in a trial. In this study, I drew on selected protocols of clinical trials testing pharmacologic treatment for chronic diseases to develop case vignettes. 628 patients who had different conditions, education levels and living places answered the case vignettes to indicate their preferences regarding the way a trial is organised. The study showed that by setting up trial procedures according to patients' preferences, trialists could increase the likelihood of patients participating in trials by 30%. Patients emphasised the need to change the one-size-fits-all approach of trial organisation and tailor the trial procedures to patients' personal preferences and situations. The model of remote trial could be a way to bring more flexibility to trial participation. Patients also made several suggestions for changing the logistical organisation of trials to improve their experience of trial participation, such as reducing waiting time, and involving local healthcare providers and primary care

doctors in trials. This study provided a proof of concept of leveraging collective intelligence of patients to improve trial organisation.

6.3. Implications

Contribution to the knowledge of methods of mobilising collective intelligence

By mobilising collective intelligence, researchers can leverage experience, knowledge, and expertise from diverse contributors to accelerate the search for solutions to address complex issues (73, 199, 200). Several previous studies had been done to explore methods of mobilising collective intelligence. Nevertheless, this work often focused on one specific methods in one research domain, which did not provide an overview of different ways to mobilise collective intelligence. This, in turn, limited the generalizability of the findings to other contexts (64-66, 164, 201). The work in this thesis has systematically described different methods of mobilising collective intelligence across different research disciplines. The framework developed from the scoping review provided a classification of purposes of mobilising collective intelligence and key elements when designing a collective intelligence project. This thesis is also the first work to have inductively explored barriers to mobilising collective intelligence and ways to overcome these from perspectives of researchers with experience of using collective intelligence methods (63-65, 201). By using a qualitative approach, I was able to identify issues that had not been described in previous literature on collective intelligence, such as the difficulties and solutions involved in motivating and engaging contributors in collective intelligence projects, thus deepening the

understanding of these new methods. For example, although previous literature about collective intelligence often focused on the use of online platform to recruit and access a wide range of participants, online platforms might limit the population to younger groups having better computer literacy or higher social economics status (i.e., be able to have a computer and access to the internet). To overcome this challenge, the respondents in the qualitative study emphasised the importance of combining these online platforms with traditional face-to-face events to approach the population that might not be familiar with the internet (160).

Impact on clinical research planning

Clinical research planning has been facing numerous complex challenges such as setting research priorities, research design, recruitment and retention of trial participants. The collective intelligence of different stakeholders could be leveraged to find solutions for these issues. Patients with their lived experience of conditions and their lives being influenced directly by participation in trials are important stakeholders who can provide insights to address challenges of trial planning (202-204). The work in this thesis has contributed a new way to involve patients and public members in trial planning. In this thesis, I have leveraged the collective intelligence of patients who suggested ways to improve the logistical organisation of clinical trials. By using vignettes, I was able to explain the complex process of trials to patients, thus solicit their opinions and ideas. Patients were able to contribute their opinions with ease at home without pressures from other stakeholders. This process might be replicated by trialists at an early stage in the design of a trial to understand patients' expectation and potential challenges when participating in trial so the research

team can adjust the way that the trial is organised accordingly. Further, in the proof-of-concept study, I solicited ideas and preferences of patients about the organisation of clinical trials. Other research questions such as choices of study design, design of intervention might require a more in-depth discussion between stakeholders. Certain online platforms have emerged to support the discussion between members of the community while providing real-time summary of the discussion or tools for participants to rank their choices (205). This method can also be scaled up to involve other stakeholder groups. Although in this thesis, I focused on involving patients' perspectives in trial planning, there are several efforts aiming to involve other stakeholders in clinical research as well as clinical trial. For example, in an online competition that searched for solutions to improve trial recruitment, the winning team comprised clinicians, nurses and computer scientists who created tools to increase doctors' awareness of on-going trials and to support them in communicating clinical about trials to patients (206). Nevertheless, the use of an online platform might not be an optimal choice for certain groups such as elderly or people who do not have access to the internet. Face-to-face meeting or in-person outreach communication activities would be more suitable to these groups (207). The framework developed in the Chapter 2 and practical advice in the Chapter 3 may guide researchers in identifying relevant stakeholders to take part in clinical research planning, how to approach and motivate them, and in selecting methods to solicit their contributions.

6.4. Future work

6.4.1. Application of collective intelligence in clinical trial planning

Patients and other stakeholders can contribute to different aspects of clinical trial planning. The European Patients' Academy on Therapeutic Innovation (EUPATI) created a roadmap describing the areas where patients and public members contribute to research planning, such as practical issues in the way research is organised, by creating patient-facing informed consent resources, and during the dissemination of trial findings to patients (*Figure 11*) (208).

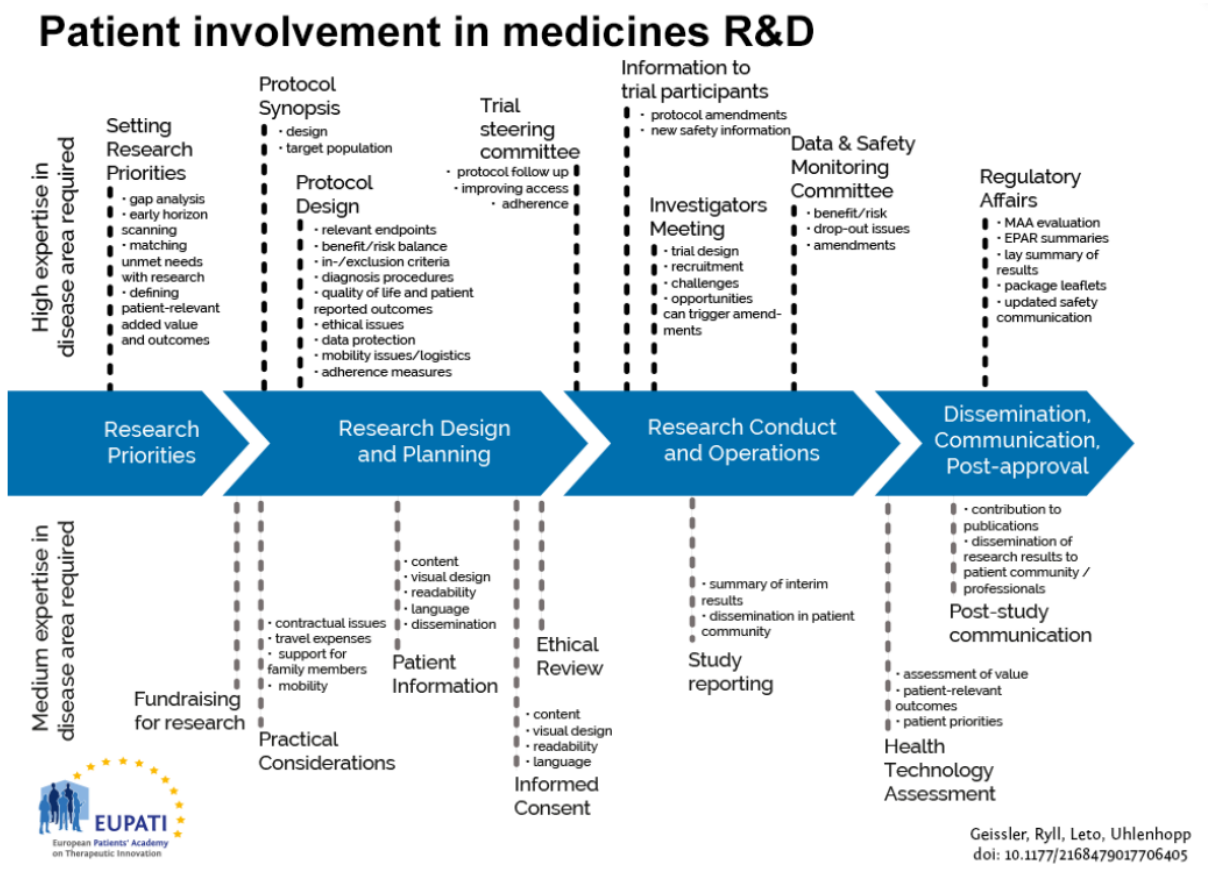


Figure 11. Patients involvement in medicines research and development (reproduced from Geissler et al (2018)) (208)

Depending on the goals for seeking patients' contributions, different methods of mobilising collective intelligence can be used. In this section, I present prospective projects to mobilise collective intelligence of patients and other stakeholders to transform clinical trial planning.

Improving clinical trial protocol

Participating in a clinical trial usually requires patients to attend more visits to hospitals and answer numerous questionnaires in addition to their usual health check-ups. Further, clinical trial procedures are becoming ever more complex over time. Getz K. and Campo R. reviewed nearly 10,000 clinical trial protocols from 2011 to 2015 and showed an increase of 25% in the number of trial visits and 70% in the total number of procedures performed (209). However, in many trials, not all follow-up visits and data collected are used efficiently. A systematic review of cancer trials showed that only 11-27% of data collected were reported in trial publications (210). This means that patients' time and efforts to attend trial visits and complete questionnaires, as well as some of the efforts of research teams to collect and verify data, are being wasted. In future research, I will explore ways to simplify trial protocols by leveraging collective intelligence of researchers, trialists and patients. Researchers and patients could identify unnecessary visits and procedures in a trial protocol. We will then compare patients' willingness to participate in the original protocol and the simplified protocol. With the use of the internet, we can approach a diverse group of patients including patients who might be underrepresented in the current models of patient and public involvement. (174, 205).

Using collective intelligence to determine minimal clinically important treatment effects

Clinically important treatment effects are used to determine whether an improvement caused by an intervention is perceived as meaningful to patients

(211). A clinically important treatment effect is important in interpreting the effect of intervention. Studies have indicated that clinical trials can show statistically significant treatment differences even though such differences have no clinical importance for patients (212). Several methods have been used to elicit patients' perspectives in determining clinical important treatment effects such as the opinion anchor-based method and opinion seeking (213, 214). However, these methods are often challenged on the grounds that the numbers of patients involved are usually limited and unrepresentative of the patient population. With methods of mobilizing collective intelligence, we can collect opinions of a large diverse group of patients who will be potential users of the treatment to determine the level of treatment effect which is meaningful to them while taking into account the adverse effects. Case vignettes for specific diseases and treatments could be used to illustrate the clinical cases to patients. Probability trade-off techniques could be used to probe patients' decisions on the meaningful treatment effect against the risks of adverse events (215). The vignettes could be co-produced with patient representatives. Patients would make their decision independently. The final minimal clinically important treatment effect would be aggregated from patients' decisions.

Other ideas of mobilising collective intelligence in research planning

Methods of mobilising collective intelligence could be used to address different challenges in clinical trial planning. From examples of initiatives using methods of mobilising collective intelligence to enhance research, in *Table 24* I outline areas where diverse stakeholders can advance clinical trial planning and ideas for ways to solicit their contribution.

Table 24. Ideas and examples of mobilising collective intelligence in research planning.

Purpose of mobilising CI	Who are participants	Type of contributions	Examples
Generate ideas: generate new research questions/ setting research priority	Patients, health care providers, medical students	Collection of ideas Competitions to select and reward the best ideas	Priority setting partnership of James Lind Alliance (44) Harvard Catalyst competition for new research ideas on diabetes (84).
Generate ideas: research ideas for trial recruitment	Patients, health care providers, trialists	Collection of ideas Collaboration to aggregate and refine ideas	PRIORITY I project (45)
Solve problems for trial recruitment	Patients, health care providers, engineers, computer scientists	Competitions for innovative ideas and solutions	Bonnie J. Addario Lung Cancer Foundation Clinical Trial Innovation Prize to improve recruitment in lung cancer trial (216)

Generate ideas: research ideas for trial retention	Patients, health care providers, trialists	Collection of ideas Collaboration to aggregate and refine ideas	PRIORITY II project (44)
Solve problem for trial retention	Patients, health care providers, engineers, computer scientists	Collection of ideas Competitions for solutions	Competitions by GlaxoSmithKline to use technologies to improve patients' adherence to trial protocol (217)
Create intellectual outputs: create content for informational material	Patients, artists, designers, education professionals	Competitions for creating content and formats of information material	Competitions to create videos to promote HIV testing (90)

Research to measure impacts of mobilising collective intelligence

Further research is needed to measure the impacts of ideas, solutions created by collective intelligence on to improve clinical research, clinical trials in particular. Tucker et al conducted a randomised controlled trial to evaluate the effectiveness of a video created by collective intelligence participants to promote HIV testing in comparison with a conventional health promotion campaign (218). The ideas proposed by participants in the proof-of-concept study could also be tested in a study within trial to measure their impacts on patients' experience with trial participation (219). There are several efforts to develop tools to measure patients' experience with trial participation. These

tools covered different domains including patients' satisfaction with trial organisation (e.g., number of visits, waiting time, research facilities) (220-222). These domains could be used to guide the selection of outcomes in the study within a trial to measure patients' experience. However, further research is still needed to standardise a minimum set of outcomes and tools to measure these outcomes to guide trialists in the planning of their studies and also to enable the comparison across studies (223).

6.4.2. Further research on collective intelligence

Reporting guideline for research involving collective intelligence

The inadequate reporting of research projects involving collective intelligence highlighted the need to develop a reporting guideline for research using these new methods. A reporting guideline lists the minimum set of items that researchers should report in publications to ensure transparency of their research methods (224). Such a reporting guideline would not only help researchers to maximize the value of the dissemination of their research but could also be used as a checklist to support researchers in research planning. To develop this reporting guideline, the guidance developed by EQUATOR network should be followed (225). The work from the scoping review and the qualitative study could be used to guide the development of items in the checklist and followed by a Delphi survey to reach consensus on the final list.

Registration of research to mobilise collective intelligence

The results of the scoping review suggested that the literature on research mobilising collective intelligence might be influenced by publication bias. Registration of such research could be a way to increase transparency in

methods used to mobilise participants and evaluate their contributions. Further, the registration could also help to avoid unnecessary duplication of research efforts. Although it might take time and effort to establish a common platform for registration of research mobilising collective intelligence across disciplines, researchers could start by registering their research plan on public repository such as Open Science Framework (226). Further research is needed to develop templates to facilitate registration of projects involving the mobilisation of collective intelligence so that the fields of research and methods used are consistently recorded. It is also important to identify appropriate incentives to encourage researchers and other stakeholders such as funders and journals to take part in the initiative.

6.5. Conclusion

Methods of mobilising collective intelligence have emerged outside the field of biomedical research to involve a large number of diverse stakeholders to enhance research efficiency. The work in this thesis systematically reviewed different ways to mobilise collective intelligence across research disciplines and developed a framework outlining key elements when planning these new types of research. My research identified barriers to these new types of research, including the reluctance of researchers to adopt these new methods and a lack of methodological guidance. Drawing on researchers' experience, I produced practical advice to guide the planning and conduct of research mobilising collective intelligence. The results helped identify areas for further development in mobilising collective intelligence to improve transparency in methodology and reporting. Based on the framework and practice advice, I

developed and implemented a proof-of-concept study to mobilise patients' collective intelligence of patients to improve logistic organisation of trial. Methods of mobilising collective intelligence could be used to involve different stakeholder groups to transform clinical trial planning.

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Appendices

Appendix 1

Included articles in the scoping review.

Studies in biomedicine and health care research

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Appendix 2

Invitation email to survey participants

From:
Cc:
To:
Subject: Re your study: [Study Title]

Dear [author],

We are conducting studies to investigate how to apply collective intelligence in clinical research. We hope this work will transform the way that clinical research has been conducted and help to reduce research waste.

As an author of [study title] published in [year of publishing], we would like to invite you to participate in an online qualitative survey to share your experience with collective intelligence. Your insights on using collective intelligence in your project is invaluable to us. In the end of the survey, you will be able to read a random answer from another participant and comment to express your opinion. All answers and comments in the open discussion will be anonymised.

We would be very grateful if you would take the time to complete our survey. Data from the survey will be aggregated and your responses will remain confidential.

The questionnaire should take around 10 minutes to complete and can be found at [- LINK].

Alternatively, you can share your experience with us through a qualitative interview which will last about 30 minutes and will be arranged at your convenience. Please contact the researcher at van.nguyen@clinicalepidemio.fr if you would like to take part in the interview.

If you have any questions, comments or queries please do not hesitate to contact us at van.nguyen@clinicalepidemio.fr

We also encourage you to please forward the link of the survey to your colleagues that you may know of who may be interested in participating this study.

Thank you for your kind time, attention, and cooperation.

Sincerely,

Van Nguyen, PhD fellow
Joint doctoral training program Methods in Research on Research (MiRoR)

Professor Isabelle Boutron,

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Fax: 33(0) 142348790

Data collected will be saved to a computer file accessible by the INSERM METHODS team in order to describe the characteristics of participants.

In keeping with the "Informatique et libertés" law, you can assert your right to access data which concerns you and have it rectified by notifying: isabelle.boutron@aphp.fr

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 676207.

Appendix 3

First page of the website

Welcome to the survey!

Your experience and knowledge of using collective intelligence is incredibly valuable to the research community to understand the advantages of this method and how to minimize its barriers.

We conduct this survey to investigate barriers and facilitators of using collective intelligence in different research fields. We hope this work will help us to understand how to apply collective intelligence and transform the way that biomedical research is being planned and conducted.

As such, we would like to ask you to answer a few questions to share your experience when using collective intelligence. You will also have the opportunity to comment on other participants' advice. Your comments will also be anonymous. The survey will take around 15 minutes to complete.

All your answers will be de-identified and stored in a secured repository in INSERM METHODS team, University Paris Decartes. To gain the greatest benefits from this study, the data could be shared with other academic researchers who would have to submit a protocol and sign a data use agreement. The protocol will be evaluated by our research team before sharing the data. You will still be able to participate in the study while opting out for data sharing.

This survey is part of MiRoR project which is dedicated to Methods in Research on Research in the field of clinical research. This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 676207.

Please tick the box to have access to the survey

I agree to take part in the study:	o Yes	o No
I agree to share my de-identified data:	o Yes	o No

Start the survey

Appendix 4

Survey questionnaire

Demographic information
1. What is your age range? ○ <20 ○ 40–49 ○ 20–29 ○ 50–59 ○ 30–39 ○ ≥60
2. Where are you located currently? (Dropdown list of continents)
3. What is your research field? (Please select all that apply) ☐ Biomedicine ☐ Psychology ☐ Technology development ☐ Computer science ☐ Education ☐ Laws, politics and governance ☐ Economics, commercial, business development ☐ Environmental science ☐ Other (please specify): _____
4. In how many projects have you used collective intelligence? ○ 1 ○ 2–5 ○ >5
Please refer to the most recent completed project in which you used collective intelligence and answer the following question
5. What is **the purpose of mobilizing collective intelligence** in your project? ☐ Evaluate ideas ☐ Generate ideas ☐ Solve problems ☐ Create intellectual products ☐ Other (please specify):_____
6. What are **the benefits of collective intelligence** that aided your decision to use it in your project?
7. What were the **most important factors** contributing to the success of mobilizing collective intelligence in your project?
8. What were the **most challenging issues** you had to face when using collective intelligence in your project and **your solutions for those challenges** (e.g. difficulties in identifying and motivating participants, designing tasks for participants, evaluate quality of participants' contribution, decision making)?
9. What **three pieces of advice** would you give to a colleague who intends to use collective intelligence in a project for the first time?
10. Would you **use collective intelligence again**?

○ Definitely yes ○ Yes ○ Perhaps ○ No ○ Definitely no Please tell us why you choose that answer:_____
11. Do you think collective intelligence will be **increasingly used in the future**? ○ Definitely yes ○ Yes ○ Perhaps ○ No ○ Definitely no Please tell us why you choose that answer:_____
Please read the advice from another participant. (Showing an answer from another participant) What do you think of this advice? Rate from 1 to 5 stars. Please comment on this advice? (Free text box for writing comment)

Appendix 5:

Information sheet to participants

PARTICIPANT INFORMATION SHEET

Barriers and facilitators of using collective intelligence

Your experience and knowledge of using collective intelligence is incredibly valuable to the research community to understand the advantages of this method and how to minimize its barriers.

We conduct this qualitative study to investigate barriers and facilitators of using collective intelligence in different research fields. We hope this work will help us to understand how to apply collective intelligence and transform the way that biomedical research is being planned and conducted.

As such, we would like to interview you to understand your experience when using collective intelligence. The interview will take around 30 minutes. If you decide at any point that you no longer wish to be part of the study, then you can withdraw without giving a reason. You can also ask for your data to be removed from the study and destroyed.

All your answers will be de-identified and stored in a secured repository in INSERM METHODS team, University Paris Decartes. After the study has finished, the results will also be submitted for publication in an academic journal and presented at conferences and will be written up as part of Van Nguyen's postgraduate research thesis and submitted for examination. If you would like to receive a copy of the findings, please let us know and we will provide you with one.

This study is part of MiRoR project which is dedicated to Methods in Research on Research in the field of clinical research. This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 676207.

This study has been authorised by CNIL. In keeping with the "Informatique et libertés" law, you can assert your right to access data which concerns you and have it rectified by notifying Professor Isabelle Boutron at isabelle.boutron@aphp.fr

If you have any question about this research, please contact Professor Isabelle Boutron at the same email address above.

Appendix 6:

Oral Consent Example Script

We would like to take you through some main points of the project that I gave you an information sheet before. In summary, the aims of my project are to understand more about the perspective and experience of participants with QRPs.

Are you still interested in taking part in the project? [Await confirmation]. Now I'd like to confirm some of the details of the project to make sure you are clear about what's involved for you:

- It's a project about exploring your experience with collective intelligence.
- If you take part, I'll need you to take part in an interview where we will discuss your experience with collective intelligence. It will last approximately 30 minutes.
- We do not expect there to be any risks or discomfort associated in this research study. However, if you feel uncomfortable then you can stop the interview at any time, without giving a reason.
- You don't have to say yes to taking part; you can ask me any questions you want before or throughout; you can also withdraw at any stage without giving a reason and without any negative consequences.
- You do not have to answer any questions that you do not wish to.
- You are aware that INSERM Ethics committee has approved this research project and how to contact research team (in the first instance) or the committee in case of any concerns or complaints. I have given you the project's ethics reference number and relevant contact details.
- We will not keep any of your details for longer than necessary.
- We may use brief quotes of what you say during the interview in the write up of this study, but they will remain anonymous.
- We will safely store your data electronically on encrypted, secure file stores. All identifiable data will be destroyed at the end of the study.
- We will audio record you unless you say that we can't.
- You're aware that our written work will be published online and this project will may also be published in an academic journal/ book / website.
- Do you agree for us to collect detail sensitive personal data?

- Are you still willing to take part? Do you give your permission for us to re-contact you to clarify information?
- [Await confirmation] So if you're happy with all of that, and have no more questions, let's start.

Appendix 7

Interview guide

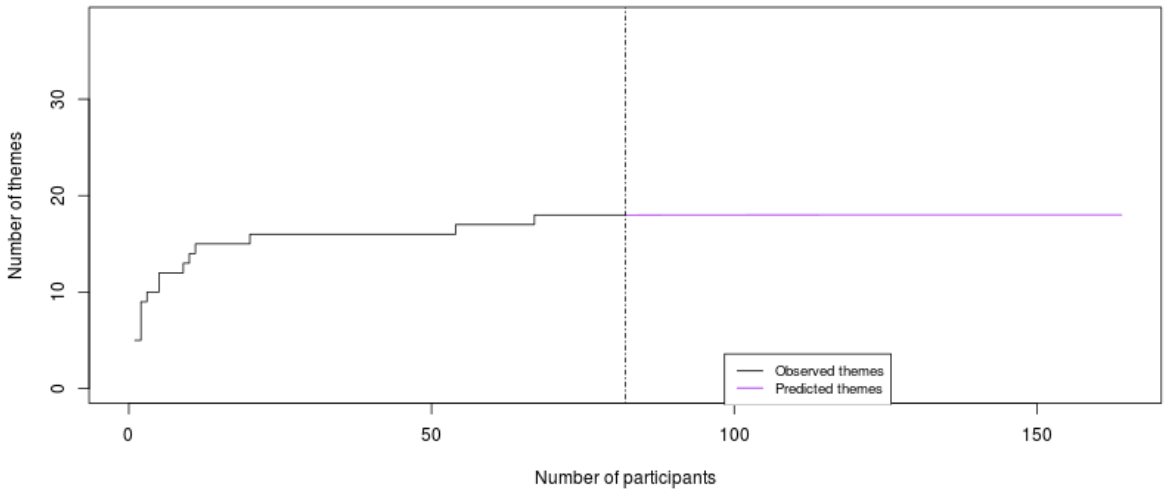
Main topic	Questions
1. Background	• To start off, could you please tell me about yourself? *Prompt* - What is your area of research? - When was the first time you heard about collective intelligence? How did you come up with the idea of using collective intelligence in your work? Do you work in a research group? What's your role in the group? • Could you please share with me more about projects that you used collective intelligence? *Prompt* - How many projects have you used collective intelligence? - What was your first project using collective intelligence? Your recent project? • Taking one of your completed projects as an example, could you walk me through that project? *Prompt* - How did the initial idea come about? How did it get started? - What were you and the team hoping to get out of using collective intelligence in your project? - How did you and your team organize it? *Prompt* - Identify participants, motivations - Tasks given to participants - Evaluate contribution of participants and decision making
2. Facilitators to mobilize	• When looking back at projects that you used collective intelligence, would you say it was a success? In what ways?

collective intelligence	• In your opinions, what were the factors contributing to the success of your project? *Prompts* - The community - The management team, expertise - Interface of the platform - Transparency in communication
3. Challenge in mobilizing collective intelligence	• What challenges did you face when using collective intelligence in your project? **Prompt** - Challenges in organization (establish core team, establish platform of organization, establish community) - Challenges in identifying and engaging participants - Challenges in designing tasks for participants - Challenges in evaluating participants' contribution - Challenges with data sharing and intellectual property - Challenges in decision making • Did you/your team overcome the challenges that you have mentioned? What did you do?
4. Future of collective intelligence	• What advice would you give to people who intend to use collective intelligence for the first time? • Would you use collective intelligence again in your future projects? Please tell me more about that. • Do you think collective intelligence will be increasingly used? Please tell me more about that. How do you think about the future of CI? • Should we raise awareness of collective intelligence among researchers, funders and community? How could we do that? • What do you think about the publication of methods of projects applying collective intelligence? What do you think about the dissemination of the results? *Prompt*: Publication bias towards positive results, reproducibility of methods

5. Other	• Is there anything else that we haven't discussed that you would like to share?

Appendix 8

Theme accumulation curve



Appendix 9

Advice which commentators disagreed with

	Advice	Comment
Involve top leaders in organization	Planning is key. Make sure you get the CEO and leadership onboard, choose a question that can solve a big challenge	Agree but leadership is not important
Define feasible research questions	Be careful about goals and expectations, be ready to be flexible and adaptive, keep in mind what is your particular goal and be honest with all participants beforehand	Collective Intelligence can help refine a goal or redirect one that seemed good but turned out not to be.
Select appropriate difficulty level	Don't ask too much to the contributors, otherwise they won't participate (or won't finish their contribution)	Depends very much on what kind of data you are looking for, and what kind of crowd you are aiming at. Some amateurs of astronomy can follow elaborated protocols for decades. The only encouragement they need is channels through which they can submit their data and some sense of being acknowledged for their contributions to science. Members of the crowd in a more general sense, naturally needs way more encouragement, feedback etc.
Select questions address complex problems	Try to find the most complex challenge people can solve.	I would not necessarily go for the most complex challenge but an important and societally highly relevant challenge
Plan feasible time frame	Make studies short, since crowdsourced users have short attention span.	Mostly good, but studies don't have to be short. I've known projects that have been going for 10 years that over 30,000 people are still engaged with. If your project will take a long time, tell people that up front but let them know they can help as much or as little as they can.
Plan feasible time frame	Make studies short, since crowdsourced users have short attention span.	We're not only talking about mass crowdsourcing, but collective intelligence can also be used with a few experts, e.g. divers to map lake floors or archaeologically interested people to think about a problem etc. Some citizen science projects have run for a long time, but of course they do need to

		fit the time resources people have and be engaging and fun. Quality control is something we always do in science.

Appendix 10

Respondents' research disciplines

Respondent identification number	Research disciplines
I01	Biomedicine and healthcare
I02	Open innovation
I03	Laws, politics, governance
I04	Computer science
I05	Economics, commercial, business development
I06	Biomedicine and healthcare
I07	Environmental science
I08	Environmental science
I09	Biomedicine and healthcare
I10	Computer science
I11	Biomedicine and healthcare
I12	Biomedicine and healthcare
I13	Biomedicine and healthcare
I14	Biomedicine and healthcare
I15	Biomedicine and healthcare
I16	Biomedicine and healthcare
I17	Biomedicine and healthcare
S01	Biomedicine and healthcare
S02	Biomedicine and healthcare, Computer science
S03	Information and communication
S04	Education
S05	Laws, politics, governance
S06	Biomedicine and healthcare
S07	Environmental science
S16	Computer science
S19	Economics, commercial, business development
S20	Computer science
S23	Education
S25	Computer science
S26	Computer science, Digital humanities
S31	Computer science; Economics, commercial, business development; Technology development
S32	Economics, commercial, business development
S33	Education
S34	Computer science; Economics, commercial, business development; Technology development
S39	Technology development
S40	Biomedicine and healthcare; Computer science
S42	Computer science; Education
S43	Economics, commercial, business development
S45	Education; Cheminformatics

S46	History
S47	Biomedicine and healthcare; Computer science
S49	Open innovation
S52	Biomedicine and healthcare; Computer science
S54	Biomedicine and healthcare; Computer science
S57	Computer science
S59	Computational linguistics
S62	Environmental science; Technology development
S65	Computer science
S66	Computer science
S67	Astrophysics
S70	Computer science; Economics, commercial, business development; Education; Technology development
S75	Environmental science
S83	No information
S86	Biomedicine and healthcare; Computer science
S88	Psychology
S92	Complex systems
S93	Computer science
S95	Emergency and disaster support
S96	Laws, politics, and governance
S100	No information
S101	Environmental science
S104	Technology development
S107	Laws, politics, governance
S109	Computer science; Economics, commercial, business development; Psychology; Technology development
S117	Social science
S120	Economics, commercial, business development
S122	Economics, commercial, business development
S123	Engineering
S128	Computer science
S129	Technology development
S130	Computer science
S133	Biomedicine and healthcare
S135	Citizen science
S141	No information
S142	Computer science
S143	Library archive
S146	Computer science
S149	Computer science; Economics, commercial, business development; Environmental science
S150	Computer science
S151	Computer science
S153	No information
S155	Computer science

Appendix 11

Ethical approval for qualitative study

CEEI - IRB

Comité d'Evaluation Ethique de l'Inserm

IRB00003888

Instituts thématiques

Inserm

Institut national de la santé et de la recherche médicale

Nos réf: CD/VB 17-077
Dossier suivi par :
Christine DOSQUET - CEEI
@ : ceei@inserm.fr

Pr Isabelle Boutron
Mme Van Nguyen Thu
Centre d'Épidémiologie Clinique
Hôpital Hôtel Dieu
1, place du Parvis Notre-Dame
75181 PARIS Cedex 4

Paris, June 13th 2017

To whom it may concern
Opinion number 17-386

Dear Madams,

The ethics evaluation committee of Inserm, the Institutional Review Board (IRB00003888, IORG0003254, FWA00005831) of the French Institute of medical research and Health, has reviewed and approved the research project entitled:

"Exploring barriers and facilitators of using collective intelligence across different settings: protocol for a multinational online qualitative survey".

The investigator undertakes to respect the protocol and to follow the recommendations proposed by the ethics evaluation committee.

Yours sincerely,

Christine DOSQUET
IRB President

CEEI / IRB
Comité d'Evaluation Ethique
de l'Inserm

IRB00003888

Inserm

La science pour la santé
From science to health

CEEI / IRB
Comité d'Evaluation Ethique de l'Inserm

Dossier suivi par : Christine Dosquet
ceei@inserm.fr

Pr Isabelle Boutron
Mme Van Nguyen Thu
Centre d'Épidémiologie Clinique
Hôpital Hôtel Dieu
1, place du Parvis Notre-Dame
75181 PARIS Cedex 4

Nos réf: CD/VB 18-064

Paris, May 15th, 2018

To whom it may concern
Opinion number 17-386.4

Dear Madams,

The ethics evaluation committee of Inserm, the Institutional Review Board (IRB00003888, IORG0003254, FWA00005831) of the French Institute of medical research and Health, has reviewed and approved the amendment of your research project entitled:

« Barriers and facilitators of using collective intelligence across different settings: protocol for a multinational online qualitative survey » (version 3.0 of April 23th, 2018).

The investigator undertakes to respect the protocol and to follow the recommendations proposed by the ethics evaluation committee.

Yours sincerely,

Christine DOSQUET
IRB President

Appendix 12

Ethical approval for the proof of concept study

CEEI / IRB
Comité d'Evaluation Ethique
de l'Inserm

IRB00003888

Inserm

La science pour la santé
From science to health

CEEI / IRB
Comité d'Evaluation Ethique de l'Inserm

Dossier suivi par : Christine Dosquet
ceei@inserm.fr

Nos réf: CD/EB 19-049

Pr Isabelle BOUTRON
Equipe METHODS
CRESS-UMR 1153
Hôpital Hôtel Dieu
1 place du Parvis Notre Dame
75004 PARIS

Paris, April 24th, 2019

To whom it may concern
Opinion number 19-580

Dear Madam,

The ethics evaluation committee of Inserm, the Institutional Review Board (IRB00003888, IORG0003254, FWA00005831) of the French Institute of medical research and Health, has reviewed and approved the research project entitled:

" Impact of mobilising collective intelligence on clinical trial design ".

The investigator undertakes to respect the protocol and to follow the recommendations proposed by the ethics evaluation committee.

Yours sincerely,

Christine DOSQUET
IRB President

République Française

CEEI / IRB de l'Inserm
101 rue de Tolbiac
75654 Paris cedex 13

Appendix 13

Case vignette for asthma patients

Aidez-nous à accélérer la recherche sur l'asthme !

Qu'est-ce qu'un essai clinique ?

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner l'asthme sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus.

Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients.

Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de notre étude

L'objectif de cette étude est de **comprendre mieux les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Description d'un exemple d'essai clinique

Un **essai clinique** vise à comparer deux traitements **de l'asthme** :

- une inhalation de corticoïdes combiné avec des broncho-dilatateurs (budésonide/formotérol) à prendre uniquement en cas de crise

ou

- une inhalation de corticoïdes (budésonide) à prendre systématiquement deux fois par jour avec deux inhalations successives de broncho-dilatateurs (terbutaline) en cas de crise

L'essai aura une durée d'**un an**.

Imaginez que vous envisagiez de participer à cet essai.

Il se déroulera à l'hôpital universitaire qui se trouve **à deux heures de voiture de chez vous**.
Si vous participez à cet essai clinique, vous rencontrerez un médecin, recevrez un des traitements et vous aurez des prises de sang à l'hôpital universitaire.

Vous avez également la possibilité de participer à l'essai **à distance depuis votre domicile**, de communiquer avec le médecin depuis votre ordinateur, de recevoir le traitement à la maison et de réaliser les bilans sanguins dans un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de l'étude. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

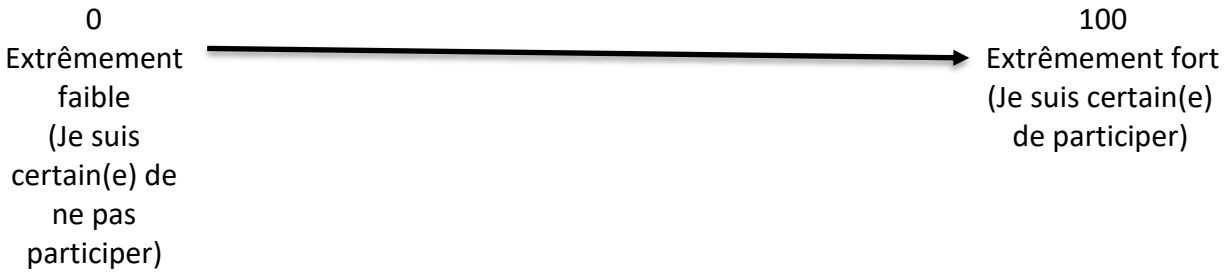
Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant les traitements et vous fournira le programme des visites d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

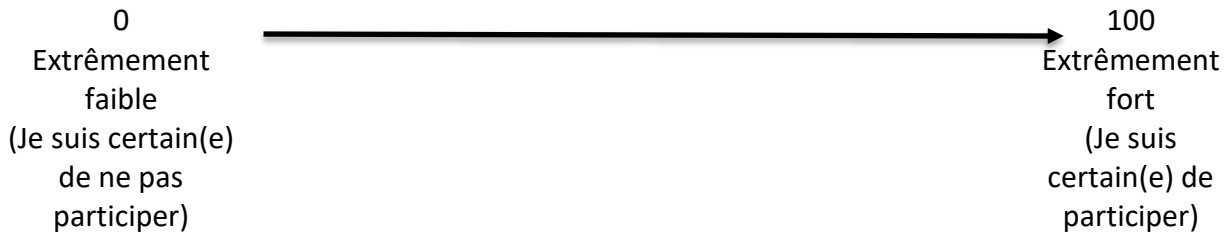
	**A l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**A l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :



Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :



Si vous avez une autre idée pour améliorer votre expérience pour recevoir les informations concernant l'essai clinique et signer le consentement, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

Au cours de l'année, vous aurez un total de six visites de suivi visant à évaluer l'évolution de votre état de santé.

- Lors de la première et de la dernière visite, vous répondrez à un questionnaire, vous aurez des prises de sang et un examen spirométrique.
- Lors de la troisième visite, vous répondrez à un questionnaire et vous aurez un examen spirométrique.
- Lors des trois autres visites, vous répondrez simplement à un questionnaire.

Où souhaiteriez-vous réaliser les visites de suivi ?

	**Toutes les visites auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● vous aurez des prises de sang et un examen spirométrique ● Chaque visite vous prendra une demi-journée environ	**O**
	**Toutes les visites auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Une infirmière participant à l'essai se rendra chez vous pour pratiquer des bilans sanguins et un test de spirométrie en fonction de vos disponibilités.	**O**
	**La visite aura lieu à l'hôpital ou à votre domicile selon votre choix** Cela implique que : ● Un mois avant la visite programmée, une infirmière participant à l'étude vous appellera et vous lui confirmerez si vous souhaitez être examiné(e) à l'hôpital ou chez vous. L'infirmière organisera les visites en fonction de votre choix.	**O**

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience de réaliser les visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique aura une durée d’un an. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

1. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
2. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
3. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
4. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confidant	Moyennement confiant	Assez confiant	Très confiant

5. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non

    Si Oui, quelle maladie ? ☐
6. Selon vous, dans quelle mesure est-il important que les patients qui participent aux essais cliniques puissent décider du moment et de la façon dont les visites sont organisées ?

○	○	○	○	○
Pas du tout important	Peu important	Moyennement important	Important	Très important

7. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous

Appendix 14
Case vignette for patients with hypercholesterolemia

Aidez-nous à accélérer les recherches sur l'hypercholestérolémie !

Qu'est-ce qu'un essai clinique ?

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner l'hypercholestérolémie sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus.

Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients.

Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de notre étude

L'objectif de cette étude est de **comprendre mieux les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Description d'un exemple d'essai clinique

Un essai clinique est actuellement en train de tester **un nouveau traitement visant à réduire le taux de cholestérol dans le sang**.

Le nouveau traitement sera pris **oralement une fois par jour au milieu du repas**.

Cet essai clinique durera quatre ans.

Imaginez que vous envisagiez de participer à cet essai.

Il se déroulera au CHU qui se trouve **à deux heures de voiture de chez vous**. Si vous participez à cet essai clinique, vous rencontrerez un médecin, recevrez un traitement et ferez des bilans sanguins au CHU.

Vous avez également la possibilité de participer à l'essai **à distance depuis votre domicile**, de communiquer avec le médecin depuis votre ordinateur, de recevoir le traitement à la maison et de réaliser les bilans sanguins dans un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de l'étude. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant votre nouveau traitement et vous fournira le programme d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

	**À l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**À l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de **ne pas** participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience pour recevoir les informations concernant l'essai clinique et signer le consentement, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

Au cours des quatre années de participation à l'essai clinique, vous aurez un total de 10 consultations de suivi visant à évaluer l'amélioration de votre état de santé grâce à ce nouveau traitement. Vous aurez une consultation tous les 6 mois.

- Lors de la première et la dernière visite, vous serez soumis à un bilan de santé, à des bilans sanguins, à une analyse d'urine et vous répondrez à un questionnaire.
- Lors des autres visites, vous serez soumis à un bilan de santé, à des bilans sanguins et vous répondrez à un questionnaire.

Où souhaiteriez-vous réaliser les consultations de suivi ?

	**Toutes les consultations auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● Ils réaliseront des bilans sanguins et à une analyse d'urine ● Chaque consultation vous prendra une demi-journée environ	**O**
	**Toutes les consultations auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Une infirmière travaillant à l'essai se rendra chez vous pour pratiquer des bilans sanguins et une analyse d'urine en fonction de vos disponibilités.	**O**
	**La visite aura lieu à l'hôpital ou à votre domicile selon votre choix** Cela implique que : ● Une semaine avant la visite programmée, une infirmière participant à l'étude vous appellera et vous lui confirmerez si vous souhaitez être examiné(e) à l'hôpital ou chez vous. L'infirmière organisera les visites en fonction de votre choix.	**O**

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience de réaliser les visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique aura une durée d’un an. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

1. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
2. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
3. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
4. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confiant	Moyennement confiant	Assez confiant	Très confiant

5. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non

    Si Oui, quelle maladie ? ☐
6. Selon vous, dans quelle mesure est-il important que les patients qui participent aux essais cliniques puissent décider du moment et de la façon dont les visites sont organisées ?

○	○	○	○	○
Pas du tout important	Peu important	Moyennement important	Important	Très important

7. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous

Appendix 15

Case vignette for osteoporosis patients

Aidez-nous à accélérer les recherches sur l'ostéoporose !

Qu'est-ce qu'un essai clinique ?

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner l'ostéoporose sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus.

Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients.

Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de notre étude

L'objectif de cette étude est de **comprendre mieux les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Description d'un exemple d'essai clinique

Un essai clinique est actuellement en train de tester **un nouveau traitement pour prévenir les fractures chez les patients qui souffre d'ostéoporose**.

Cet essai clinique durera trois ans.

Ce traitement sera administré par **injection sous-cutanée une fois par mois pendant les premières 12 mois**. Après, vous prendrez de l'alendronate sous forme de cachet une fois par semaine pendant deux ans.

Imaginez que vous envisagiez de participer à cet essai.

Il se déroulera au CHU qui se trouve à **deux heures de voiture** de chez vous. Si vous participez à cet essai clinique, vous rencontrerez un médecin, recevrez un traitement et ferez des bilans sanguins au CHU.

Vous avez également la possibilité de participer à l'essai **à distance depuis votre domicile**, de communiquer avec le médecin depuis votre ordinateur, de recevoir le traitement à la maison et de réaliser les bilans sanguins dans un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de l'étude. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant votre nouveau traitement et vous fournira le programme d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

	**A l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**A l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de **ne pas** participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience pour recevoir les informations concernant l'essai clinique et signer le consentement, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

Au cours des trois années de participation à l'essai clinique, vous aurez un total de 18 consultations de suivi visant à évaluer l'amélioration de votre état de santé grâce à ce nouveau traitement.

- Durant la première année, vous aurez une visite par mois. À chaque visite, vous répondrez à un questionnaire. Ils réaliseront des bilans sanguins à l'occasion de six visites. Ils réaliseront une radiographie et une mesure de la densité osseuse à la première et 12ème visites.
- Durant la deuxième et la troisième années, vous aurez cinq visites en tout, une tous les six mois environ. À chaque visite, vous répondrez à un questionnaire et vous soumettrez à des bilans sanguins. Lors de deux visites, ils réaliseront une radiographie et une mesure de la densité osseuse.

Où souhaiteriez-vous réaliser les consultations de suivi ?

	**Toutes les consultations auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● Ils réaliseront des bilans sanguins, une radiographie et une mesure de la densité osseuse comme prévu ● Chaque consultation vous prendra une demi journée environ	**O**
	**Toutes les consultations auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Prendre un rendez-vous pour réaliser une radiographie et une mesure de la densité osseuse en fonction de vos disponibilités ● Une infirmière participant à l'étude se rendra chez vous pour pratiquer des bilans sanguins en fonction de vos disponibilités.	**O**
	**La visite aura lieu à l'hôpital ou à votre domicile selon votre choix** Cela implique que : ● Une semaine avant la visite programmée, une infirmière participant à l'étude vous appellera et vous lui confirmerez si vous souhaitez être examiné(e) à l'hôpital ou chez vous. L'infirmière organisera les visites en fonction de votre choix.	**O**

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0 100

200

Extrêmement faible (Je suis certain(e) de ne pas participer)

Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience de réaliser les visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique aura une durée d’un an. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

1. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
2. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
3. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
4. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confiant	Moyennement confiant	Assez confiant	Très confiant

5. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non

    Si Oui, quelle maladie ? ☐
6. Selon vous, dans quelle mesure est-il important que les patients qui participent aux essais cliniques puissent décider du moment et de la façon dont les visites sont organisées ?

○	○	○	○	○
Pas du tout important	Peu important	Moyennement important	Important	Très important

7. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous

Appendix 16
Case vignette for osteoarthritis patients

Aidez-nous à accélérer les recherches sur l'ostéoarthrite !

Qu'est-ce qu'un essai clinique ?

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner l'ostéoarthrite sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus.

Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients.

Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de notre étude

L'objectif de cette étude est de **comprendre mieux les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Description d'un exemple d'essai clinique

Un **essai clinique** vise à tester **un nouveau traitement pour soulager la douleur liée à l'ostéoarthrite sur le long terme**.

L'essai se déroulera pendant un an.

Ce nouveau traitement est **administré par injection sous-cutanée tous les 2 mois**, soit trois fois sur une année, par une infirmière agréée.

Imaginez que vous envisagiez de participer à cet essai.

L'essai se déroulera au CHU qui se trouve à **deux heures de voiture** de chez vous. Si vous participez à cet essai, vous rencontrerez un médecin, recevrez un traitement et ferez des bilans sanguins au CHU.

Vous avez également la possibilité de participer à l'essai **à distance, depuis votre domicile**, de communiquer avec le médecin depuis votre ordinateur, de recevoir le traitement à votre domicile et de réaliser les bilans sanguins auprès d'un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de l'étude. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant votre nouveau traitement et vous fournira le programme d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

	**A l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**A l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de **ne pas** participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience pour recevoir les informations concernant l'essai clinique et signer le consentement, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

Au cours de l'année où vous participerez à l'essai clinique, vous aurez un total de neuf consultations de suivi visant à évaluer l'amélioration de votre état de santé grâce à ce nouveau traitement.

- Dans le cadre des six visites prévues, vous devrez répondre à un questionnaire, vous soumettre à un bilan de santé et à un bilan sanguin, et à trois reprises ils réaliseront une radiographie et un ECG.
- Lors de trois visites, vous aurez un bilan de santé et vous répondrez à un questionnaire.

Où souhaiteriez-vous réaliser les consultations de suivi ?

	**Toutes les consultations auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● Vous soumettre à des bilans sanguins, une radiographie et un ECG comme prévu ● Chaque consultation vous prendra une demi-journée environ	**O**
	**Toutes les consultations auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Prendre un rendez-vous pour réaliser une radiographie et un ECG dans un laboratoire près de chez vous en fonction de vos disponibilités ● Une infirmière participant à l'étude se rendra chez vous pour pratiquer des bilans sanguins selon vos disponibilités.	**O**
	**Les visites auront lieu à l'hôpital et à votre domicile à votre convenance** Cela implique que : ● Une semaine avant la visite programmée, une infirmière participant à l'étude vous appellera et vous lui confirmerez si vous souhaitez être examiné(e) à l'hôpital ou chez vous. L'infirmière organisera les visites en fonction de votre choix.	**O**

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0 100

Extrêmement faible (Je suis certain(e) de ne pas participer)

Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience de réaliser les visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique aura une durée d’un an. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

1. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
2. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
3. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
4. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confiant	Moyennement confiant	Assez confiant	Très confiant

5. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non

    Si Oui, quelle maladie ? ☐
6. Selon vous, dans quelle mesure est-il important que les patients qui participent aux essais cliniques puissent décider du moment et de la façon dont les visites sont organisées ?

○	○	○	○	○
Pas du tout important	Peu important	Moyennement important	Important	Très important

7. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous

Appendix 17

Case vignette for diabetic patients

Aidez-nous à accélérer les recherches sur le diabète !

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner le diabète sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus. Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients. Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de cette étude est de **mieux comprendre les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Cet essai clinique est fictif mais il s'inspire de l'organisation habituelle des essais cliniques dans le domaine. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Un exemple d'essai clinique fictif

Nous vous présentons un essai clinique fictif qui teste **un nouveau traitement de diabète**.

Le nouveau traitement sera pris **oralement une fois par jour, le matin**.

Cet essai clinique durera trois ans.

Imaginez que vous envisagiez de participer à cet essai.

Il se déroulera **à l'hôpital universitaire**. Si vous participez à cet essai clinique, vous rencontrerez un médecin, recevrez un traitement et ferez des bilans sanguins **à l'hôpital universitaire**.

Vous avez également la possibilité de participer à l'essai à distance depuis votre domicile, de communiquer avec le médecin **depuis votre ordinateur**, de recevoir le traitement à la maison et de réaliser les bilans sanguins dans un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de cet essai. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant votre nouveau traitement et vous fournira le programme d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Il y a trois façons de recevoir les informations concernant l'essai clinique et signer le consentement :

	**À l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**À l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de **ne pas** participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible
(Je suis certain(e) de ne pas participer)

100
Extrêmement fort
(Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer l'organisation de cette visite, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

Au cours des trois années de participation à l'essai clinique, vous aurez un total de 14 consultations de suivi visant à évaluer votre état de santé **: 8 consultations dans la première année et une consultation tous les 4 mois dans la deuxième et troisième année**.

- Dans la première année, à chaque visite, vous aurez **un bilan de santé**, et vous répondrez à **un questionnaire**. À la visite du 1er, 3eme, 7eme, 10eme et 12eme mois vous aurez **des bilans sanguins**, **une analyse d'urine**. À la visite de première, 7emeet 12eme mois, vous aurez en plus un ECG.
- Dans la deuxième et troisième année, à chaque visite vous aurez **un bilan de santé**, **des bilans sanguins, une analyse d'urine**, un ECG et vous répondrez à **un questionnaire**.

Il y a trois façons de réaliser les consultations de suivi ?

	**Toutes les consultations auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin dans la matinée entre 7 heure et 11 heures ● Etre à jeun et ne pas prendre le médicament avant la visite ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● Ils réaliseront des bilans sanguins, à une analyse d'urine, un ECG comme prévu ● Chaque consultation vous prendra une demi-journée environ	**O**
	**Toutes les consultations auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Une infirmière travaillant pour l'essai se rendra chez vous pour pratiquer l'ECG, des bilans sanguins et une analyse d'urine en fonction de vos disponibilités. Vous devrez être à jeun avant la réalisation de la visite.	**O**
	**La visite aura lieu à l'hôpital ou à votre domicile selon votre choix** Cela implique que : ● Vous devez au début de l'étude indiquer les visites que vous souhaitez faire sur site ou à la maison. Si vous voulez changer l'organisation, vous devrez prévenir l'équipe environ deux mois avant.	**O**

Où souhaiteriez-vous réaliser les consultations de suivi ?

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer) → 100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer) → 100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer) → 100 Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience de réaliser les visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique durera trois ans. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

1. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
2. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
3. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
4. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confiant	Moyennement confiant	Assez confiant	Très confiant

5. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non
6. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous

Appendix 18
Case vignette for patients with endometriosis

Aidez-nous à accélérer les recherches sur l'endométriose !

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner l'endométriose sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus. Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients. Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de cette étude est de **mieux comprendre les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Cet essai clinique est fictif mais il s'inspire de l'organisation habituelle des essais cliniques dans le domaine. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Un exemple d'essai clinique fictif

Nous vous présentons un essai clinique fictif qui teste **un nouveau traitement pour réduire la douleur liée** à **l'endométriose**.

Cet essai clinique durera un an et demi.

Le nouveau traitement sera pris **oralement deux fois par jour pendant six mois.**

Imaginez que vous envisagiez de participer à cet essai.

Il se déroulera **à l'hôpital universitaire**. Si vous participez à cet essai clinique, vous rencontrerez un médecin, recevrez un traitement et ferez des bilans sanguins **à l'hôpital universitaire**.

Vous avez également la possibilité de participer à l'essai à distance depuis votre domicile, de communiquer avec le médecin **depuis votre ordinateur**, de recevoir le traitement à la maison et de réaliser les bilans sanguins dans un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de cet essai. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant votre nouveau traitement et vous fournira le programme d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Il y a trois façons de recevoir les informations concernant l'essai clinique et signer le consentement :

	**A l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**A l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de **ne pas** participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer l'organisation de cette visite, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

L'essai durera un an et demi. Vous aurez un total de 11 consultations de suivi visant à évaluer votre état de santé.

- Durant **les premières six mois**, vous aurez **une visite par mois**. À chaque visite, vous aurez **un bilan de santé**, **des bilans sanguins**, **un test de grossesse** et vous répondrez à **un questionnaire.** Au 1er, 3ème et 6ème mois, vous aurez **un examen gynécologique.** Au sixième mois, vous aurez en plus une **échographie endovaginale, une biopsie de l'endomètre et une mesure de la densité osseuse**.
- Durant **les six mois suivants**, vous aurez **trois visites au** 7ème, 9ème, et 12ème **mois**. À chaque visite, vous aurez **un bilan de santé,** un test de grossesse et vous répondrez à **un questionnaire**. A**u** 7ème et 9ème **mois**, vous aurez **des bilans sanguins**. Au 12ème **mois**, vous aurez **une mesure de la densité osseuse**.
- Durant les dernières six mois, vous aurez deux visites au 15ème et 18ème mois. À chaque visite, vous aurez **un bilan de santé** et vous répondrez à **un questionnaire.** À la dernière visite, vous aurez **une mesure de la densité osseuse.**

Il y a trois façons de réaliser les consultations de suivi :

	**Toutes les consultations auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● Ils réaliseront des bilans sanguins, et tous les autres tests et examens comme prévu ● Chaque consultation vous prendra une demi-journée voire une journée environ	**O**
	**Toutes les consultations, en dehors de la visite du 6ème mois qui aura lieu à l'hôpital, auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Prendre un rendez-vous avec votre gynécologue pour réaliser les examens gynécologiques, ● Prendre un rendez-vous et réaliser une mesure de la densité osseuse en ville en fonction de vos disponibilités ● Une infirmière participant à l'étude se rendra chez vous pour pratiquer des bilans sanguins en fonction de vos disponibilités.	**O**
	**La visite aura lieu à l'hôpital ou à votre domicile selon votre choix** Cela implique que : ● Vous devez au début de l'étude indiquer les visites que vous souhaitez faire sur site ou à la maison. Si vous voulez changer l'organisation, vous devrez prévenir l'équipe environ deux mois avant.	**O**

Où souhaiteriez-vous réaliser les consultations de suivi ?

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer) → 100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer) → 100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer) → 100 Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer l'organisation des visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique durera un an et demi. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

1. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
2. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
3. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
4. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confidant	Moyennement confiant	Assez confiant	Très confiant

5. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non
6. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous

Appendix 19
Case vignette for patients with diabetes

Aidez-nous à accélérer les recherches sur le diabète !

Les essais cliniques visent à déterminer si les nouveaux médicaments conçus pour soigner le diabète sont **sûrs et efficaces**.

Cependant, participer à un essai clinique peut-être **difficile** pour les patients. Ils doivent **se déplacer à l'hôpital pour les visites**, avoir des consultations et des examens en plus. Il arrive donc qu'à cause d'une organisation trop complexe, les patients **ne participent pas** aux essais ou n'effectuent pas les visites et **sortent** de l'essai. Il a été montré que 70% des essais cliniques s'arrêtent par manque de participation des patients. Cela empêche l'avancée la recherche clinique et l'identification de traitements efficaces.

L'objectif de cette étude est de **mieux comprendre les préférences des patients** afin **d'améliorer l'organisation** des essais cliniques. Ainsi, les patients effectueront toutes les visites et les chercheurs pourront disposer de suffisamment d'informations pour évaluer le traitement.

De quelle manière pouvez-vous nous aider ?

Nous allons vous décrire un exemple d'essai clinique. Cet essai clinique est fictif mais il s'inspire de l'organisation habituelle des essais cliniques dans le domaine. Nous allons vous proposer différentes manières d'organiser les visites (en se déplaçant sur site ou à domicile via internet)

Vous devrez de nous indiquer votre préférence.

Un exemple d'essai clinique fictif

Nous vous présentons un essai clinique fictif qui teste **un nouveau traitement de diabète**.

Le nouveau traitement sera pris **oralement une fois par jour, le matin**.

Cet essai clinique durera trois ans.

Imaginez que vous envisagiez de participer à cet essai.

Il se déroulera **à l'hôpital universitaire**. Si vous participez à cet essai clinique, vous rencontrerez un médecin, recevrez un traitement et ferez des bilans sanguins **à l'hôpital universitaire**.

Vous avez également la possibilité de participer à l'essai à distance depuis votre domicile, de communiquer avec le médecin **depuis votre ordinateur**, de recevoir le traitement à la maison et de réaliser les bilans sanguins dans un laboratoire près de chez vous.

Quelle est l'organisation qui vous conviendrait le mieux pour cet essai ?
Nous allons vous présenter les différentes étapes de cet essai. Nous vous demanderons de choisir l'organisation qui vous semble la plus adaptée.

En répondant à ces questions, vous nous aiderez à améliorer l'organisation des essais cliniques.

Consentement éclairé

Avant de participer à un essai clinique, l'équipe de recherche vous expliquera le déroulement de l'essai, vous donnera toutes les informations concernant votre nouveau traitement et vous fournira le programme d'évaluation. Vous signerez un formulaire de consentement si vous êtes d'accord pour participer.

Il y a trois façons de recevoir les informations concernant l'essai clinique et signer le consentement :

	**À l'hôpital** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Signer le formulaire de consentement si vous souhaitez participer OU retourner chez vous pour en discuter avec votre famille pour ensuite revenir à l'hôpital afin de signer le consentement quand vous serez prêt(e). ● Garder une copie du formulaire de consentement.	**O**
	**À la maison par internet** Vous devrez : ● Regarder une vidéo en ligne qui vous présentera l'essai ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● En discuter avec votre famille si vous le souhaitez ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**
	**À l'hôpital et à la maison** Vous devrez : ● Vous rendre à l'hôpital, attendre de voir un médecin ● Rencontrer le médecin qui vous expliquera le déroulement de l'étude ● Poser des questions au médecin pendant la visite ● Rentrer chez vous et en discuter avec votre famille ● Contacter par téléphone un médecin de l'essai clinique à n'importe quel moment durant les horaires de travail si vous avez des questions ● Signer le formulaire de consentement sur votre ordinateur lorsque vous serez prêt(e) ● Une copie du consentement vous sera envoyée par mail ou par la poste selon votre choix	**O**

Où souhaiteriez-vous recevoir les informations concernant l'essai clinique et signer le consentement ?

Si cette étape est réalisée à l'hôpital, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible (Je suis certain(e) de **ne pas** participer)

100
Extrêmement fort (Je suis certain(e) de participer)

Si cette étape est réalisée à la maison par internet, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible (Je suis certain(e) de ne pas participer)

100
Extrêmement fort (Je suis certain(e) de participer)

Si cette étape est réalisée à l'hôpital et à la maison, quelle serait la probabilité que vous participiez à l'essai :

0
Extrêmement faible (Je suis certain(e) de ne pas participer)

100
Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer l'organisation de cette visite, n'hésitez pas à nous en faire part :

Consultations dans le cadre de l'essai clinique

Au cours des trois années de participation à l'essai clinique, vous aurez un total de 14 consultations de suivi visant à évaluer votre état de santé **: 8 consultations dans la première année et une consultation tous les 4 mois dans la deuxième et troisième année**.

- Dans la première année, à chaque visite, vous aurez **un bilan de santé**, et vous répondrez à **un questionnaire**. À la visite du 1er, 3eme, 7eme, 10eme et 12eme mois vous aurez **des bilans sanguins**, **une analyse d'urine**. À la visite de première, 7emeet 12eme mois, vous aurez en plus un ECG.
- Dans la deuxième et troisième année, à chaque visite vous aurez **un bilan de santé**, **des bilans sanguins, une analyse d'urine**, un ECG et vous répondrez à **un questionnaire**.

Il y a trois façons de réaliser les consultations de suivi ?

	**Toutes les consultations auront lieu à l'hôpital** Pour chaque visite, vous devrez : ● Vous rendre à l'hôpital et attendre de voir un médecin dans la matinée entre 7 heure et 11 heures ● Etre à jeun et ne pas prendre le médicament avant la visite ● Rencontrer le médecin qui réalise votre bilan de santé ● Remplir un questionnaire avec le médecin ● Ils réaliseront des bilans sanguins, à une analyse d'urine, un ECG comme prévu ● Chaque consultation vous prendra une demi-journée environ	**O**
	**Toutes les consultations auront lieu chez vous** Pour chaque visite, vous devrez : ● Avoir une consultation à distance par webcam avec le médecin qui réalise votre bilan de santé ● Répondre personnellement à un questionnaire en ligne ● Une infirmière travaillant pour l'essai se rendra chez vous pour pratiquer l'ECG, des bilans sanguins et une analyse d'urine en fonction de vos disponibilités. Vous devrez être à jeun avant la réalisation de la visite.	**O**
	**La visite aura lieu à l'hôpital ou à votre domicile selon votre choix** Cela implique que : ● Vous devez au début de l'étude indiquer les visites que vous souhaitez faire sur site ou à la maison. Si vous voulez changer l'organisation, vous devrez prévenir l'équipe environ deux mois avant.	**O**

Où souhaiteriez-vous réaliser les consultations de suivi ?

Si les visites de suivi sont effectuées à l'hôpital, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible ⟶ 100 Extrêmement fort

(Je suis certain(e) de ne pas participer)

(Je suis certain(e) de participer)

Si les visites de suivi sont effectuées à la maison, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si les visites de suivi sont effectuées selon votre choix, quelle est la probabilité que vous participiez à l'essai :

0 Extrêmement faible (Je suis certain(e) de ne pas participer)

100 Extrêmement fort (Je suis certain(e) de participer)

Si vous avez une autre idée pour améliorer votre expérience de réaliser les visites de suivi, n'hésitez pas à nous en faire part :

Recevoir les résultats de l’essai clinique

Votre participation à l’essai clinique durera trois ans. Toutefois, l’essai clinique parviendra à son terme seulement une fois que le dernier patient aura réalisé toutes ses visites, ce qui peut prendre plusieurs mois à compter de la date à laquelle votre participation sera terminée.

Une fois l’essai clinique achevé, les chercheurs vous informeront de vos résultats personnels et des résultats globaux de l’essai clinique (c’est à dire le traitement est-il efficace ou non ?).

Comment souhaitez-vous recevoir les résultats finaux de l’essai clinique ?

- En rencontrant personnellement un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- Par un appel à distance par webcam avec un membre de l’équipe de chercheurs à l’hôpital qui vous expliquera les résultats
- En recevant une synthèse des résultats par la poste
- En recevant une synthèse des résultats par mail

À propos de vous

8. Vous habitez dans :
    - Une zone urbaine (une ville ou une banlieue, une ville moyenne à grande)
    - Une zone rurale (campagne, village/petite ville)
9. Diriez-vous que les services suivants sont situés à proximité de votre domicile ?
    - Pharmacie
    - Médecin généraliste
    - Spécialiste
    - Hôpital
10. Combien de temps faut-il pour aller à l'hôpital universitaire le plus proche de chez vous ?
    - Moins d'une heure
    - De 1 heure à 2 heures
    - De 2 heures à 5 heures
    - Plus de 5 heures
11. Dans quelle mesure vous sentez-vous à l'aise avec l'utilisation d'Internet ?

○	○	○	○	○
Pas du tout confiant	Peu confiant	Moyennement confiant	Assez confiant	Très confiant

12. Avez-vous déjà participé à un essai clinique ?
    - Oui
    - Non
13. Si vous souhaitez nous faire part d'autres commentaires, veuillez nous compléter ci-dessous