Health Matters

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Promoting Equity, Diversity and Inclusion (EDI) in Clinical Trial Accruals

A Change Management Workshop in Operationalizing Implementation

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REPORT BY

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Introduction

Various logistical barriers in current clinical trial accrual procedures in Canada, and worldwide, have a negative impact on diverse population representation, leading to possible effects on real world outcomes, and inequitable access to innovative and life-saving medicines for patients. In recent years, much attention has been placed on understanding what these barriers are, and how it is affecting Equity, Diversity and Inclusion (EDI) in clinical trial participation. Although several solutions have been tested, implementation of these solutions have not resulted in impactful systemic changes due to complex operational structures, system rigidity, and siloed workflows. Change is difficult but necessary to improve clinical trial execution and exceptional patient care, especially in cancer.

In April 2024, a two-day conference organized by Myeloma Canada, a non-profit patient organization, gathered representatives from all groups involved in clinical trial procedures: pharmaceutical sponsors, clinical research organizations (CROs), researchers, clinical research nurses, hospital administrators, and advocacy groups anchored by patients to workshop through solutions for operationalizing EDI in clinical trial accrual. Without zeroing in on one specific community, situation, or disease type, the goals of the meeting were to: 1) take a bird's eye approach to trial operations; 2) identify one to two process shortcomings that can have a negative impact on trial participation; and 3) workshop change management strategies through a design-thinking approach. Ultimately, the findings from the meeting are intended to serve as a blueprint for a model project to integrate EDI in all institutions performing clinical trials and sponsors/researchers designing trials.

Background

The workshop was based on Human-Centered Design (HCD) – a method that is often used in various industries to approach complex problems with multifaceted challenges, such as those encountered in clinical trial design. HCD is not a linear thinking process and requires an iterative approach to develop solutions. As per ISO 9241-210:2010 (E), *"HCD is an approach to interactive systems that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors/ ergonomics, and usability knowledge and techniques."* The approach enhances effectiveness, efficiency, and user well-being, while improving satisfaction, accessibility, and sustainability. It mitigates potential negative impacts on health, safety, and performance, ensuring the system meets user needs while promoting inclusivity and well-being. The iterative nature of this process ensures solutions evolve with real-world user feedback [1].

A key element of HCD is usability knowledge—without it, even the best solutions may fail if users cannot access or benefit from them. Usability refers to how easy and efficient a system is for users to interact with, ensuring minimal errors and high satisfaction. In clinical trial design, improving usability translates to making trials accessible, clear, and convenient for participants, by simplifying procedures, reducing burden, and ensuring effective communication throughout.

Incorporating EDI can improve usability by addressing the diverse needs of underrepresented populations. By considering the varied facets that shape an individual's identity—such as cultural background, socioeconomic status, ability, gender, sexual orientation, geography, language, or age—early in the design process, trials can better encourage participation and engage individuals who feel confident, respected, and valued. This approach can help reduce barriers related to accessibility and cultural sensitivity, fostering trust and supporting sustained participation. Ultimately, inclusive design can create more equitable and impactful outcomes for everyone involved.

The evolution of human-centered design methods can be traced back to the 1950s, when the Stanford Design Division was established by John E. Arnold, a psychologist and engineer [2]. This approach was used in industrial design practices as a means to improve industrial efficiency and increase production, where the aim was to "fit the task to the worker". Since then, the approach has evolved and expanded to include the full spectrum of a user's experience, which employs a more holistic approach by considering physical and cognitive needs of the user, as well as their organizational, social and emotional needs [3].

With today's complex healthcare challenges, HCD methodology is increasingly being recognized as a promising process and mindset to develop solutions to complex health care delivery systems where resources are limited and tasks are complex and often critical. In 2016, Erwin and Krishnan's published their editorial "Redesigning healthcare to fit with people" in the *British Medical Journal*, where they reinforced the notion that implementing a HCD approach is vital to addressing current healthcare challenges: *"The key is to shift our focus from helping people to fit our care delivery system, to one where we design our care delivery system to fit people where they live, work, learn, play, and receive healthcare"* [3].

Methodology

The workshop was part of a 2-day conference, where day 1 centered on learning and gaining perspectives from contributors across various disciplines and impacted groups to identify challenges and opportunities in the context of EDI in clinical trial accruals. Day 2 focused on workshopping solutions, brainstorming ideas, identifying priorities and laying the groundwork for next steps.

Day 1 included panel discussions with patients, presentations from researchers, clinical research nurses, pharmaceutical professionals and CROs. This is a key element for conducting a successful HCD workshop because it ensures all parties have been exposed, to some degree, to the challenges of one another, thus creating a more holistic understanding of bigger picture issues, leading to better informed solutions. Two disciplines representing the government/regulators perspective and the research ethics boards (REBs) perspective were not in attendance at the workshop. The role of government would have been to provide insight on what regulators seek from an EDI standpoint to approve trial designs, and REBs to inform on ethical cautions and boundaries in research practices.

Workshop participants

For the HCD workshop on day 2, to ensure a broad range of perspectives were considered, the goal was to include as many interested, impacted and involved parties in clinical trials as possible. Participants included patient advocates, pharmaceutical sponsors, CROs, researchers, clinical research nurses, hospital administrators, and advocacy groups. Eight teams were built with pre-assigned seating to ensure diverse viewpoints within each group, and were assigned a Team Captain, patient partners that were coached beforehand on workshop procedures.

Not all parties were represented at each table; however, the outcomes of the workshop remained the same. Although including relevant expertise in brainstorming exercises provided some relevant background information, the goal of assigning diverse seating in HCD workshops is to reduce bias from habitual knowledge, professional experience and personal baggage from entering the discussion and forming pre-conceived barriers in brainstorming.

Workshop structure

The workshop kicked off with an introduction to change management concepts and HCD thinking. Numerous HCD models have evolved over the years, and for the purposes of this workshop, a 5-stage approach was used, inspired by a model popularized by the Hasso Plattner Institute of Design at Standford [6].

The 5 stages of HCD are *empathize, define, ideate, prototype* and *test*. The focus of this workshop was on the first 3 steps, to generate possible outcomes that can be further explored and progress to the prototyping and testing phase via a pilot project.

HCD places end-users, in this case clinical trial participants (patients), at the centre of the problem-solving process. By anchoring discussions on patients, empathizing and understanding their needs and barriers, workshop participants can more effectively develop solutions that are inclusive and attainable.

Participants were encouraged to remember the three key aspects of the human experience, collectively known as the 3-H model: *Head, Heart,* and *Hand*. They were invited to approach all challenges using this model. *Heart* emphasizes emotional connection, empathy, and understanding. *Head* focuses on rational decision-making and comprehension of information. Finally, *Hand* concentrates on taking action and implementing solutions.

Step 1
Empathize

The purpose of this step is to ensure that participants are able to empathize with a patient's situation before problem-solving. Exercising empathy is a challenging step, but an essential one. It is at the core of the HCD process. It allows us to understand why people do things the way they do them, and to consider their values, beliefs and needs—not just specifically related to the problem at hand, but in a more holistic and comprehensive way.

To facilitate this step, four fictitious personas were built before the workshop, with two groups assigned to each persona (eight total). Real-life anecdotal patient experiences were used as the basis for these personas to reflect current realities in healthcare. All identifying information was stripped away from each persona, to focus solely on highlighting their challenges and not their backgrounds. A short background story was written for each persona, removing personal details such as language, race/culture, gender, sexual orientation, disease type, or location. This allowed participants to easily envision themselves in the shoes of the patient and reduced biases.

My name is Casey

I live in Never Never Land, with a partner and young children, and am the sole breadwinner of the family. 3 years ago, I was diagnosed with snuffleupagus and have been receiving ongoing treatment at the local cancer centre ever since. Although cumbersome, between work schedules and family obligations, visits to the hospital and treatment schedules have been mostly manageable. With a lower middle-income household, and with rising cost of living and a young family to care for, I cannot afford the luxury of retiring early, nor take a long-term leave from work.

Recently, my oncologist, Dr Clooney, has noticed some signs of disease progression and is evaluating the next course of action. Dr Clooney is exploring a new and promising clinical trial that could have great benefit, but the problem is, the trial requires me to travel to Atlantis to receive treatment weekly. The treatment requires weekly blood work in Atlantis, periodic scans, and the treatment is administered subcutaneously.

Moving to Atlantis is not an option and travel to treatment would require me to take off a minimum of 2 days of work per week (without pay). Dr Clooney is afraid this might be one of the few viable options and is worried the trial is inaccessible, although the healthcare team are willing to do what they can to help.

Figure 1 - Persona 1 of 4: Casey

My name is Sam

I moved to Canada with family 1 year ago to settle down in Emerald City. Being new to the country, I am learning a new language and have been taking courses ever since. Although mostly conversational, it still remains a second language for me, and I struggle to understand complex terms.

A few weeks ago, during a hospital visit after a bad fall, I was also diagnosed with pinkyitis, and was referred to a specialist for follow up. With my limited understanding of the second language, my comprehension of the disease and treatment options are a challenge, not to mention my anxiety of navigating the healthcare system in a new country, with no community or supports yet. Dr Oetker would like to propose a new clinical trial that has just become available at the centre however, not only am I leery of taking part in an experimental study, but culturally speaking, pinkyitis is not something that is discussed openly in my community.

Figure 2 - Persona 2 of 4: Sam

My name is Robin

I was recently diagnosed with inferno, an incurable disease with limited treatment options. My doctor tells me a new clinical trial has become available that would require ongoing treatment and frequent visits to the hospital, however my community has not had good experiences with the medical system and experimental treatments make us nervous. Many of us do not feel in a safe space at the hospital, and often feel discriminated against by the system. Generally speaking, there is a large lack of understanding and disconnect between the traditional healthcare system and the needs/beliefs of my community. I have a good relationship with my physician, but the trial that being proposed is not available at my centre. This means, my treatments would be given at another centre, and I would be under the care of someone new.

I feel powerless, vulnerable, and don't feel safe signing onto a study under these conditions.

Figure 3 - Persona 3 of 4: Robin

My name is Drew

I moved to Canada with family 1 year ago to settle down in I live in in the Greater Metropolis Area and do not have any caregivers or supports, and currently do rotational shift work for a living. Currently, I am being treated for bippity boppity boo at Metropolis General Hospital (MGH) and up until this point, the treatment plan has been an all-oral regimen with quarterly follow ups at the hospital for bloodwork. Managing treatments and medical appointments have been doable to date, and I have been able to keep working, earning just enough to support the rising cost of living, which has been a struggle as of late. Frequent medical appoints are difficult due to unpaid time off.

My numbers have been progressing, and an opportunity has come up to participate in a clinical trial at MGH, but would now require injections twice per week with weekly bloodwork at the hospital. Although the trial sounds hopeful, frequent hospital visits during traditional business hours are just not possible for me.

Figure 4 - Persona 4 of 4: Drew

Each persona was presented to the eight teams in a plenary discussion and participants were asked to put themselves in the position of each, and answer the following questions:

- *"If this were me, how would I feel?"*
- *"If this were me, what would I need?"*

Each Team Captain captured the responses for the persona assigned to their table.

Step 2
Identifying barriers

The purpose of this step was to further define the challenges faced by each persona by identifying their barriers to enroll in a clinical trial. It allowed workshop participants to notice the formulation of any patterns or connections amongst issues raised, and consolidated what may seem like a scattered collection of information into insights and actionable problem statements.

Participants were asked to answer the question "*If this were me, what barriers might I face?*" and prompted to consider various types of barriers, including but not limited to:

1. **Logistical/Administrative:** Distance, transportation, time commitments, work/family responsibilities, complex enrollment processes, limited access to information, lack of support.
2. **Financial:** Costs, lost income, insurance coverage concerns.
3. **Health-related:** Ineligibility based on criteria, fear of side effects, extra burden of tests/treatments.
4. **Psychosocial:** Lack of awareness, mistrust, language/cultural barriers, stigma, age, gender or sexual orientation.
5. Impact on family/caregivers.

Each Team Captain captured the responses for the persona assigned to their table.

Step 3
Empathize

Once all four personas and their barriers were discussed by the groups, the ideation step was conducted, in three rounds, at each table with the support of Team Captains.

Round 1:

Participants at each table were asked to discuss the persona assigned to their table and what they would need to overcome the barriers identified in the previous step. The main goal of this round was to encourage open, creative thinking, prompting participants to imagine “perfect world” scenarios without constraints. They were given instructions to use sticky notes and limit one idea per sticky note.

Team Captains employed the following prompts to guide the process, understanding that it can be challenging to think outside the box, particularly for those with extensive professional expertise in the field. This challenge is often attributed to the “curse of knowledge” phenomenon, where deep familiarity with a subject can unintentionally constrain creative thinking.

Table 1
Ideation Prompts for Team Captains & Facilitators

- *What would you do if you were in charge?*
- *Let’s imagine we’re time travelers from the future who’ve already solved this problem. How did we do it?*
- *If we had unlimited resources, what unconventional solutions could we explore to overcome this barrier?*
- *How might we reframe this obstacle as an opportunity for innovation or growth?*
- *What if failure wasn’t an option? How might that change the way we approach overcoming this obstacle?*
- *Consider the most successful companies or individuals in our field. How do you think they would tackle this obstacle?*
- *If we could borrow a solution from another industry or discipline, what might that look like?*
- *What are some “out-of-the-box” ideas that initially seem unreasonable but could actually work to overcome this obstacle?*
- *What if we could combine two seemingly unrelated concepts to create a solution for this obstacle? What would those concepts be?*

Team Captains were also equipped with prompts to use if participants encountered obstacles. In such cases, captains were advised to add these challenges to the list of barriers and guide participants back into an "everything is possible" mindset to sustain idea generation.

Table 2
“Unblocking” Prompts for Team Captains & Facilitators

- *What do you think is the root cause of this obstacle? Understanding it better might help us find a solution.*
- *Sometimes obstacles can lead to the most innovative solutions. Let’s think creatively about how we can turn this challenge into an advantage.*
- *What if we approached this obstacle from a completely different angle? How might that change our perspective?*

Round 2:

To mitigate the effects of groupthink, participants, with the exception of Team Captains, were instructed to switch tables, allowing them to build on work started by another group, but for a ***different persona***.

Groupthink is a phenomenon that can occur even when individuals are working together for the first time, such as in a workshop setting. It arises from the natural human tendency to prioritize consensus over critical thinking, which can lead members to adopt what they perceive as the majority opinion, even if they have reservations about its validity or effectiveness. As a result, diverse perspectives may be unintentionally suppressed, and decision-making becomes less effective. By rotating participants and having them focus on a new persona, this "fresh eyes" approach encourages broader thinking, leading to solutions that are more adaptable and better suited to address the diverse challenges of different individuals.

Round 3:

Participants returned to their original persona and were encouraged to explore the sticky notes left by other teams to gain fresh insights into the ideas and perspectives previously discussed. Teams were then asked to discuss and assess the overall picture, identifying any gaps or overlooked aspects.

The focus was now on understanding which ideas stood out, why certain barriers attracted more attention, and how the teams might address any barriers that were missed or not fully developed. This round also aimed to help participants recognize emerging themes and consider if some ideas could be grouped together for a more cohesive approach. Team Captains were provided with prompts to guide and structure team discussions.

Table 3
"Barrier-breaking" Prompts for Team Captains & Facilitators

- *Which barriers seem to have attracted the most ideas? Why might this be?*
- *Which barriers did not attract the most ideas? Why might this be?*
- *How can we address the barriers that we missed or didn't build much on?*
- *What themes seem to be forming, if any?*
- *Which ideas could be grouped together?*

Step 4
Putting Our Best Foot Forward

With several potential paths discussed and themes identified throughout the day, teams were then tasked with selecting ***one idea*** to develop further. They had to agree on why a particular idea was chosen and identify the specific problem it would address. Next, they had to identify resources needed to bring their idea to fruition while considering any potential challenges, along with strategies to overcome them. Team Captains were provided with the following types of prompts to guide these discussions to help steer the conversation and maintain a constructive, solution-focused dialogue.

Table 4
Solution-focused Prompts for Team Captains & Facilitators

Feeling and Meaning:

- *How do you feel about the chosen idea?*
- *What would it mean to have this happen?*
- *Why is this important?*

Impact:

- *How would this impact this specific persona?*
- *What unintended negative impacts could this generate for the persona or others?*

Informative, fact-based:

- *How will we measure success?*
- *How much time would we need to make this happen?*
- *Who do we need to make this happen?*
- *What do we need to make this happen? (knowledge, funding, material, process, policy, etc.)*

Challenge:

- *What might go wrong?*
- *What obstacles might come up?*
- *What workarounds can we come up with?*
- *Who do we need to help up overcome this?*
- *What do we need to overcome this? (knowledge, funding, material, process, policy, etc.)*

Focusing:

- *"Hold that thought. May I suggest we come back to point X before moving on to this new idea?"*
- *How will this idea help ensure persona can successfully access the clinical trial?*

Motivation:

- *What motivates you in your role to make this happen?*
- *How would this change impact you, personally?*
- *Who do we need to "win over"? Whose buy-in do we need? How do we motivate them?*
- *How do we create a win-win situation to get buy-in?*

Action-oriented:

- *If you were personally in charge, what's the first realistic and achievable step you could take tomorrow morning?*

Step 5
Presenting the Solutions

As a final step of the workshop, each team presented the solution they developed for their assigned persona. Although multiple solutions were possibly generated for each of the four scenarios, each team was asked to select and present one solution they felt was the most feasible to implement in the short-term.

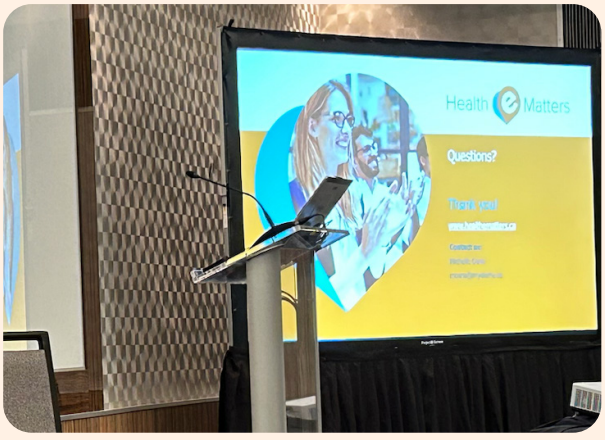
The goal was to move forward with a selected idea in the form of a pilot project, ensuring that the workshop's efforts will lead to actionable results.

Although a change management project can unfold over several months, given the condensed nature of this two-day workshop, depth was prioritized over quantity. The meeting focused on exposing participants to at least two of the four personas within the allotted time (rather than all four). While additional rounds would have allowed the teams to workshop all four personas, this approach ensured more meaningful and in-depth discussions within the time constraints for each persona.

Proposed solutions

Although working groups brainstormed independently and each persona had different barriers and needs, six of the eight groups proposed a similar solution for each of the personas: a type of navigation service that can be offered to patients considering enrolling in a trial (and their healthcare team) to work through inhibiting barriers they may encounter. Furthermore, it was suggested to offer this service as a resource to patients and healthcare providers *before* considering a clinical trial. The goal of the service is to source resources (internally or externally) that respond to needs that are inhibiting patients from enrolling in a trial (needs that are unrelated to the treatment itself or eligibility). It does not exclude the need to consider other EDI elements in protocol design or throughout the trial spectrum; however, the biggest unmet need for enrollment, identified from the patient perspective, begins before the screening and protocol consent process, regardless of the barriers.

Several ways that the service can be offered, either at the institution level (social worker, employed patient partner, or clinical trial navigator), or through pharmaceutical industry support (through a contracted support service or third-party patient support program) were discussed. To determine the best course of action and initiate a pilot project, a follow up meeting entitled *Phase 0* is scheduled to take place in March 2025. The goal of the next meeting will be to bring all key decision-makers to the table to workshop/design a clinical trial model in consideration of the Health eMatters IMPACT outcomes (the clinical trial navigation service).



Conclusions

By placing the patient at the centre of the HCD process without zeroing in on a specific underrepresented population, participants are able to empathize with the "human" at the most basic level, leverage their multidisciplinary viewpoints without biases to focus solely on finding a workable solution to their barriers.

By zooming out and looking at the big picture, the realization that patients, regardless of their backgrounds, experience many of the same barriers, and therefore implementing a general comprehensive clinical trial navigation program with personalized service is a concrete approach to operationalizing EDI in clinical trial accrual practices.

The workshop resulted in a defined operational program that can have a benefit for all patients. In addition, this humanized and patient-centric approach to clinical research can be scalable, and implementable at a very specific stage in the clinical trial accrual process.

The *Phase 0* project will determine the best course of action to implement a pilot project, and how to evaluate measurable outcomes and impact in a real-world setting. Workshop participants will include key-decision makers, such as researchers, REBs, national and international pharmaceutical partners, CROs, clinical research nurses, trial coordinators and patient advocates.

Given that clinical trials are becoming more complex with the emergence of novel therapies, the burden on the patient is higher, and leads to inequitable access to care, negative impact on cost, accrual, and study biases. Thus, building a navigation model that operationalizes EDI practices in increasingly complex clinical trial environments is ideal for trial efficiencies, cost effectiveness, and research outputs, and ensures that all patients have access to the best possible care as the priority focus.

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