The Case for Implied Consent for Clinical Study Participation

By: *Jay Virani, Vice President, Strategy and Client Experience, Sciteline*
Date: *March 4, 2025*

Clinical research is the backbone of medical innovation. Yet, despite its critical role in advancing healthcare, participant recruitment remains a significant bottleneck. Many promising clinical studies struggle to enroll enough diverse participants, delaying breakthroughs that could save lives. One of the biggest challenges? The common and long-standing requirement for explicit consent before researchers can even contact potential participants about research opportunities.

I recently came across Hamilton Health Sciences "Explore Research" initiative, a program designed to make research participation more accessible and inclusive. This initiative allows research teams to proactively screen patient records and reach out to individuals who may be eligible for clinical studies, all while maintaining patient autonomy by offering an “opt-out” option. By streamlining outreach and reducing barriers to participation, "Explore Research" is helping to create a more efficient and equitable research landscape.

Learning about this program reinforced my belief that implied consent for research participation outreach is a necessary step in modernizing clinical trial recruitment and addressing long standing access and equity challenges that have been discussed in the industry for decades but have made limited progress. However, with clinical trial technology infrastructure that makes consent management easy, addressing these issues can start today.

Empowering Patients to Control Their Involvement

In 2015, a study surveyed 1,602 residents of Ontario and British Columbia to assess their understanding and willingness to participate in clinical trials. The findings revealed that while clinical trials were generally viewed positively, 43% of respondents felt not very informed or not at all informed about them.[1]

Despite concerns that implied consent to be contacted for clinical study opportunities may compromise patient autonomy, it actually strengthens patient choice and engagement in clinical studies.

Under an implied consent model, individuals are informed that they may be contacted about relevant studies but retain full control over their participation— and they can opt out at any time. Instead of limiting awareness due to stringent consent requirements, this approach empowers patients with more opportunities to engage with potentially life-changing clinical studies that they can discuss with medical professionals.

---

[1] Willison DJ, Richards DP, Orth A, Harris H, Marlin S. Survey of Awareness and Perceptions of Canadians on the Benefits and Risks of Clinical Trials. Ther Innov Regul Sci. 2019 Sep;53(5):669-677. doi: 10.1177/2168479018805433. Epub 2018 Oct 29. PMID: 30373453; PMCID: PMC6710611.

Hamilton Health Sciences' "Explore Research" initiative exemplifies this model in action. By allowing research teams to proactively identify and reach out to eligible patients, the program ensures that more individuals have access to information about relevant studies without unnecessary barriers.

Increasing Diversity and Representation in Research

Despite immigrants comprising nearly a quarter of Canada's population, they account for less than 2% of clinical trial participants. [2] ***In 2020, 75% of participants in clinical trials for medications approved by the U.S. Food and Drug Administration (FDA) were white.*** [3]

The lack of diversity in clinical trials is a well-documented issue. Many marginalized communities, including racial minorities, individuals from lower socioeconomic backgrounds, and rural populations, are underrepresented in research. Further, traditional recruitment models rely heavily on patients actively seeking out opportunities, favoring those with higher health literacy and access to medical resources.

By shifting to an implied consent model for outreach, we can change this dynamic. Instead of placing the burden on patients to discover clinical studies, researchers can proactively connect with a broader and more representative pool of participants. This ensures that new treatments are tested on diverse populations, leading to more equitable healthcare solutions for all.

Improving Access to Research for a Wider Range of Individuals

In 2022, approximately 4.9% of global rare disease clinical trials included Canadian sites, a decrease from 6.9% in 2010.[4]

For many individuals, participating in a clinical study isn't a matter of reluctance—it's a matter of awareness. Under the current system, countless potential participants never even hear about studies they qualify for. Implied consent bridges this gap by enabling researchers to reach out directly to individuals who may benefit from participation.

Consider patients with rare diseases or those seeking innovative treatment options that aren't yet widely available or come at a high cost. Many of them would welcome the opportunity to participate in clinical studies, but traditional recruitment methods fail to connect them with these opportunities. By implementing implied consent for initial outreach, we remove unnecessary hurdles and create a more inclusive research ecosystem.

Additionally, a centralized research database can provide insights into patient populations, helping research sponsors identify opportunities to bring more rare disease clinical trials to where they are needed most.

---

[2] https://acrpnet.org/2024/03/04/enhancing-diversity-in-clinical-trials-canadas-promise?
[3] https://www.nature.com/articles/d41586-018-05049-5
[4] Clinical Trials in Canada – Research Note, April 2023. Innovative Medicines Canada

Ensuring Equitable Access to Research Opportunities

Patients residing 250 kilometers or more from treatment centres have 29% lower odds of enrolling in clinical trials compared to those living within 15 kilometers.[5]

Ethical research must be accessible to everyone—not just those with the resources to navigate complex clinical trial landscapes. With the support of technology-driven solutions, implied consent is a necessary step toward leveling the playing field. It ensures all patients, regardless of background or geographical location, are equally informed about clinical research opportunities without requiring them to actively search for information.

Health Canada has already recognized the need for modernizing clinical trial regulations to improve access to novel therapies. By adopting implied consent for outreach, we can align with this vision, ensuring that research recruitment strategies are efficient, equitable, and patient-centred.

Scalable Technology Implementation is a Prerequisite to the Implied Consent Model

Adopting an implied consent model is only half the battle. Health systems must implement technology solutions that make the process of managing implied consent easy, intuitive, and scalable to ensure its success.

Finding a unicorn – one system that does everything – is impossible. However, identifying integrated technology solutions that add value across different points of the clinical trial process is achievable with the right technology partner.

When evaluating clinical trial technology solutions, key considerations should include:

- **Integrations:** Can the solution integrate with existing EMR or Health Information System infrastructure? Seamless integration ensures data continuity and minimizes duplication of efforts.
- **Data Insights:** Does the solution provide deidentified insights and reporting capabilities? Data captured in the system can inform resource allocation, recruitment efforts, and identify opportunities to offer studies to populations that may benefit from them the most.
- **Patient and Community Engagement:** Can the solution provide information to patients and communities that is more accessible, easier to understand and offers them a pathway to take part in research? Normalizing research as a care option means keeping patients and communities informed and involved in the research process from beginning to end.
- **Resource Limitations and Administrative Burden:** Can the solution provide research teams with easy-to-use tools that create efficiencies at the site level? Replacing manual

[5] Shapiro GK, Santiago AT, Pittman T, et al. Disparities in clinical trial enrollment at a Canadian comprehensive cancer center: a 15-year retrospective study. Cancer. 2024; 130(16): 2782-2794. doi:10.1002/cncr.35331

paper-based processes with digital workflows and smart electronic data capture enables sites to take on more studies with existing resources and provides sponsors with faster results.

Moving Toward a Patient-Centered Research Future

The future of clinical research must be patient-centric, inclusive, and efficient. Implied consent for outreach doesn't have to mean forcing participation—it can mean removing unnecessary barriers to awareness while respecting individual choice. Hamilton Health Sciences' "Explore Research" approach should serve as a model for how we can responsibly modernize research recruitment, ensuring that more people can contribute to and benefit from medical advancements.

Let's move toward a future where research doesn't just wait for patients to seek it out but actively reaches those who need it most.

About Siteline

At Siteline, we are committed to driving positive change through technology. By embracing innovative participant recruitment strategies, leveraging technology, and prioritizing patient engagement, we strive to make research more accessible, diverse, and impactful to Canadians.

Stay Connected

Learn how Siteline's technology is transforming clinical trial recruitment. Visit www.siteline.com to explore our solutions.

Want more insights on clinical research innovation? Follow us on LinkedIn for the latest thought leadership and industry updates.

###