Clinical
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Ontario

Engaging patient partners in the clinical trials space and beyond

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Dawn Richards, PhD
Director of Patient and Public Engagement

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Vision

Make Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards.

Mission

Strengthen, promote and capitalize on Ontario's competitive advantages to conduct high-quality clinical trials.

Strategic Priorities

Streamline

Streamline processes to help make high-quality clinical trials more timely, efficient and cost-effective.

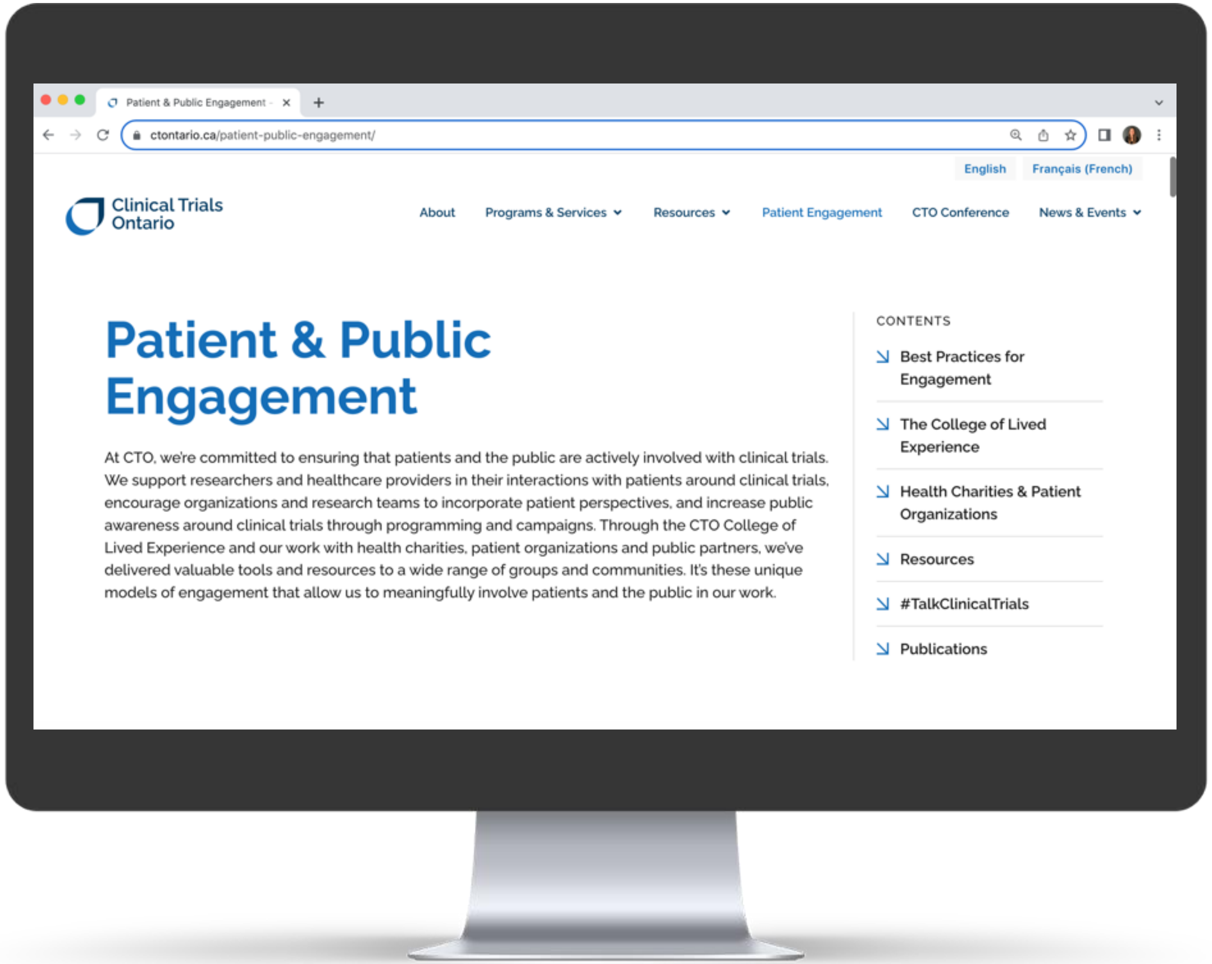
Engage

Engage with patients and the public to increase awareness, foster collaboration and improve how clinical trials are conducted.

Promote

Promote Ontario's competitive advantages and clinical trial capacities to attract more trials and industry investment to the province.

CTO’s work in patient and public engagement



Patient & Public Engagement

At CTO, we're committed to ensuring that patients and the public are actively involved with clinical trials. We support researchers and healthcare providers in their interactions with patients around clinical trials, encourage organizations and research teams to incorporate patient perspectives, and increase public awareness around clinical trials through programming and campaigns. Through the CTO College of Lived Experience and our work with health charities, patient organizations and public partners, we've delivered valuable tools and resources to a wide range of groups and communities. It's these unique models of engagement that allow us to meaningfully involve patients and the public in our work.

- College of Lived Experience
- Some advice on approach

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College of Lived Experience

Who

- 24 members
- Range of experiences with clinical trials (some have been participants and/or patient research partners)
- From all over Ontario (including rural, urban, northern, etc.)
- Range of ages
- Patients and caregivers (from different disease and condition areas, including rare diseases, oncology, mental health, vision loss, etc.)

What

- Advise CTO on projects
- Advise CTO partners on projects
- Mentor each other with respect to opportunities outside of the College

Best practices for engagement

- Have resources and a budget to support engagement
- Be flexible
- Communicate clearly
- Close the loop
- Engage a large group so there isn’t pressure to participate

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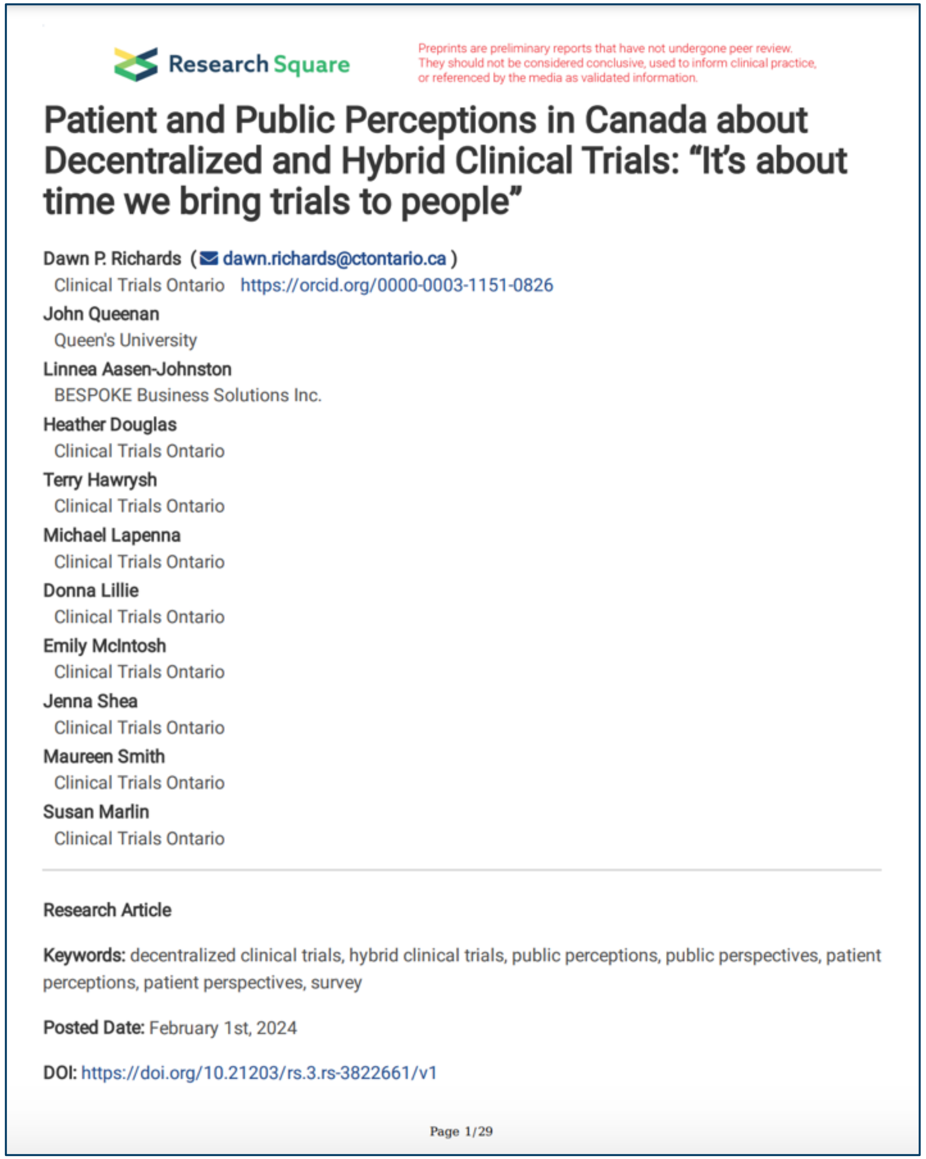
An example of our work together



Research Square

Patient and Public Perceptions in Canada about Decentralized and Hybrid Clinical Trials: "It's about time we bring trials to people"

Dawn P. Richards (dawn.richards@ctontario.ca)
Clinical Trials Ontario https://orcid.org/0000-0003-1151-0826
John Queenan
Queen's University
Linnea Aasen-Johnston
BESPOKE Business Solutions Inc.
Heather Douglas
Clinical Trials Ontario
Terry Hawrysh
Clinical Trials Ontario
Michael Lapenna
Clinical Trials Ontario
Donna Lillie
Clinical Trials Ontario
Emily McIntosh
Clinical Trials Ontario
Jenna Shea
Clinical Trials Ontario
Maureen Smith
Clinical Trials Ontario
Susan Marlin
Clinical Trials Ontario

Research Article

Keywords: decentralized clinical trials, hybrid clinical trials, public perceptions, public perspectives, patient perceptions, patient perspectives, survey

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We can learn from patient partners

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Research Involvement
and Engagement

COMMENT **Open Access**

Reflections on patient engagement by patient partners: how it can go wrong

Dawn P. Richards[1,2,3*†], Sabrina Poirier[4†], Vina Mohabir[5], Laurie Proulx[6,7], Sue Robins[8] and Jeffery Smith[9]

Abstract

As six patient partners in Canada, we aim to contribute to learning and to provide an opportunity to reflect on patient engagement (PE) in research and healthcare environments. Patient engagement refers to "meaningful and active collaboration in governance, priority setting, conducting research and knowledge translation" with patient partners as members of teams, rather than participants in research or clinical care. While much has been written about the benefits of patient engagement, it is important to accurately document and share what we term 'patient engagement gone wrong.' These examples have been anonymized and presented as four statements: patient partners as a check mark, unconscious bias towards patient partners, lack of support to fully include patient partners, and lack of recognizing the vulnerability of patient partners. The examples provided are intended to demonstrate that patient engagement gone wrong is more common than discussed openly, and to simply bring this to light. This article is not intending to lay blame, rather to evolve and improve patient engagement initiatives. We ask those who interact with patient partners to reflect so we can all work towards improving patient engagement. Lean into the discomfort with these conversations as that is the only way to change these all too recognizable examples, and which will lead to better project outcomes and experiences for all team members.

Keywords Patient engagement, Family engagement, Patient and public involvement, Power dynamics in healthcare, Power imbalance, Tokenism, Patient partner

Plain English summary

We are six patient partners in Canada who aim to contribute to learning and to provide an opportunity to reflect on patient engagement (PE) in research and healthcare environments. Patient engagement refers to "meaningful and active collaboration in governance, priority setting, conducting research and knowledge translation," where patient partners are members of the teams, rather than participants in research or those seeking clinical care. It appears more has been written on the benefits rather than the risks of patient engagement and we feel it is important to document and share what we call 'patient engagement gone wrong.' We have anonymized these examples and sorted them into four statements: patient partners as a check mark, unconscious bias towards patient partners, lack of support to fully include patient partners, and lack of recognizing the vulnerability of patient partners. These statements and their examples are meant to show that patient engagement gone wrong is more common than discussed openly, and to simply bring this to light. With this commentary, we do not mean to lay blame, and instead wish to evolve and improve patient engagement initiatives. We ask those who interact with patient partners to reflect so we can all work

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[†] Dawn P. Richards and Sabrina Poirier: Shared first authorship.

*Correspondence:
Dawn P. Richards
dawn.p.richards@gmail.com
Full list of author information is available at the end of the article

6 patient partner authors

Bringing to light some of the experiences we've had (and we know others have) so the patient engagement community can learn from these situations, to encourage discussion and growth (like today!)

Preprint: downloaded **>550** times, **>3,400** views

Paper: **>7,800** accesses, **9** cites, **211** on Altmetric

Four statements where PE may go wrong – how to avoid these

Statements Describing Patient Engagement Gone Wrong	Explanation	Questions for the Research Team to Ask Themselves
Patient Partners as a Check Mark	Also known as tokenism; inviting someone's participation but not wanting them there or listening to their perspectives, and therefore not acknowledging their insights, contributions, or ideas.	1. How do we accept feedback from patient partners and integrate it into our work? 2. How can we ask more thoughtful questions of patient partners about their lived experiences? 3. How can we create safer and more inclusive spaces for real and meaningful discussions? 4. How can we share our power and privilege with patient partners?
Unconscious Bias Towards Patient Partners	Lived experiences are often are not viewed as true expertise and given less credence and respect. This may be unintentional and often relates to ableism. Unconscious bias contributes to power imbalances on the team.	
Lack of Support to Fully Include Patient Partners	Failure to provide physical and other supports to patient partners so they may fully participate as team members.	
Lack of Recognizing the Vulnerability of Patient Partners	Failure to appreciate that patient partners often re-live emotional or even traumatic parts of their lives for the sake of a project. This means being vulnerable, sometimes in spaces with people with whom they are not very familiar.	

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Two examples in the outcomes space

OMERACT®
Outcome Measures in Rheumatology

- Committed to improving outcomes for patients through advancing the design and quality of clinical studies
- Supports the development of Core Outcome Sets (COS), identifying patient and disease-relevant areas to be measured (domains) and measurement instruments for use in clinical trials, including those for regulatory approval of new treatments
- The arthritis community has identified pain and fatigue as being important outcomes to patients

Kirwan, JR, Hewlett, SE, Heiburg T, Hughes RA, Carr M, Hehir M, et al. Incorporating the patient perspective into outcome assessment in rheumatoid arthritis--progress at OMERACT 7. J Rheumatol. 2005;32(11):2250-6.

Duchenne Muscular Dystrophy

- First developed a draft guidance document for industry that was submitted to the U.S. Food and Drug Administration in 2014
- Led by Parent Project Muscular Dystrophy, which engaged the greater community (parents, academia, industry), lots of conversations with FDA
- Updated in 2024 and represents a collaboration between the FDA, the Duchenne community, and industry stakeholders

Furlong P, Bridges JF, Charnas L, Fallon JR, Fischer R, Flanigan KM, Franson TR, Gulati N, McDonald C, Peay H, Sweeney HL. How a patient advocacy group developed the first proposed draft guidance document for industry for submission to the U.S. Food and Drug Administration. Orphanet J Rare Dis. 2015 Jun 24;10:82. doi: 10.1186/s13023-015-0281-2. PMID: 26104810; PMCID: PMC4486430.

McDonald C, Camino E, Escandon R, Finkel RS, Fischer R, Flanigan K, Furlong P, Juhasz R, Martin AS, Villa C, Sweeney HL. Draft Guidance for Industry Duchenne Muscular Dystrophy, Becker Muscular Dystrophy, and Related Dystrophinopathies - Developing Potential Treatments for the Entire Spectrum of Disease. J Neuromuscul Dis. 2024;11(2):499-523. doi: 10.3233/JND-230219. PMID: 38363616; PMCID: PMC10977441

Some advice

- Do a pilot or work with a small group before going large
- Have the resources to do this
- Be transparent if you're learning together
- Learn from resources and others already working in this space
- Enjoy the magic you co-create

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Thank you!

dawn.richards@ctontario.ca
www.ctontario.ca

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