Canadian Cancer Trials Group

New Investigator Workshop
Patient Centred Research Overview

August 2017

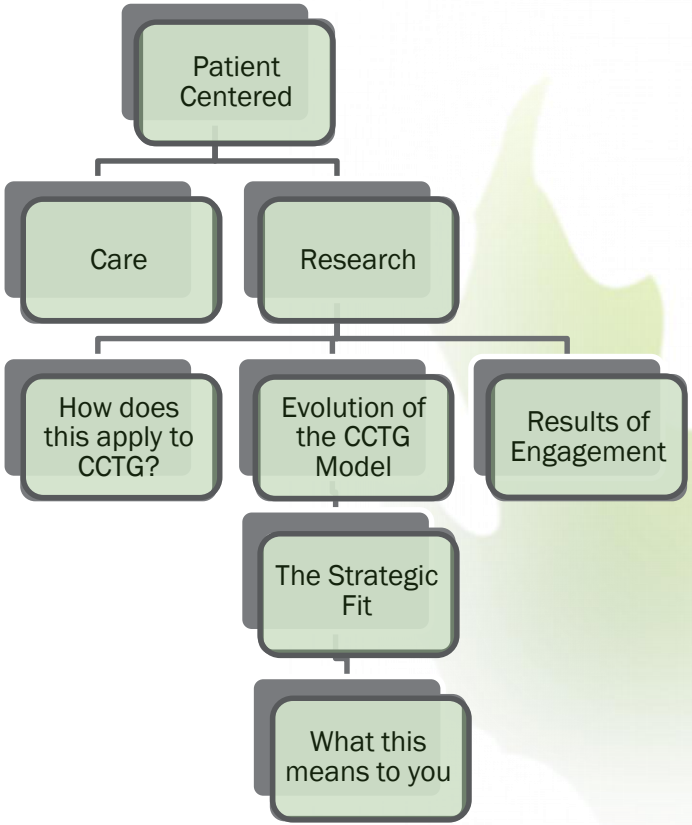
Janice Hodgson, Breast Disease Site Committee

on behalf of Judy Needham, Chair

Lay Representative Committee

Overview

- Patient Centred Care
- Patient Centered Research
- How This Applies to CCTG
- Evolution of CCTG Model
- Results of Engagement
- The Strategic Fit



Canadian Cancer Trials Group

What is Patient Centred Care?

- Patient Centred Care
- Patient Centered Research
- How Applies to CCTG
- Evolution in CCTG
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- Results

The practice of caring for patients (and their families) in ways that are meaningful and valuable to the individual patient. It includes

- listening to, informing and involving patients in their care and decision-making, recognizing they are individuals with their own unique values and preferences.

"In patient centered care as well as in evidence-based practice from which it grew, the patient is at the center of the decision making process, including the selection of the treatment **(intervention)** and whether the treatment is a success **(outcome)**."

*So seeking **outcomes** that matter to the patient (and, therefore, to the practitioner) is an important consideration when developing a research question. So the patient perspective in defining the research protocol is critical.*

Excerpt from the ***eight principles of patient-centered care*** highlighted in research conducted by the Picker Institute and Harvard Medical School

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DOEs, POEs, and POEMs

1. Disease-Oriented Evidence (DOE)

Refers to evidence from studies that measure the etiology, prevalence and pathophysiology of diseases. They give us insight into the disease process.

2. Patient-Oriented Evidence (POE)

Refers to evidence/outcomes of studies that measure things a patient would care about, such as improvement of symptoms, quality of life, cost of the intervention, morbidity or mortality, length of stay, etc.

Let's take a closer look at each.

Source: Farley Library Research Guides

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DOEs, POEs, and POEMs

1. Disease-Oriented Evidence (DOE)

Disease-oriented evidence comes from studies that illuminate the etiology, prevalence and pathophysiology of diseases. They give us insight into the disease process.

However, disease-oriented evidence as a stand-alone is not always helpful in the clinical management of patients.

In some instances, studies' preliminary data were promising or intermediate results looked good, but when real patients and outcomes were measured, results were disappointing or even showed the intervention to be unsafe.

An example is the HOPE trial.

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DOEs, POEs, and POEMs

The HOPE trial

A previous study of B vitamins and folic acid showed lowering of homocysteine levels, an independent predictor of the risk of developing cardiovascular disease (CVD), logically concluding that using these supplements will prevent or treat CVD.

However the HOPE trial (N Engl J Med 2006;354:1567-1577) showed that there was no difference in the combined risk of cardiovascular death, myocardial infarction, or stroke between groups who used vitamin B and folic acid and those who did not.

Patients may spend on preparations that do lower a number on a lab test but ultimately make no difference in their risk of heart disease and death.

So is a DOE (disease-oriented evidence) study as a stand-alone enough?

Source: Farley Library Research Guides

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DOEs, POEs, and POEMs

2. Patient-Oriented Evidence (POE)

*Therefore seeking **outcomes** that matter to the patient (and, therefore, to the practitioner) is an important consideration when developing a research question.*

This kind of evidence is called **Patient-Oriented Evidence (POE)** and refers to outcomes of studies that measure things a patient would care about, such as improvement of symptoms, quality of life, cost of the intervention, morbidity or mortality, length of stay, etc.—essentially whether the intervention helps patients live longer or better lives.

If a POE would change practice, it becomes a **POEM (Patient-Oriented Evidence that Matters)**.

Source: Farley Library Research Guides

What is Patient Centred Research?

DOEs, POEs, and POEMs

Challenges

- for the researcher, in applying a combination of DOEs and POEs in their research questions.
- and for the health care professional, in identifying, validating and applying POEMs in practice.

In summary, from a patient perspective,

- Ideally, patient Centred research would consist of studies with a combination of DOEs and POEs.
- Involving the patient perspective in creating the research protocol is critical.

Source: Farley Library Research Guides

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IN THE UK

The Value of Community Membership to the Board

- Til Wykes of King's College London highlights the need for public participation in research by saying, "For treatments to be anywhere near feasible and useful for patients in the NHS (UK), it is essential that patients are involved in every step of the research process: from setting the research questions, guiding us on the best outcomes, helping us communicate and determine what's feasible considering the restrictions of the illness."
- In fact, research by Ellis and Wykes (2013) highlights how involving members from the community aids in the recruitment process threefold:
  a. Language used in materials such as information sheets is more appealing or easier to understand for patients because of vetting by other patients;
  b. Patients have insight into the realities of living with a health problem and therefore understand which designs will be the least burdensome; and
  c. Patients are more willing to participate in research that they know has involved other patients, as the principle of patient involvement is in itself appealing.

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IN CANADA CIHR -> SPOR

- Strategy for Patient Oriented Research

Using SPOR to inform us, in Canada

- Patient engagement is defined as fostering a climate in which researchers, health care professionals, decision-makers and policy-makers understand the value of patient involvement.
- The patient perspective is integrated into every step of the research process including developing research questions, defining research objectives, collecting data, and evaluating results.
- It is important for Canada to raise the bar and push the boundaries in order to build our capacity to engage patients in truly innovative roles and ways.

How Does This Apply to CCTG?

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Canadian Cancer Trials Group (CCTG) recognizes the value and importance of engaging patients and is leading the way in Canada in including the patient voice in all aspects of the clinical trial lifecycle as it sets its research agenda over the coming years.

- Patient engagement has become increasingly important as evidenced by the Patient/Public Involvement (PPI) movement in the UK, the Canadian Institute for Research Strategy for Patient-Oriented Research (SPOR), and our own results within CCTG.
- Integrating the patient perspective into the CCTG's overall strategic agenda will help ensure the research agenda has the greatest impact on cancer patients in Canada and around the world.

How Does CCTG Embrace Patient Centred Research?

CCTG has implemented a model of **dedicated** public and patient involvement, the Lay Representative. The Lay Representative is recruited to disease site committees similar to academic committee members with a 3 year extendable term.

- The role of the CCTG Lay Representative has evolved over the past four years to enable integration of the patient perspective into many steps of the research process within CCTG with the aim of
  - research questions that matter to patients, and
  - improved accrual.
- CCTG is committed to implementing best practices and materials to foster and facilitate patient engagement.

Evolution of the Lay Rep Role in CCTG

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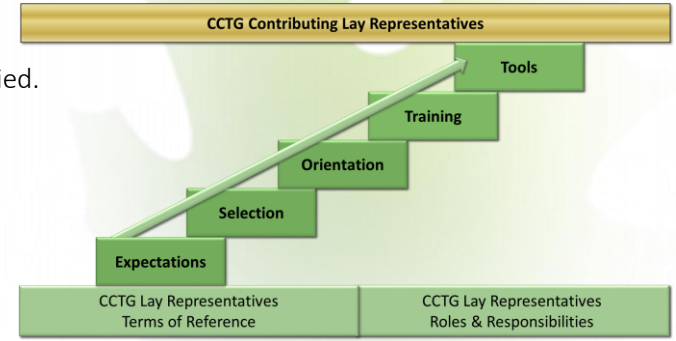
Pre 2012 – Meeting Centric

- Lay Reps were recruited to Disease Site Committees, primarily to attend Spring Meeting and Quarterly DSC calls, listen and provide a patient perspective to the best of one's ability.
- The role was primarily one of a passive meeting attendee.

Move from Meeting Centric → Committee Centric

Following an internal eco-analysis of the role within CCTG, a pragmatic building block approach was taken to work on the opportunities identified.



Expectations - reviewed and redefined

Recruitment and Orientation

- Recruitment package created and distributed.
- Interviews process developed and conducted with candidates
- Engagement sessions with Committee leadership

Tools & Training

- Understanding the role - CCTG Lay Rep Manual modelled on the CCSRI manual created
- Understanding and tracking trials - Trial Matrix Report and Trial worksheets for meetings and tracking
- Training - Training sessions face-to-face, WebEx, and on-line.

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2012 – 2014 Committee Centric

- Recognizing the challenges for individuals of a different than scientific background to engage in scientific discussions, in 2013 a review of the current situation resulted in the creation of a Lay Representative agenda aimed at identifying opportunities and creating tools to enhance Lay Representative involvement.
- The role transitioned from one of passive attendance to collaborative participation.

Evolution of the Lay Rep Role in CCTG

The Lay Rep Team Committee Representation

1. Brain - Robin Fried
2. Breast - Janice Hodgson, Bob Taylor
3. GI - Marie Terese-Little, Lynne Bezanson
4. GU - Richard Wassenburg, Erwin Wanderer
5. Gyne - Martina Wood, Leslie Schroeder
6. Hematology - Aldo Del Col, Marg Redlick
7. H&N
8. Lung - Ron Climenhaga, Carol Gordon
9. Melanoma - David McMullen
10. Sarcoma
11. Symptom Control - Robin Fried

1. Quality of Life/ Survivorship - David McMullen
2. Economic Analysis – Cathy Rippin-Sisler
3. CSTB - Joan Petrie

Scientific Committees

- Disease Sites
- IND Program
  Carol Gordon
- Endpoint Committees

Oversight Committees

- Clinical Trials
  Chair + 1 Rep Rotating
- Data Safety Monitoring
  Ron Climenhaga/Judy N.
- Strategic Executive Advisory
  Judy Needham

Support Committees

- CRA
- Pharmacy
- Auditing Monitoring
- Lay/Patient
- Centre Representative
- RTQA

> 80 member sites and 2,100 Investigators

Operations and Statistics Centre at Queen's (100 Staff & 12 Faculty)

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Evolution of the Lay Rep Role in CCTG

The Lay Rep Team

Geographic Representation

A strong, Pan-Canadian, collective patient voice,
a unique asset to CCTG

"our voice is different than your voice" Patrick Sullivan, Ac2orn

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Evolution of the Lay Rep Role in CCTG

Skill Set Representation

Primary Cancer Survivors or Caregivers, plus

- Accounting
- Auditing
- Business Administration
- Education
- Engineering
- Health Information Management
- Marketing
- Medical Services
- Medical Industry
- Project Management
- Provincial Government Roles
- Real Estate & Property Management
- Research
- Research Translation and Communications

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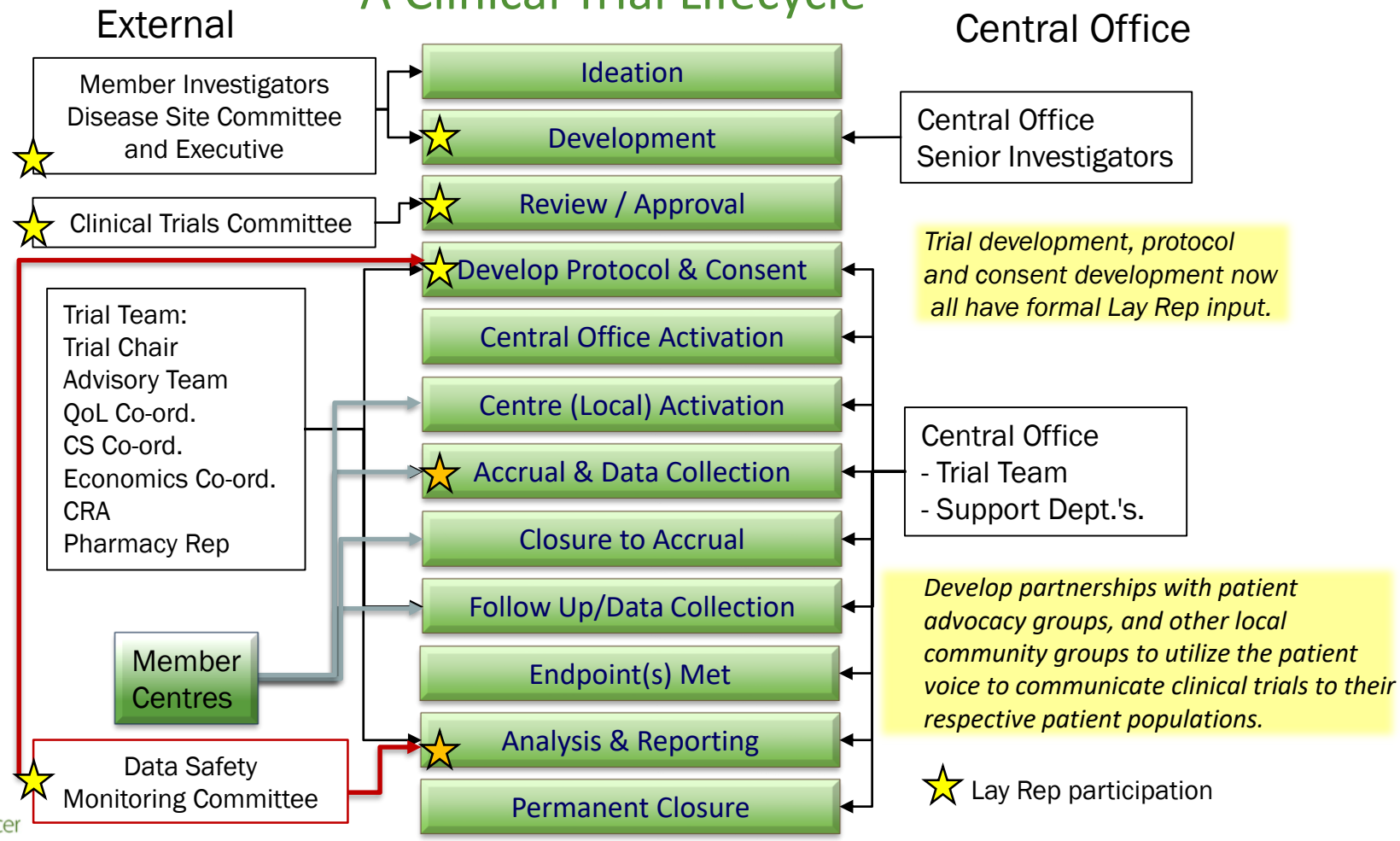
2015 – 16 Product Centric

- An external eco-system analysis of PPI in other countries resulted in identification of opportunities to add yet more depth to the role, and further influence clinical trial results by involvement in the processes to identify, prioritize, design, conduct (accrue), and disseminate results of trials conducted by CCTG.
- The role is now moving from participatory to full engagement as a strategic enabler to the delivery of CCTG trials.

A Clinical Trial Lifecycle



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2016 – 17 Patient Centric

Meeting Centric

+

Committee Centric

+

Product Centric

=

Patient Centred Research

Canadian Cancer Trials Group

Results of Patient Engagement in CCTG

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Increasing Awareness of Clinical Trials in Canada

✓ Canada-wide survey for women with gyne cancers to gauge their awareness of and experience with clinical trials – Mary Manojlovich

Gyne Patients Clinical Trials Awareness Survey	Respondents	
	English	French
Q #12 - Did your doctor ask you about participating in a clinical trial?	107	71
Yes	43.0%	46.5%
No	**57.0%**	**53.5%**
Q #13 - Was a trial available for you to participate in?	108	71
Yes	32.4%	38.0%
No	24.1%	15.5%
Don't know	**43.5%**	**46.5%**
Q #15 - Would you have liked the opportunity to participate in a clinical trial?	70	42
Yes	**87.1%**	**61.9%**
No	12.9%	38.1%
Question #27 - Overall, are you happy with your decision to participate in a clinical trial?	24	22
Yes	**100.0%**	**95.5%**
No	0.0%	4.5%

Results of Patient Engagement in CCTG

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Increasing Awareness of Clinical Trials in Canada (cont'd.)

- ✓ Trial specific awareness publications (i.e. British Columbia Cancer Foundation Newsletter) aimed at influencing accrual to specific trials – Marie-Terese Little, Pauline Lai
- ✓ Partnering with Patient Advocacy Groups with patient friendly publications aimed at influencing accrual (i.e. Colorectal Cancer Canada) – Judy Needham

Influencing Industry

- ✓ Utilized the collective patient voice to successfully appeal and reverse an Industry decision to terminate drug supply for a trial.

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Influencing the Research Question

- ✓ PR 19 – A Randomized Phase II Trial Evaluating High Dose Rate Brachytherapy and Low Dose Rate Brachytherapy as Monotherapy in Localized Prostate Cancer
  - Changed the protocol to include Quality of Life (QOL) of the patient **and their spouse/partner;** Richard Wassersug, Lay Representative on the GU Committee
- ✓ Breast Disease Site Dream Team – Janice Hodgson, Lay Representative on the Breast Disease Site Committee
- ✓ Increased Patient Centred Research within all Disease Site Committees through formalized input into protocol and consent development in the Clinical Trial Lifecycle; updated template for new trial proposals to include accrual plans and lay summary.

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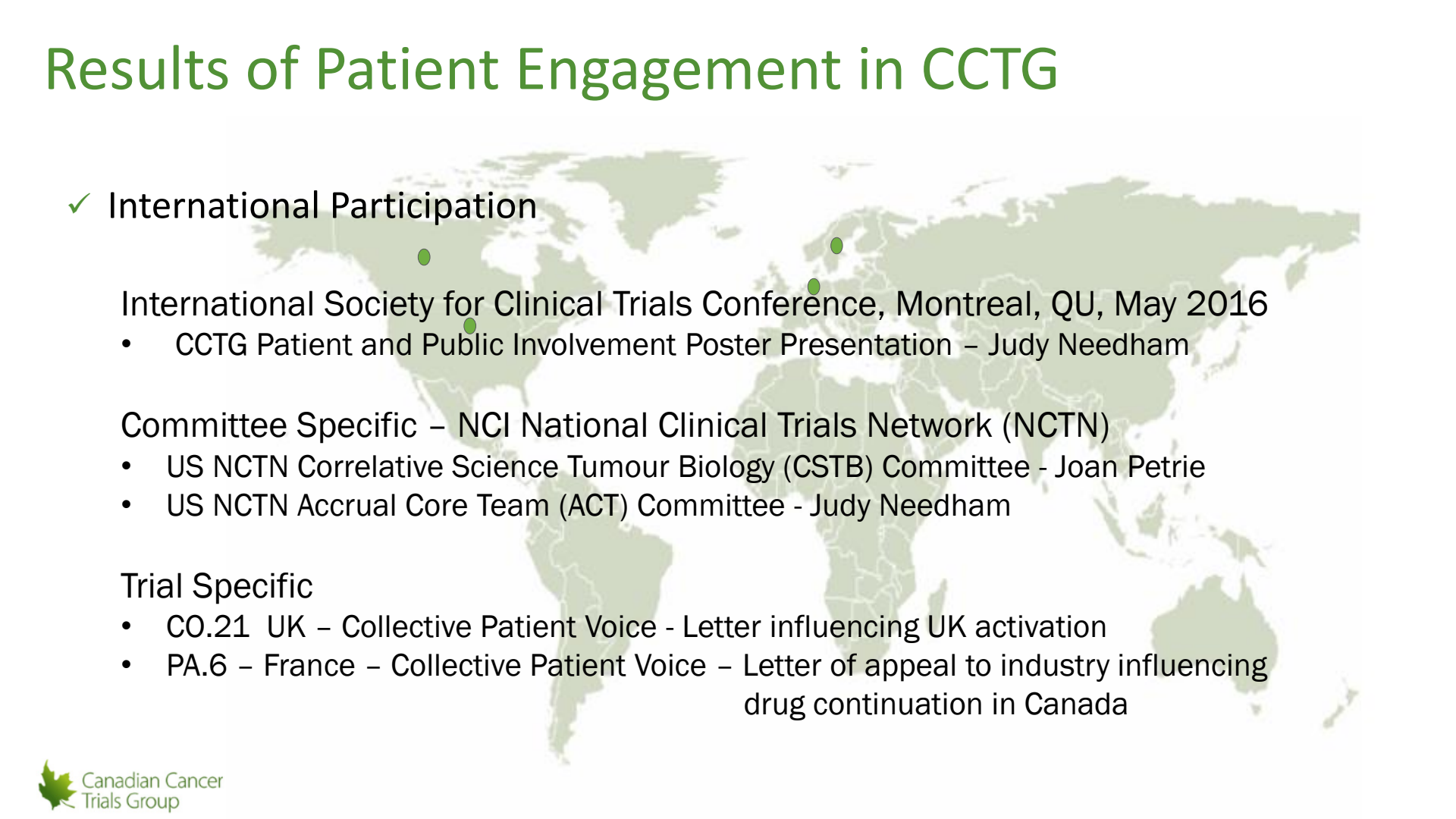
Influencing New Trial in the Pipeline

✓ MYX.1 – A Phase II Study of High-Dose Weekly Carfilzomib plus Cyclophosphamide and Dexamethasone in the Treatment of Relapsed Multiple Myeloma; coordinated through Mr. Aldo Del Col, CCTG Lay Representative on the Hematology Site Committee and Chief Scientific Advisor of Myeloma Canada.

Sharing Best Practices

✓ Shared CCTG best practices and materials, and provided assistance in developing processes, manuals and tools through strong collaborations with Canadian Cancer Society (CCS), Canadian Cancer Clinical Trials Network (3CTN), Network of Networks (N2), Canadian Cancer Action Network (CCAN), Clinical Trials Transformation Initiative, Duke University (CTTI).

Results of Patient Engagement in CCTG



✓ International Participation

International Society for Clinical Trials Conference, Montreal, QU, May 2016

- CCTG Patient and Public Involvement Poster Presentation – Judy Needham

Committee Specific – NCI National Clinical Trials Network (NCTN)

- US NCTN Correlative Science Tumour Biology (CSTB) Committee - Joan Petrie
- US NCTN Accrual Core Team (ACT) Committee - Judy Needham

Trial Specific

- CO.21 UK – Collective Patient Voice - Letter influencing UK activation
- PA.6 – France – Collective Patient Voice – Letter of appeal to industry influencing drug continuation in Canada

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Publications

- ✓ "Whose Tissue is it Anyway?" NCIC CTG Lay Reps response to CMAJ, 2013 – Joan Petrie
- ✓ Needham J, Nomikos D, Stanton H. Integrating Patient/Public Involvement in the Canadian Cancer Trials Group. Poster Presentation, Society for Clinical Trials 37th Annual Meeting, May 15-18, 2016, Montreal, QC
- ✓ Needham J, Nomikos D, Stanton H, The Canadian Cancer Trials Group Lay Representative Committee. Poster Presentation, CCS, November 2016

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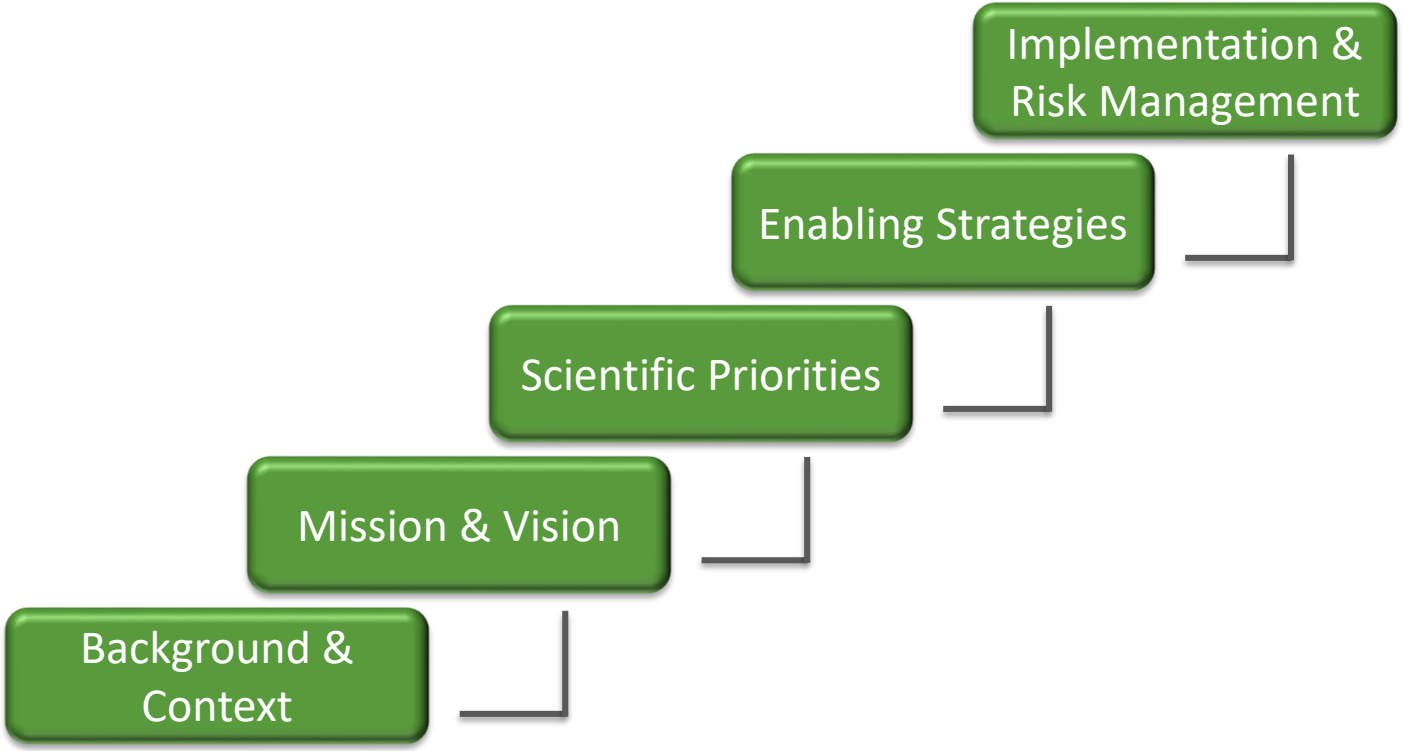
How does this model fit into the Canadian Cancer Trials Group 2016 - 21 Strategic Plan?

Components of the Strategic Plan



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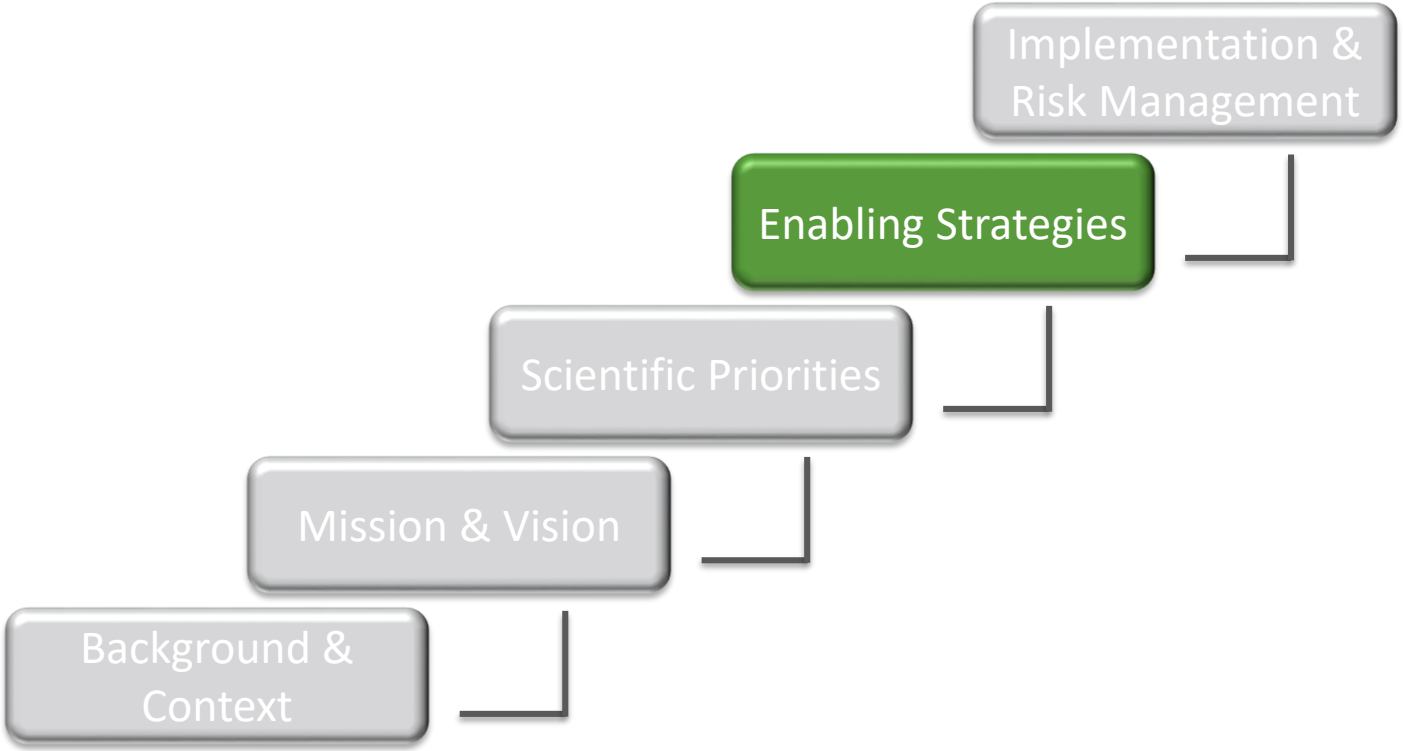

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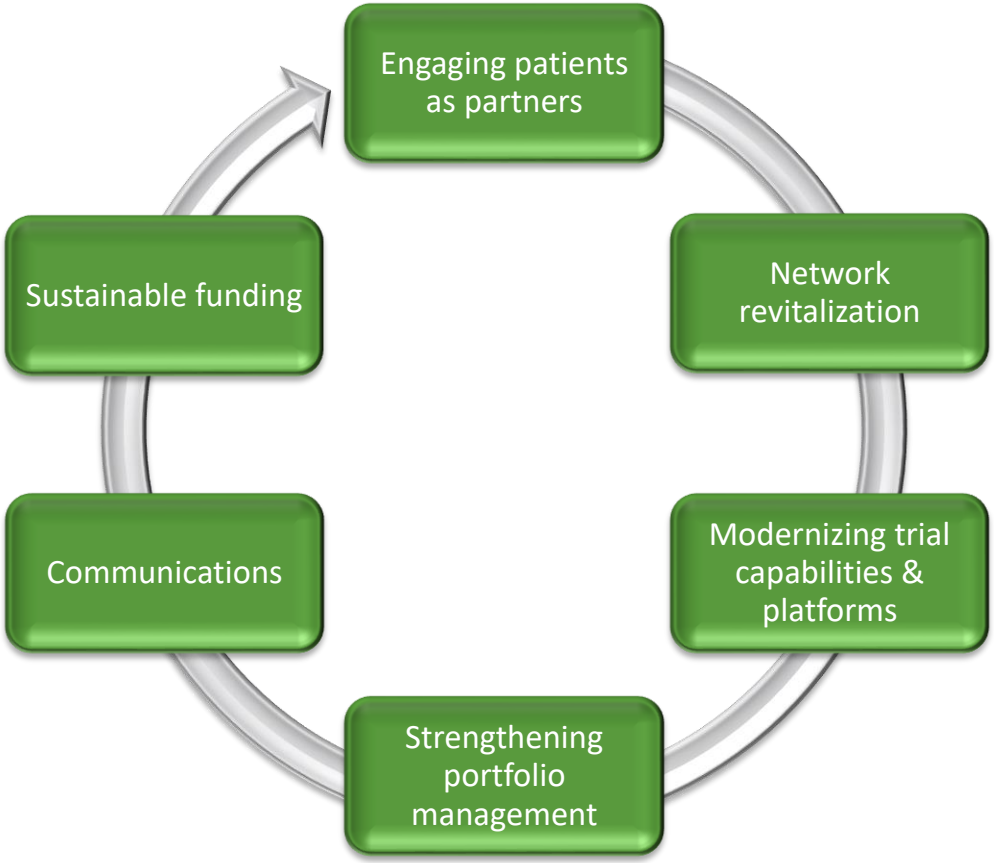
Enabling Strategies



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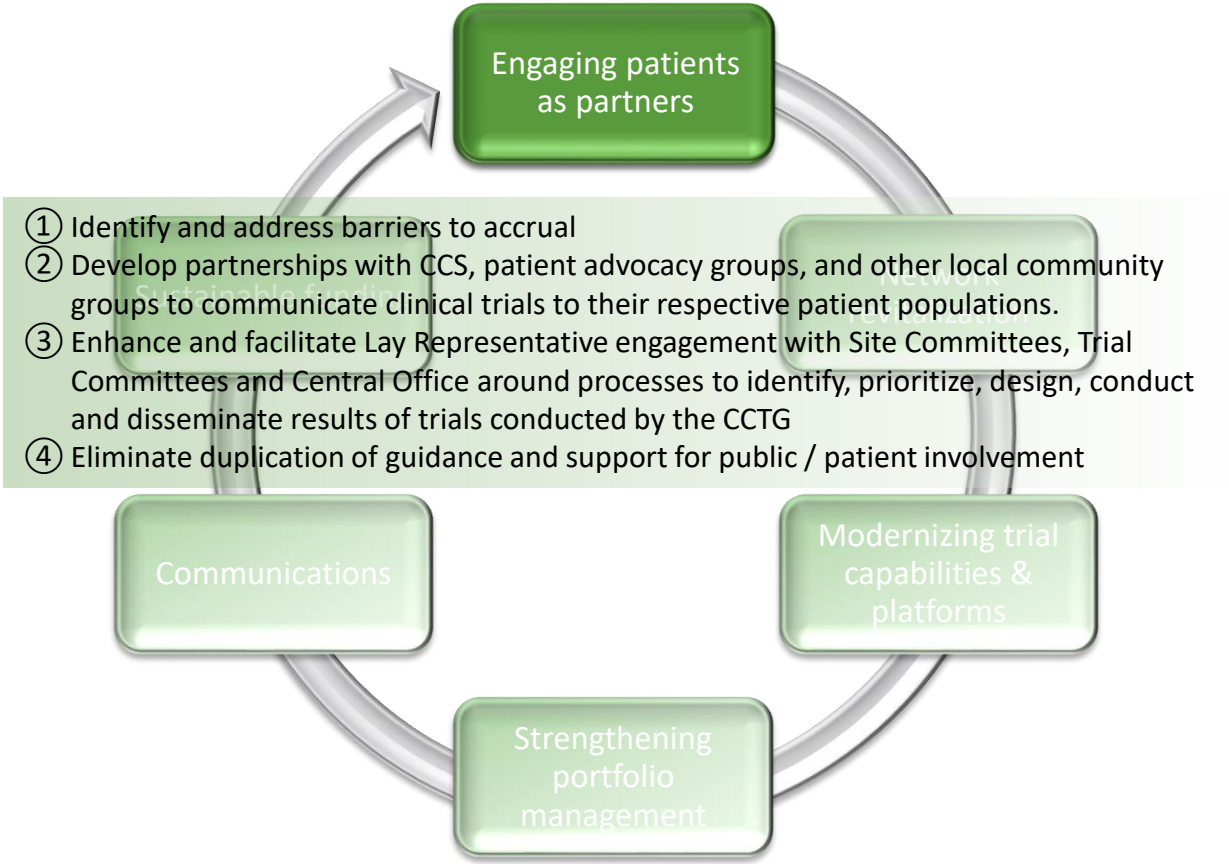

Canadian Cancer Trials Group

What Does This Mean to You?

- An opportunity to utilize and include the patient perspective in formulating patient centred outcomes right from the time a trial is an idea.
  - In formulating the research question
    - marrying patient centred outcomes with disease centred outcomes.
  - In developing the trial design, it's protocol, consent, and accrual materials
    - helping formulate the materials to be appealing to patients
- An opportunity to capitalize on a strong patient body presenting
  - diversity in expertise (knowledge brokers),
  - voices of communities across Canada (Pan-Canadian representation),
  - a collective patient voice to influence accrual, industry, governments.
- Challenges
  - Recognizing and addressing barriers to inclusion of public engagement

Thank You!

Looking forward to working together.

Questions?