



Canadian
Cancer Clinical
Trials Network

Network of Networks (N2)



DEVELOPMENTS IN THE CLINICAL TRIALS ENVIRONMENT

Two Initiatives

February 27, 2014

Karen Arts,

Director Canadian Cancer Clinical Trial Network (3CTN)

Chair of the Board of N2



Objectives

Update on 2 National Initiatives

- Network of Networks (N2)
- Canadian Cancer Clinical Trials Network (3CTN)



Common Challenges

- Are we all “Special” ? Do we all need our own version of everything
- How to create efficiencies and streamline process?
 - Requires collaboration across Canada,
 - across stakeholders and
 - across therapeutic areas
- Can we establish a framework that allows us to work towards networking and collaboration?
- Can we speak with one voice, to advocate for clinical research?
- It makes sense to collaborate and to work towards common practices, solutions, and harmonization where possible.





What is N2?

- A national alliance of clinical research stakeholders with common interests
- Established as Not-For-Profit in 2007
- **Not new**, instead an aligning of common ground, across many parties and stakeholders
- N2 is in a unique position and able to tackle national challenges while leveraging regional/provincial initiative
- Common challenges identified, leads to discussions, consensus and solutions
- Five year Strategic Plan





“We are all N2”

- ~70 Organizations and growing
- Universities and Colleges
- Disease Networks
- Institutions:
 - Research Site Administration, e.g. VP Research
 - Investigators/Researchers
 - Clinical Research Nurses
 - Research Coordinators and other Site Personnel
- Community researchers
- Pharmaceutical Industry
- Government
- Patient and Consumer Interest Groups
- Alliance with other groups (e.g. CTTI, Summit, 3CTN, ISCT, CTRNet, ACAHO, CAURA etc)





Strategic Initiatives

- Equip clinical research professionals with the necessary tools and programs to conduct high quality research with integrity, efficiency, and continuous quality improvement
- Develop a sustainability plan for N2; seeking and securing sufficient funding and resources to enable N2 to implement the strategic plan
- Act as a national voice, advocating for issues affecting or influencing clinical research in Canada
- Leverage the national alliance, bridging and coordinating regional and provincial initiatives



Relevance of N2, now more than ever

- Rising Costs of Development & Pressure on R&D budgets, More complex research and regulatory environment, Competitive environment, loss of opportunity, More education, support and resources needed
- **Examples common issues:**
 - Rising cost and deficits
 - Patient Recruitment issues
 - Inefficient processes
 - Lengthy delays to start up trials
 - Lack of metrics
 - Lack of formal uniform, nationwide standards and research best practices
 - HC findings: inadequate processes and systems, education and SOPs
 - Inadequate research support from government and institutions
 - Silos; “we are special” phenomenon
- **Common solutions: N2:**
 - Network, one voice
 - Patient Recruitment strategy, portal and materials
 - Harmonize, educate, streamline, leverage (contracts, budgets, tools, ethics, recruitment etc)
 - Metrics initiative
 - SOPs, Education, Quality HRP program
 - Quality Initiatives
 - Collaborate with others
 - Initiative to Streamline Clinical Trials, ACAHO, CAREB, CTRNet, Provincial Groups etc.



Examples Alignment – CT summit Strategy

Strategy 1: Establish short & longer term implementation capacity for this action plan & coordination of other CT improvement activities		Strategy 2: Improve business operations through better cost, quality, and speed of clinical trial start up times.		Strategy 3: Shape a positive future business environment & signal Canada's interest globally with information & incentives.	
Recommendation	Details	Recommendation	Details	Recommendation	Details
Recommendation 1. Establish an implementation headquarters & resources to implement action plan & to coordinate existing clinical trial improvement activity.	Coordination & implementation focus & resource are required for this plan as is coordination of existing CT initiatives. CIHR SPOR leadership to be approached.	Recommendation 4. Improve efficiencies of ethics reviews- common forms and metrics and advance strategic considerations like accreditation & harmonization.	Leveraging appropriate expertise, common consent & ethics application forms will be developed to reduce confusion and cost. It will begin with feasibility & option assessment. Strategic issues like accreditation also require detailing.	Recommendation 8. Optimize intellectual property protection policy & SR&ED Tax Credits	We can improve the attractiveness of Canada as an investment partner by adjusting IP and SR&ED policy.
Recommendation 2. Measure, monitor, manage and market CT performance improvements	As the intent of the plan is to attract business, results need to be measured & communicated.	Recommendation 5. Develop a database of registries to identify eligible patients & consider national recruitment strategy.	Using appropriate privacy considerations, improve recruitment by focussing on the use of registries & a national recruitment strategy.	Recommendation 9. Signal our interest globally - open a concierge (storefront) service for investors	Beginning on a small scale, communicate CT assets & improvements to global companies. Consider concierge or storefront for investors.
Recommendation 3. Integrate health system and research infrastructure to address issues which affect CTs because of the impact on research and healthcare.	A bold long term vision is needed for issues impacting health care & research & thereby CTs. This will enable cost containment considerations and sustainability.	Recommendation 6. Adopt common SOPs, training and certification that are already available.	Resources will be sought for broader use of N2's common SOPs, training & certification to increase trust & efficiency.		
		Recommendation 7. Improve and use the model clinical trials contract (mCTA)	Upon pilot completion, adjust the mCTA as needed & communicate use to global offices.		



Examples Alignment – 3CTN

Working Group	Objective	Activity	Timeline
Business Practices	Performance - Initiation	3CTN tools for streamlining trial initiation, feasibility and workload assessments	Immediate
		Disseminate ISCT recommendations	Short term
		Standard of care costing initiative	Long term
Best Clinical Trial Practices	Performance, quality - Regulatory compliance	N2 SOPs or equivalent at all sites	Immediate
		Education & Training required by HC and TCPS	Immediate
		3CTN will collaborate with existing ethics streamlining initiatives	Short term
Information Technology	Performance - Ethics	3CTN will assist with EDGE system roll-out	Immediate
	Performance, Quality	3CTN will assist with EDGE system roll-out	Immediate
Biospecimens and Imaging	Performance, Quality	SOPs for biospecimen and imaging	Immediate
		Checklist for equipment and resources for biospecimen handling at sites	Immediate
		Training and certification of staff by CTRNet	Short term
		Imaging activities will be developed in first 2 years	Short term
Research Priorities	Impact, sustainability	Economic and patient impact of clinical trials on health care system	Long term
		Innovation in clinical trials methods	Long term
Lay Representation	Impact, sustainability	Lay representation throughout 3CTN	Immediate
		Develop framework and role description	Immediate
		Collaborate with Canadian Cancer Action Network	Immediate





N2 ANNUAL MEETING

Members and other interested stakeholders will be gathering at the N2 Seventh Annual Meeting at the St. Andrew's Club,

**Toronto, Ontario
February 20-21**

A chance to network, hear updates on our Strategic Plan and Committee work and the introduction of our new Division 5 course. It's sure to be an informative and energizing two days.

COMING UP

Quality Committee Mtg:
March 20, 2014

CARE/N2 SOP Sub-
Committee Mtg:
April 9, 2014

Stakeholder Mtg:
May 26, 2014

N2

February 2014
**NETWORK OF NETWORKS
RÉSEAU DES RÉSEAUX**

2014 LOOKS LIKE A GREAT YEAR!

A Message from the Board of Directors

Happy New Year to all the members from your Board of Directors. 2014 promises to be an exciting and transformative year for N2. We will be operationalizing our strategic plan with our sub-committees having submitted plans aligned with our strategic priorities. Check out the plan at www.n2canada.ca. Other initiatives (Clinical Trial Summit, Canadian Cancer Clinical Trial Network), where N2 plays a pivotal role, will be hitting their stride this year and we anticipate working with these groups to meet our common objectives. The board has been working hard as we comply with the new not-for-profit regulations. Thank you to Linda Bennett for guiding us through this process. We also want to thank all our members for the work they continue to do. N2 is a grass roots organization and our success rests on the shoulders of our members, committee chairs and committee members. We are looking forward to seeing many of you at our Annual General Meeting in Toronto as we chart our way forward for this year.



N2 NETWORKS CONTINUE TO GROW

The popularity of the Network of Networks continues to increase as researchers discover the value of engagement. N2 now has

67 MEMBERS!

Among the newest to join our growing community are:

- CHU de Quebec: Hopital du Saint Sacrement
www.chudequebec.ca

- CSSS de Gatineau
www.csssgatineauqc.ca

Please help welcome our newcomers.

THE MISSION OF N2

To enable and enhance clinical research capability and capacity in Canada.

www.n2canada.ca





Canadian
Cancer Clinical
Trials Network

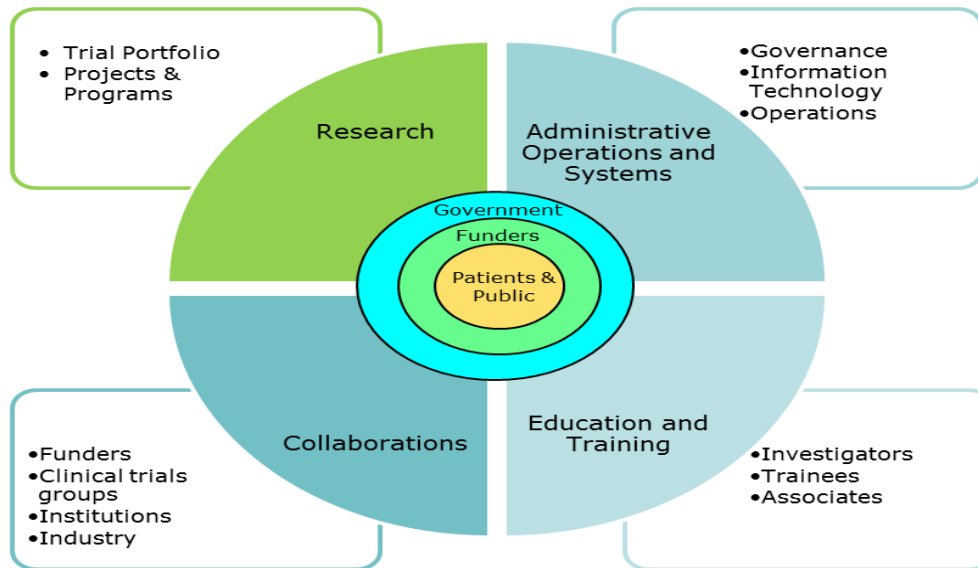
A Pan-Canadian Cancer Trial Initiative

Science Access Outcomes

February 18, 2014

Canadian Cancer Clinical Trial Network

Creation of a pan-Canadian program to strengthen academic-sponsored cancer clinical trials capacity to improve patient outcomes



3CTN Vision and Mission Statement

Vision:

Canadians with cancer and those at risk will have the best available cancer treatments through access to and efficient execution of academic cancer clinical trials.

Mission:

To support and improve the efficient delivery of clinical trial results that may change medical practice by addressing impediments to patient access and execution of academic cancer clinical trials through funding, resources and advocacy to improve the clinical trial environment.



3CTN Objectives

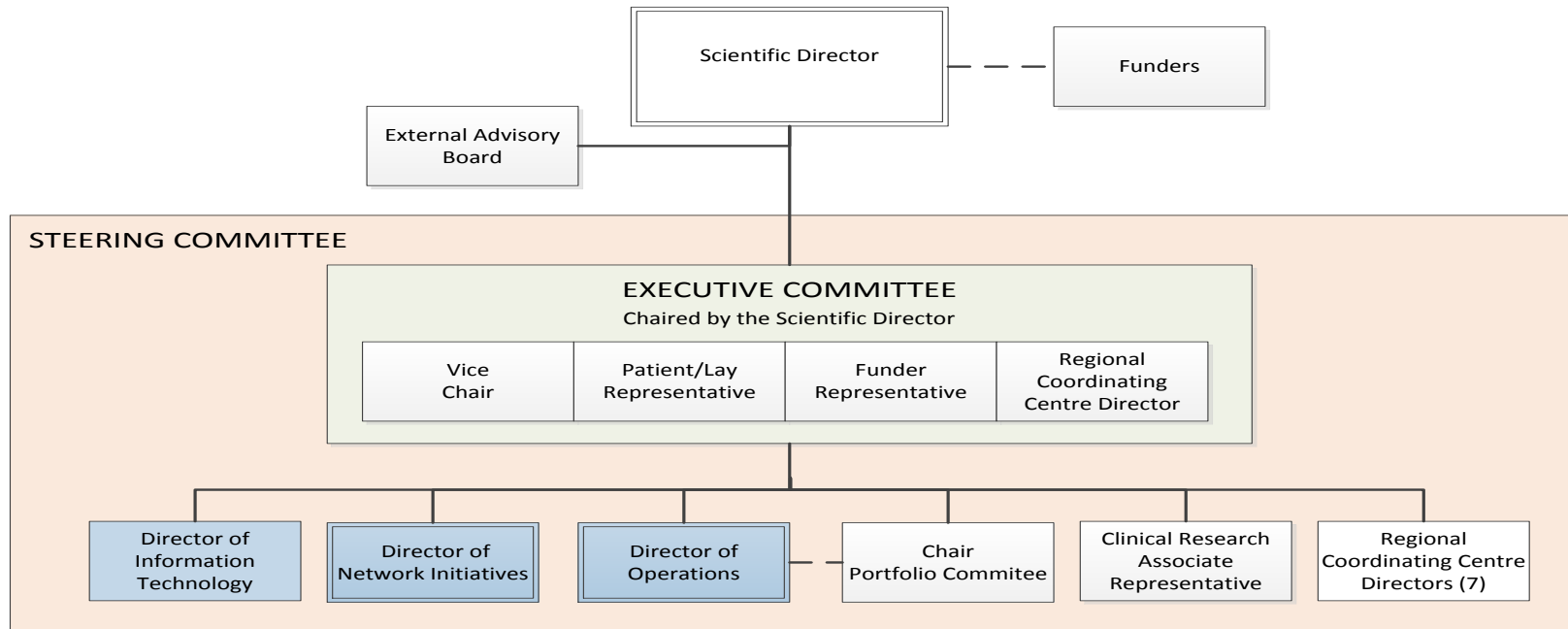
1. To improve patient access to academic clinical trials:
 - Improve adult patient recruitment by greater than 50% within 4 years and 100% within 6 years
 - Improve recruitment of pediatric patients
 - Improve the numbers of centres opening and recruiting to academic trials and the numbers of trials/centre
2. improve site performance of academic trials:
 - Improve trial initiation timelines
 - Improve trial forecasting and trial recruitment on target
 - Maintain 100% regulatory compliance
 - Improve biospecimen and imaging collection and management in trials



3CTN Objectives continued

3. To improve the trial environment for the conduct of academic clinical trials through collaboration and facilitation of important national trial initiatives:
 - Education and training of trial personnel;
 - Ethics streamlining;
 - Pathology collection for trials;
 - Privacy legislation and its impact on trials;
 - Standard of care definitions and costing models.
4. To demonstrate impact of the network and academic trials on the Canadian Health System:
 - Develop and maintain a portfolio of academic trials that will ensure the enthusiastic participation of the academic trialists and patients and impact patient care;
 - Support research on the costs and impact of academic clinical trials and the network and trial innovation.

3CTN Governance

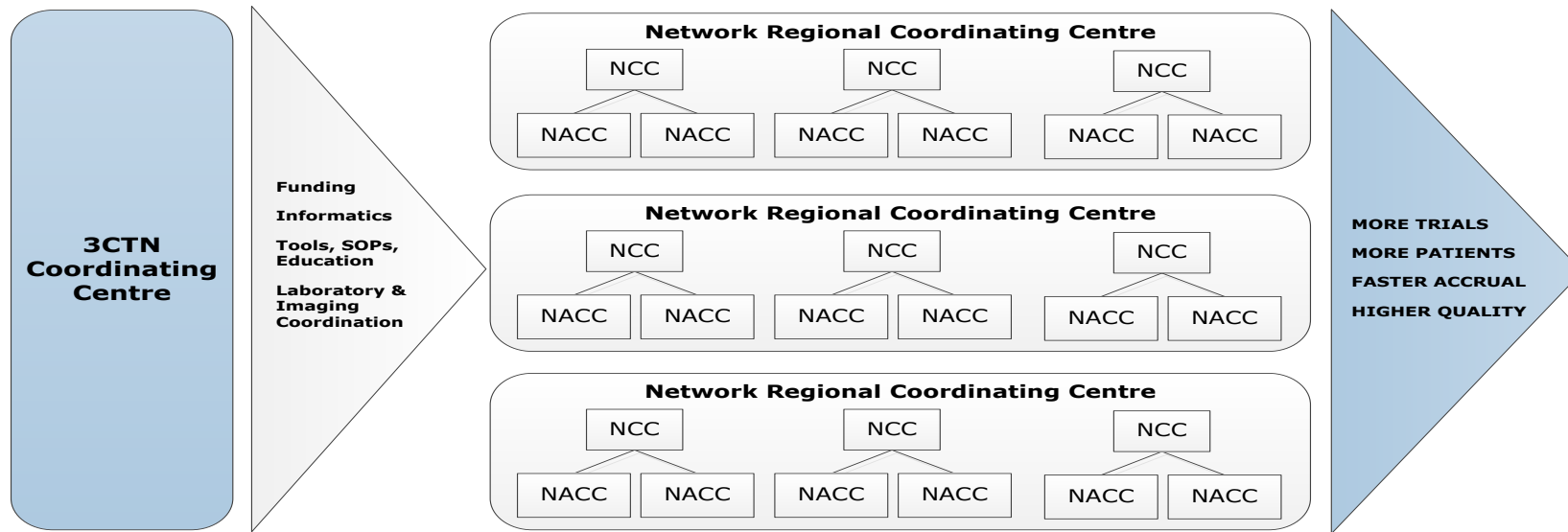


 Internal Operational Management

Strategic Teams

1. Strategic team for clinical trial and network performance
 - Responsible for evaluating network performance, identifying problems and proposing new initiatives, tools, education, training, and mentoring to improve the efficiency and quality of trial activities.
2. Strategic team for clinical trial and network impact
 - Responsible for special initiatives, research projects and review of outputs and outcomes that will demonstrate impact of the network on the academic trial environment, patients and health care system.
3. Strategic team for academic trial and network sustainability
 - Responsible for strategies that will enhance the long term sustainability of trials and the network. This includes engagement, advocacy, and partnerships.

3CTN Operational Structure



NRCC: Network Regional Coordinating Centre (~7)
NCC: Network Cancer Centre (~18)
NACC: Network Affiliated Cancer Centre

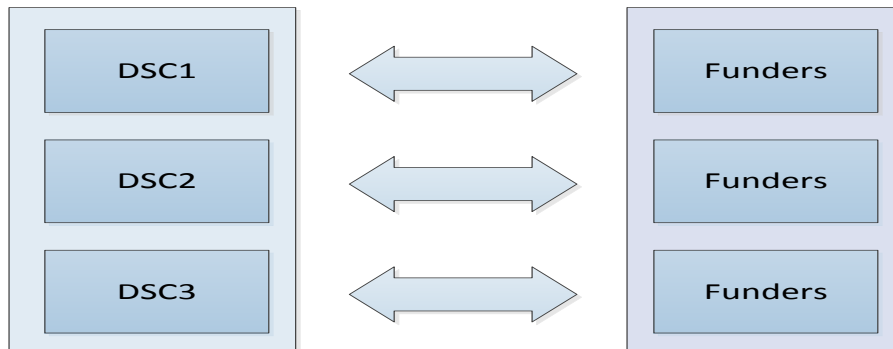
Network Clinical Trials Portfolio

- Portfolio of academic clinical trials reflecting the priorities of clinicians, researchers, patients, ministries of health and funders;
- Scientific Oversight:
 - Standing Portfolio Committee
 - Meet twice annually to review portfolio balance and performance;
 - Ad-hoc meetings to review potentially eligible trials;
- Operational Management:
 - Operational management provided by Coordinating Centre;
 - Activities include:
 - Review of initial Portfolio applications;
 - Posting eligible studies to www.3ctn.ca;
 - Communication to stakeholders;
 - Collection and review of Portfolio related metrics;
 - Creation of reports;
 - Administrative support to Portfolio Committee.

Network Clinical Trials Portfolio

DSC:

- Identify trial priorities, duplications, gaps
- Scientific advice
- Review proposals



Funders:

- Identify trial priorities
- Funding opportunities

Across disease sites,
expertise and resources.



Highest Network Priorities

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Phase 1 Update

- CCRA-RFA Award
- Establish the Steering Committee, Scientific Committees, Working Groups, and Advisors/champions and Internal infrastructure
- Extensive stakeholders consultations across Canada,
 - Funders, Regional meetings, Clinical trialists and opinion leaders, Clinical operational personnel, Regional stakeholders
- Expression of Interest (~50)
- First stakeholder meeting Nov 2014
- 2nd stakeholder meeting Feb 2014
- Finalize business plan Feb-March
- Final case due March 14, 2014
- Formalize funding of 36M/4 years
- Kick-off Phase 2: Implementation May 1, 2014 - March 31, 2018

Questions?

Director/3CTN Chair N2 Board of Directors

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