Earlier Access to Breakthrough Treatments for Patients: Coordination of Clinical Trials at the RCN

Mitali Ruths, Caroline Rousseau, Thierry Alcindor, Petr Kavan, Adrian Langleben, Wilson Miller

RCN Strategic Priority: Leading-Edge Treatments

Introduction

- A world-class cancer center offers patients earlier access to breakthrough treatments before they're widely available, typically through specialized access programs or clinical trials.
- One of the main reasons given by patients for not taking part in a clinical trial is that they didn't know the studies were an option for them. Fewer than 5% of adults with cancer will take part in a clinical trial, while 60% of children under age 15 do (Source: American Cancer Society). This is one reason that survival rates for childhood cancer have increased so dramatically in the last few decades.
- Since April 2015, as per the MSSS, all clinical trials must be reviewed by the ethics committee of each hospital, and not by an academic institution. The result is that for the Sponsor of the study, each RCN hospital is considered a different site, with site-specific contracts, budget, and a different PI at each. This is very limiting for the following reasons:

It promotes competition between the 3 hospitals for PI-ship when the Sponsor of the study is restricted to only a few Canadian centers.

It limits our ability to contribute to research publications as it is more difficult to have an impact in terms of patient recruitment (and thus research publications) since each site is on its own.

It promotes inequity in cancer care delivery since not all patients have the same opportunity to cutting-edge cancer treatments across the RCN.

It especially disadvantages the patients served by SMHC and its clinicians with research interest since they lack the regulatory support and patient volumes to attract trials on their own, but can contribute significantly to a clinical trials network.

From the viewpoint of a Sponsor, It increases clinical trial activation times if trials are to be initiated at 3 independent sites.

Improved coordination, dedicated resources, and collaboration between stakeholder are now, more than ever, necessary for the success clinical research activities across the RCN.

Clinical Trial Activities Across the RCN

- Multidisciplinary tumor site groups with trials on web site
- 1 2 Different clinical research groups within the network
- 43+ Unique trial sponsors
- 149+ Active clinical trials

Centre for Clinical Research Program Innovative Medicine Clinical Research Unit Breast (Thirwell) NRG NRG (NSABP, RTOG, COG) (NSABP, RTOG, COG) McGill Genitourinary Gynecology • Radiation therapy Multiple Myeloma Hepatobiliary **RCN** coordination mcgill.ca/rcr-rcn/clinical-trials Figure 1: Twelve different clinical research groups independently manage trials within the MUHC

and JGH. RCN consolidates clinical trial information from each manager. All active trials are

Short-term objectives (12 months)

openly accessible to patients and clinicians via the website.

Clinical Trial Contact Points

- Release first RCN Clinical Trials Metrics Report
- Map regulatory approval process to assist key stakeholders in opening clinical trials
- Expand RCN clinical trial website to include trials in melanoma and sarcoma
- Institute transfer plans by disease site group to support inter-institutional patient referral to best specialized therapy

Expected patient impact

- Earlier access to breakthrough treatments
- Greater patient self-management of care through information and education of clinical trial options (RCN clinical trials repository on the website)
- Improved clinical trial follow-up for inter-institutional transfers (no patients lost to follow-up)

Why Measure Clinical Trial Performance?

INTERNAL

- Identify areas for process improvements
- Provide data-driven rationale to leadership for resource allocation
- Distribute/manage workload across teams
- Establish performance benchmarks

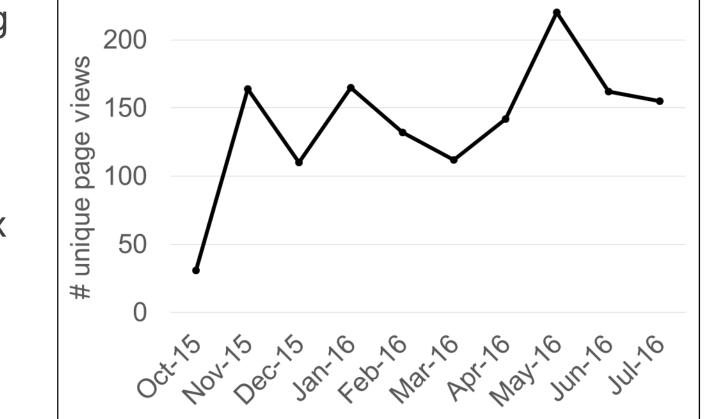
EXTERNAL

- Identify areas of competitive advantage
- Ability to complete site feasibility questionnaires with real data



Achievements to date

- Improved disease site group synergy, engagement, and communication
 - Monthly newsletter
 - Clinical research meeting



- RCN Clinical Trials website for six major disease sites listing active trials with study coordinator information
 - Figure 2: Use of RCN clinical trial website since inception Master list of all clinical trials – active, pending, and on hold with patient accrual numbers
 - Initial data for metrics collection
 - number of trials by disease site
 - trials opened per Pl
 - o trials opened per PI that reached target accrual]
 - patients recruited per MD
 - % patients enrolled per disease site
 - number of patients screened per disease site

Looking ahead: long-term objectives

- Clinical trials are available at all three network hospitals, with interinstitutional contracts
- Recruitment rates are comparable to world-class cancer centres
- Processes in place for patients to access to the most effective emerging treatment (clinical trial or other specialized access program) irrespective of the RCN hospital in which they are treated.

Acknowledgements

Natacha Albarracin, Penny Chipman, Adele Cascini, Linda Chin, Tasnim Daginawala, Sayeh Davoudi, Andrea Dumont, Sophie Lorenzo, Oleg Loutochin, Aline Mamo, Cathy Meany, Marianna Perna, Linda Robitaille, Nancy Renouf, Rajesh Sharma







