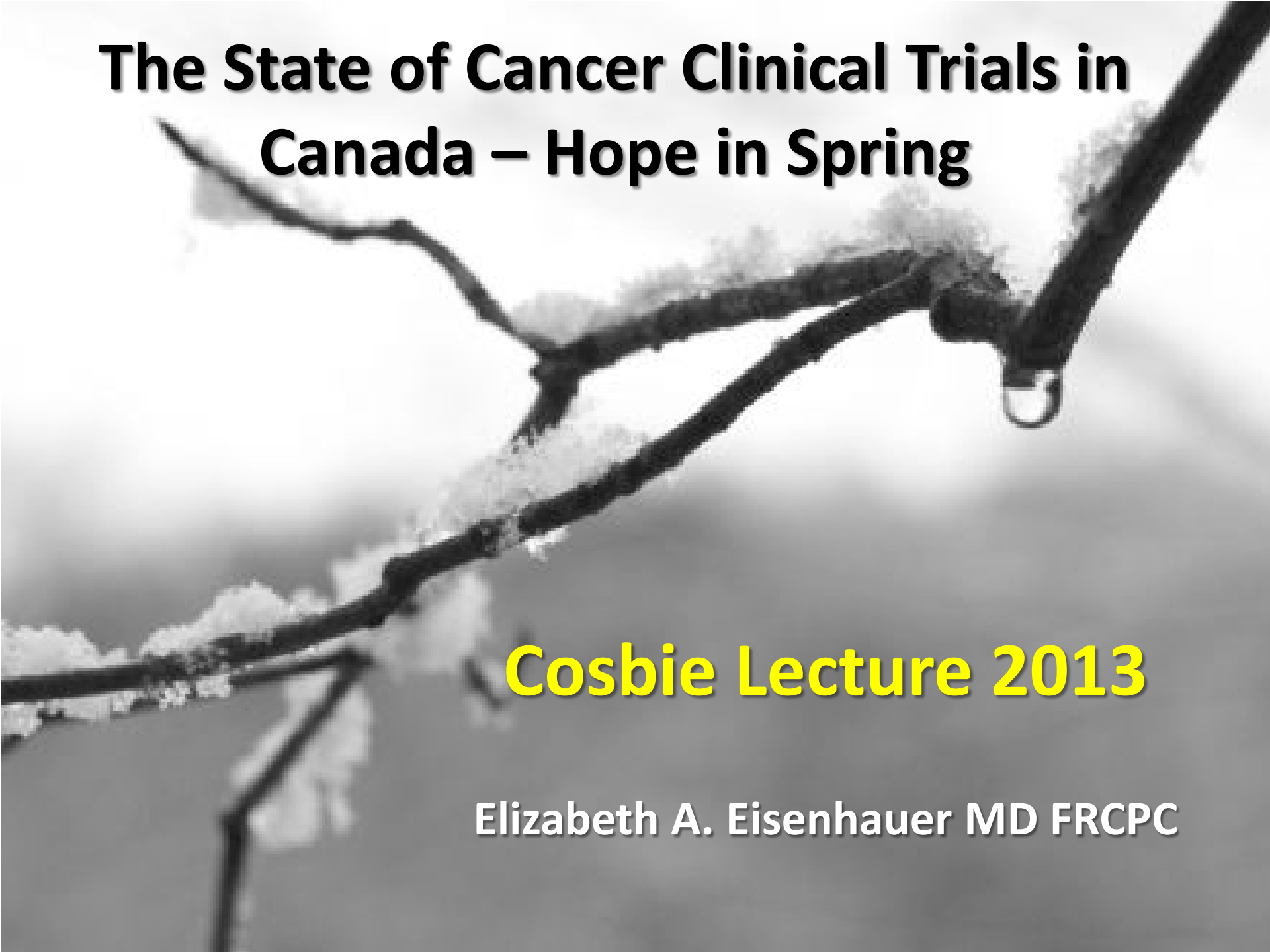
The State of Cancer Clinical Trials in Canada – Hope in Spring



Cosbie Lecture 2013

Elizabeth A. Eisenhauer MD FRCPC

Outline

- Background - the story behind today's topic
- Cancer Trials in Canada –
  - The CCRA report
  - The recommendations
- Implementing Recommendations
- Hope in Spring

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Background –

- **Canadian Cancer Research Alliance:**
  - Alliance of 33 government agencies and charities that together fund ~$530 M/yr cancer research in Canada (2010 investment report)
    - Co-chairs: E. Eisenhauer and C. Williams
    - Executive Office support:
      Canadian Partnership Against Cancer

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Background –

- **2009-10: CCRA developed first Pan-Canadian Cancer Research Strategy**
  - National consultations, surveys, key interviews and literature reviews led to 24 items for Action by CCRA collaborators
  - A recurring theme – “Cancer clinical trials in Canada are under threat”
  - **Action Item #11: Threat to Cancer Clinical Trials**

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Report and Make Recommendations on Cancer Clinical Trials In Canada

- Need for a national discussion on status of clinical trials in Canada.
- Canada's leadership role in clinical trials, particularly *academic/cooperative group trials* is under threat
- Critical to address this: Future clinical research derived from molecular science will demand novel approaches, designs, embedded translational questions and speed.

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CCRA Working Group Membership

Lead Agencies	**Canadian Cancer Society**	**Michael Wosnick**
		Ralph Meyer (NCIC CTG)
	CCRA Secretariat	**Stuart Edmonds**
		Elizabeth Eisenhauer
Partner Agencies	**Alberta Cancer Foundation**	**Barbara Hiscock (later Teresa Radwell)**
	BC Cancer Agency	**Kim Chi**
	Canadian Association of Provincial Cancer Agencies	**Heather Logan**
	Cancer Care Ontario	**Joseph Pater**
	Fonds de récherche de Québec - santé	**Anne-Marie Mes-Masson**
	Ontario Institute of Cancer Research	**Nicole Onetto**
		Janet Dancey
	Terry Fox Research Institute	**Vic Ling**
Consultant		**Greg Williams**

Working Group Primarily Focussed on *Academic/Cooperative Group Studies*

Pharma trials

- Ideas from pharmaceutical industry, may be shaped by clinical investigators
- Major goal: assess efficacy and safety to new drugs to allow approval by Health Canada, FDA etc.
- Sponsor: Pharma
- Data collected, analysed by Pharma

"Academic" Trials

- Ideas from clinical investigators and scientists: Cooperative Groups, or individual investigators
- Major goal: improve cancer outcomes
- Includes studies of new drugs, technologies, biomarkers, palliative care
- Funding: granting agencies, Pharma grants, other
- Sponsor: investigators
- Data collected, analysed by investigators

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Working Group (CTWG) Goals

- Obtain evidence to support (*or* refute) perception that the cancer clinical trial system is in jeopardy.
- Identify trends in the clinical research environment
- Survey approaches being undertaken in Canada and internationally which could be extrapolated to Canada
- Undertake a cost-benefit analysis of cancer clinical trials: what are the real costs and what are the benefits of having a robust and healthy clinical trials activity?
- Align with CIHR Strategy on Patient Oriented Research (SPOR)
- ***Make recommendations***

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Working Group Activity

- Accrual patterns in cooperative groups, BC, ON
- Trial complexity review: 28 NCIC CTG trial protocols and consent forms 1995-2000 (n=14) and 2005-2010 (n=14)
- Survey major clinical trials units in BC, AB, ON, QC
- Review trends in regulation and ethics review
- Literature review: costs and benefits of cancer clinical trials
- 35 key informant interviews (patients, investigator, administrator, funders, pharma and more)
- Review reform initiatives underway in the US, UK and EU supported by interviews
- Discussions with CIHR leadership of the SPOR initiative
- ***March 29, 2011: Stakeholder meeting to agree, refine recommendations***

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Findings and Trends:

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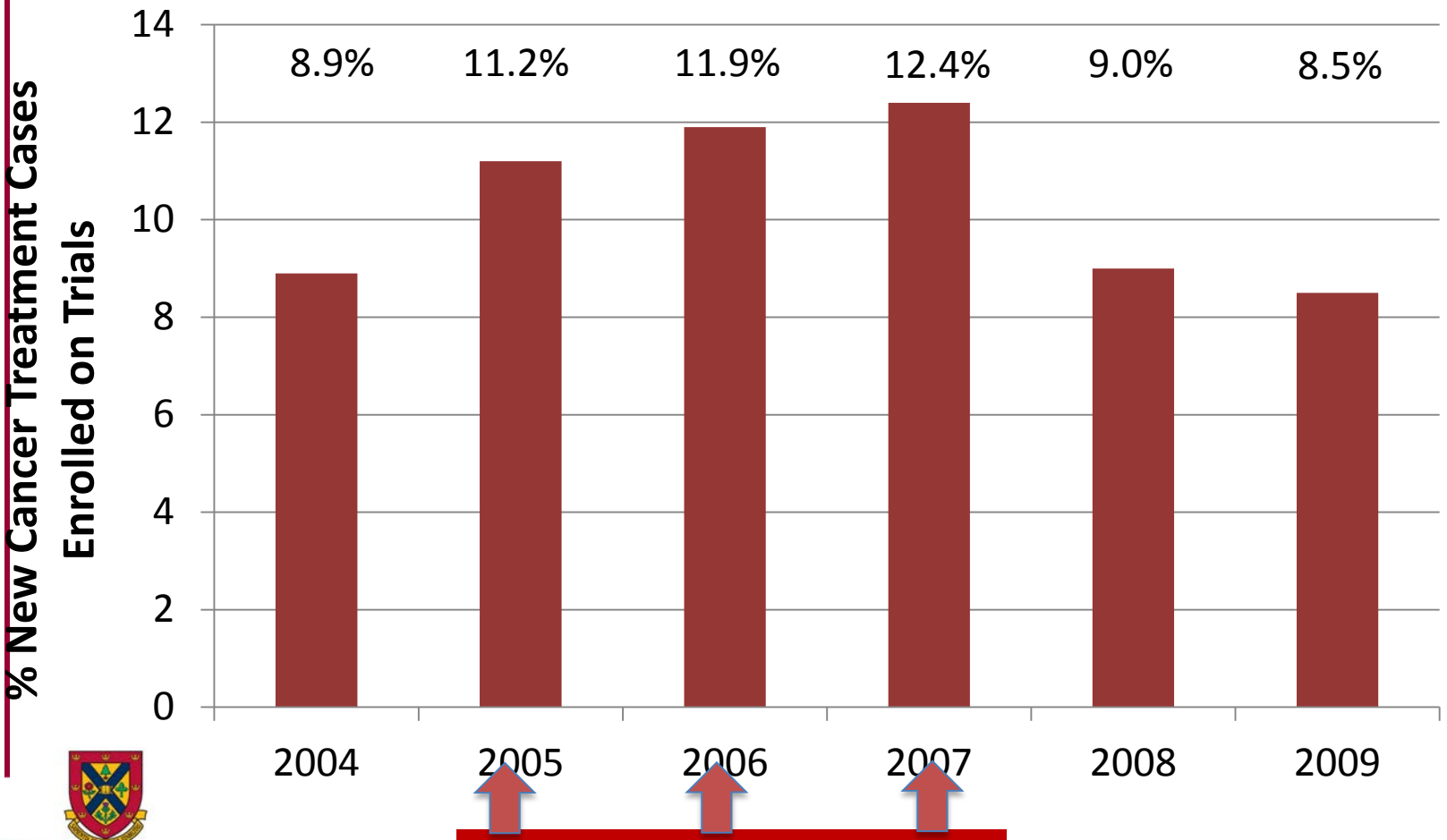
Ontario Population Based Data:

% Cases Enrolled on Clinical Trials falling



OICR Infrastructure Funding

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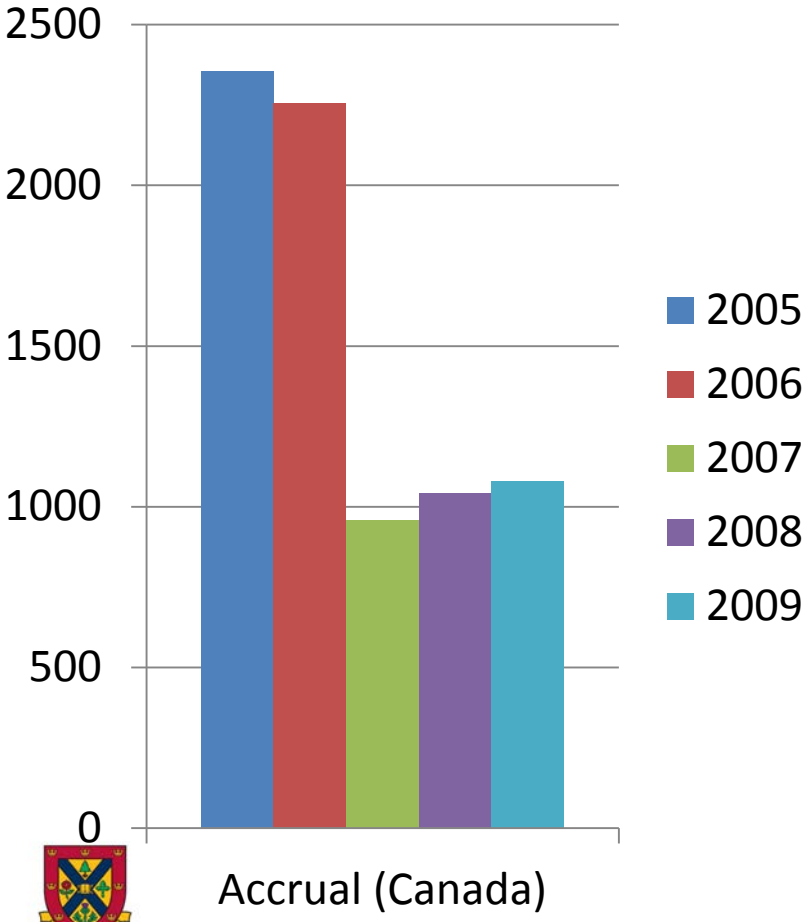
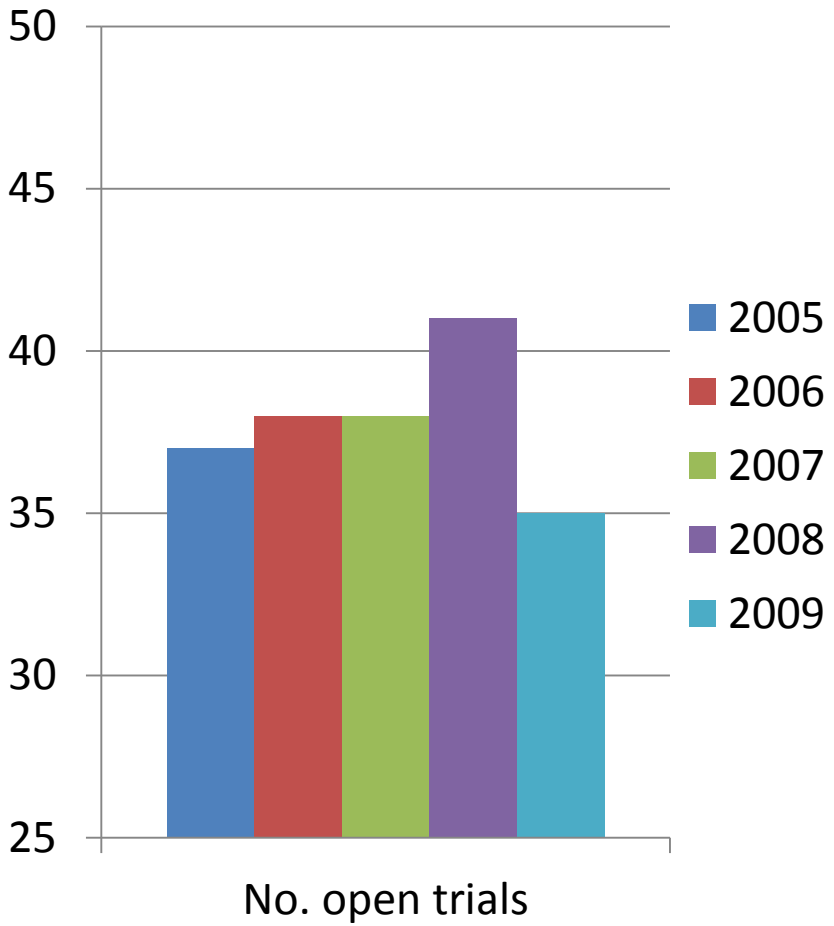
ACCRUAL– National academic trials (NCIC CTG)

(some likely related to closure of large adjuvant breast trial)





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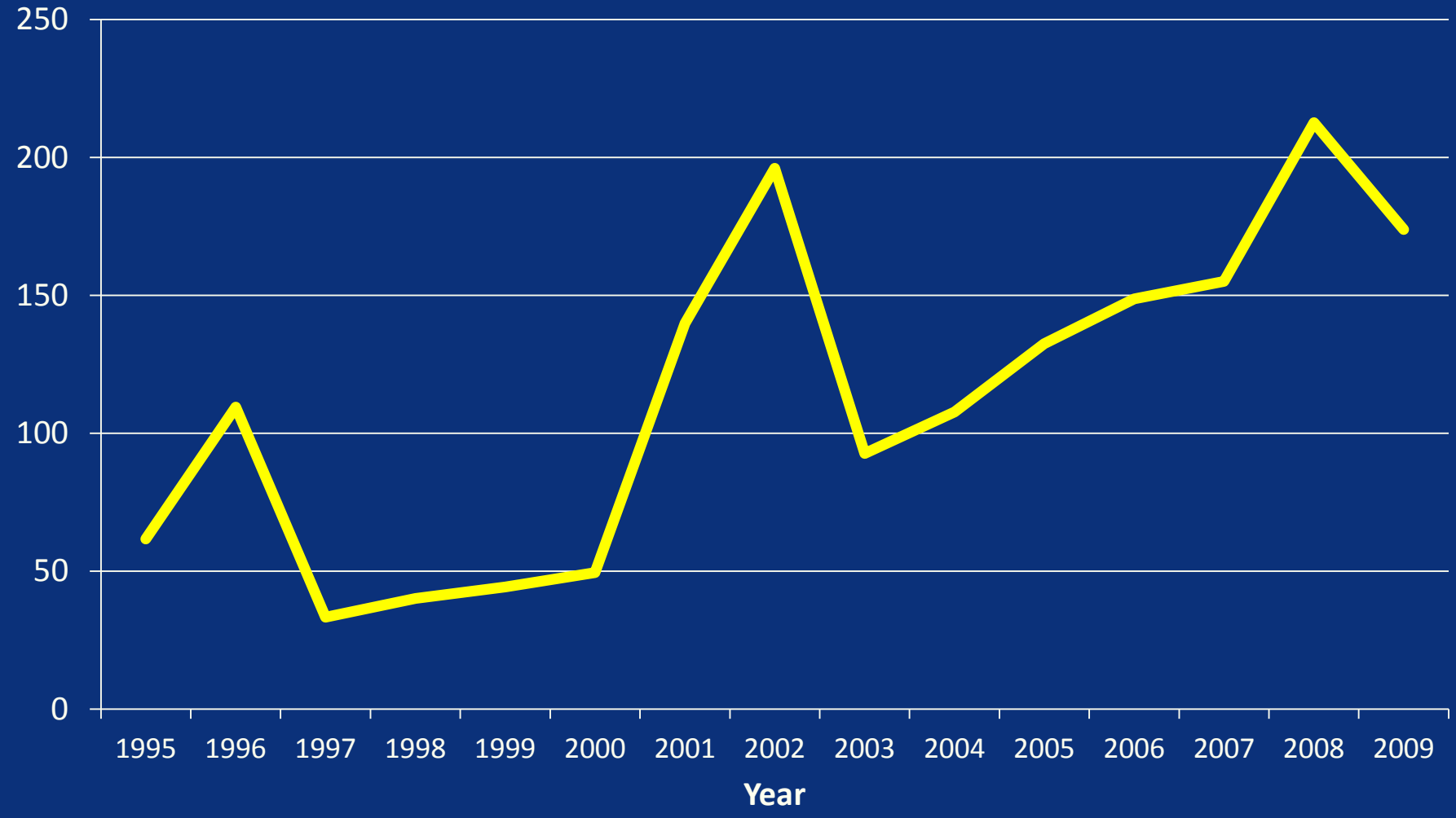
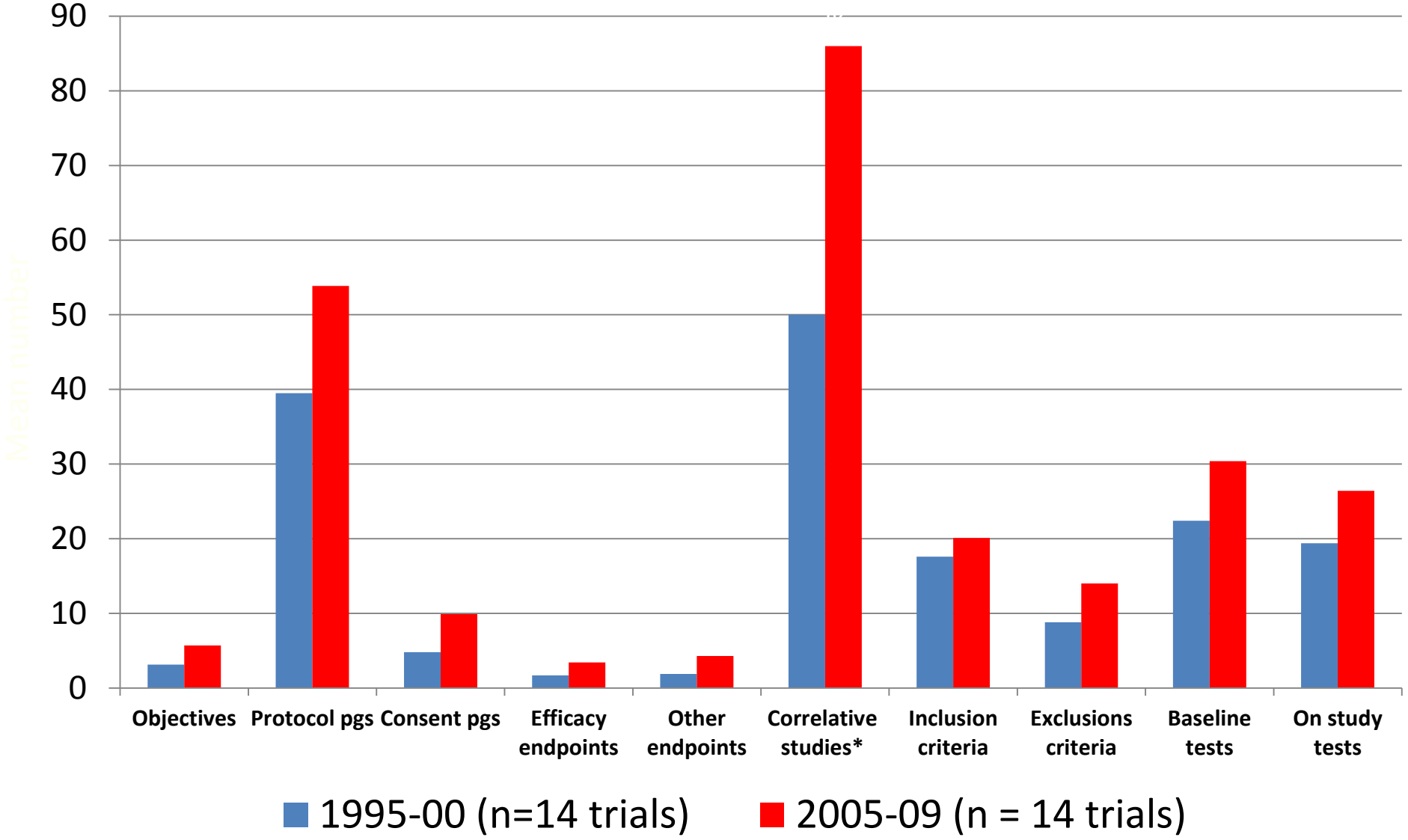
TRIAL ACTIVATION LONGER
(Academic trials - NCIC CTG Data)

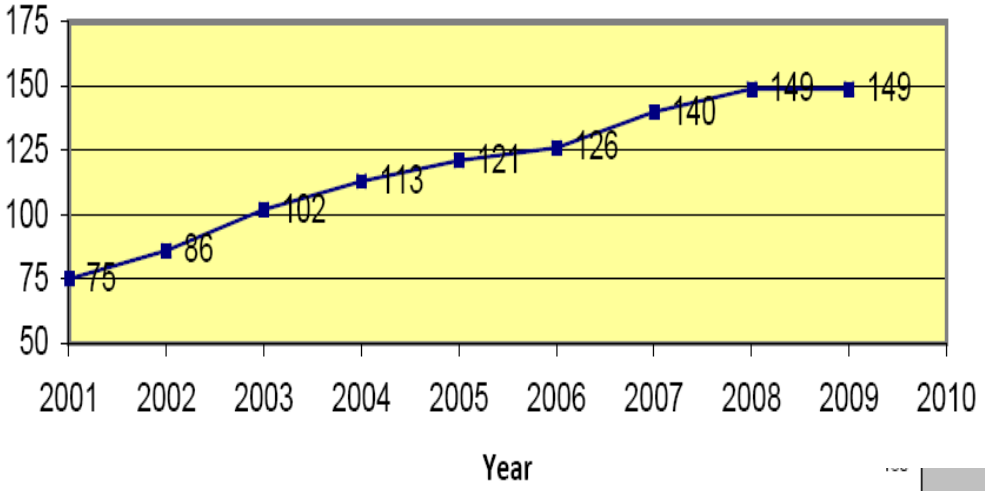
Average Time (Days) for
First Centre Activation 1995-2009



TRIAL COMPLEXITY INCREASING
NCIC CTG protocol metrics over last decade

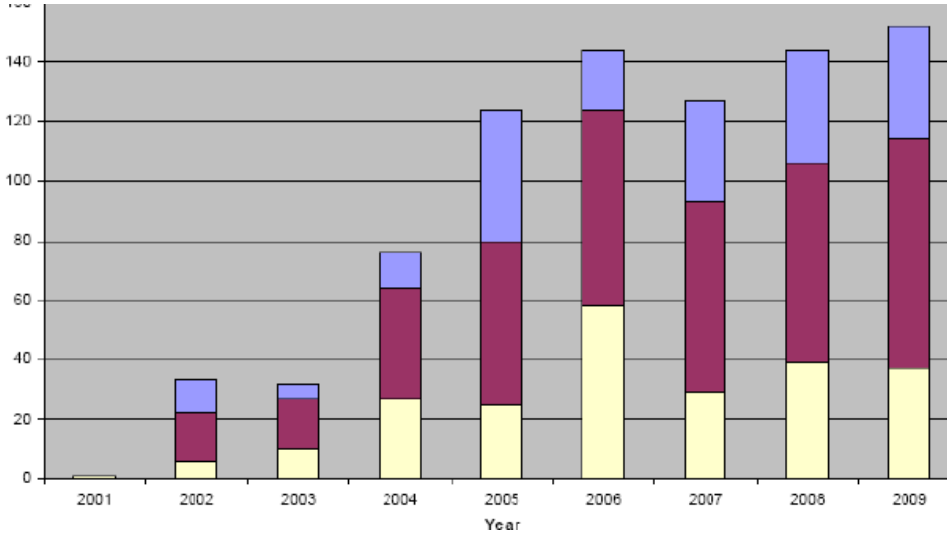


IMPACT of Food and Drug Regulations (2001): Workload/staffing ⬆for <u>same number of trials</u> (NCIC CTG data):

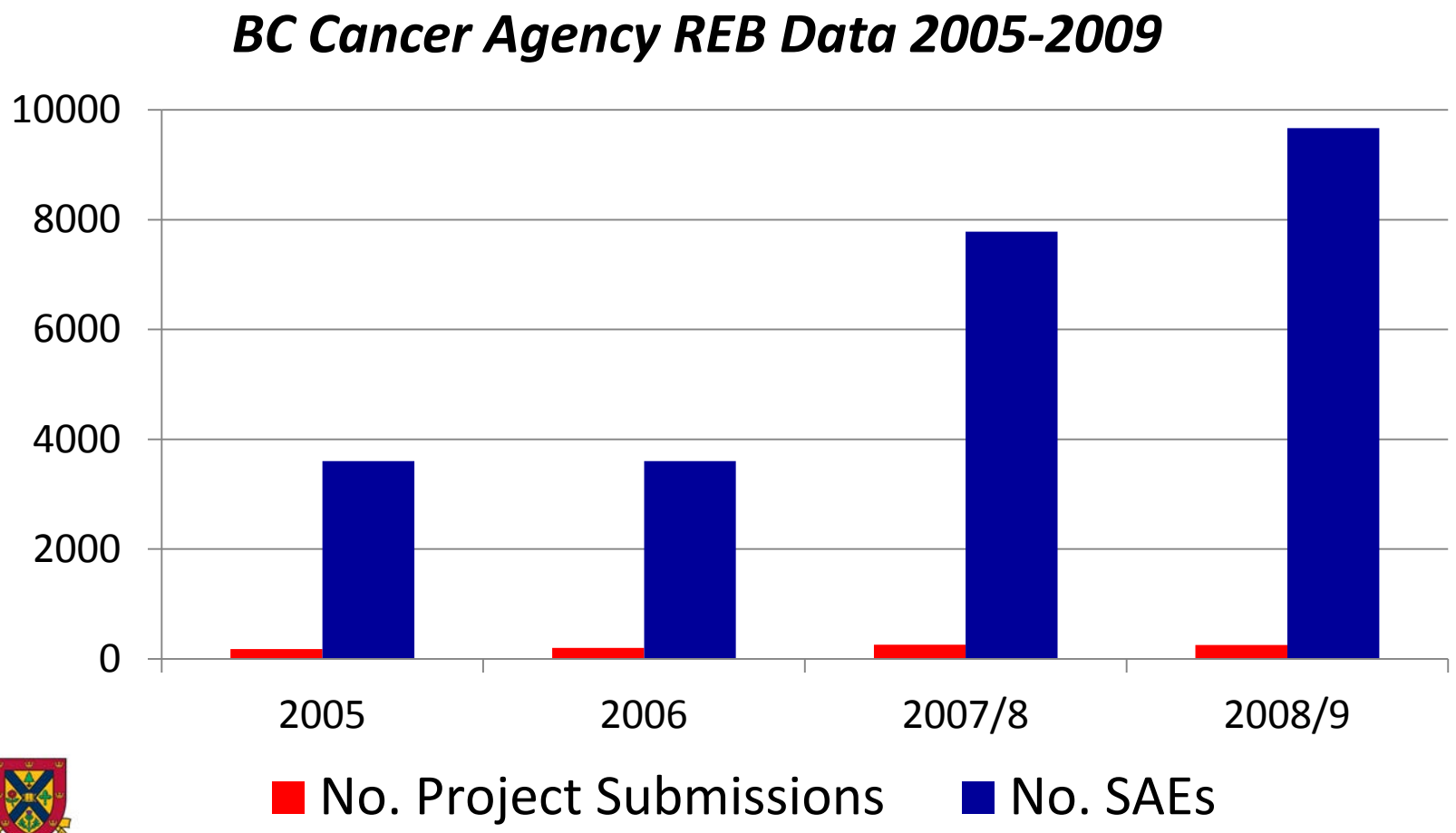


← Staffing changes

Amendments filed to Health Canada →



Health Canada regulations (2001) adding more work (amendments, monitoring, SAEs etc.)



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Findings and Trends:

Trial Infrastructure – in Cancer Centres

- Survey of major cancer centres (AB, BC, ON, QC)
- Key findings –trends over last decade:
  - Institutional support for clinical trial infrastructure (staff primarily) has **declined or disappeared**
  - No. of trials opened/year **same or slightly more**
  - No. pts accrued/year **stable or slightly less**
  - **No. staff about double**: work *per patient* ***increased***
  - **Cost recovery efforts** by institutions increased: Non-standard of care costs, flat fees for pharmacy, radiology, pathology etc.
  - ***Trial mix shifted from mainly cooperative group to mainly industry sponsored: $$ from industry main reason given***

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Summary of Findings in 2011: WE HAVE A PROBLEM

- Trial accrual declining (data not all consistent)
- Time to open/accrue to trials increasing
- Trial costs and complexity rising – 21st century science
- Administrative work increasing: contracts, regulatory, safety
- Decreased institutional funding support and indeed perception that trials may be source of revenue
- Change in ***type*** of trials being done – *increasingly Canada's cancer trials "agenda" is dominated by trials from pharma sector*
- **At same time: Enhanced expectations –** faster, better trials of new treatments incorporating biomarkers, genomics and more….

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Switching Gears: *Cost Benefit Analysis of Cancer Clinical Trials*

- Why a C-B analysis?
  - Common perception that patients on clinical trials consume more health care resources….but do they?
  - ***What benefits, besides funding, do trials bring?***
  - Goal: to understand various perspectives and provide summary to illuminate the debate about support of clinical trials by health care system

→ *some highlights*

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ORIGINAL RESEARCH

Early release. Published at www.cuaj.ca on July 16, 2012. Subject to revision.

Incremental costs of prostate cancer trials: Are clinical trials really a burden on a public payer system?

Britney Jones;[*] *Rachel Syme;*[†] *Misha Eliasziw;*[‡] *Bernhard J. Eigl, MD*[±]

[*]Research Assistant, Alberta Health Services, Alberta Clinical Cancer Research Unit, Tom Baker Cancer Centre, Calgary, AB; [†]Executive Director of Research, Alberta Health Services, Alberta Clinical Cancer Research Unit, Calgary, AB; [‡]Biostatistics, Department of Public Health and Community Medicine, Tufts University School of Medicine, Boston, MA; [±]Medical Leader, Alberta Clinical Cancer Research Unit, Tom Baker Cancer Centre, Calgary, AB

Cite as: *Can Urol Assoc J* 2012. http://dx.doi.org/10.5489/cuaj.11302

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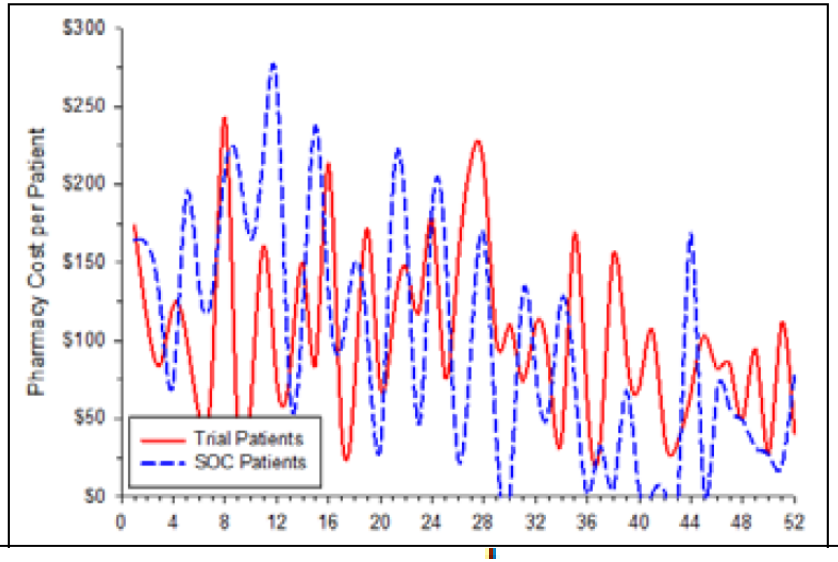
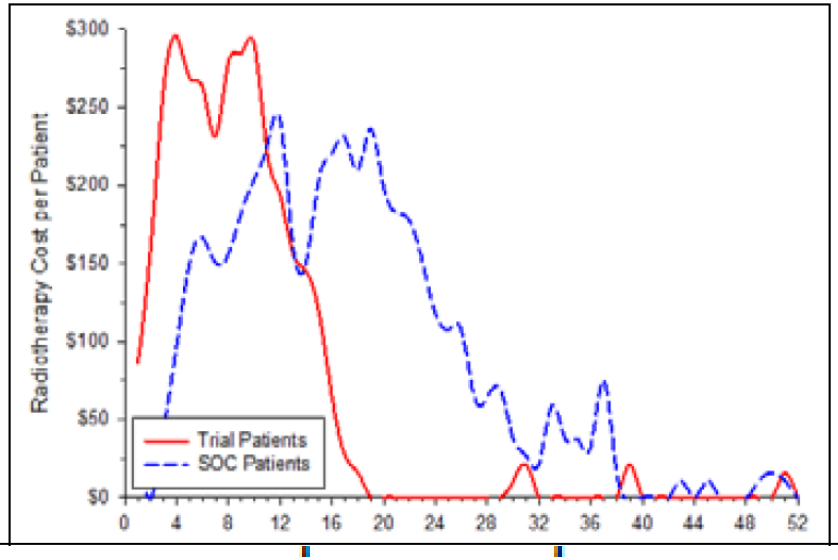




Results: No difference in overall resource utilization was seen between trial and SOC patients (two-tailed t-test, n = 118, $p = 0.99$).

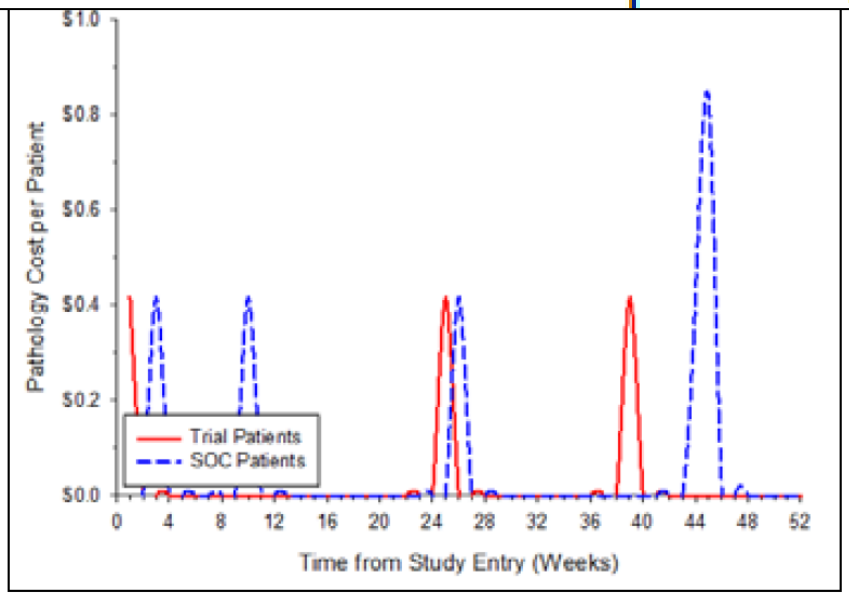


Fig. 8. Mean per patient costs of diagnostic imaging for clinical trial enrollees versus standard of care patients over 52 weeks. *P*-values: group = 0.002; time = 0.06; group x time = 0.14.

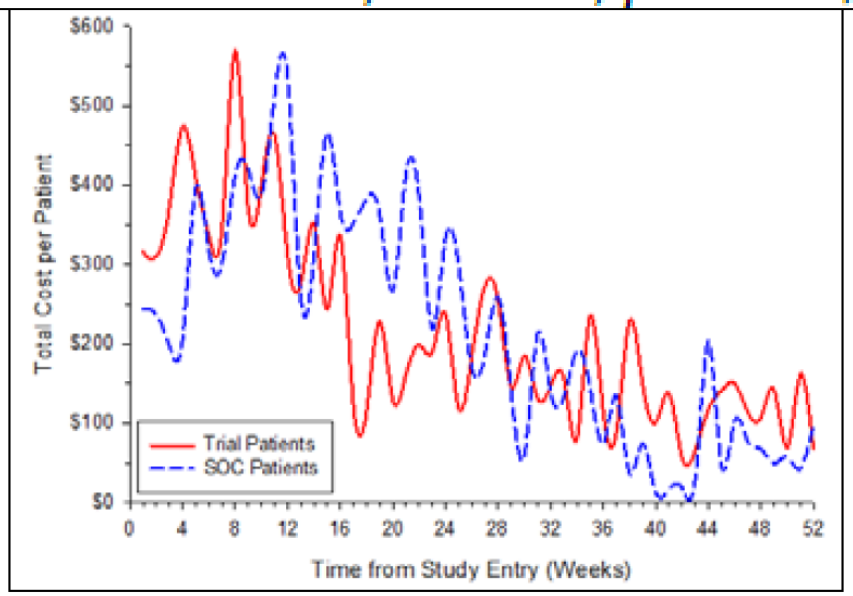
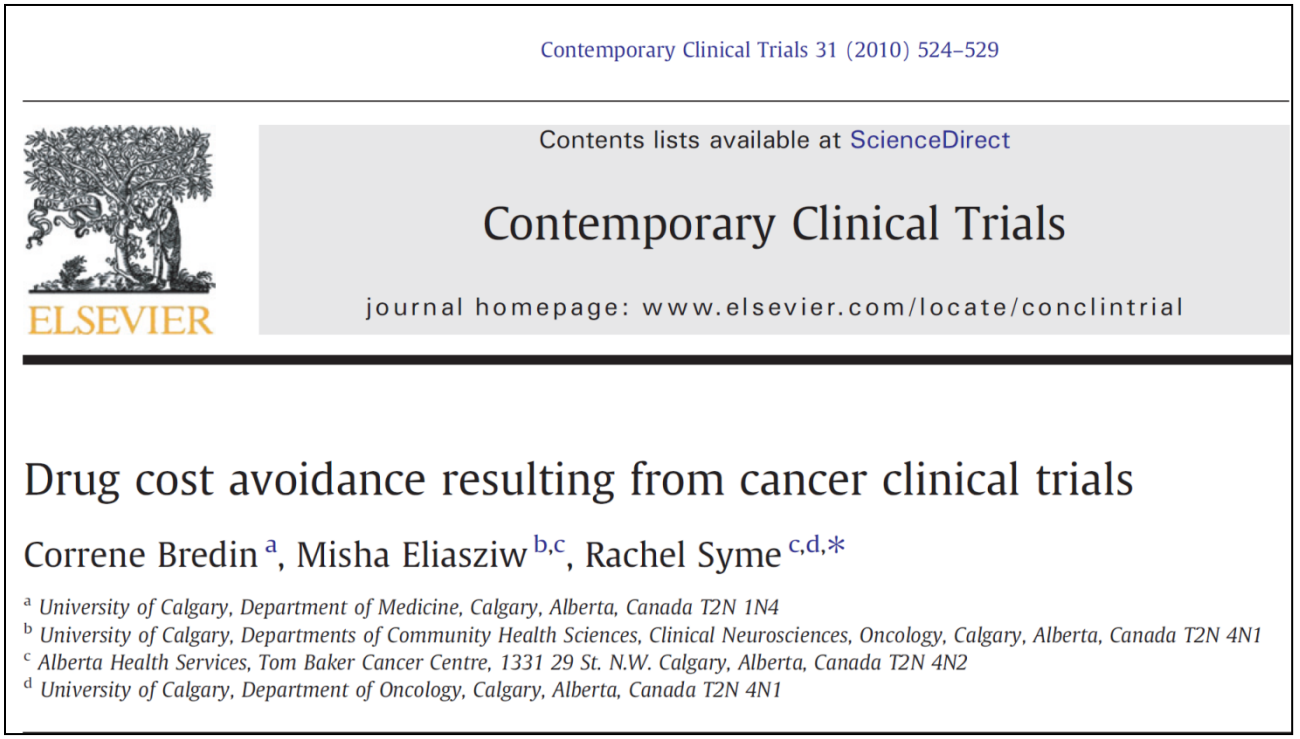


Fig. 9. Mean per patient costs of pathology for clinical trial enrollees versus standard of care patients over 52 weeks. *P*-values: group = 0.21; time = 0.12; group x time = 0.49.

Similar results in other cancer studies:

Ref	Population/Design	Observation	Time frame	P-value
Wagner (1999)	61 patients in Phase II/III with matched case controls	Trial patients costs **were 5-11% higher**	5 y	***NS***
Fireman (2000)	135 patients in NCI sponsored trials with matched controls	Trial patient costs were **10% higher**	1 y	***NS***
Bennett (2000)	35 patients on Phase II trials and matched controls	Mean trial patient costs **10% lower**	6 m0	***NS***
Bennett (2001)	377 patients on Phase II/III clinical trials matched with controls on standard care – a review of 5 pilot studies	Costs ranged from **10% lower** for trial patients to **23% higher** in a review of 5 studies	6 mo-5 y	***NS***
Goldman (2003)	932 non-pediatric patients enrolled in 1 of 35 different trials, Phases I-III, matched with 696 non-participants	Treatment costs, excluding administration, for clinical trial patients were **6.5% higher** (3.8% higher for phase III trials)	2.5 y	***NS***

Drug Cost Savings – Canadian Data



Contemporary Clinical Trials 31 (2010) 524–529

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Drug cost avoidance resulting from cancer clinical trials

Correne Bredin [a], Misha Eliasziw [b,c], Rachel Syme [c,d,*]

[a] University of Calgary, Department of Medicine, Calgary, Alberta, Canada T2N 1N4
[b] University of Calgary, Departments of Community Health Sciences, Clinical Neurosciences, Oncology, Calgary, Alberta, Canada T2N 4N1
[c] Alberta Health Services, Tom Baker Cancer Centre, 1331 29 St. N.W. Calgary, Alberta, Canada T2N 4N2
[d] University of Calgary, Department of Oncology, Calgary, Alberta, Canada T2N 4N1

- Alberta team studied cost avoidance for drugs that otherwise would have been funded by institution.
  - 101 protocols 1992–2007
  - Actual drug cost avoidance a median of **$1377.00 to $23,751.00 per patient** between tumor groups.
- Multiple non-Canadian studies – **confirm findings**

Drug cost savings: Other Data

Reference	Study Population/ Design	Time-frame	Finding
MacDonagh (2000)	Review of records of two hospitals.	1 Fiscal Year	Cost avoidance from drugs in trials was **$2.9 million** (8% of hospital drug budget). Diseases with largest cost-avoidance were HIV/AIDS and cancer.
Lafleur (2004)	139 trials at a single institution	2 Fiscal Years	Annualized cost avoidance was **$2.6 million**
Uecke (2008)	88 oncology clinical trials in 11 German hospitals	3 Fiscal Years	Actual cost avoidance was **$2 million.**

Summary - Costs/Benefits for Institutions to Supporting Clinical Trials

- Data to date: health care costs are **not** significantly higher for patients enrolled on clinical trials - *but Canadian data limited*
- Important benefits:
  - Improving patient outcomes
  - Recruit/retain highly qualified physicians, nurses and other personnel
  - Quality of care (data not shown)
  - Pharmacy savings by drug cost avoidance

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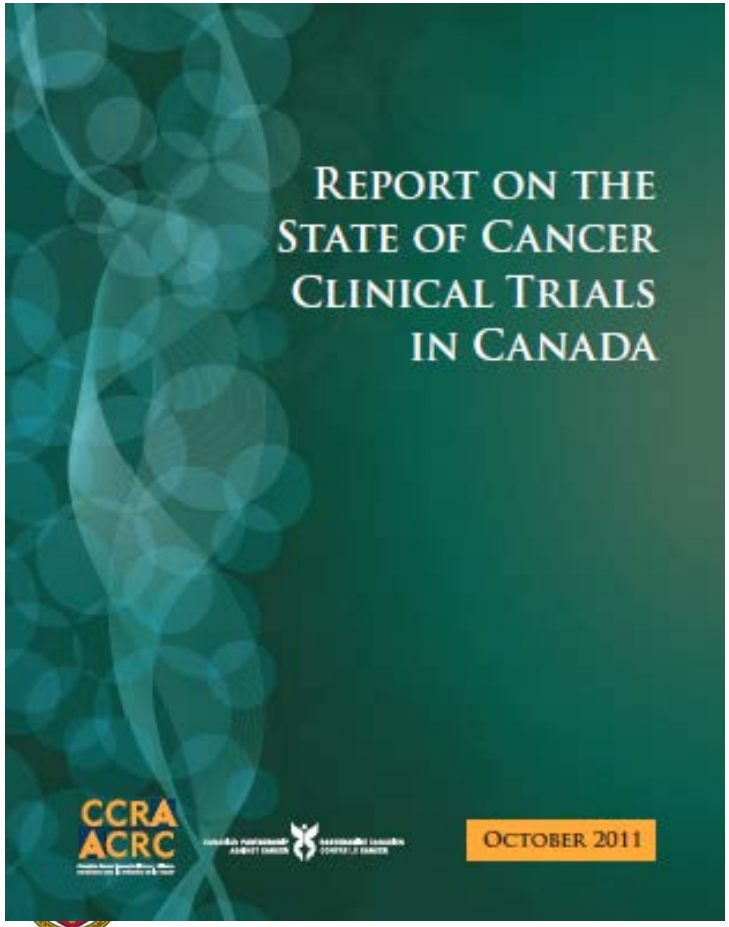
Final CTWG Report and Recommendations Published October 2011



As of Dec 12, 2012:

> 56,000 downloads of this report

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http://www.ccra-acrc.ca/PDF%20Files/CT%20report%20Oct%202011.pdf

Recommendations and Vision – CTWG Final report

- Vision: to improve health and wellbeing of Canadians by ensuring Canada is at the forefront internationally in clinical cancer research at a time of unprecedented opportunity for advances that are emerging from fundamental science
- Four recommendations

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Four Recommendations

1. Create a Pan-Canadian Infrastructure Program that Supports Cancer Clinical Trials
2. Streamline Clinical Regulatory Environment.
3. Consolidate or Develop Reciprocity in Research Ethics Boards
4. Reduce non-Value Added Steps in Trial Development and Conduct

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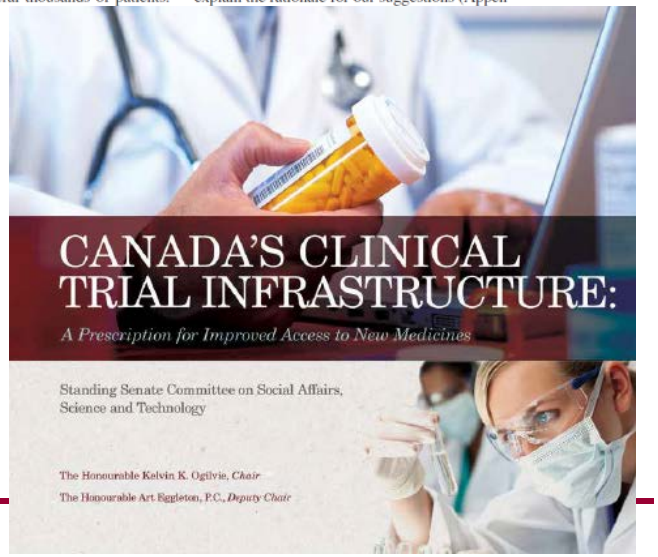
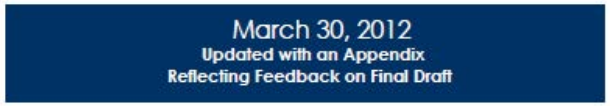
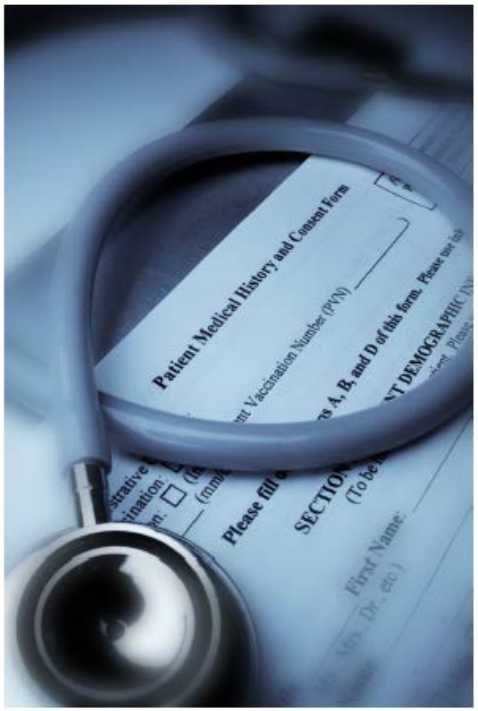
Some more Context -

Issues identified not limited to academic trials, not limited to cancer, and not limited to Canada







Recommendation 2: Streamline Clinical Regulatory Environment

Engage with Health Canada and other key stakeholders to propose non-legislative changes to the Food and Drug Regulations, through guidance or other similar documents that will improve the efficiency of clinical trials and ensure or enhance safety and reduce the amount of work and the costs

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"Initiative to Streamline Clinical Trials"
Working Group

- Established in summer 2012 under Chair Karen Arts (N2) and co-Chair Lesley Seymour (NCIC CTG)
- Membership reflective of multiple therapeutic areas with academic trials interests:
  - Cancer cooperative groups
  - Pediatric consortium
  - HIV/AIDS cooperative group
  - Cardiovascular/population academic group
  - Provincial agencies
  - Hospitals/cancer centres

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Membership

Arts, Karen	Chair: OICR, N2
Bosch, Jackie	Co-Chair, Population Health Research Institute
Brodeur-Robb, Kathy	C17
Filice, Michelle	Sunnybrook Health Sciences Centres
Halton, Jackie	Senior Medical Officer C17
Julian, Jim	Associate Director, OCOG
McCarty, Donna	OCOG
Ostrovsky, Alex	Canadian HIV Clinical Trial Network
Pankovich, Jim	Canadian HIV Clinical Trial Network
Urton, Alison	NCIC-CTG
Brown, Jasmine	OZMOSIS, Princess Margaret Hospital
David, Marilyn	Alberta Health Services
Degendorfer, Pameral	Princess Margaret Hospital
Grant, Janice	BC Cancer Agency
Hansen, Clive	NCIC-CTG
Piaseczny, Mirek	Canadian HIV Clinical Trial Network
Seymour, Lesley	Co-Chair: NCIC-CTG
Syme, Rachel	Alberta Health Services
Thakur, Manisha	PHRI

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Overarching goal

To develop guidelines (Guidance Document) pertinent to the conduct of clinical trials in Canada for which a Clinical Trial Application is required (Food and Drug Regulation C.05.005) and which are conducted by an academic group, institution or investigator.

The purpose of the Guidance will be to reduce burden of work in compliance while maintaining patient safety and trial quality.

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Progress has been substantial

- Six thematic areas where variation in practice is seen, problems are identified, or opportunities exist to clarify and harmonize
- For each theme, issues or ideas are identified, regulations cited, data sought, guidance proposed
- ***May 24 2013 – Meeting of working group and Health Canada representatives to review and refine proposed guidelines.***

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Examples of Questions to Address in Guidance Content

Area	Some examples – proposed guidance
CTA requirements	Should standard of care comparator arms be considered non-investigational, even if not labeled for that indication?
Monitoring	Should on site monitoring plan be based on risk/phase of trial, so that not all trials may require on site monitoring ?
Equipment and Facilities	Should equipment related to standard of care procedures not be subject to monitoring/checks?
Delegation of Duties	
Validation of Electronic Systems	
Source Documents	

Four Recommendations

1. Create a Pan-Canadian Infrastructure Program that Supports Cancer Clinical Trials
2. Streamline Clinical Regulatory Environment.
3. Consolidate or Develop Reciprocity in Research Ethics Boards
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1. Create a Pan-Canadian Infrastructure Program that Supports Cancer Clinical Trials

Stable Institutional Clinical Trials Support

Create a model for stable clinical trials infrastructure funding in Canada that will substantially increase recruitment to peer-reviewed and cooperative group clinical trials. *This model should be based on the highly successful UK NCRN that includes infrastructure funding for key trial team personnel, tissue collection support and other common tools and resources*. National, regional or provincial funding may be needed but the goal is to *coordinate the program at a pan-Canadian level.*

Trial Personnel Credentialing

Work with national clinical trials leaders to reduce the duplication of effort in investigator and trial personnel qualification processes, such as GCP and ethics training, Standard Operating Procedures. For example, create a national repository of acceptable modules for an agreement among trial sponsors such that certification from one any is equivalent to certification from another.

1. Create a Pan-Canadian Infrastructure Program that Supports Cancer Clinical Trials (cont'd)

Contract Language

Work with key institutional stakeholders and partner with others engaged in clinical trials, to develop common contract language around confidentiality, tissue access and intellectual property and indemnification for use by major universities and hospitals.

Trial Budgeting Tools

Spearhead a coordinated effort to share best practices and tools for budget development and forecasting. Furthermore, standardize cost schedules for standard of care, pharmacy services, pathology, medical records, imaging, etc., across cancer centres so that the tools and processes are effectively utilized.

Trial Decision Making

Encourage clinical trials units and cooperative groups to adopt and implement portfolio management tools to support a balanced and strong portfolio of potentially practice-changing cancer clinical trials.

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Canadian Partnership Against Cancer

- Has taken leadership role in developing an initiative to address recommendation #1
- Multi-stage, multi-partnered process
- A key driver for this decision was some evidence that *clinical research active health centres or systems have better cancer outcomes overall than those that have limited/no research*

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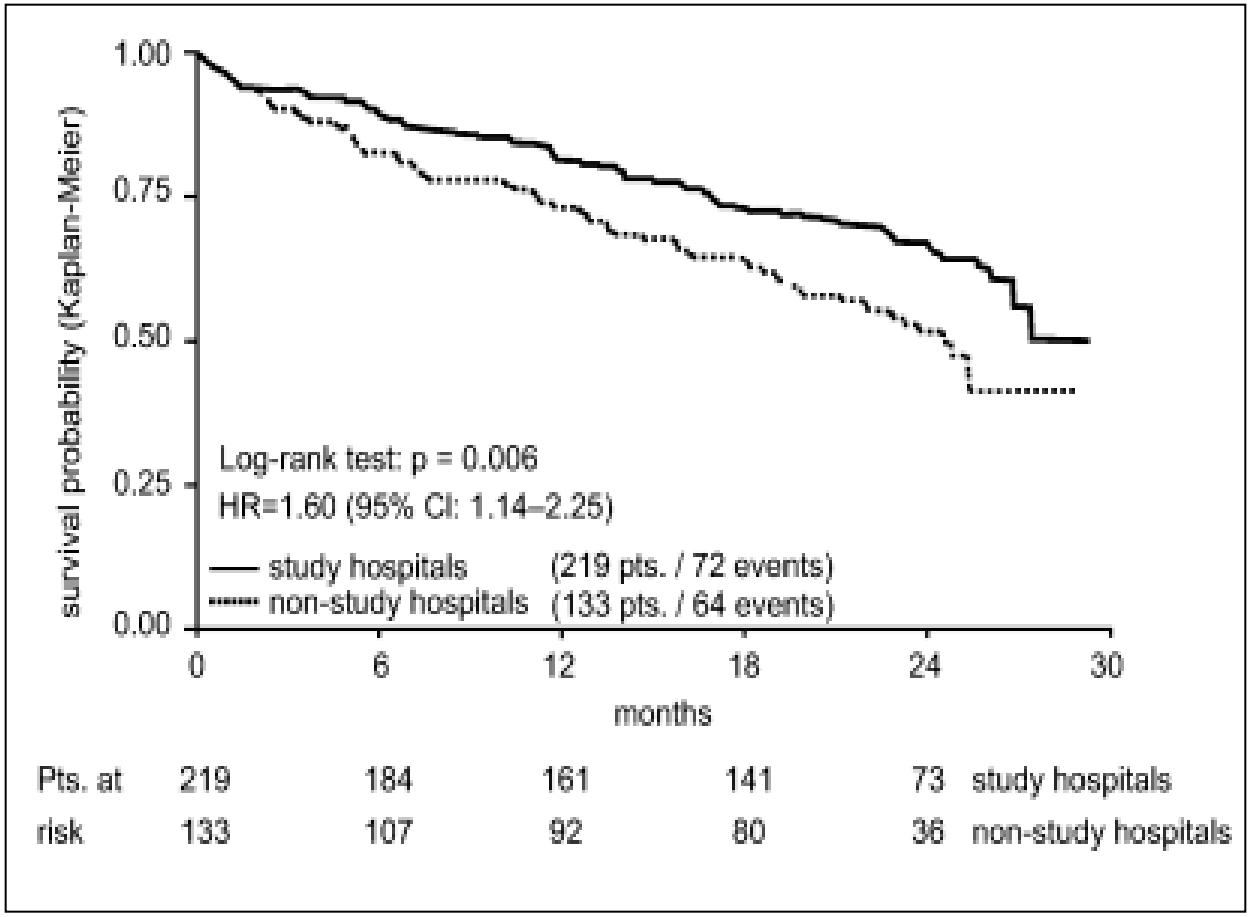
Example – Ovarian Cancer in Germany:
research active healthcare systems deliver healthcare better



Pattern of care and impact of participation in clinical studies on the outcome in ovarian cancer
Du Bois et al, Int J Gynecol Cancer 2005, 15, 183.

Ovarian Cancer

1/3 of EOC in 3months in Germany in 2001 were analysed(476 pts);

Outcomes of whole Institutions not individual patients;

80/165 hospitals participated in studies.

Steering Committee

- Provincial representatives
- Cancer Centres
- Patient representative
- Research Ethics
- Research Funding agencies
- Clinical Trial Experts
- CPAC (EE and Stuart Edmonds)

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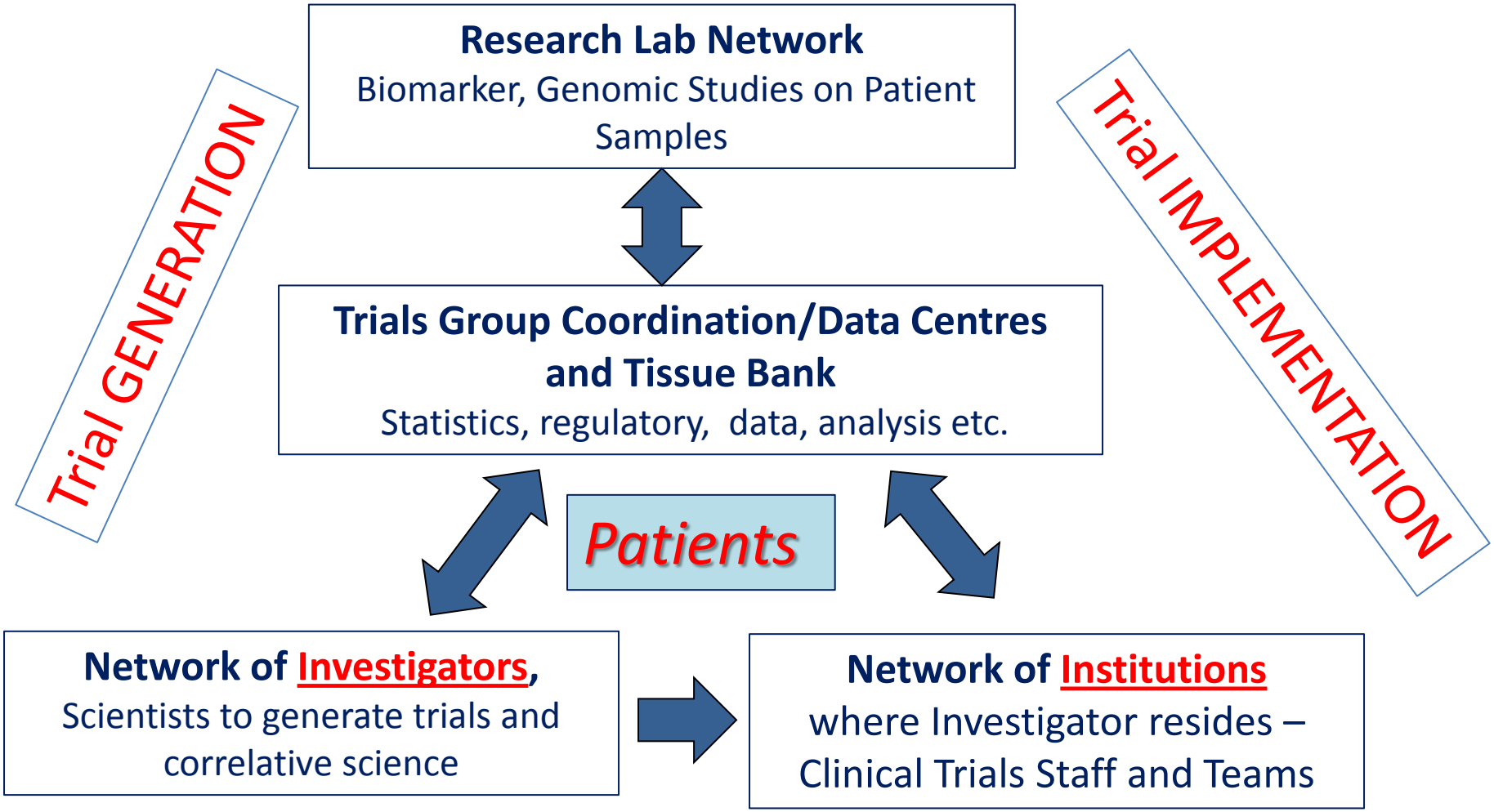
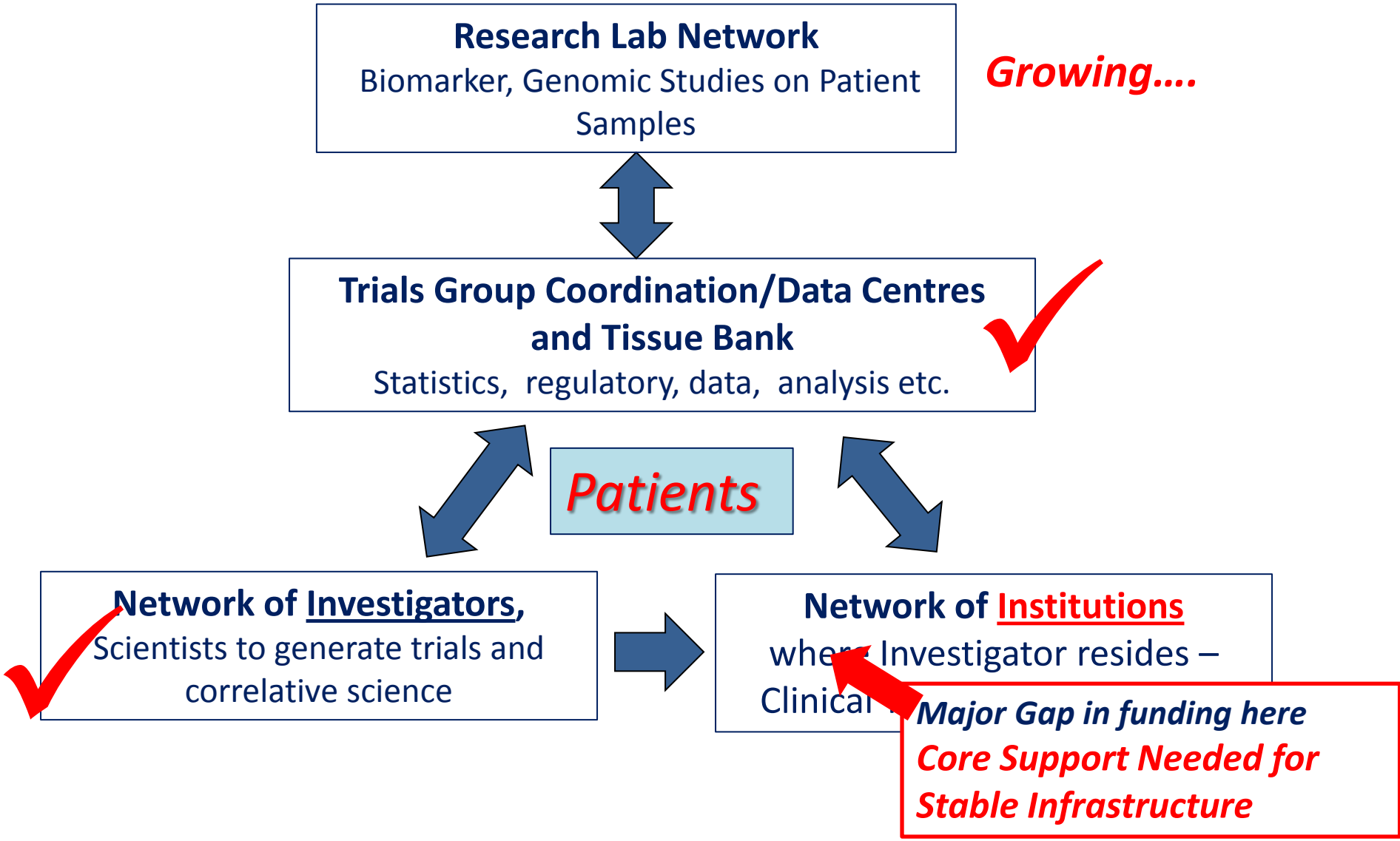
Vision – Successful Cancer Trials System in Canada

Four key elements – all need support



Vision – Successful Cancer Trials System in Canada

Four key elements – all need support



A Model for Canadian Initiative –

The National Cancer Research Network in England

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1990's- UK Cancer Outcomes

- Poor outcomes compared to many European countries
- Strategic review committees (1995, 1999)
- Direct discussion with Ministers (2000)
- **National Cancer Plan** developed (2000)
  - Regional Cancer Care Delivery networks established
  - **National Cancer Research Network (NCRN)** established:

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NCRN – from 2000 National Cancer Plan:

The NCRN will provide a world class base for the conduct of clinical trials and other well designed research within three years.

The NCRN will be a ***managed research network mapping onto the cancer service networks across the country****.*

The quality, speed and co-ordination of clinical research will be enhanced and research will be better integrated with cancer care

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NCRN mission

to benefit patients
by improving the coordination, integration, quality, inclusiveness and speed of cancer research

Created in England in 2001, fully established by 2004

Sister networks in Scotland (2002), Wales (1998) & Northern Ireland (2007)

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How it was intended to work

- **Coordinating Centre –** funded to **implement the program of infrastructure support**
- **Funding from Department of Health** for coordinating centre and funding to flow through the Coordinating centre to **Local Research Networks** to support clinical trials teams and activities
- Each Local Research Network was mapped onto a **clinical care service network**

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NCRN Planning Sequence

- **2000:** A Governmental Tender Specification:
  Coordinating Centre: Competitive bids to coordinate network
  - £1.5 M/year
  - Inaugural Director: Prof. Peter Selby
- **2001-2005: Implementation** of NCRN by selected coordinating centre:
  - **£250,000 per million people / year**
- **Total: £20 M per year from Dept. of Health**
- **Targets**
  - **double** trial recruitment in 3 years
  - Increase speed, participation, integration, quality

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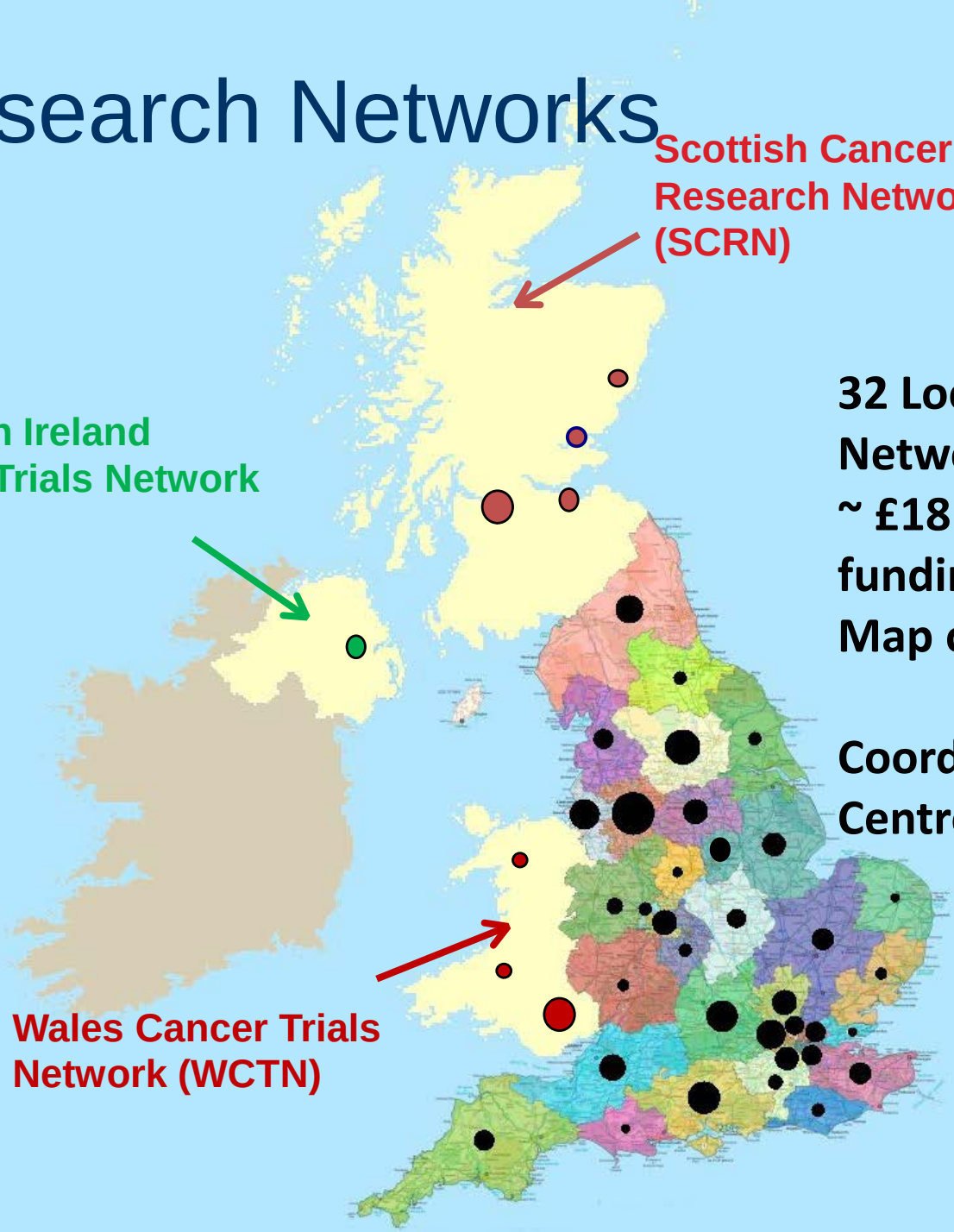
Coordinating Centre Activities

- Set up local research networks – AND FUND THEM
- Research Management
- Trial Portfolio Definition
- Industry linkages
- Training and Education
- Research Governance/Advice
- Information Systems
- Patient and Public Involvement
- Experimental Medicine
- Specialty Groups
- Communication

NCRN
National Cancer Research Network

Research Networks



NCRN

32 Local Research Networks

~ £18m core funding

Map on to NHS

Coordinating Centre funding

What did Local Research Network clinical sites **do** with the funding?

- *Infrastructure support was to enhance accrual to a **Portfolio** of trials* that were academic multicentre studies funded by MRC and CRUK
- Funding to each LRN after agreements in place, Funding for:
  - Clinical Lead and Research Network Manager
  - Core staff + locally negotiated support

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National Portfolio of Clinical Trials

- Clinical trials personnel funded by NCRN in LRNs worked on ***opening and accruing patients to national portfolio of trials***
- The Department of Health in England (the funder) established **Eligibility Criteria** for inclusion of studies in the NCRN Portfolio
- Studies automatically eligible were those that:
  - Had majority of their research funding provided by National Institute for Health Research (NIHR) , other areas of Government
  - Other non-commercial Partners such as Cancer Research UK

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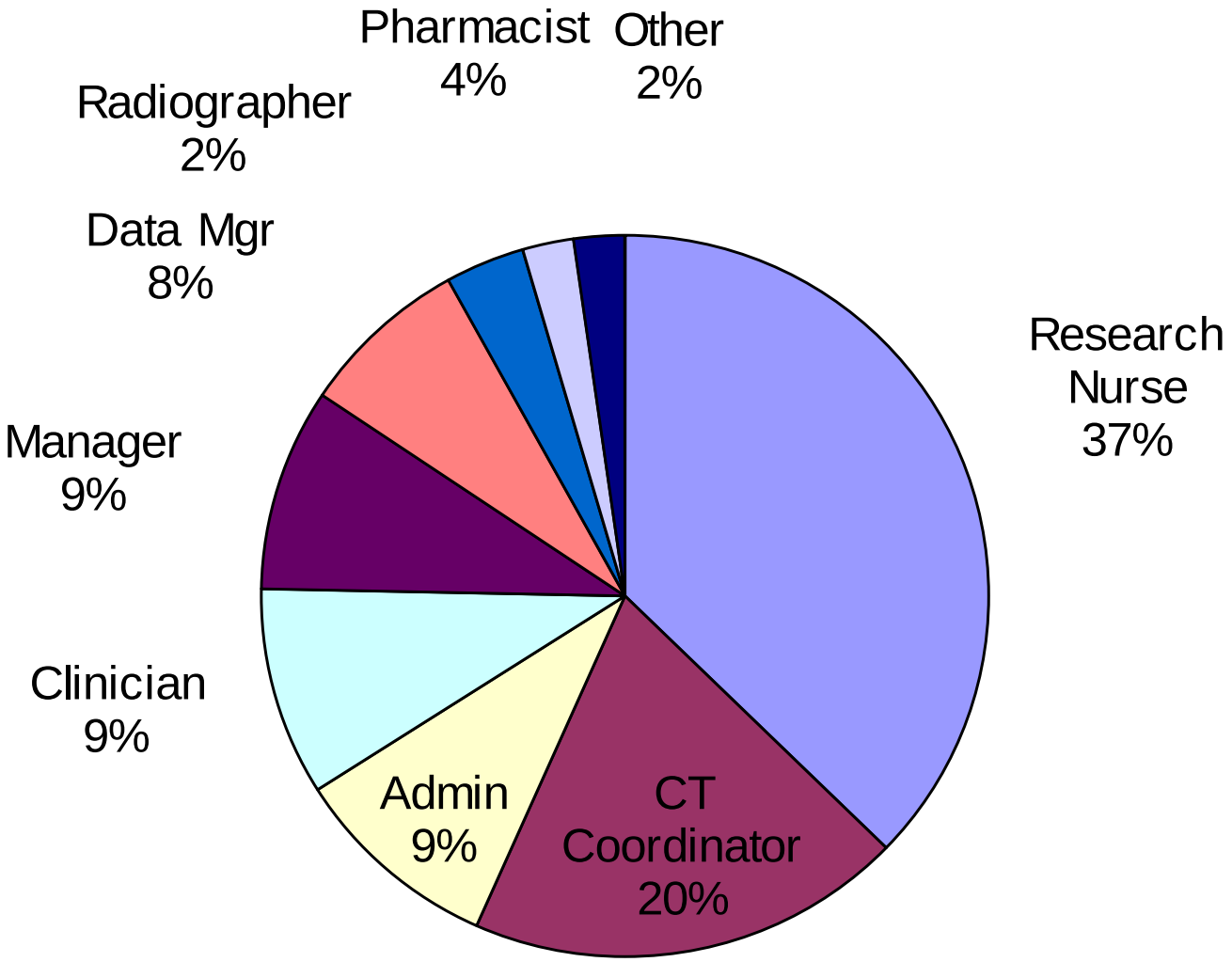
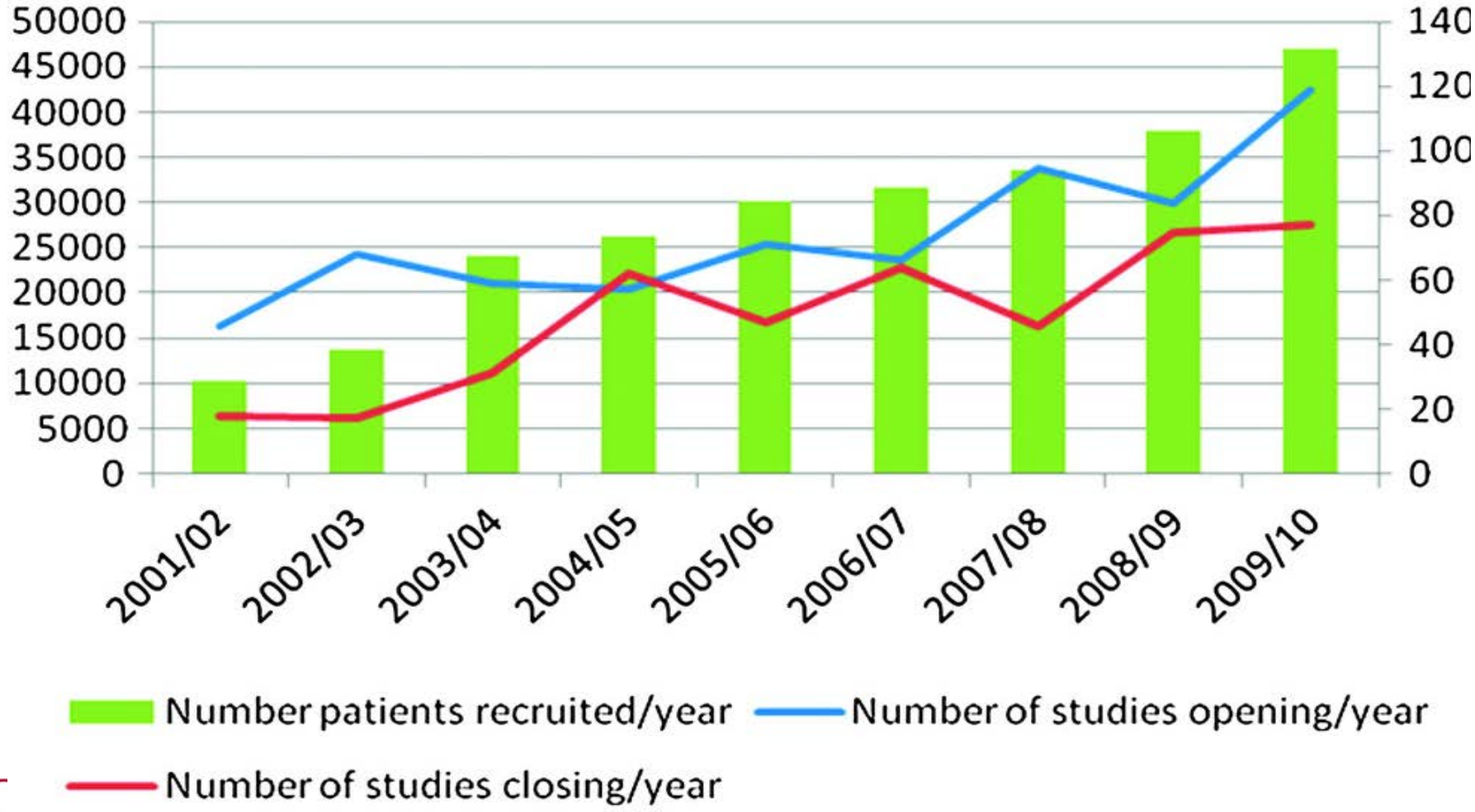
Who was hired with NCRN funding?

Workforce Profile for NCRN Appointments*



* Does not include non-NCRN funded staff working on NCRN portfolio trials

Results: NCRN studies between 2001 and 2010: Total patients recruited Numbers of studies in “portfolio” open/closed



Cameron D et al. Ann Oncol 2011;22:vii29-vii35

Can this work in Canada???

- Steering Committee thought it could - but would need investment of **$8-10M/yr** (~$250,000/million pop'n)
- Some important differences/challenges here:
  - Will need to build on existing cancer care system AND existing clinical trials research groups
  - NCRN in England – one health jurisdiction – we have 10+
  - NCRN funded by one funder (Dept. of Health) – in Canada no one funder with enough funding – **need consortium of funders**.
  - Unlikely that Ministries of Health in Canada will provide funding, at least initially. Work must be done to show value add and cost effectiveness of a Canadian Cancer Trials Network to be sustained by health dollars.

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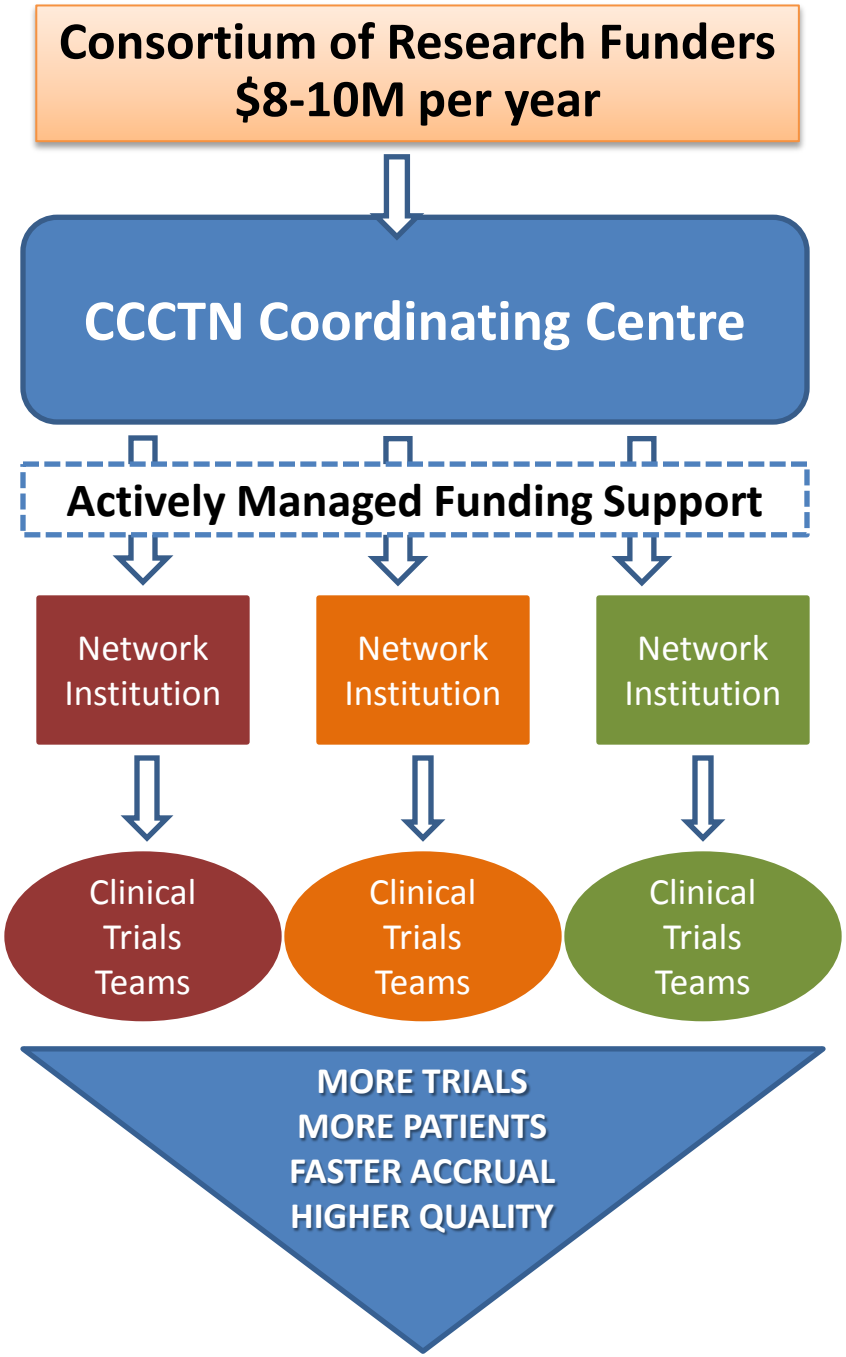
Canadian Clinical Cancer Trials Network (CCCTN)



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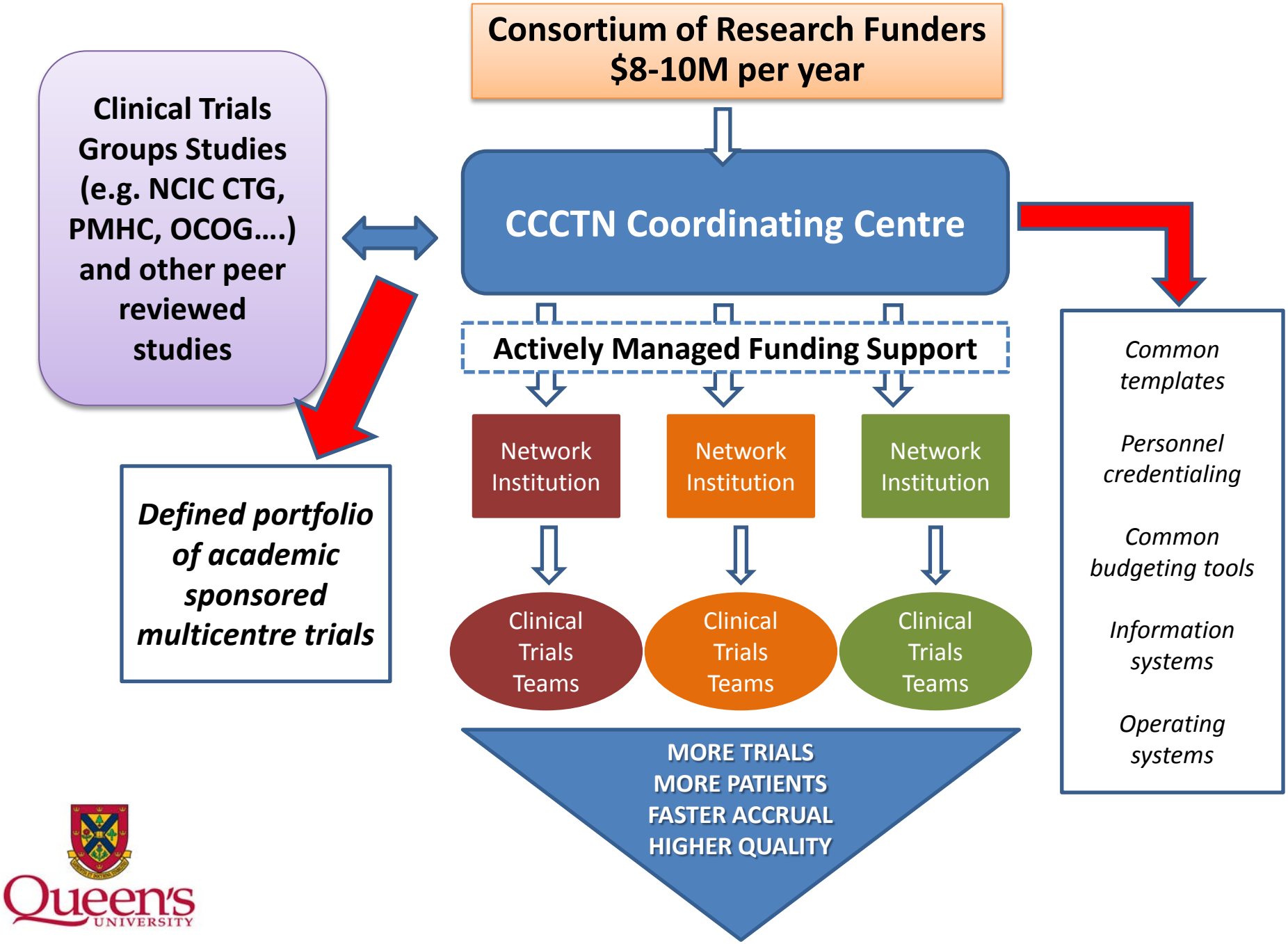

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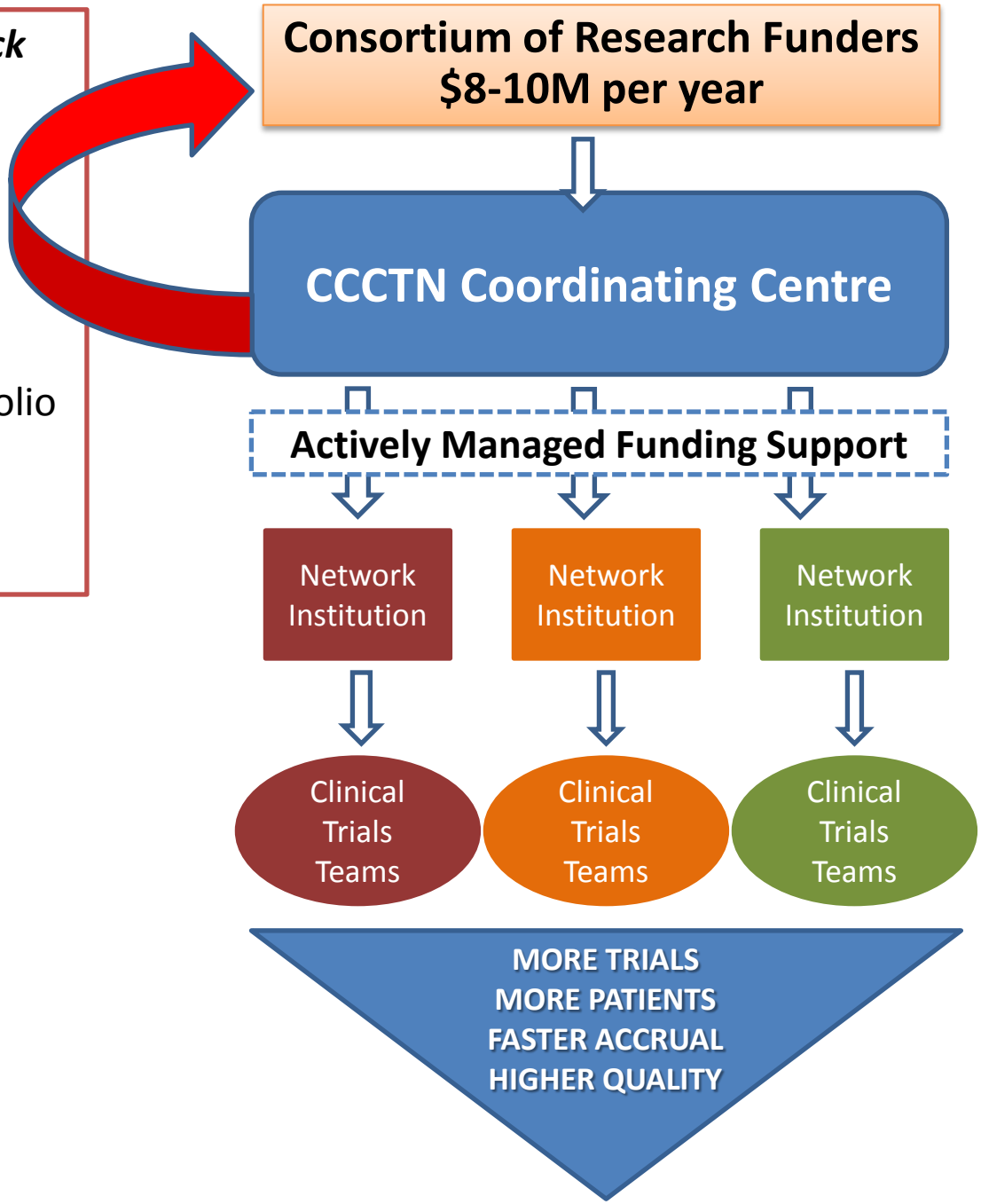
Regular report back on deliverables:

- No. of network institutions,
- Accrual
- No. trials open/closed
- Results of portfolio trials
- Evaluation of impact



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How to make this a reality?

- Must start with identification of Coordinating Centre to develop initiative fully (Phase I)
  - **Competitive RFA process**
- Once selected, Coordinating Centre leader to work with CPAC to consolidate funding commitments from other agencies during phase I (funded by CPAC)
- Full implementation to be launched following approval of business plan, funding committed

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The CCCTN Coordinating Centre RFA

CCRA ACRC

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Request for Applications
For The Coordinating Centre of the Canadian Cancer Clinical Trials Network (CCCTN)

RFA# RS2012-02P

Issue date:	Friday, November 9, 2012
Deadline for receipt of NOI	Friday, November 30, 2012 before 5 pm ET
Eligible applicants notified	Wednesday, December 5, 2012
Applicant information meeting (Toronto)	Tuesday, December 18, 2012
Full application deadline	Friday, February 15, 2013 before 5 pm ET
Competitive peer review of applications	March 2013
Announcement of successful applicant	May 6, 2013
Approval of funding for Coordinating Centre plan development (Phase 1)	June 7, 2013
Plan for Coordinating Centre due date (Phase 1 deliverable)	Friday, December 13, 2013
Peer Review of business plan developed by Coordinating Centre	February 2014
Pending approval of business plan, full funding and implementation of Phase 2 of CCCTN	April 2014

Applications reviewed April 3-4,2013

International/ National Expert Panel including trialists, provincial leaders and patient representation – Chaired by Prof, Peter Selby (inaugural NCRN Director)

April 25: Coordinating Centre and Director Announced

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April 25th, 2013

Options

Strengthening Canada's capability to conduct practice-changing clinical trials

The Partnership teams up with the Ontario Institute for Cancer Research

Dr. Janet Dancey,

The Canadian Partnership Against Cancer is investing in a pan-Canadian approach to strengthen Canada's ability to conduct practice-changing clinical trials and improve cancer outcomes for Canadians. With funding from the Partnership, the Ontario Institute for Cancer Research (OICR) has been selected to develop the Coordinating Centre for the Canadian Cancer Clinical Trials Network, the leadership and administrative hub of the still-to-be-created pan-Canadian clinical trials network. Dr. Janet Dancey, Program Director of the High Impact Clinical Trials Program at OICR will lead the Coordinating Centre. The NCIC-Clinical Trials Group and N2 (Network of Networks) are

Momentum Gathering-

Much Work to be done over Next 6-8 months

- To ensure success of this initiative Dr. Dancey along with clinical trial leaders from across Canada (in this room!), CPAC leaders, N2 and NCIC CTG and other stakeholders will need to work hard together
- ***Commitments from 9+ additional funding agencies in development and will need to be confirmed.***

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A Time of Renewal and Hope

- Much needed infrastructure support for cancer centres and hospitals engaged in clinical trials will open the door to ***more participation, more trials, and more opportunities for patients***

- For Academic Groups such as NCIC CTG, whose trials will be enabled by this initiative – more than ever there is opportunity to bring forward the ***exciting questions that will shape clinical practice of the future, improving the outcomes of patients , and reduce the burden of suffering.***

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Thank You!