Canadian Association for Independent Clinical Research/l'association canadienne pour la recherche clinique indépendante

www.caicr-acrci.org

INTRODUCTION TO CAICR: A TALE OF TWO STUDIES

Case studies of the Independent Clinical Research Sector

Case Study 1: JUPITER Trial

Title: Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein, Ridker et al NEJM Nov. 20, 2008

- 18,000 pt. landmark study in ↑CRP & ↓LDL
- Canada a major contributor
- Single ethics review for 83 Canadian FM/community cardiology sites in most provinces
  - Reviewed full board June 27/03, approved July 8
  - 2-3 day turnaround for investigator OK
  - multi-year study, 4 amendments, similar turnaround time for amendments and re-approvals

Case Study 2/2a: Tamiflu IIT Studies CAI001-10 & CAI002-

(both submitted for publication, see clinicaltrials.gov for more info)

- Total 35 sites b/n two studies: 265 screened, 162 randomized subjects
- Global CRO contacted Trial Management Group:
  - i) proven site pt. recruitment
  - ii) rapid site recruitment;
  - iii) infrastructure to support IIT
- CRO could not meet timeline so withdrew; TMG assumed project all Canada
  - - 64 days from project approval to FPI
- Positive Roche Global/Roche Canada experience main factor to entrusting TMG
- Existing internal & external expertise allowed study to meet primary objective
- Success of first study led to a second study
  - *Collaboration w academic centre (CHUQ) allowed 2nd study to come to Canada
- Canadian companies participated as sub-contractors: McDougall Scientific, Bay Area Research Logistics (Hamilton),
- Single ethics review & approval w/n 2 weeks for all sites in almost all provinces

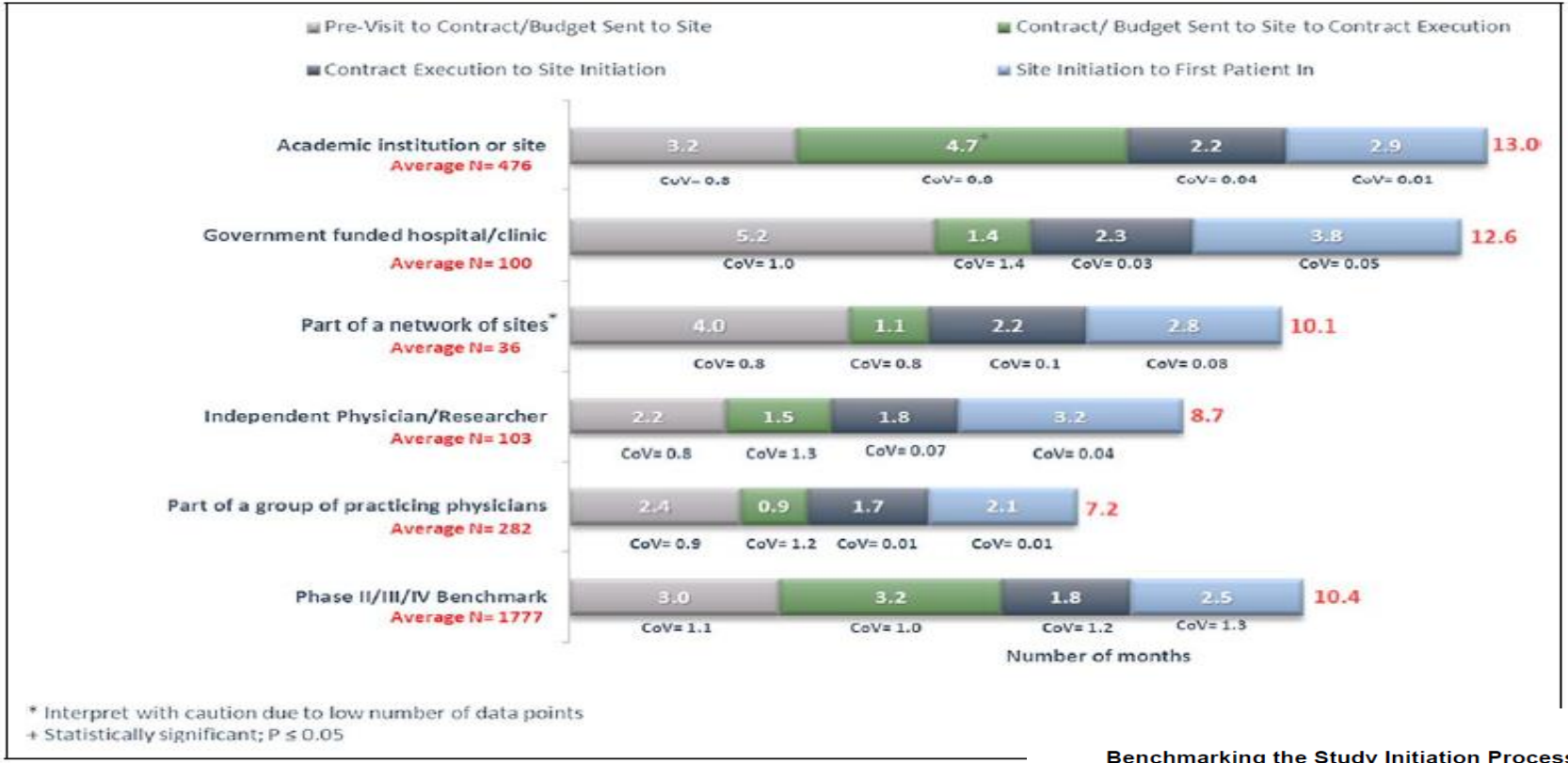

Figure 2. "First patient in" cycle time by type of site.

Benchmarking the Study Initiation Process
Mary Jo Lamberti, Cindy Brothers, Dan Manak and Ken Getz
Therapeutic Innovation & Regulatory Science 2013 47: 101
DOI: 10.1177/2168479012469947

The online version of this article can be found at:
http://dij.sagepub.com/content/47/1/101

Why CAICR: "Canadian government launches massive overhaul of clinical research process to create infrastructure" Centerwatch, Sept. 12, 2011 Report on CT Summit September 2011: ACAHO, Rx&D, CIHR

- CIHR developing a national ethics organization, as well as a master contract for pharma to use with Canadian researchers.
- Individual provinces taking the lead with various "stakeholders"
- National ethics organization modeled after the British system
  - each province to have "alpha ethics centers" recognized by other provinces
  - provinces have the option to not accept the evaluation of another province's alpha ethics center and instead render their own
  - commercial IRBs exist in Canada, but they are not being considered as possible ethics centers
  - "…success is totally dependent on **alignment of all the various stakeholders..."**

CAICR/ACRCI

- **Mission:** To promote development of independent clinical research by
  - Promoting ethical and scientific quality in clinical research
  - Representation on boards, colleges or other significant platforms.
  - Maintenance of ethically sound practices for the best interest of research subjects, the benefit of science and the general population
- **Goals**
  - Effective representation of our stakeholders
  - Attracting new clinical studies to Canada
  - Patient engagement
- **Criteria for Membership**
  - Independent private Canadian businesses actively engaged in conducting clinical trials
    - Single Sites
    - SMOs
    - CROs that conduct studies on participants, e.g., Phase 1 units
    - Individuals
    - Canadian Independent IRB/REB
      - No shared ownership or other affiliation with Research Site, SMO or CRO

Founding Members

CAICR/ACRCI

IRB INSTITUTIONAL REVIEW BOARD SERVICES

PIRC Pharmaceutical Integrated Research Corporation

LMC Making Healthy Easier La Santé Simplifiée
DIABETES • METABOLISM • ENDOCRINOLOGY

nutrasource diagnostics inc.
From nature to science... From science to you.

Ronald Fehst Research Consultants

TRIAL MANAGEMENT GROUP INC.
A higher standard

inc Research Early Phase

Toronto Memory Program

KGK synergize

Additional Members and Growing…

CAICR/ACRCI

cmx research partner urology · oncology

TRUST, INTEGRITY, RESULTS

inVentiv Health clinical

MannaResearch Canadian Clinical Trials

PMR | Probity Medical Research

Clinical Research Niagara

ADA Medical

BioPharma SERVICES INC.

INFLAMAXRESEARCH INC

Algorithme Pharma AN ALTASCIENCES COMPANY

Q&T RESEARCH Health is what we're all about

Canadian Centre for Clinical Trials

CO MEDICA RESEARCH NETWORK INC

Prairie Clinical Research
Saskatchewan

Membership Survey

- Investigators in all provinces
- Central REB review for most provinces = single review
- 533 FT/135PT/28 Casual Employees
- 272 investigators:
  - est. access to >1 million patients + > 100,000 NHV subjects
- Additional 232 Ft &37 Pt Employees at sites
- Sites range from 5 to >200 Clinical Trials/year
- 97.4% recruitment to contract

"…success is totally dependent on alignment of *all* the various stakeholders..."

Mutual Cooperation for Mutual Benefit:

The Whole *is* Greater than the Sum of Its Parts