Population Health Research Institute

Who we are
We are an Academic Research Organization

Founded in 1999 as a joint research institute of:

McMaster University
and
Hamilton Health Sciences Corporation.

Evolved from Preventive Cardiology and Therapeutics Research Program (established in 1992)
Our Mission Statement

“To conduct trans-disciplinary research to improve major health outcomes in common and neglected conditions affecting Canadians and populations across the world”
Our Philosophy and Mandate

Large, Simple, Randomized Trials

Provide leadership in international health research

by being active in the education of individual researchers

and building capacity internationally for the development of global research programs.
Number of Publications

Year


Number of Publications

26 29 19 36 34 33 45 54 75 78 106 115 134 121 149 146 161 204 225 267 281 320 359
Publications in High Impact Journals

- N Engl J Med (I.F.=51.6)
- Lancet (I.F.=39.1)
- JAMA (I.F.=29.9)
- BMJ (I.F.=17.2)
- Circulation (I.F.=15.2)
- Eur. Heart J (I.F.=14.1)
- Ann Int Med (I.F.=13.9)
- Diab. Care (I.F.=7.7)
Citations – Top 25 PHRI papers

Number of Citations - January 14, 2016

- HOPE Ramipril, NEJM 2000: 5,310
- INTERHEART, Lancet 2004: 3,861
- CURE, NEJM, 2001: 3,611
- RE-LY, NEJM 2009: 1,859
- PCI-CURE, Lancet 2001: 1,825
- MICRO-HOPE, Lancet 2000: 1,505
- ONTARGET, NEJM 2008: 1,284
- INTERHEART Obesity, Lancet 2005: 1,274
- HOPE Albuminuria, JAMA 2001: 1,221
- Global Burden of CV Dis Part 1, Circ 2001: 1,212
- HOPE Vit E, NEJM 2000: 1,103
- CHARM-Preserved, Lancet 2003: 1,000
- CHARM-Added, Lancet 2003: 1,000
- CHARM-Overall, Lancet 2003: 967
- HOPE-2, Homocysteine lowering, NEJM 2006: 953
- DREAM Rosi, Lancet 2006: 923
- HOPE Renal, Ann Int Med, 2001: 912
- INTERHEART Psychosocial, Lancet 2004: 811
- AVERROES, NEJM 2011: 792
- ACE-Pooling, Lancet 2000: 764
- CHARM-Alternative, Lancet 2003: 750
- Renal Outcomes in ONTARGET, Lancet 2008: 717
- Aspirin Resistant Thromboxane, Circ 2002: 693
- POISE Trial, Lancet 2008: 693
HOPE Study – 9.5k, 267, 19 (93 – 99)

• Effects of an Angiotensin-Converting Enzyme Inhibitor, Ramipril, on Death from Cardiovascular Causes, Myocardial Infarction, and Stroke in High-Risk Patients

• ACEIs improve the outcome in patients with LV dysfunction, whether or not they have symptomatic heart failure.

• This study assessed the role of an ACEI, ramipril, in patients who were at high risk for cardiovascular events but who did not have LV dysfunction or heart failure.

• “Ramipril significantly reduces the rates of death, myocardial infarction, and stroke in a broad range of high-risk patients who are not known to have a low ejection fraction or heart failure”
RE-LY Study – 18k, 951, 44 (05 – 09)

- Randomized Evaluation of Long Term Anticoagulant Therapy (RE-LY) Comparing the Efficacy & Safety of Two Blinded Doses of Dabigatran Etexilate With Open Label Warfarin for the Prevention of Stroke & Systemic Embolism in Patients With Non-Valvular Atrial Fibrillation

ACEIs improve the outcome in patients with LV dysfunction, whether or not they have symptomatic heart failure.

- FDA Approved in 2011

- PHRI’s first experience with FDA audit of our processes and procedures in the data management
  - Heavily focused on patient safety aspects (SAE/AE), completeness and correctness of the data and adherence to GCP based on our SOPs and activities
Global Network Footprint

Over 1,500 centres in 86 countries in all inhabited continents
Areas of Focus

**Prevention**
The primary and secondary risk factors of cardiovascular disease (CVD)

**Diabetes**
Early detection, prevention and treatment

**Neglected Diseases**
Prevention and Treatment of Neglected Diseases in developing countries

**Renal**
Treatment and prevention of renal disease

**Heart Failure**
Exploring Treatment and Monitoring modalities for long-term stabilization
Areas of Focus

**Arrhythmia**
Heart arrhythmias

**Stroke**
Identification, prevention and treatment of stroke

**Thrombosis**
Prevention and Treatment of Thrombosis and Impact on CVD
Areas of Focus

Perioperative Medicine and Surgery
Patient care before, after and during surgery; as well as efficacy of different surgical procedures

Acute Coronary Syndrome
Treatment of acute coronary syndromes

Knowledge Translation
How we can translated research into healthcare
Areas of Focus

Global Health
Social and Economic Determinants of Health

Population Genomics
Exploring Birth Cohorts and Genetic Risk in Populations

Nutrition
Investigating Impact of Nutrition on Diseases

Health Policy and Systems
Investigating Impact of Health Systems on Prevention and Treatment of Diseases
Our Capabilities

• Study Design
• Protocol Development
• Data Management
• Site Management
• Statistical Analysis
• Research Contracts and Finance
• Validated IT Infrastructure, Applications and Custom Developed Systems
• Quality Assurance (Policies, SOPs, Internal Audits, Quality Systems)
• Clinical Research Laboratory and BioBank (CRLB)
Breadth of Managed Studies

Current Studies by Therapeutic Area (August 2016)

- Thrombosis
- Stroke
- Renal
- Population Health
- Perioperative and Surgery
- Networks / C-SPIN
- Knowledge Translation
- Global Health
- CVD Prevention
- Cardio- Oncology
- Arrhythmia
- Acute Coronary Syndromes
- Diabetes/Adiposis

# of Studies
Study Type and Status

Number of Studies by Study Type

- Interventional - Drug: 43%
- Interventional - Device: 12%
- Interventional - Procedure: 18%
- Observational - Epi: 14%
- Observational - Followup: 4%
- Observational - Registry: 9%

Current Studies - August 2016

- Planning: 10
- Active Phase: 60
- Reporting: 10
Studies Started by Year
48 of 90 studies initiated within last 3 years!
Study Complexity is Increasing

• Multi arm randomizations to several different drug combinations and more complex inclusion and exclusion criteria
• Drug logistic management across the world from central depots
• Increasing need for strict adherence to regulatory guidance
• Increasing need for flexibility in data collection with better dynamic questionnaires, immediate qc checks, offline capabilities, etc
• Introduction of genetic phenotyping in the analysis of efficacy based on genetic markers
How do we manage?

• Standardizing processes and streamlining where possible
• Being open to improved processes and approaches where needed
• Maintaining in-house development to customize where necessary
• Leveraging our experience and tools like DataFax to their fullest
• Hiring motivated, passionate and dedicated people
• Investing in the infrastructure and resources necessary to remove bottlenecks to achieving goals

• Maintain relevance to population health needs and establishing a reputation for strong scientific process and quality of results
  • Which helps ensure fiscal sustainability through repeat business
Our Experienced Team

- 45 Principal Investigators (*Clinical Scientists*)
- ~10 Research Fellows annually

- 310 Research Staff
  - Bio-Statisticians
  - Research Coordinators
  - Data Management Specialists
  - Information Technology professionals
  - Quality Assurance experts
  - Epidemiologists, Health Professionals (RN, OT, PT, RD)
  - Masters and PhD prepared
Our Economies of Scale

- >300,000 participants currently enrolled worldwide in >70 active research studies
- Number of studies with over 10,000 people: >20
- Total funding for core activities received by PHRI scientists over last 10 years is ~$200 M (both granting agencies and industry)
Our Custom Apps (Research Operations Management Environment)

ROME is a PHRI Developed Web Based System that is/has:

• Integrated to DataFax via DFimport/export use
• Randomization Management
• Investigational Product (IP) Management (logistics)
• Site Management
• Central User Account Management
• Offline Mobile Device Interface Capabilities
• Custom Report Management
• Validated Baseline Configurable Starting Point for Rapid Study Initiation
Modern and Capable Infrastructure

- 80% Virtualized (VMWare) Windows (80) & Unix Servers (8)
  - 5 ESX Host Cluster with Dell R720 16 Core 256MB Servers
  - Physical servers for heavy duty analytics (Stats and Genetics)
- Over 600TB of SAN and NAS (NetApp) based Protected Storage
  - Backup to deduplication based disk storage pools
  - Replicated daily to geographically distant (>50km) D.R. site
- Brocade Network Backbone Utilizing 1, 10 and 40Gb connectivity
  - Fully redundant teamed network interfaces to all servers
  - 100Mbps Internet Bandwidth
- Core/Critical Services Replicated to D.R. Site
  - DataFax, Storage, Unblinding, Randomization, Helpline
- Current up-to-date business/study applications DataFax 2014, SAS 9.4, HylaFax
- Ability to work remotely and securely from any WiFi location on the globe
Thank You. Questions and Answers