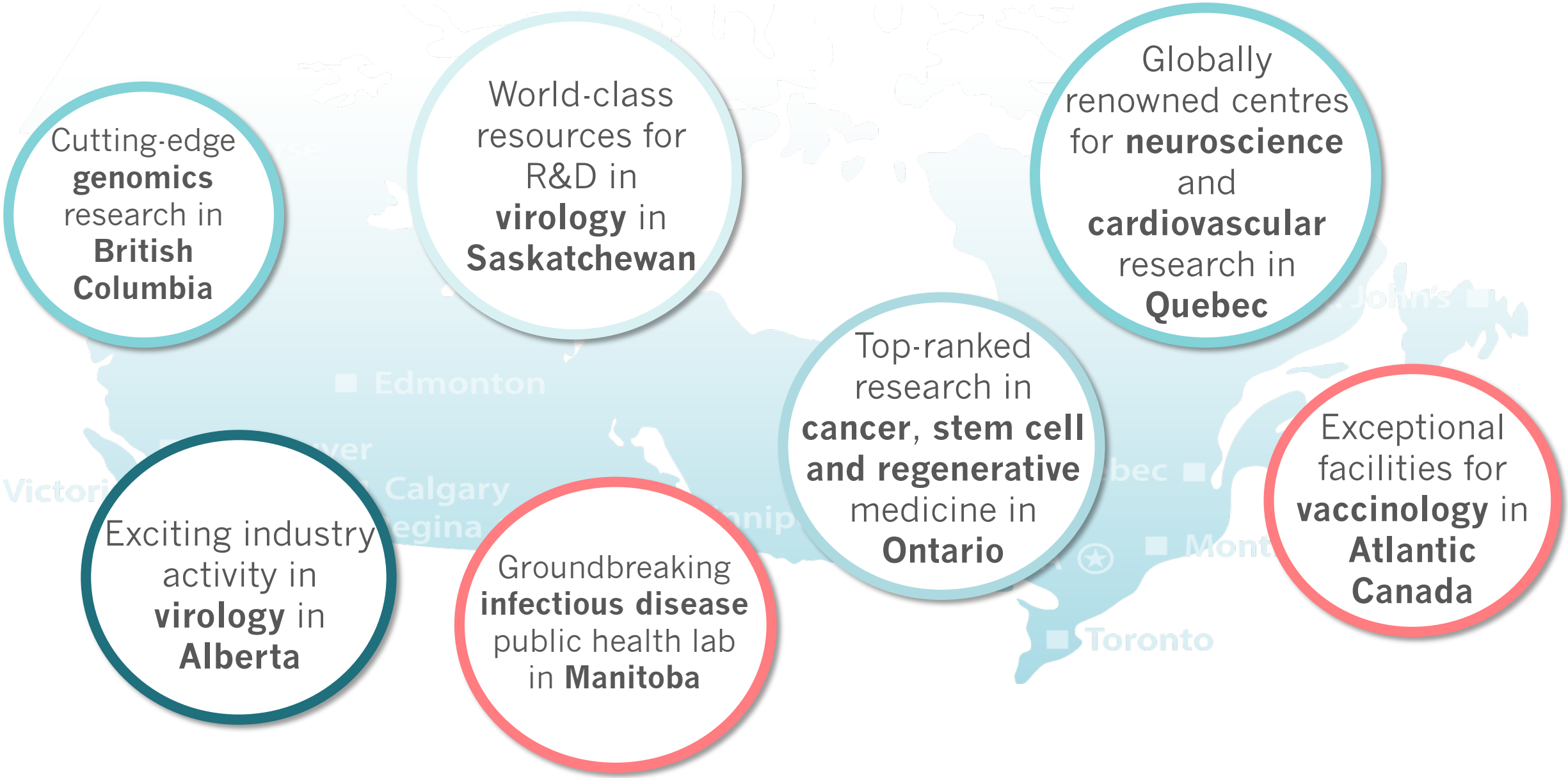
Initiatives for enhancing the Canadian Clinical Research Environment

We are in a global leadership position in areas that include basic and translational research:

Proudly Canadian



Cutting-edge **genomics** research in **British Columbia**

World-class resources for R&D in **virology** in **Saskatchewan**

Globally renowned centres for **neuroscience** and **cardiovascular** research in **Quebec**

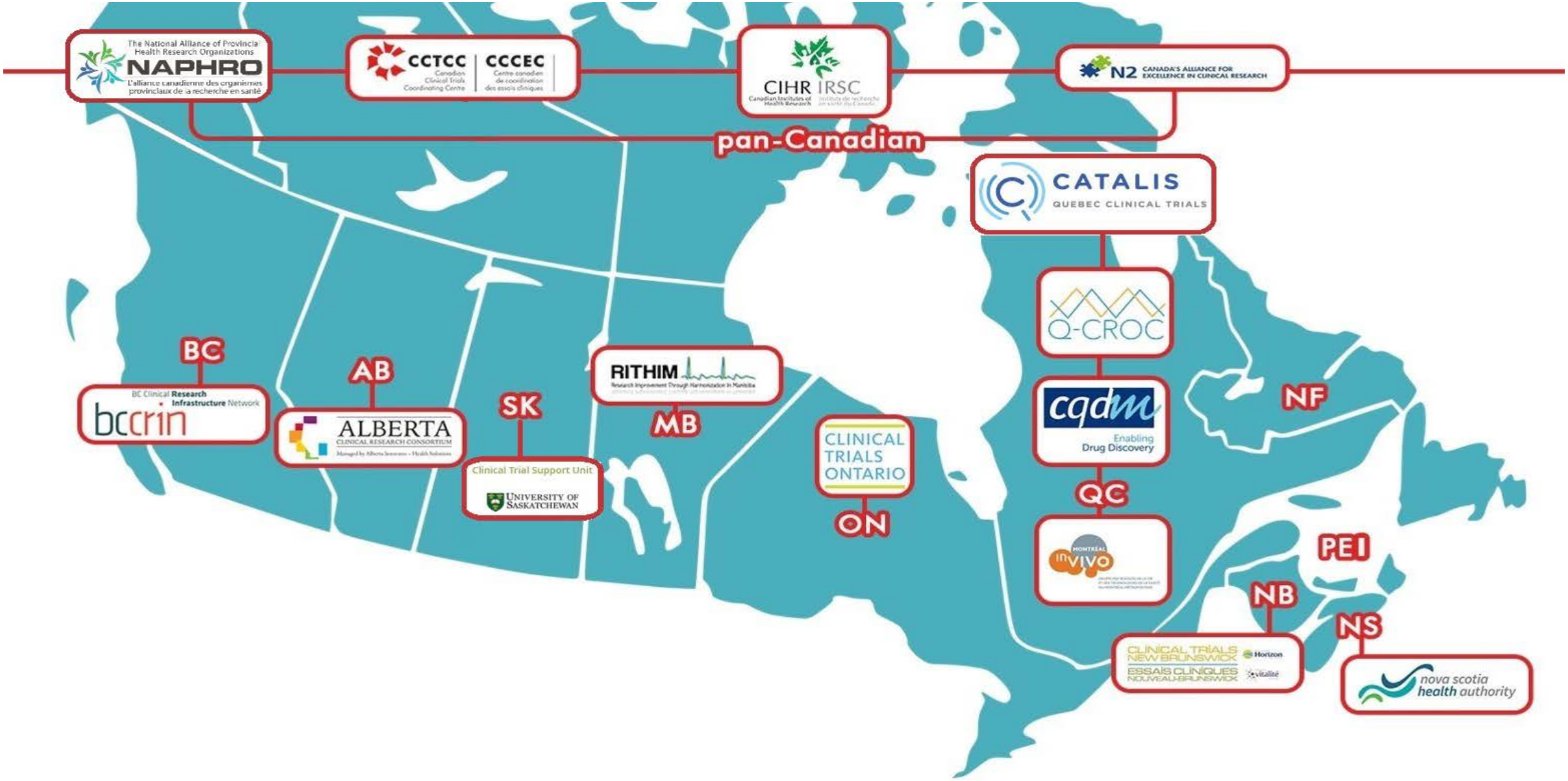
Top-ranked research in **cancer**, **stem cell and regenerative** medicine in **Ontario**

Exceptional facilities for **vaccinology** in **Atlantic Canada**

Exciting industry activity in **virology** in **Alberta**

Groundbreaking **infectious disease** public health lab in **Manitoba**

Canadian Initiatives to Boost Clinical Research



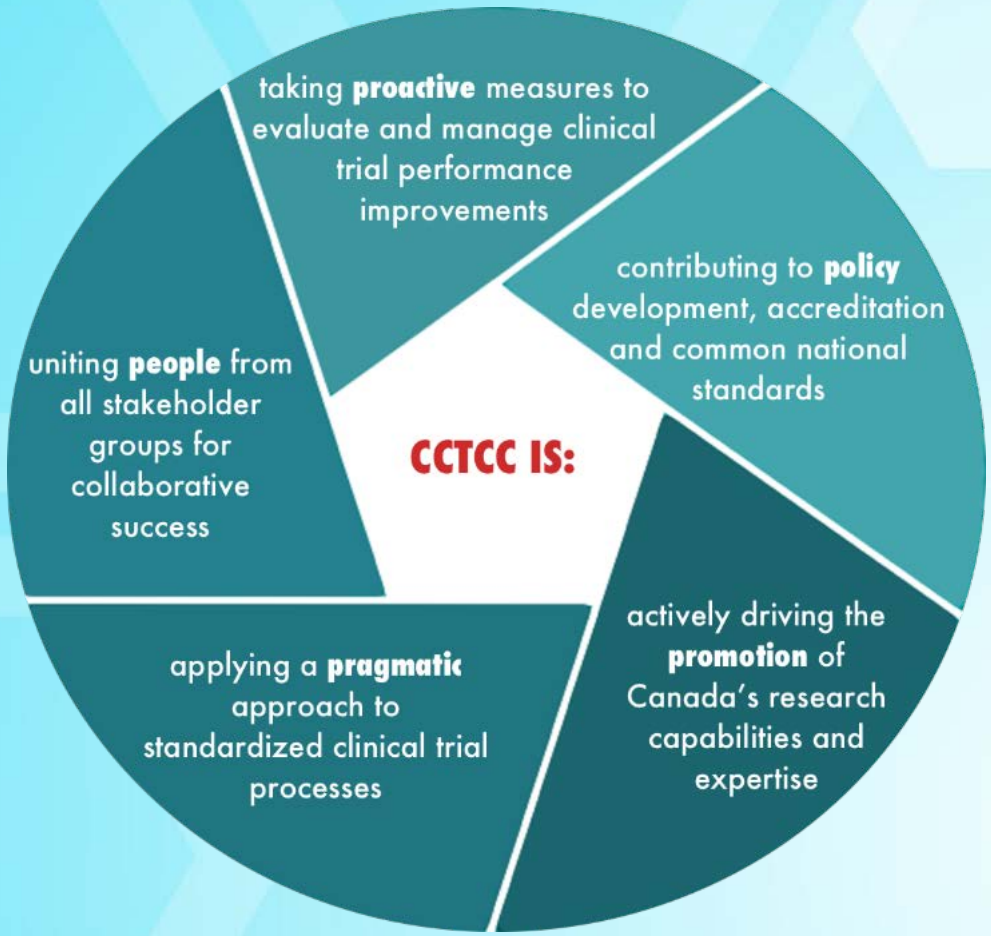
CCTCC
Canadian Clinical Trials Coordinating Centre

CCCEC
Centre canadien de coordination des essais cliniques

STRENGTHENING CLINICAL TRIALS FOR CANADIANS
RENFORCEMENT DES ESSAIS CLINIQUES POUR LES CANADIENS

Canadian Clinical Trials Coordinating Centre (CCTCC)

Kathryn Nijssen
Initiatives Manager



CCTCC is a demonstration of the unique commitment between

industry,

government

and healthcare institutions

to improve the operational environment for clinical trials in Canada.

The CCTCC's key objectives are to improve the operational environment for clinical trials in Canada and promote the country as a destination of choice for clinical trials.

CCTCC
Canadian Clinical Trials Coordinating Centre

CCCEC
Centre canadien de coordination des essais cliniques

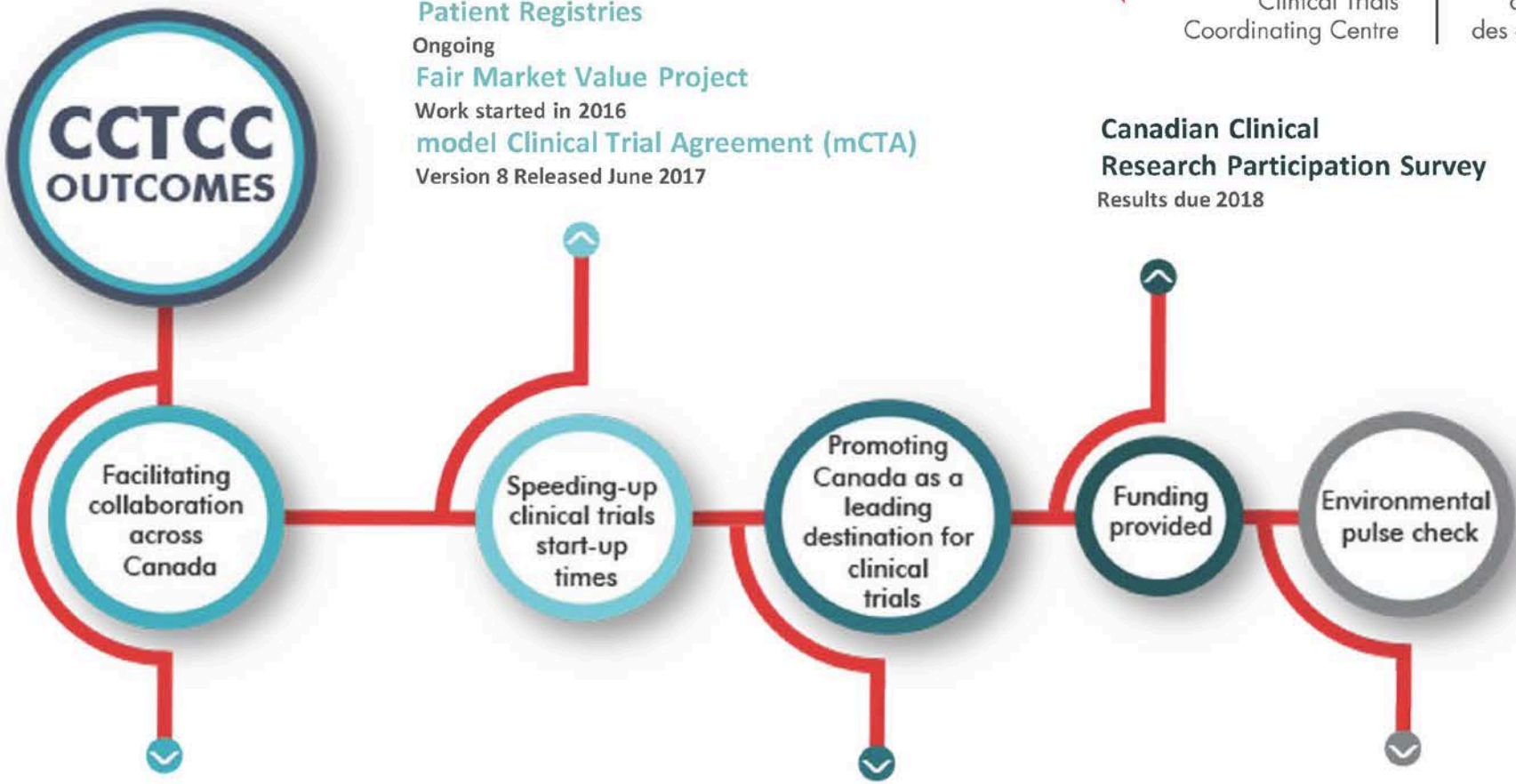
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015

Patient Registries
Ongoing

Fair Market Value Project
Work started in 2016

model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

Canadian Clinical Research Participation Survey
Results due 2018



National Advisory Group
Est. SEPT 2014

Provincial Clinical Trials Organizations' Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016

Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017

Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018

CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

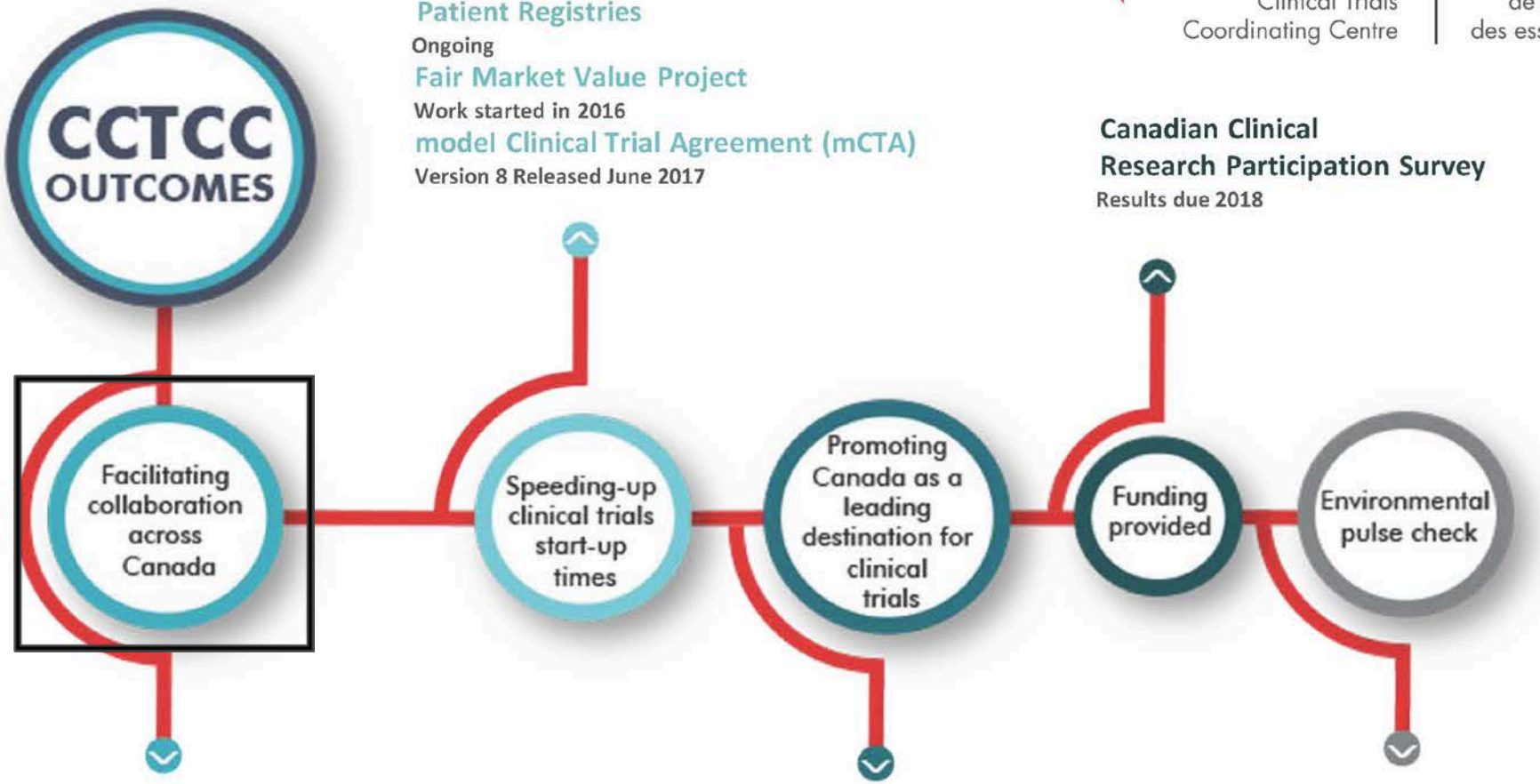
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015

Patient Registries
Ongoing

Fair Market Value Project
Work started in 2016

model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

Canadian Clinical Research Participation Survey
Results due 2018



National Advisory Group
Est. SEPT 2014

Provincial Clinical Trials Organizations' Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016

Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017

Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018

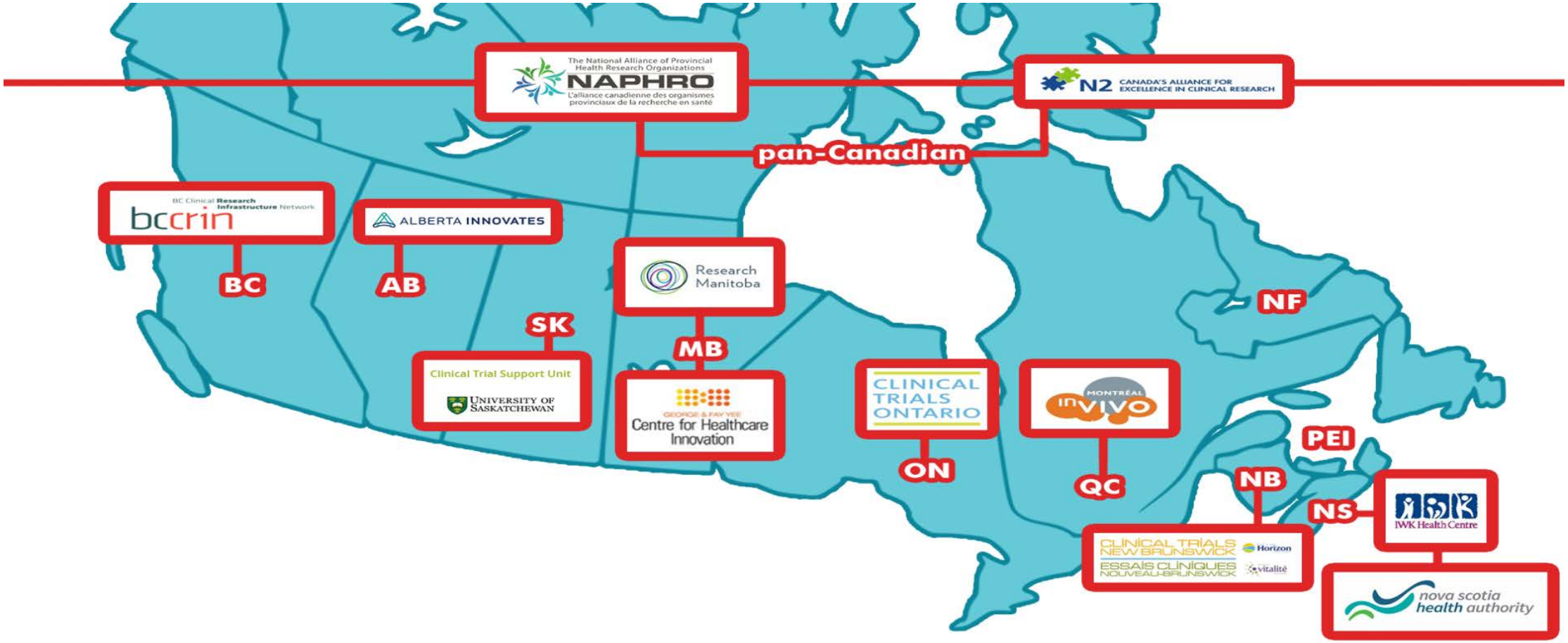
NATIONAL ADVISORY GROUP

- pan-Canadian expert group providing input & advice on CCTCC's activities

PROVINCIAL CT ORGANIZATIONS' MEETINGS

- Foster collaboration
- Engage for projects
- Identify emerging issues
- Prevent duplication of effort

Provincial CT Organizations Meetings



COLLABORATION

CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

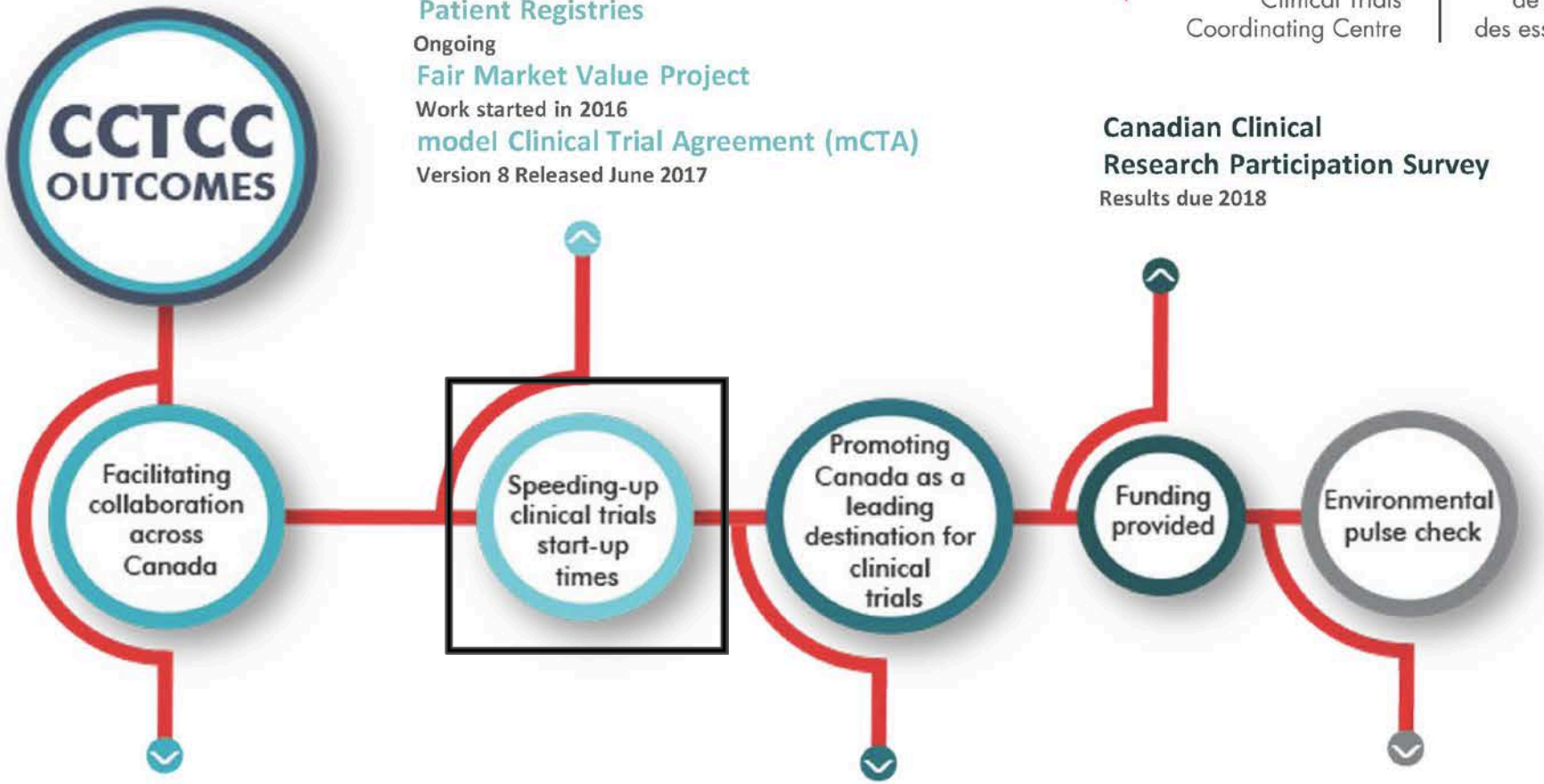
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015

Patient Registries
Ongoing

Fair Market Value Project
Work started in 2016

model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

Canadian Clinical Research Participation Survey
Results due 2018



National Advisory Group
Est. SEPT 2014

Provincial Clinical Trials Organizations' Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016

Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017

Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018

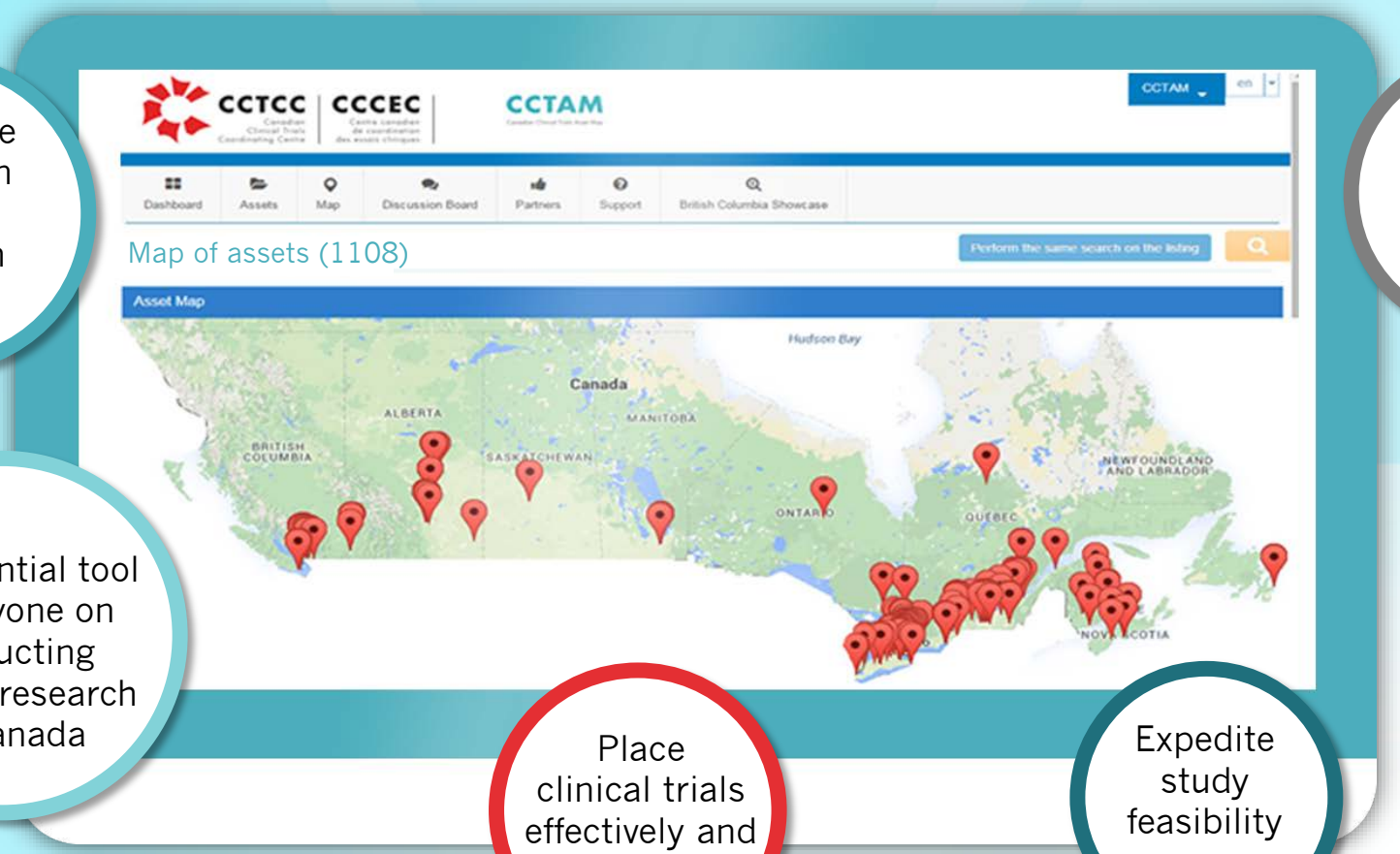
WHAT IS THE CCTAM?

CCTAM
Canadian Clinical Trials Asset Map

- Web-based, 'living, easily searchable, interactive database of Canadian clinical research capabilities:
  - investigators, clinical research sites, hospitals, institutions, research ethics boards, CROs, SMOs , etc.
- First pan-Canadian, pan-therapeutic, up-to-date, research inventory with an integrated map-based search function
- Currently over 1100 assets (40% asset growth since launch in June 2015)
- Access the CCTAM by visiting www.cctam.ca

Canadian Clinical Trials Asset Map (CCTAM)

Showcase Canadian clinical research assets



Reduce clinical trial start-up times

An essential tool for anyone on conducting clinical research in Canada

Unique in the world

Place clinical trials effectively and efficiently

Expedite study feasibility process

www.cctam.ca | cctam@cctcc.ca

CCTAM

CCTAM webinars available upon request.

CCTCC
Canadian Clinical Trials Coordinating Centre

CCCEC
Centre canadien de coordination des essais cliniques

CCTAM

Canadian Clinical Trials Asset Map

PATIENT REGISTRIES

CCTAM
Canadian Clinical Trials Asset Map

- Populating in the CCTAM to facilitate CT feasibility studies & patient recruitment
- Key criteria used in selecting registries:
  - ✓Active registry
  - ✓10 registrants min.
  - ✓Point of contact
  - ✓Diagnosis identified by an approved care team
  - ✓Data accessible to external parties for purposes of CT recruitment
- **Actively working to contact and populate in the CCTAM**

MODEL CLINICAL TRIAL AGREEMENT (mCTA)

- Canada-wide initiative to:
  - ✓standardize CT agreements by developing language for all clauses
  - ✓bring efficiencies to clinical research process
- Collaboration with CLEAR (TransCelerate-supported) project to incorporate CLEAR language within the mCTA
- mCTA's Team Canada consists of site/institution & sponsor representatives

mCTA – CURRENT STATUS

- **Adoption and Implementation stage** after comprehensive stakeholder consultations in 2015 & 2016
- Reviewed by an independent legal counsel[1] for consistency of terminology use & definitions, & clarifying ambiguous wording
- **mCTA Version 8, consultation report & communication deck are available for use**
- Working with sponsors and sites to establish a review committee that will ensure the continued relevance of the contract

FAIR MARKET VALUE (FMV) PROJECT

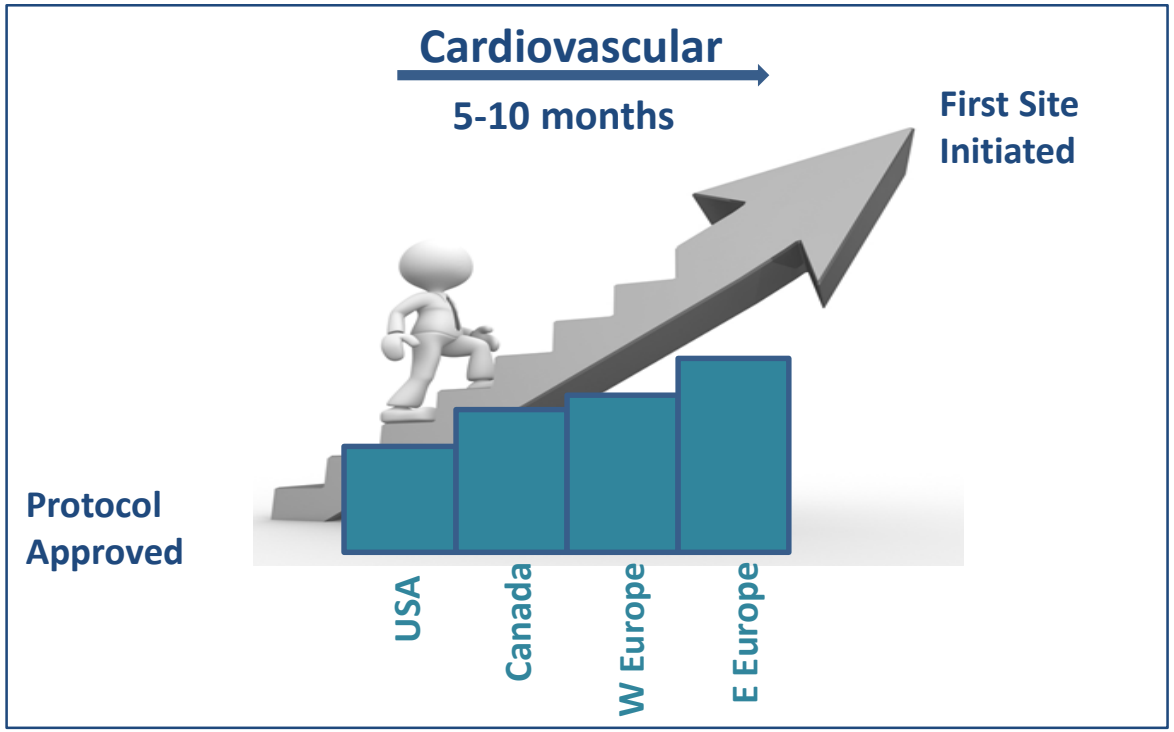
- Direct result of the model CT Agreement (mCTA) project

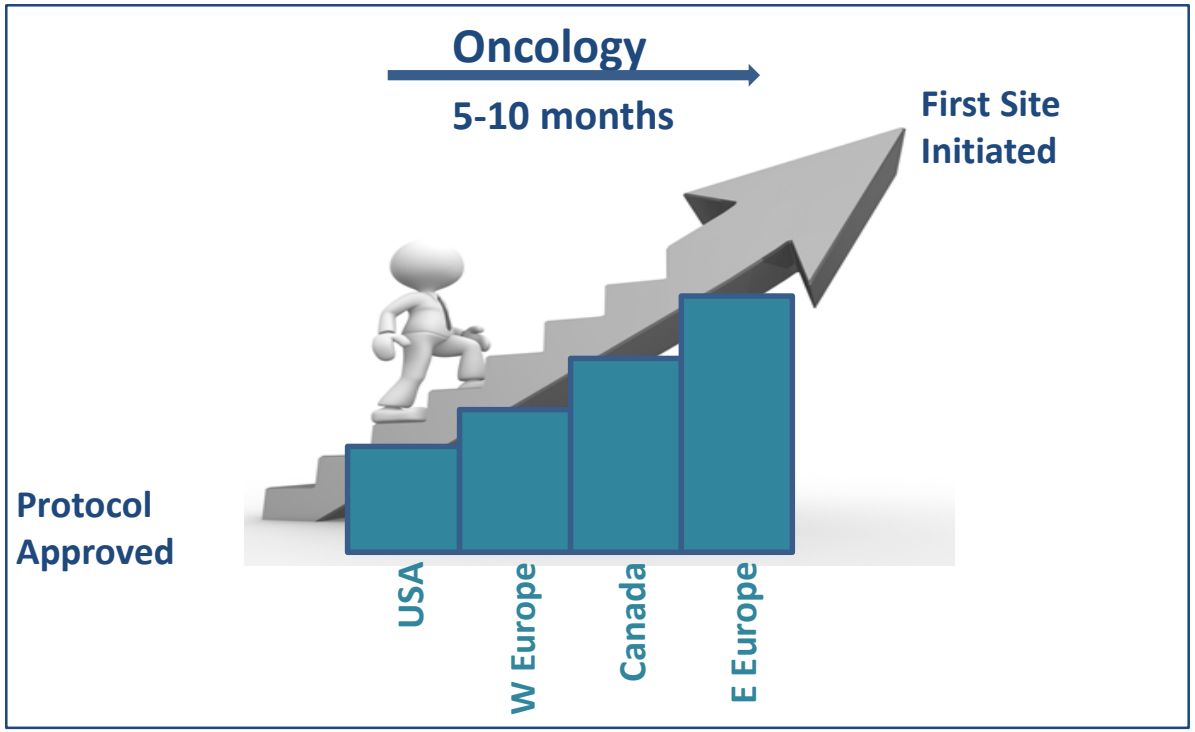
✓ **Goals:**
  - Reduction of clinical trial (CT) budget negotiation times
  - Reduction of CT study start-up timelines
  - Introduction of CT efficiencies and streamlining of budget negotiations

✓ **Reasons to tackle FMV:**
  - Address increasing CT start-up times
  - Ensure Canada's CT competitiveness globally

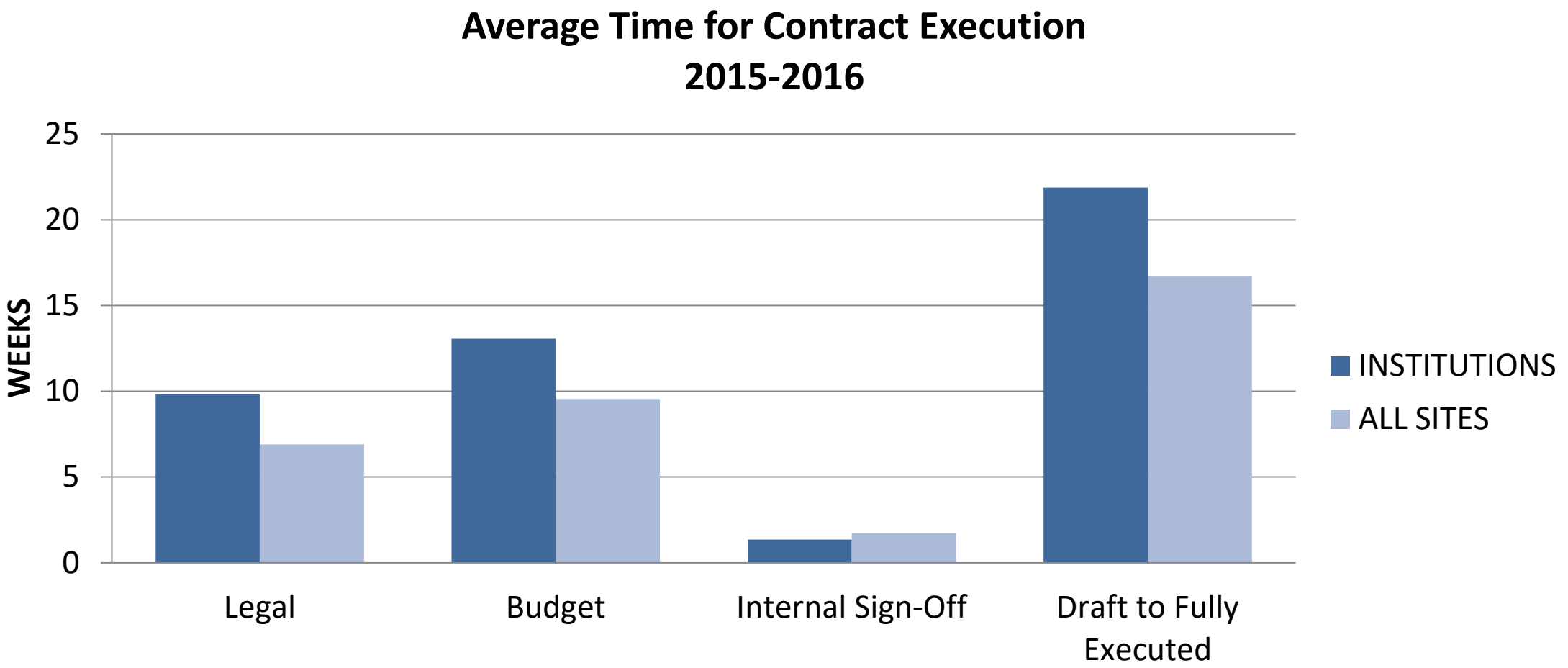
FMV BACKGROUND – STUDY START-UP

- Canada start-up is competitive compared to Europe for CV but not for Oncology trials
- Challenges with start-up in Canadian institutions (IRB, contracts, budgets)





CONTRACT TIMELINES



CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

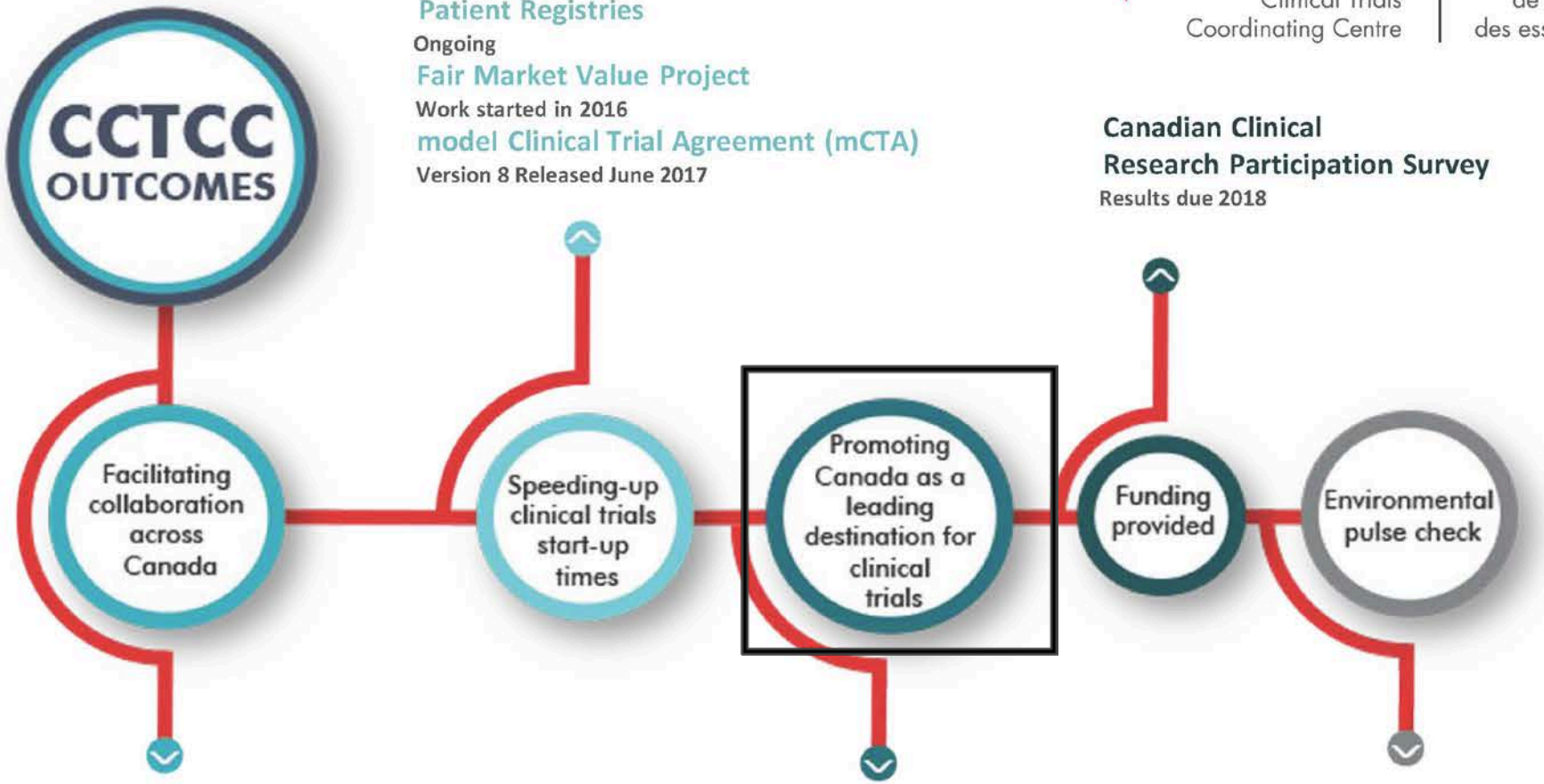
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015

Patient Registries
Ongoing

Fair Market Value Project
Work started in 2016

model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

Canadian Clinical Research Participation Survey
Results due 2018



National Advisory Group
Est. SEPT 2014

Provincial Clinical Trials Organizations' Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016

Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017

Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018

"Clinical Trials – the Canadian Advantage" Investment Case

- Consistent narrative communicating Canada's clinical trials advantages globally focused on:
  - ✓ Speed
  - ✓ Quality
  - ✓ Incentives
- Intended for presentations to global offices of CT sponsors
- Customizable based on audience's needs
- Next steps:
  - ✓ Possible additional modules
  - ✓ Keep content updated
- Access here

CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

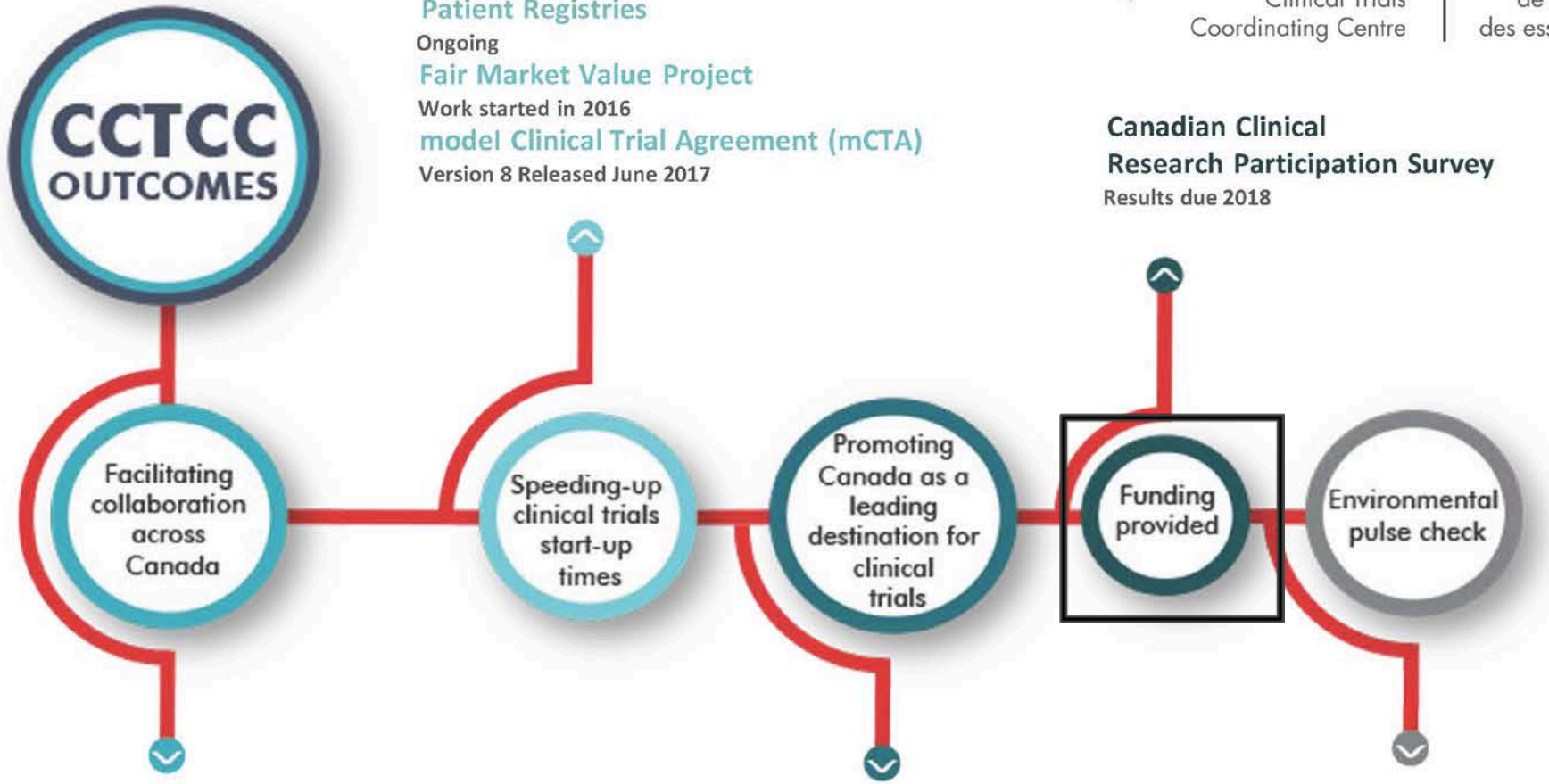
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015

Patient Registries
Ongoing

Fair Market Value Project
Work started in 2016

model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

Canadian Clinical Research Participation Survey
Results due 2018



National Advisory Group
Est. SEPT 2014

Provincial Clinical Trials Organizations' Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016

Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017

Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018

Clinical Research Participation Survey

Engage. Listen. Act.

Hosted at www.bccrin.ca/survey

- First pan-Canadian survey enabling patients & healthy volunteers to provide input & advice on their CT experience
- Anonymous, online experience survey by Clinical Trials BC (formerly BCCRIN). Part of the BC Academic Health Science Network
- Pan-Canadian Expansion supported by the CCTCC
- Adults, or parents of a child, who have been invited to participate in a clinical trial and either enrolled, declined or did not meet the screening requirements are eligible
- Part of a broader strategy to engage Canadians in the clinical research process
- Data will be used to improve recruitment and retention outcomes for clinical research sites, investigators and sponsors by developing strategies designed to address provincial and national research participant perspectives and concerns

Clinical Research Participation Survey Update October 2017

- Enrollment target of > 1000 reached April 2017
- Analysis by CHEOS commenced September 2017
- Results expected November 2017
- Planned publication
- Knowledge translation planning has commenced
- **Questions**: Alison Orth at Clinical Trials BC - aorth@bcahsn.ca

CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

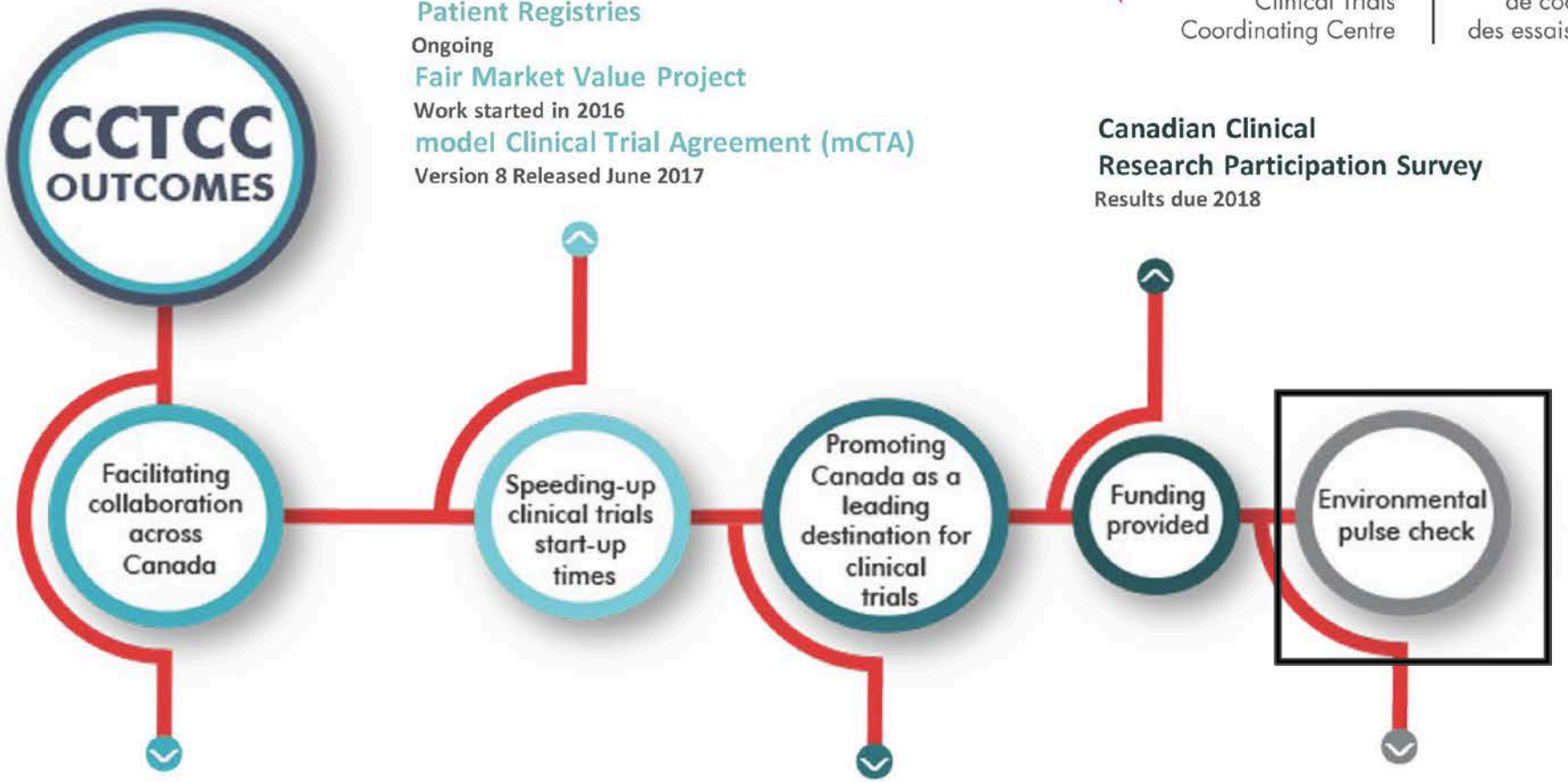
Canadian Clinical Trials Asset Map (CCTAM)
Launched JUN 2015

Patient Registries
Ongoing

Fair Market Value Project
Work started in 2016

model Clinical Trial Agreement (mCTA)
Version 8 Released June 2017

Canadian Clinical Research Participation Survey
Results due 2018



National Advisory Group
Est. SEPT 2014

Provincial Clinical Trials Organizations' Meetings
1st meeting NOV 2015
2nd meeting APR 2016
3rd meeting NOV 2016

Investment Case
Launched Summer 2016

Clinical Trials Panel at BIO 2016
JUN 2016

Research Ethics Boards Issues
Report Released Summer 2016
CCTCC & HC Response Released JAN 2017

Canadian Clinical Trials Metrics
Updated Metrics due Spring 2018

RESEARCH ETHICS BOARD REPORT

- The impact of the Canadian experience of REB centralization & harmonization
- Recommendations for the future to ensure Canada's competitiveness on a global scale
- CCTCC & Health Canada prepared a joint response to the WG's report
- More information is available here

CLINICAL TRIALS METRICS

- Quantitative metrics, e.g.:
  - ✓# of newly randomized subjects, opened sites, trials, trials by phase in Canada & globally (phases I,II,II, IV, other)
- Operational metrics, e.g.:
  - ✓average time/days to REB approval, contract & budget
- Quality metrics, e.g.:
  - ✓patient recruitment, validity, retention, & protocol & dosing deviations (international comparison)
- Investment metrics, e.g.:
  - ✓total CT Investment in Canada (by province) vs. other countries (including CROs)

CONTACT US

WEB: www.cctcc.ca

EMAIL: knijssen@cctcc.ca

Phone: 613-875-3457

CCTCC
Canadian
Clinical Trials
Coordinating Centre

CCCEC
Centre canadien
de coordination
des essais cliniques

THANK YOU