ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Accelerating Clinical Trials (ACT) Consortium

P.J. Devereaux, MD, PhD
Nominated Principal Applicant of ACT Consortium
Population Health Research Institute
Hamilton, Ontario, Canada

Goals of presentation

- Background
- Central guiding principle of ACT Consortium
- Overview of structure
- Some high-level goals of ACT

Canadian trial landscape

- Canadian should take pride in impact Canadian trials have had on improving health globally
  - however,
  - we have to also acknowledge that COVID-19 pandemic uncovered serious issues related to conducting RCTs in Canada

Canadian trial landscape

- Successful Canadian trials have primarily occurred due to researchers having mindset of long-distance runner
  - trialists have succeeded because of perseverance not because of system
- COVID-19 required trialists to function as sprinters; however
  - barriers and operational bottlenecks to conducting trials in Canada prevented this from happening
  - as a result, Canada was dependent on other countries like UK
    - which conducted trials efficiently and established treatments that substantially reduced mortality

Biotechnology

- Canadian biotechnology and RCT communities rarely intersect
  - consequently few Canadian researchers undertake RCTs evaluating Canadian biotechnologies
- Few, if any, Canadian small- medium-size biotech companies
  - have capital to fund clinical trials required to obtain regulatory approval
- Few major pharmaceutical or biotechnology companies have their headquarters in Canada
  - funding decisions for large trials are made by global headquarters
    - this limits opportunities for Canadians to lead clinical trials

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

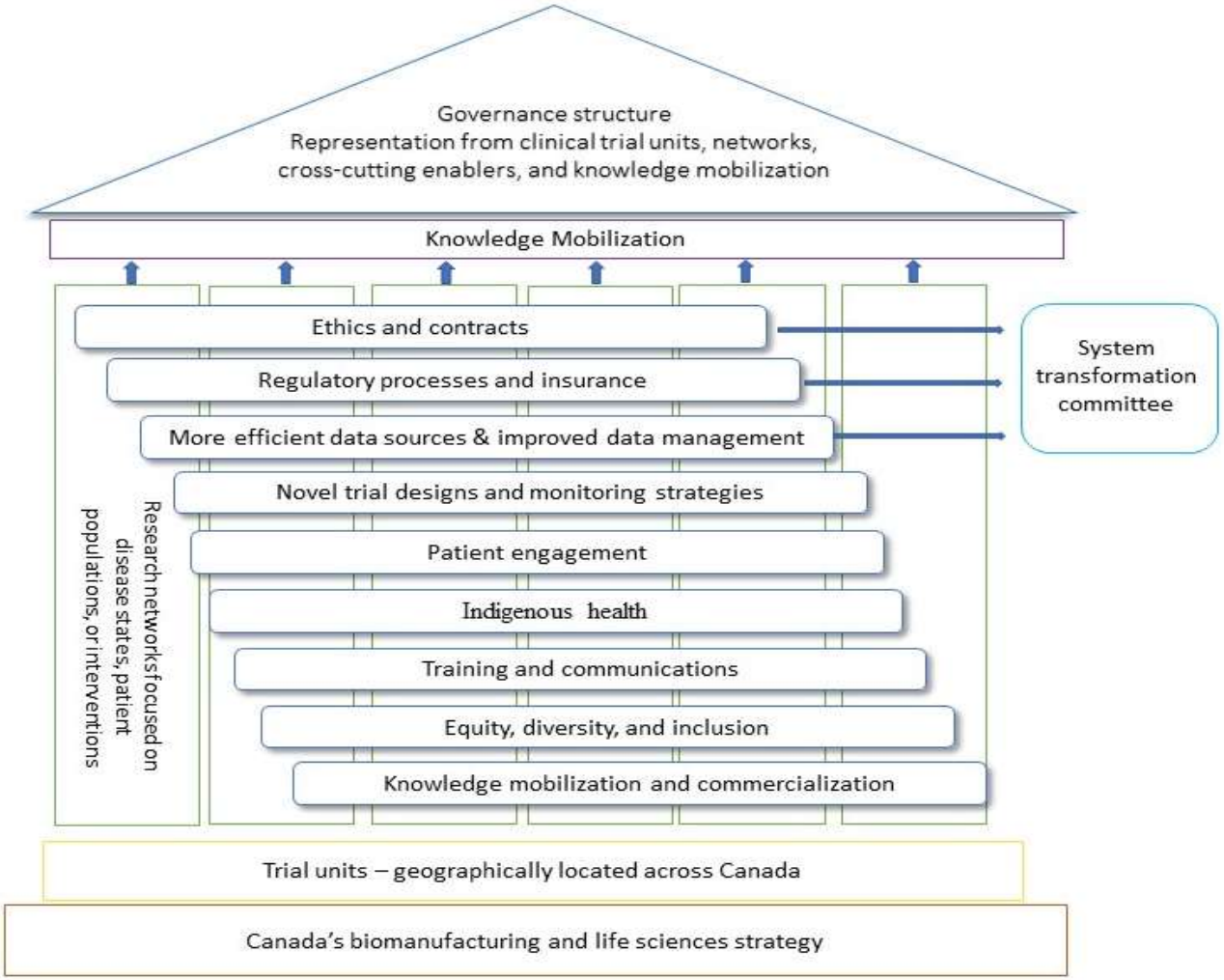
Accelerating Clinical Trials (ACT) Consortium

funded to address these challenges

Central guiding principle

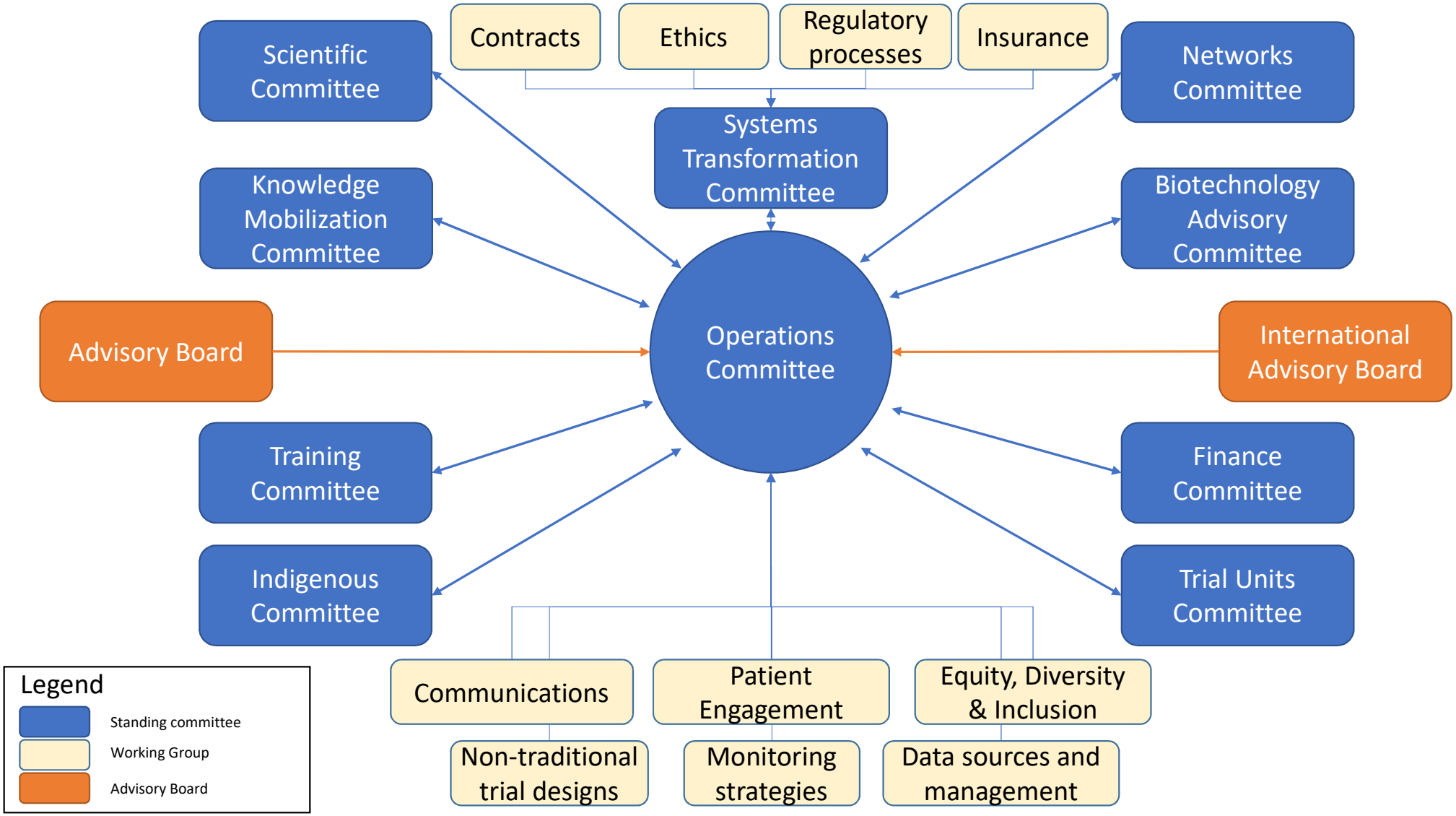
- Our activities will accelerate, optimize, and facilitate the conduct, implementation, and results translation from high-quality, high-impact RCTs to improve health in Canada and around the world

Structure


Governance structure
Representation from clinical trial units, networks, cross-cutting enablers, and knowledge mobilization
Knowledge Mobilization
Ethics and contracts
Regulatory processes and insurance
More efficient data sources & improved data management
Novel trial designs and monitoring strategies
Patient engagement
Indigenous health
Training and communications
Equity, diversity, and inclusion
Knowledge mobilization and commercialization
Research networks focused on disease states, patient populations, or interventions
System transformation committee
Trial units – geographically located across Canada
Canada's biomanufacturing and life sciences strategy

ACT

- >300 investigators
- >800 HQP
- 23 Canadian Universities and all medical schools
- Spans from NS to BC and Nunavut


Scientific Committee
Contracts
Ethics
Regulatory processes
Insurance
Networks Committee
Systems Transformation Committee
Knowledge Mobilization Committee
Biotechnology Advisory Committee
Advisory Board
Operations Committee
International Advisory Board
Training Committee
Finance Committee
Indigenous Committee
Trial Units Committee
Communications
Patient Engagement
Equity, Diversity & Inclusion
Non-traditional trial designs
Monitoring strategies
Data sources and management
Legend
Standing committee
Working Group
Advisory Board

Networks and trial units

- Expand and support existing clinical trial networks and develop new networks in areas of need
- Adopt successful international approaches to trial conduct
  - portfolio program
- Ensure trial units have resources and expertise to conduct high-quality, high-impact trials

Accelerate conduct and efficiency of RCTs

- We need systems that are in best interest of Canadians
  - single national ethic approval process
  - simplify contract process
    - master clinical trial agreements
  - efficient data sources
    - participant identification and outcome data
  - increase expertise in non-traditional trial designs

Expand Canadian participation in international trials and vice versa

- Share collaborative connections
- Insurance
  - open market too expensive
  - need captive insurance company structure for Canadian RCTs

Strengthen coordination of Canadian clinical trials, facilitate harmonization across trial units and networks

- Shared electronic trial master file across trial units
  - comply with regulatory requirements
- Canadian drug packaging and distribution and biobanking

Democratize clinical trials

- Create equitable access to trial participation
  - portfolio program
  - novel partnerships
    - pharmacies
- Communications strategy

Improve process of involving Indigenous peoples in trials

- Indigenous people should identify their health priorities
- Trials should be funded to address these priorities
- Support, expand, and foster Indigenous clinical trialists

Growing funding pie

- Too much time wasted among Canadian health researchers debating how to divide CIHR funding pie
- Learn from EU
  - Canadian trialists need to help support and grow Canadian biotechnology industry by evaluating their products in RCTs
- Work with Canadian headquarters of major pharmaceutical or device companies to
  - bring more trials to Canada and have more Canadian clinical trial units lead trials funded by these companies

Demonstration projects

- RFA -1 high-impact RCTs that need additional funding for successful completion
  - will publicly report their results by January 15, 2025
- RFA -2 non-traditional and efficient designs and trials within trials to improve efficiency and quality of trials
- RFA -3 RCTs evaluating Canadian biotechnology
- RFA -4 new networks in areas of need
- More RFAs in year 2

Training

- Partnering with funded CTTPs

Annual Consortium Meetings

- First meeting Apr 17-18th, 2023 - Hamilton Ontario
- Goals
  - provide an overview of ACTs objectives, plans, and structure
  - bring Canadian biotechnology and Canadian researchers together

ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Summary

- ACT has ambitious plans
- Key to achieving goals
  - systematic structure
  - broad representation
  - partnerships