



# Accelerating Clinical Trials (ACT) Consortium

Contracts Working Group Update

# Challenges with Contracts

- ▶ Regulatory obligation to enter into contracts regarding clinical trials
- ▶ High volume of contracts
- ▶ Specialized knowledge required to review these contracts
- ▶ Legal landscape is changing quickly (i.e. responding to COVID challenges, changing privacy laws, new AI challenges)
- ▶ Understaffed institutions
- ▶ Staff turnover
- ▶ Studies change and may have evolving contractual needs
- ▶ Each institution has different and changing requirements

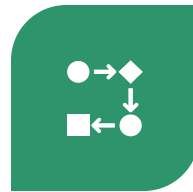
# Working Group Objectives and Deliverables



ACCELERATE THE CONDUCT AND EFFICIENCY OF CLINICAL TRIALS IN CANADA



STRENGTHEN COORDINATION AMONG CANADIAN CLINICAL TRIALS, FOSTERING COLLABORATION AND HARMONIZATION AMONG TRIAL UNITS, NETWORKS, AND STAKEHOLDERS.



REDUCE CYCLE TIMES IN THE NEGOTIATION AND EXECUTION OF AGREEMENTS.



DEVELOP MASTER CLINICAL TRIAL AGREEMENT(S) AND TEMPLATES.



CREATE ADDITIONAL TOOLS, TEMPLATES, AND RESOURCES TO STREAMLINE CLINICAL TRIAL CONTRACTS IN CANADA.



RECRUIT AND ONBOARD ADOPTEES

# Contracts Working Group Initial Composition

ACT Clinical Trial Unit	Institution
Centre for Cardiovascular Innovation (CCI)	University of British Columbia
Canadian VIGOUR Centre (CVC)	University of Alberta
Health Policy Trials Unit, Centre for Health Policy, O'Brien Institute for Public Health	University of Calgary
Clinical Trial Unit, Centre for Healthcare Innovation (CHIRON)	University of Manitoba
Accelerating Randomized Trials Unit (ARTU)	Lawson Health Research Institute
Ottawa Hospital Research Institute (OHRI)	Ottawa Hospital Research Institute
Population Health Research Institute (PHRI)	McMaster University
Research Institute -McGill University Health Centre (RI-MUHC)	McGill University
Clinical Trial Unit, Population Health and Optimal Research Practices (SPPOS)	CHU de Quebec-Université Laval
Canadian Centre for Vaccinology (CCfV)	Dalhousie University
Maternal Infant Child and Youth Research Network (MICYRN)	Not for Profit- Research Organization

# Current Working Group Membership

79 individuals

~ 47  
institutions/organizations

# Current Focus: Inter-Institutional Agreements



# Governing Data and Sample Sharing Agreement

Binding agreement with pre-negotiated terms and conditions. The purpose is to enable focused negotiations, leading to reduced execution timelines



Includes:

(1) Transfer Letter: Outlining project specific details and an opportunity to specify any deviations to the agreement.

(2) Joinder Letter: Allow for future adoptees

# Governing Data and Sample Sharing Agreement

Finalized in Feb 2024

Execution copy circulated Feb 2024 which included 29 parties

13 new adoptees

Quebec is exploring onboarding upwards of 25 parties through Regroupement project



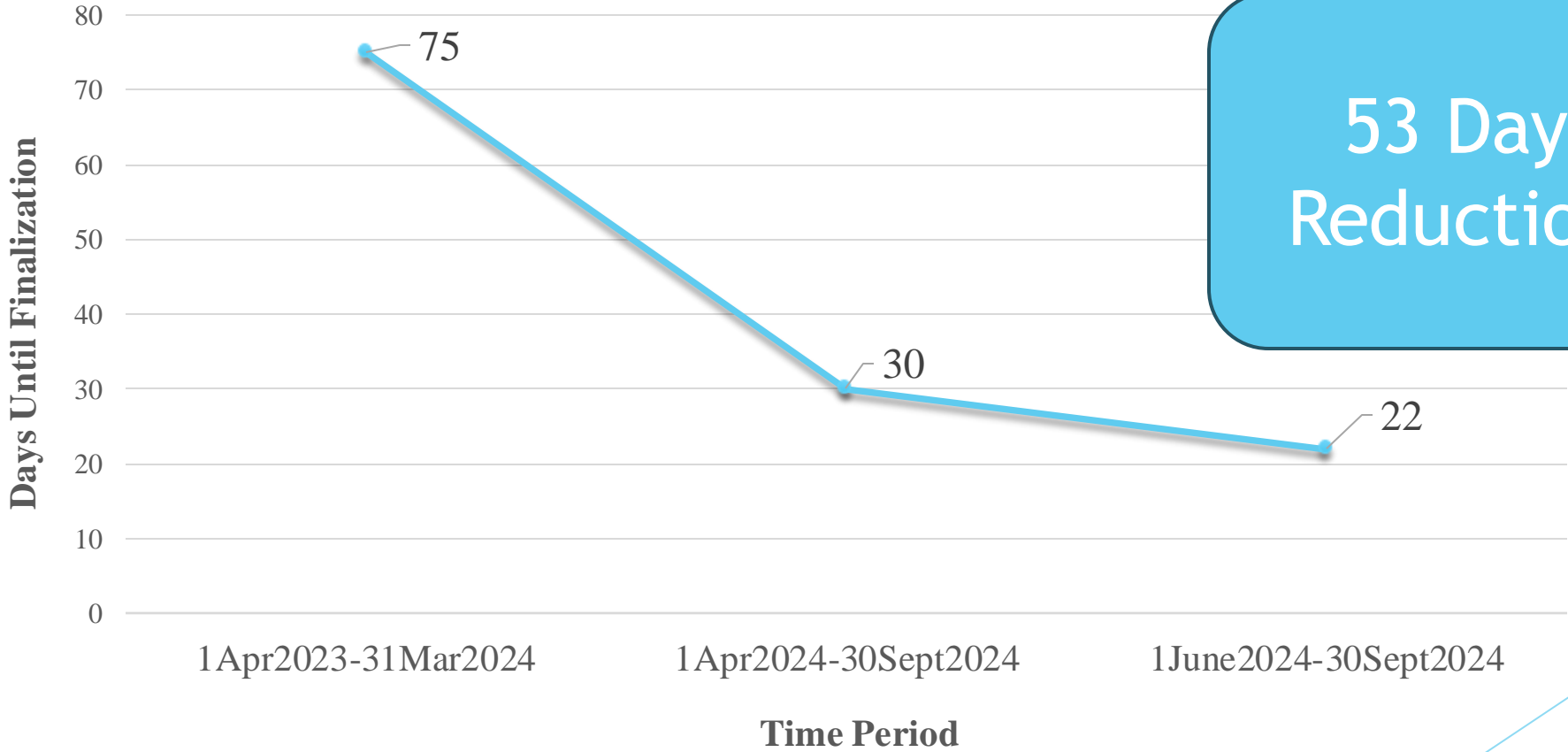
# DSSA Signatories

Alberta Health Services and University of Alberta  
Alberta Health Services and University of Calgary  
Belong Ottawa  
Bruyere Research Institute  
Centre Intégré Universitaire de Santé et de Services Sociaux du Nord-  
de-l'Île-de-Montréal  
Children's Hospital of Eastern Ontario Research Institute Inc. (CHEO)  
CHU de Québec-Université Laval  
Dalhousie University  
Governors of the University of Alberta  
Hamilton Health Sciences Corporation  
Hospital for Sick Children  
Izaak Walton Killam (IWK) Health Centre  
Kingston General Health Research Institute  
Kingston Health Sciences Centre  
Lawson Health Research Institute  
Maternal Infant Child and Youth Research Network  
McMaster University  
Mego Nerses, Registered Psychotherapist  
Montfort  
Oak Valley Health  
Ottawa Heart Institute Research Corporation  
Ottawa Hospital Research Institute

Ottawa Inner City Health Inc.  
PHSA on behalf of BC Cancer  
PHSA on behalf of BC Children's Hospital and Women's Hospital  
Providence Health Care Society  
Queen's University  
Queensway Carleton Hospital  
Research Institute of the McGill Health Centre  
Saskatchewan Health Authority  
Shared Health Manitoba  
Sunnybrook Research Institute  
Unity Health Toronto  
University Health Network (UHN)  
University of British Columbia  
University of Manitoba  
University of Ottawa  
University of Ottawa Institute of Mental Health Research  
University of Saskatchewan  
Vancouver Coastal Health Authority  
Western University  
William Osler Health System

# Impact of gDSSA at OHRI

## Cycle Times for gDSSA



53 Day Reduction

# Sub-Site Template Agreement for Clinical Trials



**SCOPE: INTER-  
INSTITUTIONAL/  
HOSPITAL BASED  
(NON-INDUSTRY)**



**AGREED UPON  
TERMS AND  
CONDITIONS TO BE  
USED AS A TOOL BY  
WG INSTITUTIONS  
AND AFFILIATED  
PARTIES**

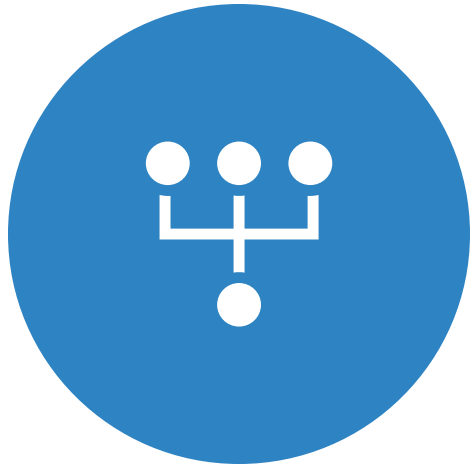


**FLEXIBLE AND  
ADAPTABLE  
LANGUAGE**



**FINAL DRAFT  
CURRENTLY UNDER  
REVIEW (SEPT 2024)**

# Next Steps:



**DEVELOP A GOVERNING (MASTER) SUB  
SITE AGREEMENT FOR TRI-COUNCIL  
FUNDED PROJECTS**



**TIMELINE: WINTER 2024**

# Contact Information



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