ACT AEC Accelerating Clinical Trials Accélérer les Essais Cliniques

Population Health Research Institute HEALTH THROUGH KNOWLEDGE

CIHR IRSC Canadian Institutes of Health Research Instituts de recherche en santé du Canada

Accelerating Clinical Trials (ACT) Consortium

Contracts Working Group Update

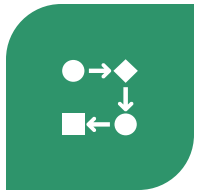
Challenges with Contracts

- 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

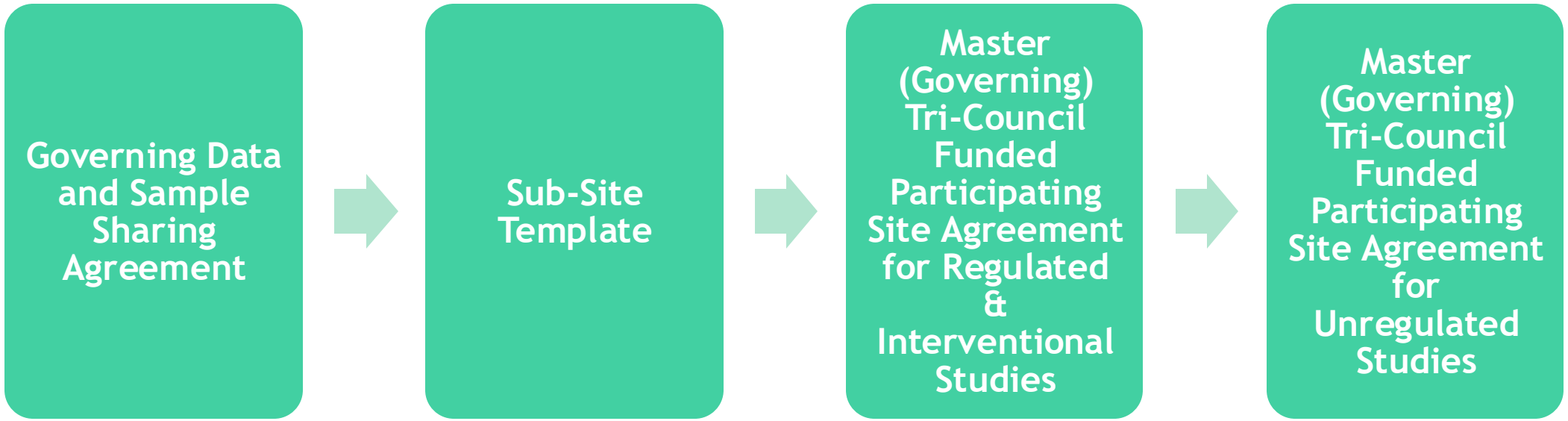
ACT Clinical Trial Unit	Institution
Centre for Cardiovascular Innovation (CCI)	University of British Columbia
Canadian VIGOUR Centre (CVC)	University of Alberta
Health Policy Trials Unit, Centre for Health Policy, O'Brien Institute for Public Health	University of Calgary
Clinical Trial Unit, Centre for 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

~80 individuals

~ 50 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

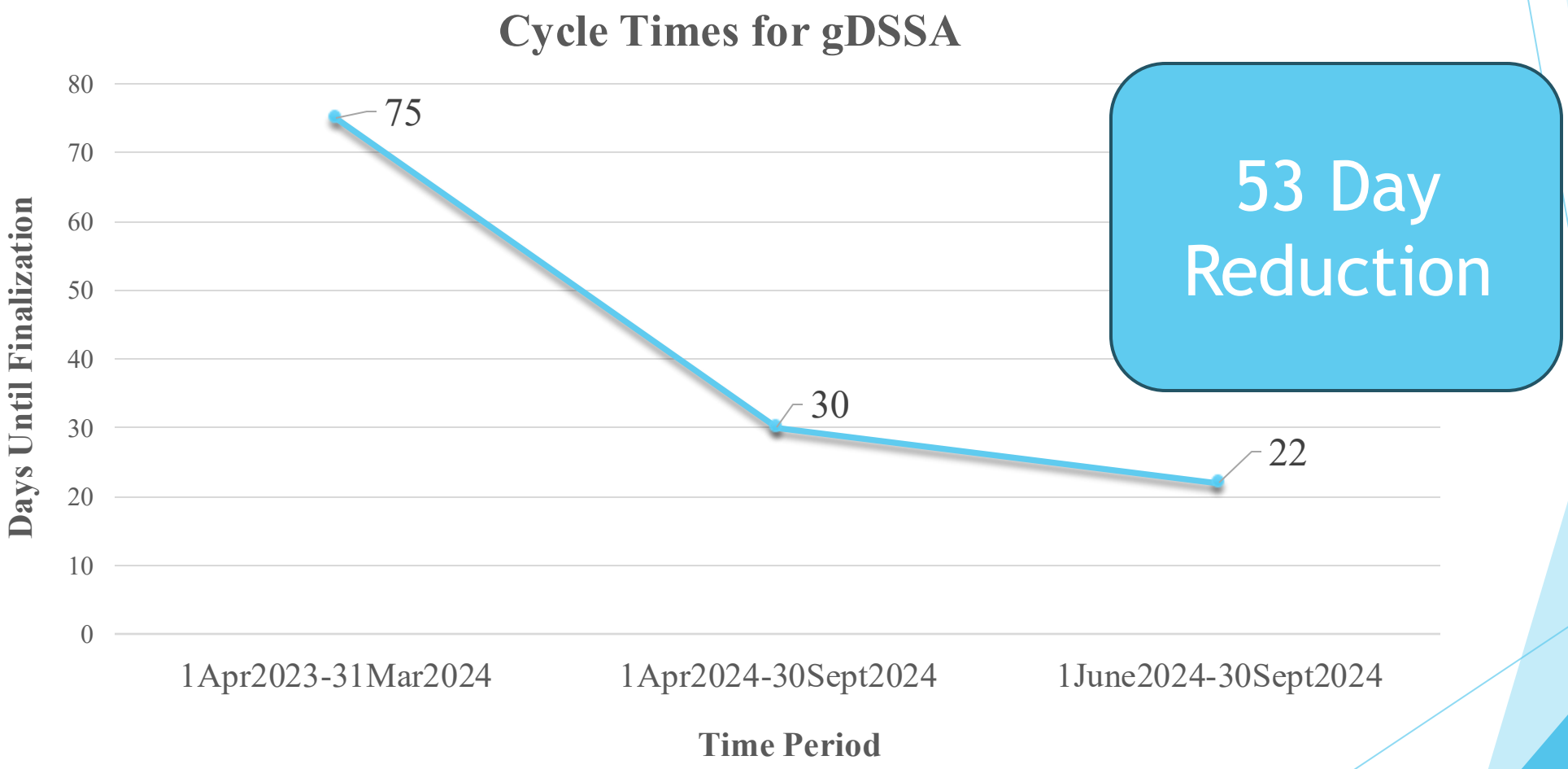
Governing Data and Sample Sharing Agreement

Finalized in Feb 2024

Execution copy circulated Feb 2024 which included 29 parties

Total of 65 adoptees

Impact of gDSSA at OHRI



Summary Table of Efficiency Gains

- **Before gDSSA Implementation:** The average number of days between the time the office opened a DSSA file to the time the office finalized the DSSA file

- **After gDSSA Implementation:** The average number of days for the finalization of all data and samples sharing agreements post gDSSA implementation

Case	Type	Before (D)	After (D)	% Reduction
3	DSSA	90	50	44.44%
5	DSSA	75	35	53.33%
6	DSA	62	46	25.81%
6	SSA	38	37	2.63%
8	DSA	73	37	49.32%
8	SSA	78	18	76.92%

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

FINALIZED FEB 2025

Governing Participating Site Agreement For Tri-Council Funded Studies: Interventional and Regulated

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 Participating Site Agreement For Tri-Council Funded Studies: **Interventional and Regulated**

Finalized on July 12, 2025

Execution copy August 2025 included 28 parties

11 ACT CTU Leads to disseminate to an additional parties for adoption

Current Signatories & Adoptees

The Research Institute of the McGill University Health Centre
Kingston Health Sciences Centre Research Institute/Kingston Health Sciences Centre
MICYRN
CHU de Québec-Université Laval
The Hospital for Sick Children (Sick Kids)
Holland Bloorview Kids Rehabilitation Hospital
IWK Health
Shared Health
Hamilton Health Sciences Corporation
Research St. Joseph's - Hamilton o/a The Research Institute of St. Joe's Hamilton
Bruyére Health Research Institute
London Health Sciences Centre Research Inc. dba. London Health Sciences Centre Research Institute (LHSCRI)
Lawson Research Institute (Lawson)
Ottawa Hospital Research Institute

Dalhousie University
The University of British Columbia
Provincial Health Services Authority (on behalf of BC Cancer)
Provincial Health Services Authority (on behalf of BC Children's Hospital and BC Women's Hospital & Health Centre)
Providence Health Care Society
Vancouver Coastal Health Authority
University of Alberta
University of Manitoba
McMaster University
Fraser Health Authority
Vancouver Island Health Authority
Unity Health Toronto
University Health Network
The University of Western Ontario
Sinai Health System
Queen's University at Kingston

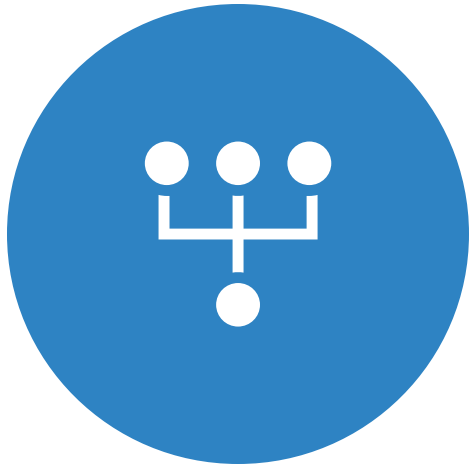
Governing Participating Site Agreement For Tri-Council Funded Studies: **Non-Regulated**

Under final review – September 2025

Expected to be sent for signature September/October 2025

11 ACT CTU Leads to disseminate to an additional parties for adoption

Next Steps:



Finalize the Governing Participating Site Agreement For Tri-council Funded Unregulated Studies

TIMELINE: OCT 2025

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