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CANSTAT

Canadian Network for Statistical Training in Trials

ANNUAL REPORT

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

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About Us

Who We Are

The **Canadian Network for Statistical Training in Trials** (CANSTAT) is a pan-Canadian, multi-institutional, and multidisciplinary network. A core element of CANSTAT is its innovative fellowship program, which is designed to equip trainees with clinical trial knowledge, technical, and professional skills as well as the practical experience needed to develop into biostatistician professionals who provide leadership in clinical trials in Canada and globally.

Our Mission

To equip trainees with the knowledge, skills, and practical experience needed to become biostatistical leaders while advancing statistical methods and fostering collaboration in clinical trials.

Our Vision

To improve the quality and innovation of statistical practices in clinical trials across Canada leading to better health outcomes.

Background

Clinical trials are a crucial tool for generating high-quality evidence about the efficacy, effectiveness, and safety of interventions, informing clinical practice, and improving healthcare for Canadians. Despite the growing demand for evidence to inform approval of new medicines, clinical practice, and public health decisions, the critical shortage in the clinical trials workforce has been identified as a significant barrier to the advancement of the clinical trial industry internationally.

Mathematics and biostatistics highly qualified personnel are uniquely suited to fill this shortage in the clinical trials workforce; however, there is a significant gap between the competencies taught in mathematics and biostatistics graduate programs compared with those required to work in clinical trials. Mathematics and biostatistics graduate programs provide graduates with a strong theoretical background in statistics, but the graduates have limited exposure to applied aspects of clinical trial design, conduct, monitoring, and analysis.

The Canadian Network for Statistical Training in Trials (CANSTAT) emerged as part of the response to addressing the shortage of clinical biostatisticians in Canada. The annual report summarizes the network's objectives, training program, governance, activities and achievements, upcoming activities, financial overview, and partnerships.

Objectives

The goal of CANSTAT is to equip trainees with clinical trial knowledge, technical, and professional skills as well as the practical experience needed to develop into trial biostatistician professionals who provide biostatistical leadership in clinical trials in Canada and globally. To achieve this goal, several specific objectives have been created:

1. To provide a solid foundation in the fundamentals of clinical trials methodology.

2. To develop a strong biostatistical foundation in the design and analysis of both conventional and innovative clinical trials.

3. To provide trainees with experiential learning opportunities within a clinical trials environment, including:

- **a.** Participating in the design, conduct, monitoring, analysis, and reporting of clinical trials.
- **b.** Cultivating skills relevant to all important biostatistical roles, including, but not limited to, critical appraisal of proposals and manuscripts, preparation of grants and manuscripts, data management, and participation in trial oversight committees.
- **c.** Developing effective biostatistical communication (oral presentation and written) and collaboration skills.
- **d.** Interacting with and learning from other professionals involved in the conduct of clinical trials.

4. To build mentor and trainee relationships that offer mutual learning experiences.

5. To promote a collaborative culture among biostatisticians and non-biostatistician researchers.

6. To build a lasting network of trainees and mentors that will raise the quality of statistical practice in clinical trials throughout Canada.

Governance and Operations

There are six committees built into CANSTAT's structure to support excellence in governance (Figure 1).

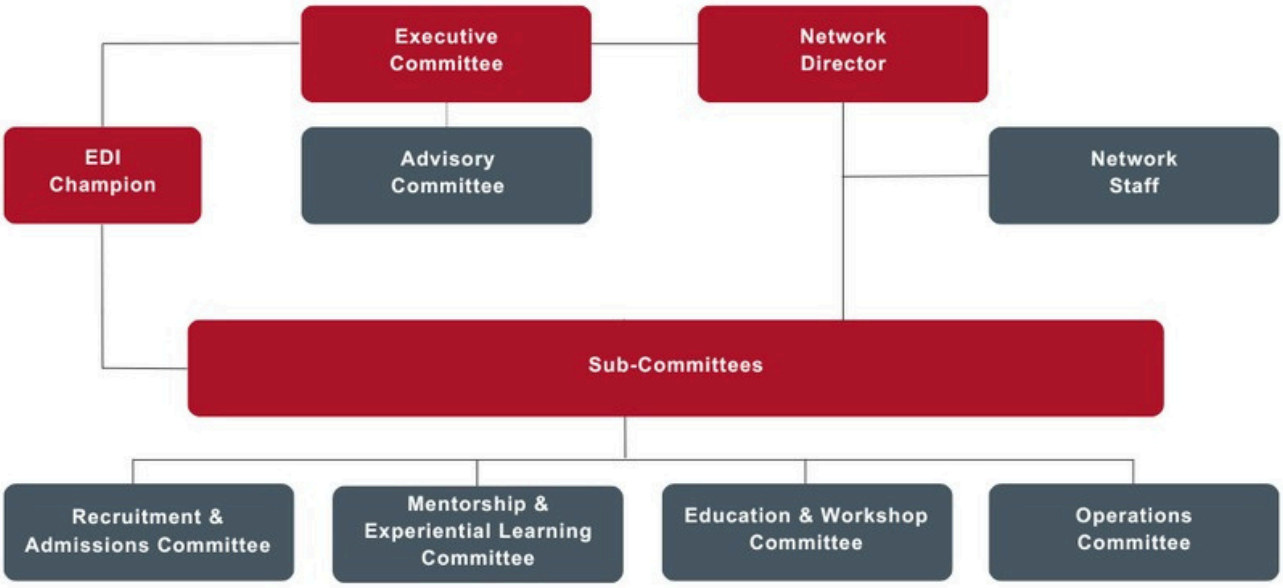

Fig 1. Organizational Structure

The responsibilities of each committee are as follows:

1 . Executive Committee
Chair: Sameer Parpia

Oversees the platform's objectives. The committee reviews and approves the operations plan, the platform budget, and evaluation metrics. They advise on strategic partnerships and collaborative initiatives to ensure efficiency is achieved across platforms.

2.Advisory Committee
Chair: Lehana Thabane

The Advisory Committee provides advice to the Executive Committee on the creation and enhancement of the CANSTAT program.

3.Recruitment & Admissions Committee
Co-Chairs: Shirin Golchi & Shun Fu Lee

Oversees the recruitment and admissions process and implements strategies to attract high-caliber trainees using EDI best practices.

4.Education & Workshop Committee
Co-Chairs: Anna Heath & Hubert Wong

Oversees the development, delivery, and sustainability of the education and workshop curriculum. They are responsible for developing, planning, and modifying online workshops and in-person capacity-building meeting content, including expert and keynote speakers.

5. Experiential Learning & Mentorship Committee
Co-Chairs: Tolu Sajobi & Kevin Thorpe
Oversees the development and monitoring of the experiential learning component, ensuring alignment with the platform's training and mentorship objectives.


6. Operations Committee
Co-Chairs: Sameer Parpia & Thi Ho
The Operations Committee is responsible for core infrastructure operations, budget oversight, policies and procedures for effective and efficient operations, risk management, platform evaluation, and capacity building meeting support.


EDI Champion
Lawrence Mbuagbaw
Responsible for ensuring that best practices in EDI are implemented in the platform governance structure and across the training platform.

Network Staff
Jacquelyn Dobinson & Valerie Bishop
Responsible for leading the day-to-day operations of CANSTAT, supporting the platform's administrative and communication activities, and vendor engagement.


Training Program Overview

CANSTAT's training program is a pan-Canadian, multi-institutional platform that trains and mentors biostatisticians in clinical trials through a mixture of experiential learning, workshops, and capacity building meetings. The program equips trainees with (1) clinical trial knowledge, (2) technical and interpersonal skills, and (3) experiential learning in clinical trials. The program's three core competencies will produce biostatistics professionals who are effective collaborators, communicators, scholars, and leaders contributing to academic and industry clinical trials in Canada.

The program is a one-year fellowship comprised of three components:

1. **Experiential learning placement**
2. **Online workshops**
3. **Capacity building meetings**

The program aims to enrol 10 trainees per year and will run for two years (i.e., 20 trainees trained). Eligible trainees must have a master's or doctoral degree in biostatistics or a relevant health sciences discipline (e.g., public health or epidemiology) with a strong statistical or quantitative background.

Training Activities and Impact: Cohort 1

8 trainees across 5 provinces in Canada.

The trainees completed the program in August 2024.

Cohort 1 participated in 52 trials throughout the country.

I. Experiential Learning Placement

The one-year experiential learning placement has trainees work under the guidance and mentorship of a biostatistician and a clinical investigator who are actively involved in clinical trials. Trainees will undertake biostatistician duties and will be exposed to aspects of the clinical trial enterprise such as ethics, non-statistical elements of study design, designing data collection forms, database design and coding, regulatory affairs issues, reporting requirements, and interacting with research staff, investigators, and IT/database experts. Collaboration and communication skills are key to successful integration within a clinical trials team and will be continually utilized and improved upon throughout the experiential learning component of this training program. Throughout the experiential learning placement, CANSTAT trainees will develop their skills by achieving a minimum of 7 out of 9 mandatory competencies and 4 optional competencies (Appendix A).

The experiential learning placements are based on David Kolb's Experiential Learning Theory, which assumes humans learn best from direct experience and critical reflection. Two assignments have been created to help facilitate this model:

- **Experiential Learning Plans:** These assignments are individualized development tools that monitor the trainees' progress and capture their goals and achievements throughout the year.

- **Reflections:** These assignments are intended to help trainees analyze their experiences in the program, consider new ways to grow and develop, and provide feedback on the program.

II. Online Workshops

There are fifteen workshops throughout the academic year (Appendix B). Each workshop consists of three components: (1) Pre-recorded video content (maximum 1.5 hours total length) introducing key concepts and principles, (2) Completion by trainees of reading and technical exercises set by the Workshop Lead (off-line, up to four hours of work), and (3) A one to two hour online discussion session including all trainees, the Workshop Lead, and available Mentors, to discuss best statistical practice on the workshop topic.

In addition, there are three presentations provided throughout the academic year. Each presentation consists of a live, online presentation followed by a discussion session with up to four hours of independent reading and exercises.

III. Capacity Building Meetings

To augment the training delivered through our online workshops and mentored experiential learning, each trainee will attend two in-person, two-day capacity building meetings at the beginning and end of their one-year training program. These in-person capacity building meetings aim to maximize the interaction between trainees and provide opportunities for networking. These meetings increase the abilities of the CANSTAT trainees, so they can perform the core functions required of a trial biostatistician and address their further development needs in a sustainable manner.

Equity, Diversity, and Inclusion

CANSTAT's commitment to the principles of Equity, Diversity, and Inclusion (EDI) includes seeking diversity in our investigators and fellows and tracking EDI data over time to monitor any inherent biases in the program. CANSTAT application forms were designed to capture data on country of origin, Canadian province of origin, nationality, eligibility to work in Canada, first language, gender, disabilities, Indigenous identity, and ethnicity. The purpose of this data collection was to:

1. Assess the diversity of our applicant pool to inform our advertisement and dissemination strategies.
2. Compare the characteristics of the candidates who applied with those who were admitted ensuring that we were not inadvertently excluding or disfavoring certain groups with our eligibility criteria and admission process.
3. Establish a baseline upon which we will monitor changes over time.

Achievements and Activities to Date

Timeline

CANSTAT's timeline spans three years (Figure 2). Year 1 was devoted to development of all aspects of its training program. This included development of workshop material, creation of recruitment and application review material, program advertisement and recruitment, website development, formalizing governance structure and committee membership, and forming partnerships. The first cohort of trainees have successfully completed the program, and the second cohort have begun.

Program Components	Year 1	Year 2				Year 3			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Program Development	X								
Cohort 1									
Experiential Learning		X	X	X	X				
Workshops		X	X	X	X				
Capacity Meeting		X			X				
Cohort 2									
Experiential Learning						X	X	X	X
Workshops						X	X	X	X
Capacity Meeting					X				X

Figure 2. Platform Timeline

Achievements

CANSTAT has achieved operational excellence by maintaining a culture of continuous improvement, adaptability, problem solving, collaboration, and high productivity.

We have developed an innovative program:

- Recruited biostatistics and non-biostatistics faculty at 16 institutions conducting trials to serve as mentors
- Recruited 21 world-renowned statisticians and experts to lead the online workshop series
- Held our first annual meeting in Toronto
- This included development of workshop material, creation of recruitment and application review material, program advertisement and recruitment, website development, formalizing governance structure and committee membership, and forming partnerships

To date, 19 fellows have either completed the fellowship, or are currently enrolled in the program. So far, CANSTAT fellows have contributed to 77 clinical trials across the country. Their contributions have included involvement in study design, development of Statistical Analysis Plans, participation in Steering Committees, preparation of grant applications, and data analysis.

Of the eight fellows who have graduated from the program, seven have indicated that they are either continuing to work in clinical trials or pursuing further education in biostatistics. This demonstrates the program's success in not only equipping fellows with the necessary skills, but also fostering a long-term commitment to advancing clinical research.

Partnerships

CANSTAT has developed 32 strategic partnerships to increase program funding, create new opportunities, and promote innovation (Appendix C). CANSTAT has partnered with institutions in various aspects including sharing videos, educational talks, and training opportunities.

Provincial Partnerships

CANSTAT has partnered with Alberta Innovates, Michael Smith Health Research BC, and Research Manitoba to co-fund trainees working within their respective province.

ALBERTA INNOVATES

Michael Smith Health Research BC

Research Manitoba

2023 Annual Meeting

The first CANSTAT Annual Meeting was held on November 14-15, 2023, in Toronto, Ontario.

The meeting goals were to:

1. Bring together trainees and mentors and create a community within CANSTAT
2. Provide an opportunity for networking and collaboration
3. Train participants and mentors to undertake their roles within the CANSTAT program

The program included presentations and workshops from world renowned statisticians and experts (Drs. Janet Wittes, Lawrence Mbuagbaw, George Wells, Thomas Fleming, Catherine Njue, Anita Benoit, and Christine Miners) on topics including clinician-statistician working relationships, leadership and mentorship, equity, diversity, and inclusion in clinical trials, confirmatory versus exploratory analysis, and estimands in trials.

The meeting was sponsored by AstraZeneca, Bayer Inc, Roche Canada, and Moderna.

Graduated Cohort

OLAWALE AYILARA

Mentors: Drs. Robert Balshaw & Lauren Kelly
Institution: University of Manitoba

Olawale is a Biostatistician at the George and Fay Yee Centre for Healthcare Innovation, University of Manitoba. His research interests include adaptive clinical trial designs, statistical and machine-learning methods for addressing missing data in clinical trials and registries, and analysis of patient-reported outcome measures.

MAUREEN CHURIPUY

Mentors: Drs. Shirin Golchi & Marie Hudson
Institution: McGill University

Maureen recently graduated from McGill University with a MSc in Public Health. Prior to her time at McGill, Maureen obtained a BSc in Biomedical Science from Trent University. Her research interests include Bayesian statistics and mental health.

ARLENE JIANG

Mentors: Drs. Anna Heath, Yongdong Ouyang & Naveen Poonai
Institution: The Hospital for Sick Children

Arlene completed her MSc in Biostatistics at Queen's University. She previously obtained a BSc in Neuroscience and Computer Science at Dalhousie University. Her research interests include application of statistical techniques to inform evidence-based healthcare practices in areas such as pain management, oncology, mental health, and health equity.

STEPHEN KUTCHER

Mentors: Drs. Nick Barrowman & Amy Plint
Institution: Children's Hospital of Eastern Ontario Research Institute

Stephen completed his doctoral degree in Epidemiology at McGill University. He obtained his MSc in Health Sciences and his BHSc in Health Sciences at the University of Ottawa. His research interests include causal inference, pharmacoepidemiology, and comparative effectiveness research.

CAROLINE LEE

Mentors: Drs. Monica Taljaard & Daniel McIsaac
Institution: Ottawa Hospital Research Institute

Caroline Lee completed her MSc in Biostatistics from Queen's University and her BScH in Neuroscience at McMaster University. Her research interests include analysis of healthcare data to improve disease management and treatment strategies, investigating the impact of socioeconomic factors on health outcomes using statistical modeling techniques, and design and analysis of randomized controlled trials to evaluate the effectiveness of novel interventions in healthcare settings.

PEIYU LI

Mentors: Professor Kevin Thorpe & Dr. David Mazer
Institution: University of Toronto

Peiyu Li obtained her MSc in Biostatistics from the University of Toronto. Her research interests include clinical trials design and analysis, survival analysis, and correlated data.

TAYLER SCORY

Mentors: Drs. Tolu Sajobi & Matthew James
Institution: University of Calgary

Tayler Scory is a statistician in the Nephrology Research Group, Department of Medicine at the University of Calgary. Tayler received her MSc in Statistics from the University of Calgary. Her research interests include pragmatic clinical trials and health services research.

YUWEI YANG

Mentors: Drs. Hubert Wong & Fidel Vila-Rodriguez
Institution: University of British Columbia

Yuwei is a statistician working at Vancouver General Hospital under the Division of General Surgery. Yuwei obtained her MSc in Statistics from the University of British Columbia. Her research interests include design of randomized control trials and statistical analysis of clinical research.

Upcoming Activities

Evaluation

CANSTAT launched an evaluation to gather data from cohort one trainees and mentors during the summer of 2024. The evaluation will be repeated in summer 2025 to gather data from cohort two trainees and mentors. The feedback will be used to modify the program.

Cohort Two

The second cohort will run from September 2024 to August 2025. CANSTAT has recruited 11 trainees for this cohort. The trainees are working at nine institutions across four provinces (Alberta, British Columbia, Ontario, and Quebec).

Annual Meeting

The second Annual Meeting is scheduled for November 5-6 in Toronto, Ontario.

Research

CANSTAT plans to implement programs and operational support that enhances collaborative and methodological research that aims to develop methods, tools and guidelines for design, conduct, analysis and reporting of clinical trials. There will be three research pillars within CANSTAT:

1. Collaborative Research Foster collaborative research among CANSTAT members, but importantly, across CANSTAT partners.

2. Methodological Research Provide opportunity and a platform for CANSTAT to collaborate and contribute to the development of novel statistical methodology in various areas of clinical trials including cluster-randomized and pragmatic trials, Bayesian adaptive trials, platform and multi- arm multi-stage designs, pilot and feasibility trials, equity and diversity trials, patient reported outcomes, external and hybrid control arms in clinical trials, and effect heterogeneity and precision medicine in clinical trials.

3. Research Training Provide opportunities for fellows to develop research skills to be able to identify appropriate statistical methodology and propose innovative and flexible designs and methods that can address new challenges in health and medicine.

Financial Overview

Summary of Revenue Sources

CIHR Grant = $2.5m

2023 Annual Meeting Sponsorship = $21,500

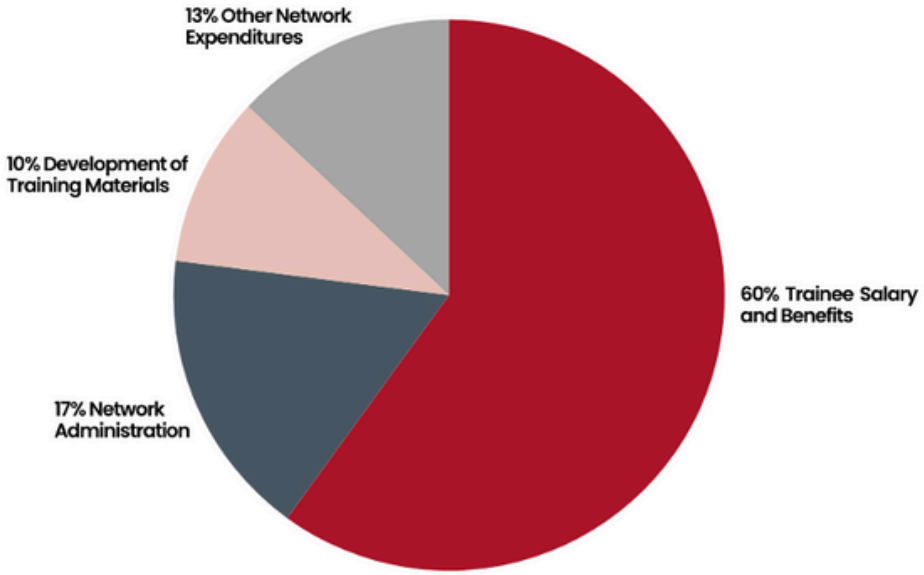

Figure 3. CANSTAT Expenditures 2023-2024

Appendices

A. Competencies

B. Workshops

C. Partners

Appendix A: Competencies

Key Concepts	Mandatory Competencies Upon completion of the CANSTAT Program, trainees will be able to…
Trial Design	Understand randomized trial design using necessary components of trial design.
Sample Size Estimation/ Power Analysis	Estimate an appropriate sample size and power calculations for new clinical trials.
Randomization	Design randomization schemes for ongoing trials.
Statistical Analysis Plan (SAP)	Develop a Statistical Analysis Plan using best practice guidelines.
Data Management	Manage data for analysis as defined in a Statistical Analysis Plan using standardized software.
Data Analysis	Analyze and interpret trial data as described in the Statistical Analysis Plan.
Steering/Executive Committee	Understand the practical aspects of running clinical trials.
Data Safety Monitoring Boards	1) Understand how to prepare and present statistical reports to Data Safety Monitoring Boards. 2) Understand how interim trial analysis can lead to recommendations on studies.
Communication	Articulate concepts clearly through oral and written communication.
Key Concepts	**Optional Competencies**
Regulated Trials	Understand the requirements and complexities of obtaining regulatory approval for clinical trials.
Grant Preparation	Write a sample size description and an analysis plan for a grant application.
Case Report Form Design/Review	Review data collection instruments to ensure that study aims can be achieved.
Manuscript Review	Complete a peer review of a submitted manuscript.

Appendix B: Workshops

Workshop/Presentation Title	Instructor(s)
Working with Non-biostatisticians	**Samantha Thomas** *Principal Biostatistician, Duke Cancer Institute*
Ethics & Regulatory Issues in Trials	**Rebecca Barnes** *Executive Director, Network of Networks (N2)* **Erin Cherban** *Chief Clinical Research Officer, CHÉOS, CIHR Canadian HIV Trials Network (CTN)*
Reproducible Research	**Richard Webster** *Interim Scientific Director, CHEO Research Institute* **Nick Barrowman** *Senior Statistician, CHEO RI* *Associate Professor, University of Ottawa*
Randomization	**Joel Singer** *Program Head, CIHR Canadian HIV Trials Network*
Role of Biomarkers as Replacement Endpoints	**Thomas Fleming** *Professor, University of Washington*
Endpoint/Outcome Selection	**Tolulope Sajobi** *Associate Professor, University of Calgary*
Sample Size and Power	**Hubert Wong** *Associate Professor, University of British Columbia* **Yongdong Ouyang** *Biostatistician, SickKids Research Institute*
Analysis Principles	**Kevin Thorpe** *Assistant Professor, University of Toronto* **Richard Cook** *Professor, University of Waterloo*
Addressing Missing Data	**Thomas Fleming** *Professor, University of Washington*
Statistical Writing and Reporting	**Nancy Butcher** *Assistant Professor, Hospital for Sick Children Research Institute*
Economic Analysis	**Karen Lee** *Director, Canadian Agency for Drugs & Technologies in Health (CADTH)*
Safety Issues	**Victoria Cornelius** *Director, Imperial College London*

Workshop/Presentation Title	Instructor(s)
Non-Inferiority Designs	**Thomas Fleming** *Professor, University of Washington*
Early-Stage Designs	**Alexia Iasonos** *Attending Biostatistician, Memorial Sloan Kettering Cancer Center*
Bayesian Design	**Frank Harrell** *Professor, Vanderbilt University Medical Center*
Adaptive Designs	**Anna Heath** *Scientist, SickKids Research Institute* **Yongdong Ouyang** *Biostatistician, SickKids Research Institute*
Design and Analysis of Vaccine Trials	**Natalie Dean** *Assistant Professor, Emory University*
Cluster Randomized and Stepped Wedge Trial Designs	**Monica Taljaard** *Senior Scientist, Ottawa Hospital Research Institute* **Yongdong Ouyang** *Biostatistician, SickKids Research Institute*

Appendix C: Partners