CANADIAN RESEARCH INITIATIVE IN SUBSTANCE MISUSE
REPORTING TEMPLATE

Background

The objectives of CRISM are:

- To identify and develop the most appropriate clinical and community-based prevention or treatment interventions for substance misuse;
- To provide evidence to support the enhancement of prevention or treatment services regarding substance misuse to decision makers and service providers; and
- To support the improvement in the quality of care and quality of life for Canadians living with substance misuse.

It is anticipated that CRISM will lead to interventions and programs that are proven to be 1) efficacious; 2) tailored to individuals in both their needs and psychosocial context; 3) feasible and applicable in clinical and community intervention settings; and 4) more easily accepted by health care and service providers.
It is expected that CRISM will result in improved evidence-based interventions for substance misuse.

CRISM was developed via a three-phased funding approach:

1. Development Grants to build teams of academic researchers and service providers around common projects in substance misuse
2. Team Grants to establish regional Nodes of research capacity including shared infrastructure between researchers and service providers.
3. Operating Grants directed towards high priority research issues will enable the Network of Nodes to work together on national studies for substance misuse. Only successful Nodes will be invited to apply for these funding opportunities.

The specific objective of the second phase is:

- To establish Nodes of research composed of researchers, service providers and representatives of people living with substance misuse with shared infrastructure to facilitate research in interventions and other therapeutic approaches to substance misuse.

The specific objectives of the first operating grant in the third phase are to:

- Support specific studies in the area of prescription drug abuse
- Support the development of the CRISM network of researchers and increase the research capacity of the Nodes.

The purpose of this reporting template is to understand the activities' of the CRISM Nodes, the CRISM Network and their collaborative research project(s), which currently includes OPTIMA.

This report is to be submitted by June 28th, 2018 to CRISM-ICRAS@cihr-irsc.gc.ca. Due to Treasury Board requirements, the Nodes and Network will submit a list of publications by April 3, 2018. For this reporting period, publications will date back to the funding start date of December 1, 2014 and go until December 31, 2017. If possible the template provided in Appendix 1 will be used.

Reporting Requirement

The Funding Opportunities for the Nodes and the PDA grant indicate that PIs will be required to contribute to the monitoring, review and evaluation of the programs. By completing this template the PIs will have met current reporting requirements.

Methodology:

The proposed reporting template is based on:

- The objectives and requirements of the funding opportunities and
- The objectives identified in their applications and committed to via the grant agreements
- Reporting requirements in the performance measurement strategy for the former National Anti-Drug Strategy and the Canadian Drugs and Substance Strategy, which identifies information required by the Treasury Board Secretariat of Canada

CANADIAN RESEARCH INITIATIVE IN SUBSTANCE MISUSE	
Note: Throughout this report, if there is any information that should not be included in the Annual Performance Report, which is to be made publicly available, please **bold and underline** this information.	
1. PERFORMANCE REPORTING PERIOD	
Fiscal Year: 2017-2018	
2. REPORT PREPARATION	
Please indicate who prepared this report, including contributors and what information sources were used.	
Report Lead	
Contributors	• Julie Bruneau, NPI Québec-Atlantic Node • Benedikt Fischer, NPI Ontario Node

	• T Cameron Wild, NPI Prairie Node • Evan Wood, NPI British Columbia Node • Denise Adams, Node manager, Prairie Node • Farihah Ali, Node manager Ontario Node • Nirupa Goel, Node manager, British Columbia • Aïssata Sako, Node manager, Québec – Atlantic Node • Alice Lam, Senior Research officer, Québec-Atlantic Node • Didier Jutras-Aswad, Lead Regional PI, OPTIMA • Jill Fikowski, National Research coordinator, OPTIMA
List information sources used to prepare the report	Please identify all sources that were used: ☐ Application ☒ Work Plan: Directed grant summary description ☒ Publications (specify, ISBN #): see publication list from April ☒ Research (specify & attach reports): see attachments ☒ Consultations (specify & attach reports) see attachments ☐ Evaluation Results (specify& attach reports) ☐ Other (specify):

3. DELIVERY

a) Have there been any changes to the operational context, objectives or planned milestones of your Network or to OPTIMA in this reporting period?

Table 1:

NETWORK
☒ Yes Please describe:

The Quebec-Maritimes Node has become the Québec Atlantic Node. The details of the reason for this change are detailed in the Québec-Atlantic Node progress report. In sum, the change was made following the Maritimes symposium in December 2017, in order for the Node name to be representative of the non-Maritimes region included and represented within the Node.

☐ No

OPTIMA	LRCUG	Opioid Guideline	Opioid supplements	
☒ Yes Please describe: See text below ☐ No	☐ Yes Please describe: ☒ No	☐ Yes Please describe: ☒ No	☒ Yes Please describe: Comprehensive review and environmental scan on relevant health economic research and accessibility of relevant Canadian data, deliverable date has been extended to 2018-2019. ☐ No	☐ Yes Please describe: ☐ No

OPTIMA
The trial has been experiencing lower than anticipated recruitment/enrolment rates in the first months following the start of the trial.. Discussion with OPTIMA's Data Safety Monitoring Board revealed that this is not unusual especially in new networks. Recent numbers show that overall the recruitment rate is increasing and getting closer to the target rate for the trial as a whole.

Both the Investigative team and the Data and Safety Monitoring Board are carefully monitoring the study progress to ensure that all recruitment efforts are continued across sites and a close eye is kept on performance and site engagement. Sites are working to adapt and enhance recruitment methods specific to local populations. Community organizations, peer research assistants and navigators are actively involved to facilitate efforts and engage the local communities.

b) Please indicate the major tasks and deliverables you expect to achieve from April 1, 2018 to March 31, 2019 (bullet form).

Table 2:

NETWORK

OPTIMA

- Increase recruitment rate. Increase enrollment target across sites, through expanding advertising budget, increasing staff allocation of hours specifically on OPTIMA across underperforming sites. Re-evaluate recruitment targets per site.
- Develop and publish the first trial implementation paper outlining key operational considerations for launching an Investigator initiated trial across Canada and the first trial within an established network.
- Work closely between Nodes to develop a knowledge translation strategy for use within and between Nodes.
- Finalize and distribute the CRISM 001-OPTIMA Authorship & Publication document.
- Identify a CRISM wide data-sharing platform to increase collaborative and scientific capacity nation-wide. Similar to the model used by the National Institutes of Health, this platform will facilitate the ongoing use of data for the trial, ancillary studies and allow greater knowledge to be created in efforts toward prevention, treatment and research efforts across sites.
- Prepare to request an extension of the OPTIMA CIHR granting period past March 2019, to properly reflect the progress and continuation of the trial beyond that date.

NETWORK

- Continue KT activities for CRISM's *National Guideline for the Clinical Management of Opioid Use Disorder*. This includes: dissemination of the guideline and summary materials to service providers, regulatory bodies, policymakers, and the general public; participation in development of regional guidelines as needed; produce documentation that facilitates access to the guideline recommendations and methodology; build relationships with strategic partners; consider development of additional materials or supplements to address specific populations or medications. June 5th, 2018, Dr Julie Bruneau will present the guideline at the Pan Canadian Physician Opioid Collaborative; an opportunity to discuss needs and potential future steps for improving care with representatives of the Royal College, College of Family Physicians and Canadian Medical association.
-
- Continue KT activities for the Lower Risk Cannabis Use Guidelines (LRCUG). This includes: continued work with regional and national stakeholders to support the dissemination and endorsement of the guidelines; revision of the current plain language KT brochure to ensure accessibility; develop a 'by youth for youth' KT resource for the LRCUGs; collaborate with the Public Health Agency of Canada (PHAC) on creating knowledge mobilization tools that aim to equip public health professionals with information and training materials to implement the guidelines; present the LRCUGs on a KT panel/national webcast hosted by the Chief Public Health Officer; develop and publish a 'public health index' for cannabis legalization to allow for monitoring and evaluation of the effects of legalization in Canada; build strategic relationships; update and expansion of evidence-based LRCUG; ongoing provision of scientific evidence and input to key national and other government stakeholders e.g. Health Canada, PHAC; ongoing LRCUG presentations and conferences with governmental and non-governmental stakeholders.
- Scale up effective intervention and evidence-based options for cannabis use disorder treatment in Canada.
- Host CRISM panels at provincial and national conferences to raise awareness and disseminate CRISM research and activities e.g. Addictions and Mental Health Conference (OUD Guideline and OPTIMA to be presented)
- Continue to meaningfully engage and build partnerships with people with lived experience, Indigenous organizations and communities, service providers, and policymakers.
- Support and further the involvement of people with lived experience, including support for attendance at the Stimulus 2018 Harm Reduction conference to be held October 3-5, 2018, in Edmonton, AB.

- Complete CRISM's scoping review of the role of psychosocial interventions in the treatment of opioid use disorder and the health economics review.
- Develop a concept proposal for CRISM renewal (CRISM 2.0).
- Continue regular communication and consultation with Health Canada to coordinate Network priorities in relation to Federal priorities and strategies.
- Capitalise on network growth and capacity building.
- Explore opportunities for initiating new clinical trials.
- Modify format and structure of the annual meeting of CRISM's National Executive committee (NEC) in order to better engage with NEC members as well as provide a forum for purposeful discussion with our CIHR partners.
- Be active in discussions and research-based actions in relation to the opioid use, cannabis and other substance related public health concerns.
- Ongoing development, establishment and consultation re: Emergency Health Threat national projects.

4. NARRATIVE SUMMARY OF PROJECTS AND KEY ACCOMPLISHMENTS OF NETWORK & NODES

a) Summary of key accomplishments from March 31st, 2017 to April 1st, 2018 that demonstrate how the Network and each Node, through the scope of funded projects, has met the CDSS goals of:

NETWORK

I. Preventing problematic drug and substance use (250 words)

The *Lower Risk Cannabis Use Guidelines* (LRCUG) were published in the American Journal of Public Health (AJPH) in June 2017, as CRISM's first evidence-based population-level prevention project for cannabis use. The LRCUG outlines 10 recommendations on how users can reduce harms related to recreational cannabis use. The LRCUG was formally launched with key stakeholders and government officials in Ottawa on June 23, 2017. The Guidelines have been formally endorsed by seven leading national partner organizations (CMA, CPHA, CCMOH, CSAM, CCSA, CAMH, CMHA and CMHH) and key government bodies (Federal Minister of Health, Government of Ontario, and Government of Quebec). The LRCUG is an essential evidence-based population-health level prevention tool for cannabis use and health risks/harms, especially to be utilized enacted under impending legalization/regulation. The main objectives of the LRCUG were to systematically review, update, and quality-grade evidence on behavioral factors determining adverse health outcomes from cannabis that may be modifiable by the user, and translate this evidence as a public health intervention tool based on an expert consensus process. These guidelines have had positive and successful uptake in both government and non-government sectors.

II. Supporting measures that reduce the negative consequences of drug and substance use (250 words)

Harm Reduction Conference

CRISM hosted a National harm reduction consultation and meeting in Montreal, Quebec on May 14, 2017, in conjunction with the 25th Harm Reduction International Conference (May 14-17, 2017). The CRISM meeting brought together members of 12 peer-based advocacy groups that represent people with lived and living experience (PLE). Approximately 30 representatives from across the country attended the CRISM meeting. In addition to hosting the meeting, the CRISM network sponsored 6 CRISM-affiliated PLE representatives to attend the meeting and the HR17 conference; CRISM support included travel expenses and conference registration. The CRISM meeting was designed as a networking opportunity where attendees from the PLE community could learn about activities and initiatives that PLE groups across Canada are undertaking, and build new collaborations among one another and with CRISM. Outcomes of this meeting included a report entitled: *CRISM Harm Reduction Consultation: Identified Needs and Supports for Effective Activities and Initiatives 2017,* which is included in the appendix of this document. This report produced from this CRISM-sponsored consultation outlines harm reduction priorities identified by meeting attendees, as well as suggestions for how CRISM can support PLE groups and initiatives.

OPTIMA

- Research personnel training for OPTIMA trial was completed and verified
- Clinical Monitoring and Data & Safety Monitoring plan developed and implemented
- Electronic Data Capture system and all electronic case report forms developed, validated and determined to be functional
- Trial protocol V5.0 approved in April 2017 and implemented September 2017.
- REB approvals were received at all participating institutions
- 5 ancillary studies were integrated into or running parallel to the main trial.
- All 7 sites endorsed for full protocol implementation between September and March 2017
- A media blitz across Nodes was held in October 2017 and January 2018 to announce the national launch of the OPTIMA trial
- Development and distribution of Institutional Research agreement
- Ongoing evaluation of the shared-cost model for execution of a national clinical trial under the CRISM initiative.

OPTIMA Recruitment:

Total Randomized participants as of March 31st, 2018: 25
Total Enrolled participants as of March 31st, 2018:46

Although the trial experienced a slow start to recruitment across all clinical sites in the first 4-5 months, there has been a significant increase in enrolment, with an average of 10 enrolled participants per month across all clinical sites. After discussion with OPTIMA's Data Safety Monitoring Board, this is not unusual especially in new networks. While the recruitment targets are equally divided between Nodes, there are variations in recruitment rates between sites and between Nodes. Both the Investigative team and the Data and Safety Monitoring Board are carefully monitoring the study progress to ensure that all recruitment efforts are continued across sites and a close eye is kept on performance and site engagement.

III. Supporting innovative approaches to treatment and rehabilitation (250 words)

National Opioid Guideline

CRISM developed the first Canadian guideline for managing opioid use disorders (OUD), which lays out the optimal strategies for a range of treatments and provides the scientific evidence basis for each type of medication. The full guideline was released with a simultaneous publication in the Canadian Medical Association Journal (CMAJ) March 5th 2018. The guideline is a critical step in supporting a wide range of health care providers to address the urgent need for evidence-based treatment for OUD. Each CRISM Node has worked towards wide dissemination of the guideline to key service providers, regulatory bodies, and policy makers, as well as pursuing in-depth training seminars for interested healthcare providers.

Section 56 exemption consultation

In close collaboration with Health Canada, CRISM led a national consultation to assess the advantages and disadvantages of the requirement for health practitioners to obtain a section 56 (s.56) exemption from the Controlled Drugs and Substances Act before prescribing methadone. We reached out to over 250 expert stakeholders and gathered data through a web-based survey and 12 regional meetings. The s.56 exemption process was identified as a major barrier to providing access to treatment for opioid-dependent patients and accordingly, CRISM recommended its removal along with additional suggestions for improving access to care. After five decades of special authorization for methadone, Health Canada has announced that it will no longer require this exemption, effective May 19, 2018, facilitating a path for providers to more easily offer a range of treatments to their patients.

Scoping review of psychosocial interventions in the treatment of opioid use disorder

The international evidence base supporting the efficacy of opioid agonist treatment (OAT) in reducing illicit opioid-related harms is extensive and compelling. However, the role of psychosocial interventions in the clinical management of opioid use disorders (OUD) is equivocal. Previous reviews have focused on RCTs that compare OAT with or without addition of non-pharmacological interventions. The objective of this project was to conduct a scoping review to take stock of the evidence available to inform the question of the role of psychosocial interventions in OAT, either as 'stand-alone' treatments or as ancillary/support options to pharmacotherapies.

The aims of this scoping review are to (1) systematically identify all studies that have investigated psychosocial interventions used in the treatment of OUD, (2) characterize the range of evidence sources available in the scientific literature with respect to study populations and types of psychosocial treatments and supported investigated, heterogeneity of study designs used to provide evidence on the role of psychosocial approaches, as well as outcome measures considered, and (3) evaluate the extent to which the relevant literature is capable of informing the question of the appropriate role of psychosocial interventions in OAT. To date, 23250 references have been screened and 408 have been included. Data extraction is ongoing.

5. CAPACITY BUILDING

a) Please describe how the Network has established and strengthened collaborations between all Node members, within Nodes.

Across all Nodes, new highly qualified personnel/new investigators have joined as members, which has increased and strengthened research capacity and collaboration.

CRISM National Guideline for the Clinical Management of Opioid Use Disorder (National Opioid Guideline)

In the development of the national guideline for opioid use disorder, the CRISM network established four regional committees (total of 43 members) to contribute to the development of the content and recommendations in the guideline. Regional committees strengthened these relationships through email and teleconference discussions. Some of these members were new to CRISM and have continued their involvement in Node-specific projects.

The BC and QA Nodes contributed their scientific writers to support the PI group in the research and writing of the guideline. All Node managers were involved in the parallel process of planning the review cycles with the 43 expert reviewers, developing and executing the guideline work plan, with Dr. Bruneau leading the scientific work. In addition, Dr Bruneau is the lead author of the CMAJ synopsis article, published March 5th 2018. All Nodes have engaged in dissemination and knowledge translation activities. This includes the NPIs, co-PIs, and collaborators, who have been invited across the country to present the guidelines to CRISM peers, knowledge users, and groups outside of the consortium's usual knowledge user base. For example, Dr. Keith Ahamad, clinical lead for the BC Node, spoke at an event hosted by the Prairie Node at a Calgary clinic, Dr. Ginette Poulin, clinical lead for the Prairie Node, made presentations in Ontario, and Dr. Bruneau has made several trips throughout Eastern Canada (Ontario and Maritimes) to present the guidelines.

During the **OPTIMA trial,** research capacity has been increased across Nodes/sites through the following activities:
1. Node research staff and clinic staff (those who were health workers with no/limited research experience at study start) have engaged in ongoing research training activities across clinical sites, this has included Good Clinical Practice, Safety, Good Documentation Practices, Health Canada Division 5, training in working with vulnerable populations and PWUD, and recruitment. The most important components of any research project with PWUD is community engagement, recruitment and retention. Teams across Nodes/sites have been developing outreach and recruitment methods specific to this population. One of the key ingredients to successful recruitment has been engagement of staff with community organizations, PWUD, local outreach teams. Development of these skills and sustaining these relationships with the local community and PWUD will leave these teams well- positioned to participate in future research projects with CRISM.

2. The trial is working with a contract research organization who provides quality assurance and clinical monitoring for the trial. Clinical monitors and quality assurance specialists have taken on the additional mentoring and training site staff while performing monitoring visits. This teaching component has provided teams the technical skills knowledge in clinical trials.
3. Investigator capacity has been built across Nodes- there are a total of 27 Investigators (co and PI's) and 5 ancillary studies operating alongside the trial. CRISM and the Investigative team on OPTIMA is in the process of developing a comprehensive strategy for the sharing of trial data through data sharing platform. Similar to the National Institute of Health, this platform will allow building of research capacity and increase in scientific outputs.

LRCUG

The Quebec-Atlantic Node and the Ontario Node have worked closely and collaborated on language translations of the LRCUG. Additionally, the Ontario Node and Québec and Atlantic Node have collaborated with the Atlantic provinces (NS and NB) for endorsement and development of KT materials, and dissemination activities with governmental bodies. Dr. Benedikt Fischer and his Ontario CRISM collaborators have presented the LRUCG at the Montreal and Halifax symposiums.

People with living/lived experience
CRISM hosted a National harm reduction consultation and meeting in Montreal, Quebec on May 14, 2017, in conjunction with the 25th Harm Reduction International Conference in Montreal, QC (May 14- 17, 2017). The CRISM meeting brought together members of 12 peer-based

advocacy groups that represent people with lived and living experience (PLE). The CRISM meeting was attended by approximately 30 representatives from across the country. In addition to hosting the meeting, The CRISM network sponsored 6 CRISM-affiliated PLE representatives to attend the meeting and the HR17 conference; CRISM support included travel expenses and conference registration. The CRISM meeting was designed as a networking opportunity where attendees from the PLE community could learn about activities and initiatives that PLE groups across Canada are undertaking, and build new collaborations among one another and with CRISM. Outcomes of this meeting included a report titled: *CRISM Harm Reduction Consultation: Identified Needs and Supports for Effective Activities and Initiatives 2017* (attached). This report outlines harm reduction priorities identified by meeting attendees, as well as suggestions for how CRISM can support PLE groups and initiatives.

There are plans to continue supporting Peer participation at the upcoming harm reduction conference in Edmonton in October 2018.

b) Please describe how and the extent to which the Nodes have improved the research capacity for the Network, including within targeted populations ((e.g., youth, Indigenous communities, correctional populations)

LRCUG

- Evidence-based KT work with the National Youth Advisory Council and the Margaret and Wallace McCain Centre for Child, Youth and Family Mental Health (CAMH) for prevention material for youth

Youth population

Collaborators from the Québec-Atlantic, Ontario and BC Nodes successfully applied for a CIHR grant for a national intervention trial on prevention entitled *Canadian Underage Substance Abuse Prevention (CUSP) Trial: A hybrid effectiveness/implementation-facilitation trial to increase access to evidence-based drug prevention for Canadian adolescents*". Funding of $1.7 million was awarded on January 23, 2018.

Effective adolescent drug prevention has become a central focus of modern national drug strategies, as more countries are considering decriminalisation of substance use. However, evidence-based drug prevention is not widely practiced and available to young people. As a result, despite having made great strides in reducing adolescent binge-drinking rates, illicit substance use remains significantly above national targets for health promotion and disease prevention in the United States and Canada. The proposed hybrid trial will test effectiveness of programme implementation of Brief personality targeted intervention developed by Conrod, Stewart when delivered through a train-the-trainers model on illicit substance use in high risk adolescents with prescription drug misuse as a novel secondary outcome. The implementation facilitation (IF) component will evaluate whether population penetrance, implementation quality and sustainability can be enhanced through an IF intervention addressing barriers to implementing evidence-based programmes for youth. Three sites linked to CRISM will assist in recruiting 9 schools each, to be randomised to one of three intervention conditions: treatment as usual (TAU); standard Preventure training (PT); or Preventure training with an implementation facilitation package (PT+IF). CRISM Node platforms and infrastructure—as appropriate and feasible—will help coordinate multi-site ethics approval, provide protocol development expertise, and bioinformatics support to facilitate data collection and sharing through diverse mechanisms.

Indigenous engagement

Each Node recognizes the importance of CRISM work targeted to Indigenous peoples and all are making efforts to include more First Nations, Inuit and Metis researchers, clinicians and communities. To that end, CRISM Nodes have initiated projects that include Indigenous populations. From a broader network perspective:

- We expect regional variation in enrolment of Indigenous clients in the OPTIMA trial. For example, preliminary work in the Prairies Node suggests that 30% of current opioid treatment clients identify as Indigenous.

- The BC and Prairie Nodes jointly supported a CIHR grant application from an Indigenous researcher entitled *A two-eye seeing approach to wholistic healing and wellness for people with drug-use experience*. This was successfully funded through the CIHR Catalyst Grant program.

Correctional Populations
Several research initiatives in collaboration with Correctional Services Canada (CSC) e.g. focusing on feasibility and outcomes of pharmacotherapy in correctional settings and determinants of drug overdose among correctional populations.

Please see individual Node reports for additional information.

c) Please list all staff including trainees supported by CDSS funding (both paid and unpaid)

Please see individual Node reports, which includes all staff involved in OPTIMA (36 paid individuals and 9 unpaid)

d) Please describe the demonstration projects and projects developed since, supported by your Node, including amount and duration of funding, project title, and principal researcher, and objective of study. Where relevant add context relating to scale up.

Please see individual Node reports

6. INFRASTRUCTURE DEVELOPMENT

a) Please briefly describe any changes to your Network's infrastructure including research space, equipment, new hires, etc.

This growing network infrastructure includes, but is not limited to:

a) the identification and securing of appropriate (e.g., clinical) research space allowing PIs, members and trainees to work together;

b) facilities for subject recruitment, randomization and clinical/non-clinical assessments;

c) medication storage/dispensing and data collection, storage and analysis capacity (both computing and personnel),

d) singular large-scale and small-scale research installations,

e) databases, libraries, high capacity communication networks, complex and high capacity data infrastructures;

f) access to bioinformatics, biostatistics expertise;

g) scientific and medical writing platforms and

h) Infrastructural centers of competence, as part of its research infrastructure.

These resources are able to meet the broad needs of the network from psychosocial to holistic intervention research to bio-medical and clinical research, enabling the publication and dissemination of the Lower Risk Cannabis guideline in a timely manner, the National guideline for the clinical management of opioid use disorder, the OPTIMA Trial paper, as well as other regional specific research projects and trials publication and or knowledge transfer documents. Added to these physical resources are the human resources: teams of dedicated and qualified scientists, research professionals and trainees. The research infrastructure serves to create a framework for meaningful engagement, knowledge transfer and education, and the leveraging of research funding and in-kind resources to promote and support more intervention research.

8. ENGAGEMENT OF PEOPLE WITH LIVED EXPERIENCE

a) Please describe how the Network has engaged with people with lived experience.

Table 11:

NETWORK
As mentioned above, CRISM hosted a national **harm reduction consultation and meeting in Montreal, Quebec on May 14, 2017**, in conjunction with the 25th Harm Reduction International Conference in Montreal, QC (May 14- 17, 2017). The CRISM meeting brought together members of peer-based advocacy groups that represent people with lived and living experience (PLE), including Canadian Association of People Who Use Drugs (CAPUD), Alberta Addicts Who Advocate and Educate Responsibly (AAWEAR), Streetworks, Safeworks, Saskatchewan Advocates for Safe Consumption (SASC), the Manitoba Harm Reduction Network (MHRN), Direction 180, Hand Up, Rural Empowered Drug Users Network (REDUN), Association Québécoise des Centres d'Intervention en Dependence (AQCID), Toronto Drug Users Union (TDUU), and Vancouver Area Network of Drugs Users (VANDU). The CRISM meeting was attended by approximately 30 representatives from across the country. In addition to hosting the meeting, The CRISM network sponsored 6 CRISM-affiliated PLE representatives to attend the meeting and the HR17 conference; CRISM support included travel expenses and conference registration.

The CRISM meeting was designed as a networking opportunity where attendees from the PLE community could learn about activities and initiatives that PLE groups across Canada are undertaking, and build new collaborations among one another and with CRISM.

Outcomes of this meeting included a report titled: C*RISM Harm Reduction Consultation: Identified Needs and Supports for Effective Activities and Initiatives 2017* (attached). This report outlines harm reduction priorities identified by meeting attendees, as well as suggestions for how CRISM can support PLE groups and initiatives.

For the **section 56 consultation**, CRISM engaged with a variety of types of stakeholders, including people with lived experience of substance use as well as family members/caregivers. A total of 24 individuals were contacted by each of the four Nodes to participate in the online survey and the regional teleconferences. This allowed a diversity of experiences and opinions to be incorporated into the major recommendations for Health Canada to improve access to treatment for opioid use disorder.

CRISM engages with the PWLE members of its national executive committee (NEC) throughout the year as well as during the annual **NEC meeting**. At this year's meeting, four PWLE (one from each Node) attended and participated in the discussions, and each gave a short presentation on their experiences and input for CRISM's projects and priorities. This increased the level of engagement and investment in CRISM's future directions from PWLE representatives.

OPTIMA: Community engagement is absolutely critical to the success of the trial. Sites have worked very closely with local community organizations, participated in outreach efforts with teams in the community. These include but are not limited to: safe consumption services, local health authorities, provincial outreach teams, people with lived experience, hiring peer research assistants engaging peer navigators. People with lived experience have been brought into recruitment efforts, oral presentations, meeting and discussion groups.

National Opioid Guideline: As part of the review process for the guideline, CRISM reached out to the national organization of people with lived experience, CAPUD, and a family members advocacy group, mumsDU. Both groups enlisted their membership to review the guideline and provide feedback on the recommendations and evidence presented. This input was extremely valuable in ensuring that the guideline was relevant to affected communities and the feedback led us to include additional information and context. These contributions were recognized in the acknowledgment section of the guideline.

LRCUG: New KT materials have been developed with active involvement by community and user groups.

9. KNOWLEDGE TRANSLATION

a) Please describe the Network and specific Node's meaningful outreach, engagement, interaction and dissemination activities with community, knowledge users, policy-makers including reports and other dissemination materials, impact on clinical practice and service providers, impact on community-based interventions, etc. (excluding PLE).

Table 12:

NETWORK

National opioid guideline: The CRISM leads were approached by the Federal Minister of Health to adapt the British Columbia clinical guideline on opioid use disorder for nationwide dissemination and implementation. CRISM convened a national panel of 43 clinical leaders from across the country to review and modify BC's guideline; the network published the national guideline on March 5th, purposed to be a key resource for evidence based opioid use treatment practices in Canada. To promote knowledge translation, we developed several summary and supplemental materials, including summary cards of the recommendations (English and French), 1-pager information sheets on slow release oral morphine and buprenorphine-naloxone, and a safety bulletin regarding the risks of withdrawal management alone. Each Node has undertaken dissemination and outreach activities in their regions, including communications with regional health authorities, regulatory bodies, and local/provincial policymakers. In BC, the national guideline was shared with leadership from the Ministries of Health and Mental Health and Addictions, as well as key personnel at BC universities, health authorities, and regulatory bodies. Québec-Atlantic Node dissemination activities included several presentations to communities of practice, Drug treatment centers and programs, Hospital departments and confirming endorsement by public health authorities and College of physicians. Ontario Node dissemination activities have included several presentations at both provincial and national conferences, as well as communications with provincial stakeholders such as Health Quality Ontario and College of Family Physicians and Surgeons of Ontario.

In addition, the CRISM NPIs and Node clinical leads have presented the guideline development process and recommendations at numerous national and international conferences, as well as in local/provincial settings. These include:

- F/P/T Special Advisory Committee (SAC) on the Epidemic of Opioid Overdoses
- Problematic Substance Use and Harms Treatment Task Group
- CSAM Annual Meeting and Scientific Conference
- CCSA Issues of Substance Conference
- Best Brains Knowledge Exchange (dedicated meeting to discuss the guideline and implementation)
- Calgary clinic presentation on slow release oral morphine
- Special F/P/T Committee on Problematic Substance Use and Harms and Special Advisory Committee on the Epidemic of Opioid Overdoses Joint Teleconference
- CCSA and Health Canada Opioid Response Team
- CHUM Department of Pharmacy
- Federation of Medical Regulatory Authorities of Canada
- Canadian Public Health Association

OPTIMA

There have been several knowledge translation, dissemination and engagement activities across the clinics sites, of notable mention have been: a) the site staff's active and ongoing involvement with local community organizations and b) hiring of peer navigators and people with lived experience to support in recruitment efforts and provide the team with invaluable information around patient experience. Additional activities have included: presentations to patient groups, information sessions, advertising and referrals from safe consumptions services, street outreach teams, social media (Craigslist, Facebook, and Twitter), internal and external site presentations (rounds, addiction physician, emergency room staff, community

health clinics), mass distribution of study information to local faculties, College of Physicians and Surgeons, local health authorities, family medicine clinics, pharmacies, shelters, inpatient and outpatient treatment services, infectious disease clinics, journal club meetings, and private OAT clinics.

In addition, the CRISM NPIs and OPTIMA RPIs have presented the trial at several conferences and meetings. These include:

- CSAM Annual Meeting and Scientific Conference
- F/P/T Special Advisory Committee (SAC) on the Epidemic of Opioid Overdoses
- CCSA Issues of Substance Conference
- 21èmes Journées Annuelles de Santé publique: Journée thématique sur "L'urgence de se préparer pour faire face aux surdoses d'opioïdes au Québec"
- Celebrating and Showcasing, Community Health Services Research: An inaugural conference hosted by the VCH-Vancouver Community Research Program & the VCH Research Institute

For the **section 56 consultation**, CRISM engaged with a variety of types of stakeholders, including health service providers, policymakers, and representatives of regulatory bodies. A total of 243 individuals (excluding people with lived experience) from all 13 provinces and territories were contacted by each of the four Nodes, and 145 of these participated in the online survey and the regional teleconferences. CRISM compiled the feedback and recommendations from the participants via a written report that was disseminated through the Health Canada website and email to all stakeholders in February, 2018. On March 21, Health Canada announce legislative changes to the Narcotics Control Regulations to ease some restrictions for accessing methadone and diacetylmorphine, effective May 19, 2018. The consultation and announced changes were also made public through Twitter and 21 media articles.

LRCUG

Several KT materials/activities have been developed for various audiences (cannabis users, health professionals, public) which have been implemented with national partners, and disseminated provincially/regionally through the various CRISM Nodes. The LRCUG have been widely disseminated within each Node, and over 20,000 copies of the LRCUG KT materials have been distributed nationally. Nodes have collaborated with one another to develop Node dissemination strategies with appropriate stakeholders.

- April 2017, Cannabis and Public Health, Consortium for the Clinical Investigation of Cannabinoids Annual Conference
- June 23, 2017 National Launch of the LRCUG, Ottawa
- September 26th 2017 – QAN Québec symposium, Montreal
- Oct 19-21, CSAM, Niagara Falls Ontario
- December 5th 2017: QAN Maritimes symposium

Furthermore, the CRISM NPIs have participated in and initiated regular communications with our CIHR and Health Canada partners in regards to CRISM activities and future strategies. These include a meeting with CIHR and the CCSA and a meeting with The Honourable Ginette Petitpas-Taylor, that were held in conjunction with the CCSA conference, as well as additional phone and in-person meetings.

	Network/OPTIMA	
Number of Research Contributions:	Pub'd	Sub'd
Peer-Reviewed Publications	2	1
Books		
Conference Presentations	10	
Conference Abstracts	4	
Guidelines	2	
Other Reports	7	
Presentations (not incl. above)	16	
Newspaper	110	
TV/Radio	106	
TOTAL	258	

c) Please describe the extent to which research knowledge has been integrated into the planning and development of treatment services

Table 14:

NETWORK
The national guideline presents 11 evidence-based recommendations for primary care practitioners, with a stepped care approach for increasing or decreasing the intensity of treatment. The goals for implementation of the guideline include increasing the numbers of healthcare providers who use evidence-based practices in their treatment of patients with OUD and provide a wider range of treatment options. Additionally, we are promoting the use of the evidence base and recommendations in educational curricula and training programs for future and current practitioners. These efforts will ultimately contribute to greater access and expansion of the continuum of care in Canada.

TABLE 15

e) Please describe any additional KT activities or highlights.

Table 16:

NETWORK

The CRISM Network communicates with its collaborators, stakeholders and the wider public through social media, including Twitter and the national website. On Twitter, we have a total of 406 followers, and posted approximately 175 tweets this past year. The national CRISM website was launched in March, 2018 with the release of the national opioid guideline and houses information on other major activities, including the cannabis guideline, OPTIMA, and the section 56 consultation. In March, the website has received approximately 780 visitors.

In Feb, 2018, CRISM submitted a letter to Health Canada in response to their request for public input regarding proposed changes to regulations for diacetylmorphine. CRISM's letter supported these changes as well as any additional actions that would promote access to this essential medication in Canada.

10. INCLUSION OF SEX AND GENDER

a) How has the Network implemented the Policy on Sex and Gender in their research? Specifically, did the Network identify any sex and/or gender differences that inform on the prevention and treatment of substance misuse?

Considerations around sex and gender during the design and development phase of OPTIMA have taken place in the following ways:

- Inclusion of women of child bearing potential in OPTIMA involved a consideration of the risk/benefit ratio for a healthy female volunteer exposed to a potentially embryotoxic therapeutic product;
- The Informed Consent documents include sufficient information regarding the potential risks to inform women so that they may make informed decisions about the potential risks and benefits of OAT and the trial;
- The timing for inclusion of women in OPTIMA, (including the timing for inclusion of women of childbearing potential) and the use of clinically acceptable pregnancy prevention measures were greatly considered when designing the OPTIMA trial and detailed in the protocol and informed consent forms;

There are also provisions for women who become pregnant during the trial that wish to continue, as well as well provisions for breastfeeding women are well indicated in the inclusion and exclusion criteria. Research has widely recognized gender differences in OAT on measures of retention and engagement in treatment, adverse events, quality of life and treatment seeking behaviour. These important differences are also included as secondary and exploratory objectives of OPTIMA. Further, demographic information on sex and gender will be collected and included in analyses. In adherence to CIHR and Health Canada guidelines, OPTIMA will apply a sex and gender-based analysis (SGBA) which will allow researchers to identify gender specific intervention opportunities and make recommendations for more tailored treatments for opioid dependence.

The OPTIMA trial has enrolled:
Biological sex: Male (53, 73.6%), Female (19, 26.4%)
Identified Gender: Man (51, 70.8%), Woman (20, 27.8%), Transgender (1, 1.4%)

Sites have taken steps to specifically target female participants and those who self-identify as women such as dissemination of trial information through various gender specific special interest groups, community organizations, shelters, and outreach centres.

Additionally, an important ancillary study is taking place alongside the main trial, run by Dr. Sherry Stewart from Dalhousie University, *'Comparing Models of Care in the Management of Prescription Opioid Misuse: Sexual Dysfunction and Treatment Compliance in Men and Women Receiving Methadone versus Buprenorphine'* builds on the current OPTIMA protocol by including a small number of additional secondary outcome measures focusing on sexual function (i.e., desire, arousal, orgasm, pain, and satisfaction). Specifically identifying gender differences in sexual functioning on both methadone and buprenorphine/naloxone.

The national opioid guideline presented the evidence for sex/gender differences in treatment outcomes, and concluded that there were no differences. As well, the guideline has a dedicated section on special considerations for treatment options during pregnancy.

11. ETHICS, LEGAL AND SOCIAL

a) Have the Nodes, the Network or OPTIMA encountered any ethical, legal and social challenges when interacting with partners, end users, knowledge users and/or the community and what has your Node done to mitigate these challenges?

Table 18:

NETWORK
☒ Yes Please describe: **OPTIMA** **Challenge:** As we progressed through the early stages of the trial, it was discovered that Alberta's privacy legislation has very specific regulations around the use of identifiable health information leaving the province and be accessed by research staff that are not located or affiliated with the Prairie clinical sites. This led to several discussions around de-identification of protected health information while continuing to ensure that the needs of the trial were being met. **Response:** The OPTIMA team has been working closely with Northern Alberta Clinical Trials and Research Centre (NACTRC) and institutional privacy officers to develop a data sharing agreement to be executed between Alberta Health Services and all parties that will have access to the protected health information within the Prairies Node.

Challenge: Following the launch of the National Guidelines for Opioid Use Disorders, the research team has recognized a shift in prescription practices and attitudes toward OAT across provinces.
Response: This has led the teams to adjust the initial recruitment strategy, which relied primarily on referrals from the healthcare system (physicians, nurses etc.) and re-directed efforts to direct to participant recruitment.

Challenge: The OPTIMA team has recognized that there are unique differences exist within each province in regards to the ability of physicians to refer patients to the trial. Physicians are motivated to acquire and retain patients at their own practice and not refer these patients out to other physicians at other sites. This has led to a decrease in physician referrals at some clinical sites.
Response: To address this, we are using collaborative efforts to disseminate information out about the trial and engage these physicians in the trial. The goal of this would be to not only build study physician capacity but also increase knowledge of the trial across different clinics.

Operational and contractual challenge:
Execution of the OPTIMA trial through 4 different funding grants has brought a series of considerable logistics challenges from contracts, agreement, memorandum of understanding, transfer of funds, payment of supplies and other hared cost.

Geography, language: Those two components remain challenges of the Canadian research landscape that we must work with.

☐ No

12. GOVERNANCE

a) Please briefly describe any changes to your network's governance structure and associated committees.

Table 19:

NETWORK
In response to CIHR's request to develop a comprehensive governance and communication strategy, the Investigative team has developed the OPTIMA Governance & Communication plan was developed and became effective September 9, 2017. (see attached) In brief, the CRISM Nominated Principal Investigators (J Bruneau, B Fischer, C Wild, E Wood; NPIs) act as the Steering Committee and provide overall direction to OPTIMA to ensure cohesive strategies and alignment with the mandate of CRISM. The Regional Principal Investigators (D Jutras-Aswad, B Le Foll, R Lim, E Socias, K Ahamad; RPIs) are responsible to CRISM for study performance at their respective Nodes. One of the Regional Principal Investigators, D Jutras-Aswad (RPI for the Quebec/Maritimes Node), has been designated by the Steering Committee as the Lead Regional Principal Investigator (Lead RPI). The Lead RPI is responsible for overall trial implementation and for providing oversight at a national level, and joins the Steering Committee.

13. ADDITIONAL COMMENTS
Please add any additional comments that are relevant to the analysis of the information provided within this report. • There is overlap in content reported in the Network progress report and that of the Node progress reports as a Network activity can be the sole priority and activity of a Node at a given time. • Expected repetition as some sections have similar answers

APPENDIX 1: CRISM Publications
Publication list was submitted was Submitted in April 2018. There no current or recent submissions to report.