CANADIAN RESEARCH INITIATIVE IN SUBSTANCE MISUSE, Phase 3:
REPORTING TEMPLATE for PRESCRIPTION DRUG ABUSE OPERATING GRANT to the CRISM NETWORK

Background
The objectives of CRISM are:

1. To identify and develop the most appropriate clinical and community-based prevention or treatment interventions for substance misuse;
2. To provide evidence to support the enhancement of prevention or treatment services regarding substance misuse to decision makers and service providers; and
3. 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 (This phase is now completed).
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 objectives of 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 research being conducted on prescription drug abuse and how it is supported by the CRISM Network.

Reporting Requirement
The Funding Opportunity indicates that PIs will be required to submit annual reports "summarizing the outcomes and describing how the grants funds were used. In addition, PIs will be required to contribute to the monitoring, review and evaluation of the programs. By completed this template the PI will have met current reporting requirements for the PDA operating grant and the CRISM Network.

Methodology:
The proposed reporting template is based on:

- The objectives and requirements of the Funding Opportunity and
- The objectives committed to in the funding applications

In addition, as CRISM was part of the National Anti-Drug Strategy's full submission to the Treasury Board Secretariat, which included a performance measurement strategy, the objectives and commitments for

the third phase have been cross referenced with those indicators for which CIHR is responsible in efforts to streamline data collection activities.

CANADIAN RESEARCH INITIATIVE IN SUBSTANCE MISUSE, PHASE 3, PDA OPERATING GRANT AND CRISM NETWORK

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

This Annual Performance report is based on the operating year Nov 1, 2015-Oct 30, 2016, as notice of funding decision was made on Dec 9, 2015 with funding term starting Nov 1, 2015.

2. REPORT PREPARATION

Please indicate who prepared Performance Report, who contributed to the report and what information sources were used.

Report Lead

Name, title, telephone #, e-mail

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Contributors and Approval:

Contributors and Approval of Report Content

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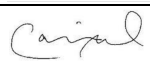
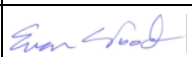
Cameron Wild	NPI-Prairie Node		Jan 18 2017
Evan Wood	NPI-BC Node		Jan 18 2017
Aïssata Sako	QM Node Manager		Jan 18 2017
Sarah Miles	ON Node Manager		Jan 18 2017
Denise Adams	Prairie Node Manager		Jan 18 2017
Nirupa Goel	BC Node Manager		Jan 18 2017
Jill Fikowski	National Coordinator, OPTIMA		Jan 18 2017

List information sources used to prepare the report

Please identify all sources that were used:

x CIHR OPTIMA application

	x OPTIMA Work Plan x Publications (specify, ISBN #): [1-3] x Research (specify & attach reports): Presentations [4-10]; Executive summary and Table of Contents of National opioid guidelines x Consultations (specify & attach reports) with OPTIMA study sites: Quebec-Maritime: September 19 & 23; Prairies: September 14-16; British Columbia: September 12-13. x Evaluation Results (specify& attach reports): CIHR peer review document x Other (specify): NPI commentaries/ letters, Power Point presentations, Network description documents

3. DELIVERY

Please review your team's application and, if applicable, your submission from the previous year.

Have there been any changes to the operational context or the objectives of your PDA project in this reporting period?

☐ Yes: Please describe:

x No

4. NARRATIVE SUMMARY AND KEY ACCOMPLISHMENTS FROM THE RESEARCH

Summarize the research project(s) and key accomplishments of the research to date.

Prescription Opioid Use Disorder operating grant: Optimizing patient centered-care: a pragmatic randomized control trial comparing models of care in the management of prescription opioid misuse (OPTIMA trial)

- CRISM NPIs developed 1 research proposal and submitted it to CIHR for review in October 2015. We responded to reviewer feedback and successfully obtained funding for OPTIMA from CIHR in November 2015.
- Upon securing funding, CRISM Node NPIs developed a governance structure for OPTIMA. This included (a) delegating one Node NPI (Julie Bruneau) as point of contact between OPTIMA and the NPI group, (b) recruiting 5 regional Principal Investigators (RPIs) for the trial (Eugenia Socias and Keith Ahamad [BC], Ron Lim [Prairies], Bernard Le Foll [ON], Didier Jutras-Aswad [QM]), (c) recruiting a National OPTIMA Research Coordinator (NRC), and (d) recruiting 4 regional OPTIMA teams including 4 Regional Study Coordinators, expert advisors, and beginning to form and develop supportive infrastructure including, communications, data management, and clinical coordination teams.
- OPTIMA RPIs and Study Coordinators collaborated to develop a detailed trial protocol for comparing two opioid assisted treatments (OATs): Methadone, with daily witnessed ingestion, and buprenorphine/naloxone, with flexible take home dosing. Collaboration to develop the trial protocol took place through weekly team conference calls between RPIs and the NRC and by follow up between RPIs and regional Study Coordinators. Study Coordinators were consulted extensively to ensure feasibility of trial implementation and that regional differences (such as health care regulations and populations) were considered. Expert consultation was provided on protocol development as appropriate. This included input from the Applied Clinical Research Unit

(ACRU) at CHU Sainte-Justine Research Centre, University of Montreal, and Dr. Annie LeBlanc, expert in patient engagement. In person meetings were also held as needed.

- CRISM NPIs recruited an international Scientific Advisory Board (SAB) and developed terms of reference for this group. The SAB will review the OPTIMA protocol.
- Each regional OPTIMA team has developed and submitted the OPTIMA trial protocol and supporting documents and regionally-tailored informed consent forms to their respective research ethics boards.
- The development of data and statistics infrastructure for OPTIMA has been contracted to URCA/ACRU. Their expertise includes bioinformatics, database and case report form development, staff training, and data coordination.
- Regional OPTIMA teams recruited 8 clinical sites from across Canada to participate in OPTIMA. Each site has committed to participant recruitment and study implementation. The sites include:
    - BC- the Rapid Access Addiction Clinic (RAAC) located in St. Paul's Hospital;
    - ON- two primary care clinics (True North Medical Centre, Sudbury Clinic) and the Addition Medicine Service located at the Centre for Addiction and Mental Health;
    - Prairies- two Opioid Dependency Clinics operated by Alberta Health Services, located in Edmonton and Calgary; and
    - QM- the External Addiction Medicine clinic of the CHUM Saint-Luc Hospital and the CRAN: Centre de recherche et d'aide pour narcomanes, both in Montreal.
- Preparation for study implementation is currently underway. This includes training all OPTIMA research staff and local clinical care teams to full competency on trial operating procedures locally and nationally to ensure compliance with REB requirements as well as Tri-Council Good Clinical Practice Guidelines.
- OPTIMA RPIs developed a protocol for soliciting proposals for ancillary studies, which was reviewed and approved by CRISM NPIs. CRISM members from all four Nodes were invited to submit proposals for ancillary studies to be carried out in conjunction with the OPTIMA trial. A total of 18 proposals were received and 9 were approved, including studies on pharmacogenomics, health economics, pain, participant awareness of naloxone distribution kits, a provincial overdose campaign, patient satisfaction, and sexual dysfunction. The ancillary studies will leverage OPTIMA or independent funds, evaluate local and national infrastructure, increase collaboration among investigators across nodes and capitalize on the knowledge gained from the OPTIMA trial.

National opioid use disorder treatment guideline

- CRISM is undertaking a project to develop a national guideline for the clinical management of opioid use disorder. The guideline will involve an extensive literature review of treatments for opioid use disorders and will provide recommendations for health care providers to guide them in choosing the most appropriate treatment for an individual patient's unique needs and circumstances. The long-term objective of the guideline is to encourage all Canadian health providers to deliver evidence-based treatments and promote consistent standards of practice across Canada. This guideline will have a direct impact on decision makers, such as provincial regulatory bodies and Ministries of Health, and service providers, with the ultimate goal of improving the care that Canadian patients receive, health outcomes, and the patient experience.
- The work plan, table of contents, and a description of the project scope and objectives have been drafted and approved by the four CRISM NPIs.
- Each Node has recruited lead clinicians for this project. These include Ramm Hering, Keith Ahamad and Leslie Rae Lappalainen (BC), Ginette Poulin (Prairies), Peter Selby (ON) and Marie-Ève Goyer (QM). Lead clinicians will chair a regional committee to review the draft guideline, and are actively recruiting clinical and health service opinion leaders in each Node to participate in the review process. Each CRISM Node is providing logistical support for lead clinicians through the Node Managers.

- The regional review process will lead to a single national guideline, authored by CRISM, which will then be disseminated to national and provincial stakeholders.

Lower-risk cannabis use guidelines (LRCUG)

- Lower Risk Cannabis Use Guidelines (LRCUG) are an evidence-based public health intervention tool for informed reduction of behavioral risk factors associated with cannabis use. The original LRCUG were developed and published in 2011 resulting from a (CIHR-funded) 'Applied Public Health Chair' initiative, and are currently undergoing a scientific update and revision, by an international scientific expert team led by Dr. B. Fischer (NPI/OCRINT). With impending cannabis legalization in Canada, the LRCUG have assumed a distinct role as a crucial public health intervention tool, for which there is increasingly wide demand across Canada. Once the scientific revisions of the LRCUG are in place, the LRCUG will undergo a comprehensive national organizational endorsement and knowledge translation effort under the CRISM umbrella. That is, the LRCUG will be presented to select leading key stakeholders in the area of substance use and public/population health for review and endorsement within a comprehensive and systematic process facilitated by the CRISM structure. Upon this step, the LRCUG will be disseminated into relevant policy and programming systems (e.g., government authorities, non-governmental substance use and public health organization at different levels) across Canada towards broad uptake and utilization.

How has the research supported the enhancement of prevention or treatment services regarding substance misuse to decision makers and service providers. Clinical practice and or community-based prevention or treatment interventions for substance misuse.

Prescription Opioid Use Disorder operating grant: OPTIMA

- Development of study teams. Each Node has developed a regional team consisting of an RPI, Study Coordinator, and project staff. Regional teams have strategically communicated with local clinicians, programs, and health system decision-makers to introduce OPTIMA, solicit local support for the trial, and to ensure that service systems are prepared to use OPTIMA results. Additionally, organizational, communication and reporting processes have been and continue to be developed with the goal of building capacity within each Node and improving inter-Node collaboration.
- Consideration of local standard of care guidelines during protocol development. Given both local requirements for treatment initiation on OAT and the pragmatic nature of the trial, the team selected study procedures based on clinical best practices and adherence to clinical research protocol. Some site modification of OAT has already occurred. For example, the Edmonton detox centre now uses Suboxone (rather than generic buprenorphine/naloxone) since Suboxone is being used at Alberta sites and it is anticipated that the study will result in increased use of Suboxone as a first line therapy (replacing methadone).
- Site selection. Each node has developed relationships with local clinical sites and staff. This will facilitate OPTIMA, but also provides a foundation for conducting future research on opioid treatment in the CRISM network. In addition, participation of local treatment sites in OPTIMA will facilitate changes in routine treatment protocols, since many participating clinicians and other health services staff are directly responsible for implementing changes in treatment regimes. Clinic staff interested in gaining research experience and participating in studies at their sites will have the opportunity to be involved in OPTIMA.
- Study implementation. Each site has begun development of site-specific Manual of Operations (MOP). Site Coordinators will work closely with the National Research Coordinator to ensure congruency between site and National MOP's to facilitate implementation. This work has identified challenges that could be the focus of future CRISM projects.

National opioid use disorder treatment guideline

- As noted above, CRISM's production of a national guideline for the clinical management of opioid use disorder will review and synthesize the scientific evidence for pharmacological treatments and other interventions and provide recommendations on the effective use of these treatments. Dissemination of the guideline is expected to have a direct impact on clinical practice and will reach a wide breadth of Canadian health service providers. The long-term objective of the guideline is to encourage the delivery of evidence-based treatments and raise the standards of care across Canada.
- Prior to release of the guideline, CRISM will reach out to provincial ministries of health and regulatory bodies for health care providers to give them opportunities to review and endorse the guideline. Endorsements will provide strong incentives and potentially, a mandate for providers to practice according to the guideline.

Lower Risk Cannabis Use Guidelines (LRCUG)

- With impending cannabis legalization in Canada, the LRCUG have assumed a distinct role as a crucial public health intervention tool, for which there is increasingly wide demand across Canada. The LRCUG will be disseminated into relevant policy and programming systems (e.g., government authorities, non-governmental substance use and public health organization at different levels) across Canada towards broad uptake and utilization.

Progress of research towards CRISM objectives	**Please describe how the research within the Network to date has:** **1. Identified and developed the most appropriate clinical and community-based prevention or treatment interventions for substance misuse** **Prescription Opioid Use Disorder operating grant: OPTIMA** ● CRISM identified pharmacological and non-pharmacological treatment interventions for prescription opioids/benzodiazepines/stimulants (including overdose) as a critical issue in Canada, and a priority for the first national CRISM research project. This priority is consistent with "Research Priorities for Prescription Drug Misuse Interventions" articulated at a workshop, organized by CIHR-INMHA and the Centre for Addiction and Mental Health in May 2015. ● Based on a literature review and clinical experience, buprenorphine/naloxone was determined to be an underutilized treatment in Canada, despite its favourable safety profile. The OPTIMA trial was designed to directly compare methadone (current Canadian standard care) and buprenorphine/naloxone treatments with the goal of demonstrating buprenorphine/naloxone as an acceptable alternative to methadone. In order to generate results that are truly relevant and practical for Canadian health care providers, the pragmatic design of the OPTIMA trial will allow for the identification of the most effective treatment in practical, real world settings. **National opioid use disorder treatment guideline** ● A systematic literature review was conducted in order to identify the most effective treatments and best practices for managing opioid use disorder. Clinical studies were scored for strength using the GRADE criteria and used to develop best practice recommendations. **2. Provided evidence to support the enhancement of prevention or treatment services regarding substance misuse to decision makers and**

	service providers. ● The proposal and protocol for the national OPTIMA trial have been developed and the study is in the process of being implemented at 8 sites across Canada. OPTIMA results will inform OAT across Canada, and provide evidence of the effectiveness and safety of buprenorphine/naloxone, as compared to methadone. ● Dissemination of the national opioid use disorder treatment guidelines will raise standards of care and promote consistency and harmonization of OAT practices across Canada. The guidelines will be used to update provincial regulations and standards, leading to growth in the number of providers delivering up-to-date evidence-based treatments. ● The LRCUG will be disseminated into relevant policy and programming systems (e.g., government authorities, non-governmental substance use and public health organization at different levels) across Canada towards broad uptake and utilization. **3. Supported the improvement in the quality of care and quality of life for Canadians living with substance misuse.** ● Increased buprenorphine/naloxone uptake from OPTIMA and national guidelines for opioid use disorder treatment will increase quality of care by promoting the use of best practices and evidence-based treatments. The expected outcomes are that the patient experience, health outcomes, and quality of life will be improved, due to the increase utilization of effective treatments and improved treatment adherence. ● Dissemination of the national opioid use disorder treatment guideline will be a catalyst for modernizing OAT throughout the country, and thus has great potential for improving quality of care for Canadians living with opioid use disorder.
Ethics, Legal and Social	**What mechanisms are in place to ensure research is conducted at the highest standard of ethics? Please address issues of recruitment, privacy and confidentiality, compensation, and dissemination of results to participants, the community and knowledge users (including interpretation of results and further communication of results).** Mechanisms in place for the OPTIMA trial include: • Peer review of the original proposal by CIHR reviewers and the CRISM Scientific Advisory Board as well as by Node expert advisors; • Research ethics board approval for each region participating in OPTIMA; • Consultation with Health Canada regarding regulatory considerations; • Administrative and operational approvals for sites, as needed; • Formation of the OPTIMA Data Safety Monitoring Board; • Participant recruitment according to core ethical principles including: respect for person, concern for welfare, and justice; • Participants will be compensated for the inconveniences that may arise from participating in OPTIMA in an amount that is within the range recommended by the REBs; • Confidentiality of participant data will be carried out according to REB requirements; • Quality assurance and monitoring will be provided by the Applied Clinical Research Unit (ACRU) at the University of Montreal;

- Clinic and research staff participating in OPTIMA will have certifications in both Tri-Council Policy on the Ethical Conduct for Research Involving Humans (TCPS2) and Good Clinical Practice (GCP) and trained in accordance with guidelines and standards of Health Canada and the REBs;
- Publications resulting from OPTIMA will be subject to peer-review;
- Results from OPTIMA will be publically available on Node websites and will be made available through other dissemination mechanisms (e.g., conference presentations, journal articles).

How has the Policy on Sex and Gender been implemented? Specifically, were any sex and/or gender differences identified 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.

Funds Leveraged Through Collaborative Research

Funds Leveraged by Research Project

Research Project	Source	Amount/year	Years	Total
OPTIMA KT (100,000 per node)	CIHR	400,000	1	400,000
Ancillary – Richardson	CIHR	20,025	1	20,025
Ancillary – Bhodan (submitted)	CIHR	300,000	3	300,000

5. NARRATIVE SUMMARY OF THE NETWORK'S ACTIVITIES AND HOW THEY SUPPORT THE RESEARCH

How have the nodes worked together to undertake collaborative research? Include main activities, frequency of meetings, description of plan for data and information sharing, etc

Network communication and collaboration

Communication and collaboration occurs throughout the CRISM network at many levels, including:

- *Nominated Principal Investigators.* The NPI group meets regularly through monthly conference calls as well as additional phone or email contact as needed. NPIs also meet on an ad hoc basis, e.g., meeting with Health Minister Philpott on October 3, 2016.
- *Node Managers.* Bi-monthly conference calls are held with CRISM Node Managers to coordinate activities. Additional phone or email contact is routinely undertaken outside this schedule. CRISM Node Managers regularly collaborate on Node website development, document production for CRISM, publications, and presentations.
- *CRISM National Executive Committee* (NEC). NPIs, Node staff/members, and CIHR staff met in person in Montreal in February, 2016 to discuss CRISM activities and updates, future sustainability, current and future priorities, and OPTIMA; NEC meets annually; planning is underway for the next NEC meeting to be held in Banff, Alberta at the end of February, 2017.
- *Node Members.* Each Node has developed communication strategies to update Node Membership on regional and national CRISM activities. These updates include funding or project calls, trainee recruitment, news articles, events, and publications. Communication strategies include list-serves, websites, social media, and newsletters; members are asked to provide relevant information for dissemination to other members via these methods.
- *Conferences and meetings.* The NPIs and CRISM members collaborated to present at the following meetings and events, including 2 international conferences:
    - Best Brains BC (March 2016) and Ontario (October 2016) [4]
    - NIDA CTN (international) April 11-13, 2016 in Gaithersburg, Maryland [5]
    - NADS: governance structure and prevention/treatment sub working group presentation September 15, 2016 [6]
    - ISAM-CSAM symposiums (2; international) October 20, 2016 in Montreal [7]
    - Canadian Agency for Drugs and Technologies in Health (CADTH) workshop on opioid dependence management Nov 3, 2016 in Yellowknife [8]
    - Health Canada/CCSA Opioid Summit Nov 18, 2016 in Ottawa [9]

Collaborative Research planning for the OPTIMA trial

- Regional PIs, Study Coordinators, and URCA/ACRU collaborated on the early planning and design steps for the study in 2 in-person meetings (February 23-24, 2016 in Montreal and May 22-23, 2016 in Vancouver).
- Regional PIs and the National Research Coordinator communicated or met in-person with the NPI designated contact (Julie Bruneau) as needed to provide updates to the NPIs. Regional OPTIMA study teams (RPIs, Study Coordinators, research staff, NPIs as needed) hold weekly conference calls as well as phone or email contact as needed to discuss implementation of the trial and to coordinate decision making and involvement of OPTIMA sites.
- Data from OPTIMA (and other studies) will be hosted on data-sharing platforms on Node websites in order to allow CRISM members access to such data for secondary analysis and future research planning.

Collaboration on documents and publications

- NPIs jointly drafted a response to Health Canada's request for comments on proposed amendments to diacetylmorphine regulations. CRISM's response highlighted that diacetylmorphine is a safe and effective treatment for individuals with severe opioid use disorder unresponsive to other treatments (submitted to Health Canada, May 30th 2016).
- NPIs have supported CRISM Node members by writing letters of support such for funding applications and performance reviews.
- Ontario Node NPI Dr. Benedikt Fischer and BC Node PIs Drs. Eugenia Socias and Keith Ahamad collaborated on an analysis paper and commentary, published jointly in the *Canadian Medical Association Journal*.[1,2] These publications highlight the rise in prescription opioids and its subsequent harms to Canadian patients, and call for urgent action to increase access to evidence-based treatments (November 2016).

Cost-sharing

- Shared expenses for CRISM Network activities are divided between Nodes. This includes shared funding for the OPTIMA National Research Coordinator salary, document development, meetings and training platforms, and participation at workshops.

Responsibility-sharing

- Responsibility for oversight or conduct of activities is divided between Nodes such as for planning and leading meetings, booking and hosting conference calls, leadership of specific projects, etc. Responsibility for these activities rotates between nodes on a 6-month basis.

Conflict Resolution

- The CRISM network and the OPTIMA trial have similar structures in place for conflict resolution. At the level of the CRISM network, Cam Wild is the designated NPI liaison for the Node Managers and facilitates communication, troubleshoots problems and mediates conflicts between NPIs and Node Managers and within Node Managers. Julie Bruneau is the designated NPI liaison for the OPTIMA trial and facilitates communication, troubleshoots problems and mediates conflicts within the OPTIMA study team and between the OPTIMA study team, NPIs, and Node Managers. Similar structures will be set up as needed for future CRISM-wide projects.

How have the nodes worked together to form a sustainable Network? i.e. shared partnerships, interactions and mechanisms of collaborating

CRISM intends to establish itself as a National and regional resource for conducting research on substance misuse interventions and influencing practice and policies through outreach and knowledge exchange. In addition to the network activities outlined in the question above, we have formed collaborations with other organizations working in the field of substance misuse/addictions in Canada:

- CCSA: CRISM had a major presence at the Health Canada/CCSA/Ontario-sponsored opioid summit conference held in November 16-18 2016, as well as several phone calls and email communication to discuss areas of collaboration. For example, we have discussed CRISM and CCSA supporting each other's policy and advocacy goals by using each of our networks to disseminate documents and news to a wider audience.
- CIHR: The CIHR initiative management team and the CRISM node managers and NPIs have taken several opportunities to capitalize on existing tools and resources to facilitate the network's capacity building and to identify gaps in resources that could benefit the network in the future. The initiative team has also facilitated opportunities for CRISM to teach and learn from partners (e.g., NADS, CADTH workshops). CIHR continues to endorse and financially support CRISM's

annual National Executive Committee meeting.

- Federal Ministry of Health: On October 3 2016, the four CRISM NPIs met with the Honourable Jane Philpott, Federal Minister of Health, to discuss topics of mutual interest, including the current opioid crisis, cannabis legalization, and the role CRISM infrastructure will play in generating timely evidence to inform practice and policy.

Each CRISM node is also working on activities to ensure CRISM's sustainability:

- The BC Node is working with the BC Ministry of Health to secure additional funding for research and policy work as well as partnering with provincial Health Authorities and the College of Physicians to develop new clinical guidelines and pathways.
- The Prairie Node is negotiating with Alberta Health Services (AHS) to become a repository of addiction health service data in Alberta. The repository would be used for quality improvement within AHS and would facilitate additional research initiatives. The Node has partnered with AHS for an OPTIMA ancillary study to answer AHS-based questions on naloxone distribution and overdose awareness, and has established a project seed funding mechanism for Node Members to build capacity.
- The Ontario Node has developed formal partnerships with federal bodies including a research partnership with Correctional Service Canada and Dr. Benedikt Fischer's (NPI) secondment as Senior Scientific Advisor for Cannabis Legalization & Regulation secretariat/Health Canada.
- The Quebec-Maritimes Node has created research and knowledge exchange partnerships with the Quebec Network on suicide, mood disorders and related disorders (RQSHA) and *l'Institut Universitaire sur les dépendances* (IUD). It has begun the process of increasing its capacity and reach by working to integrate Newfoundland and Labrador members and created a protocol and research development program for members.

Collaborations & Partnerships of the Network through Research

# of collaborators within the Network: 205

Please describe the type and value of these collaborations:

Numbers reflect applicants from each Node that were listed on the original CIHR application

Organization Type	# Individuals	# Institutions	Value
Academic research	104	29	The expertise of these researchers spans numerous disciplines including addiction medicine, mental health, neuropharmacology, HIV/AIDS, epidemiology, health policy and economics, statistics, sociobehavioural sciences and others. The collective expertise of this group is highly valuable in guiding the design, development, implementation, and analysis of research projects, as well as advising on best practices for knowledge translation.
Knowledge User: Policy Maker/Government /Regulatory Authority	37	31	Policy makers at municipal/provincial health ministries/authorities serve as consultants on research and policy priority areas. Collaboration with these ministries and regulatory bodies are essential for translating CRISM research into municipal and provincial public health policy and advocacy related to substance misuse.
Knowledge User: Service Providers	42	30	Service providers are essential in the delivery of evidence-based, best practices for substance use treatment to patients and in leading the education of future health care professionals. These collaborators participate in the translation of research findings into regional health policy and programming, particularly in areas of quality improvement.
Knowledge User: Advocate/ Person with lived experience	14	15	These people and organizations are key providers of peer-based support, education, and advocacy for patients, family members, and the substance using community. They serve as consultants on research and policy priority areas relevant to the affected community and are valuable partners in building public awareness, community engagement, and in translating research findings for education and advocacy.
Knowledge User: Foundation / Institute / Education/ Non-profit	4	5	Educational and non-profit institutes are important cross-sectoral bodies that link research practice with service provision and offer a unique combination of research and end-user perspectives.
Knowledge User: Professional Organization	4	5	Access to policy and decision makers for specific health care professions.

# of partnerships, defined as collaborators external to the Network: 129

Please describe the type and value of these partnerships:

Numbers reflect Node members added after the original CIHR application

Organization Type	# Individuals	# Institutions	Value
Academic research	36	7	As above
Knowledge User: Policy Maker/Government /Regulatory Authority	25	9	As above
Knowledge User: Service Providers	44	45	As above
Knowledge User: Advocate/ Person with lived experience	14	10	As above
Knowledge User: Foundation / Institute / Education/ Non-profit	6	2	As above
Knowledge User: Professional Organization	3	1	As above
Other	1	1	Minister of Health: discussed topics of mutual interest and the role CRISM infrastructure will play in generating timely evidence to inform practice and policy

Knowledge Exchange related to collaborative research (including publications from research and those relating to the Network)

Research Contributions		
	# Published	**# Submitted**
Data Resources	0	0
Peer-Reviewed Publications	2 [1,2]	1 [3]
Books	0	0
Conference Presentations/Abstracts	7 [4-9]	1 [10]
Other Reports	0	0

Public Outreach and Media Coverage	
Presentations	1
Newspaper	5
TV/radio	9
Social Media	60 followers 107 tweets
Other (including meetings, cross training)	www.crismprairies.ca www.qmcrism-icras.com

	From NADS Performance Measurement Strategy	
	# of knowledge exchange opportunities with the public, partners and other stakeholders	454

	Please describe the Network's meaningful outreach, engagement, and dissemination activities with end users and the community. End users and community partners (not including research partners) affiliated with the Nodes include stakeholders representing provincial governments, health authorities, foundations/institutes/centres, patient advocacy groups, treatment centres, and regulatory bodies for health practitioners. We have facilitated meetings with each of these partners in order to develop relationships and assess collaborative potential and needs. Initial communication with the Network members was carried out by email and our electronic Node-specific newsletters. The newsletters included updates on regional and National CRISM activities, provided members with links to relevant Canadian and US initiatives (e.g., CIHR Strategy for Patient-Oriented Research; Substance Abuse and Mental Health Services Administration), and informed members of opportunities to participate in consultative processes with stakeholders. With the launch of our websites (www.crismprairies.ca, www.qmcrism-icras.com), information designed to enhance member collaboration is also available. To communicate with network members and the wider public, we created a Twitter account, in which research articles, news, policy decisions, events, and advocacy campaigns are posted. We have steadily gained followers and we post almost on a daily basis, including live tweeting from the Opioid Summit in November 2016. One important way that our partners have benefitted from Network activities is in the reduction of redundancy among partners, such as in solicitation of OPTIMA ancillary projects where members with common interests were partnered and encouraged to build a single project proposal. We have engaged with various local and national organizations, such as the Canadian Centre on Substance Abuse (CCSA), the National Institute on Drug Abuse (NIDA) and the Thunderbird Partnership to discuss areas of mutual interest and collaboration for knowledge translation and dissemination work. For the national opioid use disorder treatment guideline, we have begun the process of engaging with regional leaders and committees and formalizing the structure for developing and reviewing the guideline. The regional leaders and NPIs will meet to achieve consensus on content and recommendations, which will then be disseminated widely to relevant stakeholders in each province. We have also presented at regional, national, and international conferences, which are detailed above. These presentations and meetings have allowed the NPIs and Regional PIs to share information about CRISM and its national projects, raising awareness of CRISM's unique role as a national resource for research and clinical expertise. The meetings also allow us to engage with potential collaborators, reviewers, and DSMB members for clinical studies. [4-9] In order to enhance our engagement with community groups, CRISM has submitted a workshop proposal for the International Harm Reduction 2017 conference being held May 14-18, 2017 in Montreal. The workshop structure will include (a) a brief overview of the National CRISM Network, (b) a brief update from each CRISM Node on how drug user advocacy organizations are represented, (c) a roundtable introduction of advocacy groups and individuals, (d) open discussion of national and international efforts to strengthen inclusion and advocacy in substance use research, and (e)

	strategic planning for collaborative initiatives. Moreover, each Node engages its peer community through local and regional activities, including representation in the governance structures, consultation meetings, community-based participatory research, and other types of engagement.[10]

	Please describe the Network's meaningful engagement and interactions with knowledge users, policy-makers including reports and other dissemination materials, impact on clinical practice and service providers, impact on community-based interventions, etc. Outcomes and impacts of OPTIMA and national guideline development/distribution are forthcoming. Impact to date is related to formation of collaborative relationships and establishing lines of communication with stakeholders. **National opioid use disorder treatment guidelines** ● As noted previously, the dissemination and implementation of the opioid use disorder treatment guideline will have a direct impact on clinical practice and will reach a wide range of Canadian health service providers. The long-term objective of the guideline is to encourage the delivery of evidence-based treatments and raise the standards of care across Canada. To meaningfully engage stakeholders in the guidelines, CRISM will reach out to provincial ministries of health and regulatory bodies for health care providers to give them opportunities to review and endorse the guidelines prior to release. **Lower Risk Cannabis Use Guidelines (LRCUG)** • The LRCUG will undergo a comprehensive national organizational endorsement and knowledge translation effort under the CRISM umbrella. That is, the LRCUG will be presented to select leading key stakeholders in the area of substance use and public/population health for review and endorsement within a comprehensive and systematic process facilitated by the CRISM structure. Upon this step, the LRCUG will be disseminated into relevant policy and programming systems (e.g., government authorities, non-governmental substance use and public health organization at different levels) across Canada towards broad uptake and utilization. CRISM will directly engage and influence policy-makers through Dr. Benedikt Fischer's (NPI/OCRINT) secondment as Senior Scientific Advisor for Cannabis Legalization & Regulation Secretariat/Health Canada, which will contribute to evidence-based public health policy reform and implementation. In addition, CRISM has engaged policy makers and regulatory bodies on a federal level through other initiatives described in this report (e.g., meeting with Minister Philpott, letter in support of changes to diacetylmorphine regulations).
	How will knowledge users communicate and apply findings? Communication may occur through direct dissemination to and from individual knowledge users as well as through node and network group communication tools such as websites, list-serves, interest or working group meetings, reports, and newsletters as well as via various forms of media. Research results and knowledge syntheses will be disseminated using the above methods as well as at local, national, and international conferences, and by submission to open-access peer-reviewed journals. Network members are preparing evidence summary documents that directly address current gaps in knowledge and that are critical to changing national and provincial

	clinical care policy. For example, we have evaluated data related to the comparative safety of OATs in preparation for dissemination of this document to decision makers and regulatory agencies. We expect this evidence to result in policy changes that make Suboxone more available as an alternative to methadone. Additional documents are being planned, including lower-risk cannabis use guidelines. Potential outcomes of OPTIMA include evidence of effect and safety of buprenorphine/naloxone based on utilization in real-world settings (8 sites across Canada) and potential to change practice to include enhanced use of buprenorphine/naloxone as a first-line treatment. To disseminate and implement the national opioid use disorder treatment guidelines, CRISM will leverage the communication networks of provincial ministries of health, regulatory bodies, and health care professional organizations. The recommendations are directly applicable to clinical practice in a variety of settings (hospital, community care, private practice, corrections, etc.). The guidelines will assist providers in determining the most effective care plan for their patients, depending on the patient's history and goals, and will guide them in making adjustments to treatment as health outcomes change.
Ethics, Legal and Social	**Has the Network encountered any challenges (i.e. ethical, legal and social) when interacting with partners, end users, knowledge users and or the community and what has the Network done to mitigate these challenges?** The CRISM network has not experienced major challenges.
Governance	**Please describe how the Network has used and involved the External Advisory Board.** CRISM's Scientific Advisory Board consists of 5 international members who are experts in addiction treatment (e.g., heroin assisted treatment) and comorbidities (e.g., HIV, pain, depression) and leading researchers in substance use interventions. The SAB provides scientific input to CRISM NPIs as needed in order to (a) assist CRISM research, and/or (b) assist CRISM NPIs to connect with complementary international research developments. The Scientific Advisory Board will provide feedback on the OPTIMA protocol including: a safety assessment; suggestions for interim analyses; advice on managing participants who request a change in treatment arm during the trial; and suggestions for streamlining the proposed outcome measures.
	Please provide a summary of pertinent strategic directions arising from discussions with your External Advisory Board relating to the Network, including how these recommendations are being implemented or justification for deviation. The Scientific Advisory Board has been formed but has not yet provided guidance on CRISM projects.
Additional Comments. Please add any additional comments that are relevant to the analysis of the	

information provided within this report.

Reference List. Please provide the full reference for any source document (APA style) that you have used as evidence in your narrative contribution analysis.

Articles

1. Fischer, B., Rehm, J., & Tyndall, M. (2016). Effective Canadian policy to reduce harms from prescription opioids: learning from past failures. *CMAJ: Canadian Medical Association Journal= Journal de l'Association Medicale Canadienne, 188(*17-18), 1240-1244. doi: 10.1503/cmaj.160356.

2. Socías, M. E., & Ahamad, K. (2016). An urgent call to increase access to evidence-based opioid agonist therapy for prescription opioid use disorders. *CMAJ: Canadian Medical Association Journal= Journal de l'Association Medicale Canadienne, 188(*17-18), 1208-1209. doi: 10.1503/cmaj.160554.

3. Fischer, B., Russell, C., van den Brink, W., LeFoll, B., Hall, W., Rehm, J., Room, R. (2016). Lower-Risk Cannabis Use Guidelines (LRCUG): An Evidence-Based Update. American Journal of Public Health, (in submission).

Presentations and Talks

4. CIHR Best Brains Exchanges

- Addiction Treatment and Recovery: Clinical and Health System Improvements, Victoria, British Columbia (March 11, 2016)
- Supporting Evidence-Informed Drug Policy: Identifying Marijuana Legalization and Regulation Data and Information Needs, Ottawa, Ontario (October 4, 2016)

5. NIH National Institute of Drug Abuse, Clinical Trial Network Annual Scientific Meeting, International Symposium, April 11-13, 2016 in Gaithersburg, Maryland

6. National Anti-Drug Strategy, governance structure and prevention/treatment sub working group presentation September 15, 2016

7. ISAM-CSAM symposiums (2; international) October 20, 2016 in Montreal

8. Canadian Agency for Drugs and Technologies in Health (CADTH) workshop on opioid dependence management Nov 3, 2016 in Yellowknife

9. Health Canada/CCSA Opioid Summit Nov 18, 2016 in Ottawa

10. 25th Harm Reduction International Conference, Strengthening inclusion and advocacy: A workshop with the Canadian Research Initiative in Substance Misuse (CRISM), May 14-17, 2017 in Montreal