Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative

National Huntington Disease Clinical Trial Strategy

Background

Prior to 2012, Huntington disease (HD) clinics in Canada worked independently with no formal mechanism in place to connect clinicians and share best practices. Those affected by HD have expressed confusion with how clinical trials work and whether they should participate. In 2012, as part of a five-year strategic plan, HSC identified a critical need to develop a national HD clinical trial strategy complete with the structure and implementation steps required to ensure Canada is prepared for HD Clinical Trials. This was the first step in connecting researchers, scientists, and clinicians to work together and develop a comprehensive national strategy that will promote health research in Canada and ensure best practices are shared and knowledge transferred.

HD Clinical Trials Consortium

In 2014, the HD Clinical Trials Consortium was created to carve a new path for the research community and provide an opportunity for clinicians, the Huntington Society of Canada (HSC) and Canada's Research-Based Pharmaceutical Companies (Rx&D) to partner in the outreach efforts to encourage participation in Huntington disease (HD) clinical trials.

The HD Clinical Trials Consortium is a conduit between researchers and individuals leading to the creation of a national HD Clinical Trial strategy. The consortium is open to Canadian Clinicians who are treating HD Participants.

The Huntington Society of Canada

HSC plays a key role in bridging the relationship between researchers and individuals by educating Canadians on the importance of the clinical trial process; how they can get involved; and why their participation is so crucial. The urgency lies, in not only educating as many people as possible, including efforts in rural and culturally diverse communities, but also ensuring clinicians have sustainable mechanisms in place to support the process.

The Society is fiscally responsible for managing funds for the *Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative.* Founded in 1973, our charitable registration number is 11896 5516 RR0001, and we are proud to voluntarily adopt the Ethical Fundraising and Financial Accountability Code and the Donor Bill of Rights published by Imagine Canada. Our mission is a world free from Huntington disease. We strive to: maximize the quality of life of people living with HD by delivering services; enabling others to understand the disease, and furthering research to slow and prevent HD.

Mission Statement

To develop and implement a National HD Clinical Trial Strategy to ensure Canada is best prepared to support clinical trial research to treat and prevent Huntington disease.

Vision Statement

Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative has reverberated across Canada. Our HD families are eagerly enrolling in clinical trials aimed at slowing down, halting and even reversing the symptoms of Huntington disease. We have attracted the most promising clinical trials to Canada because of our cross-country network of certified sites, combining both research and clinical practice that utilize the highest ethics and standards to protect the health and safety of participants as well as the integrity and value of the research being undertaken. Our vision is that the approval process for HD clinical trials is streamlined, harmonized among multiple jurisdictions, and efficient. Our Canadian HD families are some of the first in the world to benefit from new treatments, as they help to slow or stop the progression of HD with HD clinical trials happening in Canada. A world free of HD is within our grasp.

Values & Guiding Principles

- World-class research and innovation should be made available to Canada's HD Participants in a timely, cohesive and efficient manner, using the highest ethical and safety standards
- All stakeholders – participants, clinicians, researchers, scientists, and pharmaceutical companies – should be encouraged to work collaboratively to develop and implement a National HD Clinical Trial Strategy
- The National HD Clinical Trial Strategy, lead by the Huntington Society of Canada, should build upon work being done by other disease groups & health organizations around the world, wherever possible
- Development and implementation of the National HD Clinical Trial Strategy should not be at the expense of the support services provided to HD families

Goals

- To support HD research with the goal of finding safe and effective treatments for HD through the clinical trial process.
- To work collaboratively with researchers, scientists, pharmaceutical companies, clinicians and members of the HD community
- To identify the components of a successful clinical trial network in Canada
- To identify issues to be addressed and obstacles to be overcome
- To undertake the steps needed to make world-class HD research and innovation available to Canadian families
- To work collaboratively with people representing other neurological diseases and movement disorders
- To work collaboratively with community, coalitions, and government agencies such as the Health Charities Coalition of Canada, Federal and Provincial ministries, Health Charities, among others.

Strategic Alliances

- **The Canadian Coalition for Genetic Fairness (CCGF)**: The Huntington Society of Canada leads this 18 member coalition that advocates to end genetic discrimination by insurers and employers based on genetic test information. Ending genetic discrimination will remove a barrier to clinical trial participation.
- **Health Charities Coalition of Canada (HCCC):** As an executive member of the HCCC, HSC collaborates with more than two dozen other national charities to share best practices and advocate for better health policies in Canada.
- **HD Buzz:** HSC is proud to be a founding funder and ongoing supporter of this international initiative. The cost-effective and one-of-a-kind web portal service delivers the latest HD research news in easy-to-understand language and is helping spark interest in upcoming clinical trials while keeping the global HD community abreast of current peer reviewed, HD Research.
- **Huntington's Disease Society of America (HDSA):** HSC shares a close relationship with our counterparts south of the border. Whether collaborating through the International Huntington Association or through one-on-one projects like *The Physician's Guide*, and research collaborations, our partnership continues to thrive.
- **Huntington Society of Quebec (HSQ):** HSQ serves the distinct needs of Quebec while maintaining strong links with HSC. An HSQ representative sits on our board of directors, and we partner to ensure all Canadians have access to the services they need.
- **European Huntington's Disease Network (EHDN):** A critical partner "across the pond," the EHDN provides a forum for different European countries to work together and advance clinical trials and research.
- **CHDI Foundation:** a privately-funded, not-for-profit biomedical research alliance that is devoted to a single disease – Huntington disease. Their mission to develop drugs that will slow the progression of Huntington disease and provide meaningful clinical benefit to Participants as quickly as possible, including Enroll-HD and other initiatives.
- **Huntington Study Group** (HSG) is dedicated to the mission of seeking treatments that make a difference to those affected by Huntington disease.
- **Canada's Research-Based Pharmaceutical Companies** (Rx&D): Rx&D is the national association representing 50 research-based pharmaceutical companies in Canada.
- **Huntington's Disease Youth Organization (HDYO):** HSC is a founding funder of this online community, which brings together young people affected by HD from around the world. By pooling our resources with other HD organizations to support HDYO, we are able to give youth a voice and deliver age-appropriate information and resources.
- **International Huntington Association (IHA):** HSC is a founding member and a current board member of this global forum dedicated to sharing best practices and resources with other HD organizations around the world.
- **Neurological Health Charities Coalition of Canada (NHCCC):** By leveraging the collective strength of more than 20 organizations, including the HSC, this coalition works to influence federal policy and improve the lives of people with neurological diseases and their caregivers.
- **Year of the Brain 2015:**
  Coordinated by the European Brain Council, with the support of over 200 Participant, clinical and industry organizations, Year of the Brain will highlight the needs of the millions of Europeans currently affected by brain disease, while raising awareness of the importance of everyone nurturing and protecting their most vital asset – their brain.
- **YPAHD:** The Huntington Society of Canada's national youth chapter, Young People Affected by HD, who provide a community and support network for young people affected by Huntington disease.

Key Strategies

1. **Establish an Implementation Committee and Potential Funding Opportunities for the Consortium Initiatives**
2. **Identify Issues to be Considered for Clinical Trial Readiness**
3. **Build Clinical Trial Site Capacity**
4. **Streamline the Clinical Trial Startup Process**
5. **Develop a Clinical Trial Recruitment Strategy**
6. **Work to Ensure the Financial Viability of Conducting Clinical Trials in Canada**
7. **Communicate World-Wide that Canada is Open for Business - Be the Go to Resource for HD Clinical Trials in Canada**
8. **Secure Funding to Support the Development of these Key Strategies**

These Key Strategies are discussed in detail on the following pages, with relevant issues and Action Steps identified for each of the key strategies.

Timeline

This Timeline has been developed from a review and prioritization of the Action Steps identified for the Key Strategies that are presented on the following pages.

- **Immediate 2015:** Create a Participant Centred Best Practices Guide, build upon the generic Clinical Trial Readiness Checklist making it HD specific and develop a Clinical Trial Mentorship Program
- **2016 – 2017:** Build clinical trial site capacity, develop a clinical trial recruitment strategy and increase the number of clinical trial sites in Canada
- **2017- 2018:** Investigate development of a clinical trial site certification program and investigate development of a clinical trial readiness training program

It should be recognized that *Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative* is a dynamic and fluid process that will need regular review and updating to reflect positive movement towards its goals and objectives and to reflect positive changes in the clinical trial landscape, both nationally and internationally.

Eight Key Strategies

Key Strategy #1: Establish an Implementation Committee and Potential Funding Opportunities for the Consortium Initiatives

- In 2012, HSC identified a critical need for a National HD Clinical Trial Strategy, with structure and implementation steps. HSC included this as a key component of the HSC five-year strategic plan
- In 2013, HSC hosted a one day roundtable meeting connecting researchers, scientists and clinicians to strengthen relationships, share best practices, and to identify methods to execute and promote HD clinical research across Canada
- In 2014, in response to the roundtable meeting, an HD Clinical Trial Consortium was initiated followed by the creation of governance documents
- The Consortium will be the driving force for implementation of a National HD Clinical Trial Strategy
- The Consortium expects to be the "go to body" for HD research in Canada
- Under the guidance of the Consortium, the following tasks have been undertaken:
    - A Governance Model has been developed and is being utilized to guide the activities of the Consortium
    - A Business Case has been developed for the National HD Clinical Trial Strategy
    - A Generic Clinical Trial Readiness Checklist has been developed
    - A Clinical Site Inventory of clinics and clinical trial sites in Canada has been completed
    - A Clinical Trial 101 Workshop was held in October 2014, bringing together 22 clinicians, researchers, scientists and other health professionals
- The Consortium will hold a workshop in October 2015 to address development of a Participant Centred Best Practices Guide*, an HD specific Clinical Trial Readiness Checklist and a Clinical Trial Mentorship Program**
- Teleconferences and workshops will continue to be undertaken and tasks will be commissioned by the Consortium as needed to further the National HD Clinical Trial Strategy
- The Consortium will review and update this National HD Clinical Trial Strategy on a regular basis to support the strategies discussed on the following pages

Action Steps:

- ❖ **Host 2015 workshop and develop a Participant Centred Best Practices Guide*, an HD specific Clinical Trial Checklist, and a Clinical Trial Mentorship Program****
- ❖ **Undertake teleconferences, workshops and tasks, as needed**
- ❖ **Review and update this National HD Clinical Trial Strategy regularly**

*** National HD Best Practices Guide to Clinical Trials in Canada:** The HD Clinical Trials Consortium will create a user friendly participant centred best practices guide. The guide will assist clinicians, who are currently conducting HD clinical trials, and those who are thinking of participating in HD clinical trials in Canada to:

- maximize the clinical study (or trial) experience to ensure it is participant centric
- address the requirements for a site to become research ready
- maximize the efficiency of the many study-related processes
- encourage more clinicians to participate in HD clinical research in Canada

**** HD National Clinical Trial Mentorship Program:** The HD Clinical Trials Consortium is presently developing a mentorship program for clinicians to engage in a formal professional relationship whereby more experienced clinicians provide support, expertise and constructive advice (including specific skills and competencies) to less experienced clinicians who are investigating participation in clinical trials within the Canadian context. The mentorship relationship may continue as the clinicians become involved in trials.

Key Strategy #2: Identify Issues to be Considered for Clinical Trial Readiness

- New scientific discoveries are expected to result in a multitude of HD clinical trials in the next few years
- Investment in clinical trials will likely occur in countries where there is a comprehensive network of clinical trial sites that have well-trained staff, standardized operating procedures, streamlined and integrated research ethics board reviews and startup procedures, electronic measurement and reporting systems, efficient business practices, and ready access to clinical trial participants
- Canada is seen as a good choice for doing HD research as we have an excellent health care model
- Currently HD clinics in Canada work independently with no formal mechanism in place to connect clinicians and share best practices between clinic sites
- There is a need for additional clinical trial sites to build capacity to accommodate the expected increase in clinical trials, and the new clinics will need strategies to ensure they will have Participants and be financially viable
- Research Ethics Board (REB) review processes take a variety of forms and can be quite lengthy and expensive, and there is a need to seek opportunities to streamline and harmonize processes across facilities including reviewing the Alberta Clinical Research Consortium
- Finalizing research contracts can be a very lengthy and costly process, and research contracts need to be standardized and to share information
- To compete internationally for research contracts, Canada must have faster clinical trial startup times and this is an issue that has been identified
- The lack of an orphan drug designation program in Canada and reimbursement of medicines, once approved, needs to be addressed
- There is a need to identify more HD Participants to increase the available potential of clinical trial participants
- Genetic discrimination in Canada is a factor in testing choices and therefore may be a barrier to participation in clinical trials
- HD families have expressed confusion about the clinical trial process and whether they should participate

Action Steps:

- ❖ **Ensure that the issues identified are addressed through the Key Strategies**

Key Strategy #3: Build Clinical Trial Site Capacity

- Canada needs more clinical trial site capacity to be able to respond to the increased HD clinical trials opportunities expected over the next several years
- Integration of research and innovation, i.e. clinical trials, into the health care delivery system, via clinicians treating HD Participants, would enhance opportunities for increasing clinical trial site capacity in the short term and provide more direct access for potential clinical trial Participants to trial sites
- We need to engage current clinicians across Canada and encourage their participation in HD clinical trials to build clinical trial capacity
- A clinical site inventory was created in 2014, which provides a variety of data about clinics across Canada serving HD Participants, including number of Participants, frequency of visits, services available, service model type, and willingness and ability to do clinical trials
- This HD Clinical Site Inventory, based upon a survey of current HD clinicians, will provide a foundation for developing an HD Clinical Trial Asset Map
- Information from the survey will also be provided to the Canadian Clinical Trials Coordinating Centre (CCTCC) to be voluntarily input into their Canadian Trials Asset Map (CCTAM) for all disease groups
- A generic clinical trial readiness checklist was developed in 2014 to aid clinicians that are new to clinical trials and to build clinical trial capacity
- The generic clinical trial readiness checklist will be made HD specific
- This HD Clinical Trial Readiness Checklist will be shared with the Health Charities Coalition of Canada to be used for clinical trial readiness by other disease groups
- The Clinical Trial 101 Workshop highlighted the need for a number of items for further action to build clinical site capacity, including the need for a Participant Centred Best Practices Guide, site certification, staff training and a Mentorship Program
- A Participant Centred Best Practices Guide for HD clinical trials will be developed following the 2015 workshop being hosted by the Consortium
- Development of a clinical trial site and/or principal investigator Certification Program will be investigated, to move away from time-consuming and costly certification at each site for each contract to a national certification program, to streamline the clinical trial startup process
- A need for a Clinical Trial Readiness Training Program has been identified, and options for scope and delivery of training will be investigated; it will be important to have this widely recognized in the pharmaceutical community to avoid duplication of, for example, specific certification modules covering "Good Clinical Practice Guideline" demanded by specific sponsors for a study
- A Clinical Trial Mentorship Program will be developed to encourage knowledge transfer among professionals and build capacity for clinical trials
- HD clinical sites who can be clinical research ready will be identified

Action Steps:

- ❖ **Develop a National HD Clinical Trial Asset Map**
- ❖ **Build upon the generic Clinical Trial Readiness Checklist to make it HD specific**
- ❖ **Prepare a Participant Centred Best Practices Guide**
- ❖ **Develop a Clinical Trial Mentorship Program**
- ❖ **Identify HD clinics who can be clinical research ready**
- ❖ **Investigate development of a Clinical Trial Certification Program**
- ❖ **Investigate development of a Clinical Trial Readiness Training Program**

Key Strategy #4: Streamline the Clinical Trial Startup Process

- Startup of a clinical trial in Canada can be a costly, inefficient and lengthy process due, in part to multiple forms, processes and standards from a variety of jurisdictions that may differ at each participating clinical trial site
- Contract negotiations and contract word-smithing by lawyers and other professionals are expensive and are often the rate-limiting step in the clinical trial startup process
- To compete internationally for HD clinical trials, Canada must have faster startup times of say 3 months, rather than the 15 months experienced by some researchers
- Streamlining the clinical trial startup process will decrease startup time, lower startup costs, and provide coordinated reviews and better safety protection for Participants
- A streamlined and efficient startup process will encourage more investment in HD clinical trials in Canada
- Development of the Participant Centred Best Practices Guide, training initiatives, and a Mentorship Program – as discussed in Key Strategy #3 – will all support an improved overall quality in submissions, which will improve the review and approval process and decrease the startup time
- Utilization of a standardized contract between sponsors, clinical sites and principal investigators would simplify and shorten the startup process for clinical trials
- Development of a standardized contract or clinical trial agreement for HD clinical trials will be investigated, building upon the work done recently on this issue for all disease groups that was funded by CIHR
- Startup times can be improved through utilization of templates for all forms including standardized Participant consent forms and standardized templates for ethics review submissions
- A common set of evaluation criteria for ethics reviews would provide clarity for application requirements and simplify evaluation of the applications
- Harmonizing ethics review processes and sharing material across the system would also result in cost and time savings
- Development of a harmonized ethics review process for HD clinical trials, with standard evaluation criteria and standard templates for forms, will be pursued, building upon work being done by others, including the Canadian General Standards Board and Health Canada, for all disease groups
- Optimization of clinical trial startup times will be enhanced by greater access to more HD clinical trial sites
- Access to potential clinical trial Participants can be achieved through use of a voluntary HD Participant registry database and development of a Participant recruitment strategy, as discussed in Key Strategy #5 with appropriate privacy controls

Action Steps:

- ❖ **Investigate development of a standardized contract or clinical trial agreement**
- ❖ **Pursue development of a harmonized ethics review process**
- ❖ **Seek opportunities to influence startup times, which can be improved through utilization of templates for all forms including standardized Participant consent forms and standardized templates for ethics review submissions**
- ❖ **Influence the utilization of a standardized contract between sponsors, clinical sites and principal investigators, which would simplify and shorten the startup process for clinical trials**

Key Strategy #5: Develop a Clinical Trial Recruitment Strategy

- More Canadian clinical trial Participants are needed for the expected increase in HD clinical trials
- It is estimated that only 18% of people at risk for HD in Canada have been tested, and this is in keeping with the number of world-wide who have chosen to pursue predictive testing
- An outreach campaign to health professionals, including GPs, community neurologists, and community agencies serving people with HD, will be conducted to increase awareness of the clinical trial process and increase awareness of opportunities for participation
- An outreach campaign to the HD community and its supporters will be developed as well, utilizing a number of platforms including media, HSC chapter events across Canada, conferences, HSC website and HD Buzz
- Many in the HD community have expressed confusion about the clinical trial process and whether or not they should participate, which should be clarified with the above- mentioned strategies
- A communications strategy will be developed and implemented to ensure that there is ongoing information available to potential participants that provides relevant and clear information and updates on the clinical trials process and generates continued enthusiasm and excitement for potential participants
- The *Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative* messaging will be of significant benefit in the outreach campaigns and communications activities and will be utilized
- An REB approved consent form, asking if individuals would like to be approached for future clinical research, would provide clinicians an opportunity to discuss specific details around potential studies and would be an initiative to work towards
- Timely access to a large population of potential clinical trial Participants is required to decrease clinical trial startup times and encourage investment in clinical trial research in Canada
- Enroll-HD maintains a registry of HD participants world-wide, and their objective is to create the world's largest database for clinical research on HD
- Generally, the Consortium conceptually supports the Enroll-HD program and registry
- All HD clinicians should be encouraged to investigate and consider registering in an Enroll-HD study, which needs 20-30 Participants to participate, as it will help with Participant recruitment and this messaging to HD clinicians can be undertaken as part of the outreach campaign to health professionals
- There is a need to promote Enroll-HD amongst the HD community, and this can be done as part of the outreach campaign to the HD community and through the communications strategy

Canada is the only G7 country that does not protect its citizens from genetic discrimination. In Canada, genetic test results can be used as a basis for genetic discrimination from insurance companies and employers. Many people at-risk for HD have chosen not to have the genetic test that is required for many clinical trials due to fears of genetic discrimination.

The Huntington Society of Canada (HSC) is advocating for genetic fairness in Canada; however, at this time, protection is not in place. HSC recognizes that choosing to participate in clinical trials is a personal decision; the Society encourages those who are interested to consult with their HSC HD Resource Centre Director or Family Service Worker to understand all aspects of this decision.

HSC will continue to advocate for genetic fairness, to benefit Canadians as a whole, and to encourage genetic HD testing to improve health care outcomes and to support the clinical trial process.

Action Steps:

- **Develop and implement an outreach campaign to health professionals to increase awareness of opportunities for potential clinician participants**
- **Develop and implement an outreach campaign to the HD community to increase awareness of opportunities to potential Participants**
- **Develop and implement a communications strategy to inform and update potential Participants about clinical trials in Canada**
- **Build upon the Be Brave Be Bold Be Ready messaging**
- **Develop and utilize a common consent form for HD clinical trials**
- **Continue to advocate for genetic fairness**

Key Strategy #6: Work to Ensure the Financial Viability of Conducting Clinical Trials in Canada

- The financial viability of conducting clinical trials in Canada will be dependent on many factors, including those already discussed such as clinical trial site readiness, improved startup times and procedures, the strength of good data collection and adequate engagement of clinical trial Participants
- In addition, issues such as performance metrics, intellectual property protection, tax credits, and an orphan drug program will all have an effect on financial viability and the attractiveness of Canada for clinical trial research
- There is a need to measure, monitor and analyze performance data for clinical trials – i.e. performance metrics – to optimize the clinical trial process in Canada and to encourage investment in clinical trials in Canada
- It would be helpful to influence common electronic database management systems across all HD clinical trials sites in Canada to enable performance metrics collection
- Development and implementation of a performance metrics collection and evaluation system will be investigated
- There is a need to increase intellectual property protection, at least to the levels offered in Europe, to be able to compete internationally for HD clinical trials
- Efforts will be made to increase intellectual property protection in Canada, working with other groups in Canada that are addressing this issue for all disease groups
- Streamlining of the administration of SR&ED tax credits will be pursued, working with other groups in Canada that are addressing this issue for all disease groups, so that tax credits are received in time to be credited to the cost of each clinical trial
- An orphan drug program provides incentives to pharmaceutical companies to develop drugs that would otherwise not be feasible for reasons such as lack of drug patentability or lack of potential to recoup the cost of developing the drug since the market is small for rare diseases
- Due to the lack of an orphan drug program in Canada, we have fewer drugs available for clinical trials than in other countries
- Health Canada has developed a draft Orphan Drug Regulatory Framework
- To be competitive in the global market for HD clinical trials and to ensure that our Canadian HD families have access to the most current clinical trials available world-wide, we need to encourage further development of a Canadian orphan drug program

Action Steps:

- ❖ **Investigate development and implementation of a performance metrics system**
- ❖ **Work to improve Intellectual Property Protection in Canada**
- ❖ **Pursue streamlining of SR&ED tax credit process**
- ❖ **Encourage development of a Canadian orphan drug program**

Key Strategy #7: Communicate World-Wide that Canada is Open for Business – Be the Go to Resource for HD Clinical Trials in Canada

- There is strong competition internationally for clinical trial contracts, and financial considerations play a large part in the decision of where to locate clinical trials
- Canada is seen as a good place to do clinical trials due in part to our health care delivery system and the overall high level of health of Canadians, but is seen as a less optimal place for clinical trials due to potentially inadequate number of clinical trial sites and participants, and inefficiencies and higher cost of conducting clinical trials, as discussed previously
- The Canadian Clinical Trials Asset Map (CCTAM) is an online, searchable database for clinical trials addressing a variety of diseases that is being developed and managed by the Canadian Clinical Trials Coordinating Centre (CCTCC)
- The goals of the CCTAM, for all disease groups, include:
    - To help sponsors identify clinical trial sites and principal investigators in Canada
    - To develop a comprehensive database of clinical research assets
    - To market Canada as a desirable location to conduct clinical trials
- The Consortium intends to openly communicate with and support the goals of the CCTCC and utilize the CCTAM
- The Consortium will promote awareness of this National HD Clinical Trial Strategy throughout the global HD community, and keep researchers, clinicians and members of the HD community updated
- To attract more clinical trials to Canada, the global clinical trials community needs to be advised when **Action Steps** identified in this Clinical Trial Strategy have been undertaken, i.e. development of the Participant Centred Best Practices Guide, HD Clinical Trial Readiness Checklist, and Clinical Trial Mentorship Program

Action Steps:

- ❖ **Utilize the CCTAM to promote Canada as a good place for HD clinical trials**
- ❖ **Promote awareness of this National HD Clinical Trial Strategy within the global HD community and keep researchers, clinicians and members of the HD community updated**
- ❖ **Communicate with the global clinical trials community as Action Steps from this National HD Clinical Trial Strategy are completed, to attract more clinical trials to Canada**

Key Strategy #8: Secure Funding to Support the Development of these Key Strategies

- Much has been accomplished already on limited financial resources and every effort will be made to continue to use funding efficiently, by building upon work done by others and embracing our partnerships and strategic alliances
- As stated in the Values and Guiding Principles, funding of this initiative cannot detract from donations that fund the HSC Family Services program, and therefore new funding sources need to be found for this initiative
- Funding may be sought from a variety of sources, including foundations, corporations, government, industry, and individuals
- Many funders are interested in funding specific activities or costs such as capital expenses, operating costs, conferences, startup costs, advocacy & awareness activities, marketing, project costs and program costs where specific budget and deliverables can be clearly identified
- Some funders will provide general funding to help achieve the stated goals and objectives with more flexibility
- Research will be undertaken to identify potential funding sources for all of the elements of this National HD Clinical Trial Strategy
- An ongoing fundraising strategy will be developed to ensure that all elements of this National HD Clinical Trial Strategy can be funded
- Funding applications will be prepared and funding secured to support this National HD Clinical Trial Strategy

Action Steps:

- ❖ **Identify potential funding sources for various elements of this National HD Clinical Trial Strategy**
- ❖ **Develop an ongoing fundraising strategy that is continually updated to ensure that all elements of this National HD Clinical Trial Strategy are funded**
- ❖ **Prepare funding applications and secure funding on an ongoing basis**

Executive Summary

The *Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative* **is a complex initiative that will benefit the health of Canada's HD families and strengthen our clinical** trials infrastructure.

Our **Mission** is clear. Our **Vision** is vibrant. Our **Values and Guiding Principles** speak to what we believe in. Our **Goals and Objectives** are achievable. Our **Strategic Alliances** are highly valued and critical to the success of this initiative.

Based on the above, a number of **Key Strategies** have been identified. Many of these Key Strategies are interrelated and will benefit from being done as parallel processes rather than consecutive processes.

Action Steps developed for each of the Key Strategies are as follows:

Key Strategy #1: Establish an Implementation Committee and Potential Funding Opportunities for the Consortium Initiatives

- Host 2015 workshop and develop a Participant Centred Best Practices Guide, an HD specific Clinical Trial Readiness Checklist and a Clinical Trial Mentorship Program
- Undertake teleconferences, workshops and tasks, as needed
- Review and update this National HD Clinical Trial Strategy regularly

Key Strategy #2: Identify Issues to be Considered for Clinical Trial Readiness

- Ensure that the issues identified are addressed through the Key Strategies

Key Strategy #3: Build Clinical Trial Site Capacity

- Develop a National HD clinical trial asset map
- Build upon the generic Clinical Trial Readiness Checklist to make it HD specific
- Prepare a Participant Centred Best Practices Guide
- Develop a clinical trial mentorship program
- Identify HD clinical sites who can be clinical research ready
- Investigate development of a clinical trial certification program
- Investigate development of a clinical trial readiness training program

Key Strategy #4: Streamline the Clinical Trial Startup Process

- Investigate development of a standardized contract or clinical trial agreement
- Pursue development of a harmonized ethics review process
- Seek opportunities to influence startup times, which can be improved through utilization of templates for all forms including standardized Participant consent forms and standardized templates for ethics review submissions
- Influence the utilization of a standardized contract between sponsors, clinical sites and principal investigators, which would simplify and shorten the startup process for clinical trials

Key Strategy #5: Develop a Clinical Trial Recruitment Strategy

- Develop and implement an outreach campaign to health professionals to increase awareness of opportunities to potential clinician participants
- Develop and implement an outreach campaign to the HD community to increase awareness of opportunities to potential Participants
- Develop and implement a communications strategy to inform and update potential Participants about clinical trials in Canada
- Build upon the **Be Brave Be Bold Be Ready** messaging
- Develop and utilize a common consent form for HD clinical trials
- Continue to advocate for genetic fairness

Key Strategy #6: Work to Ensure the Financial Viability of Conducting Clinical Trials in Canada

- Investigate development and implementation of a performance metrics system
- Work to improve Intellectual Property Protection in Canada
- Pursue streamlining of SR&ED tax credit process
- Encourage development of a Canadian orphan drug program

Key Strategy #7: Communicate World-Wide that Canada is Open for Business - Be the Go to Resource for HD Clinical Trials in Canada

- Utilize the CCTAM to promote Canada as a good place for HD clinical trials
- Promote awareness of this National HD Clinical Trial Strategy within the global HD community and keep researchers, clinicians and members of the HD community updated
- Communicate with the global clinical trials community as Action Steps from this National HD Clinical Trial Strategy are completed, to attract more clinical trials to Canada

Key Strategy #8: Secure Funding to Support the Development of these Key Strategies

- Identify potential funding sources for various elements of this National HD Clinical Trial Strategy
- Develop an ongoing fundraising strategy that is continually updated to ensure that all elements of this National HD Clinical Trial Strategy are funded
- Prepare funding applications and secure funding on an ongoing basis

This **Timeline** has been developed from a review and prioritization of the above Key Strategy Action Steps.

- **Immediate 2015**: Create a Participant Centred Best Practices Guide, build upon the generic Clinical Trial Readiness Checklist making it HD specific and develop a Clinical Trial Mentorship Program
- **2016 – 2017**: Build clinical trial site capacity, develop a clinical trial recruitment strategy, and increase the number of clinical trial sites in Canada
- **2017- 2018**: Investigate development of a clinical trial site certification program and investigate development of a clinical trial readiness training program

It should be recognized that *Be Brave Be Bold Be Ready: Clinical Trial Readiness Preparation Initiative* is a dynamic and fluid process that will need regular review and updating to reflect positive movement towards its goals and objectives and to reflect positive changes in the clinical trial landscape, both nationally and internationally.