Ontario Brain Institute

Annual Plan

2020-2021

January 31, 2020
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Commonly Used Acronyms

AACPDM American Academy of Cerebral Palsy & Developmental Medicine
AODA Accessibility for Ontarians with Disabilities Act
AD Alzheimer’s disease
ALS amyotrophic lateral sclerosis
AxON Atlas of Ontario Neuroscience
BASE BioArray Software Environment
BEAM Brain-Eye Amyloid Memory Study
BIO Biotechnology Innovation Organization
BPS Broader Public Service
BPSA Broader Public Service Act
Brain-CODE Centre for Ontario Data Exploration
CAHO Council of Academic Hospitals of Ontario
CAMH Centre for Addiction and Mental Health
CAN-BIND Canadian Biomarker Integration Network in Depression
CARA Canadian Association of Research Administrators
CC-ABHI Canadian Centre for Aging and Brain Health Innovation
CCNA Canadian Consortium on Neurodegeneration in Aging
CCRM Centre for Commercializing Regenerative Medicine
CDE Common data elements
CDRIN Canadian Depression Research and Innovation Network
CFMM Western’s Centre for Functional and Metabolic Mapping
CIMT constraint induced movement therapy
CIFAR Canadian Institute for Advanced Research
CIHR Canadian Institutes of Health Research
CIT core innovation team
CNS central nervous system
CP cerebral palsy
CP-NET Cerebral Palsy Integrated Neuroscience Discovery Network
CQDM Quebec Consortium for Drug Discovery
CRO contract research organization
DBS deep brain stimulation
DICOM Digital Imaging and Communications in Medicine
DSM V Diagnostic and Statistical Manual of Mental Disorders
EDC electronic data capture
EEG electroencephalography
EHIL Electronic Health Information Laboratory
EMIF European Medical Information Framework
EMT entrepreneurship and management training
EMR Electronic Medical Record
EpLink The Epilepsy Research Program of the Ontario Brain Institute
ERR ethics restriction reports
ESP Evaluation Support Program
FedDev Federal Economic Development Agency for Southern Ontario
FTE full-time equivalent
GA4GH Global Alliance for Genomics and Health
GMFCS Gross Motor Function Classification System (for Cerebral Palsy)
HIPA Health Information Protection Act
HQO Health Quality Ontario
HQP highly qualified personnel
HTA Health Technology Assessment
HTX Health Technology Exchange
HVRS Home Virtual Reality System
IAC Industry Advisory Council/International Advisory Council
ICES Institute for Clinical Evaluative Sciences
ICGC International Cancer Genome Consortium
ID Integrated Discovery
IDP Integrated Discovery Program
IHPME Institute of Health Policy, Management and Evaluation
IP intellectual property
IUPESM International Union for Physical and Engineering Sciences in Medicine
JHSA joint health and safety committee
JLA James Lind Alliance
JLABS Johnson & Johnson innovation labs
KOL key opinion leader
KT knowledge translation
LIBD Lieber Institute for Brain Development
LORIS Longitudinal Online Research and Imaging System
LSO Life Science Ontario
MassBio Massachusetts Biotechnology Council
MDAO Mood Disorder Association of Ontario
MDD major depressive disorder
MDDT Movement Disorders Diagnostics Technologies
MEDEC Canadian medical technology industry association
MEG magnetoencephalography
MNE multi-national enterprise
MNI Montreal Neurological Institute
MOHLTC Ministry of Health and Long-Term Care
MRIS Ministry of Research, Innovation and Science
NDAR National Database for Autism Research
NERD Neurotech Early Research and Development
NIFTI Neuroimaging Informatics Technology Initiative
NIH National Institutes of Health
NIO Neurotechnology Industry Organization
NIMH National Institute for Mental Health
OACRS Ontario Association of Children’s Rehabilitation Services
OBI Ontario Brain Institute
OBIC Ontario Brain Innovation Council
OBIF Ontario Brain Institute Foundation
OBIO Ontario Bioscience Industry Organization
OCE Ontario Centres of Excellence
OCHIS Office of the Chief Health Innovation Strategist
OCUR Ontario Council on University Research
OECD Organization for Economic Co-operation and Development
OG Ontario Genomics
OHSA Occupational Health and Safety Act
OHTAC Ontario Health Technology Advisory Committee
OIRM Ontario Institute for Regenerative Medicine
OISE Ontario Institute for Studies in Education
OLTCA Ontario Long-Term Care Association
ONDRI Ontario Neurodegenerative Disease Research Initiative
OSC Ontario Science Centre
PAC patient advisory committee
PbD Privacy by Design
PET positron emission tomography
PFAC patient and family advisory committee
PHI personal health information
PHIPA Personal Health Information Protection Act
POND Province of Ontario Neurodevelopmental Disorders Network
REDCap Research Electronic Data Capture
QA/QC quality assurance / quality control
QL/QoL quality of life
REB research ethics board
ROI return on investment
RRI Rotman Research Institute
rTMS repetitive transcranial magnetic stimulation
SAC science advisory council
SIT science innovation team
SGC Structural Genomics Consortium
SME small and medium-sized enterprise
SOP standard operating procedures
SPReD Stroke Patient Recovery Research Database
TBI traumatic brain injury
TECHNA Institute for the Advancement of Technology for Health
TOR terms of reference
TRA threat risk assessment
TRI Toronto Rehabilitation Institute
UHN University Health Network
UTI ultrasonic transcranial imaging
WBI Weston Brain Institute
Ontario Brain Institute Annual Plan for 2020-2021

Introduction

The Ontario Brain Institute accelerates discovery and innovation to benefit patients and the economy, today and for generations to come. We are pioneering a ‘team science’ approach that brings together researchers, clinicians, industry, patients, and their advocates to foster discovery and deliver innovative treatments and services that improve the lives of those living with brain disorders. OBI initiatives will have a significant impact on quality of life, cost of care and the economy of Ontario.

This Annual Plan presents the activities, milestones and metrics for the 2020/21 fiscal year in accordance with the 5 Year Operational Plan for 2018 to 2023 and is directly related to the OBI Vision. It reflects input from the various reviews undertaken as part of the renewal process – the Scientific Reviews of the OBI ID Programs, the OBI Wide External Review and the review by the Science and Industry Advisory Committees to the President and Scientific Director of OBI. This document demonstrates how OBI will address the recommendations to increase its capacity in commercialization and informatics/analytics through Brain-CODE, as well as support the neuroscience community across Ontario.

OBI’s model of integrated discovery achieves impact for patients, accelerates the commercialization of research advances, and changes the research culture. This Annual Plan outlines how we will continue the process of integrating the research programs within primary care, focusing on the molecular underpinnings of the disorders, scaling-up of the tech sector, enhancing data-driven decision making, and embedding patient priorities in the research activities. With the support of the Government of Ontario, OBI is committed to continuing to achieve its milestones and make significant advances towards attaining its overarching goal of making a transformative impact on health, brain research and Ontario’s economy.
OBI Areas of Focus and 2019-2020 Key Accomplishments

Over the past year, OBI continued its focus on better serving the one in three Ontarians who are living with a brain disorder. Our goals of improving brain health and creating economic wealth continue to be supported by our approach to collaborative research, data sharing, new neurotech company formation and community engagement.

Our strength lies in our ability to support quality research based on scientific excellence that advances our understanding of brain disorders. This year:

- A performance management framework has been introduced to each of our research programs. This framework codifies the OBI model of integrated discovery in the form of key performance indicators. The framework will also inform discussions and decisions related to program performance, areas of improvement and key areas of strength.
- Our POND program leveraged the infrastructure and the database created via OBI, and successfully received a grant to study adults with autism. The data from this study will be entered into Brain-CODE and integrated with the existing POND database to get continuity of life span data.
- ID Programs have made significant progress in data analysis and cross-platform collaborations which has resulted in excellent publications addressing cross-disorder issues.
- A centralized online reporting system has been introduced to track program performance and streamline information flow and integration.
- A new Advisory Council has been approved to advise OBI on the international significance of our activities to ensure Ontario neuroscience research and economic development initiatives are globally significant.

An integrated and collaborative approach to science is the cornerstone of OBI’s work. We continue to work towards a learning healthcare system, improving health, building community and creating economic opportunities through this approach and have demonstrated that by:

- Entering into an MOU with Praxis Spinal Cord Institute to collaborate on areas of mutual benefit given the relationship between spinal cord injuries and brain disorders.
● OBI and Pfizer Canada announcing a joint award for industry-based internships. The program will increase capacity for start-up based internships aimed at supporting Ontario’s neurotech cluster. The partnership will dedicate a total of $250,000 to be matched in part by the participating employer, to support 14 interns over the next four years.
● EpLINK running a trial on cannabidiol, which is being conducted in partnership with Aurora Cannabis' subsidiary MedReleaf. This trial focuses on adults with drug-resistant epilepsy.
● ONDRI starting a collaboration with the MINT Memory Clinics (Multi-specialty Interprofessional Team). These clinics build capacity for dementia diagnosis and care in communities, improving care and access for Ontarians living with dementia.
● CAN-BIND launching an ECT (electroconvulsive therapy) - ketamine comparison study. The aim of this study is to show that compared to ECT, ketamine treatment produces faster therapeutic action, has fewer side effects, requires fewer/shorter hospitalizations for patients, and will be less expensive.
● Holding the 4th Indigenous suicide prevention workshop in Peterborough on September 28-29, and the 5th in Sault St. Marie on October 27, 2019. Indigenous youth were training in suicide alertness (safeTALK) and life promotion photography (Photovoice). In partnership with the Chiefs of Ontario and the Ontario First Nations Young Peoples Council, the project aims to reduce suicide rates in Indigenous communities.
● Working with the Ontario Science Centre as Knowledge Sponsor to develop their ‘Mindworks; exhibit and to develop programming to support the exhibit. MindWorks gives visitors the opportunity to explore topics such as decision-making, memory and emotions in a fun and hands-on way. The exhibit was launched in September and will run until April 2020 with various programming and outreach events happening throughout.

Collaboration and data sharing break down the silos in research and helps to decrease the time it takes for discoveries to move from the lab to life. OBI has continued to move forward with data integration and sharing opportunities including:

● Three data-linkages between Brain-CODE data and ICES resulting in the linking of deep research data with broad, health-system utilization data.
● A third open data release in June with the release of MRI phantom quality assurance data for external research groups to use for analyses. This data release tied in with a workshop on MRI quality control and quality assurance led by Dr.
Stephen Strother’s group at the Organization for Human Brain Mapping 2019 conference in Rome, Italy.

- A demo of an upcoming POND clinical data release on Brain-CODE was featured at the International Society for Autism Research (INSAR) conference in Montreal in May. This demo, featuring an interactive dashboard on the Brain-CODE platform, allowed researchers to query the clinical data of 2000+ participants to provide first-hand experience of potential future analyses. The data release will allow external researchers to conduct additional investigations, expediting potential discoveries in our understanding of neurodevelopmental disorders.

- Supporting the ID Programs as they bring in external collaborators for data analysis support including a European-based investigator to support CAN-BIND in its data analysis.

- Being an active member in both the Canadian Open Neuroscience Platform (CONP) Technical Steering Committee and CONP Ethics & Governance Committee. OBI has worked with the CONP Ethics & Governance Committee on the development of Commercialization and Publication Policies for CONP.

- Being involved in the Regulatory & Ethics Working Group of the Global Alliance for Genomics and Health (GA4GH) and was engaged in the review and development of its Consent Policy, its Privacy and Security Policy, and its 2020 Strategic Roadmap over the summer.

The OBI model is also about moving technologies into the market place and helping companies develop and grow. This includes development of entrepreneurial skills to help new companies develop faster, supporting companies through start up phases and linking companies to various management and advisory services. Over the past year we have had many successes including:

- The placement of 4 interns in Tech Transfer Offices across the province (Hospital for Sick Children, Western University, Holland Bloorview Kids Rehabilitation Hospital, and University of Windsor).

- An internship that established a collaboration between ONDRI and Adhawk, an Ontario SME. This is the first industry partnership for ONDRI. The intern is using the ONDRI gold-standard eye tracking tasks to validate a wearable devise that could allow for remote monitor of eye tracking.

- 6 new neurotech entrepreneurs selected in June of this year for its 2019-2020 cohort.

- Over the past year, OBI’s portfolio of companies has raised in excess of $109.3 million to further support the development of their technologies.
At OBI we take a great deal of pride in helping to take the innovative work that happens in the confines of a lab and translating it into real life – ultimately better supporting individuals with brain disorders as well as their families and caregivers. Together, we’ll further improve clinical care, support the development of relevant enterprises, advance new treatments and products to the market, and streamline knowledge exchange from researcher to patient, and patient to researcher.

In the coming year OBI will continue to build upon our success to date and through our collaborative model ensure we achieve improvements in healthcare and economic opportunities through integration, collaboration, data sharing and building community.

**OBI Leveraging**

OBI has committed to achieving a cumulative 2:1 ratio of leveraged investments in its 2018-2023 contract with the Ontario Government. OBI has exceeded its target for 2019/20 with funding available for 2020/2021.

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OBI’s Operational Plans for 2020-2021 By Priority

Focus Area: Build a Learning Healthcare System

OBI is uniquely poised to help build a learning healthcare system - by integrating research and patient care and moving research from the lab and clinics into the community. The learning health care system embeds research into patient care and ensures that research findings are translated into evidence-based clinical practice and health system change to bring about real patient and economic impact.

The ID Programs are large-scale multi-disciplinary, multi-institution collaborative efforts that bring together researchers, clinicians and industry partners, as well as patients and their advocates. Their goal is to drive patient-focused, high impact research across multiple sites, disciplines, and sectors. They are built on the underlying principles of research excellence, patient focus, integration, standardization and translational drive.

OBI will continue to fund and manage six pan-Ontario multidisciplinary research programs in the areas of cerebral palsy, epilepsy, depression, neurodegenerative disorders, neurodevelopmental disorders and concussion.

Through the performance management framework, OBI will ensure that the activities of the ID Programs are aligned with OBI’s Vision by the ongoing monitoring and evaluation of the programs against the milestones set for each program. OBI will be supported in these efforts through the scientific, industry, patient and community advisors that are critical to our approach. These advisors provide advice and actionable milestones, referred to as program benchmarks, to ensure scientific excellence, economic impact, and patient impact. The ID Programs enable us to build on Ontario’s key neuroscience assets and address areas of brain disorders that have a very large personal, societal, and economic burden.

OBI will ensure that the programs continue to adhere to the ID Program research principles:

1. A focus on internationally ranked, leading edge science;
2. A focus on the patient;
3. Integration (across sectors, sites and disciplines);
4. Standardization; and
5. A translational thrust.
OBI’s research is focused on gaining a deeper understanding of brain disorders and will yield new insights into the underlying mechanisms of disease. OBI is committed to the idea of using this research to drive improvements in health. Therefore, we work to ensure that as research advances our knowledge of brain disorders, the public benefits through better diagnosis and screening, new treatments, and updated policies. This includes increased translation of research into new treatments and tools, enhanced patient-care through evidence-based practice, faster movement of research finding to patients, and increased public access to information about brain research, brain disorders, tools, and treatments.

OBI has built one of the most comprehensive and secure brain research databases in the world: Brain-CODE. OBI’s 40 contracts with universities and research hospitals across Ontario provide agreement for data to be stored in Brain-CODE. This level of data harmonization and sharing is unprecedented among institutions nationally and internationally. As the number of participants and the richness of data continues to grow within Brain-CODE, the potential to leverage these data (i.e., through federations with other national and international databases) grows exponentially.

The pristine and well curated datasets in Brain-CODE are of considerable value and create both improved healthcare and economic development opportunities. Its primary purpose will still be to support our researchers – but it will be engaged with national and international opportunities to provide a consistent and secure approach to data collection including management, storage, and analysis. Privacy and security will remain at the forefront of the initiative and the sharing of data will be based within the context of international standards.

National and international data sharing opportunities will be pursued. The continued development, improvement and support of Brain-CODE will be a key priority of OBI in the coming year. Much of the new development will take place through funds that will be generated through the participation in national and international activities where grant or contract funding will be possible. Examples of this include:

- Brain-CODE will be a key element of the broader Canadian Open Neuroscience Platform (CONP), an infrastructure that is in part being funded by a Brain Canada grant.
- OBI has been approached to include Brain-CODE in applications to the Federal Government’s Strategic Innovation Fund program to help manage, curate, store and share data in an appropriate fashion.
- OBI will continue to participate in the Digital Technology Supercluster to build partnerships and opportunities with the cluster and individual companies for project funding to support informatics development needs.
- OBI will be following up on its very successful event – in partnership with Nature Neuroscience and CAMH – on data sharing to improve dementia research which may lead to Brain-CODE either being linked to other informatics platforms or forming a core piece of an integrated solution.

**Action Item #1 – Integrate Research into a Community Care Setting**

Building a learning healthcare system involves integrating research in the primary care setting. This is where most people with brain disorders receive their care.

*A learning healthcare system is defined by the Institute of Medicine as a process where “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience”¹*

OBI is working with each of its ID Programs to create partnerships with frontline service organizations, including primary care e.g. MINT Memory Clinics, Project ECHO; ECT-Ketamine study; ONDRI@Home; and First Nation communities; where discovery from the clinical research program is immediately applied into the local care setting.

In 2019 OBI started the ONDRI@Home initiative. ONDRI@Home is assessing sleep, mobility, and cognitive health in daily life through wearable technologies as a means to monitor individuals with neurodegenerative diseases. Assessing people living with illness in their homes will help to reduce the burden associated with visits to the clinic and knowing how they live and manage day-to-day will provide clinicians with new tools to augment diagnostics and shape current care and treatment practices. A pilot project, assessing patients in the community setting, has been completed. The results of this pilot were then used to develop a second-phase feasibility patient-cohort study, including participants from the ONDRI cohort. This feasibility study is well underway at

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the Sunnybrook Hospital and expected to complete patient recruitment in 2020. Data analysis and scale up in other locations to follow.

CONNECT launched a pilot feasibility study at the St. Michaels hospital. This pilot aims at studying head injuries in a novel way in order to enhance care. Participants presenting at the hospital’s emergency department are being assessed as early as 24 hours post-injury (a unique feature compared to other head injury studies) and followed for up to 12 weeks. Data collected include the following platforms: imaging, blood biomarkers, motion and gait, eye movements, neuropsych assessments, and patient reported outcomes. The purpose of this study is to collect information from the same adults over a 12-week period, and in a harmonized multi-scale system approach. This knowledge can help clinicians deliver the right treatment to the right patient at the right time. The study data collection is projected to complete in 2020 and cross-platform data analysis completed by 2021. Lessons learned from this pilot study, including feedback from participants, will be compiled into a white paper to inform future directions.

CAN-BIND has completed data collection for the Wellness study - a collaboration with Janssen R&D- and is coordinating data management. This study involves real-time data capture with mobile devices to help predict markers of relapse. CAN-BIND and Janssen R&D investigators have jointly completed quality assurance and quality control processes on data and are planning for joint analysis. CAN-BIND plans to use their findings to inform the use of mobile device markers for predicting relapse following depression treatment with other therapies.

CAN-BIND has initiated the ECT (electroconvulsive therapy)/Ketamine study and patient recruitment will continue through 2020-21. This study is co-funded by the hospitals and is an example of a learning health care system in that research results from the lab are directly being used to influence care in the hospital setting. ECT is the current gold standard therapy in the treatment of major depressive disorders and ketamine has emerged as a new and potential better treatment. CAN-BIND study will help inform treatment options.

OBI has launched GEEK (Growing Expertise in Evaluation and Knowledge Translation) a new program that supports the scale and spread of community-based initiatives that provide care and support for those living with a brain disorder (e.g., memory clinics, family and patient education, etc.). GEEK support includes a robust evaluation plan so that community-based organizations can collect the data necessary to improve their
services and supports and inform applications for longer-term more sustainable forms of support from other sources. The first cohort saw programs funded in the areas of community inclusion for adults with developmental disabilities, complex care for individuals with brain injury, and employment skills program for youth with disabilities. A second call for applications was sent out with the expectation of starting the second cohort in April 2020. OBI has reviewed 16 letters of intent for the GEEK program and matched six community organizations with evaluators to help develop an evaluation proposal as part of their full application.

**Action Item #2 – Engage and Educate the Public**

OBI is also moving research from the lab into the community by continuing to:

- support research programs in developing knowledge translation initiatives.
- host public talks that address stigma, empower people with lived experience, and educate the public.
- create awareness campaigns as part of Brain Awareness Week and other opportunities addressing facts and myths about people living with brain disorders.
- provide information on OBI supported research on the website and invite applications for OBI’s Event Funding program to support neuroscience-related events and activities.

Through this approach, OBI activities will be expanded beyond the bench to the bedside and increase the level of public education and outreach in our research programs and the broader neuroscience community.

OBI is building capacity to increase the knowledge translation efforts of the ID Programs by convening knowledge translation and communications and supporting their efforts. OBI is working with the Ontario Science Centre as the knowledge partner for their Mindworks exhibit to engage the public in activities related to brain health.

**Action Item #3 – Integrating Industry and Research**

OBI also integrates research with industry for economic impact. The commercialization activities of OBI’s neurotech cluster initiatives will continue to include, scientific and clinical validation, user feedback, the Internship, ONtrepreneurship and the NERD Programs to support the growth of neurotechnology companies across Ontario and the incorporation of these Ontario-based technologies into the Ontario healthcare system.
Several recent Phase 3 clinical trial failures resulted in many multi-national enterprises pulling out of the neuroscience space and spinning out venture-backed biotechnology firms to develop their neuroscience assets. Therefore, OBI will continue to engage multi-national enterprises and will expand our scope to include mid-size biotechnology companies to help secure further partnerships for our ID Programs. Examples of partnerships may include target validation, data analysis, clinical trials, reuse of clinical trial samples.

**Action Item #4 – Health Technology Adoption in the Care Setting (revised title)**

Innovations arising from the ID Programs have the potential for economic impact through cost-savings to the healthcare system. OBI will catalogue the ID Program technologies to determine market readiness and suitability for the Ontario healthcare system. For technologies that are poised for healthcare impact, OBI will work with our network of clinicians, companies, patient groups and policymakers to provide a comprehensive case for adoption to the Ministry of Health and Long-Term Care.

**Action Item #5 - Brain-CODE – Building the Capacity for Analytics Based in Artificial Intelligence and Machine Learning**

Data science, machine learning and artificial intelligence are areas of increasing importance to research, healthcare and economic development. Consistent with the OBI Wide External Panel recommendations, OBI is proposing to expand its data sciences focus by building on its existing informatics and analytics platform Brain-CODE to:

- provide world class informatics tools based in artificial intelligence and machine learning to support the ID Programs.
- provide data, analytical workspaces, and tools to engage the broader neurosciences community – nationally and internationally in the analysis of data.
- engage industry to stimulate the development of new intellectual property, tools and treatments.
- strengthen its relationship with the Vector Institute and the Toronto Machine Learning Series to stimulate the development of new analytical tools and algorithms to be included in Brain-CODE and support the creation of new companies and new products for existing companies to add to the marketplace.
OBI is an Associate member of the Digital Technology Supercluster consortium of industry participants, academia and not for profits on a national basis who have been awarded funding under the federal supercluster initiative. OBI will continue to be a key component of the Precision Health Pillar in this supercluster. OBI has already been involved in an application in collaboration with the Autism Sharing Initiative. The application’s aim was to connect national and international autism databases while adhering to standards from the Global Alliance for Genomics and Health (GA4GH). GA4GH is a policy-framing and technical standards-setting organization, seeking to enable responsible genomic data sharing within a human rights framework.

Action Item #6 – Linking Brain-CODE Data with ICES Data

Brain-CODE is a critical link between research, healthcare and economic development. The pristine and well curated datasets in Brain-CODE are of considerable value and create both improved healthcare opportunities and economic development opportunities. Critical to this is the linking of the deep data that comes from OBI’s ID Programs with the broad health administrative data that is contained at ICES and within electronic medical Records.

OBI and ICES have successfully linked datasets in order to create an algorithm that will enable OBI/ICES to determine the health administrative costs of children with autism spectrum disorder. Two other successful linkages have also been completed in the areas of (i.) a ketogenic diet study for patients with epilepsy and (ii.) screening for depression, obstructive sleep apnea and cognitive impairment to identify stroke clinic patients at risk of adverse outcomes.

From these pilot linkage studies, it has been determined that OBI and ICES are poised to implement a more regularized approach to data sharing to demonstrate the value of digital phenotyping and impacts of potential changes on the health care system. OBI and ICES are in the process of developing a routine linking protocol encompassing all participants on Brain-CODE to allow for more immediate linkages.

Action Item #7 – Participating in National and International Data Sharing Opportunities

The Brain-CODE platform is unique in its ability to facilitate both external collaborations to enhance Ontario’s research system and link with health administrative data for more effective health outcomes. All ID Programs have now provided Exclusivity Plans on how
they would like to see datasets from their respective studies released to external third-party researchers.

On a national level, Brain-CODE is building linkages with McGill’s Longitudinal Online Research and Imaging System (LORIS) to federate databases with the Canadian Consortium for Neurodegeneration and Aging (CCNA), creating similar data sharing opportunities and benefits.

Brain-CODE continues to be used by CAMH, which has established a centralized database powered by Brain-CODE for research being conducted at the institute. OBI and CAMH are exploring the possibility of co-developing data models and improving data integration functionality. OBI, Indoc Research, & CAMH have submitted a joint application to CANARIE to support such a co-development proposal.

In addition, Brain-CODE is a key element of the broader Canadian Open Neuroscience Platform (CONP), an infrastructure that is being funded in part by a Brain Canada grant. OBI co-hosted the annual CONP workshop in Toronto in April 2019 and are active members of the CONP Technical Steering Committee and CONP Data Governance and Ethics Committee. OBI will continue to provide support in the development of the CONP portal and related policies and guidelines.

In follow up to the “Redefining Neurodegeneration: A global collaboration to share deep phenotyping data” conference, co-hosted with CAMH, and Nature Neuroscience, the group held two additional meetings to discuss how we can move forward on a use case that will demonstrate feasibility and provide leverage for securing funding. OBI will use our unique expertise in big data governance to determine what can and cannot be shared across the databases that are involved in the use case.

**Focus Area: Grow a Globally Competitive Neurotechnology Cluster**

OBI is growing a globally competitive neurotechnology cluster by training highly qualified personnel and working with partners to create a seamless pipeline of support for Ontario companies.

OBI strives to catalyze the collaborative approach to supporting Ontario companies by working with entrepreneurs and companies across Ontario and in the broad
neuroscience community. OBI will continue to support entrepreneurs through the ONtrepreneurs program.

To address the need for increased capital in Ontario’s neurotechnology cluster and to support small and medium sized enterprises, OBI will continue the Neurotech Early Research & Development (NERD) funding program. This program funds product development or testing at Ontario-based Contract Research Organizations on behalf of selected companies that have an engaged follow-on investor, to address development gaps or the valley of death as it is sometimes referred to. OBI will be evolving the NERD program away from grant-based funding to a lending-based program, providing opportunities for OBI to benefit from the resulting company growth.

OBI will forge strong relationships with local, national and international partners to attract investments and to make Ontario a globally-recognized neurotechnology cluster. Through this approach OBI will work across all of Ontario and engage with the broader neuroscience’s community.

OBI continues to support the growth of the NeuroTech Ontario cluster ecosystem and foster collaborations between industry, institutions, and other innovation-based organizations. Activities and events are organized to engage the cluster’s players as well as attract experts and resources from outside the ecosystem. To track the resources in the neurotech cluster, OBI has continued to update and make improvements to AXON (Atlas for Ontario Neuroscience) – an application that provides information on the broader neuroscience community in Ontario.

The goal moving forward is to have several strategic partnerships with both large multinational enterprises and mid-size biotechnology companies to establish OBI as a preferred product development partner. These relationships may lead to a variety of collaborations including the validation of NeuroTech-based clinical trial outcome measures and the creation of joint ventures with Ontario companies.

Developing management skills in neuroscience graduates is necessary to support growth in the regional neurotech cluster, its existing and new companies, and to improve the quality and competitiveness of human capital. OBI is growing Ontario’s neuroscience management talent through the entrepreneurship and internship programs. These programs support Ontario Government objectives related to training, innovation and healthcare improvement through technology development.
OBI will continue to support internships at OBI or at industry and institutional partner organizations across the province through the innovation-based internship program. The combination of OBI funding and matching funds from the partner organizations makes for particularly attractive internships and helps facilitate “off the bench” experiential training for recent graduates. In addition to the valuable training opportunity, the internship program provides start-ups with valuable human capital to help grow the company. Many of the interns find full-time employment with their placement organization, which is helping to build management capacity within the NeuroTech cluster.

**Action Item #8 – Improving Access to Capital**

As indicated, OBI strives to catalyze the collaborative approach to supporting Ontario companies by working with entrepreneurs and companies across Ontario and in the broad neuroscience community. OBI will continue to support neurotechnology cluster development through its internship, entrepreneurship and NERD programs and will use the partnership with Praxis Spinal Cord Institute to expand its capacity.

To address the need for increased growth capital in Ontario’s neurotechnology cluster and to support small and medium sized enterprises, OBI will scale up the NERD funding program and work with the investment community to address development gaps or the valley of death as it is sometimes referred to.

Lastly, OBI will forge strong relationships with local, national and international partners to attract investments and to make Ontario a globally-recognized neurotechnology cluster.

**Action Item #9 – Working across the broader Ontario Neurotech Cluster**

OBI plans to expand its lead role in developing central nervous system products in terms of increasing the funding level and developing formal relationships with co-funding and follow-on funding partners across Canada and globally. OBI will engage in fund raising initiatives to increase the funds available to work with the neurotech community across Ontario. Through this approach OBI will work across all of Ontario and engage with the broader neurosciences community.
More specifically, OBI will:

- increase interactions with Ontario companies and ID Programs.
- increase interactions across Canada to find the best partners to support Ontario based neurotechnologies.
- increase integration with company support programs across Ontario.
- forge a path for Ontario-based technologies to have an impact in the Ontario healthcare system.
- categorize and consider expansion of focus of the portfolio companies.
- manage the use of Brain-CODE to validate/help develop data companies.
- review the need to create an entity that will consolidate IP/technologies across Ontario for follow-on investment/partnership.
- Partner with local/international organizations to promote Ontario’s neurotech cluster and increase exposure of OBI’s portfolio companies.
- provide internship support for Ontario NeuroTech companies and industry-related entities.
- increase cluster promotion.
- support for scale-up activities through cluster partners.

The goal moving forward is to have several strategic partnerships with larger multinational enterprises (MNE) and/or mid-size biotechnology firms to establish OBI as a preferred product development partner. These relationships may lead to a variety of collaborations including clinical trials and the co-founding of Ontario companies. More specifically, OBI’s activities in the commercialization space will catalyze:

- the joint development of pre-clinical assets;
- phase 2 clinical trials;
- combined implementation of policy initiatives;
- phase 4 studies with patient advocacy groups;
- key opinion leader role(s) for OBI researchers; and
- collaborative primary care initiatives.

Action Item #10 – Data Analytic Capacity Building

With the evolution of OBI’s commercialization programs and of Brain-CODE, OBI must be poised to help develop the growing number of Ontario data companies through validating their software platforms and algorithms. In addition to supporting our research community, as mentioned earlier, this will help to further build the artificial and machine learning capacity in Ontario and keep Ontario at the leading edge of this field. OBI will strengthen its relationship with the Vector Institute and the Toronto
Machine Learning Series to stimulate the development of new analytical tools and algorithms to be included in Brain-CODE and support the creation of new companies and new products for existing companies to add to the marketplace. OBI will also lever its involvement in the Digital Technology Supercluster to help develop and grow companies in the AI and Machine Learning market space.

**Focus Area: Improve Brain Health**

OBI is focused on getting research findings to patients faster, improving public access to reliable information about brain research, brain disorders, tools and treatments, and building stronger connectivity with research, industry, and patients.

OBI will continue to involve the broader research, clinical, industry and community advisors in the process of getting the messages out about results of the research and commercialization, the potential successes and celebrate the opportunities for improvements in healthcare.

OBI is engaging patients and public in neuroscience and their health care by fostering knowledge translation and exchange and facilitating linkages between researchers and decision-makers for the uptake and use of evidence through the Patient and Community Advisory Committees, partnerships with other organizations and publicly accessible events like our public talks.

OBI involves patients, care partners/givers and advocates in research by integrating the patient voice in research through the Patient and Community Advisory Committees for each ID Program, which meet quarterly. OBI will continue to host an annual Patient and Community Advisory Committee workshop.

OBI is evaluating the impact of investments by refining and implementing the evaluation plan it developed in conjunction with the newly constituted Outreach Advisory Committee, involving global leaders in evaluation, knowledge translation, and public engagement.

**Action Item #11 – Engaging those with Lived Experiences and the Public**

OBI engages patients and public in neuroscience and their health care by fostering knowledge translation and exchange and facilitating linkages between researchers and
decision-makers for the uptake and use of evidence through the Patient and Community Advisory Committees, partnerships with other organizations and publicly accessible events like our public talks.

OBI will involve patients, care partners/givers and advocates in research by continuing to integrate the patient voice in research through the Patient and Community Advisory Committees for each ID Program, which meet quarterly. OBI will continue to host an annual Patient and Community Advisory Committee workshop. OBI has helped to build lasting relationships between its research programs, and patient advocacy groups. Due to the stable and long-term funding of these research programs, meaningful partnerships between researchers and neurological charities have been created and expanded. In total, OBI has created partnerships between the five ID Programs and the 21 patient advocacy groups shown below.

Through strategic outreach activities (past examples include Primary Care Collaborative Memory Clinics and Minds in Motion), OBI will translate research into improved efficiencies in health care service delivery and facilitate linkages between researchers and decision-makers for the uptake and use of evidence.
Action Item #12 – Link to government priorities

OBI engages government and policy makers to ensure that research informs policy and policy informs research by imbedding OBI staff and researchers within the Ontario government projects such as the development of a capacity planning model for dementia care. Through this mechanism OBI ensures that the research results are directly aligned with government strategies for improved care. As part of this, OBI will continue to work with the Chiefs of Ontario to scale a youth suicide prevention program to First Nation Communities, helping to support a province-wide mental wellness initiative for Indigenous youth. To date, 36 communities were reached and over 100 youth have been trained. Six additional workshops are planned for the rest of this year. OBI will work with health innovation policymakers to enable the adoption of new technologies in the healthcare setting. For example, OBI works with Health Quality Ontario on their brain-related health technology assessments by providing feedback on the utility of certain technologies and/or helping to recruit key opinion leaders that will assist HQO in generating their recommendations.

OBI served on the provincial dementia strategy advisory council and the dementia capacity planning working group. We will continue to work closely with government to ensure that Ontario experts are being brought forward to help advise on important provincial programs related to brain disorders.

OBI has two programs that are actively engaged in Ontario Project ECHO Programs, our epilepsy program (EpLink) and our neurodevelopmental disorders program (POND, focused on autism). Both the epilepsy ECHO and the autism ECHO are fully established and actively training front-line practitioners based on best practice and latest evidence.

Action Item #13 – Evaluating Effectiveness

In order to build a culture of evaluation within community organizations, OBI will embed evaluation as a required component of all support for community-based organizations. As an example, each program has developed a logic model to map their theory of change and impacts. We also hosted a workshop for GEEK participants and other community-led partner organizations to help them identify how to most effectively use their evaluation outputs to secure funding and plan for sustainability. Similarly, OBI has embedded a culture of evaluation within its ID Programs by creating logic models and will be working with them to identify their metrics for measuring success.
Action Item #14 - Impact of Brain Disorders

OBI also intends to update the report “Brain Disorders in Ontario: Prevalence, Incidence and Costs from Health Administrative Data” produced in partnership with the Institute of Clinical Evaluative Sciences. As a first step we are working to develop codes that will identify brain disorders that are currently unidentifiable through administrative data, such as autism. The first version of the report is being used by several patient advocacy groups and health planning units as a resource, including Epilepsy Ontario, Parkinson Canada, and Ontario community epilepsy agencies. This report is one of the most frequently cited Applied Health Research Question reports produced by Institute of Clinical Evaluative Sciences.

Focus Area: ID Programs – Areas of Impact

The ID Programs are built on the underlying principles of research excellence, patient focus, collaboration, integration, standardization and translational drive. The integrated discovery approach is the key component of our innovation system. A system that is designed to create knowledge and move that knowledge faster into improvement in healthcare and economic opportunities. The system is based on the fundamental principle of people being at the centre of the system and their engagement in the process is key to success.

OBI will ensure that the ID Programs adhere to the following research principles:

a) A focus on internationally ranked, leading edge science;
b) A focus on the patient;
c) Integration (across sectors, sites and disciplines);
d) Standardization; and
e) A translational thrust.

OBI has created a vibrant and collaborative ecosystem that links researchers, clinicians, companies, and the patient community not only within Ontario, but also with other networks across Canada and around the world. Through this invaluable network, OBI and its partners are striving to ensure its work drives impact in neuroscience and establish Ontario as a world leader in brain research, commercialization, and care.
Action Item # 15 – Ensure the ID Programs Operate Consistent with the OBI Vision

OBI continues to work with each of the ID Programs to ensure that they operate consistent with OBI’s strategic priority to create a learning healthcare system and funding and activities in alignment with the OBI model as recommended by the External Review.

Each of the ID Programs has developed a logic model that highlights the short-term outputs and long-term goals of the program. This logic model and the implementation of the performance management framework will enable us to keep the Programs focused towards prioritized activities (e.g. those with healthcare impacts). We will also continue to hold quarterly Strategic Planning meetings with each program to allow for joint planning and to monitor milestone progress. In cases where there is a failure to meet milestones or to adhere to the OBI model, these meetings will provide an opportunity to provide warnings and adjust accordingly.

The ID Programs’ clinical framework will continue to drive OBI’s Innovation System. OBI funding will continue to reflect this and will not duplicate or replace what other funding agencies provide. OBI’s support of basic science will be limited to reverse translational research that is closely tied to the clinical component and thus contributes to development and validation of models and/or biomarkers.

Action Item #16 – Implementation of a Performance Management Framework for ID Programs

OBI has developed and implemented a performance management framework (IDP Snapshot) that is based on its logic model. We are now working with each ID Program to utilize their logic models to inform budgets, timelines, milestones, and deliverables. This updated performance management framework will create clear linkages to the Programs and the health and economic impacts that they will achieve.

Action Item #17 – Funding Opportunities for Concussion

In the upcoming fiscal year, OBI will continue to support Concussion Ontario Network: Neuroinformatics to Enhance Clinical care and Translation (CONNECT) with seed funding to allow for completion and analysis of the pilot feasibility clinical study that has launched at St. Michael’s hospital. Funding will also support a management structure
within the program to allow for further harmonization of CONNECT with other national and international studies and continue to build a strong research network by using the same common data elements.

The program will also continue to map capacity across Ontario institutions to allow it to launch in other sites should funding be available. In the coming years OBI will also examine the opportunities to gain new resources to support CONNECT and expand its ability to compare and contrast mechanisms linked to brain ‘injury’ to brain ‘disease’ and allow the exploration of well-established but poorly understood links between concussion, post-concussive syndrome, depression and anxiety.

Focus Area: Building Capacity for Revenue Diversification and Program Growth

The need to generate additional revenue above the level of funding provided by the Province of Ontario has been demonstrated as necessary to increase our capacity for research, economic growth and improvements in brain health. Government has provided a significant investment in OBI and that investment should be levered to generate increased investments from philanthropy, national and international foundations and others to increase the knowledge base in brain diseases and disorders. Wherever possible OBI will work with its partners – researchers, programs, foundations and their institutions – to generate and collaborate on fund raising activities.

The 2020/21 Revenue plan includes a total target of $1m for Other revenue generation. The plan is based on: $150k in revenue being generated through fee for services and grant revenues; and $850k in fund raising initiatives. The fund-raising activities will be focused on individual philanthropy giving and international foundations. The revenue plan does not reflect any revenue from federal innovation programs. OBI will continue to seek funding from the Digital Technology Supercluster and the Strategic Innovation Fund of the federal government as mentioned earlier but given the past uncertainties around these funds will only reflect these funds in the plan as the funding and associated expenditures are approved.

Action Item #18 – Fund Raising

OBI established a specific fund-raising target of $7M over a 3-year time period beginning in 2019/20 to increase capacity to support research initiatives, increase growth
opportunities for small and medium sized companies and expand its programs and services to the broader Ontario neuroscience community. OBI will be evaluating different approaches to accomplish this and then determine how it will go forward with fund raising initiatives as a mechanism to build out its capacities.

**Action Item – Leveraging**

OBI’s 2020-2021 leveraging plans include:

1. Through the Performance Management Framework, the research programs will focus on maximizing grant impact, especially those that are federally funded, to ensure that we are recognizing and accounting for all potential research-driven leveraged funds. An additional $25 to 30m in leveraged funds is anticipated from our research programs.

2. Funding application to the federal innovation programs with a target of $1 to 2m in funding.

3. OBI’s commercialization activities including the Neuroscience Early Research and Development Program and the Entrepreneurship Program are expected to raise up to $3 to 5m in follow-on funding.

4. Knowledge Translation activities are anticipated to raise up to $1M through its GEEK Program, Event Funding Program, and partnerships with neurological charities.

5. Other partnership activities are anticipated to generate $3 to 5m in leveraged funds.
Appendix 1 - 2020-2021 Milestones by Priority

1) **Build a learning healthcare system by integrating research and care, and fueling it with next generation informatics and analytics**
   a) Ongoing management of six current ID Programs, ensure alignment with OBI Vision and adherence to the OBI model
      i) Ongoing implementation of each ID Program standardized clinical framework
      ii) Conduct annual analysis of cross-ID Program Brain-CODE common data elements to look at disease comorbidities
      iii) Conduct an annual bibliometric analysis on ID Program publications
      iv) Conduct annual cross-IDP workshops to build capacity and create opportunities for cross-program collaborations
      v) Ongoing management of advisory capacities to support patient, industry and scientific input into the programs
   b) Active testing of biomarkers in the community care setting
      i) Continue ONDRI@Home
      ii) Continue biomarker testing for depression
      iii) Initiate new biomarker trial in other ID Programs
   c) Advanced analytics for disease modeling and diagnostics
      i) Ongoing development of new IP, analytic tools, and treatments through participation in federal innovation funding programs
      ii) Ongoing engagement between ID Programs, AI experts and analytical tools to increase Brain-CODE’s analytical capacity
   d) Quality improvement processes for healthcare
      i) Initiate EpLink studies on the Ontario Epilepsy ECHO program to better understand health outcomes
      ii) Establish partnerships between each ID Program and primary care providers
   e) New treatments
      i) Catalyze clinical trials and clinical validation studies through ID programs
   f) National and international data sharing and linkages
      i) Complete 2nd phase of work related to the Canadian Open Neuroscience Platform as a mechanism to engage with the broader neurosciences community – nationally and internationally
      ii) Ongoing Brain-CODE data releases for 3rd party usage
      iii) Ongoing data federation across the ID Programs
   g) If appropriate, initiate policy processes related to the provincial adoption of ONDRISeq as genetic screen for dementia risk assessment
   h) Full implementation of recommendations from OBI Wide External review to ensure a world class informatics platform to support the ID Programs
2) Growing a Globally Competitive Neurotechnology Cluster
   a) Scale-up of small companies
      i) Continue with scaled up NERD program
   b) Attract and develop new management talent and increase employment in the neurotech cluster
      i) Continue OBI ONtrepreneurs program
      ii) Continue OBI’s internship program
   c) Procure home grown products into healthcare system
      i) Work with innovation partners on new technologies and companies coming through our programs
   d) Work across the broader neurotech cluster to:
      i) increase interactions with Ontario companies and ID Programs
      ii) increase integration with company support programs across Ontario
      iii) categorize and triage portfolio companies
      iv) increase cluster promotion
   e) Hold annual meeting on the potential for consolidation of similar IP/technology across research institutions participating in the ID Programs

3) Engaging and empowering the public and patient community to improve brain health
   a) Data-driven decision making / policies
      i) Create forum to host policy discussions on brain health, link to government priorities
      ii) Ongoing work to develop codes for capturing autism and depression in administrative data
   b) Patient research priorities addressed in research
      i) Initiate third patient priority setting partnership
   c) Community-based implementation pilots
      i) Continue implementation of GEEK Program
      ii) Continue to scale suicide risk reduction program with Ontario First Nations in partnership with CANBIND and Chiefs of Ontario
   d) Cost-effective healthcare outcomes and interventions
      i) Develop and disseminate tools to promote brain health
   e) Health system planning using research and administrative data
      i) Continue to explore opportunities for linking of research and health administrative data
   f) Self-management of health
      i) Continue OBI Public Talks series to educate and inform public
4) **Operational**
   a) **External Review**
      i) Complete and submit report on External Review of first half of operations
   b) **OBI Advisory Council**
      i) Ongoing management of advisory capacities to support patient, industry and scientific input into the programs
Appendix 2 – 2020-2021 Metrics

Build a learning healthcare system by integrating research and care, and fueling it with next generation informatics and analytics

- Embedding research into front-line care
  - Number of partnerships between our ID Programs and front-line care organizations
  - Number of research pilots embedded in the community care setting
  - Number of front-line care providers involved in ID Program research
  - Number of data federations with front line provider EMRs

- Increase the connectivity of the Ontario research community
  - Strength of connectivity across our network through the Atlas for Ontario Neuroscience (www.axon.braininstitute.ca)
  - Amount of national and international research grants and awards due to ID Program involvement
  - Percentage growth in Brain-CODE users and capacity
  - Impact narratives from members of the ID Programs

- Better integrate research, industry, and patients
  - Percentage growth in ID Program partnerships
  - Number of federations with other databases (including ICES)
  - Number of external data access requests
  - Number of studies where patients are involved in setting research priorities
  - Number of partnerships between research and patient community to translate and implement evidence
  - Impact narratives from OBI’s external advisors and key stakeholders

- Increase recognition of Ontario as a world leader in brain research, commercialization, and care
  - Number and quality of research publications
  - Number of invites to share OBI model provincially, nationally, and internationally
  - Number of Brain-CODE licensing agreements
  - Number of collaborations nationally and internationally
  - Percentage of OBI-funded studies that are multi-institutional, multi-disciplinary, and multi-modal
  - Impact narratives from leadership of partner organizations
Growing a Globally Competitive Neurotechnology Cluster

OBI will measure success of these initiatives through the following metrics:

- ONtrepreneurs and NERD – follow on investments
- # of strategic partnerships with MNEs / funders
- # of interns per year / % follow-on employment
- # of new companies engaged in discussions over the 5 years
- # new companies supported over the 5 years
- # new co-funders or cluster partners
- Creation of a well-defined roadmap connecting startups to resources
- Global recognition of the cluster demonstrated by the engagement of international companies and investors
- Increase investment in Ontario neurotech companies
  - Measure the growth in the value and size of the companies that we invest in
- Increase the number and sustainability of Ontario-based companies
  - Measure the number of companies that we support and nurture as it relates to their longevity
- Increase jobs in Ontario
  - Number of jobs created through our companies and their employee retention rates
  - Number of HQP trained

Improving Brain Health of Ontarians

- Enhance patient-care through evidence-based practice (practice)
  - Number of policies and tools using evidence from our research programs
  - Number consultations with our researchers in the development of toolkits
  - Renewal of Burden of Brain Disorders Report in partnership with ICES
- Move research findings to patients faster (knowledge)
  - Number of plain language summaries for our research programs
  - Number of patients and families engaged in our family days and science days
  - Number of partnerships between research and patient community to translate and implement evidence
- Increase translation of research into new treatments and tools (products)
  - Number of patents granted and development of intellectual property
- Number of clinical trials
- Number of market-ready interventions that will improve the quality of life of Ontarians and beyond
- Increase public access to information about brain research, brain disorders, tools, treatments
  - Number of people that we engage in our research programs both online and in person
### Appendix 3 2020-2021 Financial Information

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*Other Revenues have offsetting expenditures of as indicated above. These expenditures do not take place unless the revenue is raised in the first place.