

SHAPING THE FUTURE OF ARTHRITIS CARE

OBRI ANNUAL REPORT 2016



OBRI

ONTARIO
BEST PRACTICES
RESEARCH INITIATIVE



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MESSAGE FROM OUR PRINCIPAL INVESTIGATOR



The Ontario Best Practices Research Initiative (OBRI) was formed in 2005 through collaborative efforts between rheumatologists, payers, researchers and patients to monitor the safety and effectiveness of treatments for people living with Rheumatoid Arthritis (RA). Today, our clinical cohort includes more than 3,000 RA patients and 69 rheumatologists from across Ontario.

OBRI's unique platform integrates clinical data from rheumatologists, patient-reported data from participants, and administrative data from the Institute for Clinical Evaluative Sciences (ICES) to monitor drug safety and efficacy, and patient quality of care. Our research priorities include the examination of **pharmacotherapy** (safety and efficacy), **clinical outcomes and practice patterns** (clinical measures, quality indicators, practice guidelines), and **population health** (epidemiology, models of care, economics).

2016 has been a busy year – we launched a new EMR data extraction pilot study, presented research at numerous international and national scientific meetings, hosted two patient information sessions, completed the second year of our SpA pilot initiative, and formed new research collaborations. We also hosted our 3rd Annual OBRI Research Day for rheumatologists, researchers, and stakeholders, and worked closely with our Patient Advisory Committee and Clinical Advisory Committee to engage patients, exchange expertise, and advance our research initiatives.

This report provides an overview of our activities in 2016. For up to date information, news, and details on current presentations and publications, please visit our website: www.obri.ca. We look forward to another productive year in 2017!

A handwritten signature in black ink, appearing to read 'C Bombardier'.

Dr. Claire Bombardier, OBRI Principal Investigator



ABOUT OBRI

Who We Are

The Ontario Best Practices Research Initiative (OBRI) is a clinical cohort linked to administrative data where patients are followed in routine care along their clinical path. It is a collaborative research platform involving rheumatologists, researchers, and patients who are working together to improve the treatment outcomes of Ontarians living with RA. Originally created as the Ontario Biologics Research Initiative, the OBRI was officially renamed in 2013 to reflect the expansion of the organization's research goals beyond the scope of biologic treatments.

Our Mission

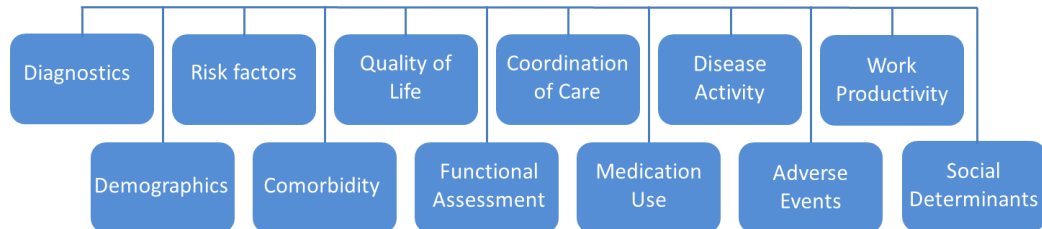
To improve the care and health outcomes for Rheumatoid Arthritis (RA) patients by gathering long-term information on therapies, clinical practice patterns, and health care utilization in the real world. Our goals are to:

1. Define safety, effectiveness, and sustainability of available RA therapies
2. Identify clinical practice patterns that improve patient health outcomes
3. Use clinical and economic data to inform efficient health care decisions

What We Do

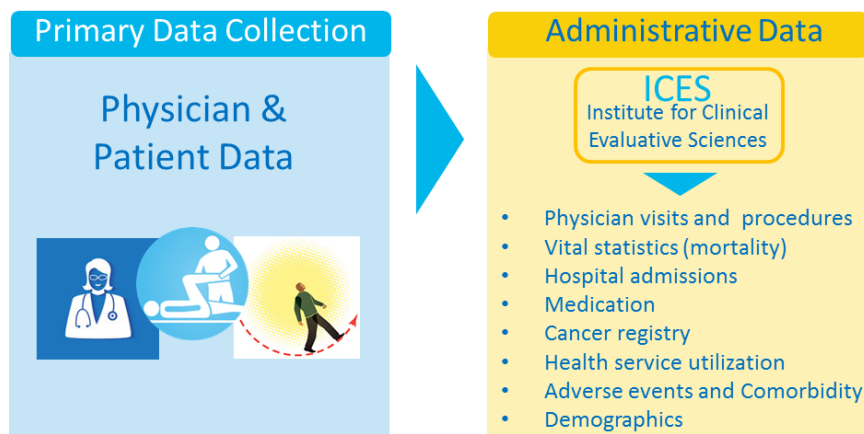
The OBRI generates outcome data specifically related to pharmacotherapy, health system efficiencies, clinical outcomes, and practice patterns. OBRI is dedicated to working with clinicians, patients, government, industry, and the scientific community to gather and analyze high-quality data on the safety and effectiveness of RA treatments for the improvement of patient health care outcomes. The OBRI team also provides leadership in best practices for ethics and consent, data management, real world data analysis, and administrative database validations.

What's in our Data?

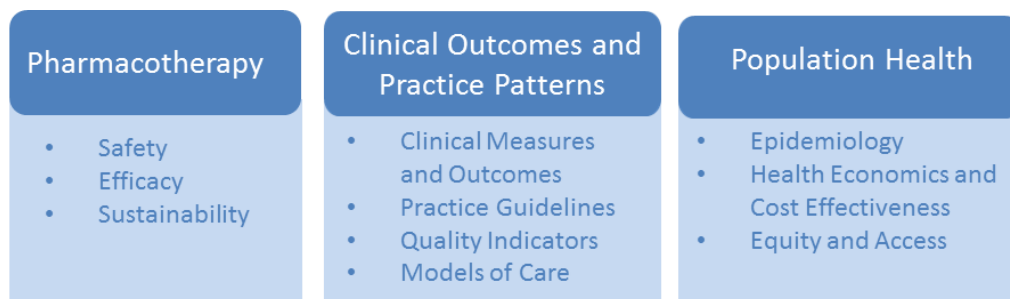


Our Data Linkages

The OBRI clinical data is linked to provincial administrative databases held by the Institute for Clinical Evaluative Sciences (ICES). The administrative databases include: physician visits and procedures, vital statistics, hospital admissions, medication, cancer registry, health service utilization, adverse events, comorbidities, and demographics.



Technology and evidence informed guidelines are being used to examine clinical outcomes, quality of care, and practice patterns leading to health system innovations through initiatives addressing models of care, epidemiology, and health economics.



2016 IN REVIEW

Our 2016 activities include:

- Launching an EMR data extraction pilot study
- Developing a data platform to monitor biosimilars
- Completing the second year of our SpA pilot initiative
- Developing new collaborations in Gastroenterology and Dermatology
- Hosting patient information sessions in Toronto and London
- Hosting our Annual OBRI Research Day for rheumatologists, researchers, and stakeholders
- Presenting research at numerous meetings including the Canadian Rheumatology Association (CRA), European League Against Rheumatism (EULAR), and American College of Rheumatology (ACR) meetings
- Working closely with our Patient Advisory Committee and Clinical Advisory Committee to exchange expertise and advance research

Recruitment Activity (as of Dec. 31st, 2016)

	RA Cohort N (%)	SpA Pilot N (%)
Patients referred to OBRI	3941 (100.0)	360 (100.0)
Patients refused	544 (13.8)	36 (10.0)
Patients with consent pending	17 (0.4)	17 (4.7)
Patients consented	3380 (85.8)	307 (85.3)
ICES linkage	3359 (99.4)	307 (100.0)
Interviewer data	3231 (95.6)	281 (91.5)
Physician data	3373 (99.8)	307 (100.0)
Withdrawals		
0-2 years	159 (4.9)	6 (2.0)
2-5 years	65 (2.1)	N/A
Patient lost to follow-up*	94 (2.8)	0 (0.0)
Patients deceased	119 (3.5)	1 (0.3)
Patients who have reached & completed:		
Baseline	3375 (99.9)	281 (91.5)
1 year follow-up	2760 (85.4)	105 (37.4)
2 year follow-up	2343 (72.5)	N/A
3 year follow-up	1968 (60.9)	N/A
4 year follow-up	1621 (50.2)	N/A
5 year follow-up	1087 (33.6)	N/A

*Interviewer not able to contact patient for ≥ 18 months AND no physician reported data has been received for ≥ 18 months

Ongoing Initiatives

1) EMR Pilot is Launched

Rheumatologists in Ontario continue to adopt and integrate electronic medical records (EMRs) into their daily practice. While most community-based rheumatologists have made the switch to EMRs, rheumatologists in academic centers are now making the switch too. Thanks to the work of the Ontario Rheumatology Association (ORA) many customizations have been made to EMR platforms for rheumatology-specific optimization and use.

With a growing number of paperless offices, the collection of clinical data and outcomes for research or practice improvement activities can only be feasible if they are made seamlessly without interrupting work flow and efficiency.

In February 2016, an OBRI data extraction pilot was launched. The main objective of the pilot was to create a rheumatology data platform that would serve to automate data extraction for OBRI related research as well as create a platform to support the development and delivery of a rheumatology-specific physician dashboard. Within the pilot, we will investigate the feasibility of extracting clinical data seamlessly from EMRs.

There has been a significant push towards big data and its utility. To optimize it, OBRI must be mindful of the need for capacity building and model development that supports data governance, data stewardship, and practice-level application for physicians. Our pilot will inform the provincial expansion to automate data extraction. We're excited about this new pilot project and look forward to sharing our outcomes with you!

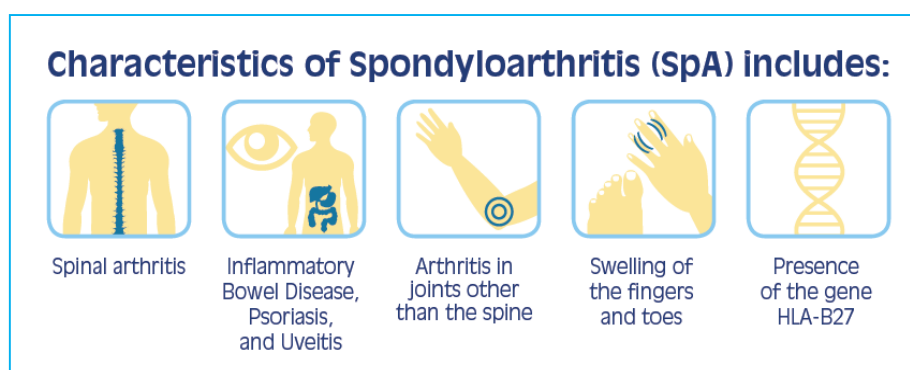
2) Research Pilot with JSS Medical Research

To support the work of our Clinical Advisory Committee (CAC), OBRI continues to partner with JSS Medical Research to advance investigator-led research questions. Researchers from OBRI, JSS, and the CAC have been working closely to advance research questions using OBRI data. We are pleased to report that over the past year three distinct research questions have been analyzed and fully developed into manuscripts. For a list of completed research questions, please visit: www.obri.ca. JSS will continue to support the work of the OBRI CAC in 2017.

3) Spondyloarthritis Pilot

Spondyloarthritis (SpA) affects 0.5-1% of the population and represents a major burden due its high prevalence, propensity to affect young adults, and need for lifelong treatment. Despite this, data on drug effectiveness and safety, disease activity and severity, functional ability, and economic impacts for patients with SpA is limited.

In order to determine the real-world disease impact, spectrum, and management of SpA, OBRI launched a 2-year pilot project to develop a clinical cohort of patients living with SpA.



Of those enrolled, 53.4% have Ankylosing Spondyloarthritis (AS), 39.3% have Psoriatic Arthritis (PsA), and 7.3% have other types of SpA. Our interim analysis has revealed that those with AS have a mean age of disease onset of 39 years, and are most likely to experience morning stiffness (72.7%), chronic back pain (66.6%), and HLA-B27 positive test results (58.3%). Those with PsA had a mean disease onset of 43.5 years, and were most likely to experience psoriasis (80.4%), peripheral arthritis (79.4%), and the presence of extra-articular features (76.2%). Disease activity scores were generally low, with a mean ASDAS (CRP) score of 2.1 and 2.2, and BASDAI of 3.5 and 4.1, for AS and PsA, respectively. 44% of PsA patients were in a state of minimal disease activity.

The SpA initiative is led by Dr. Vinod Chandran and 12 community-based rheumatologists in Ontario. Over 300 patients from 12 Ontario rheumatology clinics are enrolled in the cohort. Results from this pilot study will inform future community-based studies on the prevalence and impact of SpA in Ontario. We look forward to sharing more data from this initiative with you soon!

Upcoming Initiatives



Observational Research: Value of Real-World Data

The Phase 4 landscape of observational research is changing rapidly for many reasons. Science is progressing; the need for post-launch data is broadening; stakeholders and payers are asking more questions about how medications perform in the real world; and technology is transforming the way data is collected.

Today, what happens post-launch is what matters. Evidence needs to be constantly available and product differentiation has to be established early in the development process to secure market access and sustained reimbursement. The science of real-world data has emerged. Furthermore, the availability of an increasing number of medications for the treatment of rheumatoid arthritis (RA), although beneficial to patients and providers, has put tremendous financial strain on payers thereby increasing the need for comparative effectiveness studies.

OBRI is well poised to support the focus on real world outcomes. Payers, providers, and decision-makers are turning to OBRI to provide comparisons of treatments that previously could only be studied in single arm cohorts. Through OBRI, we can now compare real world effectiveness of different treatment groups with similar indications rather than relying on historical data for comparisons. The large number of patients in OBRI also allows for comparisons of “matched” controls or similar patients using different treatments.



Platform for Biosimilars

Biosimilars have become a hot topic in Canada, and it is clear there is a place for them in our health care system, as they offer a potential for significant cost savings in the treatment of chronic diseases – particularly in Rheumatology, Gastroenterology and Dermatology.

With many new products entering the market, there is a growing need to understand the long-term safety, effectiveness, and economic benefit of biosimilars. In fact, some suggest that biosimilars should have more monitoring requirements because they have been authorized based on a reduced nonclinical and clinical data package, as compared to those of respective reference biologic products. As such, their benefit-risk profiles may not be fully known until post market surveillance is well established.

Unlike Europe, Canada has no mandated post-marketing pharma co-vigilance program for

biologics or biosimilars. While there are regulatory requirements for new drugs that require the completion of post-marketing safety studies and reporting of results to Health Canada, often studies are completed by pharmaceutical companies and only take place for a limited timeframe. This leaves results vulnerable to bias, and makes long-term trends of safety/effectiveness impossible to detect. Additionally, patients in clinical practice often have comorbidities, which are not represented in short term drug safety trials. These patients need to be monitored, along with comparator groups, to quantify drug risks/benefits.

In 2014, a new legislation called Vanessa's Law was passed to strengthen the regulation of therapeutic products and improve the reporting of adverse reactions by healthcare institutions. Once enacted, changes will be made to improve Health Canada's ability to collect post-market information and take action when serious risks are identified. However, until this law is enacted, there are no long term mandated regulatory systems in place.

OBRI is committed to monitoring long-term real world safety and effectiveness of all biologics including biosimilars in Ontario. While OBRI is not a mandated or regulatory agency, it is well positioned to collect real world data for physicians, patients, researchers, and policy makers on the long-term safety/effectiveness of biologics and biosimilars.



Dermatology & Gastroenterology Collaboration

Long-term data on the safety/effectiveness of biologics and biosimilars is not only of interest to rheumatologists, but also to gastroenterologists and dermatologists.

Patients with chronic dermatologic and gastric diseases often need systemic treatments to effectively control their disease activity. The introduction of biologic agents has greatly increased over the last decade, providing patients with more options. Unfortunately, there is also a lack of real world data available to clinicians and even payers.

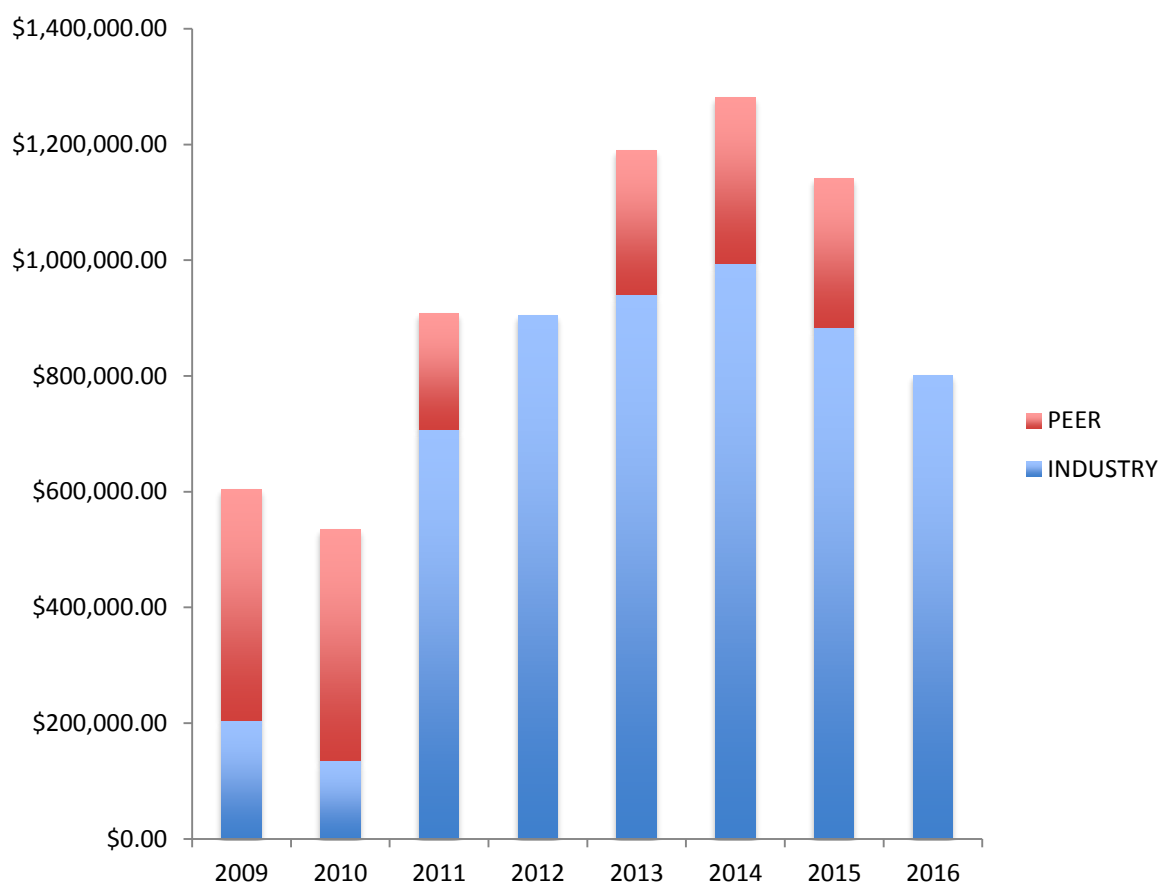
OBRI is taking on a new leadership role by collaborating with Ontario dermatologists and gastroenterologists. We are excited to leverage the data platform infrastructure we have created so it can be used to monitor the long term safety and effectiveness of biologic treatments in other chronic diseases.

Financial Report

At OBRI, our main source of revenue comes from sponsorship, however peer-reviewed funding has been awarded to OBRI for specific research activities.

In 2016, OBRI received sponsorship from 10 industry partners. Sources of funding revenue from 2009-2016 are presented below.

OBRI Funding Revenue



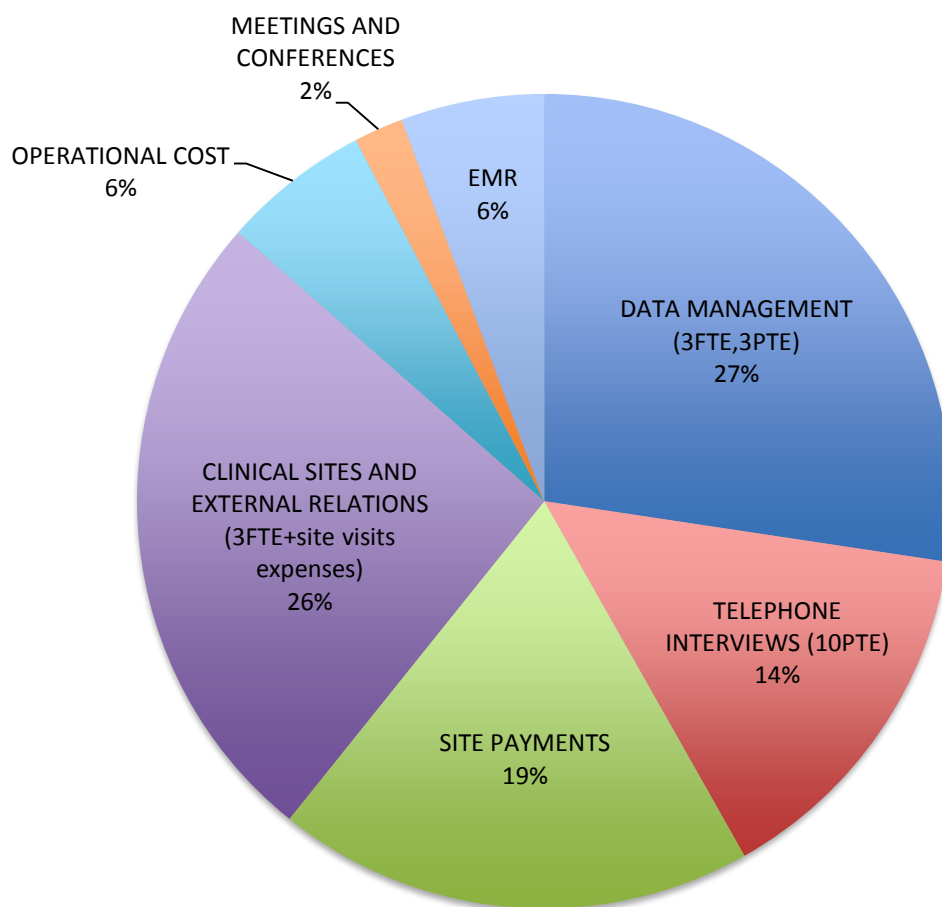
OBRI Expenditures

OBRI's expenditures for the 2015/2016 fiscal year totaled \$1,207,157.

Costs for data management were highest (27%), followed by support for clinical sites and external relations (26%), site payments (19%), telephone interviews (14%), operational costs (6%), electronic medical record (EMR) contract costs (6%) and costs for meetings and conferences (2%).

Expenditures

Fiscal Year: April 2015 – March 2016



Meetings & Conferences Attended

- American College of Rheumatology (ACR) Annual Scientific Meeting, Washington, DC. Nov 11-16, 2016
- Arthritis Alliance of Canada (AAC) Annual Meeting, Montreal, QC. Oct 27-28, 2016
- European League Against Rheumatism (EULAR) Annual Scientific Meeting, London, UK. Jun 8-11, 2016
- Ontario Rheumatology Association (ORA) Annual Meeting. Minnett, ON. May 27-29, 2016
- Childhood Arthritis & Rheumatology Research Alliance (CARRA) Conference. Toronto, ON. April 16, 2016
- Ontario Rheumatology Association (ORA) EMR Users Forum. Toronto, ON. March 4, 2016
- Canadian Rheumatology Association (CRA) Annual Scientific Meeting. Lake Louise, AB. Feb 17-20, 2016
- Arthritis Alliance of Canada (AAC) Meeting. Lake Louise, AB. Feb 17, 2016.
- Recap Meeting from 2nd EULAR Registers and Observational Drug Studies (RODS) Annual Meeting, Toronto. Feb 5, 2016

Awards Received

- Ontario Medal of Good Citizenship, awarded to Jennifer Boyle, OBRI Patient Advisory Committee Member, Dec. 2016
- American College of Rheumatology Distinguished Clinician Scholar Award, awarded to Dr. Claire Bombardier, OBRI Principal Investigator, Nov. 2016
- American College of Rheumatology Master Award, awarded to Dr. Carter Thorne, OBRI Investigator and Clinical Advisory Committee Member, Nov. 2016
- Best Podium Presentation at University of Toronto Ogryzlo Day, awarded to Mark Tatangelo, PhD Candidate, Jun. 2016

Patient Advisory Committee (PAC)

The OBRI Patient Advisory Committee (PAC) is a volunteer-led group comprised of patient representatives with rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis. The PAC works to improve patient wellbeing through the promotion of rights detailed in the *Canadian Arthritis Patients Charter*.

The OBRI PAC provides guidance to the OBRI research team through:

- The communication of patient perspectives to research staff, students, investigators, and other stakeholders
- Priority setting, project planning, and decision making
- Patient engagement, communication, and retention activities
- The dissemination of research/knowledge to patients and caregivers

Accomplishments in 2016 include:

- The production of an annual patient newsletter to keep patients informed about OBRI research, news, and events
- The co-facilitation of two 2016 OBRI Patient Information Sessions to communicate OBRI research activities
- The development of plain-language summaries to communicate OBRI research findings of patients
- The provision of ongoing support/direction to OBRI team related to project development, expansion, recruitment, and dissemination

Patient Advisory Committee:

- Catherine Hofstetter
- Jennifer Boyle
- Anne Lyddiatt
- Michael Mallinson
- Denis Morrice
- Attia Qamar
- Nancy Roper



Clinical Advisory Committee (CAC)

The Clinical Advisory Committee (CAC) was developed in 2015 to provide the OBRI with leadership for the development and investigation of clinically-relevant research questions. Members of the CAC work closely with OBRI staff and JSS Medical Research to explore new research questions relevant to rheumatology care.

Accomplishments in 2016 include:

- Three scientific poster presentations at the Canadian Rheumatology Association (CRA) Annual Scientific meeting in Lake Louise, AB
- Two scientific poster presentations at the American College of Rheumatology (ACR) Annual Scientific meeting in Washington, D.C.
- The development of 3 manuscripts for peer-reviewed publication

Clinical Advisory Committee:

- Dr. Vandana Ahluwalia
- Dr. Claire Bombardier
- Dr. Vinod Chandran
- Dr. Alfred Cividino
- Dr. Edward Keystone
- Dr. Janet Pope
- Dr. Carter Thorne



OBRI Investigators

Dr. Vandana Ahluwalia*	Dr. Brian Hanna	Dr. Shikha Mittoo
Dr. Zareen Ahmad	Dr. Nigil Haroon	Dr. Ami Mody
Dr. Pooneh Akhavan	Dr. Jackie Hochman	Dr. Angela Montgomery
Dr. Lori Albert	Dr. Anna Jaroszynska	Dr. Manisha Mulgund*
Dr. Catherine Alderdice	Dr. Sindhu Johnson	Dr. Edward Ng
Dr. Michael Aubrey	Dr. Raman Joshi	Dr. Tripti Papneja
Dr. Henry Averbs**	Dr. Allan Kagal	Dr. Viktoria Pavlova
Dr. Sibel Aydin <i>NEW 2016</i>	Dr. Arthur Karasik*	Dr. Louise Perlin
Dr. Sangeeta Bajaj	Dr. Jacob Karsh	Dr. Janet Pope
Dr. William Bensen*	Dr. Edward Keystone	Dr. Jane Purvis
Dr. Sankalp Bhavsar	Dr. Nader Khalidi	Dr. Gina Rohekar
Dr. Raja Bobba <i>NEW 2016</i>	Dr. Imtiaz Khan**	Dr. Sherri Rohekar
Dr. Claire Bombardier	Dr. Bindee Kuriya	Dr. Thanu Ruban
Dr. Arthur Bookman	Dr. Margaret Larché	Dr. Nooshin Samadi
Dr. Simon Carrette	Dr. Arthur Lau*	Dr. Saeed Shaikh
Dr. Antonio Cabral <i>NEW 2016</i>	Dr. Nicole Le Riche***	Dr. Ali Shickh
Dr. Raj Carmona	Dr. Felix Leung	Dr. Rachel Shupak
Dr. Andrew Chow*	Dr. Frances Leung	Dr. Doug Smith
Dr. Patricia Ciaschini*	Dr. Dharini Mahendira	Dr. Elaine Soucy
Dr. Alfred Cividino	Dr. Mark Matsos	Dr. Jonathan Stein
Dr. Dana Cohen	Dr. Heather McDonald-Blumer	Dr. Andy Thomspon
Dr. Sanjay Dixit*	Dr. Ines Midzic <i>NEW 2016</i>	Dr. Carter Thorne*
Dr. Derek Haaland*	Dr. Nataliya Milman <i>NEW 2016</i>	Dr. Sharon Wilkinson***

* RA & SpA

** SpA

*** Retired

Interviews: Collecting Patient Reported Outcome Measures

Part of what makes the OBRI unique is our ongoing collection of patient reported outcome measures through structured telephone interviews with patients. Patient reported data is collected on a regular basis to document patient experiences with disease activity, quality of life, comorbidity, socioeconomic status, functional ability, and work productivity. These interviews, combined with physician-reported data and administrative data, provide us with a holistic picture of the RA care landscape in Ontario.

We'd like to thank our dedicated team of interviewers for their ongoing role in ensuring patient data is collected in a standardized manner.

OBRI Interviewers

- Lisa Guerin
- Sarah Heinzle
- Joanne Kennedy
- Lynda Linderman
- Andrea McClintock
- Janet Money
- Colleen Perrin
- Linda Rosengarten
- Gail Walker
- Sharon Zwarych



OBRI TEAM



OBRI Staff

- Claire Bombardier, MD, OBRI Principal Investigator
- Sandra Couto, Director of Partnership and Stakeholder Relations
- Vinod Chandran, MD, Principal Investigator, SpA Initiative
- Angela Cesta, Clinical Research Coordinator
- Mohammad Movahedi, MD, PhD, Research Associate II
- Carol Mously, Study Site Coordinator
- Xiuying Li, Data Manager
- Laura Fullerton, Research Associate I
- Leanie Culanding, Budget and Finance Manager (part-time)
- Sunita Timilshina, Data Entry Clerk (part-time)
- Cheryl Dawson-Titus, Administrative Assistant (part-time)

OBRI Student(s)

- Mark Tatangelo, PhD candidate, University of Toronto

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