INSTITUTE OF HEALTH ECONOMICS
ALBERTA CANADA

IHE Symposium

Biologic and Biosimilar Therapies
The Future of Biologic and Biosimilar Therapies for the Management of Rheumatoid Arthritis in Alberta Health Care

May 29, 2014
The Westin Hotel
Edmonton, Alberta

Program

Moderator: **Dianne Mosher**, *University of Calgary*

09:00 – 09:15 Welcome and Opening Remarks
Glenn Monteith, *Chief Delivery Officer, Alberta Health*

09:15 – 09:30 Biologic and Biosimilar Therapies - The Changing Landscape of the Management of Rheumatoid Arthritis
Dianne Mosher, *Chief, Division of Rheumatology, Department of Medicine, University of Calgary*

09:30 – 10:30 Biologic Therapies in Rheumatoid Arthritis Project
Walter Maksymowych, *Professor, University of Alberta*

Liam Martin, *Professor, University of Calgary*

10:30 – 10:45 Break

10:45 – 12:30 Implications of Biologic Therapies for Rheumatoid Arthritis from from multiple perspectives

Patient Perspective
Cheryl Koehn, *Founder and President, Arthritis Consumer Experts (ACE)*

Public Payer Perspective
Micheal Guirguis, *Drug Stewardship Pharmacist, AHS*

Private Payer Perspective
Suzanne Lepage, *Private Health Plan Strategist*

Industry Perspective
Cate McCready, *VP External Affairs, BIOTECanada*

12:30 – 13:30 Lunch break

Program

13:30 – 14:00 Health Canada's Policies on Biologic and Biosimilar Therapies
Agnes Klein, *Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics at Health Canada, Health Canada*

14:00 – 14:30 Biologics and Subsequent Entry Biologics: Health Technology Assessment Perspectives from CADTH and Common Drug Review (CDR)
Chander Sehgal, *Director, Common Drug Review (CDR) and Optimal Use, Canadian Agency for Drugs and Technologies in Health (CADTH)*

14:30 – 14:45 Break

14:45 – 15:45 **Panel discussion**

How does Alberta ensure its leading role for best patient outcomes for Rheumatoid Arthritis?

Moderator: **Deborah Marshall,** *Associate Professor, University of Calgary and Arthur J.E. Child Chair in Rheumatology*
Panelists: **Walter Maksymowych, Liam Martin, Cheryl Koehn, Micheal Guirguis, Suzanne Lepage, Cate McCready, Chander Sehgal**

Questions

15:45 – 16:00 Wrap- up

16:00 – 17:00 Reception

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Speakers

Dr. Dianne Mosher is currently Professor of Medicine and the Chief of the Division of Rheumatology at the University of Calgary. She has practiced Rheumatology for the past twenty years having graduated from Dalhousie Medical School in 1983 where she also completed her Internal Medicine and Rheumatology residency training.
Dr. Mosher is a past president of the Canadian Rheumatology Association and the co -author of "Living Well with Arthritis," Penguin Press, 2002. She was involved in the development of several national initiatives including the "Arthritis Bill of Rights" and was co-chair of the 2005 "Summit on Standards for Arthritis Prevention and Care." In recognition of this work, Dr. Mosher was awarded the Canadian Rheumatology Association Distinguished Rheumatologist Award in 2008. Dr. Mosher is past co-chair and current president of the Arthritis Alliance of Canada (formerly the Alliance for a Canadian Arthritis Plan), a coalition of arthritis stakeholders. Under her guidance, they released "The Impact of Arthritis in Canada: Today and Over the Next 30 Years" in October of 2011 and the "Joint Action on Arthritis: A Framework to Improve Arthritis Prevention and Care in Canada" in September of 2012. Her research interests are primarily in clinical epidemiology with a focus on models of care for arthritis and outcome measures for patients with inflammatory arthritis. In February 2013, she was awarded the Governor General of Canada's Queen Elizabeth Diamond Jubilee Medal to honor her significant work in the area of arthritis care in Canada.

Dr. Walter Maksymowych, is a Professor in the Department of Medicine, Division of Rheumatology at the University of Alberta. He is also a Senior Scholar of the Alberta Heritage Foundation for Medical Research, a member of the Canadian Arthritis Network Centres of Excellence, advisory board member of the Assessments in Ankylosing Spondylitis International Working Group, and Scientific Chair of the Alberta Rheumatoid Arthritis and Pharmacovigilance Program and Outcomes Research in Therapeutics (RAPPORT) committee. He has served on the Task Force for the FDA Industry Guidance Document for Clinical Trials in Ankylosing Spondylitis. He is past-Chair of the Scientific Committee of the Canadian Rheumatology Association, and past-Chair of the Medical Advisory Board of the Spondylitis Association of America and the American College of Rheumatology Spondyloarthropathy Study Group.
Dr. Maksymowych graduated from the University of Manchester School of Medicine, United Kingdom and completed his postgraduate training at the University of Edmonton and the Children's Hospital Medical Center, Cincinnati, Ohio. He holds Fellowships in the Royal College of Physicians of Canada, the American College of Physicians, and the Royal College of Physicians of the UK. He has authored over one hundred peer-reviewed papers as well as numerous abstracts and book chapters, and has been invited to speak at both national and international meetings. His primary research interests are advanced therapeutics, ankylosing spondylitis and other sero-negative spondyloarthropathies, rheumatoid arthritis, and the genetics of arthritis.

Speakers

Dr. Liam Martin is a Professor of Medicine and a Rheumatologist at the University of Calgary. He graduated in Medicine from University College Dublin, National University of Ireland. He took his postgraduate training in Internal Medicine in Ireland and his Rheumatology training in Winnipeg, at the University of Manitoba. He did a post-doctoral fellowship at the University of Calgary with Dr. Marvin Fritzler. Dr. Martin's interests are focused on improving patient care in rheumatic diseases through clinical research and education. He is the co-principle investigator of the Alberta Pharmacovigilance program with Dr. Walter Maksymoych, University of Alberta.

Cheryl Koehn is a national arthritis advocate, a community leader and a published author. In November 2000, Cheryl founded Arthritis Consumer Experts (ACE) and its JointHealth™ family of programs. In May 1999, Cheryl became the consumer representative on CAN's management and research and development committee, and was elected chair of its Consumer Advisory Council (CAC). She was re-elected co-chair of this volunteer council in September 2002. She served as a consumer community representative on the CAN Partnerships and Sustainability Committee and along with her Aboriginal colleague, Joyce Greene, spearheaded the development of CAN's Aboriginal Research Initiative, the first of its kind in Canada. Cheryl's other committee memberships include:

- Member organization representative, Alliance for the Canadian Arthritis Program
- Co-Founder and member organization representative, Best Medicines Coalition
- Co-chair, Summit on Standards for Arthritis Prevention and Care
- Current and two-time Chair and Member organization representative, Better Pharmacare Coalition

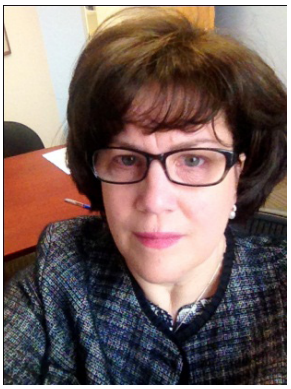
Developer of the 2009-2010 National Arthritis Awareness Program, a partnership between ACE and The Arthritis Society. In addition to these, Cheryl and her ACE colleagues regularly represent the views of Canadians living with arthritis at governments across Canada.

Dr. Micheal Guirguis BSc. Pharm, PhD currently engages stakeholders to initiate initiatives that maximize drug effectiveness, safety and sustainability in Alberta Health Services. Previously, Dr. Guirguis provided scientific and administrative support to the Alberta Health and Wellness Expert Committee on Drug Evaluation and Therapeutics, specifically in the areas of interchangeability and bioequivalence.

Dr. Guirguis received his Bachelors of Pharmacy and PhD from the University of Alberta. His PhD work focused on the Pharmacokinetics and Pharmacodynamics of drug/disease interactions. Following completion of his PhD, Dr. Guirguis worked at Abbott Laboratories and Covance Labs, as a clinical pharmacokineticist supporting the design and analysis of pharmacokinetic studies. Dr. Guirguis is an active educator, as an Adjunct Professor of Pharmacy and Pharmaceutical Sciences at the University of Alberta supporting education and research in Pharmacometrics, and Pharmacokinetics. As well as a Recognized Instructor and Dissertation Advisor at the University of Liverpool/Laureate online based Masters in Clinical Research. Dr. Guirguis has had a long standing interest in Subsequent Entry Biologics Chairing American Society of Clinical Pharmacology and Therapeutics 2009 Annual meeting workshop titled "Developing Biosimilars: Opportunities and Challenges" and presenting at the CADTH 2010 Symposium titled "Considerations for the Use of Subsequent-Entry Biologics in Canada"

Speakers

Suzanne Lepage is a private health plan strategist who bridges the pharmaceutical and group benefits industry.
Prior to beginning her consulting practice, Suzanne was National Manager Private Healthcare with Roche Canada. During that time she developed and executed private healthcare strategies and managed a patient assistance program for biologic medications. Prior to joining the pharmaceutical industry Suzanne worked in group benefits in a wide variety of roles for almost 20 years. Most recently she was the Product Manager for the drug programs at Manulife Financial. She is a frequent speaker and contributor to both private market and pharmaceutical industry conferences and publications.



Cate McCready, with fifteen years of practical experience in the field of communications and public affairs Cate McCready joined BIOTECanada in November of 2001 and currently serves in the role of Vice President, External Affairs.Her current role with BIOTECanada encompasses the development of national programs designed to inform and highlight the value of biotechnology innovation in Canada. This includes leading advocacy, media relations, and public awareness activities of the association to showcase the industry. Her experience includes more than eight years of service within the federal government. This included roles for federal ministers and to the Prime Minister of Canada. Prior to her federal government experience she served in corporate and non-profit roles for national organizations.

Dr. Agnes Klein is the Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products in Health Canada's Biologics and Genetic Therapies Directorate (BGTD). Dr. Klein received her medical degree from the University of Toronto, and trained in Endocrinology, Medical Biochemistry and Public and Community Health. She joined Health Canada and the Drugs Directorate in late 1974 and has occupied many and varied scientific and management positions within the department and its regulatory arms, including having acted as the Director of the Bureau of Human Prescription Drugs and as Director for the Biologics and Genetic Therapies Evaluation Centre. From 2001 to 2004, she was the Manager (Clinical Evaluation Division) of a newly created division responsible for Clinical Trial Application as well as the pre-market review and decisions regarding post-market events relating to biological/biotechnology agents. Since September 2004, Dr. Klein has served as Senior Medical Advisor and Acting Director for a newly created evaluation centre within BGTD. She is an active member of several medical and scientific organizations nationally and internationally.

Speakers

Dr. Chander M. Sehgal, MD, MBA

Before joining CADTH (Canadian Agency for Drugs and Technologies in Health) as the Director, Common Drug Review (CDR) and Rapid Response in March 2011, Dr. Chander Sehgal worked in the pharmaceutical industry for past six years in Canada across various functions including Medical Affairs, Reimbursement Planning and Health Economics and Outcomes Research. Chander completed a full-time MBA from the Richard Ivey School of Business, University of Western Ontario, London, Ontario in 2009 and specialized in healthcare stream. Chander has also completed a postgraduate program in Health Economics from the Center of Health Economics, University of York, York, UK. Chander's current role is Director, CDR and Optimal Use of Drugs.

Dr. Deborah Marshall, PhD

Deborah Marshall holds a Canada Research Chair, Health Services and Systems Research as an Associate Professor at the University of Calgary and the Arthur J.E. Child Chair of Rheumatology Outcomes Research in the McCaig Institute of Bone and Joint Health and the Institute of Public Health. She has experience in technology assessment agencies, academia and pharmaceutical and diagnostics industry research settings in Canada, the United States, and Europe. She was previously Vice President, Global Health Economics and Outcomes Research at i3 Innovus, managing health economic projects globally for diagnostic and pharmaceutical products. Dr. Marshall's research program, funded through grants from the Canadian Institutes for Health Research, Alberta Innovates Health Solutions, the Canadian Arthritis Society, Genome Canada, and the USs National Institutes of Health (NIH), is focused on measuring preferences using conjoint analysis, personalized medicine, cost-effectiveness analysis and simulation modeling in the health system. Dr. Marshall, Past President of the Board of Directors of the International Society or Pharmacoeconomics and Outcomes Research (ISPOR), is also an active member of the ISPOR Good Research Practices on Conjoint Analysis Task Forces focusing on applications in health, analysis and experimental design. She also serves on the Board of Directors of Health Technology Assessment International (HTAi) and the editorial boards of the International Journal for Technology Assessment in Health Care and The Patient.