The Clinical Research Association of Canada & the Canadian Chapter of ACRP Presents:

NEW MODELS & BEST PRACTICES IN CLINICAL RESEARCH

Thursday, May 29th, 2014
Novotel Montreal Airport Hotel
2599 boul. Alfred-Nobel, Montreal, Quebec, H4S 2G1

The Clinical Research Association of Canada (CRAC) is pleased to partner with the Canadian Chapter of ACRP to bring you a full day of clinical research education in Montreal!

CRAC and ACRP Canadian Chapter members will be able to take part in the event at a discounted registration rate. Mark your calendars, and be sure to take advantage of the special pricing for this event!

This full-day program includes all sessions, breakfast, lunch and coffee breaks.

CONFERENCE REGISTRATION FEES:

Conference fee includes: all sessions, continental breakfast, lunch, coffee breaks, and parking.
In an effort to be environmentally responsible, electronic copies of conference materials will be available to paid registrants prior to the event.

CRAC Member	ACRP Canadian Chapter Member	Not a member of ACRP Canadian Chapter or CRAC
$170.00*	$170.00**	$210.00***

AGENDA AT A GLANCE

8:00 - 8:30	**Registration and Breakfast**
8:30 - 8:45	**Welcome and Introductions**
08:45 - 9:30	**A New Clinical Research Model: NEOMED Institute** Dan Chiche, MD - Vice-President, Clinical Development and Medical Affairs NEOMED Institute
09:30 - 10:15	**Risk Based Monitoring: A Site's Perspective** Martine Regoli - Director of Quality Systems Manna Research
10:15 – 10:30	**Networking Break**
10:30 - 11:15	**Start-Up Clinical Study Team** Joanne Gavalakis M.Sc – Manager, Clinical Research Montreal Health Innovations Coordinating Center (MHICC), Division of the Montreal Heart Institute
11:15 – 12:00	**The Value Chain in CRO - Pharma partnerships; why being different pays out?** Teodor Burtea, M.D – Medical Director Ferring Canada
12:00 – 1:15	**Lunch**
1:15 – 2:00	**Who's the Boss? The World of the Independent CRA** Jim Cochrane, Senior CRA & Owner Recherche Clinique Cochrane
2:00 - 2:45	**The Future of Clinical Research in Quebec and Canada** Pierre Gervais, B.Pharm, L.Pharm, M.Sc – President, Executive Director Q&T Research
2:45 - 3:00	**Networking Break**
3:00 - 3:45	**Improving Clinical Research Capabilities Through Expert-Focused Collaborations: A business model for the future** Eric Legault, M.Sc., MBA – Director, Scientific Project Management & Development Algorithme Pharma
3:45 - 4:30	**Panel Session**
4:30 - 4:45	**Closing Remarks**

DETAILED PROGRAM

8:00 - 8:30 **Registration and Breakfast**

8:30 - 8:45 **Welcome and Introductions**

08:45 - 9:30 **A New Clinical Research Model: NEOMED Institute**

Dan Chiche, MD - Vice-President, Clinical Development and Medical Affairs
NEOMED

NEOMED, based in Montreal, Quebec, Canada is a novel organization which acts as a catalyst of growth for the Canadian life sciences sector, contributing directly to translate early-stage discoveries from the vast reservoir of Canadian academic and Biotech innovations into economic prosperity and improved health outcomes.

NEOMED aims to bridge academic research with the real needs of the BioPharma industry and investors of the life science sector in order to deliver needed treatments to patients and the society at large. Created in November 2012 as a Public-Private (founding partners are Quebec Government, AstraZeneca and Pfizer) not-for-profit organization, NEOMED identifies, finances and implements innovative drug discovery projects to bring them up to human proof –of-concept.

Learning Objectives:

1. Ways to fill the gap between academic innovation and assets appealing for pharmas.
2. Alternative ways to do early clinical research,
3. Value of partnership with public research unit / ARO.

09:30 - 10:15 **Risk-Based Monitoring: doing more with less**

Martine Regoli, Director of Quality Systems
Manna Research

The clinical trial industry is evolving. In an effort to improve participant safety and data integrity, regulators are encouraging trial sponsors to transition from a focused on-site monitoring approach they have traditionally employed toward a risk-based approach that utilizes a combination of centralized and on-site monitoring techniques to ensure patient safety and data quality.

With the implementation of RBM by CROs and monitors, many questions have arisen with regards to its effectiveness and how it impacts investigational sites. Are sites prepared to handle this new approach? What is required? How should it be implemented? This session will explore these questions and more…

Learning Objectives:

1. Understanding Risk-Based Monitoring
2. Planning and implementing the model at the site level
3. Pros and cons of RB monitoring; how do sites respond to non-traditional monitoring models?

10:15 – 10:30 **Networking Break**

10:30 - 11:15 **Start-Up Best Practices**

Joanne Gavalakis M.Sc – Manager, Clinical Research
Montreal Health Innovations Coordinating Center (MHICC), Division of the Montreal Heart Institute

An organization that invests in a strong and qualified start-up team has a much better chance of delivering a successful study. The organization has paid attention to essential timelines; budget and most importantly they have understood the importance of reducing the turn-around time from bench to bedside, which is the ultimate purpose of all clinical studies.

Success is defined by shorter recruitment period and target patient recruitment, with no protocol deviations. Success is also defined as quality of data that is generated from clinical and operational teams who are reliable, accountable, trustworthy, respecting and abiding to all local regulatory requirements and ICH/GCP guidelines.

For any Academic Research Organization (ARO) and Clinical Research Organization (CRO) repeat business is crucial to its survival and reputation. Hence the above points for success must be always top of mind.

Learning Objectives:

1. Optimize site relationships from site selection
2. Ensure to have adequate and qualified resources to cover the workload at study start
3. Meet expectations of all stakeholders

11:15 – 12:00 **The Value Chain in CRO-Pharma Partnerships: why being different pays out?**

Teodor Burteau, M.D. – Medical Director
Ferring Canada

Learning Objectives:

1. Understanding current outsourcing models
2. Defining "partnership" in the context of CRO-Pharma relationships
3. Practical advice on how to stand-out as a service provider and focus on long-term relationship building

12:00 – 1:15 **Lunch**

1:15 – 2:00 **Who's the Boss? The World of the Independent CRA**
Jim Cochrane, Senior CRA & Owner
Recherche Clinique Cochrane

Jim Cochrane is the Owner of Recherch Clinique Cochrane. In this session, he will detail his background story, including his education and start in clinical research, as well as opportunities which lead him to his decision to become an independent CRA.

Jim will discuss his process and transformation from employee to businessman and will highlight the many hats you learn to wear when owning your own business. He will share insights on how to find work as an independent CRA, and what type of work you can take on.

He will address issues such as contract and workload management, how to maintain a life/work balance, how to manage your own career, training and how to keep aware of industry trends.

Jim will address some of the pros and cons of being an independent CRA, in order to help you determine "is being an independent for you?"

Learning Objectives:

1. How you might become an independent CRA: what are the business skills that are required
2. What are the considerations in managing your skills, training, time, workload
3. Know some of the Pro's and Con's of being an independent CRA

2:00 – 2:45 **The Future of Clinical Research in Quebec and Canada**
Pierre Gervais, B.Pharm, L.Pharm, M.Sc – President, Executive Director
Q&T Research

Learning Objectives:

1. An overall perspective of Canadian and Quebec clinical research will be made
2. A parallel will be made between Canada and other countries/regions
3. Conclusions will be about tendencies of upcoming clinical research and therapeutic domains.

2:45 – 3:00 **Networking Break**

3:00 - 3:45 **Improving Clinical Research Capabilities Through Expert-Focused Collaborations: A business model for the future**

Eric Legault – Director, Scientific Project Management & Development
Algorithme Pharma Inc.

The last decade brought numerous challenges to the clinical research industry. These challenges stemmed from developments in various areas including ethics, scientific, medical or regulatory advancements and financial instabilities. These challenges stressed the need to remodel the clinical research service offering to ensure it remains innovative and creative in how it approaches drug development. A part of solution to this increasing need for innovation could be driven by close collaborations with specific industry experts, to provide most appropriate development solutions: the expert-focused collaborations.

In a context where niche expertise is becoming a key factor in success of clinical trial planning and execution, how does this collaborative approach respond to varying development needs? How would an expert-focused collaboration meet these market expectations?

This session aims to review recent challenges faced by the clinical research industry and, how these changes impact sponsors and CRO directly. Ultimately, considering this evolving environment, how an expert-focused collaboration business model could be the solution to meet drug development requirements and exceed the market's expectations.

Learning Objectives

1. Understand environmental changes that occurred in the clinical research industry in the last decade
2. Understand how the impact on the clinical research service offering market
3. Understand how new creative and innovative models such as the expert-focused collaboration could meet new market's expectations

3:45 - 4:30 **Panel Session**

4:30 - 4:45 **Closing Remarks**

SPEAKER BIOGRAPHIES

Dan Chiche, MD - Vice-President, Clinical Development and Medical Affairs at NEOMED

Dan Chiche is in charge at NEOMED of the design, implementation and publication of clinical trials and related regulatory aspects. In addition, he brings the long-term medical vision and a deep understanding of R&D opportunities and constraints to NEOMED's search for value creation. Dan also serves a key role in building a solid network with Pharma companies.

In 2007, Dan founded Kompas Medical Services Inc., a company providing support to Biotechs, Pharmas, and other institutions including Venture Capital firms. As an independent consultant, Dan has supported recently many early clinical programs in various indications: fibrosis, oncology, fungal infection, diabetes, hypertension, and Alzheimer disease. He also interacted many times with VCs in Montreal as well as in other countries such as USA and France, mainly by performing due diligence or providing expert's opinion on Health Technologies. Prior to this, Dan worked for over 20 years within the top tier pharmaceutical companies Glaxo and Bristol-Myers Squibb, where he served as an executive in Clinical Research and Medical Affairs. He has been involved in key aspects of clinical development for compounds in various therapeutic areas and as such, is very familiar with the clinical research standards of the ICH, FDA and EMEA. While working for big pharmaceutical companies, his areas of specialities were anti-infective, anti-viral and Immunology. Dan is a Medical Doctor, initially trained in Intensive Care Medicine and Emergency Medicine, with additional education in biostatistics both from Paris-Sud University and holds a Master in Marketing and Commercial Development (equivalent to an MBA) from HEC in France. Dan has a particular interest in clinical R&D models, early clinical trials and productivity in R&D.

Eric Legault – Director, Scientific Project Management & Development at Algorithme Pharma Inc.

Mr. Eric Legault is the Director of the Scientific Project Management & Development division at Algorithme Pharma and joined the company in 2006. Mr. Legault leads a group of scientists specialized in Project Management. He also leads the Project Development group who is evaluating every single inquiry to ensure a successful operational and safety feasibility of these projects.

Mr. Legault is a graduate of Medicine Faculty of Laval University. He also has a Master in Business Administration with Dean's Honors. He has over 14 years of experience in clinical research and has initiated his career as a project manager. Over this period, he has designed, created and managed three different Phase I/II units and managed several different professionals.

Since initiation of his career, Mr. Legault directly managed above 400 drug development programs at various stages (Phase I to IV).

Joanne Gavalakis, M.Sc. Manager, Clinical Research at the Montreal Health Innovations Coordinating Center (MHICC), Division of the Montreal Heart Institute

A graduate of the University of Montreal with a M.Sc. in Pharmacology, with emphasis on drug metabolism, Joanne has been in the pharmaceutical industry for over 30 years, in pre-clinical and clinical research combined. Joanne began her career in basic research drug development, where she made significant contributions for over 12 years working for Ayerst Pharmaceutical and Bio-Mega / Boehringer Ingelheim respectively. Joanne's extensive experience in drug metabolism and Phase I clinical research, allowed her to play a key role in the start up of two clinical research operations, namely Phoenix International Life Sciences and Maxxam Analytic Inc. both in the Montreal region. As lead project manager at Merck Frosst Canada Inc., Joanne brought to completion numerous global clinical trials Phase II – III, predominately in the area of HIV, including HIV vaccines. Joanne's leadership skills have been further refined in the position of Regional Monitoring Manager for Astrazeneca Canada Inc. thus making her a valuable asset to MHICC in the position of Manager, Clinical Research.

Teodor Burtea, M.D – Medical Director, Ferring Canada

Dr. Burtea is the Medical Director at Ferring Pharmaceuticals were he is responsible for leading the medical team to ensure they provide comprehensive medical affairs support to the commercial team for new and existing brands in order to achieve corporate objectives. He is of also responsible for the development and management of all clinical programs, medical science liaisons, medical information and pharmacovigilance activities.

Dr. Burtea has held senior medical positions with Shire, Sanofi and Vertex and he has held the position of Medical Director, Gastroenterology with Ferring USA. He has contributed to several scientific publications.

Dr. Burtea holds a Doctorate in Medicine – European Union license from the Faculty of Medicine of the Carol Davila University of Medicine and Pharmacy in Bucharest, Romania. He also holds a Professional Certificate in Management, Concentration Marketing from the Open University Business School in London, UK. He completed an Executive Development course at the McGill Executive Institute of McGill University in Montreal, Canada and he is accredited with the Canadian Council of Continuing Pharmaceutical Education.

Jim Cochrane – Senior CRA & Owner, Recherche Clinique Cochrane

Jim Cochrane is a clinical research professional specializing in clinical monitoring and GCP auditing and is the owner of Recherche Clinique Cochrane. He began his career in clinical research in 1994 after graduating from Concordia University with a Bachelors' in Exercise Science and the University of Waterloo with a Masters' in Kinesiology (exercise physiology).

After a brief start with Glaxo as both data manager and regional CRA, he established himself over 4 and half years as a senior data manager and clinical/data project manager with Phoenix

International Life Sciences. Following short stays with Pfizer and Moncoa Medical Research, again in both data management and clinical research, his career as a home-based CRA took off in 2001 when he joined Innovus Research (now i3 Research). He became an ACRP certified CRA in 2004 and in 2008, cut-backs at i3 Research presented him with an opportunity to become an independent clinical research consultant.

Since then, Jim has worked with pharmaceutical companies, CROs and independent sites as CRA, Auditor and Quality Specialist.

Pierre Gervais, B.Pharm, L.Pharm, M.Sc – President, Executive Director at Q&T Research

Pierre Gervais is a registered pharmacist and a pharmacologist graduated from the University of Montreal.

Pierre has 15 years of diversified R & D experience with drug companies as CRA, Clinical Scientist, Research Manager and Associate Medical Director. He was involved in the strategic planning and development of key compounds like Nicoderm, sucralfate and diltiazem.

Pierre founded Q & T Research – Sherbrooke in 1996, a private research centre dedicated in clinical research with drug companies. Q & T is now a research group made of 27 employees, health professionals or consultants and is active in 11 therapeutic areas. As research director, Pierre is involved in establishing and maintaining the high quality standards supporting a pivotal Phase II – III multi-therapeutic clinical research groups.

Pierre partnered with Dr. Patrice Nault, cardiovascular surgeon and Dr. Doria Grimard, microbiologist to structured respectively Q&T Research Outaouais and Q&T Research Chicoutimi.

Pierre is a founding member and ex-President of the Quebec Association of Clinical Research (AQRC) an association dedicated in promoting excellence in clinical research.

Martine Regoli – Director of Quality Systems at Manna Research

Martine Regoli joined MannaResearch with over 10 years of managing and monitoring clinical trials in BioPharma and CROs as a Senior Clinical Research Associate. Prior to pursuing a career in Pharma, Martine obtained her Master's of Science Degree from McGill University in Psychiatry and Neuroscience where she also conducted academic research. Martine's role as Director of Quality Systems at MannaResearch is to determine, negotiate and establish agreements for quality standards & procedures and to act as a catalyst for change and improvement in performance/quality for all Manna Research sites.

REGISTRATION

Conference seating is limited. Please register early to avoid disappointment.
Registration Deadline: May 22, 2014
Registration can be done via
1. CRAC Website at: http://www.craconline.ca/meeting.php
OR
2. ACRP Canadian Chapter website at:
http://www.acrpnet.org/GetInfoFor/InternationalChapters/Canada.aspx

Registration payments must be made through PayPal only (automatic link on registration form). Registration will not be accepted without receipt of correct payment.

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$170.00*	$170.00**	$210.00***

*Registrants must be paid-up CRAC members in good standing **at the time of registration** to receive the CRAC member conference rate.

Registrants must be paid-up Global and Canadian Chapter members in good standing **at the time of registration to receive the ACRP chapter member conference rate.

*** Not an ACRP Canadian Chapter member? Visit the ACRP website at www.acrpnet.org to join the Canadian Chapter. Please note that you MUST be a Global member before you can join the Chapter.

*** Not an ACRP Global member? Visit the ACRP website at www.acrpnet.org to become a Global member, then join the Canadian Chapter. Please note that you MUST be a Global member before you can join the Chapter.

*** Not a CRAC member? Visit the CRAC website at http://www.craconline.ca/ to become a CRAC member.

Prices are in Canadian Currency. The ACRP Canadian Chapter Education Committee reserves the right to cancel or postpone the event due to circumstances beyond its control. In the event of

cancellation, all registrants will be notified before the event and receive a full registration fee refund. The Canadian Chapter is not responsible for any other costs incurred by registrants.

Cancellation Policy — Cancellations must be received no later than May 22, 2014 for a full refund. A $75 administrative fee will apply to ALL cancellation requests received after May 22, 2014. NO REFUNDS will be issued for "No-Show" registrants. Substitutions are allowed (see below).

Substitutions/Replacements — If you are unable to attend for any reason, you may transfer your registration to another individual. The registrant must provide a request and a completed form for the person replacing them. The replacement registrant must meet the above qualifications to receive any applicable discount. Please send all cancellation or substitution requests or enquiries to: info@craconline.ca or canadianchapter@acrpnet.org

ACRP CONTINUING EDUCATION CONTACT HOUR APPLICATION

NEW: There is no charge for contact hours available at all ACRP Canadian Chapter Events.

Contact hours have been applied for through ACRP (6.5). Membership is not required for online registration/application of contact hours.

To receive contact hours: go to your "My Tests, Evaluations, and Certificates" (TEC) record on the ACRP website and complete the evaluation within 30 days following the event.

You MUST sign the conference attendance sheet, to prove participation.

NEW MODELS & BEST PRACTICES IN CLINICAL RESEARCH
MONTREAL MEETING LOCATION

"**New Models & Best Practices in Clinical Research**" will be held at the Hotel Novotel Montreal Airport. The Novotel Montreal Airport is located in the heart of the Montreal Technoparc, just 10 minutes from Pierre E. Trudeau International Airport and 15 minutes from the city centre.

The Novotel Montreal Airport is located at 2599 boulevard Alfred Nobel, Ville St-Laurant. For directions and map, please visit: http://www.novotel.com/gb/hotel-6011-novotel-montreal-airport/location.shtml or call the hotel at: (514) 337-3222.

DIRECTIONS:
From Pierre Elliott Trudeau airport: take highway 520 Est and take exit 13 Nord (Laval). Then take the exit for 40 Ouest (Ottawa/Gatineau). Stay in the service lane and you will see signs for Boulevard Alfred Nobel. The exit for Boulevard Alfred Nobel is after Parkway Plaza auto shop. Take Alfred Nobel Blvd, the hotel is on your left after the traffic light.

Hotel shuttle available from 6 am to 10 pm.

HOTEL ACCOMODATIONS:
A conference rate is available for conference attendees at a rate of $149.00 on May 28th, 2014 and $139.00 on May 29th (+applicable taxes). Please contact the hotel at: (514) 337-3222 for reservations.

We hope to see you in Montreal!

~ Your CRAC Executive