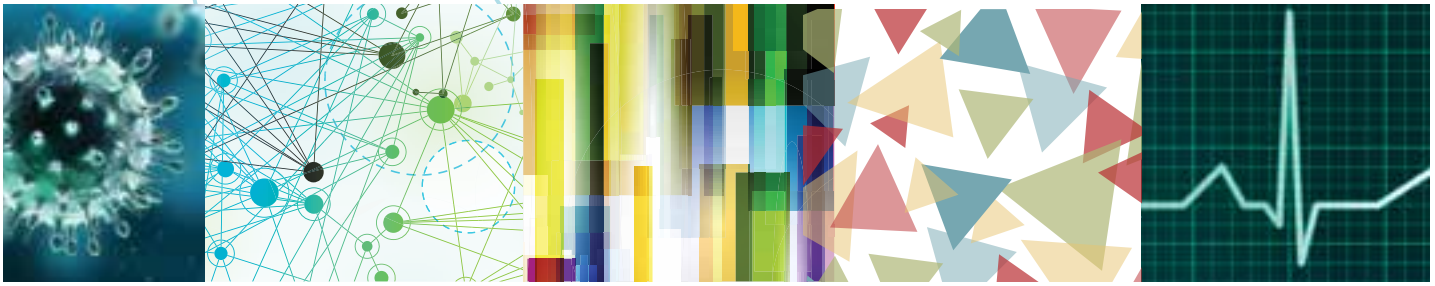
BRC 2013 Annual Report



From the Board of Directors

We are pleased with the progress the BioPharma Research Council (BRC) has achieved in 2013.

Early in the year Joanne Gere joined us as Executive Director. While building infrastructure and enhanced resources, she is working closely with the BRC team to develop strategic plans, and with our growing group of more than 3,500 participants who inform our intriguing activities.

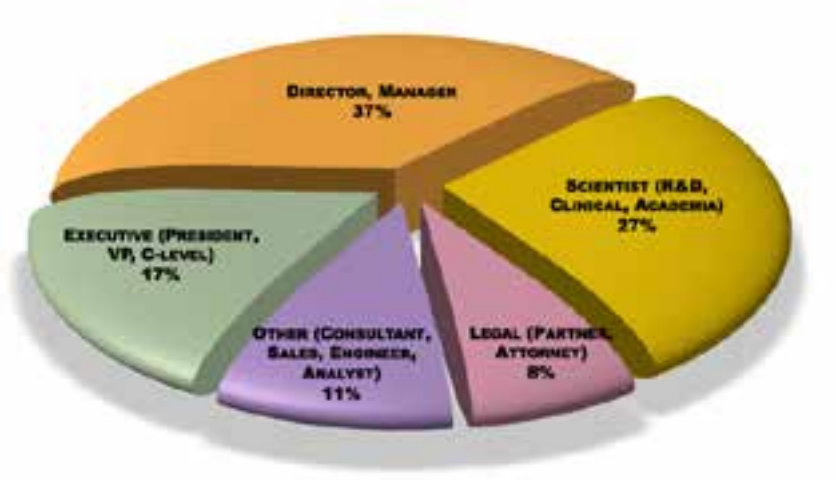
Program Director Dr. Doranelly (Dolly) Koltchev continues to lead in the developing content for the in-person and virtual programs. She chairs a very active and diverse Scientific Advisory Board of experts who provide insight and strong connections throughout the community.

BRC support staff has grown as well, with Kyle Carney joining as Communications Associate, and Kristin Ward as Graphics Associate.

We look forward to increased growth in membership and an exciting and informative 2014.

Rich Brandwein and Ronnye Schreiber
Board of Directors

Who Participates in our Programs?



Job Function / Seniority

From the Program Director

The BioPharma Research Council continued to promote the exchange of scientific knowledge throughout 2013 by offering diverse programs to the biopharmaceutical community.

The breadth and depth of our programs couldn't have been possible without the guidance and expert opinion of the BRC Scientific Advisory Board. The dedication, expertise and willingness to actively participate in programs, from idea to completion, by all members of the Board are greatly appreciated. In addition, our growing relationships with foundations specializing in specific therapeutic areas or diseases bring fresh perspectives on the latest breakthroughs and challenges.

Biosimilars Development and Regulatory Pathways addressed current trends from business perspective to regulatory issues to payors strategies through case studies and global adoption practices. Interactive discussions among the participants and live streaming of the talks provided an excellent atmosphere for cross pollination of ideas.

Triangle Biotech Research Symposium 2013 in North Carolina brought together (for the second year) scientists, exhibitors, business development and IP experts to discuss the latest innovations in the region. New this year were the poster session and recordings of all presentations.

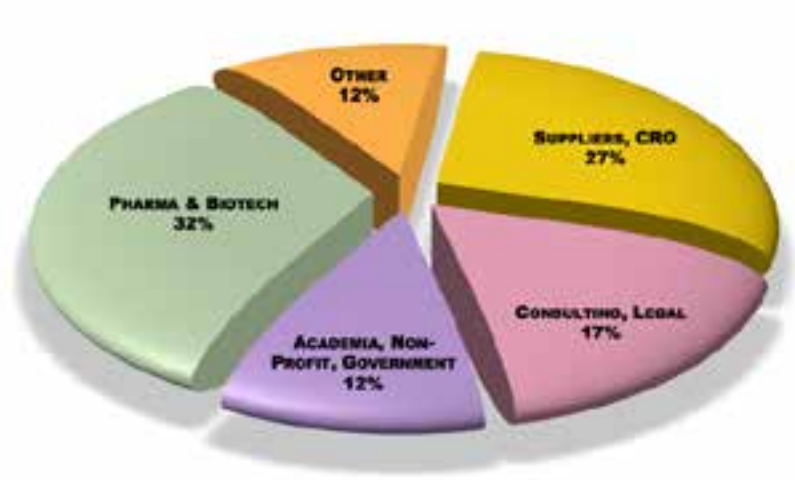
Best Practices IV: Preclinical Outsourcing was presented in a new format, including live broadcast of the presentations.

BRC Forums aimed at diving deep into specific therapeutic areas- diabetes, Alzheimer's drug discovery research, imaging biomarkers in cardiovascular disease and vaccines. Like all of our programs, they provided opportunities for reaching out to experts across industry, academia and nonprofit organizations, thus stimulating in-depth exchange of ideas and expertise.

Overall 2013 BRC programs have set the pace for unleashing the creativity and opening new avenues for future growth and exploration.

Dolly Koltchev, PhD
Program Director
BioPharma Research Council

Who Participates in our Programs?



Affiliation

BioPharma Research Council

The BRC is an association for scientists across the entire discovery, development, and delivery community.

Through committees, conferences, webinars, and educational programs, we stimulate interaction to provide catalyst for fresh collaborations and partnerships.

Our activities are made possible through the energies and expertise of professionals from industry, academia, nonprofit, government, and supplier laboratories, and teams throughout the region and the globe.

BRC

Table Of Contents

6..... History

7..... Conferences and Forums

- Current Trends in Biosimilars Development and Regulatory Pathways
- Triangle Biotech Research Symposium 2013
- Best Practices IV: Preclinical Outsourcing

10..... Forums

- Therapeutics Forum: Diabetes & Endocrinology
- Therapeutics Forum: Future Perspectives in Alzheimer's Research
- Therapeutics Forum: Cardiovascular
- Therapeutics Forum: Virology (Herpes and Shingles Vaccines)

12..... Scientific Advisory Board

13..... Awards for Outstanding Contributors

Our History

The BioPharma Research Council (BRC) is an independent, nonprofit organization founded in 2009 to support the broad community of scientists and business professionals in the biopharmaceutical space. By addressing scientists who are making and developing discoveries throughout the biotech/pharmaceutical pipeline, we provide an environment for interaction that can lead to better communication, enhanced collaboration, and faster, more effective medical progress.

"Over time we have received frequent requests to take a role in helping expand connections among companies, universities, and other scientific environments."

- Ronnye Schreiber

Researchers from the academic, industry, nonprofit, government, & supplier laboratories, CRO/CMO's and other services contribute as committee members, speakers, moderators, and Scientific Advisory Board members.

BRC has grown through significant support from its Foundation Sponsor PlanetConnect. For close to 20 years, PlanetConnect has been producing complex, proprietary, internal corporate pharmaceutical and biotech symposia for individual pharmaceutical and biotech companies. Confidential internal research conferences have focused upon IT, R&D, Analytical Research, Manufacturing and other areas of interest.

"While we have helped many key international biopharmaceutical companies and departments to hold confidential meetings," says Ronnye Schreiber, President of PlanetConnect and of the BRC Board of Directors. "Over time we have received frequent requests to take a role in helping expand connections among companies, universities, and other scientific environments."

By helping to create the BRC we are able to support programs that are open to all and that allow scientists to share knowledge and ideas across boundaries."

PlanetConnect's founders, Ronnye Schreiber and Rich Brandwein,continue to provide support and guidance as the organization grows.

"We started running conferences at Bell Labs in the early days of web-based computing," says Mr. Brandwein. "After many years of producing internal symposia, we are able to support the BRC by leveraging strong relationships with pharmaceutical and supplier companies, and facilitate dialog and debate that can stimulate innovative thinking across all of the entities that contribute to medical progress."

"...we are able to support the BRC by leveraging strong relationships with pharmaceutical and supplier companies, and facilitate dialog and debate that can stimulate innovative thinking across all of the entities that contribute to medical progress."

- Rich Brandwein

In 2012 Dolly Koltchev, Ph.D. became Program Director, and Joanne Gere joined as Executive Director in 2013.

Programs

Biosimilars Development and Regulatory Pathways

April 9, 2013

Chemical Heritage Foundation Philadelphia

Presenters:

Michael C. Rice
Senior Consultant
Defined Health

Douglas C. Hicks
Vice President
iBio, Inc.

Yan Yang
Director
The Jackson Laboratory

David Shen
Vice President
Teva Pharmaceuticals

Daniel L. Menichella
Chief Business Officer
Zyngenia

Paul Gallagher
President
Compass Group

Joseph P. Furh
Professor
Widener University

Michiel E. Ultee
Chief Scientific Officer
Laureate Biopharmaceutical Services

Glen Kazo
President
Prolonged Pharmaceuticals

Christopher J. Holloway
Chief Scientific Officer
ERA Consulting Group

Weihong Hsing
Partner
Panitch Schwarze Belisario & Nadel LLP

Current Trends in Biosimilars Development and Regulatory Pathways in the Global Marketplace addressed topics ranging from the global regulatory landscape for biosimilars and biobetters to legal considerations, business perspectives, recent scientific breakthroughs, services market (CRO, CMO, clinical trials), and uptake from patient perspectives.

"In recent years, biopharmaceuticals have become the fastest growing segment of the global healthcare development market," says Dr. Dolly Koltchev, BRC Program Director. "Patent expirations and demand for top-selling biologics brands in key therapeutic areas like cancer, diabetes, and autoimmune diseases have opened new opportunities for developing cost effective follow-on biologics (biosimilars). "

Triangle Biotech Research Symposium 2013

August 20, 2013

Research Triangle Park, Raleigh, NC

Presenters:

Alice Bonnen
Attorney
Myers Bigel Sibley & Sajovec

Afreen Allam
President
Cromoz, Inc.

Nancy Baker
Owner
ParlezChem

Al Shpuntoff
Bioinformatics Consultant
AFS Infomatics

Deanna Nelson
Owner
BioLink Life Sciences

Rob Schwartzman
Attorney
Myers Bigel Sibley & Sajovec

Wanona Satcher
Project Manager
City of Durham

Randall Lanier
Senior Director of Virology
Chimerix, Inc.

Sonia Grego
Research Scientist
RTI International

Hongwei Xie
Director
KBI Biopharma

Jack Thornquest
Senior Scientist Mass Spectrometrist
Scynexis, Inc

Andrew Carr
Director Bioinformatics
Accelerated Technology Laboratories

Yan Yang
Business Unit Manager
The Jackson Laboratory

Sissel Juul
Biomedical Engineering
Duke University

Stephen Ezell (Keynote)
Senior Analyst
Information Technology & Innovation Foundation

Building relationships among regional experts helps develop partnerships, collaborations, and a more successful environment for progress in human health. Delegates from the academic, biopharma, agricultural biotech, and personalized medicine research communities, as well as IP experts, consultants, and suppliers gathered for this lively symposium. Presentations, exhibits, and posters expressed the region's contributions to research, development, devices, instrumentation, analysis, and more.

Best Practices IV:
Preclinical Outsourcing

November 20, 2013

Conference Center at Ocean Place
Long Branch, NJ

Presenters:

Patrick M. Dentinger
President and CEO
Absorption Systems

Kuldip Dave
Senior Associate Director
Michael J. Fox Foundation

Mitchell M. Wong
Principal
The Exeter Law Group

Thomas Macpherson
Managing Director
Zensights

Christopher J. Kemper
Principal
PharmaNavigators, LLC

Rachel F. Lane
Assistant Director
Alzheimer's Drug Discovery Foundation

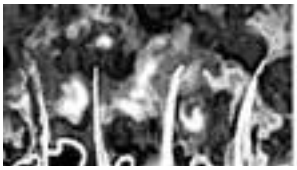
Raghvendra Sahai
President
EuTech Scientific Services

The program evaluated effective use of contract research organizations (CROs) by academia, industry and nonprofit entities to develop innovative therapeutics.

"As biopharmaceuticals have developed into a 50 billion dollar a year industry, preclinical outsourcing has become a common practice. Companies have become reliant on outside, specialized services to supplement their internal research and development," said Program Director Dolly Koltchev, PhD.

"Our speakers presented their most effective practices in preclinical outsourcing for feeding drug development pipelines, building strong relationships that lead to advancements in curing human disease."

The topics covered by the presenters provided thoughtful insight into current industry trends, as well as ideas to increase the efficiency and productivity of the preclinical process; utilizing modern technology to cut the costs and risks of preclinical research were underlying themes found in the presentations.



BRC THERAPEUTICS FORUM DIABETES AND ENDOCRINOLOGY

Diabetes and Endocrinology
February 5, 2013
Princeton Marriott

Presenters:

Steve Stagliano
Corporate Account Manager
Medtronic

Poul Strange
Medical Director and President
Integrated Medical Development, LLC

The EMA published new guidance on June 29, 2013, covering the development of all diabetes drugs. These guidelines went into effect in November making it very relevant for all people involved in diabetes drug development. "The use of devices allowing continuous blood glucose monitoring is encouraged and regarded as useful in adults and children to describe overnight glucose profiles and postprandial hyperglycaemia." There are 5 separate mentions of Continuous Glucose Monitoring (CGM) within the guidelines covering orals, insulins and other injectable.

Researchers and regulatory experts discussed the specific implications of the guidance, its possible interpretation, and data analytic techniques to get the most value from the data captured with this technology. Different product options and tradeoffs were addressed as well as practical tips and tricks for successfully integrating CGM into clinical trial protocols.

BRC THERAPEUTICS FORUM ALZHEIMER'S Research Update

Future Perspectives in Alzheimer's Research
March 5, 2013
Princeton Marriott

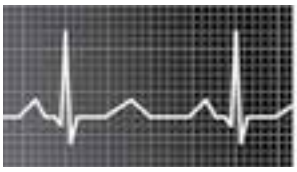
Presenters:

Howard Fillit
Director and Chief Science Officer
Alzheimer's Drug Discovery Foundation

Poul Strange
Researcher
Feinstein Institute for Medical Research

The BRC Therapeutic Forum provided an overview of the current status of the drug discovery process in academia and the pharmaceutical industry. In addition, the outcome of recent and ongoing clinical studies was discussed.

"This is an important moment to take a look at the current state of Alzheimer's research," said Dr. Dolly Koltchev, Program Director of the BioPharma Research Council. "Recent disappointing clinical data emphasizes the need for a discussion on these failures, and to evaluate innovative approaches for future directions in finding effective treatments for this devastating disease".



BRC THERAPEUTICS FORUM CARDIOVASCULAR Imaging Biomakers

Cardiovascular Imaging Biomakers

August 6, 2013

Princeton Marriott

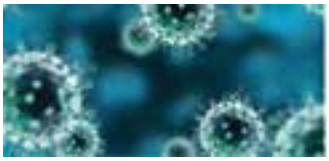
Teri Conte
Region Manager
FUJIFILM Visualsonics, Inc.

Terri A. Swanson
Senior Scientist
Pfizer

Nitin Aggarwal
Senior Research Investigator
Bristol-Myers Squibb

The program addressed important questions in developing imaging biomarkers and evaluating cardiotoxicity off-target effects for preclinical and clinical studies of cardiovascular disease.

Cardiovascular disease includes a wide variety of conditions that, despite the advances of pharmaceutical R&D, represent still unmet medical needs. It is the leading cause of death in the developed world; therefore treatment of cardiovascular disease is currently a major focus for developing innovative programs, therapeutics and diagnostics modalities for the pharmaceutical industry. In addition, cardiotoxicity remains a major cause of concern during preclinical, clinical and post-approval withdrawal of medicines. Cardiotoxicity is observed mainly with anticancer drugs, but is also correlated with treatment with other classes of drugs, including antibiotics, antidepressants, and antipsychotics.



BRC THERAPEUTICS FORUM VIROLOGY

BRC Forum: Virology

September 17, 2013

Princeton Marriot

Harvey M. Freidman
Professor of Medicine/Infectious Disease
Director, Botswana-UPenn Partnership
Univesity of Pennsylvania

Thomas Heineman
Director, Global Clinical Developement, Vaccines
GlaxoSmithKline Biologicals

The program evaluated different subunit antigen vaccines. The vaccine for herpes simplex attempts to induce high titers of neutralizing antibodies to prevent primary infection, while the zoster vaccine targets T-cell responses in an effort to prevent relapses of the chickenpox virus.

Herpes simplex virus is the leading cause of genital ulcer disease worldwide. First time infections are often painful and many individuals suffer from frequent recurrent infections. Concern about transmission of the virus to sexual contacts creates anxiety in infected individuals. Spreading the infection to the fetus during labor and delivery can be life threatening for the newborn. Another major concern about genital herpes is that it increases the individual's susceptibility to HIV infection by 3-fold, or for those individuals co-infected with HSV and HIV, the risk of transmitting HIV increases 3-fold. A vaccine is sorely needed to prevent HSV genital ulcer disease.

Zoster (shingles) is the clinical disease that occurs when the virus that causes chickenpox relapses. Zoster presents as a painful red rash with fluid filled vesicles that follows a dermatome distribution on the skin. The incidence of zoster increases with aging and is more common in immunocompromised individuals. The most frequent serious long-term complication from zoster is persistent, severe pain in the area of the rash. The persistent pain is referred to as post-herpetic neuralgia. A live virus vaccine is available for patients over age 50 in an effort to prevent zoster; however, the vaccine is not considered safe in immunocompromised individuals and is not highly immunogenic in subjects over age 70.

Scientific Advisory Board

We appreciate the BRC Scientific Advisory Board's energetic participation, which assures the scientific depth and focus of our activities. Each SAB member contributes significant insights and perspectives, reflecting experiences in academic, industry, government, nonprofit, and supplier entities.

Chair:

Dolly Koltchev Ph.D.
Program Director
BioPharma Research Council

Members 2013-2014:

Jaymie DeWitt
Director, Business Development
Molecular Imaging Inc.

Deborah Dougherty Ph.D.
Professor and Vice-Chair
Management & Global Business
Rutgers University

Sathapana (Sam) Kongsamut Ph.D.
Owner and Principal, Rudder Serendip LLC

Joan Krakowsky Ph.D.
Clinical Research Project Manager
CHDI Foundation, Inc.

Terry Stouch Ph.D.
President
Science for Solutions, LLC

Carole Wilmot Ph.D.
C Wilmot Consulting, LLC

Howard Young Ph.D.
Deputy Chief of the NCI Laboratory of Experimental Immunology
Chair of the NIH Immunology Interest Group

2013 Awards

Terry Stouch
President
Science for Solutions

Outstanding Contributor to: The Scientific Advisory Board and the Growth of the BRC

Sam Kogsamut, Ph.D.
Principal
Rudder Serendip LLC

Outstanding Contributor to: The Scientific Advisory Board and the Growth of the BRC

Teri Conte
Region Manager
FUJIFILM Visualsonics

Outstanding Contributor to: BRC Forums on Emerging Technologies

---

Gabor Fari
Director, Business Development and Strategy
Health & Life Sciences
Microsoft

Outstanding Contributor to: Information Technology Development

---

George Karam
Global External Research Lead
Pfizer Pharmatherapeutics

Outstanding Contributor to: The Development of BRC Best Practices in Outsourcing

---

Jack Heslin
Enterprise & Key Account Executive
MAKERBOT

Outstanding Contributor to: The Future of Biomedical Innovation

BRCD2D

Data to Drugs and Diagnostics

June 11-12, 2014

New Jersey Convention and Exposition Center

Cloud Computing, Mobile Applications, Big Data Analytics, Pipeline Development, and More...

Coming in 2014:

In addition to a series of Webinars and the continuation of many of our ongoing themes, we are developing a major conference and exposition that is open to all.

D2D: Data to Drugs and Diagnostics will focus on enabling IT tools and solutions driving innovation throughout the therapeutics life cycle, including translation into clinical practice.

It will bring together a large community of experts, thought leaders, researchers, developers and suppliers from across the pharmaceutical/biotechnology enterprise, academia, government agencies, and nonprofit organizations in the life sciences space.

12 Tracks, Major Keynote Addresses, Panel Discussions, Interactive Sessions, Poster Presentations, and Pre-conference Workshops will provide many opportunities for interaction that is the hallmark of the BRC. The Exhibit Floor will include over 100 key companies in the biopharmaceutical industry, including IT suppliers, research and health care nonprofit organizations.

The D2D Codefest will offer challenges in addressing data from discovery to medical device software and hardware.

Five months of Free pre-event webinars, roundtables, and other opportunities will help grow the community of experts who are building tomorrow's breakthrough healthcare solutions.

www.brcd2d.com
www.biopharmaresearchcouncil.org

Questions? Call!
Joanne Gere, Executive Director, 732-403-3137
jgere@biopharmaresearchcouncil.org