BIOMARKER summit

Includes the three co-located conferences:

8th Oncology Biomarkers
4th Neurological Biomarkers
4th Inflammatory & Immunological Biomarkers

Keynote Speakers

Mark E. Curran
Vice President, Immunology
Systems Pharmacology & Biomarkers
Janssen

Sudhir Srivastava
Chief, Cancer Biomarkers Research Group
Division of Cancer Prevention
National Cancer Institute, NIH

John Wagner
Senior Vice President
Head, Clinical & Translational Sciences
Takeda Pharmaceuticals

MARCH 18-20, 2015 • SAN DIEGO, CA
The Biomarker Summit 2015 will bring together leaders in the field to discuss the issues and challenges scientists and researchers face in all aspects of the biomarker and diagnostic development process from discovery to translation to commercialization. A wide variety of important topics will be covered including biomarker identification, validation, and translation strategies, bioinformatics and systems biology approaches to personalized medicine, big data analytics and management, regulatory and reimbursement trends, companion diagnostics development, and much more. Assembling leading scientists, researchers, decision-makers and other players across the industry spectrum, the Biomarker Summit 2015 provides a unique opportunity to gain the latest biomarker developments in three major therapeutic areas, formally organized into the following tracks:

**8th Oncology Biomarkers**
This meeting provides a forum for experts in industry, academia and government to discuss the latest developments in the oncology biomarker research arena. Topics include circulating tumor cells, cell free DNA, digital pathology and imaging biomarkers.

**4th Neurological Biomarkers**
Leading experts will focus on the development of CNS biomarkers for drugs and diagnostics from CSF and blood, as well as imaging approaches.

**4th Inflammatory & Immunological Biomarkers**
Delegates will discuss the unmet medical needs in autoimmune diseases, respiratory diseases, kidney disease, lupus, IBD and other inflammatory diseases.

### CALL FOR PAPERS
To be considered for a short oral presentation, please submit an abstract by **February 18, 2015**. Selected presentations will be based on quality of abstract and availability. Selected abstracts will be notified via email or telephone 2-3 weeks before the conference. Presentation slots fill up fast so please submit your abstract soon.

Click on the following conferences to submit an abstract:

- **8th Oncology Biomarkers**
- **4th Neurological Biomarkers**
- **4th Inflammatory & Immunological Biomarkers**

### SPONSORSHIP OPPORTUNITIES
GTCbio conferences bring together high-level influential leaders with decision-making authority from the pharmaceutical industry, academia, and government. Our approach offers a more intimate and networking-oriented environment geared towards connecting experts within their fields to further collaborate on new and existing research.

- Sponsors/exhibitors will receive the delegate list a week before and a week after the conference.

- Meeting exhibit space is shared between all conferences, providing sponsors/exhibitors with access to delegates at all co-located meetings. Exhibitors are located in the same room where all networking functions take place, including coffee breaks, snack stations, breakfast, and reception.

- Your corporate logo will be placed on the cover page of the conference brochures, the USB proceedings given to all conference delegates, and on the presentation screen during all breaks to enhance your company's visibility at the event. Your logo will also be featured on the conference website, with a link to your company's website.

*For sponsorship and exhibit opportunities, please contact:*

**Amber Kempf**
Account Executive
amber.kempf@gtcbio.com
Quanterix is a developer of ground-breaking tools in high definition diagnostics. Its Simoa platform uses single molecule measurements to access previously undetectable proteins. With this unprecedented sensitivity and full automation, Simoa offers significant benefits to both research and clinical testing applications. Quanterix was established in 2007 and is located in Lexington, Massachusetts.

Abcam is a provider of protein research tools and services, with an unrivaled range of products and expert technical support, enabling scientists to analyze living cells at the molecular level and improving the understanding of health and disease. To find out more, please visit www.abcam.com

Our goal is to make protein analysis simpler, more quantitative and affordable. Our comprehensive portfolio of tools includes Simple Western systems that quantify protein expression and Biologics systems that probe the structure and purity of protein-based therapeutics.
Metanomics Health - a BASF group company - is the leading company offering targeted and non-targeted metabolite profiling to healthcare customers in industry and academia. We serve pharma, nutrition and diagnostics customers, making them more successful through biomarker identification and validation across a broad range of applications.

Viracor-IBT is a CAP/CLIA accredited laboratory providing large molecule biomarker support for phase I-IV trials. Viracor-IBT has 30+ years of experience in molecular testing, immune response monitoring, allergy/hypersensitivity testing. Expertise includes custom assay design, optimization, transfer and validation. Our streamlined processes provide more options and flexibility for your specific needs.

The Ohio Clinical Trials Collaborative (OCTC) arose from an initiative of Governor John Kasich to create a premier research medical corridor in Ohio. The OCTC was founded with a mission to establish Ohio as one of the most efficient and effective states in which industry sponsors can develop new medical devices, medications and treatment strategies. Operating in the capacity of a central business development office, the OCTC delivers the pharmaceutical and medical device industry access to the vast resources of Ohio’s research academic institutions and medical centers and hospitals. The OCTC coordinates entrance and exit of teams of medical experts as a sponsor’s product moves from research to commercial launch, thereby providing the sponsor a high degree of economic efficiency while simultaneously getting access to best in class medical advice and expertise.
### AGENDA AT A GLANCE

#### Day 1 - Wednesday March 18, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00</td>
<td>Registration</td>
</tr>
<tr>
<td>12:55</td>
<td>Plenary Keynote Session</td>
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</tbody>
</table>
| 1:00  | **Transformative Potentials of Biomarkers in Clinical Application: Early Detection, Diagnosis and Prognosis**  
Sudhir Srivastava, Chief, Cancer Biomarkers Research Group, Division of Cancer Prevention, National Cancer Institute, NIH |
| 1:45  | **Companion Diagnostics in Autoimmune Disorders: Improving Outcomes in RA and IBD**  
Mark E. Curran, Vice President, Immunology, Systems Pharmacology & Biomarkers, Janssen |
| 2:30  | Plenary Session: Big Data Analytics for Biomarkers Development            |
| 2:55  | **Harnessing the Power of Healthcare Data with Advanced Data Analytics to Drive Personalized Treatment**  
Diane Wuest, Lead, Precision Medicine Initiatives, GNS Healthcare |
|       | **Parag Mallick, Assistant Professor, Canary Center for Cancer Early Detect, Stanford University** |
| 3:20  | Afternoon Networking and Refreshment Break                                |
| 3:50  | Integrated Analytics in Predictive Biomarker Discovery                    |
|       | Chinnappa Kodira, Bioinformatics Strategy Leader, Comp Biology & Biostatistics, GRC, GE Global Research |
| 4:15  | Using Big Data Towards Personalized Treatment Selection and Multi-marker Real Time Diagnostics |
|       | Mohammad M. Afshar, Chief Executive Officer, Ariana Pharma               |
|       | Plenary Panel Discussion: Companion Diagnostics Development & Partnering Strategies |
| 4:40  | **Panelists:**                                                           |
|       | Trevor Page, Director, Corporate Business Development, Dako               |
|       | Nicole Jean, Corporate Business Development, Global Product & Portofolio Strategy, AstraZeneca |
|       | Ian McCaffery, Oncology Biomarker Development, Companion Diagnostics, Genentech |
|       | Hakan Sakul, Executive Director & Head of Diagnostics, Site Head, Development Operations Worldwide R&D, Clinical Research and Precision Medicine, Pfizer |
| 5:25  | Day 1 Concludes                                                          |

#### Day 2 - Thursday, March 19, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>7:00</td>
<td>Registration &amp; Continental Breakfast</td>
</tr>
<tr>
<td>8:00</td>
<td>Three Concurrent Conferences</td>
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<tr>
<td></td>
<td><strong>8th Oncology Biomarkers</strong></td>
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<tr>
<td></td>
<td><strong>Session I: Liquid Biopsy: Non-Invasive Approaches to Diagnostics</strong></td>
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<td></td>
<td><strong>4th Neurological Biomarkers</strong></td>
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<tr>
<td></td>
<td><strong>Session I: Imaging Approaches in CNS Drug Discovery &amp; Development</strong></td>
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<td><strong>4th Inflammatory &amp; Immunological Biomarkers</strong></td>
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<tr>
<td></td>
<td><strong>Session I: Biomarkers of Early Progressive Inflammatory &amp; Immunological Diseases</strong></td>
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<tr>
<td>10:05</td>
<td>Morning Networking &amp; Refreshment Break</td>
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### Day 2 - Thursday, March 19, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session II: Emerging Discovery Pipelines</th>
<th>Session III: Emerging Discovery Pipelines (cont.)</th>
<th>Session IV: Immuno-Oncology Biomarker Discovery</th>
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<tbody>
<tr>
<td>10:50</td>
<td>CSF &amp; Blood Based Biomarker Approaches</td>
<td>Developments in Neurological &amp; Neurodegenerative Disorders</td>
<td>Biomarker Development in Neuropsychiatric Disorders</td>
</tr>
<tr>
<td>12:15</td>
<td>Lunch On Your Own</td>
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<tr>
<td>1:45</td>
<td>Biomarkers &amp; Surrogate Endpoints for Clinical Trials in Inflammatory Diseases</td>
<td>Novel Approaches to Immunological Biomarkers</td>
<td>Fluid Based Biomarkers Approaches (Synovial, Salivary, Urine)</td>
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<tr>
<td>3:25</td>
<td>Afternoon Networking &amp; Refreshment Break</td>
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### Day 3 - Friday, March 20, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Plenary Keynote Session</th>
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</thead>
<tbody>
<tr>
<td>7:30</td>
<td>Who Owns Biomarker Qualifications and Surrogate Endpoints?</td>
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<tr>
<td>8:00</td>
<td>Plenary Session: Novel Technologies in Biomarker Development</td>
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<tr>
<td>8:45</td>
<td>Activity-based Probes: Novel Tools in Biomarker Development</td>
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<tr>
<td>9:10</td>
<td>Novel Biomarkers Through Precise Definition of Immune Repertoires</td>
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<tr>
<td>9:35</td>
<td>MRM-based Multiplexed Quantification of Proteins and Phospho-signaling in Tissues and Cell Lines</td>
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<tr>
<td>10:00</td>
<td>Morning Networking Break</td>
</tr>
<tr>
<td>10:30</td>
<td>Frequent Regulatory Variants in Drug Target Genes: Potential for Predictive Biomarker Panels</td>
</tr>
<tr>
<td>10:55</td>
<td>Plenary Session: Overcoming Challenges of Clinical Validation &amp; Translation</td>
</tr>
<tr>
<td>11:20</td>
<td>Can We Use Biomarkers to Successfully Make Decisions Prior to Large Outcomes Trials in Cardiovascular Drug Development?</td>
</tr>
<tr>
<td>11:45</td>
<td>Lunch Provided by GTCbio</td>
</tr>
</tbody>
</table>

*All times are approximate and subject to changes without notice*
AGENDA AT A GLANCE

Day 3 - Friday, March 20, 2015

Plenary Session: Overcoming Challenges of Clinical Validation & Translation (cont.)

12:45
Consideration for the Use of Comprehensive Genomic Profiling in Oncology Clinical Care and Clinical Trials
Roman Yelensky, Senior Director, Biomarker & Companion Diagnostic Development, Foundation Medicine

1:10
Plenary Panel Discussion: Non-Profits Perspectives on Biomarkers

Panelists:

Douglas Macdonald, Director, Drug Discovery & Development, CHDI Foundation
Lucie Bruijn, Chief Scientist, The ALS Association
Tim Turnham, Executive Director, Melanoma Research Foundation

1:35
Plenary Panel Discussion: Regulatory & Reimbursement Trends in Biomarker Development

Panelists:

Jennifer Madsen, Senior Director, Economic & Regulatory Affairs, College of American Pathologists
Rina Wolf, Vice President, Strategic Commercialization, Consulting and Industry Affairs, XIFIN
John Lubniewski, Chief Business Officer, HTG Molecular Diagnostics
Felix Freuh, Chief Scientific Officer, Human Longevity, Inc.

2:20

3:05
Conferences Conclude

PLENARY KEYNOTE SPEAKERS

Sudhir Srivastava
Chief, Cancer Biomarkers Research Group
Division of Cancer Prevention
National Cancer Institute, NIH

Mark E. Curran
Vice President, Immunology
Systems Pharmacology & Biomarkers
Janssen

John Wagner
Senior Vice President
Head, Clinical & Translational Sciences
Takeda Pharmaceuticals

Hakan Sakul
Executive Director & Head of Diagnostics
Site Head, Development Operations Worldwide R&D, Clinical Research and Precision Medicine
Pfizer
PLENARY SPEAKERS

Using Big Data Towards Personalized Treatment Selection and Multi-marker Real Time Diagnostics
Mohammad M. Afshar
Ariana Pharma

Can We Use Biomarkers to Successfully Make Decisions Prior to Large Outcomes Trials in Cardiovascular Drug Development?
David Kallend
The Medicine Company

Activity-based Probes: Novel Tools in Biomarker Development
Amos Baruch
Genentech

Multimodal and Multiscale Technologies And Analytics for Predictive Biomarker Discovery
Chinnappa Kodira
GE Global Research

Plenary Panel Discussion: Non-profits Perspectives on Biomarkers
Lucie Bruijn
The ALS Association

Panel Discussion: Regulatory & Reimbursement Trends in Biomarker Dev.
John Lubniewski
HTG Molecular Diagnostics

Novel Biomarkers Through Precise Definition of Immune Repertoires
Guy Cavet
Atreca

Plenary Panel Discussion: Non-Profits Perspectives on Biomarkers
Douglas Macdonald
CHDI Foundation

Panel Discussion: Regulatory & Reimbursement Trends in Biomarker Dev.
Parag Mallick
Stanford University

Plenary Panel Discussion: Companion Diagnostics Development & Partnering Strategies
Nicole Jean
AstraZeneca

Plenary Panel Discussion: Overcoming Challenges of Clinical Validation & Translation
Ian Mccaffery
Genentech

For an updated speaker list visit: https://www.gtcbio.com/conferences/biomarkers-summit-speakers
Mass Spectrometry and the Identification and Validation of Circulating Biomarkers

Jennifer Madsen
College of American Pathologists

Trevor Page
Dako

Amanda Paulovich
Fred Hutchinson Cancer Research

Wolfgang Sadee
Ohio State University

For an updated speaker list visit: http://www.gtcbio.com/conference/oncology-biomarkers-speakers

PLENARY SPEAKERS

Plenary Panel Discussion: Companion Diagnostics Development & Partnering Strategies

Jennifer Madsen
College of American Pathologists

Trevor Page
Dako

Amanda Paulovich
Fred Hutchinson Cancer Research

Wolfgang Sadee
Ohio State University

Diane Wuest
GNS Healthcare

Roman Yelensky
Foundation Medicine

8TH ONCOLOGY BIOMARKERS - DISTINGUISHED SPEAKERS

Developing Blood Based Biomarkers for Early Detection and Screening in Cancer

Wendy Alderton
Abcodia

Approaches to Jointly Validate Biomarkers and Identify Targets for Cancer

Raj Batra
UCLA Geffen School of Medicine, VAGLAHS

Mass Spectrometry and the Identification and Validation of Circulating Biomarkers

Daniel Chelsky
Caprion Proteomics

In Situ Immunoprofiling: New Insights into Tumor Behavior and Microenvironment

Fiona Ginty
GE Healthcare

Pro-NT and Pro-ENK: Novel Biomarkers for Breast Cancer Risk Prediction

Karla Gonye
Sphingotec

Molecular Urine Tests for Prostate Cancer Detection and Management

Jack Gorskopf
Hologic
8TH ONCOLOGY BIOMARKERS - DISTINGUISHED SPEAKERS

Stephen Johnston
Biodesign Institute, Arizona State University

Developing CTC Assays to Support Early Clinical Trials of Targeted Therapies
Steven Pirie-Shepherd
Pfizer

Ann Kapoun
OncoMed Pharmaceuticals

Automated Genomic Interpretation of Sub-chromosomal Fetal Copy Number Variation by Sequencing Circulating Cell-free DNA from Maternal Plasma
Ali Torkamani
The Scripps Translational Science Institute, The Scripps Research Institute

Thomas Kleen
Epiontis GmbH

Patient Selection Approaches Using Protein and Gene-based Predictive Biomarkers in Early Phase Trials: Two Case Studies

MicroRNA-based Discovery Pipeline for Companion Diagnostics
Robert Wassman
Rosetta Genomics

Pierluigi Mauri
Proteomics & Metabolomics Laboratory - CNR; Institute for Biomedical Technologies (ITB-CNR)

Clinical Proteomics Pipeline for Biomarker Discovery & Validation

Epigenetic Immune Cell Markers - Enabling Next Generation Immunoprofiling for Immuno-Oncology Trials

Immunosignatures as a Universal, Comprehensive Diagnostic Platform

For an updated speaker list visit: http://www.gtcbio.com/conference/oncology-biomarkers-speakers
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<thead>
<tr>
<th><strong>4TH NEUROLOGICAL BIOMARKERS - DISTINGUISHED SPEAKERS</strong></th>
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<tbody>
<tr>
<td><strong>Biomarkers for Traumatic Brain Injury</strong></td>
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</table>
| Denes Agoston  
*School of Medicine, USU* |
| **Use of MDD Score for the Identification of Comorbid Major Depressive Disorder (MDD) in Patients with Chronic Pain** |
| John Bilello  
*Ridge Diagnostics* |
| **ALS Biomarker Development** |
| Lucie Bruijn  
*The ALS Association* |
| **Translatable Kinetic Biomarkers: Current and Future Applications to Neurodegenerative Diseases** |
| Patrizia Fanara  
*Kinemed* |
| **Biomarker Development in Mood Disorders** |
| Maura Furey  
*Janssen Pharmaceuticals* |
| **Single-Molecule Array Technology For the Ultra-Sensitive Detection of Biomarkers: Applications in CNS** |
| Andreas Jeromin  
*Quanterix* |
| **Development and Application of PET Imaging Probes for Neurodegenerative Diseases** |
| Hartmuth Kolb  
*Janssen R&D* |
| **Translational Biomarkers for Alzheimer’s Disease (AD) Drug Development and Plasma AD Biomarker Research** |
| Yoshiya Oda  
*Eisai* |
| **Magnetic Resonance Spectroscopy Biomarkers of Neurodegeneration** |
| Gulin Oz  
*University of Minnesota* |
| **Longitudinal Plasma Amyloid in Alzheimer’s Disease Clinical Trials** |
| Robert Rissman  
*University of California San Diego* |
| **Biochemical Strategies for Improving Difficult Assays in CSF and Blood** |
| J Randall Slemmon  
*Janssen R&D* |
| **Blood Markers to Identify Alzheimer’s Disease: From Protein to MicroRNA** |
| Xuemei Zhao  
*Merck* |

For an updated speaker list visit: [www.gtcbio.com/conference/neurological-biomarkers-speakers](http://www.gtcbio.com/conference/neurological-biomarkers-speakers)
4TH INFLAMMATORY & IMMUNOLOGICAL BIOMARKERS - DISTINGUISHED SPEAKERS

Proteome-scale Exploration of Human Adaptive Immune Reactivity
Alex Abbas
Genentech

Selecting Biomarkers to Accelerate Drug Development in Nephrology
Mahmoud Loghman-Adham
Baxter Healthcare

Accelerating Protein Biomarker and Drug Target Discovery Using Proseek Multiplex
Andrea Ballagi
Olink Bioscience

Mass Spectrometric Immunoassays for Immunological Biomarkers
Dobrin Nedelkov
Arizona State University

Digital Quantification of Pre-clinical Inflammation Markers on the Erenna® Single Molecule Counting Immunoassay Platform
Joseph Barco
Singulex

Urinary Exosome Paradigm for Kidney Function
Satish Ramachandra
University of California San Diego

Novel Approaches to Identification of Predictors of Response in Heterogeneous Immunologic Diseases
Carrie Brodmerkel
Janssen R&D

Circulating miRNAs as Biomarkers in Diabetes - Preliminary Results from Cross-Sectional and Longitudinal Studies
Attila Seyhan
Florida Hospital, Massachusetts Institute of Technology

Understanding Low-Level C-Peptide Secretion as a Biomarker for Risk of Complications in Type 1 Diabetes
Denise Faustman
Massachusetts General Hospital, Harvard Medical School

Disease Heterogeneity and the Development of Stratification Biomarkers for New Asthma Therapeutics
Dirk Smith
Amgen

The Next Generation of Translational Research
Brian Idoni
Sanguine BioSciences

Signs of the Unseen: Biomarkers and Surrogate Endpoints in Chronic Obstructive Pulmonary Disease (COPD)
Ziad Taib
AstraZeneca

Metabolomic Biomarker Discovery for Acute and Chronic Inflammatory Conditions
Thomas Jonsson
Metabolon

Biomarker Discovery and Development for Acute & Chronic Inflammatory Conditions in Heart, Lung & Kidney Diseases
Scott Tebbutt
The Centre of Excellence for Prevention of Organ Failure

For an updated speaker list visit: www.gtcbio.com/conferences/inflammatory-immunological-biomarkers-speakers
CONFERENCE DETAILS

The Westin San Diego
400 West Broadway
San Diego, CA 92101
619-239-4500

Discounted Group Rate: $209.00 per night
Discount Deadline: February 24, 2015
Mention GTC to receive the group rate.

Online Reservations:
https://www.starwoodmeeting.com/Book/Biomarker

Early Registration Discount:
20% until January 18, 2015
10% until February 18, 2015

Register for 2 the 3rd goes FREE with coupon code: RCDVB

To register online, visit: https://www.gtcbio.com/register/biomarkers-summit

REGISTRATION

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<tr>
<th>Summit</th>
<th>Commercial</th>
<th>Academic / Govt</th>
<th>Student</th>
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QUICK REGISTRATION - FAX TO 626-466-4433

First Name: ___________________________ Last Name: ___________________________
Title: ___________________________ Company: ___________________________
Discount Coupon Code: ______________________________________________________________________________________________________
Card #: ___________________________ Exp. Date: __________________________ CSV #: ___________________________
Cardholder Name: ______________________________________________________________________________________________________
Signature: ______________________________________________________________________________________________________
Billing Address: ______________________________________________________________________________________________________
City: ___________________________ State: __________________________ Zip: __________________________

VENUE

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PROCEEDINGS

If you are unable to attend the conference you can purchase the proceedings by downloading the order form here.
Fill out the order form and fax it to 1 (626) 433-4433 or email it to proceedings@gtcbio.com.