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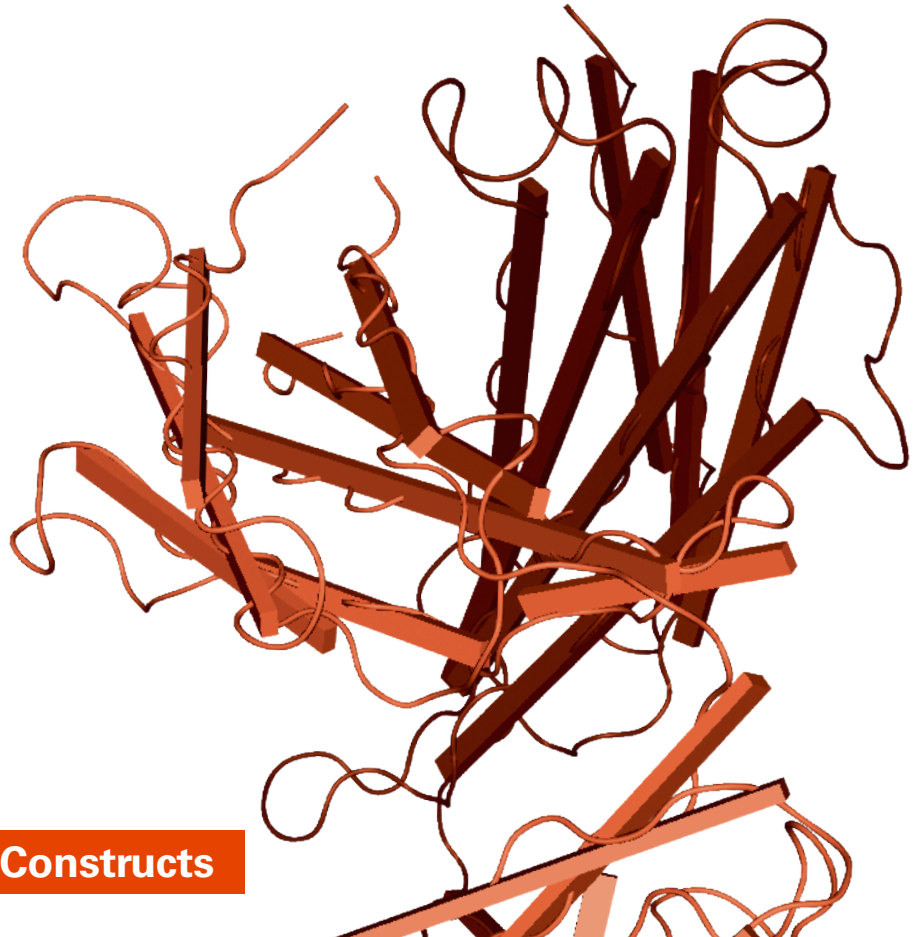
NOVEMBER 11-12, 2013
Hyatt Regency on Capitol Hill | Washington, DC

2ND ANNUAL

PK/PD of Novel Constructs

Optimizing Bispecific Antibodies and ADCs



KEYNOTE SPEAKER

Ranjana Advani, M.D.,
Saul A. Rosenberg Professor of Lymphoma, Professor of Medicine/Oncology, **Stanford Cancer Institute**

CO-LOCATED WITH

CHI's Fifth Annual
Immunogenicity Summit 2013
November 11-13, 2013
Hyatt Regency on Capitol Hill
Washington, DC

ImmunogenicitySummit.com/**Novel-Constructs**

Cambridge Healthtech Institute,
250 First Avenue, Suite 300,
Needham, MA 02494
www.healthtech.com

CONFERENCE SHORT COURSES*

SUNDAY, NOVEMBER 10

1:30 - 4:30 pm SC1: Basics of Immunogenicity Testing for Innovators and Biosimilars

Instructors: Jim McNally, Ph.D., Senior Principal Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.
Melody Sauerborn, Senior Expert, Immunogenicity and Bioanalysis, TNO, a Netherlands Applied Research Center

This interactive session will enable attendees to work out a basic immunogenicity preclinical and clinical testing strategy for various molecules including bi-functional and other novel scaffolds. Areas of difficulty will be discussed with specific case studies. Attendees are encouraged to contribute with their own experiences and to bring questions for discussion or submit to the meeting organizers in advance.

The following topics will be covered:

- Basic issues regarding screening, confirmatory and titer assays
- Assay methodologies and various technologies
- Current approaches to data analysis and cutpoints
- Preclinical and clinical considerations
- Common problems

5:30 - 8:30 pm Dinner SC2: Challenges of Immunogenicity Assessment for Innovators and Biosimilars

Instructors: Jim McNally, Ph.D., Senior Principal Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.
Melody Sauerborn, Senior Expert, Immunogenicity and Bioanalysis, TNO, a Netherlands Applied Research Center

This interactive session of intermediate will focus on the potential challenges of immunogenicity testing in preclinical and clinical development and present case studies demonstrating how they can be handled. Attendees are encouraged to contribute with their own experiences and to bring questions for discussion or submit to the meeting organizers in advance.

The following topics will be covered:

- Challenges and approaches to resolve commonly encountered issues
  - Multi-domain binding proteins
  - Pre-existing ADAs
- Emerging trends in the development of neutralizing antibody assays
- Cross reactivity to endogenous proteins
- Clinical implications of ADAs
- Regulatory guidance and guidelines

5:30 - 8:30 pm Dinner SC3: PK/PD Bioanalyis for Novel Biotherapeutics

Sponsored by GYROS

Lee Abberley, Ph.D., Team Leader, DMPK, GlaxoSmithKline, US
Lindsay E. King, Ph.D., Senior Principal Scientist, Pfizer Inc

Novel constructs, such as anti-drug conjugates (ADCs) and bispecific antibodies, now exist as promising candidates in biotherapeutic pipelines. With aggressive timelines and contraction in the biopharma labor force, assay development can pose challenges beyond typical assays for pharmacokinetics and pharmacodynamics. Several bioanalytical techniques can be employed to measure these novel constructs. This short course will cover assay technologies to measure ADCs and bispecific antibody therapeutics for pharmacokinetics and pharmacodynamics presented by various biopharma scientists.

** Separate Registration Required*

TUESDAY, NOVEMBER 12 | 6:30 – 9:00 PM

Dinner SC4: Immunogenicity Risk Assessment and Regulatory Strategy

Instructors: Laurie Graham, Product Quality Reviewer, Division of Monoclonal Antibodies FDA/CDER
Susan Kirshner, Ph.D., Associate Chief, Laboratory of Immunology, Therapeutic Proteins, Biotechnology, CDER/FDA
Robin Thorpe, Ph.D., FRCPath, Head, Biotherapeutics Group, National Institute for Biological Standards and Control

The following topics will be covered:

- Priorities for the regulator: Hierarchy of concerns; data requirements; common gaps
- Integrated approach: Risk identification; aligning identified risks with CMC, bioanalytical, nonclinical and clinical strategy; ongoing risk management
- Interactive case study: Illustration of preparation of an effective response to a regulatory scenario pertaining to immunogenicity-related risks for an investigational therapeutic protein
- Questions and Answers

Topics to be discussed include:

- Benefits of timely discussion with the regulators
- Neutralizing antibody assays (NAbs): When are they necessary?
- The case for binding assays versus cell-based assays for NAbs
- Novel products and biosimilars: what challenges are the regulatory authorities seeing and anticipating?
- Pitfalls to avoid

Dinner SC5: Developing Potency Assays to Ensure Successful Biologics

Instructor: Timothy Schofield, Senior Fellow, MedImmune

This interactive short course will enable attendees to develop methods and strategies for developing and validating bioassays that support the identification and development of their biotherapeutics products. It will include coverage of assays to test both activity and potency, including cell-based and biochemical based systems.

MONDAY, NOVEMBER 11

7:30 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

Nahor Haddish-Berhane, Ph.D., Senior Principal Scientist, Pfizer

Clinical Experience with PK/PD of Novel Constructs

» KEYNOTE PRESENTATION:

8:35 Impact of Brentuximab Vedotin in the Treatment of Lymphoma

Ranjana Advani, M.D., Saul A. Rosenberg Professor of Lymphoma, Professor of Medicine/Oncology, Stanford Cancer Institute

The recent FDA approval of Brentuximab vedotin (ADCETRIS®) an anti CD 30 antibody drug conjugate represents a major therapeutic advance in Hodgkin Lymphoma and Anaplastic Large Cell Lymphoma therapy after almost three decades. Pivotal trials report overall response rates exceeding 70% in patients with relapsed or refractory disease. These results, have led to investigation of Brentuximab vedotin in the front line setting in combination with chemotherapy and is rapidly changing the standard of care of CD30-positive lymphoproliferative malignancies.

9:05 Do Look a Gift Horse in the Mouth: Using PKPD Modelling to Evaluate Novel Biologic Constructs

Balaji Agoram, Ph.D., Director, PKPD and Bioanalysis, MedImmune, Inc.

The talk will cover the use of mathematical models - termed systems pharmacology models - to predict the PKPD characteristics of novel biologic constructs and modify them in the design stages.

9:35 Trends in Novel Constructs: Quality Attributes That May Impact PK or Mechanism of Action

Marjorie A. Shapiro, Ph.D., Chief, Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, FDA/CDER

Current trends in antibody development include novel constructs, cocktails, antibody-drug conjugates and Fc engineering to enhance or reduce effector function or to enhance PK. This presentation will highlight current trends in MAb development with a focus on analytical studies and control strategies to support the development of novel products.

10:05 Sponsored Presentation *(Opportunity Available)*

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

Nonclinical PK/PD of ADCs: Where Are the Opportunities for Improvement?

11:15 PK-PD Considerations in the Development of Antibody-Maytansinoid Conjugates

Jan Pinkas, Ph.D., Director, Pharmacology, ImmunoGen, Inc.

11:45 Exploiting the Properties of Fleximer™ to Improve Pharmacokinetics: Applications to Small Molecules, Biologicals, and Antibody-Drug Conjugates

Timothy B. Lowinger, Ph.D., CSO, Mersana Therapeutics

Fleximer is a highly biocompatible, fully biodegradable polyvalent polymer with unique properties, which include tremendous water solubility, plasma stability, and the ability to improve pharmacokinetics and biodistribution. Examples of the application of Fleximer to improve the drug-like qualities of proteins, small molecules and antibody-drug conjugates will be presented.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:45 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Use of Mechanistic PK/PD Modeling

2:15 Chairperson's Remarks

Nahor Haddish-Berhane, Ph.D., Senior Principal Scientist, Pfizer

2:20 Does It Take Two or Four to Tango? Modeling & Simulation of Bispecific Antibodies in Oncology

Tamara Van Steeg, Ph.D., Senior Consultant PK/PD, LAP&P Consultants BV

Modeling and simulation is a powerful tool to aid understanding in complex systems with multiple interactions. As such, M&S is especially useful in the development of bispecific antibodies by assessing the interactions of these molecules with its biological target already at an early stage. The interplay of M&S activities, experimental data and available knowledge on the system (e.g. receptor densities) will provide guidance on the strategies for further development of these drugs.

2:50 Could We Have a Ballpark Idea about Tumor Targeting Prior to the Accurate Measurement?

Guozheng Liu, Ph.D., Research Assistant Professor, Radiology, University of Massachusetts Medical Center

This talk introduces a very simple kinetic model that considers a solid tumor as a "reactor," aiming to prepare researchers to get some information about tumor accumulation with less efforts or prior to feasible measurement. It will rationalize the authors' observations on tumor accumulation by pretargeting, summarize them into "rules of thumb", and provide some general insights to tumor accumulations.

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Guiding ADC Development by Employing PK/PD Modeling and Simulation Approaches

Nahor Haddish-Berhane, Ph.D., Senior Principal Scientist, Pfizer

The talk will highlight a diverse set of multi-scale models, including a PBPK model for ADC, which can used to support ADC programs at various development stages. Two different case studies will be presented to demonstrate the utility of PK/PD models for preclinical-to-clinical translation of ADC efficacy. Use of mathematical models to guide the discovery of ADC and precision medicine approach will be briefly discussed.

4:30 PK/PD Modeling to Determine Individual Dose Response

Rakesh Sindhi, M.D., Professor of Surgery, Co-Director, Pediatric Transplantation, Children's Hospital of Pittsburgh

Anticipating efficacy and safety before early or late phase clinical trials can promote informed use of novel drugs and regimens. PK/PD modeling of immunosuppressant(s) using *ex-vivo* cell-based assays will be discussed to illustrate several uses for clinical drug development. These uses include identifying effective doses and biomarkers which can be used as companion diagnostics and surrogate endpoints.

» 5:00 pm PANEL DISCUSSION WITH SPEAKERS

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 End of Day One of PK/PD of Novel Constructs

TUESDAY, NOVEMBER 12

Nonclinical PK/PD of Multi-Specific Modalities

8:30 am Chairperson's Remarks

8:35 Discovery Phase Support for Large Molecule Therapeutics with Multiple Specificities: New Challenges in Bioanalytical and Pharmacokinetic Assessment

Chris Macaraeg, Senior Associate Scientist, PKDM, Amgen

The future of large molecule therapeutics includes increasingly complex biologics with multiple target specificities. While there is an urgency to shorten discovery time, the complexity of these molecules creates additional bioanalytical challenges. Multiple ligand binding assays are necessary to fully assess their pharmacokinetic properties, determine their functional activities and identify potential biotransformation. The presentation will focus on the bioanalytical challenges associated with these multi-specific molecules and present case studies where different approaches were used to overcome these challenges.

9:05 PK Optimization of Bispecific DART Proteins for Clinical Use

Syd Johnson, Ph.D., Vice President, Antibody Engineering, MacroGenics, Inc.

Manufacturability, stability and pharmacokinetics have been challenges to effective development of bispecific antibodies for clinical use. We have developed and optimized several formats of our highly stable Dual-Affinity Retargeting (DART®) proteins that address these issues. Multiple examples will be presented of DART proteins approaching the clinic for oncology, autoimmunity or infectious disease applications. Challenges of nonclinical toxicology for these highly potent molecules in relevant species will also be discussed.

9:35 Testing Strategies for the Assessment of Bispecific T cell-engaging BiTE® Antibodies and Their Transition into the Clinic

Benno Rattel, Ph.D., Executive Director, Nonclinical Development ARM, AMGEN Research (Munich) GmbH

Bispecific T-cell engagers, commonly referred to as BiTE® antibodies, are comprised of two different flexibly linked single-chain antibodies, one directed against a tumor antigen and one targeting CD3. BITE® antibodies can transiently link tumor cells with resting polyclonal T-cells for induction of a surface target antigen-dependent re-directed lysis of tumor cells, closely mimicking a natural cytotoxic T-cell response. Strategies for nonclinical assessment and for defining a safe clinical starting dose, and lessons learnt in the clinic will be presented.

10:05 Sponsored Presentation *(Opportunity Available)*

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

pH-Dependent Binding Antibodies

11:10 Engineering of pH-Dependent Binding Antibodies for Improved Pharmacokinetics

Changshou Gao, Ph.D., Fellow, Antibody Discovery & Antibody Engineering, MedImmune

Antibody-mediated serum half-life extension of soluble antigens (antibody buffering) and receptor antigen-mediated antibody clearance can negatively impact antibody efficacy and increase the need for high dosing. Antibodies with pH-dependent binding can address both of these issues by offering decreased antibody buffering allowing better clearance of soluble antigens and reducing target-mediated clearance of receptor binding antibodies. We'll discuss different approaches to engineer pH-dependent mAbs for enhanced potency through improved pharmacokinetics.

11:40 PK Modeling of Sweeping Antibody; Antigen Sweeping Effect of Antibody with pH-Dependent Antigen Binding and Increased FcR Binding

Yuki Iwayanagi, Ph.D., Research Scientist, Preclinical Research, Chugai Pharmaceutical Co. Ltd.

Sweeping antibody with enhanced FcR-mediated cellular uptake of the antigen-antibody complex and pH-dependent endosomal antigen dissociation enables elimination of the antigen from plasma. Sweeping antibody provides novel approach to target antigens which was difficult to be targeted by conventional antibody. Using PK model analysis, we describe the antigen sweeping effect of sweeping antibody in comparison to conventional high affinity antibody.

12:10 pm End of PK/PD of Novel Constructs

HOTEL & TRAVEL

Conference Hotel:

Hyatt Regency Washington on Capitol Hill
400 New Jersey Avenue NW
Washington, DC 20001
Phone: 888-421-1442

Discounted Room Rate: $285 s/d

Discounted Room Rate Cut-off Date: October 14, 2013

Please visit our conference website or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

We realize that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block at the conference hotel allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

Flight Discounts:

Special discounts have been established with American Airlines for this conference.

- Call American Airlines 1-800-433-1790 and use Conference code 12N3AB.
- Go to www.aa.com/group and enter Conference code 12N3AB in promotion discount box.
- Contact our dedicated travel agent, Rona Meizler, at 617-559-3735 or rona.meizler@protravelinc.com.

Why Stay at The Hyatt Regency Washington on Capitol Hill?

- Steps from the Smithsonian and the National Mall
- Minutes from restaurants, museums, entertainment and the arts
- Complimentary wireless internet in attendee guest rooms
- Heated indoor lap pool
- Environmentally friendly – Green Seal certified

Car Rental Discounts:

Special rental discounts have been established with Hertz for this conference.

- Call Hertz 1-800-654-3131 and use our Hertz Convention Number (CV): 04KL0004
- Go to www.hertz.com and use our Hertz Convention Number (CV): 04KL0004

Sponsorship, Exhibit, and Lead Generation Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre and post-show delegate lists. Customizable sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on early will allow you to maximize exposure to qualified decision-makers!

Agenda Presentations

Showcase your solutions to a guaranteed, highly-targeted audience. Package includes a 15 or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding and access to cooperative marketing efforts by CHI.

Breakfast & Luncheon Presentations

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects. Evening will be customized according to sponsor's objectives i.e.:

- Purely social
- Focus group
- Reception style
- Plated dinner with specific conversation focus

Exhibit

Exhibitors will enjoy facilitated networking opportunities with high-level conference delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

***Inquire about additional branding opportunities!**

Looking for additional ways to drive leads to your sales team? CHI can help through:

Custom Lead Generation Programs:

- Targeted campaign promotion to unparalleled database of 800,000+ individuals in the life sciences
- Experienced marketing team promotes campaign, increasing awareness and leads

Live Webinars:

- Assistance in procuring speakers
- Experienced moderators
- Dedicated operations team to coordinate all efforts

Whitepapers:

- Industry recognized authors, with vast editorial experience, available to help write your whitepaper
- Host and promote one of your existing whitepapers

CHI also offers market surveys, podcasts, and more!

To customize your participation at this event, please contact:

Tim McLucas
Business Development Manager
781-972-1342 | tmclucas@healthtech.com

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2ND ANNUAL

PK/PD of Novel Constructs

Optimizing Bispecific Antibodies and ADCs

NOVEMBER 11-12, 2014
Hyatt Regency on Capitol Hill
Washington, DC

Pricing and Registration Information

	Commercial	Academic, Government, Hospital-affiliated
SUMMIT PRICING - BEST VALUE!		
Summit Pricing – Includes access to 4 conferences, excludes short courses.		
Advance Registration Discount until October 4, 2013	$2699	$1199
Registrations after October 4, 2013, and on-site	$2899	$1299
STANDARD CONFERENCE PRICING		
Standard Conference Pricing – Includes access to 2 concurrent conferences, excludes short courses.		
Advance Registration Discount until October 4, 2013	$1749	$849
Registration after October 4, 2013 and on-site	$1949	$979

Monday, November 11 - Tuesday, November 12	Tuesday, November 12 - Wednesday, November 13
(T1) Immunogenicity Assessment & Strategies	(T3) Immunogenicity Risk Assessment & Mitigation
(T2) PK/PD of Novel Constructs	(T4) Optimizing Bioassays for Biologics

SHORT COURSES		
One short course	$699	$399
Two short courses	$999	$699
Three short courses	$1299	$899

SC1: Basics of Immunogenicity Testing
Dinner SC2: Challenges of Immunogenicity Assessment
Dinner SC3: PK/PD Bioanalysis for Novel Biotherapeutics
Dinner SC4: Immunogenicity Risk Assessment and Regulatory Strategy
Dinner SC5: Developing Potency Assays to Ensure Successful Biologics

If you are unable to attend but would like to purchase the Immunogenicity Summit CD for $750 (plus shipping), please visit ImmunogenicitySummit.com. Massachusetts delivery will include sales tax.

CONFERENCE DISCOUNTS

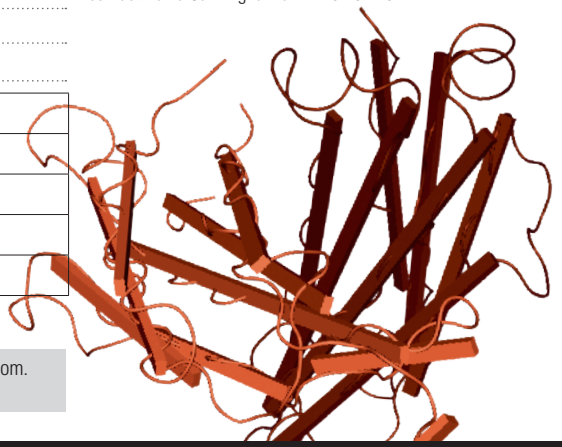
Poster Submission-Discount ($50 Off)
Poster abstracts are due by **October 16, 2013**. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com.

**CHI reserves the right to publish your poster title and abstract in various marketing materials and products.*

Alumni Discount SAVE 20%: Cambridge Healthtech Institute (CHI) appreciates your past participation at the Immunogenicity Summit. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

Register 3 - 4th is Free! Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472



How to Register: ImmunogenicitySummit.com

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Please use keycode MHP F when registering