Schedule at a Glance

Thursday, February 28
7:00 am – 8:00 am  Breakfast
8:00 am – 8:10 am  Welcome and Introductions
8:10 am – 8:55 am  Keynote Address
8:55 am – 10:25 am  Session 1: PreClinical Development
10:25 am – 10:40 am  Break
10:40 am – 12:30 pm  Session 2: Clinical Development
12:30 pm – 1:30 pm  Lunch
1:30 pm – 3:30 pm  Session 3: Case Studies in Protein Therapeutics
3:30 pm – 3:45 pm  Break
3:45 pm – 5:15 pm  Session 4: Industry and Academic Relationships in Biologic Development
5:15 pm – 6:30 pm  Reception

Friday, February 29
7:00 am – 8:00 am  Breakfast
8:00 am – 8:05 am  Welcome and Overview
8:05 am – 10:15 am  Session 5: Regulatory Strategies in the Global Arena
10:15 am – 10:30 am  Break
10:30 am – 12:00 pm  Session 6: Case Studies in Vaccines
12:00 pm – 1:00 pm  Lunch
1:00 pm – 2:40 pm  Session 7: Case Studies in Cellular Therapeutics
2:40 pm – 3:00 pm  Break
3:00 pm – 4:40 pm  Session 8: Case Studies in Gene Therapies
4:40 pm – 5:00 pm  Closing Comments

Thank You to Our 2008 Primer Supporters
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General Information

PRIMER OVERVIEW
iSBTc created the Oncology Biologics Development Primer (OBDP) to meet the needs of the biological therapy community by educating physicians and researchers on the worldwide regulatory paths for biological therapy development. Through facilitating collaborative interactions between regulators, preclinical scientists, clinical investigators and industry, the OBDP helped to ensure that active, innovative new therapies will be rapidly and appropriately moved into clinical testing.

The program was a key forum for continuing exploration and discussion of best practices for worldwide biologics development. Through the expertise of the invited speakers, panel members and course attendees, this rigorous and challenging program curriculum facilitated understanding, open discussion, and exploration of the development issues surrounding biologic agents for cancer.

INTENDED AUDIENCE
Physicians and scientists in academia, industry and regulatory agencies who have an interest in the strategic, preclinical, clinical and regulatory aspects of efficient oncology biologics development.

MEETING OBJECTIVES
- Provide a framework for dissemination of information for those actively involved in the development of biologic oncology therapeutics including discussion of new methodologies for best practices in preclinical testing and clinical trial design.
- Create a forum for dialogue among regulatory agencies, industry members and academic investigators regarding strategies for oncology biologics development.
- Encourage and enhance strategic thinking for oncology biologic therapeutics development by designing the preclinical and clinical development roadmap to achieve the desired goals.
- Gain an understanding of regulatory expectations and requirements in the development and approval process for oncology biologic therapeutics.

DESired OUTCOMES
- Understand where to find key informational resources and implement best practices regarding the development of oncology biological therapeutics.
- Form important relationships between regulatory agencies, industry members and academic investigators that result in effective strategies for oncology biologics development.
- Understand the concepts and processes for achieving the scientific and regulatory objectives by focusing both preclinical and clinical strategies to drive efficient development of oncology biologic therapeutics.
- Understand regulatory expectations and requirements and incorporate these ideas into the clinical trial design.
Program Schedule

Thursday, February 28

8:00 am – 8:10 am  Welcome and Meeting Introduction
Robert J. Zimmerman, SD – Zimmerman Consulting (Program Organizer)

8:10 am – 8:55 am  Keynote Address
Regulatory Overview of Oncology Biologics Product Development from Bench to First-in-Man
Raj Puri, MD, PhD – Food and Drug Administration

8:55 am – 10:25 am  Session 1: Preclinical Development
8:55 am  Cell and Gene Therapy Products for Cancer Treatment
Ying Huang, PhD – Food and Drug Administration, CBER
9:20 am  Biological Therapeutics for Cancer Treatment
Andrew J. McDougal, PhD, DABT – Food and Drug Administration, CDER
9:45 am  Principles of Preclinical Development and Validation of Molecular Markers/Biomarkers of Toxicity and Efficacy for Cancer Therapies
Samir Khleif, MD – National Cancer Institute, CCR
10:10 am  Developing Biologies for Phase I Trials: Manufacturing and Toxicology Challenges
Anthony R. Welch, PhD – National Cancer Institute

10:40 am – 12:30 pm  Session 2: Clinical Development
10:40 am  Phase I Design Issues: Surrogate Markers/Selecting Pts/Special Inclusion-Exclusion Criteria
Susan Jerian, MD – OncoRD, Inc.
11:20 am  Phase II and Beyond Issues
John M. Kirkwood, MD – University of Pittsburgh Cancer Institute
11:50 am  Good Clinical Research Practice – Working in the World of Regulated Research
Marta Fields – Amgen, Inc.

1:30 pm – 3:30 pm  Session 3: Case Studies in Protein Therapeutics
1:30 pm  Cytokines: Lessons from Single Digit Cytokines IL2, IL7
Crystal Mackall, MD – National Cancer Institute, Pediatric Oncology
1:50 pm  Cytokines: Lessons from Double Digit Cytokines IL12, IL18 and Counting
Michael T. Lotze, MD – University of Pittsburgh Cancer Institute
2:10 pm  Antibodies: CTLA4 Antagonist Therapy for Cancer
Rachel Humphrey, MD – Bristol Myers-Squibb Company
2:30 pm  Antibodies: CD40 Agonist Development for Cancer
Robert Vonderheide, MD, D.Phil – University of Pennsylvania, Abramson Family Cancer Research Institute
2:50 pm  Panel Discussion
Moderator: Susan Jerian, MD – OncoRD, Inc.

3:45 pm – 5:15 pm  Session 4: Industry & Academic Relationships in Biologic Development
3:45 pm  Academic Drug Development: Bench to First-in-Man without Industry
Elizabeth Jaffe, MD – Johns Hopkins University
4:00 pm  Industry Perspective: What Industry Expects from Academic Partnerships
David R. Parkinson, MD – Nodality Inc.
4:15 pm  Academic Perspective: Role of Tech Transfer in Academia and Common Out-Licensing Criteria
Chris Moulding – USC Stevens Institute for Innovation
4:30 pm  Panel Discussion
Moderator: Robert J. Zimmerman, SD – Zimmerman Consulting
Program Schedule

Friday, February 29

8:00 am – 8:05 am  
**Welcome and Overview**
Robert J. Zimmerman, SD – Program Co-Organizer

8:05 am – 10:15 am  
**Session 5: Regulatory Strategies in the Global Arena**

8:05 am  
EU Perspective on Regulatory Issues for Biologics  
Robert Charnas, PhD – Amgen, Inc.

8:40 am  
Japan Perspective on Regulatory Issues for Biologics  
Ken Takeshita, MD – Celgene Corporation

9:15 am  
Clinical Trial Design Issues for Combination Products and Combination Therapies  
Patricia Keegan, MD – Food and Drug Administration

9:45 am  
Panel Discussion  
Moderator: Robert J. Zimmerman, SD – Zimmerman Consulting

10:30 am – 12:00 pm  
**Session 6: Case Studies in Vaccines**

10:30 am  
Dendritic Cell Based Vaccines:  
Lothar H. Finke, MD – ARGOS Therapeutics

10:50 am  
Cancer Vaccines  
Frederic Lehmann, MD – GlaxoSmithKline Biologicals s.a.

11:10 am  
Nucleic Acid Based Vaccines  
Laurence Elias, MD – Geron Corporation

11:30 am  
Panel Discussion  
Moderator: Michael Lotze, MD – University of Pittsburgh Cancer Institute

1:00 pm – 2:40 pm  
**Session 7: Case Studies in Cellular Therapeutics**

1:00 pm  
Overview of Adoptive Transfer T Cell Therapy for Cancer  
Nicholas P. Restifo, MD – National Cancer Institute

1:20 pm  
NK Cell Therapeutics for Cancer  
Jeffrey Miller, MD – University of Minnesota

1:40 pm  
Adoptive T Cell Transfer of Regulatory T Cells for GVHD  
Carl H. June, MD – University of Pennsylvania

2:00 pm  
Mesenchymal Stem Cell Therapy with Prochymal™ for GVHD  
C. Randal Mills, PhD – Osiris Therapeutics, Inc.

2:20 pm  
Panel Discussion  
Moderators: Carl H. June, MD – University of Pennsylvania  
C. Randal Mills, PhD – Osiris Therapeutics, Inc.

3:00 pm – 4:40 pm  
**Session 8: Case Studies in Gene Therapies**

3:00 pm  
Oncolytic Viruses: Reovirus  
Matt Coffey, PhD – Oncolytics Biotech, Inc.

3:20 pm  
Gene Modified T Cell Therapy  
Michel Sadelain, MD, PhD – Memorial Sloan-Kettering Cancer Center

3:40 pm  
Adenovirus Vectors  
Sunil Chada, PhD – Introgen Therapeutics, Inc.

4:00 pm  
Panel Discussion  
Moderator: Mercedes Serabian, MS, DABT – Food and Drug Administration, CBER

4:40 pm – 5:00 pm  
**Closing Comments**
Robert J. Zimmerman, SD – Program Co-Organizer
## Primer Faculty

### Organizing Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Susan Jerian, MD *</td>
<td>OncoRD, Inc.</td>
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<td>Carl H. June, MD *</td>
<td>University of Pennsylvania</td>
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<td>Mercedes Serabian, MS, DABT</td>
<td>Food and Drug Administration, CBER</td>
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* Note: The faculty marked with an asterisk have indicated a financial relationship with Merck & Co., Inc., a supporter of this program.
US Reference Materials

CMC
   http://www.fda.gov/cber/gdlns/tnindcmc.htm

2. Instructions and Template for CMC Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs) (August 2003)
   http://www.fda.gov/cber/gdlns/cmcsomcell.htm

   http://www.fda.gov/cber/gdlns/retrogt1000.htm

4. Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (February 1997)

Pre-Clinical
1. Guidance for Industry: S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (July 1997; ICH)

   http://www.fda.gov/cber/gdlns/somgene.htm

Clinical
1. Gene Therapy Clinical Trials – Observing Subjects for Delayed Adverse Events (November 2006) - CBER Long-Term Follow-up for Gene Therapy Trials
   www.fda.gov/cber/gdlns/gtclin.html

2. Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (May 2007) - Oncology Endpoints (CDER)
   www.fda.gov/cder/guidance/7478fnl.htm

3. Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (May 1998)

4. FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (December 1998)
   http://www.fda.gov/cder/guidance/1484fnl.htm

5. Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (July 2005)
   http://www.fda.gov/cder/guidance/5541fnl.htm

6. Exploratory IND Studies (July 2006)
   http://www.fda.gov/cder/guidance/7086fnl.htm
US Reference Materials

Clinical (continued)

7. **AE (Adverse Event) Reporting – Improving Human Subject Protection** *(April 2007)*
   http://www.fda.gov/cber/gdlns/advreport.pdf

8. **Establishment and Operation of Clinical Trial Data Monitoring Committees** *(March 2006)*
   http://www.fda.gov/cber/gdlns/clintrialdmc.htm

GCP Reference Material

1. **Code of Federal Regulations Title 21 Part 312 – Investigational New Drug Application**

2. **Code of Federal Regulations Title 21 Part 50 – Protection of Human Subjects**

3. **Code of Federal Regulations Title 21 Part 54 – Financial Disclosure by Clinical Investigators**
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54


5. **International Conference on Harmonisation – E6 Good Clinical Practice; Consolidated Guidance**


7. **FDA Information Sheet: FDA Inspections of Clinical Investigators**

Regulatory

1. **Fast Track 2004**
   http://www.fda.gov/ceder/guidance/5645fnl.htm

2. **Phase I**
   http://www.fda.gov/ceder/guidance/clin2.pdf

3. **QT/QTc testing**
   http://www.fda.gov/ceder/guidance/6922fnl.htm

4. **Target Product Profile**
   http://www.fda.gov/ceder/guidance/6910dft.htm

5. **FDA – 1572 Form**
Regulatory (continued)


7. **3500 MedWatch Form** – The FDA Safety Information and Adverse Event Reporting Program

8. **3500A MedWatch Form**

9. **IND Meetings for Human Drugs and Biologics (FDA)**
   www.fda.gov/cder/guidance/3683.fnl.htm

    http://www.fda.gov/cder/guidance/2125fnl.htm

    http://www.fda.gov/Cder/guidance/5667fnl.htm
EU Reference Materials

European Legislation

1. EUDRALEX – The Rules Governing Medicinal Products in the European Union
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm

2. Regulation on Advanced Therapy

3. Updated Regulation on the EMEA and Pharmacovigilance

4. Updated Directive on Human Medicinal Products

5. Clinical Trials Directive

6. Directive on Investigational Medicinal Products and Importation


8. Orphan Medicinal Products

9. Criteria for Orphan Medicinal Products


11. Regulation on Pediatric Development


EU Reference Materials

European Legislation (continued)

14. **Volume 10 of Eudralex Devoted to Clinical Trial legislation**

Chapter I: Application and Application Form

1. **Guidance on Clinical Trial Application, Notification of Substantial Amendments and Declaration of the End of the Trial**

2. **Ethics Committee Application**
   [http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/12_ec_guideline_20060216.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/12_ec_guideline_20060216.pdf)

3. **Guidance on the EUDRACT Data Base**

Chapter II: Monitoring and Pharmacovigilance

1. **Guidance on Collection, Presentation and Verification of AE Reports from Clinical Trials**

2. **Guidance on EU Database on SUSARs**

Chapter III: Quality of Investigational Medicinal Products

1. **Good Manufacturing Practices**

2. **Annex 13 to Good Manufacturing Practices**

3. **EU Format for Manufacturing Authorization**

4. **GMP Status of Manufacturers in Third Countries**

5. **Guideline: Quality Requirements for Investigational Medicinal Products in Clinical Trials**
Chapter V: Additional Information

1. Content of Trial Master File and Archiving  

2. Q & A – Clinical Trial Documents  

3. Guidance on Investigational Medicinal Products for Clinical Trials  

Chapter VI: Legislation

1. Manufacture and Importation of Investigational Medicinal Products  

2. Marketing Authorization – Notice to Applicants  
   http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm

UK Links – MHRA and others

1. Electronic Medicines Compendium  
   http://emc.medicines.org.uk

2. Clinical Trials  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=101

3. Applying for a Clinical Trial Application  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=723

4. Maintaining a Clinical Trial Application  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=983

5. Making Clinical Trial Applications  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=1123

6. Additional Information  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=1177

7. Fees for Clinical Trials  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=1124

8. Forms for Clinical Trials  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=1125

9. Safety Reporting – Annual Safety Reports and SUSARs  
   http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=993
EU Reference Materials

General Information

1. **EudraPharm** – A source for all medicinal products in Europe

2. **Heads of Agencies**

3. **French Agency – AFSSAPS** *(English Language Link)*

4. **List of Ongoing Clinical Studies in France** *(in French)*
   [http://agmed.sante.gouv.fr/htm/5/repec/repec0.htm](http://agmed.sante.gouv.fr/htm/5/repec/repec0.htm)

5. **Medical Products Agency** *(Sweden site in English)*

6. **Danish Medicines Agency – Legislation** *(English)*

Guidelines

1. **Link to CHMP Efficacy and Safety Guidelines**

2. **Pharmacokinetics of Therapeutic Proteins**

3. **Evaluation of Anticancer Medicinal Products in Humans**

4. **Annual Safety Report Template** – an example
   [www.ucl.ac.uk/biomed-r-d/guides/guide_asrprep_submission.doc](http://www.ucl.ac.uk/biomed-r-d/guides/guide_asrprep_submission.doc)

5. **Radiation Protection**

6. **Radiation Protection – UK Specific Legislation**
   [http://www.corec.org.uk/applicants/docs/NHS_REC_Application_Form_v5_Content_Changes.doc](http://www.corec.org.uk/applicants/docs/NHS_REC_Application_Form_v5_Content_Changes.doc)

7. **EMEA – Guideline on Adjuvants in Vaccines for Human Use** *(January 2005)*

8. **EMEA – Guideline on Strategies to Identify and Mitigate Risks for First-in-Human Clinical Trials with Investigational Medicinal Products** *(July 2007)*
   The most recent official English translation of the industry “Bible” in Japan. The Pharmaceutical Affairs Laws have not changed substantially with respect to biologics since 2005.

2. **Commercialization of Pharmaceutical and Biologics Research: Regulations You Should Know** (*website*) - Contains links to Japanese language documents describing in fairly simple terms the preclinical and clinical regulations on biologics.

3. **Kitasato University-Harvard School of Public Health Symposium Home Page** (*website*) –
   Contains useful English and Japanese language slide presentations by various experts in the general field of pharmaceutical industry and drug development.
   [http://www.pharm.kitasato-u.ac.jp/biostatis](http://www.pharm.kitasato-u.ac.jp/biostatis)

4. **Biologics Forum** (*Japanese-language website*) – Group that hosts an annual meeting on biologics. Contains links to useful PowerPoint presentations in both English and Japanese.
Additional Reference Materials

Journal Articles, Papers, Editorials

1. Preclinical Safety Testing of Monoclonal Antibodies: The Significance of Species Relevance by Kathryn Chapman, Nick Pullen, Mark Graham and Ian Ragan

2. Safety Assessment of Biotechnology-Derived Pharmaceuticals: ICH and Beyond
   by Mercedes Serabian and Anne Pilaro
   [http://www.toxpath.org/stp_journal_archive/VOL%2027,%20NO%201,%20PART%20NA,%201999.PDF](http://www.toxpath.org/stp_journal_archive/VOL%2027,%20NO%201,%20PART%20NA,%201999.PDF)

3. Preclinical Development Strategies for Novel Gene Therapeutic Products
   by Anne Pilaro and Mercedes Serabian
   [http://www.toxpath.org/stp_journal_archive/VOL%2027,%20NO%201,%20PART%20NA,%201999.PDF](http://www.toxpath.org/stp_journal_archive/VOL%2027,%20NO%201,%20PART%20NA,%201999.PDF)

4. Use of Nontraditional Animals for Evaluation of Pharmaceutical Products by Abigail Jones
   Opinion piece. Published in: *Informa Healthcare*, 2006

5. Understanding and Applying Regulatory Guidance on the Nonclinical Development of Biotechnology-Derived Pharmaceuticals by David Snodin and Peter Ryle

   Published in: Elsevier’s *Clinical Reviews in Oncology Hematology*, 2007, pp 34-42.

7. Points to Consider Regarding Safety Assessment of Biotechnology-Derived Pharmaceuticals in Non-Clinical Studies (English Translation) by Takahiro Nakazawa, Shuichi Kai, Mutsufumi Kawai, Eiji Maki, Fumio Šagami, Hiroshi Onodera, Satoshi Kitajima and Tohru Inoue

8. Preclinical Safety Evaluation of Monoclonal Antibodies by Roly Foulkes


10. Phase I Trial Design for Solid Tumor Studies of Targeted, Non-Cytotoxic Agents: Theory and Practice by Parulekar W and Eisenhauer E

11. Non-Toxicity Endpoints in Phase I Trial Designs for Targeted, Non-Cytotoxic Agents by Korn E
Additional Reference Materials

Journal Articles, Papers, Editorials (continued)


Additional Reference Materials

Websites to Consider for Bench to Beside Development of New Agents

1. **Clinical and Translational Science Awards** (CTSA) is a national consortium funded through Clinical and Translational Science Awards to transform how clinical and translational research is conducted. [www.ctsaweb.org](http://www.ctsaweb.org).

2. **Developmental Therapeutics Program at the NCI/NIH** has a number of grants and contracts programs that provide support for various stages of new drug development from preclinical feasibility and toxicology support to the production of clinical grade reagents including IND filing assistance (Rapid Access to Interventional Development (RAID)) program. [www.dtpnci.nih.gov](http://www.dtpnci.nih.gov).

3. **Financial Conflict of Interest** is an increasingly important issue to consider when intellectual property is licensed to biotechnology or pharmaceutical companies for clinical development. The American Association of Medical Colleges (AAMC) provides guidelines for investigators that have been adopted by many Universities for use by University Conflict of Interest Committees that manage these conflicts. These guidelines can be found at: [www.AAMC.org/research/COI/](http://www.AAMC.org/research/COI/).

Other Resources *(as taken from the presentation of Dr. Raj Puri)*


5. **Summary ICH Workshop on Oncolytic Viruses and Future ICH Considerations Paper:** [www.ICH.org](http://www.ICH.org), Gene Therapy Discussion Group


2008 iSBTc Educational Program Preview

**Primer on Tumor Immunology and Biological Therapy of Cancer**

*October 30, 2008 ~ San Diego, CA*

This primer will provide a current overview of immunology as it applies to cancer etiology, biology and therapy. The target audience for this program is basic and clinical investigators from academic, regulator, and biopharmaceutical venues. The audience includes clinicians, researchers, students, post-doctoral fellows and allied health professionals.

**Topics to be Addressed:**
- Adoptive T Cell Therapy
- Anti-Angiogenic Therapies
- Antibody Therapy of Cancer
- Approach to Identification and Therapeutic Exploitation of Tumor Antigens
- Blocking Anti-T Cell Checkpoints
- Cytokines
- Immune Adjuvants
- Immune Monitoring of Cancer Immunotherapy
- Mechanisms of Immune-mediated Tumor Lysis
- T Reg Cells

**Program Objectives:**
- Provide a current overview of immunology as it applies to cancer etiology, biology, and therapy.
- Present in-depth concepts of cellular immunology and the host-tumor-immune system interactions.
- Present in-depth concepts of humorally-based immune therapies
- Present in-depth concepts of cytokine biology and role in cancer therapy
- Educate the audience regarding the foundation and methods for clinical trials of biologic / immunologic topics

**Expected Outcomes:** Attendees will learn the current status and the most recent advances in biologic therapies including cancer vaccines, vaccine adjuvants, host-tumor interactions and the role of the innate and adaptive immune systems in tumor immunology and therapy.

**Organizers:**
Patrick Hwu, MD ~ MD Anderson Cancer Center
Kim Margolin, MD ~ City of Hope

**Workshop on Inflammation in Cancer Development**

*October 30, 2008 ~ San Diego, CA*

This small group, interactive workshop will assemble thought-leaders in the field to discuss inflammation and its role in cancer with an expected results publication following the program.

**Meeting Features:**
Small group, interactive settings; Expert lectures; Breakout sessions; Held in conjunction with the iSBTc Annual Meeting

**Organizers:**
Lisa M. Coussens, PhD ~ University of California, San Francisco
Steve Dubinett, MD ~ University of California, Los Angeles
Michael Karin, PhD ~ University of California, San Diego
George Weiner, MD ~ University of Iowa
The iSBTc Annual Meeting facilitates exchange of the most cutting edge preclinical and clinical data on the use biological therapies in cancer between basic scientists and clinicians from academic, regulatory and industrial venues. This meeting will allow various investigators to share and build on their data, ultimately leading to better patient outcomes in cancer.

**Topics to be Addressed:**
- Adoptive Transfer
- Cancer Stem Cells and the Host Response
- Endpoints, Response Criteria for Clinical Trial Design
- Enhancing Cancer Vaccines
- Innate Immunity to Tumors
- TH-17, Cytokines and T Cell Subsets
- Tumor Escape / Tumor Microenvironment
- Tumor Targeting Monoclonal Antibodies

**Intended Audience:** The target audience for the Annual Meeting includes both basic and clinical investigators involved in cancer research comprising members of academic, pharmaceutical and regulatory agencies. Attendees will include basic scientists, clinicians, graduate students, and post-doctoral fellows, as well as other allied health professionals.

**Program Objectives:**
- Promote scientific exchange of most recent advances and data in the biological treatment of cancer, as well as advances in basic cancer biology with relevance for anti-tumor immunity
- Promote the generation of new ideas incorporating these advances and explore their potential for impact on treatment outcomes
- Discuss the latest clinical developments regarding application of biologic approaches and establish dialogue between academic, government, and industry regarding implications as well as future directions
- Educate and provide perspective to the audience on the broad range of scientific developments in cancer and biological approaches to therapy
- Discuss current approaches to immunological monitoring
- Discuss current regulatory guidelines and how they impact clinical trials as well as resource availability

**Organizers:**
- Thomas A. Davis, MD - Celldex Therapeutics, Inc.
- Thomas F. Gajewski, MD, PhD - University of Chicago
- William J. Murphy, PhD - University of Nevada
- Hideaki Tahara, MD, PhD - University of Tokyo

**Webinar**

“Primer on Tumor Immunology and Biological Therapy”

The free iSBTc webinar, “Primer on Tumor Immunology and Biological Therapy” is now available for viewing at the iSBTc website, www.isbtc.org, as well as for purchase on CD-ROM. This Primer provides an overview of tumor immunology and biological therapy by leaders in the field to educate viewers on both the biologic underpinnings of the field, as well as recent basic science and clinical developments. This webinar was created from the live program that was held in conjunction with the iSBTc 22nd Annual Meeting in Boston, MA.

The webinar consists of video-taped presentations by each speaker synchronized to their slide-set as it appeared during the program. This webinar will be available online through 2008. A CD-ROM of this program is available for a minimal fee. By purchasing the CD, you'll be able to keep this valuable tool and view it at anytime.

For more information about these upcoming iSBTc programs, please visit [www.isbtc.org](http://www.isbtc.org).
About iSBTc

The International Society for Biological Therapy of Cancer (iSBTc) was established in 1984 to facilitate the exchange and promotion of scientific information about the use of biological cancer therapies. The iSBTc defines biological cancer therapies as those based on host response mechanisms used to control or prevent tumor growth. The iSBTc is a 501 (c)(3) not for profit organization of medical professionals with a constituency of academic, government, industry, clinical, and basic scientists from around the world. The Society was founded on the belief that new systemic therapeutic treatments would continue to complement chemotherapies and move into the mainstream in the fight against cancer. To aid in this effort, iSBTc provides channels for the constructive discussion of current clinical trial results and methodologies, as well as a means to collaborate on new initiatives in tumor immunology and biological therapy. It is these key interactions and innovations that help advance the progress of cancer research and therapies and ultimately lead to better patient outcomes.

iSBTc Core Purpose
To improve cancer patient outcomes by advancing the development and application of biological therapy.

iSBTc Core Values
- **Interaction** – exchange of information and education among basic researchers and clinicians
- **Innovation** – development and application of biological therapy; seeking the best research and thinking related to the Society’s purpose and vision
- **Leadership** – defining what is new and important

**Disease States**
iSBTc programming and membership covers the full spectrum of both solid tumors and hematologic malignancies including:
- Breast
- Colorectal
- Head & Neck
- Hepatocellular
- Kidney
- Leukemia
- Lung
- Lymphoma
- Melanoma
- Neuroblastoma
- Ovarian
- Prostate
- Renal Cell

**Medical Specialties**
iSBTc members and delegates represent many areas of biological science including:
- Cell Biology
- Dermatology
- Genetics
- Gynecologic Oncology
- Hematology
- Immunotherapy
- Internal Medicine
- Medical Oncology
- Microbiology
- Molecular Biology
- Pediatric Oncology
- Pharmacology / Toxicology
- Radiation Oncology
- Radiology
- Stem Cell Biology
- Surgical Oncology
- Transplantation
iSBTc Leadership and Staff

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