

**U.S. AND EUROPEAN IMMUNOLOGISTS PUBLISH JOINT POSITION PAPER ON NEW INITIATIVE TO IMPROVE RELIABILITY AND INTERPRETATION OF DATA DERIVED FROM T CELL-BASED IMMUNE MONITORING ASSAYS**

*MIATA (Minimal Information About T cell Assays) Project Seeks Broad Participation and Consensus on the Construction of a Universally Accepted Reporting Framework*

(November 22, 2010 – New York, New York, USA, and Mainz, Germany). A joint position paper by researchers associated with the Cancer Immunotherapy Consortium of the Cancer Research Institute (CIC-CRI) and the Association for Cancer Immunotherapy (CIMT), describing the path toward successful generation of a broadly acceptable framework for reporting data from T cell immune assays, was published last week in the journal *Cancer Immunology, Immunotherapy*. In the paper, the authors outline current challenges in the reporting, analyzing, and comparing of immunological data derived from T cell assays, and describe a global initiative now under way to establish solutions to these challenges based on collaborative input from the international community of T cell assay experts across the fields of cancer immunology, autoimmunity, and infectious diseases.

The initiative, called the Minimal Information About T cell Assays (MIATA) Project and launched in October 2009, aims to achieve a broad consensus on which T cell assay parameters should be reported in scientific publications and to propose a mechanism for reporting these in a systematic manner. Such a framework would allow objective interpretation of data across laboratories. Currently, no universally accepted guidelines exist to facilitate a meaningful interpretation and comparison of data from these assays.

“Immune therapies, such as therapeutic cancer vaccines, have been conceptually attractive for many years,” explains Cedrik Britten, of the CIMT Immunoguiding Program and first author of the paper. “These therapies work by inducing tumor-specific T cells, so immunologists have regularly used T cell assays at all stages of clinical development to monitor their immunological effects in patients.” The problem, Britten says, lies in the difficulty to correlate T cell assay results with clinical events, and this has caused some to doubt the meaningfulness of such data.

Further challenges, Britten adds, stem from the heterogeneous performance characteristics of many of the underlying immune assays. “There are multiple methods and assay protocols to monitor the quality and quantity of antigen-specific T cell responses, many of which have been custom developed and utilized by single laboratories.” By establishing reporting standards, the MIATA working group proposes mechanisms that will facilitate comparison of results generated across institutions.

“MIATA promotes transparency at every level and proposes a user-friendly and technically precise framework to report results in scientific publications,” says Sylvia

Janetzki, coordinator for the CIC-CRI ImmunoAssay Proficiency Panel Program and co-author on the paper.

The MIATA Project focuses on five important variables known to influence the outcome of the three most commonly used T cell-based immune monitoring assays, namely ELISPOT, peptide-MHC multimer staining, and intracellular cytokine staining. The variables include: 1) how samples from the patient or donor are collected and handled; 2) how the assay is carried out; 3) how data from the assay is acquired and analyzed; 4) how results are evaluated and what their relationship is to the patient's health; and 5) how the laboratory environment operates in terms of quality controls, staff training, adoption of standard operating procedures, and auditing processes, among other factors.

The MIATA Project is patterned after similar, well-established minimal information frameworks for other biological research areas, including genome sequencing, flow cytometry, and protein functional evaluation. Many such guidelines are registered through the Minimal Information about Biological and Biomedical Investigations (MIBBI) portal ([www.mibbi.org](http://www.mibbi.org)) and have become standard requirements for publication in many scientific journals.

MIATA Project coordinators first announced their intent in a letter to the editors of the scientific journal *Immunity* published in the journal's October 16, 2009, online edition. The group has since posted a comprehensive draft document online ([www.miataproject.org](http://www.miataproject.org)), which has evolved over the past year based on community feedback via the Web site and from discussion at workshops and conferences.

**Reference Publications:**

C.M. Britten, S. Janetzki, et al. [Minimal information about T cell assays: the process of reaching the community of T cell immunologists in cancer and beyond](#). *Cancer Immunol Immunother.* Published online 15 Nov 2010.

Janetzki, Britten et al. MIATA: [Minimal Information About T cell Assays](#). *Immunity*, Volume 31, Issue 4, 527-528, 16 October 2009 .

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**About the Cancer Immunotherapy Consortium of the Cancer Research Institute**

The Cancer Immunotherapy Consortium (CIC), a program of the Cancer Research

Institute, is an international association of more than eighty pharmaceutical and biotechnology companies and academic institutions that share a common interest in immunotherapy research and development. CIC's mission is to improve patient care by making cancer immunotherapies part of the standard-of-care in oncology. CIC provides a platform that allows its stakeholders to advance the field by working together to achieve solutions to scientific and developmental challenges creating a single and powerful voice within the biomedical research community. From these collaborative, community-wide efforts, CIC has developed and published a number of landmark recommendations for practical solutions to key challenges in the field, including the development of new immune related response criteria and clinical trial endpoints for evaluation of cancer immunotherapy impact on patient health. Founded in 2002 as the Cancer Vaccine Consortium (CVC), CIC amended its name in early 2010 to represent more accurately the broader diversity of the many promising clinical developments in immune-based treatment of cancer beside vaccines, including monoclonal antibodies and other modulators of immunity. For more information, visit <http://www.cancerresearch.org/consortium>

#### **About the Cancer Research Institute**

The Cancer Research Institute (CRI), established in 1953, is the world's only non-profit organization that is dedicated exclusively to transforming cancer patient care by advancing scientific efforts that are leading to new and effective immune system-based strategies to treat, control, and prevent cancer. Guided by a world-renowned Scientific Advisory Council that includes four Nobel laureates and twenty-nine members of the National Academy of Sciences, CRI has invested nearly \$200 million in support of research conducted by immunologists and tumor immunologists at the world's leading medical centers and universities, and has contributed to many of the key scientific advances that have led to the recent explosion of interest in the potential for immunotherapy to change the face of cancer treatment. To accelerate the pace of progress in the field, CRI convenes and coordinates global collaborations among academics, industry scientists and decision makers, regulatory representatives, and health research associations focused on discovery, development, and refinement of new cancer immunotherapies. A founding visionary and scientific leader in tumor immunology, CRI is helping to shape the emerging field of immuno-oncology, and is ushering in a new era of medical progress to bring more treatment options to cancer patients sooner.

The Cancer Research Institute has one of the lowest overhead expense ratios among non-profit organizations, with more than 85 percent of its resources going directly to the support of its science, medical, and research programs. CRI meets or exceeds all 20 standards of the Better Business Bureau Wise Giving Alliance, the most comprehensive U.S. charity evaluation service, and has earned the GuideStar Exchange Seal, indicating our commitment to the transparency of our organizational information to donors, funders, those we serve, the public, and regulators. CRI has also received an 'A' grade for fiscal disclosure and efficiency from the American Institute of Philanthropy as well as

top accolades from other charity watchdog organizations. For more information, visit <http://www.cancerresearch.org>.

### **About the Association for Cancer Immunotherapy (CIMT)**

The Association for Cancer Immunotherapy (CIMT) is an information and education platform aiming to facilitate the development of new immunotherapies against cancer for the benefit of patients. CIMT was founded in 2002, and has its home office in Mainz, Germany. The association hosts the largest European expert meetings on cancer immunotherapy, publishes therapeutic guidelines and has established two topic-specific working groups: the CIMT Regulatory Research Party, focusing on the regulatory aspects of drug development, which has established itself as a partner for European regulatory authorities; and the CIMT Immunoguiding Program (CIP), which focuses on the quality control and harmonization of immunomonitoring assays. To reach its goals, CIMT closely cooperates with various partners, among them Cancer Research Institute's Cancer Immunotherapy Consortium (CRI-CIC). Visit [www.cimt.eu](http://www.cimt.eu) for more information.

### **About the CIMT Immunoguiding Program (CIP)**

CIP comprises a network of 45 actively participating laboratories across Europe. The main objective of CIP is to establish high quality immunomonitoring assays to guide development of new immune therapeutics. With this aim, CIP organizes large proficiency panels to reach quality control and harmonization of commonly applied T-cell assays across institutions. This is made possible due to significant support from a research grant from the Wallace Coulter Foundation (Miami, Florida, USA). So far, CIP has focused on the enumeration of antigen-specific T cells by ELISPOT as well as MHC multimer and intracellular cytokine staining by flow cytometry. Results of testing phases are published in peer-reviewed journals and guidelines are freely available on the association's homepage.

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