



CMI Techniques Standardization for Vaccine Responses Evaluation

Annecy, Les Pensières September 15-17, 2008

Background

Cell mediated immunity (CMI) is a critical component of the immunological responses contributing to the protection against many infections, cancer, and autoimmune diseases. The scientific community has faced and now recognize the limitations of vaccines approaches relying on antibody response only to confer protection against intracellular pathogens such as HIV and HCV. This has brought more attention on the role of CMI in the development of new vaccines. The recent emerging therapeutic vaccine field to fight cancer, as well as atopic or autoimmune diseases has further participated to the better understanding of the CMI role in protection.

Up to recently, major technical and logistical difficulties have prevented the vaccine Industry to implement solid and extensive CMI monitoring strategies for vaccine development. Most of the technologies were too complex, tedious and time consuming to be applied to thousand of samples. Those techniques also usually require fresh cells or other tissue samples in large quantities and were very difficult to standardized due to the technical as well as biological variabilities. Over the past 15 years, considerable progresses have been made in deciphering and understanding the cellular components and effector phases of the immune system. This together with the emergence of new and simplified technologies that can be automated, starting from sample preservation to the final read-outs, including sophisticated analysis software enable vaccine developers to work on standardization of the immunomonitoring assays and to reconsider the evaluation in the clinical phases of the cellular component of the immune response induced by their candidate vaccines.

The Mérieux Foundation is pleased to organize this meeting to focus on CMI monitoring for vaccine evaluation, covering new technology developments and standardizations and also touching automation and High Through Put Screening (HTS). The Foundation welcomes invited scientists, immunologists, vaccinologists, representatives from industry and international institutions to Les Pensières Conference Center, in Annecy, France, from the 15th to 17th of September 2008, to attend to "CMI Standardization techniques in evaluation of vaccine response". Its purpose is to give an update and discuss the current status of CMI technology standardization, evaluating progresses in the field, identifying the gaps that still need to be filled, and the potential of these new technologies for routine evaluation of the vaccine candidates requiring a cellular component.

The Conference's strategic objectives include:

- ⇒ **To review progresses and state of the art in technology development for monitoring CMI.**
- ⇒ **To focus the discussions on the needs for standardization to comply with ethical and regulatory requirements.**
- ⇒ **To foster dialogue among different actors of the scientific and decisional communities involved in CMI technology development and CMI monitoring of vaccine responses.**

Each speaker has been asked to specifically address one or more of these objectives in their presentation. There will be a professionally prepared report of the Conference's presentations and discussions including specific responses to the above objectives.

Monday, September 15th, 2008

17h30-18h30	► <i>Registration</i>	
18h30-18h45	Welcome Address	B. MIRIBEL
18h45-19h15	Keynote lecture: <i>Future of CMI monitoring in vaccine development</i>	M. DAVIS
19h45	► Welcome Dinner	

Tuesday, September 16th, 2008

SESSION I	State of the art in CMI technology development ► Chaired by: J. LOUIS ; M. DAVIS	
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08h30-08h50	<i>Human B cell response to vaccination</i>	M. SLIFKA
08h50-09h10	<i>Discussion</i>	
09h10-09h30	<i>Monitoring human memory T cells: what to measure and how to measure it</i>	P. CHATTOPADHYAY
09h30-09h50	<i>Discussion</i>	
09h50-10h10	<i>Measure of innate immunity</i>	E. VIVIER
10h10-10h30	<i>Discussion</i>	
10h30-11h00	<i>Coffee break</i>	
11h00-11h20	<i>Structural and functional assay to measure antigen specific CD8 T cell</i>	G. PANTALEO
11h20-11h40	<i>Discussion</i>	
11h40-12h00	<i>Microarray monitoring profiling</i>	R. SEKALY
12h00-12h20	<i>Discussion</i>	

12h20-14h00	Lunch	
SESSION II	Standardization: Regulatory and ethical Requirement ▶Chaired by: M. PFLEIDERER ; L. MARKOFF	
14h00-14h20	<i>Monitoring of CMI responses in early life</i>	A. MARCHANT
14h20-14h40	<i>Intracellular cytokine staining standardization</i>	M. JAIMES
14h40-15h00	<i>Results and harmonization guidelines from two large-scale international ELISPOT proficiency panels conducted by the CVC</i>	S. JANETZKI
15h00-15h30	Coffee break	
15h30-15h50	<i>Harmonization of T cell immunomonitoring within the CIMT Monitoring Panel- correct protocol choices and additional sources of variation</i>	C. BRITTEN
16h10-16h30	<i>Statistical analysis of CMI data</i>	Z. MOODIE
16h30-16h50	<i>FDA perspective on cellular assay standardization and validation</i>	L. MARKOFF
16h50-17h45	Panel Discussion	
19h00	▶ Dinner	

WEDNESDAY, September 17th, 2008

SESSION III	CMI Evaluation in Vaccine Development ▶Chaired by: M. SZTEIN , B. AUTRAN	
08h30-08h50	<i>CMI evaluation in Dengue vaccine development</i>	B. GUY
08h50-09h10	Discussion	
09h10-09h30	<i>Correlates of protection in the elderly: Measures of the cellular response to influenza vaccination</i>	J. Mc ELHANEY
09h30-09h50	Discussion	
09h50-10h10	<i>Correlation between tumor regression and T cell response in cancer vaccination</i>	P. COULIE
10h10-10h30	Discussion	
10h30-11h00	Coffee break	
11h00-11h20	<i>Monitoring cellular immunity induced by vaccination against Tuberculosis</i>	W.HANEKOM
11h20-11h40	Discussion	

11h40-12h00	<i>Measure of cellular immune response in HIV clinical trials</i>	B. AUTRAN
12h00-12h20	<i>Discussion</i>	
12h20-14h00	►Lunch	

SESSION IV	Looking in the Future: Enabling Technology, automation and HTS ►Chaired by: Gil BERNARD ; Tobias KOLLMANN	
14h00-14h20	<i>ImmunID: B and T cell repertoire analysis: a biomarker of treatment efficiency</i>	N. PASQUAL
14h20-14h40	<i>Discussion</i>	
14h40-15h00	<i>In Vitro Biomimetic Human Immune System Models: MIMIC System</i>	W. WARREN
15h00-15h20	<i>Discussion</i>	
15h20-15h40	<i>A novel multiparametric flow cytometry-based cytotoxicity assay simultaneously immunophenotype effector cells</i>	AD. DONNENBERG
15h40-16h00	<i>Discussion</i>	
16h00-16h20	<i>New insights into mathematical modelling of the immune system</i>	C. CHAN
	<i>Discussion</i>	
16h20	►End of the meeting Coffee	