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TRAINING-WORKSHOP
ON EFFECTIVE TRANSLATION OF VACCINE R&D

1-day training in frame of the IPA SIIF-funded project "Becoming entrepreneurial: Knowledge transfer from the University of Rijeka Faculty of Medicine to the biotechnology business sector"

15 October 2013
Lecture hall, Faculty of Medicine, Rijeka

PROGRAMME

08:45 – 09:00	Opening words: **Prof. Dr. Stipan Jonjić**
09:00 – 09:30	**Prof. Dr. William J Britt** *University of Alabama at Birmingham, USA* "Congenital CMV infection - neuroinvasion as an argument in favour of a live CMV vaccine"
09:30 – 10:15	**Prof. Dr. Martin Messerle** *Hannover Medical School* "Generation of CMV-based vaccine vectors - Strategies and Challenges"
10:15 – 11:00	**Prof. Dr. Stipan Jonjić** *University of Rijeka Faculty of Medicine (MEDRI)* "What have we learnt so far using MCMV and HCMV expressing NKG2D ligands as vaccine vectors?''
11:00 – 11:30	Coffee break
11:30 – 12:45	**Round table & brainstorming with the IPA project team members: Clinically oriented R&D at MEDRI , part I** **Participants:** *Hannover Medical School (Prof. Dr. Martin Messerle)* *Institute of Immunology, Zagreb (Prof. Dr. Sabina Rabatić)* *Center for Research and Knowledge Transfer in Biotechnology of the University of Zagreb (Dr. Beata Halassy, Dr. Maja Šantak)* *Clinical Hospital Centre Rijeka (TBD)* Key questions: Is clinically oriented R&D at MEDRI possible? What requirements (including ethical) must be satisfied? What are the necessary steps for the translation of the CMV vector towards the clinics? Is clinically oriented R&D at MEDRI necessary? What are the experiences of the local hospitals and public health institute in this regard? What experiences can be shared by a national vaccine manufacturer?
12:45 – 13:30	**Prof. Dr. Ulrich Kalinke** *TWINCORE – Centre for Experimental and Clinical Infection Research, Hannover* "In the aftermath of TGN1412: new preclinical approaches for the assessment of mAb and vaccine function"
13:30 – 14:30	Lunch
14:30 – 16:00	**Round table & brainstorming with the IPA project team members: Clinically oriented R&D at MEDRI, part II**

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OVERALL OBJECTIVES

- ***to increase the capacity*** *of University of Rijeka Faculty of Medicine (MEDRI) for conducting R&D activities that meet the needs of the biotechnology industry*
- ***to acquire specific knowledge*** *essential in supporting the health care system and its users*

KEY QUESTIONS

What are the technological requirements for vaccine development at MEDRI?

How to define the applicability of herpesviral vectors in clinical medicine?

How to perform risk assessment in regards to clinical trials design?

How to draft the strategies for development of live recombinant vaccines in accordance with the clinically approved protocols?

TRAINING STRUCTURE

- *Morning session on possible strategies for implementation of vaccine R&D in preclinical settings*
- *Afternoon session defining specific strategic directions for the Center for Proteomics with the Round table*

BACKGROUND TO THE TRAINING-WORKSHOP

The most successful vaccines used in the human history have been based on live-attenuated microbes. Effective vaccines against several relevant human pathogens are still missing. Moreover, for some pathogens, full protective immunity is not achieved even after natural infection, which means that an effective vaccine needs to induce immune response that is superior to the one induced by natural infection. **Cytomegaloviruses (CMVs), members of the herpesvirus family, have several properties that suggest their utility as suitable vaccine vectors.** After infection, CMVs remain attenuated, but permanently present in their hosts. In addition, they possess a large DNA genome, allowing the accommodation of a large number of foreign genes.

The research team involved in this action has generated a recombinant CMV vaccine in collaboration with the partner institution (MHH). It expresses RAE-1γ, a ligand for activating immune receptor, instead of the viral protein which would normally prevent the RAE-1γ expression. This recombinant virus was profoundly attenuated *in vivo* and has tremendous potential for enhancing the efficiency of T cell response (Slavuljica et al, ***J Clin Invest.*** **2010**). The expression of vectored antigens of several relevant pathogens in the context of recombinant CMV resulted in their improved immunogenicity and enhanced antigen-specific T cell responses, thus suggesting that highly attenuated recombinant herpesviruses can be used as suitable vaccine vectors. The further aim is to **develop a human analogue of the recombinant virus and to take one step forward toward the clinical studies**.

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THE PROJECT IN BRIEF

Croatia is faced with extremely low levels of transformation of scientific discoveries into innovations to be further exploited by the biotechnology industry. In collaboration with Hannover Medical School and eight associate institutions, the group of Prof. Stipan Jonjic from the University of Rijeka Faculty of Medicine is implementing an IPA-funded action focused around two strategic projects, vaccine vectors and antibodies, which target reliable therapeutic and diagnostic tools for protection against pathogens of major public health significance. The action should help bridge the gap between pre-commercial and commercial stages of research and promote the University of Rijeka as a leading innovator in the Croatian public R&D sector.

Croatia has been lagging behind the EU and other developed countries with respect to translation of biomedical research results generated at academic institutions into the commercial sector. This weakness results in brain drain and low motivation of young researchers for pursuing careers in the life sciences, insufficient usage of resources available at basic research institutions, limited R&D in the existing industrial sector and weak level of competitiveness on the international market.

The aim of this project is to improve **innovation capabilities** of the University of Rijeka Faculty of Medicine (MEDRI) through utilization of its potential for applied research **towards biotechnology industry needs**. In collaboration with the partner institution, Hannover Medical School, and eight associates from the Croatian and the EU academia and industry, MEDRI is implementing two strategic projects which will serve as a knowledge transfer and commercialization spring board.

For the first one, the ultimate goal is the development of a **prototype of a vaccine vector platform based on a live attenuated herpes virus**. Its relevance draws from the huge global demand for new and efficient approaches in designing vaccines to various pathogens and tumours.

The second strategic project should result in the acquired **commercialization know-how for the existing unique collection of antibodies** as well as different antibody-related services. These antibodies represent indispensible research tools for the scientific community and biotechnological industry and at the same time potential targets for diagnostic and therapeutic applications.

Applied R&D activities are in this action complemented by **training sessions and secondments** to associate institutions. At the same time, the action strives to increase the number of partnerships of MEDRI with the innovative biotechnology companies as well as enhance its visibility, through various **dissemination and networking activities** targeting both the scientific community and the general public, which will on the long run benefit from the generated healthcare products, vaccine platform and antibodies services and bank.

The project is funded by IPA III C SIIF (Science Investment and Innovation Fund) in the amount of EUR 439.951, from 2013 to 2015. The project web-site is: http://www.siif-croatia.com/en/osobne-karte-projekata/medicinski-fakultet-u-rijeci.