TABLE OF CONTENTS

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INTRODUCTION

A growing number of medicines are based on biological molecules such as proteins and monoclonal antibodies. These novel drugs have resulted in new, more effective treatments for a number of serious conditions. Yet sometimes these medicines trigger a response from the patient's immune system, which can decrease the effectiveness of the drug or cause severe side effects.

The aim of the IMI-founded ABIRISK project **"Anti-Biopharmaceutical Immunization: Prediction and Analysis of Clinical Re to Minimize the Risk",** is to shed new light on the factors behind this immune response. The project, which represents the first concerted effort to solve this problem, officially kicked off March 1st, 2012. ABIRISK project will aid in the creation of new, safer **biopharmaceuticals (BPs)** and also generate tools to determine how individual patients are likely to respond to them both in clinical trials and after release to the market.

The ABIRISK consortium (presently made up of thirty-five partners, twenty-four of which are academic institutions, nine are EFPIA member companies and two are small and medium enterprises, with thirteen countries represented), has been designed to meet all of these requirements in order to target three types of disorders: **Hemophilia A, Multiple sclerosis and Inflammatory diseases: inflammatory rheumatisms (including rheumatoid arthritis) and inflammatory bowel diseases.**

ABIRISK Project will collect data both retrospectively from patients suffering from various types of diseases and treated with various BPs at European centers with a high level of experience in clinical research and will prospectively recruit additional patients in dedicated studies during the 5 years of this program. Guidelines and Standard Operating Protocols for the study of anti-drug immunization will be established and used to standardize the collection of prospective data from these patients.

ABIRISK Project thus represents a unique opportunity to create an interdisciplinary task force of clinical centers especially designed to study immune responses against biopharmaceuticals.

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WELCOME

Dear Reader,

We would like to welcome you to the January 2015 the **ABIRISK Scientific Newsletter**. The Scientific Newsletter gives you a monthly update on the most relevant literature related to ABIRISK topics published around the globe, both inside and outside ABIRISK consortium.

This month, we chose to highlight a review by Pandey and Sauna on the potential use of pharmacogenetic factors in the predicting and circumventing unwanted therapeutic protein immunogenicity.

In addition, you will find in this issue some regulatory news on biopharmaceuticals

We look forward to your visit on **ABIRISK** website for more information and updates on the program.

Enjoy reading !

Best wishes

The ABIRISK management team

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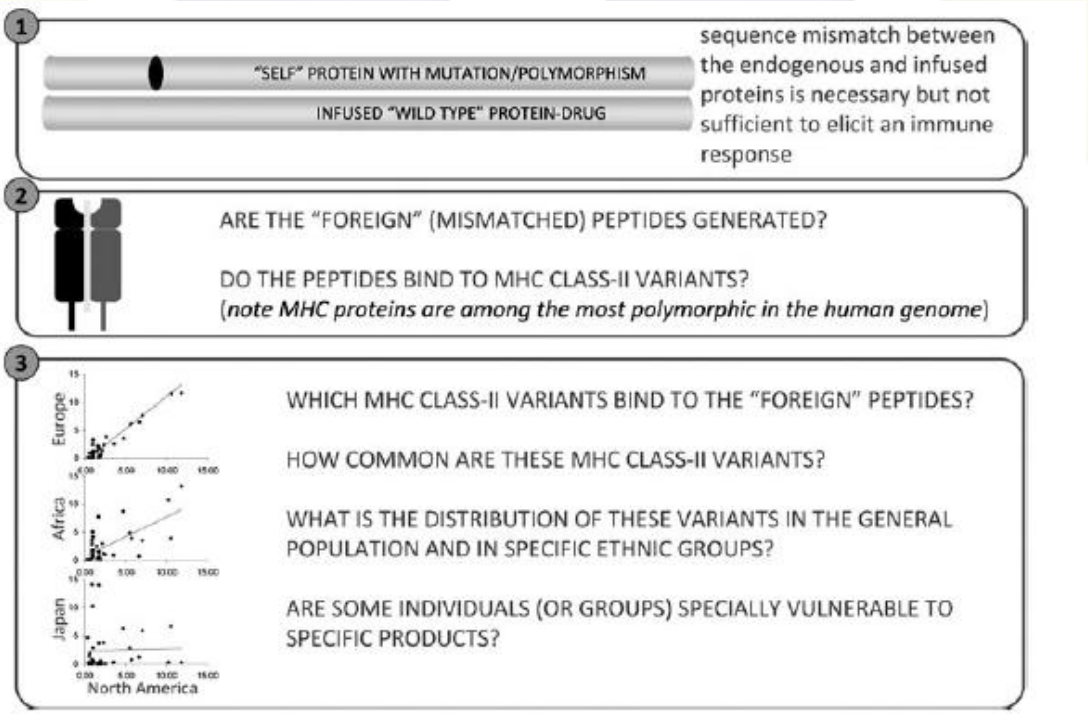
LITERATURE

This month's selected article

In this review, Pandey and Sauna discuss potential pharmacogenetic determinants of immunogenicity, how these can be measured, and also present clinical examples in the field of Haemophilia where such pharmacogenetic approach to predicting and circumventing immunogenicity may prove to be useful.

Three main pharmacogenetic criteria are highlighted: 1) the sequence homology between the endogenous protein and its therapeutic counterpart; 2) the number of MHC class II binding epitopes that can be derived from the therapeutic protein; 3) the presence of a functional CD4 T cell repertoire specific for those epitopes in one taken individual :



All these parameters are measurable and taken together should allow the tailoring of therapeutic protein with reduced immunogenicity and/or the identification of patient populations at higher risk of developing unwanted immunogenicity and resistance to treatment

Pharmacogenetics and the Immunogenicity of Protein Therapeutics.
Pandey GS, Sauna ZE.
J Interferon Cytokine Res. 2014 Dec;34(12):931-937.

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Revision: 18, Authorised
December 2014

Human medicines European public assessment report (EPAR): Humira, adalimumab
Revision: 37, Authorised
December 2014

Human medicines European public assessment report (EPAR): Cimzia, certolizumab pegol
Revision: 12, Authorised
December 2014

Opinion/decision on a Paediatric Investigation Plan (PIP): Benlysta, belimumab
Therapeutic area: Immunology-Rheumatology-Transplantation
Updated
December 2014

Public summary of the evaluation of a proposed paediatric investigation plan: Belimumab for treatment of systemic lupus erythematosus
December 2014

Opinion/decision on a Paediatric Investigation Plan (PIP): Turoctocog alfa pegol
Therapeutic area: Haematology-Hemostaseology
Updated
December 2014

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Opinion/decision on a Paediatric Investigation Plan (PIP): Voncento, Human coagulation factor VIII / von Willebrand factor
Therapeutic area: Haematology-Hemostaseology
Updated
December 2014

Opinion/decision on a Paediatric Investigation Plan (PIP): tabalumab
Therapeutic area: Immunology-Rheumatology-Transplantation
Updated
December 2014

Overview of comments received on draft guideline on similar biological medicinal products
December 2014

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