



EXTERNAL NEWSLETTER

ISSUE 7 - SEPTEMBER 2014

WWW.ABIRISK.EU

Dear colleagues, dear friends and supporters of ABIRISK,

we are pleased to present you the seventh issue of the external newsletter of **Anti-Biopharmaceutical Immunization: prediction and analysis of clinical relevance to minimize the risk -ABIRISK- Project.**

ABIRISK External Newsletter will be filled with interesting information mainly for all groups external to the ABIRISK consortium that may have an interest in our research and progress.

Please don't hesitate to forward this mail to anyone who could also be interested in reading it. If they want to receive their own newsletter in the future they can write at newsletter@abirisk.eu. If you're not interested in receiving our newsletter anymore, you can unsubscribe via mail.

In order to contribute to the contents of the newsletter, please send news, photos and other material related to ABIRISK areas of research at newsletter@abirisk.eu

We hope you will enjoy reading our latest news.

Best regards,
The ABIRISK management team

THE ABIRISK PROJECT

ABIRISK is an Innovative Medicine Initiative 3rd Call project on Anti-Biopharmaceutical Immunization. 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** 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.

ABIRISK Project aims to provide an integrated approach to **anti-drug immunization**, bringing together, in an extensive and coordinated manner, a large network of clinicians from various specialties with broad experience in the care of patients treated with various type of **biopharmaceutical products** developing **anti-drug antibodies**, biologists familiar with the immune monitoring of patients, scientists specialized in the mechanisms of immunogenicity, methodologists and biostatisticians. In addition the collaboration with a large network of private pharmaceutical industries under the European Federation of Pharmaceutical Industries and Associations (EFPIA), will ensure direct transfer of the experimental findings into **biopharmaceutical product** development and patient management. Collectively, this group will critically evaluate the immunogenicity of existing **biopharmaceutical products** for **Hemophilia A, Multiple Sclerosis, and Inflammatory Diseases**. The **ABIRISK consortium**, constituting unique task forces for each of these complementary contributions, should improve our ability to predict immunogenicity and to minimize the risk of immunization against **biopharmaceutical products**.

The **ABIRISK project** consortium is presently made up of **thirty-eight partners, twenty-six** of which are **academic institutions, nine are EFPIA member companies** and **three** are small and medium enterprises (**SMEs**). Thirteen countries are represented: The United Kingdom, France, Italy, Germany, Switzerland, Denmark, Belgium, the Netherlands, Spain, Sweden, Austria, Israel and Czech Republic.

The consortium is co-ordinated by GlaxoSmithKline (Dr. Daniel Sikkema, Project coordinator) and Institut National de la Santé et de la Recherche Médicale (INSERM; Prof. Marc Pallardy, Managing entity), and will receive over €30 million funding over 5 years from 1st March 2012.

The list of ABIRISK partners and more information on the project can be found on the website (www.abirisk.eu)



The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° [115303], resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.
www.imi.europa.eu

PROJECT NEWS

SEVENTH EDITION OF MARTIN VILLAR HAEMOSTASIS AWARD 2014 (GRIFOLS SCIENTIFIC AWARD)

We have the pleasure to announce that the publication "**Development of inhibitory antibodies to therapeutic factor VIII in severe hemophilia A is associated with microsatellite polymorphisms in the HMOX1 promoter**" by Repesse Y et al. *Haematologica*. 2013; 98(10):1650-55 has been granted the Martin Villar Haemostasis Award 2014 - Clinical Research Prize - (Grifols scientific award).

The Martín Villar Haemostasis Awards aim to recognize the value of young investigators who have devoted their activities to basic or clinical research on hemostasis and blood coagulation disorders.



By rewarding best published scientific work, the program aims to encourage further studies in this field (www.martinvillar-awards.com).



Grifols is a global healthcare company with a 70-year legacy of improving people's health and wellbeing through the development of life-saving plasma medicines, diagnostics systems, and hospital pharmacy products (www.grifols.com).

The work has been conducted in the frame of the **ABIRISK consortium by the groups of Sébastien Lacroix-Desmazes, ABIRISK Partner 2 Institut National de la Santé et de la Recherche Médicale - INSERM, Paris, France, in collaboration with the group of Johannes Oldenburg, ABIRISK Partner 14 Universitaetsklinikum - UKB, Bonn, Germany.**

The authors have identified for the first time polymorphisms in the heme oxygenase-1-encoding gene (HMOX1) promoter that are associated with the development of factor VIII (FVIII) inhibitors in hemophilia A patients. Development of inhibitors against FVIII occurs with a prevalence of 30% and represents the major complication of the disease as inhibitors block the activity of FVIII making the replacement therapy with FVIII concentrates ineffective. In their study, the authors identified 6 genotype repeats of which the genotype group including L alleles was found more frequent among inhibitor patients than in non-inhibitor patients. This important finding represents a step forward towards the approach of reducing the risk for inhibitor development in hemophilia patients.



ABIRISK 2014 Steering Committee Meeting

On the 30th September and 1st October 2014, the **2014 Steering Committee Meeting of ABIRISK Project** was held in Copenhagen (Denmark) at the Hotel Crowne Plaza Copenhagen Towers. The meeting was organized by **ABIRISK Partner 35 Novo Nordisk A/S**.

ABIRISK 2014 Steering Committee Meeting was organized mainly for the Principal Investigators of the project and about 40 participants attended the meeting in Copenhagen.

The meeting started with the Work Packages (WPs) and Cohort Leaders meetings. The scope of these subgroup meetings was to revise the scientific objectives and the scientific status of the different WPs. The second day of the meeting started with the presentation of **Peter Hecht** (Sanofi-Aventis Deutschland GmbH; **Scientific Coordinator of the IMI project "Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes" – IMIDIA**) titled **"How to finalize an IMI programme"**. The presentation of Peter Hecht was focused on the aims, management organization and major achievements obtained by the **IMIDIA Project**. Peter Hecht presentation was followed by the Steering Committee meeting. The Steering Committee meeting was mainly focused on the presentation of the scientific achievements reached in the period as well as on the plan for the next phase of the project.



ABIRISK presented at key immunogenicity meetings

Bernard Maillère (ABIRISK Partner 5 Commissariat à L'Energie Atomique et aux Energies Alternatives - CEA) has been invited to present the progress of the ABIRISK Project to the **2014 International Bioanalytical Congress - Section Immunogenicity for Biologics** (Maritim proArte Hotel, Berlin, Germany, September 9-10 2014).



The International Bioanalytical Congress has provided a huge and genuine platform for the leaders and peers of the industry to gather and discuss on the latest innovations and discoveries made in the field. The conference has also promoted products and services to the audience scientists working in assay development, biophysical analysis, and stability testing and method validation.

UPCOMING EVENTS

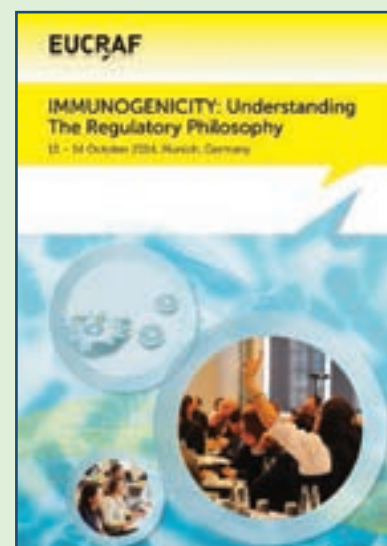
OCTOBER

IMMUNOGENICITY: Understanding The Regulatory Philosophy

Following its inaugural introduction in 2012, EUCRAF is proud to announce its **2nd workshop on Immunogenicity** taking place in **Munich, Germany on October 13 - 14, 2014.**

The central theme of this workshop is understanding the regulatory philosophy that will specifically examine topics on how to comply and fulfill regulatory expectations for presentation of information required to mitigate immunogenicity-related risks of biotherapeutics.

The aim of this 1.5-day interactive workshop is to discuss and clarify suitable approaches for satisfying regulatory expectations for presentation of the information required to enable a balanced assessment of risks of undesirable immunogenicity.



RECENT PUBLICATIONS GENERATED BY ABIRISK PARTICIPANTS OUTSIDE THE PROJECT

HLA alleles as biomarkers of high-titre neutralising antibodies to interferon- β therapy in multiple sclerosis.

Núñez C, Cénit MC, Alvarez-Lafuente R, Río J, Fernández-Arquero M, Arroyo R, Montalbán X, Fernández O, Oliver-Martos B, Leyva L, Comabella M, Urcelay E.
J Med Genet. 2014 Apr 19

Tocilizumab in the Treatment of Rheumatoid Arthritis: A Cost-Effectiveness Analysis in the UK.

Diamantopoulos A, Finckh A, Huizinga T, Sungher DK, Sawyer L, Neto D, Dejonckheere F.
Pharmacoeconomics. 2014 May 23

Development of a Universal Anti-Adalimumab Antibody Standard for Interlaboratory Harmonization.

Gils A, Vande Castele N, Poppe R, Van de Wouwer M, Compennolle G, Peeters M, Brouwers E, Vermeire S, Geukens N, J Declerck P.
Ther Drug Monit. 2014 Jun 5

Biomarkers in multiple sclerosis: an update for 2014.

Fernandez O, Martin R, Rovira A, Llufríu S, Vidal-Jordana A, Fernandez-Sanchez VE, Alvarez-Cermeno JC, Izquierdo G, Arroyo-Gonzalez R, Rodriguez-Antiguedad A, Casanova-Estruch B, Montalban X.
Rev Neurol. 2014 Jun 16;58(12):553-570

Unraveling Natalizumab Effects on Deregulated miR-17 Expression in CD4(+) T Cells of Patients with Relapsing-Remitting Multiple Sclerosis.

Meira M, Sievers C, Hoffmann F, Rasenack M, Kuhle J, Derfuss T, Kappos L, Lindberg RL.
J Immunol Res. 2014;2014:897249

Current and Future Therapies Targeting the Immune System in Multiple Sclerosis.

Loleit V, Biberacher V, Hemmer B.
Curr Pharm Biotechnol. 2014 Jun 16

Levels of Drug and Anti-drug Antibodies are Associated with Outcome of Interventions after Loss of Response to Infliximab or Adalimumab.

Yanai H, Lichtenstein L, Assa A, Mazor Y, Weiss B, Levine A, Ron Y, Kopylov U, Bujanover Y, Rosenbach Y, Ungar B, Eliakim R, Chowers Y, Shamir R, Fraser G, Dotan I, Ben-Horin S.

Clin Gastroenterol Hepatol. 2014 Jul 24

Adalimumab drug and antibody levels as predictors of clinical and laboratory response in patients with Crohn's disease.

Mazor Y, Almog R, Kopylov U, Ben Hur D, Blatt A, Dahan A, Waterman M, Ben-Horin S, Chowers Y.

Aliment Pharmacol Ther. 2014 Jul 15. doi: 10.1111/apt.12869.

Hypersensitivity Reactions to Biologic Agents.

Vultaggio A, Castells MC.

Immunol Allergy Clin North Am. 2014 Aug;34(3):615-632.

Th17 and Non-Classic Th1 Cells in Chronic Inflammatory Disorders: Two Sides of the Same Coin.

Cosmi L, Liotta F, Maggi E, Romagnani S, Annunziato F.

Int Arch Allergy Immunol. 2014 Jul 12;164(3):171-177.

ABIRISK COMMUNICATION TOOLS

PRESS RELEASE

Updating the original version generated by IMI Communication Office, **ABIRISK kick-off meeting fact sheet** has been created to promote ABIRISK project to broad audience mainly through institutional websites of ABIRISK partners, highlighting that the project has been started.

PROJECT BROCHURE

Official **ABIRISK Brochure** has been created and distributed to ABIRISK partners to disseminate information about the project in any suitable occasion (meetings, congresses, workshops, exhibition, shows or open forum, etc.) to broad audiences.

SCIENTIFIC NEWSLETTER

The **ABIRISK Scientific Newsletter**, an update on ABIRISK topics-related literature and international regulation, is sent to all consortium members and key opinion leaders in the different ABIRISK fields each month, posted on ABIRISK website and advertised on LinkedIn in several Immunogenicity-focused groups.



PROJECT WEBSITE

The main source for information on the project is ABIRISK website (www.abirisk.eu) where you will find the list of ABIRISK partners and their contact, more detailed information on the project, recent news on the project, all ABIRISK publications and press release, and the ABIRISK Scientific Newsletter.

ABIRISK WEBSITE has been visited by a monthly average of 980 people worldwide in the first 8 months of 2014!