



EXTERNAL NEWSLETTER

ISSUE 8 - DECEMBER 2014

WWW.ABIRISK.EU

Dear colleagues, dear friends and supporters of ABIRISK,

*we are pleased to present you the eighth 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 milion 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

ABIRISK Project Fourth General Assembly

On the **16th, 17th and 18th of March 2015**, the **Fourth General Assembly of ABIRISK Project** will be held in **Brussels (Belgium)** at Pfizer Limited Headquarter.

ABIRISK Fourth General Assembly will be organized only for the partners of the project and more than 100 participants are expected to attend the meeting in Brussels.

The meeting will start with ABIRISK Work Packages sub-meetings and the ABIRISK Executive Project Management Team. The first day of the ABIRISK General Assembly will start with the ABIRISK Steering Committee meeting followed by the update on main project successes, issues and challenges for the third year of the project, an update on activity around Hemophilia, data base demonstration, and an update on the clinical trials.

The second day of the ABIRISK General Assembly will be completely dedicated to science and it will start with the presentation of **Alessandro Sette (La Jolla Institute for Allergy & Immunology - CA - United States - ABIRISK Scientific Advisory Board Member)** titled **"Experimental and computational approaches to prediction of immunogenicity"**. Alessandro Sette presentation will be followed by two sessions of oral presentations as well as of poster sessions.

All scientific sessions will be focused on the most important scientific achievements obtained so far by the ABIRISK Consortium members. Amongst speakers, several young scientists will have the opportunity to present recent data generated by their belonging groups in the area of ABIRISK interests.



PROJECT NEWS

AMY LOERCHER (ABIRISK Partner 1 GlaxoSmithKline Research & Development Limited - GSK) has been invited to present the developments and challenges of the ABIRISK Project to the **Mastering Immunogenicity Conference 4 (British Consulate-General, Boston MA, USA, September 15-16 2014)**.

The 2014 Mastering Immunogenicity had the highest content of academic contributions of any meeting in this series. Particularly strong was the focus on mechanisms of immune tolerance and immune regulation.



PETER MILANOV (ABIRISK Partner 27 DRK-Blutspendedienst Baden-Württemberg - Hessen gemeinnützige GmbH - DRK-BSD) has been invited to present the ABIRISK Project to the **47th Annual Congress of the German Society for Transfusion Medicine and Immunohematology (Dresden, Germany, September 9-12 2014)**.



YANN GALLAIS (ABIRISK Partner 2 Institut National de la Santé et de la Recherche Médicale - INSERM) has been invited to present the ABIRISK Project to the **LabEx LERMIT Annual Symposium (Orsay, France, November 21 2014)**. LERMIT is an interdisciplinary laboratory composed of high-profile biologists, chemists and physico-chemists joining their forces to collectively explore new therapeutic avenues. LERMIT common goal is to combat three major classes of diseases presenting a continuous threat to the society: cancer, cardiovascular diseases, and infectious and immune diseases.



RECENT PUBLICATIONS GENERATED BY ABIRISK PARTICIPANTS OUTSIDE THE PROJECT

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

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.

Role of coagulation-associated processes on FVIII immunogenicity in a mouse model of severe hemophilia A.

Gangadharan B, Delignat S, Ollivier V, Gupta N, Mackman N, Kaveri SV, Lacroix-Desmazes S.
J Thromb Haemost. 2014 Sep 30.

Role for Therapeutic Drug Monitoring During Induction Therapy with TNF Antagonists in IBD: Evolution in the Definition and Management of Primary Nonresponse.

Papamichael K, Gils A, Rutgeerts P, Levesque BG, Vermeire S, Sandborn WJ, Castele NV.
Inflamm Bowel Dis. 2014 Sep 12.

Review of the novelties presented at the 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) (I).

Fernandez O, Alvarez-Cermeno JC, Arnal-Garcia C, Arroyo-Gonzalez R, Brieva L, Calles-Hernandez MC, Casanova-Estruch B, Comabella M, Garcia-Merino JA, Izquierdo G, Meca-Lallana JE, Mendibe-Bilbao MM, Munoz-Garcia D, Olascoaga J, Oliva-Nacarino P, Oreja-Guevara C, Prieto JM, Ramio-Torrenta L, Romero-Pinel L, Saiz A, Rodriguez-Antiguedad A, Grupo Post-Ectrims GP.
Rev Neurol. 2014 Sep 16;59(6):269-280.

The relationship between infliximab concentrations, antibodies to infliximab and disease activity in Crohn's disease.

Vande Castele N, Khanna R, Levesque BG, Stitt L, Zou GY, Singh S, Lockton S, Hauenstein S, Ohrmund L, Greenberg GR, Rutgeerts PJ, Gils A, Sandborn WJ, Vermeire S, Feagan BG.
Gut. 2014 Oct 21.

Prior response to infliximab and early serum drug concentrations predict effects of adalimumab in ulcerative colitis.

Baert F, Vande Casteele N, Tops S, Noman M, Van Assche G, Rutgeerts P, Gils A, Vermeire S, Ferrante M.
Aliment Pharmacol Ther. 2014 Oct 2.

Efficacy and safety of rituximab in elderly patients with rheumatoid arthritis enrolled in a French Society of Rheumatology registry.

Payet S, Soubrier M, Perrodeau E, Bardin T, Cantagrel A, Combe B, Dougados M, Flipo RM, Le Loët X, Shaefferbeke T, Ravaud P, Gottenberg JE, Mariette X.
Arthritis Care Res (Hoboken). 2014 Sep;66(9):1289-95.

Alemtuzumab: A new therapy for active relapsing-remitting multiple sclerosis.

Hartung HP, Aktas O, Boyko AN.
Mult Scler. 2014 Oct 24.

Molecular mechanism underlying the impact of vitamin D on disease activity of MS.

Munger KL, Köchert K, Simon KC, Kappos L, Polman CH, Freedman MS, Hartung HP, Miller DH, Montalbán X, Edan G, Barkhof F, Pleimes D, Sandbrink R, Ascherio A, Pohl C.
Ann Clin Transl Neurol. 2014 Aug;1(8):605-17.

Regulatory B cells are induced by gut microbiota-driven interleukin-1 β and interleukin-6 production.

Rosser EC, Oleinika K, Tonon S, Doyle R, Bosma A, Carter NA, Harris KA, Jones SA, Klein N, Mauri C.
Nat Med. 2014 Oct 19.

Personalized medicine in rheumatoid arthritis: is the glass half full or half empty.

Huizinga TW.
J Intern Med. 2014 Oct 14.

Natalizumab exerts a suppressive effect on surrogates of B cell function in blood and CSF.

Warnke C, Stettner M, Lehmsiek V, Dehmel T, Mausberg AK, von Geldern G, Gold R, Kümpfel T, Hohlfeld R, Mäurer M, Stangel M, Straeten V, Limmroth V, Weber T, Kleinschnitz C, Wattjes MP, Svenningsson A, Olsson T, Hartung HP, Hermsen D, Tumani H, Adams O, Kieseier BC.
Mult Scler. 2014 Nov 12.

Significant clinical worsening after natalizumab withdrawal: Predictive factors.

Vidal-Jordana A, Tintoré M, Tur C, Pérez-Miralles F, Auger C, Río J, Nos C, Arrambide G, Comabella M, Galán I, Castilló J, Sastre-Garriga J, Rovira A, Montalban X.
Mult Scler. 2014 Nov 12

UPCOMING EVENTS

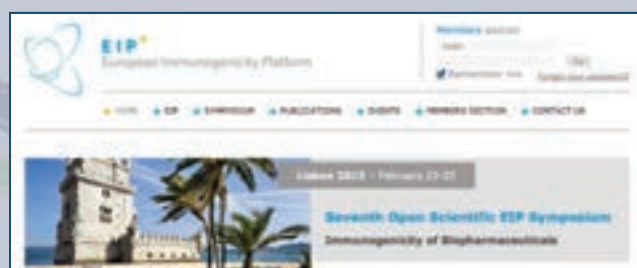
At the **2015 AAAAI Annual Meeting (Houston USA, February 20-24)**, it will be possible to earn CME/CE, learn about cutting-edge research and enrich the networking connections. Over thousands of allergist/immunologists, allied health and related healthcare professionals for five full days with hundreds of educational offerings on a variety of topics including: allergic disease; asthma; immunotherapy; food allergy and GI disease; skin disease; PIDD; practice management; new technologies; and health care reform.



Other features include:

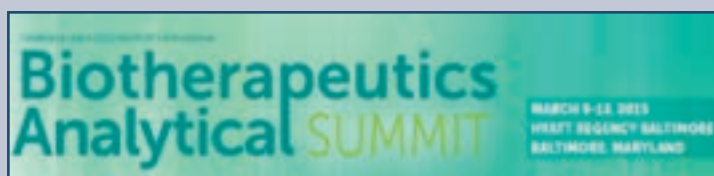
- Plenary Sessions, Keynote Talks and Symposia
- Poster Hall and Featured Poster Session
- Oral Abstract Sessions
- Seminars/ Problem-Based Workshops and interactive learning experiences
- Pro/Con Debates
- Exhibit Hall filled with the latest products and services

The **European Immunogenicity Platform, Lisbon 2015 – February 23-25**, acts as a central meeting place for European biopharmaceutical companies and scientific experts active in the field of immunogenicity.



Its scope is:

- Interaction with authorities regarding immunogenicity guidelines
- Formulate active recommendations regarding immunogenicity
- Stimulate research addressing the clinical and non-clinical effects of unwanted immunogenicity
- Collaboration between academia and pharmaceutical companies,



Comparability for Biologics, will present advances from leaders in the field on a wide range of analytical technologies together with their application for product characterization with the goal of making biotherapeutics that are well characterized, safe, efficacious and meet regulatory standards. The presentations cover a variety of biotherapeutics including ADCs, glycoproteins, mAbs and Non-mAb therapeutics, fusion proteins, and interferons.

The **6th annual Biotherapeutics Analytical Summit (March 9-13 2015, Baltimore, USA)**, a week-long event comprising 3 conferences and 5 short courses. The 3 conferences, focusing on Analytical Methodology and PTMs, Characterization & Compliance, and



The **9th World Immune Regulation Meeting**, will take place in Davos, Switzerland (**18 - 21 March 2015**) with special focus on Development and Maintenance of Immune Tolerance and Role of Tissues in Immune Regulation.

As ever, immune regulation is the hottest issue in basic and clinical sciences. With an outstanding list of speakers in this field, WIRM will become one of the key scientific event of the year 2015, being big enough to learn from other disciplines and small enough to personally meet the experts.

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 over
1000 people worldwide during 2014!**