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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 September 2016 issue of 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.

Each month we draw your attention to a selection of articles that we think make a difference in their respective fields.

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 articles

1. The first and elegant demonstration that depending of the type of the T cell response against therapeutic antibodies, tolerance, immunization or allergic reactions are achieved :

Circulating T cells to infliximab are mainly detectable in treated patients developing anti-drug antibodies and hypersensitivity reactions.
Vultaggio A, Petroni G, Pratesi S, Nencini F, Cammelli D, Milla M, Prignano F, Annese V, Romagnani S, Maggi E, Matucci A; ABIRISK Consortium.
Clin Exp Immunol. 2016 Aug 29.

2. A Large multicenter prospective randomised trial, with clinical and pathophysiological significant findings :

HLA-DRB1*11 and variants of the MHC class II locus are strong risk factors for systemic juvenile idiopathic arthritis.
Ombrello MJ, Remmers EF, Tachmazidou I, Grom A, Foell D, Haas JP, Martini A, Gattorno M, Özen S, Prahalad S, Zeft AS, Bohnsack JF, Mellins ED, Ilowite NT, Russo R, Len C, Hilario MO, Oliveira S, Yeung RS, Rosenberg A, Wedderburn LR, Anton J, Schwarz T, Hinks A, Bilginer Y, Park J, Cobb J, Satorius CL, Han B, Baskin E, Signa S, Duerr RH, Achkar JP, Kamboh MI, Kaufman KM, Kottyan LC, Pinto D, Scherer SW, Alarcón-Riquelme ME, Docampo E, Estivill X, Gül A; British Society of Pediatric and Adolescent Rheumatology (BSPAR) Study Group; Childhood Arthritis Prospective Study (CAPS) Group; Randomized Placebo Phase Study of Rilonacept in sJIA (RAPPORT) Investigators; Sparks-Childhood Arthritis Response to Medication Study (CHARMS) Group; Biologically Based Outcome Predictors in JIA (BBOP) Group, de Bakker PI, Raychaudhuri S, Langefeld CD, Thompson S, Zeggini E, Thomson W, Kastner DL, Woo P; International Childhood Arthritis Genetics (INCHARGE) Consortium.
Proc Natl Acad Sci U S A. 2015 Dec 29;112(52):15970-5

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Immunogenicity

Risks of inhibitors from recombinant Factor VIII: a quarter of a century to reach the conclusion.
Burnouf T, Strengers P.
J Thromb Haemost. 2016 Aug 6.

Inhibitor development in two cousins receiving full-length factor VIII (FVIII) and FVIII-Fc fusion protein.
Ragni MV, Alabek M, Malec LM.
Haemophilia. 2016 Aug 8.

TRUST trial: BAY 86-6150 use in haemophilia with inhibitors and assessment for immunogenicity.
Mahlangu J, Paz P, Hardtke M, Aswad F, Schroeder J.
Haemophilia. 2016 Aug 8.

Detection of anti-drug antibodies using a bridging ELISA compared with radioimmunoassay in adalimumab-treated rheumatoid arthritis patients with random drug levels.
Jani M, Isaacs JD, Morgan AW, Wilson AG, Plant D, Hyrich KL, Chinoy H, Barton A.
Rheumatology (Oxford). 2016 Aug 25.

Personalized therapy with TNF-inhibitors in Crohn's disease: optimizing treatment outcomes by monitoring drug levels and anti-drug antibodies.
Steenholdt C.
Dan Med J. 2016 Aug;63(8).

Secukinumab, a Fully Human Anti-Interleukin-17A Monoclonal Antibody, Exhibits Minimal Immunogenicity in Subjects with Moderate to Severe Plaque Psoriasis.
Reich K, Blauvelt A, Armstrong A, Langley RG, Fox T, Huang J, Papavassilis C, Liang E, Lloyd P, Bruin G.
Br J Dermatol. 2016 Aug 12

Key insights to understand the immunogenicity of FVIII products.
Goudemand J, Peyvandi F, Lacroix-Desmazes S.
Thromb Haemost. 2016 Aug 31;116(Suppl. 1):S2-S9.

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Methods

Storage Conditions of Conjugated Reagents Can Impact Results of Immunogenicity Assays.
Kubiak RJ, Lee N, Zhu Y, Franch WR, Levitskaya SV, Krishnan SR, Abraham V, Akufongwe PF, Larkin CJ, White WI.
J Immunol Res. 2016;2016:1485615.

Comparison of infliximab drug measurement across three commercially available ELISA kits.
Lee MW, Connor S, Ng W, Toong CM.
Pathology. 2016 Aug 23. pii: S0031-3025(16)39762-8.

Dextrose-mediated aggregation of therapeutic monoclonal antibodies in human plasma: Implication of isoelectric precipitation of complement proteins.
Luo S, Zhang B.
MAbs. 2015;7(6):1094-103.

Biosimilars

Comparative assessment of clinical response in patients with rheumatoid arthritis between PF-05280586, a proposed rituximab biosimilar, and rituximab.
Williams JH, Hutmacher MM, Zierhut ML, Becker JC, Gumbiner B, Spencer-Green G, Melia LA, Liao KH, Suster M, Yin D, Li R, Meng X.
Br J Clin Pharmacol. 2016 Aug 16.

Biomarkers

Integration of known DNA, RNA and protein biomarkers provides prediction of anti-TNF response in rheumatoid arthritis: results from the COMBINE study.
Folkersen L, Brynedal B, Diaz-Gallo LM, Ramsköld D, Shchetynsky K, Westerlind H, Sundström Y, Schepis D, Hensvold A, Vivar N, Eloranta ML, Rönnblom L, Brunak S, Malmström V, Catrina A, Moerch UG, Klareskog L, Padyukov L, Berg L.
Mol Med. 2016 Aug 15;22.

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Can baseline serum microRNAs predict response to TNF-alpha inhibitors in rheumatoid arthritis?
Cuppen BV, Rossato M, Fritsch-Stork RD, Concepcion AN, Schenk Y, Bijlsma JW, Radstake TR, Lafeber FP; all SRU investigators.
Arthritis Res Ther. 2016 Aug 24;18:189.

A combination of cellular biomarkers predicts failure to respond to rituximab in rheumatoid arthritis: a 24-week observational study.
Stradner MH, Dejaco C, Brickmann K, Graninger WB, Brezinschek HP.
Arthritis Res Ther. 2016 Aug 24;18:190.

Crowdsourced assessment of common genetic contribution to predicting anti-TNF treatment response in rheumatoid arthritis.
Sieberts SK, Zhu F, García-García J, Stahl E, Pratap A, Pandey G, Pappas D, Aguilar D, Anton B, Bonet J, Eksi R, Fornés O, Guney E, Li H, Marín MA, Panwar B, Planas-Iglesias J, Poglayen D, Cui J, Falcao AO, Suver C, Hoff B, Balagurusamy VS, Dillenberger D, Neto EC, Norman T, Aittokallio T, Ammad-Ud-Din M, Azencott CA, Bellón V, Boeva V, Bunte K, Chheda H, Cheng L, Corander J, Dumontier M, Goldenberg A, Gopalacharyulu P, Hajiloo M, Hidru D, Jaiswal A, Kaski S, Khalfaoui B, Khan SA, Kramer ER, Marttinen P, Mezlini AM, Molparia B, Pirinen M, Saarela J, Samwald M, Stoven V, Tang H, Tang J, Torkamani A, Vert JP, Wang B, Wang T, Wennerberg K, Wineinger NE, Xiao G, Xie Y, Yeung R, Zhan X, Zhao C; Members of the Rheumatoid Arthritis Challenge Consortium, Greenberg J, Kremer J, Michaud K, Barton A, Coenen M, Mariette X, Miceli C, Shadick N, Weinblatt M, de Vries N, Tak PP, Gerlag D, Huizinga TW, Kurreeman F, Allaart CF, Louis Bridges S Jr, Criswell L, Moreland L, Klareskog L, Saevarsdottir S, Padyukov L, Gregersen PK, Friend S, Plenge R, Stolovitzky G, Oliva B, Guan Y, Mangravite LM, Bridges SL, Criswell L, Moreland L, Klareskog L, Saevarsdottir S, Padyukov L, Gregersen PK, Friend S, Plenge R, Stolovitzky G, Oliva B, Guan Y, Mangravite LM.
Nat Commun. 2016 Aug 23;7:12460.

Genomic stratification by expression of HLA-DRB4 alleles identifies differential innate and adaptive immune transcriptional patterns - A strategy to detect predictors of methotrexate response in early rheumatoid arthritis.
Stuhlmüller B, Mans K, Tandon N, Bonin MO, Smiljanovic B, Sörensen TA, Schendel P, Martus P, Listing J, Detert J, Backhaus M, Neumann T, Winchester RJ, Burmester GR, Häupl T.
Clin Immunol. 2016 Aug 25. pii: S1521-6616(16)30276-5.

Animal models

Antibody-Based Targeted Delivery of Interleukin-22 Promotes Rapid Clinical Recovery in Mice With DSS-Induced Colitis.
Bootz F, Ziffels B, Neri D.
Inflamm Bowel Dis. 2016 Sep;22(9):2098-105.

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The Effect of Induced Antibodies with Respect to Neutralization, Clearance Rate and Functional Activity in a Rabbit/Infliximab Model.
Henriksen ML, Teisner A, Kjeldsen J, Kalliokoski O, Hau J, Hansen SW.
In Vivo. 2016 09-10;30(5):557-65.

High-affinity monoclonal IgA regulates gut microbiota and prevents colitis in mice.
Okai S, Usui F, Yokota S, Hori-I Y, Hasegawa M, Nakamura T, Kurosawa M, Okada S, Yamamoto K, Nishiyama E, Mori H, Yamada T, Kurokawa K, Matsumoto S, Nanno M, Naito T, Watanabe Y, Kato T, Miyauchi E, Ohno H, Shinkura R.
Nat Microbiol. 2016 Jul 4;1(9):16103.

Non-genetic risk factors in haemophilia A inhibitor management - the danger theory and the use of animal models.
Lövgren KM, Søndergaard H, Skov S, Wiinberg B.
Haemophilia. 2016 Aug 26.

Treating experimental arthritis with the innate immune inhibitor interleukin-37 reduces joint and systemic inflammation.
Cavalli G, Koenders M, Kalabokis V, Kim J, Tan AC, Garlanda C, Mantovani A, Dagna L, Joosten LA, Dinarello CA.
Rheumatology (Oxford). 2016 Aug 26.

SEC Based Method for Size Determination of Immune Complexes of Therapeutic Antibodies in Animal Matrix.
Boysen M, Schlicksupp L, Dreher I, Loebbert R, Richter M.
J Immunol Res. 2016;2016:9096059.

Systemic Lupus Erythematosus

A critical review of clinical trials in systemic lupus erythematosus.
Mahieu MA, Strand V, Simon LS, Lipsky PE, Ramsey-Goldman R.
Lupus. 2016 Sep;25(10):1122-40.

Interferon-targeted therapy in systemic lupus erythematosus: Is this an alternative to targeting B and T cells?
Kalunian KC.
Lupus. 2016 Sep;25(10):1097-101.

Targeted B cell therapies in the treatment of adult and pediatric systemic lupus erythematosus.
Hui-Yuen JS, Nguyen SC, Askanase AD.
Lupus. 2016 Sep;25(10):1086-96.

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T-cell-directed therapies in systemic lupus erythematosus.
Nandkumar P, Furie R.
Lupus. 2016 Sep;25(10):1080-5.

Impact of concomitant medication use on belimumab efficacy and safety in patients with systemic lupus erythematosus.
Schwarting A, Dooley MA, Roth DA, Edwards L, Thompson A, Wilson B.
Lupus. 2016 Aug 3

A Regulatory Feedback between Plasmacytoid Dendritic Cells and Regulatory B Cells Is Aberrant in Systemic Lupus Erythematosus.
Menon M, Blair PA, Isenberg DA, Mauri C.
Immunity. 2016 Mar 15;44(3):683-97.

Rheumatoid Arthritis

Methotrexate monotherapy and methotrexate combination therapy with traditional and biologic disease modifying anti-rheumatic drugs for rheumatoid arthritis: A network meta-analysis.
Hazlewood GS, Barnabe C, Tomlinson G, Marshall D, Devoe DJ, Bombardier C.
Cochrane Database Syst Rev. 2016 Aug 29;8:CD010227.

Effectiveness of golimumab for rheumatoid arthritis in patients with an inadequate response to tocilizumab.
Matsuno H, Katayama K.
Mod Rheumatol. 2016 Aug 23:1-6.

A genomics-based systems approach towards drug repositioning for rheumatoid arthritis.
Xu R, Wang Q.
BMC Genomics. 2016 Aug 22;17 Suppl 7:518.

Monotherapy with biologic disease-modifying anti-rheumatic drugs in rheumatoid arthritis.
Choy E, Aletaha D, Behrens F, Finckh A, Gomez-Reino J, Gottenberg JE, Schuch F, Rubbert-Roth A.
Rheumatology (Oxford). 2016 Aug 21.

Inflammatory Bowel Disease

Early remission status predicts long-term outcomes in patients with Crohn's disease treated with certolizumab pegol.
Melmed GY, McGovern D, Schreiber S, Kosutic G, Spearman M, Coarse J, Sandborn WJ.
Curr Med Res Opin. 2016 Aug 22:1-5.

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A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of Brodalumab in Patients With Moderate-to-Severe Crohn's Disease.
Targan SR, Feagan B, Vermeire S, Panaccione R, Melmed GY, Landers C, Li D, Russell C, Newmark R, Zhang N, Chon Y, Hsu YH, Lin SL, Klekotka P.
Am J Gastroenterol. 2016 Aug 2.

Golimumab for moderately to severely active ulcerative colitis.
Kedia S, Ahuja V, Makharia GK.
Expert Rev Clin Pharmacol. 2016 Aug 18:1-10.

Pharmacokinetics and Exposure-response Relationship of Golimumab in Patients with Moderately-to-severely Active Ulcerative Colitis: Results from Phase 2/3 PURSUIT Induction and Maintenance Studies.
Detrez I, Gils A.
J Crohns Colitis. 2016 Jul 31

Multiple Sclerosis

Ocrelizumab for the treatment of relapsing-remitting multiple sclerosis.
Menge T, Dubey D, Warnke C, Hartung HP, Stüve O.
Expert Rev Neurother. 2016 Aug 23.

Interferon Beta: From Molecular Level to Therapeutic Effects.
Haji Abdolvahab M, Mofrad MR, Schellekens H.
Int Rev Cell Mol Biol. 2016;326:343-72.

ACCLAIM: A randomized trial of abatacept (CTLA4-Ig) for relapsing-remitting multiple sclerosis.
Khoury SJ, Rochon J, Ding L, Byron M, Ryker K, Tosta P, Gao W, Freedman MS, Arnold DL, Sayre PH, Smilek DE; ACCLAIM Study Group.
Mult Scler. 2016 Aug 1.

Benefit-Risk of Therapies for Relapsing-Remitting Multiple Sclerosis: Testing the Number Needed to Treat to Benefit (NNTB), Number Needed to Treat to Harm (NNTH) and the Likelihood to be Helped or Harmed (LHH): A Systematic Review and Meta-Analysis.
Mendes D, Alves C, Batel-Marques F.
CNS Drugs. 2016 Aug 18.

Alemtuzumab for Multiple Sclerosis.
Willis MD, Robertson NP.
Curr Neurol Neurosci Rep. 2016 Sep;16(9):84.

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The 11-year long-term follow-up study from the randomized BENEFIT CIS trial.
Kappos L, Edan G, Freedman MS, Montalbán X, Hartung HP, Hemmer B, Fox EJ, Barkhof F, Schippling S, Schulze A, Pleimes D, Pohl C, Sandbrink R, Suarez G, Wicklein EM; BENEFIT Study Group.
Neurology. 2016 Aug 10.

Regulatory Cell Populations in Relapsing-Remitting Multiple Sclerosis (RRMS) Patients: Effect of Disease Activity and Treatment Regimens.
Rodi M, Dimisianos N, de Lastic AL, Sakellaraki P, Deraos G, Matsoukas J, Papathanasopoulos P, Mouzaki A.
Int J Mol Sci. 2016 Aug 25;17(9).

Hemophilia

Emerging drugs for the treatment of hemophilia A and B.
Morfini M, Zanon E.
Expert Opin Emerg Drugs. 2016 Sep;21(3):301-13.

Porcine recombinant factor VIII: an additional weapon to handle anti-factor VIII antibodies.
Mannucci PM, Franchini M.
Blood Transfus. 2016 Jul 25:1-4.

Definitions in hemophilia: resolved and unresolved issues.
Blanchette VS, Srivastava A.
Semin Thromb Hemost. 2015 Nov;41(8):819-25.

Recombinant porcine sequence factor VIII (rpFVIII) for acquired haemophilia A: practical clinical experience of its use in seven patients.
Tarantino MD, Cuker A, Hardesty B, Roberts JC, Sholzberg M.
Haemophilia. 2016 Aug 10.

Basic immunology

Molecular mechanisms of action of anti-TNF-α agents - Comparison among therapeutic TNF-α antagonists.
Mitoma H, Horiuchi T, Tsukamoto H, Ueda N.
Cytokine. 2016 Aug 24. pii: S1043-4666(16)30468-9.

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Opinions/Commentaries/ Across diseases reviews

Perspectives of ofatumumab as CD20 targeted therapy in rheumatoid arthritis and other autoimmune diseases.
Pers YM, Jorgensen C.
Immunotherapy. 2016 Sep;8(9):1091-6.

Clinical trials of biosimilars should become more similar.
Kay J, Isaacs JD.
Ann Rheum Dis. 2016 Aug 25

A Systematic Review on Infliximab and Adalimumab Drug Monitoring: Levels, Clinical Outcomes and Assays.
Silva-Ferreira F, Afonso J, Pinto-Lopes P, Magro F.
Inflamm Bowel Dis. 2016 Sep;22(9):2289-301.

Drivers of costly treatment strategies in rheumatoid arthritis.
Huizinga TW, Gröndal G.
Lancet. 2016 Jul 16;388(10041):213-4.

Recommendations for authors of manuscripts reporting inhibitor cases developed in previously treated patients with hemophilia: communication from the SSC of the ISTH.
Iorio A, Barbara AM, Bernardi F, Lillicrap D, Makris M, Peyvandi F, Rosendaal F; Subcommittee on Factor VIII, Factor IX & Rare Coagulation Disorder.
J Thromb Haemost. 2016 Aug;14(8):1668-72.

A Critical Review of Biosimilars in IBD: The Confluence of Biologic Drug Development, Regulatory Requirements, Clinical Outcomes, and Big Business.
Ha CY, Kornbluth A.
Inflamm Bowel Dis. 2016 Aug 25.

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REGULATION

EMA

Opinion/decision on a Paediatric investigation plan (PIP): Lemtrada, Alemtuzumab
Therapeutic area: Neurology (updated)

Opinion/decision on a Paediatric investigation plan (PIP): Cosentyx, Secukinumab
Therapeutic area: Immunology-Rheumatology-Transplantation (updated)

Orphan designation:
Humanised IgG1 monoclonal antibody against human eotaxin-2
for the: Treatment of systemic sclerosis (updated)

Human medicines European public assessment report (EPAR): Simponi, golimumab
Revision: 24, Authorised

Human medicines European public assessment report (EPAR): RoActemra, tocilizumab
Revision: 20, Authorised

Human medicines European public assessment report (EPAR): Betaferon, interferon beta-1b
Revision: 27, Authorised

Human medicines European public assessment report (EPAR): Avonex, interferon beta-1a
Revision: 27, Authorised

Human medicines European public assessment report (EPAR): MabThera, rituximab
Revision: 38, Authorised

Clinical investigation of recombinant and human plasma-derived factor VIII products (updated)

Scientific guideline:
Guideline on development, production, characterisation and specification for monoclonal antibodies and related products - Revision 1
Adopted

WC500211640.pdf

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Scientific guideline :
Guideline on production and quality control of animal immunoglobulins and immunosera for human use - Revision 1
Adopted

WC500211639.pdf

Report: Workshop report - Developing a framework of collaboration between the European Medicines Agency (EMA) and academia

Clinical investigation of medicinal products for the management of Crohn's disease (updated)

Development of new medicinal products for the treatment of ulcerative colitis (updated)

Scientific guideline:
Draft guideline on the development of new medicinal products for the treatment of Ulcerative Colitis - Revision 1
Draft: consultation open

WC500211431.pdf

Scientific guideline:
Draft guideline on the development of new medicinal products for the treatment of Crohn's Disease - Revision 2
Draft: consultation open

WC500211430.pdf

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