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 Relevance 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 October 2013 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.

This month, we chose to draw your attention to the mathematical modeling of anti-drugs antibodies formation proposed by Chen et al. in the AAPS Journal.

In addition, you will find in this issue some news from the regulatory field together with a selection of forthcoming scientific conferences of interest.

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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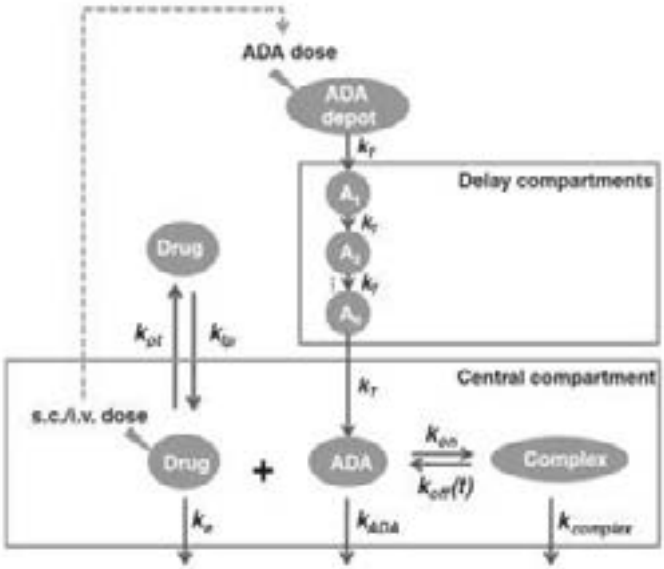
LITERATURE

This month's selected article

In this paper published in the AAPS Journal in October, Chen et al. propose a mathematical pharmacokinetic/anti-drug-antibody (PK/ADA) model , which could serve as a new tool for predicting immunogenicity of therapeutic proteins.

The authors took advantage of two PK data sets from adapted multiple and repeated dose toxicokinetic studies conducted in preclinical species, to construct a mathematical model based on a traditional one-compartment pharmacokinetic/pharmacodynamic (PK/PD) model, which they adapted to reflect the kinetics of ADA formation and maturation through the addition of so-called 'delay' compartments :



The hypothesis forming the basis of the model is that altered drug PK data contains information about the extent and timing of ADA formation, providing that ADA-mediated drug clearance through ADA-drug complex formation can account for variations in PK data.

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Drug PK variables (*e.g.* Kp_t, K_{tp}) were determined experimentally in absence of ADA (after first drug dosing), whereas some drug-non specific ADA variables (K_{on}, K_{ADA}) were acquired from the literature.

Then, by fitting drug PK profiles while accounting for ADA mediated drug clearance, the authors could estimate or derive from the model protein-specific ADA parameters of interest such as : maximum ADA response, sensitivity of ADA response to drug dose level, affinity maturation rate, time lag to observe an ADA response, and the elimination rate for ADA–drug complex. Interestingly, by simulating ADA responses to various drug dose levels, bell-shaped curves reminiscent of that of antigen dose-response, were generated.

Taken together, these results suggest that this new PK/ADA model could be applied to predict immunogenicity of therapeutic proteins. However, further experimental validation will be needed , requiring the development of reliable quantitative ADA assays to allow determining empiric ADA absolute concentrations.

A Mathematical Model of the Effect of Immunogenicity on Therapeutic Protein Pharmacokinetics.

Chen X, Hickling T, Kraynov E, Kuang B, Parng C, Vicini P.

AAPS J. 2013 Aug 30.

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Immunogenicity

2012 AAPS National Biotech Conference Open Forum: A Perspective on the Current State of Immunogenicity Prediction and Risk Management.

Rajadhyaksha M, Subramanyam M, **Rup B.**

AAPS J. 2013 Aug 30.

Drug levels, anti-drug antibodies, and clinical efficacy of the anti-TNFα biologics in rheumatic diseases.

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Clin Rheumatol. 2013 Jul 26.

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Ratanji KD, Derrick JP, Dearman RJ, Kimber I.

J Immunotoxicol. 2013 Aug 6.

The role of DMARDs in reducing the immunogenicity of TNF inhibitors in chronic inflammatory diseases.

Jani M, Barton A, Warren RB, Griffiths CE, Chinoy H.

Rheumatology (Oxford). 2013 Aug 14.

Immunogenicity of anti-tumour necrosis factor drugs in rheumatic diseases.

Spinelli FR, Valesini G.

Clin Exp Rheumatol. 2013 Aug 26.

Methods

Drug interference in immunogenicity assays depends on valency.

Rispens T, Hart MH, Ooijevaar-de Heer P, van Leeuwen A, Vennegoor A, Killestein J, Wolbink GJ, van der Kleij D.

J Pharm Biomed Anal. 2013 Jul 30;85C:179-185.

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Development of a biosensor-based immunogenicity assay capable of blocking soluble drug target interference.

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J Immunol Methods. 2013 Aug 6

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Pharm Res. 2013 Aug 15

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Development of a Human Antibody Tolerant Mouse Model to Assess the Immunogenicity Risk Due to Aggregated Biotherapeutics.

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J Pharm Sci. 2013 Aug 7

Soluble human CD83 ameliorates lupus in NZB/W F1 mice.

Starke C, Steinkasserer A, Voll RE, Zinser E.

Immunobiology. 2013 Jun 17.

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Locally injected Infliximab ameliorates murine DSS colitis: Differences in serum and intestinal levels of drug between healthy and colitic mice.

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Dig Liver Dis. 2013 Aug 1.

Biomarkers

Serological identification of fast progressors of structural damage with rheumatoid arthritis.

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Arthritis Res Ther. 2013 Aug 14;15(4):R86.

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Challenges and opportunities in SLE clinical trials.

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Curr Opin Rheumatol. 2013 Sep;25(5):606-15.

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Rheumatoid Arthritis

PEGylated drugs in rheumatology--why develop them and do they work?

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Rheumatology 2013 Aug 20

IL-6 pathway-driven investigation of response to IL-6 receptor inhibition in rheumatoid arthritis.

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BMJ Open. 2013 Aug 19;3(8):e003199.

Comparison of the inhibition mechanisms of Adalimumab and Infliximab in treating TNFα-associated diseases from a molecular view.

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J Biol Chem. 2013 Aug 13

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Ann Rheum Dis. 2013 Aug 5.

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Emery P, Sebba A, **Huizinga TW.**

Ann Rheum Dis. 2013 Aug 5.

Use of leflunomide plus TNF-α inhibitors in rheumatoid arthritis.

Murdaca G, Spanò F, Puppo F.

Expert Opin Drug Saf. 2013 Jul 29.

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A randomised, double-blind, parallel-group study of the safety and efficacy of subcutaneous tocilizumab versus intravenous tocilizumab in combination with traditional disease-modifying antirheumatic drugs in patients with moderate to severe rheumatoid arthritis (SUMMACTA study).

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Ann Rheum Dis. 2013 Jul 31.

Insights into the efficacy of golimumab plus methotrexate in patients with active rheumatoid arthritis who discontinued prior anti-tumour necrosis factor therapy: post-hoc analyses from the GO-AFTER study.

Smolen JS, Kay J, Matteson EL, Landewé R, Hsia EC, Xu S, Zhou Y, Doyle MK.

Ann Rheum Dis. 2013 Jul 29.

Update on the use of abatacept for the treatment of rheumatoid arthritis.

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The impact of conventional DMARD and biological therapies on CD4+ cell subsets in rheumatoid arthritis: a follow-up study.

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Clin Rheumatol. 2013 Aug 11.

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Mélet J, **Mulleman D**, Goupille P, Ribourtout B, Watier H, Thibault G.

Arthritis Rheum. 2013 Aug 5.

Outcome assessments in rheumatoid arthritis.

Gilek-Seibert K, Prescott K, Kazi S.

Curr Rheumatol Rep. 2013 Nov;15(11):370.

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IBD

Individualised therapy is more cost-effective than dose intensification in patients with Crohn's disease who lose response to anti-TNF treatment: a randomised, controlled trial.
Steenholdt C, Brynskov J, Thomsen OO, Munck LK, Fallingborg J, Christensen LA, Pedersen G, Kjeldsen J, Jacobsen BA, Oxholm AS, Kjellberg J, Bendtzen K, Ainsworth MA.
Gut. 2013 Jul 22.

Ustekinumab for the treatment of Crohn's disease.
Khanna R, Feagan BG.
Immunotherapy. 2013 Aug;5(8):803-15.

Drug advances in inflammatory bowel disease.
Speight RA, Mansfield JC.
Clin Med. 2013 Aug;13(4):378-82.

Taking Crohn's disease personally.
Chowers Y.
Rambam Maimonides Med J. 2013 Apr 30;4(2):e0011.

Type I IFNs Regulate Effector and Regulatory T Cell Accumulation and Anti-Inflammatory Cytokine Production during T Cell-Mediated Colitis.
Kole A, He J, Rivollier A, Silveira DD, Kitamura K, Maloy KJ, Kelsall BL.
J Immunol. 2013 Aug 2.

The Extra Burden of Infliximab Infusions in Inflammatory Bowel Disease.
Buisson A, Seigne AL, D'huart MC, Bigard MA, Peyrin-Biroulet L.
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Multiple Sclerosis

Early detection of neutralizing antibodies to interferon-beta in multiple sclerosis patients: binding antibodies predict neutralizing antibody development.

Hegen H, Millonig A, Bertolotto A, **Comabella M**, Giovanonni G, Guger M, Hoelzl M, Khalil M, Killestein J, **Lindberg R**, Malucchi S, Mehling M, **Montalban X**, Polman C, Rudzki D, Schautzer F, Sellebjerg F, Sørensen P, **Deisenhammer F**.

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Outteryck O, Ongagna JC, Brochet B, Rumbach L, Lebrun-Frenay C, Debouverie M, Zéphir H, Ouallet JC, Berger E, Cohen M, Pittion S, Laplaud D, Wiertlewski S, Cabre P, Pelletier J, Rico A, Defer G, Derache N, Camu W, Thouvenot E, Moreau T, Fromont A, Tourbah A, Labauge P, Castelnovo G, Clavelou P, Casez O, Hautecoeur P, Papeix C, Lubetzki C, Fontaine B, Couturier N, Bohossian N, Clanet M, Vermersch P, de Sèze J, Brassat D; BIONAT network, and CFSEP.

Eur J Neurol. 2013 Jun 12.

Interferon beta 1b following natalizumab discontinuation: one year, randomized, prospective, pilot trial.

Gobbi C, Meier DS, Cotton F, Sintzel M, Leppert D, Guttmann CR, Zecca C.

BMC Neurol. 2013 Aug 2;13:101

Immune competence after alemtuzumab treatment of multiple sclerosis.

McCarthy CL, Tuohy O, Compston DA, Kumararatne DS, Coles AJ, Jones JL.

Neurology. 2013 Aug 7.

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Hemophilia

Different factor VIII neutralizing effects on anti-factor VIII inhibitor antibodies associated with epitope specificity and von Willebrand factor.

Yada K, Nogami K, Shima M.

Br J Haematol. 2013 Jul 24.

Factor VIII gene (F8) mutation and risk of inhibitor development in non-severe hemophilia A.

Eckhardt CL, van Velzen AS, Peters M, Astermark J, Brons PP, Castaman G, Cnossen MH, Dors N, Escuriola-Ettingshausen C, Hamulyak K, Hart DP, Hay CR, Haya S, van Heerde WL, Hermans C, Holmström M, Jimenez-Yuste V, Keenan RD, Klamroth R, Laros-van Gorkom BA, Leebeek FW, Liesner R, Mäkipernaa A, Male C, Mauser-Bunschoten E, Mazzucconi MG, McRae S, Meijer K, Mitchell M, Morfini M, Nijziel M, Oldenburg J, Peerlinck K, Petrini P, Platokouki H, Reitter-Pfoertner SE, Santagostino E, Schinco P, Smiers FJ, Siegmund B, Tagliaferri A, Yee TT, Kamphuisen PW, van der Bom JG, Fijnvandraat K.

Blood. 2013 Aug 7.

Development of long-acting recombinant FVIII and FIX Fc fusion proteins for the management of hemophilia.

Shapiro A.

Expert Opin Biol Ther. 2013 Sep;13(9):1287-97.

Basic immunology

Fueling Immunity: Insights into Metabolism and Lymphocyte Function.

Pearce EL, Poffenberger MC, Chang CH, Jones RG.

Science. 2013 Oct 11;342(6155):1242454.

Opinions/Commentaries

Proposal for a new nomenclature of disease-modifying antirheumatic drugs.

Smolen JS, van der Heijde D, Machold KP, Aletaha D, Landewé R.

Ann Rheum Dis. 2013 Sep 26.

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Approval of the first biosimilar antibodies in Europe: A major landmark for the biopharmaceutical industry.
Beck A, Reichert JM.
MAbs. 2013 Jul 24;5(5

IBD: Golimumab in ulcerative colitis: a 'ménage à trois' of drugs.
Danese S.
Nat Rev Gastroenterol Hepatol. 2013 Jul 30.

European Union Clinical Trials Register: on the way to more transparency of clinical trial data.
Egger GF, Herold R, Rodriguez A, Manent N, Sweeney F, Saint Raymond A.
Expert Rev Clin Pharmacol. 2013 Aug 24

Systems approaches to human autoimmune diseases.
Banchereau R, Cepika AM, Pascual V.
Curr Opin Immunol. 2013 Sep 18

Quality assurance mechanisms for the unregulated research environment.
Riedl DH, Dunn MK.
Trends Biotechnol. 2013 Oct;31(10):552-4

Inflammasome and cytokine blocking strategies in autoinflammatory disorders.
Moll M, Kuemmerle-Deschner JB.
Clin Immunol. 2013 Jun;147(3):242-75.

Anti-CD20 monoclonal antibodies: Beyond B-cells.
Avivi I, Stroopinsky D, Katz T.
Blood Rev. 2013 Aug 13.

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REGULATION

EMA

Human medicines European public assessment report (EPAR): MabThera, Rituximab
Revision: 30, Authorised
September 2013

Pending EC decision: Cimzia, certolizumab pegol
Opinion date: 19-Sep-2013

Pending EC decision: NovoEight,turoctocog alfa
Opinion date: 19-Sep-2013

Pending EC decision: Kineret, anakinra
Opinion date: 19-Sep-2013

Opinion/decision on a Paediatric Investigation Plan (PIP): RoActemra, tocilizumab
Therapeutic area: Immunology-Rheumatology-Transplantation (updated)
September 2013

Opinion/decision on a Paediatric Investigation Plan (PIP): -, tofacitinib
Therapeutic area: Immunology-Rheumatology-Transplantation (updated)
September 2013

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CONFERENCES & MEETINGS

2013		
October		
ACR/ARHP joint meeting	25-30, San Diego, USA	http://acrannualmeeting.org/
November		
Annual meeting of the French Society for Immunology	4-7, Paris, France	http://www.alphavisa.com/sfi/2013/
AAPS	10-14, San Antonio, Texas, USA	http://www.aaps.org/annualmeeting/
December		
British Society for Immunology Annual Congress	2–5, Liverpool, UK	http://www.bsicongress.com/
2014		
January		
Keystone Symposium: Inflammatory Diseases: Recent Advances in Basic and Translational Research and Therapeutic Treatments	17–22, Vancouver, Canada	http://www.keystonesymposia.org
2nd Immunogenicity and Immunotoxicity Conference	29-31, San Diego, CA, USA	http://www.gtcbio.com
February		
Sixth Open Scientific EIP Symposium	24-26, Lisbon, Portugal	http://www.e-i-p.eu/
AAAI	28-4 March, San Diego, USA	http://annualmeeting.aaaai.org/
March		
PEGS 10th summit	5-9, Boston, Massachusetts, USA	http://www.pegsummit.com/
ABIRISK General Assembly	*12-13, Brussels, Belgium*	ABIRISK
15th Annual Immunogenicity for Biotherapeutics conferer	17-20, Baltimore, USA	http://www.iirusa.com/immunogenicity
World Immune Regulation Meeting VIII	19-22, Davos, Switzerland	http://www.wirm.ch/WTM/HOME.html
Biotherapeutics Analytical Summit	24-28, Baltimore, USA	http://www.biotherapeuticsanalyticalsummi
9th Congress on Autoimmunity	26-30, Nice, France	http://www2.kenes.com

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