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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 **June 2014** 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 a paper by the AIRE-MB group exploring the practical application of acid dissociation of adalimumab/anti-adalimumab complexes in monitoring drug-related immunogenicity in adalimumab-treated patients.

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

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

A growing body of evidence suggests that the development of anti-Drug Antibodies (ADA) may alter bioavailability and thus clinical efficacy of biotherapeutics (BPs). Timely determination of ADA status of BP-treated patients is therefore expected to gradually become an inherent part of overall patient monitoring. Indeed, when a patient appears resistant to treatment, clinicians could benefit from this additional piece of information in their decision making process : increase the BP dose, switch to a different BP, abandon the use of BPs altogether and revert to small molecule drugs only, or else. But this means ADA measurement needs accuracy.

Reliable ADA measurement comes against the issue of drug interference in immunogenicity assays. Most assays routinely used in the clinic will only detect free ADA, but not those in complex with the drug present in the serum of treated patients. Hence, a patient would be found positive for ADA only if ADA production exceeds drug through levels. Acid dissociation of serum ADA-drug complexes prior to measurement of ADA is known to improve assay sensitivity and thereby limit false negative results.

In the current publication, Llinares-Tello and collaborators on behalf of the AIRE-MB group implemented acid dissociation when monitoring ADA in rheumatoid arthritis and ankylosing spondylitis patients treated with adalimumab, an anti-TNFα therapeutic antibody.

In patients exhibiting a subtherapeutic adalimumab serum concentration (<3mg/L), no ADA could be detected using the conventional ELISA Promonitor® assay. However, when prior acid dissociation was applied, 55% of those same patients exhibited detectable levels of ADA. Acid dissociation-enhanced assay sensitivity was confirmed in drug tolerance parallel experiments.

Based on these results, the authors went on to propose the following analytical algorithm for monitoring drug bioavailability in adalimumab-treated patients :

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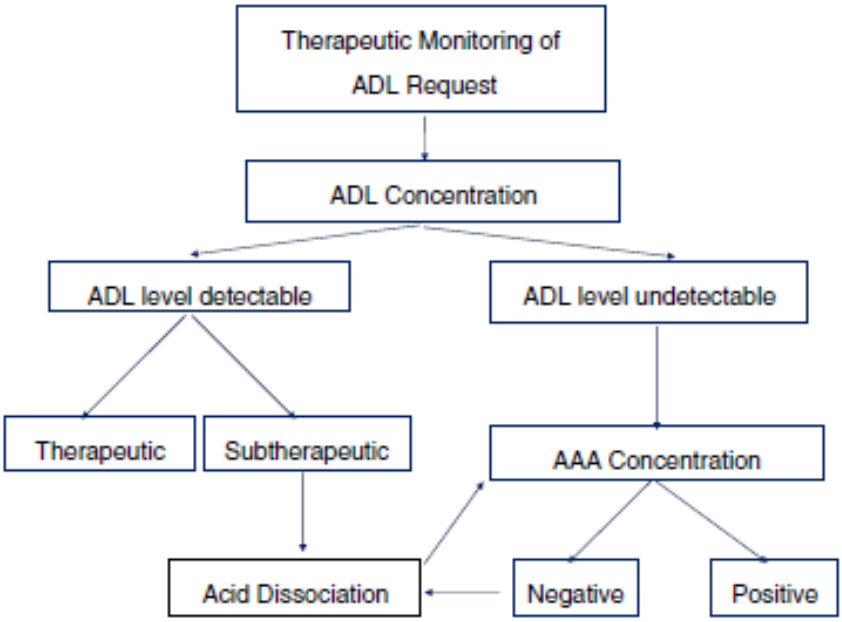

Legend : ADL = adalimumab; AAA =anti-adalimumab antibodies

Practical application of acid dissociation in monitoring patients treated with adalimumab.

Llinares-Tello F, Rosas-Gómez de Salazar J, Senabre-Gallego JM, Santos-Soler G, Santos-Ramírez C, Salas-Heredia E, Barber-Vallés X, Molina-García J; AIRE-MB Group.

Rheumatol Int. 2014 May 10.

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Immunogenicity

Practical Considerations for the Pharmacokinetic and Immunogenic Assessment of Antibody-Drug Conjugates.
Sauerborn M, van Dongen W.
BioDrugs. 2014 May 20

Recommendations for the characterization of immunogenicity response to multiple domain biotherapeutics.
Gorovits B, Wakshull E, Pillutla R, Xu Y, Manning MS, Goyal J.
J Immunol Methods. 2014 May 24. pii: S0022-1759(14)00155-0

Methods

Thermally induced degradation pathways of three different antibody-based drug development candidates.
Fincke A, Winter J, Bunte T, Olbrich C.
Eur J Pharm Sci. 2014 May 27. pii: S0928-0987(14)00219-X.

Animal models

Therapeutic efficacy of three bispecific antibodies on collagen-induced arthritis mouse model.
Li Q, Ren G, Xu L, Wang Q, Qi J, Wang W, Zhou B, Han X, Sun C, Wu Q, Yu Y, Peng Z, Zheng S, Li D.
Int Immunopharmacol. 2014 Jul;21(1):119-127.

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Biomarkers

Detection of dynamic frequencies of Th17 cells and their associations with clinical parameters in patients with systemic lupus erythematosus receiving standard therapy.

Wen Z, Xu L, Xu W, Xiong S.

Clin Rheumatol. 2014 May 10

Stimulated PBMC-produced IFN-γ and TNF-α are associated with altered relapse risk in multiple sclerosis: results from a prospective cohort study.

Simpson S Jr, Stewart N, van der Mei I, Otahal P, Charlesworth J, Ponsonby AL, Blizzard L, Dwyer T, Pittas F, Gies P, Taylor B.

J Neurol Neurosurg Psychiatry. 2014 May 1.

Systemic Lupus Erythematosus

GWAS identifies novel SLE susceptibility genes and explains the association of the HLA region.

Armstrong DL, Zidovetzki R, Alarcón-Riquelme ME, Tsao BP, Criswell LA, Kimberly RP, Harley JB, Sivils KL, Vyse TJ, Gaffney PM, Langefeld CD, Jacob CO.

Genes Immun. 2014 May 29.]

Increased expression of Toll-like receptors (TLRs) 7 and 9 and other cytokines in systemic lupus erythematosus (SLE) patients: Ethnic differences and potential new targets for therapeutic drugs.

Lyn-Cook BD, Xie C, Oates J, Treadwell E, Word B, Hammons G, Wiley K.

Mol Immunol. 2014 May 24;61(1):38-43

Efficacy and safety of rituximab in the treatment of non-renal systemic lupus erythematosus: A systematic review.

Cobo-Ibáñez T, Loza-Santamaría E, Pego-Reigosa JM, Marqués AO, Rúa-Figueroa I, Fernández-Nebro A, Cáliz RC, López Longo FJ, Muñoz-Fernández S.

Semin Arthritis Rheum. 2014 Apr 13.

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Arthritis

Long-term safety of subcutaneous abatacept in rheumatoid arthritis: Integrated analysis of clinical trial data of up to 4.75 years of treatment.

Alten R, Kaine J, Keystone E, Nash P, Delaet I, Genovese MC.

Arthritis Rheumatol. 2014 Apr 29.

Good response to infliximab in rheumatoid arthritis following failure of interleukin-1 receptor antagonist.

Bao J, Yue T, Li T, He DY, Bao YX.

Int J Rheum Dis. 2014 May 5.

The randomized placebo phase study of rilonacept in the treatment of systemic juvenile idiopathic arthritis (RAPPORT).

Ilowite NT, Prather K, Lokhnygina Y, Schanberg LE, Elder M, Milojevic D, Verbsky JW, Spalding SJ, Kimura Y, Imundo LF, Punaro MG, Sherry DD, Tarvin SE, Zemel LS, Birmingham JD, Gottlieb BS, Miller ML, O'Neil K, Ruth NM, Wallace CA, Singer NG, Sandborg CI.

Arthritis Rheumatol. 2014 May 16

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

Treatment of juvenile idiopathic arthritis: a revolution in care.

Stoll ML, Cron RQ.

Pediatr Rheumatol Online J. 2014 Apr 23;12:13.

Pharmacology of biosimilar candidate drugs in Rheumatology: a literature review.

Araújo F, Cordeiro I, Teixeira F, Gonçalves J, Fonseca JE.

Acta Reumatol Port. 2014 Jan-Mar;39(1):19-26.

Efficacy and safety of infliximab-biosimilar compared to other biological drugs in rheumatoid arthritis: a mixed treatment comparison.

Baji P, Péntek M, Czirják L, Szekanecz Z, Nagy G, Gulácsi L, Brodszky V.

Eur J Health Econ. 2014 May 16.

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.
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Plasma Levels of IL-37 and Correlation with TNF-α, IL-17A, and Disease Activity during DMARD Treatment of Rheumatoid Arthritis.

Zhao PW, Jiang WG, Wang L, Jiang ZY, Shan YX, Jiang YF.

PLoS One. 2014 May 1;9(5):e95346.

The Effect of Intravenous Golimumab on Health-related Quality of Life in Rheumatoid Arthritis: 24-week Results of the Phase III GO-FURTHER Trial.

Bingham CO 3rd, Weinblatt M, Han C, Gathany TA, Kim L, Lo KH, Baker D, Mendelsohn A, Westhovens R.

J Rheumatol. 2014 May 1.

Budget impact analysis of biosimilar infliximab (CT-P13) for the treatment of rheumatoid arthritis in six Central and Eastern European countries.

Brodszky V, Baji P, Balogh O, Péntek M.

Eur J Health Econ. 2014 May 16.

IL-6 targeting compared to TNF targeting in rheumatoid arthritis: studies of olokizumab, sarilumab and sirukumab.

Tanaka Y, Martin Mola E.

Ann Rheum Dis. 2014 May 15.

Biological therapy in inflammatory rheumatic diseases: issues in Central and Eastern European countries.

Péntek M, Poór G, Wiland P, Olejárová M, Brzosko M, Codreanu C, Brodszky N, Gulácsi L.

Eur J Health Econ. 2014 May 16

Intravenous golimumab in rheumatoid arthritis.

Cohen MD, Keystone EC.

Expert Rev Clin Immunol. 2014 May 15:1-8.

Suppression of innate and adaptive B cell activation pathways by antibody coengagement of FcγRIIb and CD19.

Szili D, Cserhalmi M, Bankó Z, Nagy G, Szymkowski DE, Sarmay G.

MAbs. 2014 Apr 23;6(4).

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.'
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Inflammatory Bowel Disease

Vedolizumab for the treatment of ulcerative colitis.
Rietdijk ST, D'Haens GR.
Expert Rev Clin Pharmacol. 2014 May 6.

Anti-IL-12/23 in Crohn's disease: bench and bedside.
Niederreiter L, Adolph TE, Kaser A.
Curr Drug Targets. 2013 Nov;14(12):1379-84. Review.

Macrophage-restricted interleukin-10 receptor deficiency, but not IL-10 deficiency, causes severe spontaneous colitis.
Zigmond E, Bernshtein B, Friedlander G, Walker CR, Yona S, Kim KW, Brenner O, Krauthgamer R, Varol C, Müller W, Jung S.
Immunity. 2014 May 15;40(5):720-33.

Pattern Recognition Receptor Signaling in Human Dendritic Cells is Enhanced by ICOS Ligand and Modulated by the Crohn's Disease ICOSLG Risk Allele.
Hedl M, Lahiri A, Ning K, Cho JH, Abraham C.
Immunity. 2014 May 15;40(5):734-46.

Utility of serum TNF-α, infliximab trough level, and antibody titers in inflammatory bowel disease.
Pallagi-Kunstár E, Farkas K, Szepes Z, Nagy F, Szűcs M, Kui R, Gyulai R, Bálint A, Wittmann T, Molnár T.
World J Gastroenterol. 2014 May 7;20(17):5031-5.

A SPECIAL MEETING REVIEW EDITION: Clinical Research Highlights in IBD: Diagnosis and Anti-Tumor Necrosis Factor Monitoring: Digestive Disease Week 2013May 18-21, 2013 • Orlando, Florida
Gastroenterol Hepatol (N Y). 2013 Aug;9(8 Suppl 4):1-16.

Utilization Trends of Anti-TNF Agents and Health Outcomes in Adults and Children with Inflammatory Bowel Diseases: A Single-center Experience.
Park KT, Sin A, Wu M, Bass D, Bhattacharya J.
Inflamm Bowel Dis. 2014 May 19.

Pharmacokinetics of Adalimumab in Inflammatory Bowel Diseases: A Systematic Review and Meta-analysis.
Paul S, Moreau AC, Del Tedesco E, Rinaudo M, Phelip JM, Genin C, Peyrin-Biroulet L, Roblin X.
Inflamm Bowel Dis. 2014 May 14.

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.
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Effects of Vedolizumab Induction Therapy for Patients With Crohn's Disease in Whom Tumor Necrosis Factor Antagonist Treatment Had Failed.

Sands BE, Feagan BG, Rutgeerts P, Colombel JF, Sandborn WJ, Sy R, D'Haens G, Ben-Horin S, Xu J, Rosario M, Fox I, Parikh A, Milch C, Hanauer S.

Gastroenterology. 2014 May 21. pii: S0016-5085(14)00656-8.

Toward a Personalized Medicine Approach to the Management of Inflammatory Bowel Disease.

Mosli MH, Sandborn WJ, Kim RB, Khanna R, Al-Judaibi B, Feagan BG.

Am J Gastroenterol. 2014 May 20.

Systems biology in inflammatory bowel diseases: ready for prime time.

Polytarchou C, Koukos G, Iliopoulos D.

Curr Opin Gastroenterol. 2014 May 15.

Blockade of lymphocyte trafficking in inflammatory bowel diseases therapy: importance of specificity of endothelial target.

Allocca M, Fiorino G, Vermeire S, Reinisch W, Cataldi F, Danese S.

Expert Rev Clin Immunol. 2014 May 12:1-11.

Multiple Sclerosis

Tolerogenic vaccines for Multiple sclerosis.

Mannie MD, Curtis AD 2nd.

Hum Vaccin Immunother. 2013 May;9(5):1032-8.

Pegylated interferon beta-1a for relapsing-remitting multiple sclerosis (ADVANCE): a randomised, phase 3, double-blind study.

Calabresi PA, Kieseier BC, Arnold DL, Balcer LJ, Boyko A, Pelletier J, Liu S, Zhu Y, Seddighzadeh A, Hung S, Deykin A; for the ADVANCE Study Investigators.

Lancet Neurol. 2014 Apr 30.

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

Immune regulation of multiple sclerosis by CD8+ T cells.
Sinha S, Itani FR, Karandikar NJ.
Immunol Res. 2014 May 21.

The Role of Endogenous IFN-β in the Regulation of Th17 Responses in Patients with Relapsing-Remitting Multiple Sclerosis.
Tao Y, Zhang X, Chopra M, Kim MJ, Buch KR, Kong D, Jin J, Tang Y, Zhu H, Jewells V, Markovic-Plese S.
J Immunol. 2014 May 21.

B cells in MS and NMO: pathogenesis and therapy.
Krumbholz M, Meinl E.
Semin Immunopathol. 2014 May;36(3):339-50.

Alemtuzumab treatment of multiple sclerosis: long-term safety and efficacy.
Tuohy O, Costelloe L, Hill-Cawthorne G, Bjornson I, Harding K, Robertson N, May K, Button T, Azzopardi L, Kousin-Ezewu O, Jones J, Compston DA, Coles A.
J Neurol Neurosurg Psychiatry. 2014 May 21.

Accelerated lymphocyte recovery after alemtuzumab does not predict multiple sclerosis activity.
Kousin-Ezewu O, Azzopardi L, Parker RA, Tuohy O, Compston A, Coles A, Jones J.
Neurology. 2014 May 16.

Mode of action and clinical studies with alemtuzumab.
Jones JL, Coles AJ.
Exp Neurol. 2014 May 2.

Hemophilia

Phase I study of BAY 94-9027, a PEGylated B-domain-deleted recombinant factor VIII with an extended half-life, in subjects with hemophilia A.
Coyle TE, Reding MT, Lin JC, Michaels LA, Shah A, Powell J.
J Thromb Haemost. 2014 Apr;12(4):488-96.

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

Basic immunology

Development and Function of Dendritic Cell Subsets.
Mildner A, Jung S.
Immunity. 2014 May 15;40(5):642-656

Nucleotide signalling during inflammation.
Idzko M, Ferrari D, Eltzschig HK.
Nature. 2014 May 15;509(7500):310-7.

Positive and negative selection of the T cell repertoire: what thymocytes see (and don't see).
Klein L, Kyewski B, Allen PM, Hogquist KA.
Nat Rev Immunol. 2014 May 16.

Opinions/Commentaries/Across diseases reviews

The Portuguese Society of Rheumatology position paper on the use of biosimilars.

Fonseca JE, Gonçalves J, Araújo F, Cordeiro I, Teixeira F, Canhão H, Silva JA, Garcês S, Miranda LC, Ramiro S, Roxo A, Pimentel-Santos FM, Tavares V, Neto A, Sepriano A, Malcata A, Faustino A, Silva C, Ambrósio C, Duarte C, Miguel C, Barcelos F, Santos H, Cunha I, Ramos JC, Gomes JA, Pimentão JB, Costa L, Maurício L, Silva M, Bernardes M, Bogas M, Coelho PC, Monteiro P, Aguiar R, André R, Leitão R, Pimenta S, Meirinhos T, Fernandes S, Las V, Castelão W.

Acta Reumatol Port. 2014 Jan-Mar;39(1):60-71.

The use of biosimilars in immune-mediated disease: A joint Italian Society of Rheumatology (SIR), Italian Society of Dermatology (SIDeMaST), and Italian Group of Inflammatory Bowel Disease (IG-IBD) position paper.

Fiorino G, Girolomoni G, Lapadula G, Orlando A, Danese S, Olivieri I; SIR, SIDeMaST, and IG-IBD.

Autoimmun Rev. 2014 Jul;13(7):751-5.

The 2013 BSR and BHPR guideline for the use of intravenous tocilizumab in the treatment of adult patients with rheumatoid arthritis.

Malaviya AP, Ledingham J, Bloxham J, Bosworth A, Buch M, Choy E, Cope A, Isaacs J, Marshall D, Wright G, Ostör AJ; on behalf of the BSR Clinical Affairs Committee & Standards, Audit and Guidelines Working Group and the BHPR.

Rheumatology (Oxford). 2014 May 12.

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

Inhibition of TNF receptor signaling by anti-TNFα biologicals primes naïve CD4(+) T cells towards IL-10(+) T cells with a regulatory phenotype and function.

Boks MA, Kager-Groenland JR, Mousset CM, van Ham SM, ten Brinke A.

Clin Immunol. 2014 Apr;151(2):136-45.

Blood gene expression profiling in pediatric systemic lupus erythematosus and systemic juvenile idiopathic arthritis: from bench to bedside.

Gilbert M, Punaro M.

Pediatr Rheumatol Online J. 2014 May 8;12:16.

Therapeutic potential of STAT4 in autoimmunity.

Liang Y, Pan HF, Ye DQ.

Expert Opin Ther Targets. 2014 May 20:1-16.

Epigenetic-based immune intervention for rheumatic diseases.

Gray SG.

Epigenomics. 2014 Apr;6(2):253-71.

Statistical and regulatory considerations in assessments of interchangeability of biological drug products.

Tóthfalusi L, Endrényi L, Chow SC.

Eur J Health Econ. 2014 May 16

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REGULATION

EMA

Human medicines European public assessment report (EPAR): RoActemra, tocilizumab
Revision: 13, Authorised
May 2014

Scientific guideline: Draft concept paper on the need for revision of the guideline on the clinical investigation of plasma-derived fibrin sealant / haemostatic products and the related core summary of product characteristics
Consultation starts : 01 June 2014
Consultation ends : 31 August 2014


Draft concept paper on the need for revisi

Pending EC decision: Plegridy, peginterferon beta-1a
Opinion date: 22-May-2014

Pending EC decision: Nuwiq,simoctocog alfa
Opinion date: 22-May-2014

Opinion/decision on a Paediatric Investigation Plan (PIP): Recombinant fusion protein consisting of human coagulation factor VIII attached to the Fc domain of human IgG1 (rFVIIIFc)
Therapeutic area: Haematology-Hemostaseology
Updated
May 2014

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Scientific guideline: Draft guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis,
Consultation open : 15 May 2014
Consultation ends : 30 November 2014

Draft guideline on clinical investigation o

Opinion/decision on a Paediatric Investigation Plan (PIP): Simponi,Golimumab
Therapeutic area: Immunology-Rheumatology-Transplantation
Updated
May 2014

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