

TABLE OF CONTENTS

INTRODUCTION	2
WELCOME	3
LITERATURE	4
This month's selected articles	4
Immunogenicity	5
Biosimilars	6
Animal models	6
Biomarkers	7
Systemic Lupus Erythematosus	8
Arthritis	8
Inflammatory Bowel Diseases	9
Multiple Sclerosis	11
Hemophilia	12
Basic immunology	12
Opinions/Commentaries/Across diseases reviews	13
REGULATION	14
EMA	14

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 Reactions 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.

WELCOME

Dear Reader,

We would like to welcome you to the February 2016 **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.

As each month, we are drawing 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

LITERATURE

This month's selected articles

1. A review proposed by our consortium that summarises the different strategies developed to enhance the half-life of FVIII :

Immunogenicity of long-lasting recombinant factor VIII products.

Ing M, Gupta N, Teyssandier M, Maillère B, Pallardy M, Delignat S, Lacroix-Desmazes S; ABIRISK consortium. Cell Immunol. 2015 Dec 19.

2. A discussion around the role of vitamin D in multiple sclerosis, a matter that is highly debated :

Can vitamin D reduce inflammation in relapsing-remitting multiple sclerosis?

Holmøy T, Torkildsen Ø. Expert Rev Neurother. 2016 Jan 22.

3. A new demonstration that presence of ADA impairs clinical outcome in rheumatic diseases treated with adalimumab. And a new demonstration that ADA occur very early: in 90% of patients exhibit ADA in the first 4 weeks :

The clinical relevance of early anti-adalimumab antibodies detection in rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis: A prospective multicentre study.

Hoxha A, Calligaro A, Tonello M, Ramonda R, Carletto A, Paolazzi G, Bortolotti R, Del Ross T, Grava C, Boaretto M, Favaro M, Teghil V, Ruffatti A, Punzi L. Joint Bone Spine. 2015 Dec 29

Immunogenicity

Pre-existing Antibody: Biotherapeutic Modality-Based Review.

Gorovits B, Clements-Egan A, Birchler M, Liang M, Myler H, Peng K, Purushothama S, Rajadhyaksha M, Salazar-Fontana L, Sung C, Xue L.
AAPS J. 2016 Jan 28.

Secukinumab, a novel anti-IL-17A antibody, shows low immunogenicity potential in human in vitro assays comparable to other marketed biotherapeutics with low clinical immunogenicity.

Karle A, Spindeldreher S, Kolbinger F.
MAbs. 2016 Jan 28

Utility of a Bayesian Mathematical Model to Predict the Impact of Immunogenicity on Pharmacokinetics of Therapeutic Proteins.

Kathman S Jr, Thway TM, Zhou L, Lee S, Yu S, Ma M, Chirmule N, Jawa V.
AAPS J. 2016 Jan 19

Evaluating and Reporting the Immunogenicity Impacts for Biological Products-a Clinical Pharmacology Perspective.

Wang YC, Wang J, Hon YY, Zhou L, Fang L, Ahn HY.
AAPS J. 2015 Dec 31

Hypersensitivity reactions during treatment with biological agents.

Puxeddu I, Caltran E, Rocchi V, Del Corso I, Tavoni A, Migliorini P.
Clin Exp Rheumatol. 2016 Jan 9.

Using monoclonal antibodies as an international standard for the measurement of anti-adalimumab antibodies.

van Schouwenburg PA, Kruithof S, Wolbink G, Wouters D, Rispens T.
J Pharm Biomed Anal. 2015 Dec 28;120:198-201.

Full validation of therapeutic antibody sequences by middle-up mass measurements and middle-down protein sequencing.

Resemann A, Jabs W, Wiechmann A, Wagner E, Colas O, Evers W, Belau E, Vorwerg L, Evans C, Beck A, Suckau D.
MAbs. 2016 Jan 13:0.

[Preventing Aggregation of Recombinant Interferon beta-1b in Solution by Additives: Approach to an Albumin-Free Formulation.](#)

Mahjoubi N, Fazeli MR, Dinarvand R, Khoshayand MR, Fazeli A, Taghavian M, Rastegar H.
Adv Pharm Bull. 2015 Nov;5(4):497-505.

Biosimilars

[Clinical data and regulatory issues of biosimilar products.](#)

Stevenson JG.
Am J Manag Care. 2015 Dec;21(16 Suppl):s320-30.

[Biosimilars: A consideration of the regulations in the United States and European union.](#)

Daller J.
Regul Toxicol Pharmacol. 2015 Dec 28

[Switching Between Infliximab Originator and Biosimilar in Paediatric Patients with Inflammatory Bowel Disease. Preliminary Observations.](#)

Sieczkowska J, Jarzębicka D, Banaszkiewicz A, Plocek A, Gawronska A, Toporowska-Kowalska E, Oracz G, Meglicka M, Kierkus J.
J Crohns Colitis. 2016 Feb;10(2):127-32.

Animal models

[An Albumin-Free Formulation for Escherichia coli-Derived Interferon Beta-1b with Decreased Immunogenicity in Immune Tolerant Mice.](#)

Haji Abdolvahab M, Fazeli A, Radmalekshahi M, Nejadnik MR, Fazeli MR, Schellekens H.
J Interferon Cytokine Res. 2016 Jan 29

[Recombinant factor VIII Fc \(rFVIIIFc\) fusion protein reduces immunogenicity and induces tolerance in hemophilia A mice.](#)

Krishnamoorthy S, Liu T, Drager D, Patarroyo-White S, Chhabra ES, Peters R, Josephson N, Lillicrap D, Blumberg RS, Pierce GF, Jiang H.
Cell Immunol. 2015 Dec 29

[Old and new therapeutics for Rheumatoid Arthritis: in vivo models and drug development.](#)

Sardar S, Andersson Å.

Immunopharmacol Immunotoxicol. 2016 Jan 15:1-12.

[Active immunisation targeting soluble murine tumour necrosis factor alpha is safe and effective in collagen-induced arthritis model treatment.](#)

Sun JH, Zhang YH, Kuang JY, Liu G, Liu YX, Liu BH.

Clin Exp Rheumatol. 2016 Jan 20.

[Antibody response to recombinant human coagulation factor VIII in a new rat model of severe hemophilia A.](#)

Lövgren KM, Søndergaard H, Skov S, Welding KN, Tranholm M, Wiinberg B.

J Thromb Haemost. 2016 Jan 19.

Biomarkers

[Differential methylation as a biomarker of response to etanercept in patients with rheumatoid arthritis.](#)

Plant D, Webster A, Nair N, Oliver J, Smith S, Eyre S, Hyrich KL, Wilson AG, Morgan AW, Isaacs J, Worthington J, Barton A.

Arthritis Rheumatol. 2016 Jan 27.

[Reduced numbers of mucosal DR\(int\) macrophages and increased numbers of CD103\(+\) dendritic cells during anti-TNF- \$\alpha\$ treatment in patients with Crohn's disease.](#)

Dige A, Magnusson MK, Öhman L, Hvas CL, Kelsen J, Wick MJ, Agnholt J.

Scand J Gastroenterol. 2016 Jan 19:1-8.

[Serum Markers in Rheumatoid Arthritis: A Longitudinal Study of Patients Undergoing Infliximab Treatment.](#)

Int J Rheumatol. 2015;2015:276815.

[Plasma concentrations of amino acid and nicotinamide metabolites in rheumatoid arthritis - potential biomarkers of disease activity and drug treatment.](#)

Smolenska Z, Smolenski RT, Zdrojewski Z.

Biomarkers. 2016 Jan 26:1-7

[Higher expression of TNF \$\alpha\$ -induced genes in the synovium of patients with early rheumatoid arthritis correlates with disease activity, and predicts absence of response to first line therapy.](#)

De Groof A, Ducreux J, Humby F, Nzeusseu Toukap A, Badot V, Pitzalis C, Houssiau FA, Durez P, Lauwerys BR. Arthritis Res Ther. 2016 Jan 20;18(1):19.

Systemic Lupus Erythematosus

Treat-to-target in systemic lupus erythematosus: are we there yet?

Mok CC.

Expert Rev Clin Pharmacol. 2016 Jan 25.

Self-reactive IgE exacerbates interferon responses associated with autoimmunity.

Renault J, Riggs JM, Karnell JL, Liarski VM, Li J, Shirinian L, Xu L, Casey KA, Smith MA, Khatry DB, Izhak L, Clarke L, Herbst R, Ettinger R, Petri M, Clark MR, Mustelin T, Kolbeck R, Sanjuan MA.

Nat Immunol. 2016 Feb;17(2):196-203.

Arthritis

Effectiveness and safety of abatacept in elderly patients with rheumatoid arthritis enrolled in the French Society of Rheumatology's ORA registry.

Lahaye C, Soubrier M, Mulliez A, Bardin T, Cantagrel A, Combe B, Dougados M, Flipo RM, Le Loët X, Shaeverbeke T, Ravaud P, Mariette X, Gottenberg JE; French Society of Rheumatology. Rheumatology (Oxford). 2016 Jan 27.

Agreements and Discrepancies between FDA Reports and Journal Papers on Biologic Agents Approved for Rheumatoid Arthritis: A Meta-Research Project.

Amarilyo G, Furst DE, Woo JM, Li W, Bliddal H, Christensen R, Tarp S. PLoS One. 2016 Jan 25;11(1):e0147556.

Drug-induced hypereosinophilia related to tocilizumab therapy for rheumatoid arthritis.

Morrisroe K, Wong M. Rheumatology (Oxford). 2015 Nov;54(11):2113-4.

Factors associated with choice of biologic among children with Juvenile Idiopathic Arthritis: results from two UK paediatric biologic registers.

Kearsley-Fleet L, Davies R, Baildam E, Beresford MW, Foster HE, Southwood TR, Thomson W, Hyrich KL. Rheumatology (Oxford). 2016 Jan 4.

Anti-TNF α agents curb platelet activation in patients with rheumatoid arthritis.

Manfredi AA, Baldini M, Camera M, Baldissera E, Brambilla M, Peretti G, Maseri A, Rovere-Querini P, Tremoli E, Sabbadini MG, Maugeri N. Ann Rheum Dis. 2016 Jan 27.

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



Innovative Medicines Initiative

[Recent advances in the use of Anti-TNF \$\alpha\$ therapy for the treatment of juvenile idiopathic arthritis.](#)

Taddio A, Cattalini M, Simonini G, Cimaz R.

Expert Rev Clin Immunol. 2016 Jan 25.

[Evaluation of golimumab for the treatment of patients with active rheumatoid arthritis.](#)

Tanaka Y, Senoo A, Fujii H, Baker D.

Expert Opin Drug Metab Toxicol. 2016 Jan 25

[Biologics beyond TNF- \$\alpha\$ inhibitors and the effect of targeting the homologues TL1A-DR3 pathway in chronic inflammatory disorders.](#)

Tougaard P, Zervides KA, Skov S, Hansen AK, Pedersen AE.

Immunopharmacol Immunotoxicol. 2016 Jan 26:1-10.

[A longitudinal genome-wide association study of anti-tumor necrosis factor response among Japanese patients with rheumatoid arthritis.](#)

Honne K, Hallgrímsdóttir I, Wu C, Sebro R, Jewell NP, Sakurai T, Iwamoto M, Minota S, Jawaheer D.

Arthritis Res Ther. 2016 Jan 18;18(1):12.

[Rheumatoid factor and anti-citrullinated protein antibody positivity are associated with a better effectiveness of abatacept: Results from the Pan-European registry analysis.](#)

Gottenberg JE, Courvoisier DS, Hernandez MV, Iannone F, Lie E, Canhão H, Pavelka K, Hetland ML, Turesson C, Mariette X, Finckh A.

Arthritis Rheumatol. 2016 Jan 27.

Inflammatory Bowel Diseases

[Anti-TNF monotherapy for Crohn's disease: a 13-year multicentre experience.](#)

Peyrin-Biroulet L, Salleron J, Filippi J, Reenaers C, Antunes O, Filipe V, Louis E, Hébuterne X, Roblin X.

J Crohns Colitis. 2016 Jan 22.

[Eldelumab \[Anti-IP-10\] Induction Therapy for Ulcerative Colitis: A Randomised, Placebo-Controlled, Phase 2b Study.](#)

Sandborn WJ, Colombel JF, Ghosh S, Sands BE, Dryden G, Hébuterne X, Leong RW, Bressler B, Ullman T, Lakatos PL, Reinisch W, Xu LA, Luo A.

J Crohns Colitis. 2015 Dec 30.

A safety assessment of anti-tumor necrosis factor alpha therapy for treatment of Crohn's disease.

Papamichael K, Mantzaris GJ, Peyrin-Biroulet L.

Expert Opin Drug Saf. 2016 Jan 22

Expert consensus paper on the use of Vedolizumab for the management of patients with moderate-to-severe Inflammatory Bowel Disease.

Armuzzi A, Gionchetti P, Daperno M, Danese S, Orlando A, Lia Scribano M, Vecchi M, Rizzello F; GIVI (Gruppo Italiano su Vedolizumab nelle IBD) Group; GIVI Gruppo Italiano su Vedolizumab nelle IBD Group.

Dig Liver Dis. 2016 Jan 7

Meta-analysis of the effectiveness and safety of vedolizumab for ulcerative colitis.

Jin Y, Lin Y, Lin LJ, Zheng CQ.

World J Gastroenterol. 2015 May 28;21(20):6352-60

Integrin-based therapeutics: biological basis, clinical use and new drugs.

Ley K, Rivera-Nieves J, Sandborn WJ, Shattil S.

Nat Rev Drug Discov. 2016 Jan 29.

Disrupted regulatory T cell homeostasis in inflammatory bowel diseases.

Pedros C, Duguet F, Saoudi A, Chabod M.

World J Gastroenterol. 2016 Jan 21;22(3):974-95. doi: 10.3748/wjg.v22.i3.974. Review.

Direct effect of infliximab on intestinal mucosa sustains mucosal healing: exploring new mechanisms of action.

Petito V, Lopetuso LR, Arena V, Stigliano E, Boninsegna A, Bibbò S, Poscia A, Alfieri S, Rosa F, Amato A, Cammarota G, Papa A, Sgambato A, Gasbarrini A, Scaldaferri F.

Dig Liver Dis. 2015 Dec 19.

Identifying patients at high risk of loss of response to infliximab maintenance therapy in paediatric Crohn's disease.

Dupont-Lucas C, Sternszus R, Ezri J, Leibovitch S, Gervais F, Amre D, Deslandres C.

J Crohns Colitis. 2016 Jan 28.

Adalimumab in pediatric Crohn's disease.

Patel AS, Suarez LD, Rosh JR.

Immunotherapy. 2016 Jan 20.

Next-Generation Therapeutics for IBD.

Löwenberg M, D'Haens G.

Curr Gastroenterol Rep. 2015 Jun;17(6):21.

Multiple Sclerosis

Alemtuzumab long-term immunologic effect: Treg suppressor function increases up to 24 months.

De Mercanti S, Rolla S, Cucci A, Bardina V, Cocco E, Vladic A, Soldo-Butkovic S, Habek M, Adamec I, Horakova D, Annovazzi P, Novelli F, Durelli L, Clerico M.
Neurol Neuroimmunol Neuroinflamm. 2016 Jan 21;3(1):e194.

Comparative efficacy of fingolimod vs natalizumab: A French multicenter observational study.

Barbin L, Rousseau C, Jousset N, Casey R, Debouverie M, Vukusic S, De Sèze J, Brassat D, Wiertlewski S, Brochet B, Pelletier J, Vermersch P, Edan G, Lebrun-Frenay C, Clavelou P, Thouvenot E, Camdessanché JP, Tourbah A, Stankoff B, Al Khedr A, Cabre P, Papeix C, Berger E, Heinzele O, Debroucker T, Moreau T, Gout O, Bourre B, Créange A, Labauge P, Magy L, Defer G, Foucher Y, Laplaud DA; CFSEP and OFSEP groups.
Neurology. 2016 Jan 29

Association of Immunotherapies With Outcomes in Relapsing-Remitting Multiple Sclerosis.

Tramacere I, Del Giovane C, Filippini G.
JAMA. 2016 Jan 26;315(4):409-10

Daclizumab high-yield process reduced the evolution of new gadolinium-enhancing lesions to T1 black holes in patients with relapsing-remitting multiple sclerosis.

Radue EW, Sprenger T, Vollmer T, Giovannoni G, Gold R, Havrdova E, Selmaj K, Stefoski D, You X, Elkins J.
Eur J Neurol. 2016 Feb;23(2):412-5..

The potential role for ocrelizumab in the treatment of multiple sclerosis: current evidence and future prospects.

Sorensen PS, Blinkenberg M.
Ther Adv Neurol Disord. 2016 Jan;9(1):44-52.

The use of immune modulating drugs for the treatment of multiple sclerosis.

Al-Khamis FA.
Neurosciences (Riyadh). 2016 Jan;21(1):4-9.

B cell-directed therapies in multiple sclerosis.

Gasperi C, Stüve O, Hemmer B.
Neurodegener Dis Manag. 2016 Feb;6(1):37-47.

Cytokine-Defined B Cell Responses as Therapeutic Targets in Multiple Sclerosis.

Li R, Rezk A, Healy LM, Muirhead G, Prat A, Gommerman JL, Bar-Or A; MSSRF Canadian B cells in MS Team.
Front Immunol. 2016 Jan 8;6:626.

Hemophilia

B-cell memory against factor VIII.

Reipert BM.
Cell Immunol. 2016 Jan 6

A subset of high titer anti-factor VIII A2 domain antibodies are responsive to treatment with factor VIII.

Eubanks J, Baldwin WH, Markovitz R, Parker ET, Cox C, Kempton CL, Meeks SL.
Blood. 2016 Jan 29

Molecular design and downstream processing of turoctocog alfa (NovoEight), a B-domain truncated factor VIII molecule.

Ahmadian H, Hansen EB, Faber JH, Sejergaard L, Karlsson J, Bolt G, Hansen JJ, Thim L.
Blood Coagul Fibrinolysis. 2016 Jan 12.

Achievements, challenges and unmet needs for haemophilia patients with inhibitors: Report from a symposium in Paris, France on 20 November 2014.

Dargaud Y, Pavlova A, Lacroix-Desmazes S, Fischer K, Soucie M, Claeysens S, Scott DW, d'Oiron R, Lavigne-Lissalde G, Kenet G, Escuriola Ettingshausen C, Borel-Derlon A, Lambert T, Pasta G, Negrer C.
Haemophilia. 2016 Jan;22 Suppl 1:1-24.

Basic immunology

Polysialylation controls dendritic cell trafficking by regulating chemokine recognition.

Kiermaier E, Moussion C, Veldkamp CT, Gerardy-Schahn R, de Vries I, Williams LG, Chaffee GR, Phillips AJ, Freiberger F, Imre R, Taleski D, Payne RJ, Braun A, Förster R, Mechtler K, Mühlenhoff M, Volkman BF, Sixt M.
Science. 2016 Jan 8;351(6269):186-90.

Autophagy enforces functional integrity of regulatory T cells by coupling environmental cues and metabolic homeostasis.

Wei J, Long L, Yang K, Guy C, Shrestha S, Chen Z, Wu C, Vogel P, Neale G, Green DR, Chi H.
Nat Immunol. 2016 Jan 25.

CD4+T cell anergy prevents autoimmunity and generates regulatory T cell precursors.

Kalekar LA, Schmiel SE, Nandiwada SL, Lam WY, Barsness LO, Zhang N, Stritesky GL, Malhotra D, Pauken KE, Linehan JL, O'Sullivan MG, Fife BT, Hogquist KA, Jenkins MK, Mueller DL.
Nat Immunol. 2016 Feb 1.

Opinions/Commentaries/Across diseases reviews

[The thymus and rheumatology: should we care?](#)

Cosway E, Anderson G, Garside P, Prendergast C.

Curr Opin Rheumatol. 2016 Mar;28(2):189-95.

[Is rheumatoid arthritis an autoimmune disease?](#)

Chemin K, Klareskog L, Malmström V.

Curr Opin Rheumatol. 2016 Mar;28(2):181-8

[Subgroup analysis in MS trials.](#)

Sormani MP.

Mult Scler. 2016 Jan 15.

[Alterations in immune function with biologic therapies for autoimmune disease.](#)

Her M, Kavanaugh A.

J Allergy Clin Immunol. 2016 Jan;137(1):19-27

[The biology behind interleukin-6 targeted interventions.](#)

Liu X, Jones GW, Choy EH, Jones SA.

Curr Opin Rheumatol. 2016 Mar;28(2):152-60.

[MS arising during Tocilizumab therapy for rheumatoid arthritis.](#)

Beauchemin P, Carruthers R.

Mult Scler. 2016 Jan 7.

[Tocilizumab and multiple sclerosis: a causal relationship? Clinical Commentary on the case report entitled -](#)

[MS arising during Tocilizumab therapy for rheumatoid arthritis.](#)

Comabella M.

Mult Scler. 2016 Jan 7.

[AVX-470, an Orally Delivered Anti-TNF Antibody for Treatment of Active Ulcerative Colitis: Results of a First-in-Human Trial.](#)

Harris MS, Hartman D, Lemos BR, Erlich EC, Spence S, Kennedy S, Ptak T, Pruitt R, Vermeire S, Fox BS.

J Crohns Colitis. 2016 Jan 28.

[Market watch: Upcoming market catalysts in Q4 2015.](#)

Liu M.

Nat Rev Drug Discov. 2015 Oct;14(10):671.

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



Innovative Medicines Initiative

[Make journals report clinical trials properly.](#)

Goldacre B.

Nature. 2016 Feb 4;530(7588):7.

[Authorized manufacturing changes of therapeutic monoclonal antibodies \(mAbs\) in European Public Assessment Report \(EPAR\) documents.](#)

Vezér B, Buzás Z, Sebeszta M, Zrubka Z.

Curr Med Res Opin. 2016 Jan 25:1-18

REGULATION

EMA

[Human medicines European public assessment report \(EPAR\): Humira, adalimumab](#)

Revision: 43, Authorised

January 2016

[Human medicines European public assessment report \(EPAR\): Benepali, etanercept](#)

Revision: 0, Authorised

January 2016

[Human medicines European public assessment report \(EPAR\): Inflectra, infliximab](#)

Revision: 9, Authorised

January 2016

[Workshop on immunogenicity assessment of biotechnology-derived therapeutic proteins](#)

European Medicines Agency, London, UK, From: 09-Mar-2016



WC500201937_
Workshop programme

[Human medicines European public assessment report \(EPAR\): Plegridy, peginterferon beta-1a](#)

Revision: 7, Authorised

January 2016

[Recombinant porcine factor VIII \(B-domain-deleted\)](#)

Orphan designation:

Updated

January 2016

[Recombinant fusion protein consisting of human coagulation factor VIII attached to the Fc domain of human IgG1 for the: Treatment of haemophilia A](#)

Orphan designation

Updated

January 2016

[Human medicines European public assessment report \(EPAR\): Enbrel, etanercept](#)

Revision: 47, Authorised

January 2016

[Opinion/decision on a Paediatric investigation plan \(PIP\): RoActemra, tocilizumab](#)

Therapeutic area: Immunology-Rheumatology-Transplantation

Updated

January 2016