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第 2 部（モジュール 2）：CTD の概要（サマリー）

2.7.5　参考文献

バイオジェン・アイデック・ジャパン株式会社

2.7.5　参考文献

著者、表題、掲載誌など	資料番号
Adamowicz-Salach A, Pawelec K, Loch T, et al. Incidence and treatment of hepatitis C virus infection in children with haemophilia in Poland. Haemophilia. 1999;5(6):436-40.	第 5.4.1-1 項
ADVATE [Antihemophilic Factor (Recombinant) Plasma/Albumin-Free Method] package insert. Westlake Village, CA: Baxter Healthcare Corporation; July 2007.	第 5.4.1-2 項
Amby LK, Seremetis S, Obergfell A, et al. Challenges of defining reliable clinical surrogate end points in haemophilia trials: a critical review. Blood Coagul Fibrinolysis. 2009;20(7):488-93.	第 5.4.1-4 項
BeneFIX® [Coagulation Factor IX (Recombinant)] prescribing information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; Nov 2011.	第 5.4.1-7 項
Björkman S, Ahlén V. Population pharmacokinetics of plasma-derived factor IX in adult patients with haemophilia B: implications for dosing in prophylaxis. Eur J Clin Pharmacol. 2012;68(6):969-77.	第 5.4.1-10 項
Bjorkman S, Shapiro AD, Berntorp E. Pharmacokinetics of recombinant factor IX in relation to age of the patient: implications for dosing in prophylaxis. Haemophilia. 2001;7(2):133-9.	第 5.4.1-9 項
Buyue Y, Chhabra ES, Wang L. The Effect of Factor IXa on Thrombin Generation Activity Determination: rFIXFc Vs. BeneFIX (R). Blood. 2011;118(21):984-.	第 5.4.1-11 項
Chang HH, Yang YL, Hung MH, et al. Pharmacokinetic study of recombinant human factor IX in previously treated patients with hemophilia B in Taiwan. J Formos Med Assoc. 2007;106(4):281-7.	第 5.4.1-13 項
Chitlur M, Warrier I, Rajpurkar M, et al. Inhibitors in factor IX deficiency a report of the ISTH-SSC international FIX inhibitor registry (1997-2006). Haemophilia. 2009;15(5):1027-31.	第 5.4.1-15 項
Chitlur M, Warrier I, Rajpurkar M, et al. Thromboelastography in children with coagulation factor deficiencies. Br J Haematol. 2008;142(2):250-6.	第 5.4.1-14 項
Chitlur M. Challenges in the laboratory analyses of bleeding disorders. Thromb Res. 2012;130(1):1-6.	第 5.4.1-16 項
Collins PW, Fischer K, Morfini M, et al. Implications of coagulation factor VIII and IX pharmacokinetics in the prophylactic treatment of haemophilia. Haemophilia. 2011;17(1):2-10.	第 5.4.1-19 項
Coppola A, Tagliaferri A, Di Capua M, et al. Prophylaxis in children with hemophilia: evidence-based achievements, old and new challenges. Semin Thromb Hemost. 2012;38(1):79-94.	第 5.4.1-20 項
Dargaud Y, Béguin S, Lienhart A, et al. Evaluation of thrombin generating capacity in plasma from patients with haemophilia A and B. Thromb Haemost. 2005;93(3):475-80.	第 5.4.1-24 項
Dargaud Y, Luddington R, Gray E, et al. Standardisation of thrombin generation test--which reference plasma for TGT? An international multicentre study. Thromb Res. 2010;125(4):353-6.	第 5.4.1-23 項
Dazzi F, Tison T, Vianello F, et al. High incidence of anti-FVIII antibodies against non-coagulant epitopes in haemophilia A patients: a possible role for the half-life of transfused FVIII. Br J Haematol. 1996;93(3):688-93.	第 5.4.1-25 項
Di Minno MN, Di Minno G, Di Capua M, et al. Cost of care of haemophilia with inhibitors. Haemophilia. 2010;16(1):e190-201.	第 5.4.1-28 項

著者、表題、掲載誌など	資料番号
Dietrich SL. The treatment of hemophilia bleeding with limited resources. Treatment of Hemophilia [Internet]. 2004; No. 1. Available from: http://www1.wfh.org/publication/files/pdf-1107.pdf.	第 5.4.1-26 項
DiMichele D. Inhibitor development in haemophilia B: an orphan disease in need of attention. Br J Haematol. 2007;138(3):305-15.	第 5.4.1-27 項
Donadel-Claeyssens S. Current co-ordinated activities of the PEDNET (European Paediatric Network for Haemophilia Management). Haemophilia. 2006;12(2):124-7.	第 5.4.1-29 項
Escobar MA. Treatment on demand--in vivo dose finding studies. Haemophilia. 2003;9(4):360-7.	第 5.4.1-32 項
European Medicines Agency. Core SPC for Human Plasma Derived and Recombinant Factor IX Products. CPMP/BPWG/1625/99. June 29, 2000. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003706.pdf. Accessed November 30, 2012.	第 5.4.1-21 項
European Medicines Agency. Guideline on clinical investigation of recombinant and human plasma-derived factor IX products. EMA/CHMP/BPWP/144552/2009. July 21, 2011. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/08/WC500109691.pdf. Accessed November 29, 2012.	第 5.4.1-30 項
European Medicines Agency. P/123/2011: EMA decision of 7 June 2011 on the agreement of a paediatric investigation plan and on the granting of a deferral for recombinant fusion protein consisting of human coagulation factor IX attached to the Fc domain of human IgG1 (rFIXFc) (EMEA-000914-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council. http://www.ema.europa.eu/docs/en_GB/document_library/PIP_decision/WC500108743.pdf. Published 2011. Accessed June, 2011.	第 5.4.1-31 項
Ewenstein BM, Joist JH, Shapiro AD, et al. Pharmacokinetic analysis of plasma-derived and recombinant F IX concentrates in previously treated patients with moderate or severe hemophilia B. Transfusion. 2002;42(2):190-7.	第 5.4.1-33 項
Ghosh K, Shetty S, Kulkarni B. Correlation of thromboelastographic patterns with clinical presentation and rationale for use of antifibrinolytics in severe haemophilia patients. Haemophilia. 2007;13(6):734-9.	第 5.4.1-37 項
Giles AR, Verbruggen B, Rivard GE, et al. A detailed comparison of the performance of the standard versus the Nijmegen modification of the Bethesda assay in detecting factor VIII:C inhibitors in the haemophilia A population of Canada. Association of Hemophilia Centre Directors of Canada. Factor VIII/IX Subcommittee of Scientific and Standardization Committee of International Society on Thrombosis and Haemostasis. Thromb Haemost. 1998;79(4):872-5.	第 5.4.1-38 項
Hartert H. Blutgerinnungsstudien mid der Thrombelastographie. 1948.	第 5.4.1-43 項
Hemker HC, Wielders S, Kessels H, et al. Continuous registration of thrombin generation in plasma, its use for the determination of the thrombin potential. Thromb Haemost. 1993;70(4):617-24.	第 5.4.1-44 項
Hemophilia of Georgia. Protocols for the treatment of hemophilia and von Willebrand disease. Treatment of Hemophilia [Internet]. 2008; No. 14. Available from: http://www1.wfh.org/publication/files/pdf-1137.pdf. Accessed December 04, 2012.	第 5.4.1-46 項
High KA. Factor IX: molecular structure, epitopes, and mutations associated with inhibitor formation. Adv Exp Med Biol. 1995;386:79-86.	第 5.4.1-45 項

著者、表題、掲載誌など	資料番号
ISTH Consensus Definitions in Hemophilia [draft]. Updated July 14, 2011. Available from: http://c.ymcdn.com/SITES/WWW.ISTH.ORG/RESOURCE/GROUP/D4A6F49A-F4EC-450F-9E0F-7BE9F0C2AB2E/PROJECTS/CONSENSUS_DEFINITIONS_IN_HEM.PDF. Accessed October 10, 2012.	第 5.4.1-47 項
Kasper CK, Aledort L, Aronson D, et al. Proceedings: A more uniform measurement of factor VIII inhibitors. Thromb Diath Haemorrh. 1975;34(2):612.	第 5.4.1-49 項
Kisker CT, Eisberg A, Schwartz B. Prophylaxis in factor IX deficiency product and patient variation. Haemophilia. 2003;9(3):279-84.	第 5.4.1-51 項
Kluft C, Meijer P. External quality assessment for thrombin generation tests: an exploration. Semin Thromb Hemost. 2010;36(7):791-6.	第 5.4.1-52 項
Kulkarni R, Soucie JM, Evatt B, et al. Renal disease among males with haemophilia. Haemophilia. 2003;9(6):703-10.	第 5.4.1-53 項
Lambert T, Recht M, Valentino LA, et al. Reformulated BeneFix: efficacy and safety in previously treated patients with moderately severe to severe haemophilia B. Haemophilia. 2007;13(3):233-43.	第 5.4.1-54 項
Langdell RD, Wagner RH, Brinkhous KM. Effect of antihemophilic factor on one-stage clotting tests; a presumptive test for hemophilia and a simple one-stage antihemophilic factor assy procedure. J Lab Clin Med. 1953;41(4):637-47.	第 5.4.1-55 項
Lewis SJ, Stephens E, Florou G, et al. Measurement of global haemostasis in severe haemophilia A following factor VIII infusion. Br J Haematol. 2007;138(6):775-82.	第 5.4.1-56 項
Luddington R, Baglin T. Clinical measurement of thrombin generation by calibrated automated thrombography requires contact factor inhibition. J Thromb Haemost. 2004;2(11):1954-9.	第 5.4.1-61 項
Manco-Johnson MJ, Abshire TC, Shapiro AD, et al. Prophylaxis versus episodic treatment to prevent joint disease in boys with severe hemophilia. N Engl J Med. 2007;357(6):535-44.	第 5.4.1-62 項
Mann KG, Butenas S, Brummel K. The dynamics of thrombin formation. Arterioscler Thromb Vasc Biol. 2003;23(1):17-25.	第 5.4.1-63 項
Martinowitz U, Shapiro A, Quon DV, et al. Pharmacokinetic properties of IB1001, an investigational recombinant factor IX, in patients with haemophilia B: repeat pharmacokinetic evaluation and sialylation analysis. Haemophilia. 2012;18(6):881-7.	第 5.4.1-64 項
MASAC Recommendation Concerning Prophylaxis (Regular Administration of Clotting Factor Concentrate to Prevent Bleeding) (Replaces #170). November 2007. New York, NY: National Hemophilia Foundation. Available from: http://www.hemophilia.org/NHFWeb/Resource/StaticPages/menu0/menu5/menu57/masac179.pdf. Accessed December 03, 2012.	第 5.4.1-65 項
Negrier C, Knobe K, Tiede A, et al. Enhanced pharmacokinetic properties of a glycoPEGylated recombinant factor IX: a first human dose trial in patients with hemophilia B. Blood. 2011;118(10):2695-701. Epub 011 May 9.	第 5.4.1-68 項
Neugebauer B, Drai C, Haase M, et al. Factor VIII products and inhibitor development: concepts for revision of European regulatory guidelines. Haemophilia. 2008;14(1):142-4.	第 5.4.1-69 項
Peters RT, Low SC, Kamphaus GD, et al. Prolonged activity of factor IX as a monomeric Fc fusion protein. Blood. 2010;115(10):2057-64. Epub 10 Jan 7.	第 5.4.1-73 項
Ragni MV, Pasi KJ, White GC, et al. Use of recombinant factor IX in subjects with haemophilia B undergoing surgery. Haemophilia. 2002;8(2):91-7.	第 5.4.1-77 項

著者、表題、掲載誌など	資料番号
Ragni MV. Rationale for a randomized controlled trial comparing two prophylaxis regimens in adults with severe hemophilia A: the Hemophilia Adult Prophylaxis Trial. Expert Rev Hematol. 2011;4(5):495-507.	第 5.4.1-78 項
Roberts HR, Eberst ME. Current management of hemophilia B. Hematol Oncol Clin North Am. 1993;7(6):1269-80.	第 5.4.1-81 項
Sahud MA, Pratt KP, Zhukov O, et al. ELISA system for detection of immune responses to FVIII: a study of 246 samples and correlation with the Bethesda assay. Haemophilia. 2007;13(3):317-22.	第 5.4.1-84 項
Shapiro AD, Di Paola J, Cohen A, et al. The safety and efficacy of recombinant human blood coagulation factor IX in previously untreated patients with severe or moderately severe hemophilia B. Blood. 2005;105(2):518-25.	第 5.4.1-87 項
Shapiro AD, Ragni MV, Valentino LA, et al. Recombinant factor IX-Fc fusion protein (rFIXFc) demonstrates safety and prolonged activity in a phase 1/2a study in hemophilia B patients. Blood. 2012;119(3):666-72 .	第 5.4.1-88 項
Sorensen B, Ingerslev J. Whole blood clot formation phenotypes in hemophilia A and rare coagulation disorders. Patterns of response to recombinant factor VIIa. J Thromb Haemost. 2004;2(1):102-10.	第 5.4.1-90 項
Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia [Internet]. 2012. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22776238. Accessed Jul 06.	第 5.4.1-93 項
Takamiya O, Kinoshita S. A simple method for detection of human factor IX inhibitor using ELISA. Scand J Clin Lab Invest. 1997;57(8):683-8.	第 5.4.1-97 項
Towfighi F, Gharagozlou S, Sharifian RA, et al. Comparative measurement of anti-factor VIII antibody by Bethesda assay and ELISA reveals restricted isotype profile and epitope specificity. Acta Haematol. 2005;114(2):84-90.	第 5.4.1-98 項
Valentino LA. Blood-induced joint disease: the pathophysiology of hemophilic arthropathy. J Thromb Haemost. 2010;8(9):1895-902.	第 5.4.1-100 項
van de Putte D, Fischer K, Makris M, et al. History of non-fatal cardiovascular disease in a cohort of Dutch and British patients with haemophilia. European Journal of Haematology. 2012a;89(4):336-9.	第 5.4.1-102 項
van de Putte DE, Fischer K, Makris M, et al. Increased prevalence of hypertension in haemophilia patients. Thromb Haemost. 2012b;108(4):750-5.	第 5.4.1-103 項
van Genderen FR, Fischer K, Heijnen L, et al. Pain and functional limitations in patients with severe haemophilia. Haemophilia. 2006;12(2):147-53.	第 5.4.1-104 項
Verbruggen B, Novakova I, Wessels H, et al. The Nijmegen modification of the Bethesda assay for factor VIII:C inhibitors: improved specificity and reliability. Thromb Haemost. 1995;73(2):247-51.	第 5.4.1-105 項
von Mackensen S, Bullinger M, Group H-Q. Development and testing of an instrument to assess the Quality of Life of Children with Haemophilia in Europe (Haemo-QoL). Haemophilia. 2004;10(Suppl 1):17-25.	第 5.4.1-106 項
von Mackensen S, Campos IG, Acquadro C, et al. Cross-cultural adaptation and linguistic validation of age-group-specific haemophilia patient-reported outcome (PRO) instruments for patients and parents. Haemophilia. 2012.	第 5.4.1-107 項
White G, Shapiro A, Ragni M, et al. Clinical evaluation of recombinant factor IX. Semin Hematol. 1998;35(2 Suppl 2):33-8.	第 5.4.1-110 項
White GC, Shapiro AD, Kurczynski EM, et al. Variability of in vivo recovery of factor IX after infusion of monoclonal antibody purified factor IX concentrates in patients with hemophilia B. The Mononine Study Group. Thromb Haemost. 1995;73(5):779-84.	第 5.4.1-109 項

著者、表題、掲載誌など	資料番号
Wiedel J, Stabler S, Geraghty S, et al. Joint replacement surgery in hemophilia. Treatment of Hemophilia [Internet]. 2010; No. 50. Available from: http://www1.wfh.org/2/docs/Publications/Musculoskeletal_Physiotherapy/TOH-50_Joint_Replacement.pdf.	第 5.4.1-113 項
World Health Organization. WHO handbook for reporting results of cancer treatment. (Offset publication no. 48). Available from: http://whqlibdoc.who.int/offset/WHO_OFFSET_48.pdf.	第 5.4.1-112 項
嶋緑倫，吉岡章. 先天性凝固異常. 三輪血液病学. 第 3 版. 東京, 文光堂, 2006, 1686-1709.	第 5.4.1-116 項
瀧正志. 定期補充療法. みんなに役立つ血友病の基礎と臨床. 改訂版. 大阪, 医薬ジャーナル社, 2012, 192-201 .	第 5.4.1-120 項