第 2 部（モジュール 2）

CTD の概要

2.7.5 参考文献

ネクセラファーマジャパン株式会社

2.7.5 参考文献

[AJMC 2019] AJMC Perspectives. The Epidemiology of Insomnia in Older Adults and Current Treatment Landscape. Am J Manag Care. 2019.
（モジュール 5.4.13）

[APA 2013] American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5). Arlington, VA, American Psychiatric Association, 2013.

[Bretz 2005] Bretz F, Pinheiro JC, Branson M. Combining multiple comparisons and modeling techniques in dose-response studies. Biometrics. 2005;61(3):738-48.
（モジュール 5.4.2）

[Bretz 2009] Bretz F, Maurer W, Brannath W, Posch M. A graphical approach to sequentially rejective multiple test procedures. Stat Med. 2009;28(4):586-604.
（モジュール 5.4.15）

[Brisbare-Roch 2007] Brisbare-Roch C, Dingemanse J, Koberstein R, Hoever P, Aissaoui H, Flores S, et al. Promotion of sleep by targeting the orexin system in rats, dogs and humans. Nat Med 2007; 13(2):150–5.
（モジュール 5.4.18）

[Buysse 2007] Buysse DJ, Thompson W, Scott J, Franzen PL, Germain A, Hall M, et al. Daytime symptoms in primary insomnia: a prospective analysis using ecological momentary assessment. Sleep Med. 2007;8(3):198-208.
（モジュール 5.4.3）

[Cruz 2014] Cruz HG, Hoever P, Chakraborty B, Schoedel K, Sellers EM, Dingemanse J. Assessment of the abuse liability of a dual orexin receptor antagonist: a crossover study of almorexant and zolpidem in recreational drug users. CNS Drugs. 2014;28(4):361-72.
（モジュール 5.4.4）

[Dorne 2003] Dorne JLCM, Walton K, Renwick AG. Human variability in CYP3A4 metabolism and CYP3A4-related uncertainty factors for risk assessment. Food Chem Toxicol 2003;41(2):201–24.
（モジュール 5.4.1）

[EMA 2012] EMA. European Medicines Agency. Guideline on the investigation of drug interactions. 2012 Jun 21.
Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf

[EMA 2015] EMA. European Medicines Agency. Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function. EMA/CHMP/83874/2014. 2015 Dec 17.
Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-evaluation-pharmacokinetics-medicinal-products-patients-decreased-renal-function_en.pdf

[FDA 2002] FDA. Guidance for Industry. Food-Effect Bioavailability and Fed Bioequivalence Studies. 2002 Dec.
Available from: https://www.fda.gov/files/drugs/published/Food-Effect-Bioavailability-and-Fed-Bioequivalence-Studies.pdf

[FDA 2009] FDA. Guidance for industry. Patient-reported outcome measures: Use in medical product

development to support labeling claims. 2009 Dec.
Available from: https://www.fda.gov/media/77832/download

[FDA 2020] FDA. Guidance for industry. Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis, and Impact on Dosing. 2020 Sep.
Available from: https://www.fda.gov/media/78573/download

[FDA 2020] FDA. Clinical Drug Interaction Studies – Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions. Guideline for industry. 2020 Jan.
Available from: https://www.fda.gov/media/134581/download

[Garnett 2018] Garnett C, Bonate PL, Dang Q, Ferber G, Huang D, Liu J, et al. Scientific white paper on concentration-QTc modeling. J Pharmacokinet Pharmacodyn. 2018;45(3):383-97.
（モジュール 5.4.5）

[Gough 1995] Gough K, Hutchison M, Keene O, Byrom B, Ellis S, Lacey L, et al. “Assessment of Dose Proportionality: Report from the Statisticians in the Pharmaceutical Industry/Pharmacokinetics UK Joint Working Party“. Drug Information Journal. 1995;29(3):1039–48.
（モジュール 5.4.6）

[Groeneveld 2016] Groeneveld GJ, Hay JL, Van Gerven JM. Measuring blood–brain barrier penetration using the NeuroCart, a CNS test battery. Drug Discov Today Technol. 2016 ;20:27-34.
（モジュール 5.4.7）

[Huizinga 2019] Huizinga CR, Zuiker RG, de Kam ML, Ziagkos D, Kuipers J, Mejia Y, et al. Evaluation of simulated driving in comparison to laboratory-based tests to assess the pharmacodynamics of alprazolam and alcohol. J Psychopharmacol. 2019;33(7):791-800.
（モジュール 5.4.19）

[ICH-E1 1994] ICH-E1. The Extent of population exposure to assess clinical safety for drugs intended for long-term treatment of non-life-threatening conditions. 1994.
Available from: https://www.pmda.go.jp/files/000156791.pdf

[Janto 2018] Janto K, Prichard JR, Pusalavidyasagar S. An Update on Dual Orexin Receptor Antagonists and Their Potential Role in Insomnia Therapeutics. J Clin Sleep Med. 2018;14(8):1399-408.
（モジュール 5.4.21）

[Pinheiro 2006] Pinheiro J, Bornkamp B, Bretz F. Design and analysis of dose-finding studies combining multiple comparisons and modeling procedures. J Biopharm Stat. 2006;16(5):639-56.
（モジュール 5.4.14）

[Pinheiro 2014] Pinheiro J, Bornkamp B, Glimm E, Bretz F. Model-based dose finding under model uncertainty using general parametric models. Stat Med. 2014;33(10):1646-61.
（モジュール 5.4.16）

[QUVIVIQ™ Revised] QUVIVIQ™ film-coated tablets. US Prescribing Information. United States Food and Drug Administration full prescribing information. Revised;1/2022, IDRS10012022.
Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214985s000lbl.pdf

[Roth 2009] Roth T. Hypnotic use for insomnia management in chronic obstructive pulmonary disease. Sleep Med. 2009;10:19–25.
（モジュール 5.4.8）

[Saper 2005] Saper CB, Scammell TE, Lu J. Hypothalamic regulation of sleep and circadian rhythms. Nature. 2005;437(7063):1257-63.

（モジュール 5.4.27）

[Schoedel 2016] Schoedel KA, Sun H, Sellers EM, Faulknor J, Levy-Cooperman N, Li X, et al. Assessment of the abuse potential of the orexin receptor antagonist, suvorexant, compared with zolpidem in a randomized crossover study. J Clin Psychopharmacol. 2016;36(4):314-23.
（モジュール 5.4.17）

[Shram 2011] Shram MJ, Schoedel KA, Bartlett C, Shazer RL, Anderson CM, Sellers EM. Evaluation of the abuse potential of lorcaserin, a serotonin 2C (5-HT2C) receptor agonist, in recreational polydrug users. Clin Pharmacol Ther. 2011;89(5):683-92.
（モジュール 5.4.20）

[Sweetman 2019] Sweetman A, Lack L, Bastien C. “Co-Morbid Insomnia and Sleep Apnea (COMISA): Prevalence, Consequences, Methodological Considerations, and Recent Randomized Controlled Trials“. Brain Sci. 2019;9(12):371.
（モジュール 5.4.9）

[Valipour 2011] Valipour A, Lavie P, Lothaller H, Mikulic I, Burghuber OC. Sleep profile and symptoms of sleep disorders in patients with stable mild to moderate chronic obstructive pulmonary disease. Sleep Med. 2011;12:367–72.
（モジュール 5.4.10）

[Verster 2011] Verster JC, Spence DW, Shahid A, Pandi-Perumal SR, Roth T. Zopiclone as positive control in studies examining the residual effects of hypnotic drugs on driving ability. Current Drug Safety. 2011;6(4):209-18.
（モジュール 5.4.22）

[Verster 2011] Verster JC, Roth T. Standard operation procedures for conducting the on-the-road driving test, and measurement of the standard deviation of lateral position (SDLP). Int J Gen Med 2011;4:359–71.
（モジュール 5.4.12）

[Verster 2012] Verster JC, Roth T. Drivers can poorly predict their own driving impairment: a comparison between measurements of subjective and objective driving quality. Psychopharmacology (Berl) 2012;219(3):775–81.
（モジュール 5.4.11）

[Zeitzer 2006] Zeitzer JM, Nishino S, Mignot E. The neurobiology of hypocretins (orexins), narcolepsy and related therapeutic interventions. Trends Pharmacol Sci 2006; 27(7):368–74.
（モジュール 5.4.30）

[Zenklusen 2020] Zenklusen I, Muehlan C, Ulc I, Liška J, Dingemanse J. The dual orexin receptor antagonist daridorexant does not affect the pharmacokinetics of the BCRP substrate rosuvastatin. Clin Exp Pharmacol Physiol. 2020;47(11):1843-49.
（モジュール 5.4.23）

[日本製薬工業協会 2016] 日本製薬工業協会. 治験における Patient Reported Outcomes-臨床開発担当者のための PRO 利用の手引きー日本製薬工業協会データサイエンス部会タスクフォース 7. 2016 Jun.
（モジュール 5.4.24）

[薬食審査発 1213 第 1 号 2011] 薬食審査発 1213 第 1 号. 睡眠薬の臨床評価方法に関するガイド

ラインについて. 2011 Dec 13.
Available from: https://www.pmda.go.jp/files/000208186.pdf
[薬生薬審発 0723 第 4 号 2018] 薬生薬審発 0723 第 4 号. 医薬品開発と適正な情報提供のための薬物相互作用ガイドラインについて. 2018 Jul 23.
Available from: https://www.pmda.go.jp/files/000225191.pdf
[薬生薬審発 0319 第 1 号 2020] 薬生薬審発 0319 第 1 号. 後発医薬品の生物学的同等性試験ガイドライン等の一部改正について. 2020 Mar 19.
Available from: https://www.pmda.go.jp/files/000234565.pdf