

## Overzicht van promoties en wetenschappelijke publicaties in 2017

### Promoties

- Abby Yu: 'Towards understanding interchangeability of generic drugs' (UM)
- Julien Tanniou: 'To lump or to split? Statistical evidence of subgroup findings in confirmatory clinical trials and the regulatory perspective'(UU)
- Sander van den Boogert: 'Trials & Tribulations. Studies on the fate, transparency and efficiency of clinical drug trials' (UU)
- Marie Elske Gispen:'Human Rights and Drug Control (UU)
- Kim Notenboom: 'The pursuit of user-friendly medicines: older people in the hot seat' (UU)

### Publicaties

Hieronder staat een overzicht van wetenschappelijke publicaties waaraan CBG medewerkers hebben (mee)gewerkt in 2017. Deze publicaties reflecteren niet noodzakelijkerwijs de mening van het CBG.

1. Annemieke Aartsma-Rus, Volker Straub, Robert Hemmings, Manuel Haas, Gabriele Schlosser-Weber, Violeta Stoyanova-Beninska, Eugenio Mercuri, Francesco Muntoni, Bruno Sepodes, Elizabeth Vroom, and Pavel Balabanov; Development of Exon Skipping Therapies for Duchenne Muscular Dystrophy: A Critical Review and a Perspective on the Outstanding Issues; Nucleic Acid Therapeutics: August 2017 DOI: 10.1089/nat.2017.0682
2. Beken S, Kasper P, van der Laan JW. Regulatory Acceptance of Alternative Methods in the Development and Approval of Pharmaceuticals. Adv Exp Med Biol. 2016;856:33-64.
3. Bernabe RDLC, van Thiel GJMW, Gispen CC, Breekveldt NS, van Delden JJM. The ambivalent place of ethics in European regulatory documents. Drug Discov Today. 2017 Oct 27. pii: S1359-6446(17)30037-5.
4. Bonertz A, Roberts G,, Hoefnagel M, Timon M, Slater J, Rabin LR, Bridgewater J, Pini C, Pfaar O,, Akdis C, Dr. Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Sheikh A, Pawankar R. Hamerlijnck D., Vieths.S. (2017) Challenges in the implementation of EAACI Guidelines on Allergen Immunotherapy: A global perspective on the regulation of allergen products. Allergy. 2017; 00:1-13.
5. Bonertz A, Roberts G, Slater JE, Bridgewater J, Rabin RL, Hoefnagel M, Timon M, Pini C, Pfaar O, Sheikh A, Ryan D, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Pawankar R, Hamerlijnck D, Klimek L, Agache I, Angier E, Casale T, Fernandez-Rivas M, Halken S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, van Wijk RG, Bonini S, Muraro A, Vieths S. Allergen manufacturing and quality aspects for allergen immunotherapy in Europe and the United States: An analysis from the EAACI AIT Guidelines Project. Allergy. November 2017.
6. Ter Braak B, Siezen CL, Lee JS, Rao P, Voorhoeve C, Ruppin E, van der Laan JW, van de Water B. Insulin-like growth factor 1 receptor activation promotes mammary gland tumor development by increasing glycolysis and promoting biomass production. Breast Cancer Res. 2017 Feb 7;19(1):14. doi: 10.1186/s13058-017-0802-0.

7. Brand W, Noorlander CW, Giannakou C, De Jong WH, Kooi MW, Park MV, Vandebriel RJ, Bosselaers IE, Scholl JH, Geertsma RE. Nanomedicinal products: a survey on specific toxicity and side effects. *Int J Nanomedicine*. 2017 Aug 22;12:6107-6129. doi: 10.2147/IJN.S139687. eCollection 2017.
8. van den Brink W, Emerenciana A, Bellanti F, Della Pasqua O, van der Laan JW. Prediction of thyroid C-cell carcinogenicity after chronic administration of GLP1-R agonists in rodents. *Toxicol Appl Pharmacol*. 2017 Apr 1;320:51-59. doi: 10.1016/j.taap.2017.02.010.
9. Bruysters MWP, Schiffelers MJ, Hoonakker M, Jungbaeck C, Ragan I, Rommel E, van der Stappen T, Viviani L, Hessel EV, Akkermans AM, Vandebriel RJ. Drivers and barriers in the consistency approach for vaccine batch release testing: Report of an international workshop. *Biologicals*. 2017 Jul;48:1-5. doi: 10.1016/j.biologicals.2017.06.006.
10. Cerreta F, Dooley B, Van Riet-Nales DA. Farmaci e anziani. *Quotidiano online di informazione sanitaria*. 17 Dec 2017. Available at: [http://www.quotidianosanita.it/stampa\\_articolo.php?articolo\\_id=56941](http://www.quotidianosanita.it/stampa_articolo.php?articolo_id=56941) en tevens op [http://www.ilfarmacistaonline.it/scienza-e-farmaci/articolo.php?articolo\\_id=56941](http://www.ilfarmacistaonline.it/scienza-e-farmaci/articolo.php?articolo_id=56941)
11. Deenen MJ, Meulendijks D. Recommendation on testing for dihydropyrimidine dehydrogenase deficiency in the ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. *Ann Oncol*. 2017 Jan 1;28(1):184. doi: 10.1093/annonc/mdw533.
12. Drumond N, van Riet-Nales DA, Karapinar-Çarkit F, Stegemann S. Patients' appropriateness, acceptability, usability and preferences for pharmaceutical preparations: Results from a literature review on clinical evidence. *Int J Pharm*. 2017 Apr 15;521(1-2):294-305. doi: 10.1016/j.ijpharm.2017.02.029. Epub 2017 Feb 14. Review.
13. Dunder K, de Graeff PA, Blind E. Comment on the editorial by Turner et al. on assessment of cardiovascular risk of new drugs for the treatment of diabetes mellitus: risk assessment vs. risk aversion by Zannad et al. *Eur Heart J Cardiovasc Pharmacother*. 2017 Jul 1;3(3):129
14. Andreas M, Farkas, Segundo Mariz, Violeta Stoyanova-Beninska, Patrick Celis, Spiros Vamvakas, Kristina Larsson and Bruno Sepodes; Advanced Therapy Medicinal Products for Rare Diseases: State of Play of Incentives Supporting Development in Europe; *Frontiers in Medicine*: May 2017 | Volume 4 | Article 53
15. Fregonese L, Greene L, Hofer M, Magrelli A, Naumann-Winter F, Larsson K, Sheean M, Stoyanova-Beninska V, Tsigkos S, Westermark K, Sepodes B; Demonstrating significant benefit of orphan medicines: analysis of 15 years of experience in Europe. *Drug Discov Today*. 2017 Oct 9. pii: S1359-6446(17)30159-9
16. Gadroen K, Kemmeren JM, Bruijning-Verhagen PC, Straus SM, Weibel D, de Melker HE, Sturkenboom MC. Baseline incidence of intussusception in early childhood before rotavirus vaccine introduction, the Netherlands, January 2008 to December 2012. *Euro Surveill*. 2017 Jun 22;22(25). pii: 30556.
17. Goedecke T, Morales D, Pacurariu A, Kurz X. Measuring the impact of medicines regulatory interventions - systematic review and methodological considerations. *Br J Clin Pharmacol*. 2017 Nov 5. doi: 10.1111/bcp.13469.
18. Gupta S, Richards S, Amaravadi L, Piccoli S, Desilva B, Pillutla R, Stevenson L, Mehta D, Carrasco-Triguero M, Neely R, Partridge M, Staack RF, Zhao X, Gorovits B, Kolaitis G, Sumner G, Stubenrauch KG, Zou L, Amur S, Beaver C, Berger I, Berisha F, Birnboeck H, Bower J, Cho

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19. Jonker CJ, van den Berg HM, Kwa MSG, Hoes AW, Mol PGM. Registries supporting new drug applications. *Pharmacoepidemiol Drug Saf*. 2017 Dec;26(12):1451-1457. doi: 10.1002/pds.4332.
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  21. Krug AW, Vaddady P, Railkar RA, Musser BJ, Cote J, Ederveen A, Krefetz DG, DeNoia E, Free AL, Morrow L, Chakravarthy MV, Kauh E, Tatosian DA, Kothare PA. Leveraging a Clinical Phase Ib Proof-of-Concept Study for the GPR40 Agonist MK-8666 in Patients With Type 2 Diabetes for Model-Informed Phase II Dose Selection. *Clin Transl Sci*. 2017 Sep;10(5):404-411.
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  27. Notenboom K, Leufkens HG, Vromans H, Bouvy ML. Learning from patients: Identifying design features of medicines that cause medication use problems. *Int J Pharm*. 2017 Jan 30;517(1-

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  30. Ponzano S, Blake K, Bonelli M, Enzmann H; European Medicines Agency Committee for Human Medicinal Products "First-in-Human Guideline Drafting Group". Promoting Safe Early Clinical Research of Novel Drug Candidates: A European Union Regulatory Perspective. *Clin Pharmacol Ther.* 2017 Nov 6. doi: 10.1002/cpt.899
  31. Van Riet-Nales DA, Schobben AFAM, Vromans H, Egberts ACG, Rademaker C. Kindvriendelijke geneesmiddelen. *Huisarts & Wetenschap.* 2017; 60(1); 15-19.
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  35. Maria E. Sheehan, Violeta Stoyanova-Beninska, Giuseppe Capovilla, Dinah Duarte, Matthias P. Hofer, Michel Hoffmann, Armando Magrelli, Segundo Mariz, Stelios Tsigkos. Nonclinical data supporting orphan medicinal product designations: lessons from rare neurological conditions; *Drug Discov Today.* 2017 Oct 4. pii: S1359-6446(17)30289-1.
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44. Christine Gispén-de Wied en Joan Deckers 2017. Onverwachte bijeffecten. In: *Biowetenschappen en Maatschappij*, kwartaal 2; 60-61.
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