Curriculum Vitae

Personal information

Elisabeth Bakker

Work experience

1. Employer: University Medical Center Groningen
   - Start date: 09/2019
   - End date:
   - Position: PhD candidate
   - Activities: Developing research skills and working on research projects for my thesis "To stimulate alignment of 'precision medicine' drug development trajectories with regulatory decision_making needs" to obtain a PhD.
   - Country: Netherlands
2. Employer: European Medicines Agency
   - Start date: 07/2021
   - End date: 07/2022
   - Position: Collaborating Expert
   - Activities: Working on a project on the use of real_world evidence to support efficacy in regulatory decision making in recent initial marketing authorisation applications and extension of indication applications
   - Country: Netherlands

Education and training

1. Subject: University of Groningen
   - Start date: 09/2017
   - End date: 08/2019
   - Qualification: Master Medical Pharmaceutical Science
   - Organisation: Pharmacoepidemiology track Research Internship at Dutch Medicines Evaluation Board
   - Country: Netherlands
2. Subject: University of Groningen
   - Start date: 09/2013
   - End date: 03/2017
   - Qualification: Bachelor Life Science and Technology
   - Organisation: Majors in Biomedical Sciences/ Behavioural and Cognitive Neurosciences Minor in Pharmacy
   - Country: Netherlands

Additional information

Publications

Bakker E, Mol PGM, Nabais J, Vetter T, Kretzler M, Nolan JJ, Mayer G, Sundgren AK, Heerspink HJL, Schiel A, de Vries ST, Gomez MF, Schulze F, de Zeeuw D and Pena MJ (2021) Perspectives on a Way Forward to Implementation of Precision Medicine in Patients With Diabetic Kidney Disease; Results of a Stakeholder Consensus_Building Meeting. Front. Pharmacol. 12:662642. doi: 10.3389/fphar.2021.662642

Bakker E, Hendrikse NM, Ehmann F, van der Meer DS, Llinares Garcia J, Vetter T, Starokozhko V, Mol PGM. Biomarker Qualification at the European Medicines Agency: A Review of Biomarker Qualification Procedures From 2008 to 2020. Clin Pharmacol Ther. 2022 Jul;112(1):69_80. doi: 10.1002/cpt.2554. Epub 2022 Mar 5. PMID: 35137949.

de Vries E, Bakker E, Francisca RDC, Croonen S, Denig P, Mol PGM. Handling of New Drug Safety Information in the Dutch Hospital Setting: A Mixed Methods Approach. Drug Saf. 2022 Apr;45(4):369_378. doi: 10.1007/s40264_022_01149_4. Epub 2022 Mar 29. PMID: 35349127; PMCID: PMC9021088.

de Vries E, Bakker E, Monster TBM, Denig P, Mol PGM. Factors Influencing Preferences and Responses Towards Drug Safety Communications: A Conjoint Experiment Among Hospital-Based Healthcare Professionals in the Netherlands. Drug Saf. 2022 Nov;45(11):1369-1380. doi: 10.1007/s40264-022-01230-y. Epub 2022 Sep 15. PMID: 36107383; PMCID: PMC9560924.

Jonker CJ, Bakker E, Kurz X, Plueschke K. Contribution of patient registries to regulatory decision making on rare diseases medicinal products in Europe. Front Pharmacol. 2022 Aug 4;13:924648. doi: 10.3389/fphar.2022.924648. PMID: 35991868; PMCID: PMC9386590.

Bakker E, Plueschke K, Jonker CJ, Kurz X, Starokozhko V, Mol PGM. Contribution of Real-World Evidence in European Medicines Agency's Regulatory Decision Making. Clin Pharmacol Ther. 2023 Jan;113(1):135-151. doi: 10.1002/cpt.2766. Epub 2022 Nov 4. PMID: 36254408; PMCID: PMC10099093.

Bakker E, Starokozhko V, Kraaijvanger JWM, Heerspink HJL, Mol PGM. Precision medicine in regulatory decision making: Biomarkers used for patient selection in European Public Assessment Reports from 2018 to 2020. Clin Transl Sci. 2023 Nov;16(11):2394-2412. doi: 10.1111/cts.13641. Epub 2023 Oct 18. PMID: 37853917; PMCID: PMC10651650.

Kubesch N, Gaitonde S, Petriti U, Bakker E, Basu S, Birks LE, Aubrun E, de Vries ST, Schneider R. Use cases of registry-based randomized controlled trials-A review of the registries' contributions and constraints. Clin Transl Sci. 2024 Nov;17(11):e70072. doi: 10.1111/cts.70072. PMID: 39558508; PMCID: PMC11573736.

Hermans AMM, Bakker E, Starokozhko V, den Otter L, Elferink AJA, Bradshaw A, Guizzaro L, Mol PGM, Pasmooij AMG. Biomarkers for neurodegenerative diseases in regulatory decision-making by the European Medicines Agency. Alzheimers Dement (N Y). 2025 Mar 27;11(1):e70072. doi: 10.1002/trc2.70072. PMID: 40151396; PMCID: PMC11947766.

Projects

PhD candidate at the University Medical Center Groningen working on the project ‘To stimulate alignment of ‘precision medicine’ drug development trajectories with regulatory decision-making needs’. This project focuses on how to implement precision medicine in the regulatory field, including stakeholder collaborations, current use of ‘novel’ biomarker, regulatory qualification of biomarkers, and other ways of generating evidence for approval of precision medicines, including real-world evidence & patient-reported outcomes.

Project manager & researcher as part of the More-EUROPA project that aims to develop, implement and establish evidentiary standards and methods to address the data and evidentiary needs of regulatory authorities and health technology assessment (HTA) bodies towards a more efficient use of RWD for the development, registration and assessment of medicinal products in Europe.

In my work, I collaborate with researcher from the Department of Clinical Pharmacy and Pharmacology at the University Medical Center Groningen, employees and interns from the Dutch Medicines Evaluation Board and employees of the European Medicines Agency. In addition I work with researchers involved in the More-EUROPA consortium.

Memberships

Other Relevant Information