Delivering Scientific Excellence and Integrity for Patient Safety

Resume

Remco M. Diab, MD, MSc, eMBA

Licensed Medical Doctor & Research Physician

Professional Summary Overview

Senior physician and patient safety leader with more than 18 years of experience in pharmacovigilance, patient safety, benefit-risk management, signal detection, and clinical development across (early) phases I – IV and post-marketing. I have led global safety strategies for major assets, built PV functions from the ground up, and guided cross-functional teams through complex developmental, regulatory, and organizational transformations.

I combine strong medical judgment with a practical, people-focused leadership style. My focus is to protect patients, strengthen compliance, and help teams move faster with clarity, accountability, and sound decision-making. I am particularly effective in environments that require structural transformation, inspection readiness, and close collaboration between PV, Clinical, Regulatory, Quality, and Medical Affairs.

Key Regulatory Submission Achievements

8 Major Novel Drug Brands successfully contributed to and launched:

- **Wayrilz®** - immunthrombocytopenia (ITP) - Sanofi - Approved
- **Kevzara®** - polyarticular Juvenile Idiopathic Arthritis (pJIA) - Sanofi - Approved
- **Kevzara®** - Polymialgica Rheumatica (PMR) - Sanofi - Approved
- **Kisqali®** - HR+/HER2- locally advanced or metastatic breast cancer - Novartis - Approved
- **Jadenu®** - Transfusional haemosiderosis - Novartis - Approved
- **Ferinject®** - Iron deficiency - Vifor Pharma (part of CSL) - Approved
- **Zoely®** - Combined Hormonal Contraceptive - MSD - Approved
- **Prevnar 13®** Vaccine - Streptococcus pneumoniae - Pfizer - Approved

Achieving Business Needs / Core Strengths

Patient Safety Leadership | Pharmacovigilance Strategy | Benefit-Risk Assessment | Signal Detection and Management | Clinical Safety | Risk Management Plans | Periodic Safety Reports | Regulatory Submissions | Inspection Readiness | CAPA | SOP Development | Audits and Inspections | Cross-Functional Governance | Team Leadership | Department Build-Up | Process Optimization | Vendor/CRO Oversight | Medical Writing | AI-Enabled PV Improvement

Education

- **Board certification and Medical Degree/License General Medicine**
  - Granted August 2008 from BIG, Dutch Medical Association (European & International level)
- **Certified Medical Doctor General Medicine**
  - Granted July 2006 from the University of Amsterdam
- **Certified Master of Science in Bio-Medical Sciences, specialisation in Oncology**
  - Granted July 2005 from the University of Amsterdam

Continued Education

2025 **Essential Executive MBA Course** | London School of Economics and Political Sciences | London, UK

2019 **Pharmacoepidemiology** | University of Aarhus | Department of Clinical Epidemiology | Aarhus, Denmark

Extracurricular Experience

02/2025 – 07/2025 | Volunteer Mentor | Women on Stage® | Basel, CH.

Tasks: Professional training and coaching, Mentor for ‘Sponsoring Women Program’

Languages

English (C2, native); Dutch (C2, native); **German** (spoken C1, written B2); French (A1) and Afrikaans (A1)

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DoB 01 June 1980 | Dutch Nationality | Holder of Swiss C Permit (EU/EFTA) | Swiss Passport Applicant

Awards

Novartis

Dec 2016 – Novartis Recognition of Outstanding Contribution for Patients Award “Breast Cancer Gold Standard” Kisqali® (Ribociclib)_– Granted by Novartis Pharmaceuticals USA

Oct 2015 – Vision Award – Granted by Novartis IMS Oncology Department

Professional Experience Overview

NDA signed with Client | Mid-sized Pharma Company, Germany & Remote in Zurich, CH | 02/2026 – Present

Head PV, Medical & Scientific Affairs (Senior Advisor — Consulting role)

Providing advisory leadership to support the restructuring and future-state design of a large Science/Pharmacovigilance (PV) function. I stepped in to ensure continuity of business operations across a 136-person PV department while helping to stabilize day-to-day activities during a major structural transformation phase.

My work focuses on defining a fit-for-purpose target operating model, improving interfaces between PV, Regulatory Affairs, Quality Management, and Medical/CMC, and identifying practical solutions to strengthen compliance, scalability, and efficiency without increasing headcount. I also support the introduction of AI-enabled approaches in PV to improve process quality, coordination, and decision support.

Sanofi | Zurich, CH | 01/2022 – 01/2026

Senior Director/ Lead Global Safety Officer (Team Lead) Rilzabrutinib and Sarilumab | 04/2022 – 01/2026

- Senior Director/ Global Safety Officer Rilzabrutinib | 01/2022 – 03/2022
  - Team Lead and Subject Matter Expert (SME) for Work-Stream “Signal Detection in Clinical Trials” | 01/2024 – 01/2026
  - Team Lead for Drive Enhancement in Clinical Trial Safety | 09/2022 – 01/2026
  - Core Team Member and Subject Matter Expert for Pharmacovigilance Activities in Clinical Development | 06/2022 – 01/2026 – *entails*: implementing novel tools to improve PV automation and Signal Detection

Led global safety strategy for Rilzabrutinib and Sarilumab across clinical development and lifecycle management. I was responsible for product safety oversight, signal detection in clinical trials, safety governance, and the medical safety content of key regulatory documents, including NDA, sBLA, BLA, PBRER, DSUR, and RMPs.

I served as team lead and subject matter expert for pharmacovigilance in clinical development, and also led work streams focused on signal detection in clinical trials and safety improvement initiatives. A key part of my role was to translate complex safety information into clear, actionable decisions for cross-functional teams, health authorities, and internal leadership.

Polyphor | Allschwil, CH | 12/2019 – 12/2021 *(company ceased to exist)*

Head Medical Safety and Pharmacovigilance

Built a global Medical Safety and Pharmacovigilance department from the ground up in a demanding biotech environment. I established the safety framework, introduced standardized documentation and signal management processes, and restructured safety reporting to improve quality, consistency, and regulatory alignment.

I also led the development of SOPs, strengthened collaboration with clinical, quality, and external partners, and created a more robust operating model for a growing portfolio. This role combined strategic leadership with hands-on execution and a strong focus on inspection readiness.

Takeda | Zurich, CH | 06/2017 – 11/2019

Director Vaccines Pharmacovigilance – Benefit/Risk Physician

Led vaccine safety and benefit-risk activities for clinical development programs, including first-in-human studies and interactions with health authorities. I supported the redesign of safety governance, including surveillance plans, committee structures, and quality-management processes to strengthen vaccine development operations.

This role required close collaboration with clinical, regulatory, and medical teams to ensure patient safety, consistent documentation, and scientifically sound decision-making. I also managed vendor relationships, PV agreements, and operational safety processes.

Novartis | Basel, CH | 07/2014 – 06/2017

Senior Director Global Patient Safety

Led patient safety activities for major oncology and hematology assets, including key regulatory submissions for Jadenu® and Kisqali®. I combined scientific oversight with operational leadership across clinical development, lifecycle management, safety documentation, audits, and inspection readiness.

The role strengthened my ability to lead in a large matrix organization, influence across functions, and connect patient safety decisions with development strategy and business priorities.

Earlier Career | 12/2003 – 02/2015

Earlier roles included senior medical safety and risk management positions at Saphar, Vifor Pharma, and Schering-Plough/MSD, as well as clinical research and surgical training roles in the Netherlands and South Africa. These experiences built my clinical foundation, broadened my therapeutic perspective, and sharpened my ability to balance medical detail with operational discipline.

Selected Achievements

- Built and led global PV and medical safety functions from the ground up.
- Led major regulatory submissions and safety strategies across FDA, EMA, and other global regions.
- Introduced signal management, standardized PV processes, and stronger governance models in resource-constrained environments.
- Recognized by Novartis for outstanding contribution to patient centered development.

Special Knowledge / IT Skills

Expertise Knowledge: Good Clinical Practice (ICH-GCP/ICH regulations and guidelines), GVP, EU Clinical Trial Directive, EMA guidelines, FDA guidelines, MHRA guidelines, E2B, R3, DSMB/DMC
IT Knowledge: Windows, Microsoft Office Suite, PowerPoint, MS TEAMs, SharePoint, Oracle, CLINtrace, ARISg, ARGUS, CTMS, Medidata, Medrio application

Memberships

- SGPM - Swiss Association of Pharmaceutical Medicine | since November 2024 rejoined
- Zug Pharma Group | since February 2024
- Basel Pharma Group | since establishment in March 2025

Additional Information

Publications

10/2024 – Publication – Publication of "Safety and efficacy of rilzabrutinib vs placebo in adults with immune thrombocytopenia: phase 3 LUNA3 study". David J. Kuter, Waleed Ghanima, Nichola Cooper, Howard A. Liebman, Lei Zhang, Yu Hu, Yoshitaka Miyakawa, Wojciech Homenda, Luisa Elena Morales Galindo, Ana Lisa Basquiera, Chuen Wen Tan, Guray Saydam, Marie Luise Hütter-Krönke, Chatree Chai-Adisaksopha, David Gómez-Almaguer, Huy Tran, Ho-Jin Shin, Ademar Dantas da Cunha Junior, Zsolt Lazar, Cristina Pascual Izquierdo, Ilya Kirgner, Elisa Lucchini, Ganna Kuzmina, Michael Fillitz, Sylvain Audia, Minakshi Taparia, Matias Cordoba, ***Remco Diab***, Mengjie Yao, Imene Gouia,

Michelle Lee, and Ahmed Daak, for the LUNA3 Trial Group **Blood – accepted for publication; NCT04562766; EudraCT 2020-002063-60.**
WEB location: https://ashpublications.org/blood/article/doi/10.1182/blood.2024027336/536104/Safety-and-efficacy-of-rilzabrutinib-vs-placebo-in or https://www.sciencedirect.com/science/article/pii/S0006497125006081

05/2024 – Publication – Publication of "Safety of sarilumab in a Japanese population with rheumatoid arthritis by age group: Data from an interim analysis of a post-marketing surveillance study". Hideto Kameda, Sadatomo Tasaka, Toshiya Takahashi, Katsuhisa Suzuki, Naoki Soeda, Hubert van Hoogstraten, ***Remco Diab***, Yoshiya Tanaka **Modern Rheumatology 2024 May 28:roae051. doi: 10.1093/mr/roae051.**
WEB location: https://academic.oup.com/mr/article/35/1/42/7683745

04/2024 – Publication – abstract – Abstract of "basic characteristics of adult patients with previously treated immune thrombocytopenia enrolled in luna 3 phase 3 placebo-controlled study of rilzabrutinib, an oral Bruton tyrosine kinase inhibitor". David Kuter, Waleed Ghanima, Nichola Cooper, Howard A Liebman, Lei Zhang, Yu Hu, Yoshitaka Miyakawa, Luisa Morales, Ana Lisa Basquiera, Chuen Wen Tan, Guray Saydam, Marie Luise Hütter-Krönke, Chatree Chatree Chai-Adisaksopha, David Gomez, Huy Tran, Ho-Jin Shin, Ademar Dantas da Cunha Júnior, Cristina Pascual Izquierdo, Ilya Kirgner, Francesco Zaja, Ganna Kuzmina, Sylvain Audia, Matias Cordoba, ***Remco Diab***, Mengjie Yao, Michelle Lee, Ahmed Daak **Abstract release date: 05/14/24 EHA Library. Kuter D. 06/13/2024; 422137; PB3371**.
WEB location: https://library.ehaweb.org/eha/2024/eha2024-congress/422137/david.kuter.basic.characteristics.of.adult.patients.with.previously.treated.html?f=menu=6*browseby=8*sortby=2*ce_id=2552*ot_id=29183*marker=5102*featured=18527

12/2023 – Presentation – Presentation of "Initial Report of Part B Phase 1/2 Efficacy and Safety Results for Bruton Tyrosine Kinase Inhibitor Rilzabrutinib in Patients with Relapsed Immune Thrombocytopenia". Nichola Cooper, A. J. Gerard Jansen, Jiri Mayer, Michael D Tarantino, ***Remco Diab***, Brad Ward, Ahmed Daak, David J Kuter **Presented at the American Society of Hematology (ASH) on December 11th, 2023, San Diego, California, USA (Dec 9 – 12, 2023) - article from 02 November 2023.**
WEB location: https://ashpublications.org/blood/article/142/Supplement 1/685/499169/Initial-Report-of-Part-B-Phase-1-2-Efficacy-and or https://www.sciencedirect.com/science/article/abs/pii/S0006497123052898

12/2023 – Presentation – Presentation of "Initial Report of Part B Phase 1/2 Efficacy and Safety Results for Bruton Tyrosine Kinase Inhibitor Rilzabrutinib in Patients with Relapsed Immune Thrombocytopenia". Nichola Cooper, A. J. Gerard Jansen, Jiri Mayer, Michael D Tarantino, ***Remco Diab***, Brad Ward, Ahmed Daak, David J Kuter **Short Talks - Industry Bleeding - No CME - 10:30AM Thu Apr 04, 2024 - Short Talks**.
WEB location: https://ashpublications.org/blood/article/142/Supplement 1/685/499169/Initial-Report-of-Part-B-Phase-1-2-Efficacy-and or https://www.sciencedirect.com/science/article/abs/pii/S0006497123052898

11/2023 – Presentation – Presentation of "Exposure-Response Analysis of Sarilumab in Patients with Polymyalgia Rheumatica". Christine Xu, Ying Liu, Jennifer Sloane, ***Remco Diab***, Hubert van Hoogstraten, Hisham Abdallah, Sreeraj Macha, Bhaskar Dasgupta **Presented at the American College of Rheumatology (ACR) 2023, San Diego, California, USA (Nov 10-15, 2023).**
WEB location: https://acrabstracts.org/abstract/exposure-response-analysis-of-sarilumab-in-patients-with-polymyalgia-rheumatica/

10/2023 – Publication – Publication of "the effectiveness of Kevzara® for relapse of polymyalgia rheumatica glucocorticoid resistant patients, with inability to taper off glucocorticoid therapy". Spiera RF et al. Sarilumab for relapse of polymyalgia rheumatica during glucocorticoid taper**. N Engl J Med 2023 Oct 5; 389 (14):1263-1272. doi: 10.1056/NEJMoa2303452**
WEB location: https://pubmed.ncbi.nlm.nih.gov/37792612/

10/2003 – Publication – Publication of "Activation of the canonical beta-catenin pathway by histamine". Sander H. Diks, James C. Hardwick, ***Remco M. Diab***, Marije M. van Santen, Henri H. Versteeg, Sander J. H. van Deventer, Dick J. Richel,

and Maikel P. Peppelenbosch **The Journal of Biochemical Chemistry Vol. 278, No. 52, Issue of December 26, pp. 52491–52496, 2003.**
WEB Location: https://pubmed.ncbi.nlm.nih.gov/14563838/

Research Projects

07/2001 – 08/2003 | Prostate Cancer Research Project, Dept. of Oncology | Lerner Research Institute, Cleveland Clinic Foundation, Cleveland, Ohio, USA
Achievement: Successful development of a novel detection pathway using biomarkers to detect prostate cancer cells vs. the existing radiologic detection method.

01/2001 – 06/2001 | Colon Cancer Research Project, Dept. of Internal Medicine | Academic Medical Centre, Amsterdam NL
Achievement: Publication of the demonstration that the canonical beta-catenin pathway is activated by histamine.

Hobbies / Interests

Fitness, Travel, Culture, Art, Cinema, Theatre, Opera, Music, Gardening and Cooking
Biking, Running, Hiking, Basketball, Swimming, Wellness and Massage.

Nutrition
Self-study of human behaviour towards food and basic needs vs. excessive needs in food, sports nutrition, and supplementation.