

CURRICULUM VITAE

Maja Hojnik



PERSONAL DETAILS

Full name and title: Maja Hojnik, MD, PhD

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Residency: United States

PROFILE SUMMARY

International medical leader experienced in clinical development and medical affairs in pharmaceutical industry:

- Research experience in immunology, including basic science, translational research, clinical development and real-world-evidence data generation
- Broad spectrum of functional capabilities and experience in medical affairs, including operational leadership and scientific proficiency in the field of rheumatology/immunology
- Due diligence and competitive intelligence experience
- Medical and scientific education/training: MD degree, specialization in Internal Medicine/Rheumatology; PhD degree in Immunology
- Strategically minded, business savvy, proactive, result-oriented and conscientious, with sound medical and scientific background, and proven ability to build and manage high-performing collaborative teams

WORK EXPERIENCE

September 2021 – present (3 years)

Associate Vice President, Rheumatology Lead, Immunology Clinical Development, Eli Lilly and Co.

- Overseeing Ph2 - Ph3b/4 clinical development in rheumatology
- Managing a team of medical directors who each supervise a team of clinical research physicians and clinical research scientists
- Acting as rheumatology development strategy lead, including membership in the board of directors for early stage medicinal products

January 2019 – August 2021 (2,5 years)

Medical Director, Rheumatology, Immunology Clinical Development, Eli Lilly and Co.

- Overseeing Ph3 and Ph3b/4 clinical development for ixekizumab and baricitinib in rheumatology (both adult and pediatric)
- Managing a team of clinical research physicians and clinical research scientists
- Leading digital innovation in rheumatology clinical development

- **Achievements through line and cross-functional matrix management:**
- Approval of ixekizumab (Taltz) for the treatment of ankylosing spondylitis (radiographic axSpA) in the United States, European Union (EU) and several countries worldwide
- Approval of ixekizumab (Taltz) for the treatment of non-radiographic axSpA in the United States (first in class of IL-17 inhibitors), EU and several countries worldwide
- License renewal and an additional year of patent exclusivity for Taltz in the EU
- Taltz label enhancement in the EU with head-to-head data versus adalimumab (Humira) in PsA and randomized withdrawal and long-term data in axSpA
- Defended baricitinib label across indications in the European Union as a response to Article 20
- Developed cross-functional clinical and translational recommendations for improvement of SLE clinical trials which will inform private-public LRA initiative with FDA
- Created innovative Ph3 program for novel MoA PD-1 agonist antibody in targeted autoimmune diseases
- Pioneered digital regulatory submission elements with FDA (first in industry)

January 2013 - December 2018 (6 years)

Medical Director, Global Medical Affairs Rheumatology (GMA), AbbVie

- **Global leadership and oversight for research in rheumatology/spondyloarthritis**
- Concept, protocol development and medical oversight for four Ph3b and Ph4 GMA sponsored studies
- Strategic guidance, scientific advice and approval for affiliate research and publications within the respective therapeutic area (TA)
- Medical/scientific input into clinical development programs for immunology assets (specifically Phase 2 and 3 for ABT-122, risankizumab and upadacitinib)
- **Global medical leadership for strategic brand planning and tactical execution**
- Medical expert for the program and content development of scientific exchange and group meetings (scientific symposia, clinical sessions). Products of scope: Humira (adalimumab) and Rinvoq (upadacitinib)
- **Professional engagement with key international external experts in rheumatology**
- Individual and group consulting (advisory boards)

July 2011 - December 2012 (1,5 year)

**Associate Medical Director Humira Rheumatology, Central and Eastern Europe (CEE),
AbbVie**

- Strategic guidance to CEE Affiliate Medical Directors for Humira/Rheumatology associated medical plans
- Leadership, coordination and oversight of regional activities supporting Humira in Rheumatology
- Design and scientific leadership of 4 regional post-marketing observational studies (PMOS) and 2 epidemiological studies that provided data supporting market access in individual countries (also nominated as one of the top 10 programs in the 2014 GMA Celebration of Science contest)

September 2010 - June 2011 (10 months)

Associate Director Area Medical, Central and Eastern Europe (CEE), Abbott

- Development and implementation of regional medical plan and oversight of affiliate plans
- Leadership and oversight of regional and affiliate medical activities, including clinical research, pharmacovigilance and quality assurance
- Medical input to regional commercial plan and initiatives

March 2004 – August 2010 (6 years)

Affiliate Medical Director, Abbott Slovenia

- Established and led affiliate medical department, including medical affairs, regulatory affairs, clinical research, pharmacovigilance and quality assurance
- Secured reimbursement of all approved Abbott medicinal products under fast-track scheme

January 2002 – February 2004 (2 years)

Rheumatology and Oncology Product Specialist, Aventis Pharma, Slovenia

- Medical support to the rheumatology and oncology product portfolio

September 1990 – December 2001 (11 years)

**Clinical and Research Fellow, Department of Rheumatology, University Medical Centre,
Ljubljana, Slovenia**

- Inpatient rheumatology ward
- Outpatient rheumatology service
- Education/training of fellows, residents and students
- Participation in phase II/III clinical trials
- Basic immunology research

EDUCATION

- 1990 **MD (Dr. med.) degree**
Medical Faculty, University of Ljubljana, Slovenia
- 1994 **M.Sc. degree in Immunology**
Medical Faculty, University of Ljubljana, Slovenia
- 1997 **Ph.D. degree in Immunology**
Medical Faculty, University of Ljubljana, Slovenia
- 2000 **Specialization in Internal Medicine/Rheumatology**
Medical Faculty, University of Ljubljana

ADDITIONAL TRAINING

- 1992 **Research fellowship** (3 months)
Research Unit of Autoimmune Diseases and Department of Medicine 'B', Sheba Medical Center
(Affiliated to Tel-Aviv University), Tel-Hashomer, Israel
Mentor: Prof. Yehuda Shoenfeld, MD
- 1993 **Research fellowship** (3 months)
Servizio di Immunologia Clinica, Spedali Civili, Brescia, Italy
Mentor: Angela Tincani, MD
- 1994 - 1995 **Research fellowship** (10 months)
Research Unit of Autoimmune Diseases and Department of Medicine 'B', Sheba Medical Center
(Affiliated to Tel-Aviv University), Tel-Hashomer, Israel
Mentor: Prof. Yehuda Shoenfeld, MD
- 1996 **Research fellowship** (3 months)
Department of Medicine II and Department of Biochemistry,
Hokkaido University School of Medicine, Sapporo, Japan
Mentors: Prof. Takao Koike, MD and Eiji Matsuura, PhD
- 1998 **Research fellowship** (3 months)
Department of Medicine II, Hokkaido University School of Medicine, Sapporo, and
Department of Biochemistry, Okayama School of Medicine, Okayama, Japan
Mentors: Prof. Takao Koike, MD and Eiji Matsuura, PhD

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type plasminogen activator (t-PA). **Fibrinolysis** 1990; 4 (Suppl 2): 108-9.

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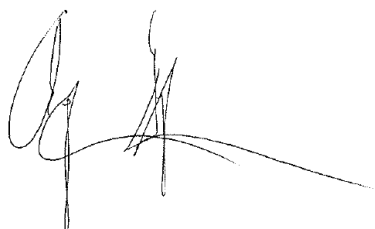
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Indianapolis, October 4, 2024