

MISSION STATEMENT AND COURSE PROGRAM



The Vienna School of Clinical Research, Public Health and Medical Education (VSCR) is an International Educational Institution based in Vienna, Austria. Since its establishment as a Center of Excellence (CoE) for clinical research and for health economy, VSCR fulfills all scientific and ethical criteria of quality for academically accredited postgraduate education. VSCR's independent educational advisory board consists of internationally renowned experts and cooperates with many other national and international academic institutions.

In November 2018 VSCR started together with Sigmund Freud University Vienna (SFU) with

international diploma courses covering the following topics:

- Health Economy and Health Outcome Research
- Decision Making for Pricing and Reimbursement
- HTA (Health Technology Assessment)

Since 2008 VSCR has successfully organized such courses for more than 1.200 participants from 30 countries. In cooperation with the Medical Faculty of Sigmund Freud University Vienna these courses are now awarded with a university certificate for any single module and with an academic (HEALTH OUTCOME RESEARCH DIPOLMA) in case of successful performance of 3 modules.

BASE MODULE

Evidence Based Decision Making for Pricing and Reimbursement: from Theory to Practice

COMPLEMENTARY MODULES

- From Clinical Evidence to HTA: An Introduction into the Basics of HTA Assessments
- From Outcome Data To Value Dossiers: An Introduction into the Basics of Successful
- HTA Negotiations
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THE PROGRAMME IS CREATED FOR MEMBERS OF: HTA & Consultancy Agencies, Educational & Research Institutions, Health Policy Organizations, Health Insurers, Health Care Providers/Commissioners, Pharmaceutical/Biotech/Medical Device/Industry



Heinrich Klech, MD, PhD
Managing Director of VSCR

"Quality is a Must, ...Excellence is a gift" (H. Klech)



BASE MODULE:

EVIDENCE BASED DECISION MAKING FOR PRICING AND REIMBURSEMENT: FROM THEORY TO PRACTICE

June 7th and 8th 2021

This module is designed for professionals working in the pharmaceutical and medical device industry, in the public health sector and those who are involved in negotiations and decision making for pricing and reimbursement.

Those who have a need to understand how evidence based decision making is being used to direct reimbursement and market access decisions will also benefit from this course.

PROGRAM DIRECTORS and Faculty:

Lieven Annemans, MSc, PhD, Senior Professor of Health Economics, Ghent University and Brussels University, Belgium, past president ISPOR

Jürgen Raths, MD, Managing Director Cordée Consulting, Geneva

Heinrich Klech MD, PhD, Professor of Medicine, Medical University Vienna, Chief Executive Officer of Vienna School of Clinical Research (VSCR)

Anna Bucsics, MD, Former Department Head, Department of Pharmaceutical Affairs, Federation of Austrian Social Insurance Institutions

OPERATIONAL COURSE DIRECTOR:

Margarete Schreiner-Karner, MSc, Operational Manager of Vienna School of Clinical Research (VSCR)

DAY 1 12:00 to 17:30 Vienna time

12:00 – 12:15 (15 min) **OPENING & INTRODUCTION** Heinrich Klech (AT)/Margarete Schreiner-Karner (AT)

12:15 – 13:15 (60 min) **LECTURE | HEALTH ECONOMIC EVALUATIONS, CONCEPTS AND PRINCIPLES** Lieven Annemans (BE)

13:15 – 13:30 (15 min) Break

13:30 – 14:15 (45 min) **LECTURE | HEALTH ECONOMIC MODELS 1, CONCEPTS AND PRINCIPLES OF DECISION TREES** Lieven Annemans (BE)

14:15 – 15:00 (45 min) **LECTURE | HEALTH ECONOMIC MODELS 2, CONCEPTS AND PRINCIPLES OF MARKOV MODELS** Lieven Annemans (BE)

15:00 – 15:30 (30 min) Lunch break

15:30 – 16:45 (90 min) **GROUP EXERCISE | DESIGN A MODEL** Lieven Annemans (BE)

16:45 – 17:00 (15 min) Break

17:00 – 17:15 (15 min) **KNOWLEDGE TEST** Margarete Schreiner-Karner (AT)



17:15 – 17:30 (15 min) **CLOSING REMARKS** Heinrich Klech (AT), Lieven Annemans (BE), Margarete Schreiner-Karner (AT), All

DAY 2 12:00 to 19:30 Vienna time

12:00 – 12:10 (10 min) **OPENING & INTRODUCTION** Heinrich Klech (AT), Margarete Schreiner-Karner (AT)

12:10 – 13:30 (80min) **LECTURE | APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT 1** Jürgen Raths (CH)

- A brief history of HTA
- Why healthcare systems engage in HTA
- Assessment versus appraisal for market access
- Key stakeholders
- The importance of perspective: Value for money versus affordability challenge in practice.

13:30–13:45 (15 min) Break

13:45–14:30 (45 min) **LECTURE | APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT 2** Jürgen Raths (CH)

- Overview of country differences in the application of HTA
- HTA for decision/policy making: pricing and reimbursement of pharmaceuticals and recent requirements for devices
- HTA and the patient perspective

14:30-15:30

(60 min) **GROUP EXERCISE | BREAK OUT SESSION ON HTA APPLICATION AND DECISION - MAKING** Jürgen Raths (CH)

15:30–16:00 (30 min) Lunch break

16:00–17:00 (60min) **LECTURE | HTA, PRICING AND REIMBURSEMENT:** Jürgen Raths (CH)

- Challenges of value assessment frameworks across markets (Germany, France, Sweden, UK)
- Main players of the national healthcare systems
- HTA methodology, process timelines and potential outcomes of evaluations
- Pricing: consequences of the HTA result
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17:00–17:30 (30 min) LECTURE | ASSESSING AND INTERPRETING THE VALUE OF ORPHAN DRUGS Anna Bucsics (AT)

17:30–17:45 (15 min) Break

17:45–18:45 (60 min) **LECTURE | KEY ELEMENTS OF A SUCCESSFUL HTA SUBMISSION** Jürgen Raths (CH)

18:45-19:15 (30 min) LECTURE | SPECIAL Lecture by R. Gallo-Daniel, president of the Austrian Vaccine Manufacturer Association (ÖVIH), Policy and Public Affairs Lead for Pfizer Corporation Austria.

Vaccines and COVID 19 Pandemia - health-economic and other learnings.

19:15–19:30 (15 min)

CLOSING REMARKS Heinrich Klech (AT), Margarete Schreiner-Karner (AT), Jürgen Raths (CH), All

FACULTY/ PROGRAM DIRECTORS



Lieven Annemans, MSc, PhD

Senior Professor of Health Economy, University Ghent, Belgium, past president ISPOR. Author of “Health Economics for Non-economists. Principles, methods and pitfalls of health economic evaluations” (Pelckmans Pro) – Revised version released in June 2018.

Lieven Annemans has twenty years of experience in health economic research in more than 20 countries and published more than 300 papers on health economic evaluations for medicines, Devices and diagnostics. He was advisor to the Belgian Minister of Health from 2001 to 2003 and president of the Flemish health council from 2003 to 2009. He was president of the International Society of Pharmaco-economics (ISPOR) in 2004–2005. He is author of books on health economic evaluations (health economics for non-economists) and on the future of health care systems. He provides international lectures, trainings and advice on health economics, health care systems and health technology assessment (HTA).



Jurgen Raths, MD, Managing Director Cordée Consulting, Geneva

Jurgen Raths is an MD from Bonn university. He has 30 years of experience in the European and global pharma business, with positions held in clinical research, medical, marketing, sales and general management in Europe and the US. Jurgen served as CEO in assignments in public and private specialty pharma companies. With Cordée Consulting, Jürgen is currently involved in various projects for vaccine companies.



Anna Bucsics, MD, Former department Head, Department of pharmaceutical Affairs, Federation of Austrian Social Insurance Institutions

Anna Bucsics has a MD from the Karl-Franzens-University of Graz, Austria, where she did postgraduate Research at the Department of Experimental & Clinical Pharmacology. In 1991 she moved to Vienna where she audited pharmaceutical expenditures at the Viennese Social Health Insurance and worked at the Main Association of Austrian Social Insurance Institutions, assessing pharmaceuticals for reimbursement. She was Head of the Department of Pharmaceutical Affairs until 2014. She was an instructor at the Department of Finance, University of Vienna and a member of the European Commission Experts Group on Rare Diseases, and has participated in European projects (EUnetHTA, the Pharmaceutical Forum, and the Platform on Access to Medicines in Europe). Currently, she is advisor to the MoCA project, (Mechanism of Coordinated Access to Orphan Medicinal Products, www.eurordis.org/content/moca) and Judicial Advisor at the Federal Administrative Court of Austria.

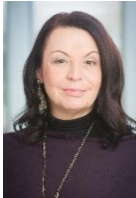


Heinrich Klech MD, PhD

Professor of Medicine, Medical University Vienna, Managing Director of Vienna School of Clinical Research (VSCR)

Heinrich Klech is an internal medicine specialist by training from the University of Vienna. He is author of more than 200 publications in the field of lung diseases and served on the editorial board of many renowned medical journals in the field of Pulmonology and Internal medicine. After a successful international academic career he changed to executive R&D management positions in the pharmaceutical industry. He held position for Central Eastern Europe, Central Asia, Middle East and Africa for Eli Lilly & Company, and led later Lilly's R&D and regulatory activities in a large part of Western Europe. In 2000 he founded the Vienna School for Clinical Research (VSCR), a not-for-profit postgraduate educational institution.

SPECIAL LECTURE and PANEL DISCUSSION



Renee Gallo-Daniel MSc

Renée Gallo-Daniel is the president the Austrian Vaccine Manufacturer Association (ÖVIH). In that role she is responsible for representing the interests of all vaccine manufacturing companies in Austria. She has an active role within the European Vaccine Manufacturer Association (Vaccine Europe). She is the leading the NVIG (National Vaccine Industry Group) coordinators group. Her current role within the pharmaceutical industry is Policy and Public Affairs Lead for Pfizer Corporation Austria.

OPERATIONAL DIRECTOR



Margarete Schreiner-Karner, MSc

Business Operations Manager of Vienna School of Clinical Research (VSCR)

Margarete Schreiner-Karner graduated from the Vienna University of Economics and Business Administration specializing in marketing and social policy. She began her career as a biomedical analyst in a medical-diagnostic laboratory for clinical chemistry and hematology, before joining the pharmaceutical industry in 2002. As product and brand manager, she was responsible for product launches, especially in the indications of obesity, diabetes with Sanofi and oncology with Takeda, in close cooperation with market access and medicine. Mrs. Schreiner-Karner was able to gather additional expertise in the context of conducting phase III clinical trials in the field of diabetes at General Hospital in Vienna, University Department of Internal Medicine III, Division of Endocrinology and Metabolism. In 2018 Mrs. Schreiner-Karner joined the VSCR team as operational manager and member of the VSCR management board.

TECHNICAL SUPPORT



Dr. Nils Mensel

Managing Partner skeirs GmbH

with a background in consulting and innovation management Nils started skeirs in 2007 to put IT related ideas into existence in the healthcare landscape. Skeirs is now providing services to international companies for the distribution of knowledge and the application learning tools.