

# FROM OUTCOME DATA TO VALUE DOSSIERS: THE BASICS OF SUCCESSFUL HTA SUBMISSIONS

7 and 11 March 2022



NEW  
ONLINE  
MODULE II

## SPEAKER HIGHLIGHT:



**Lieven Annemans, MSc, PhD**

Senior Professor of Health  
Economics, Ghent University,  
Belgium

## SCIENTIFIC COURSE DIRECTORS:

Prof. Lieven Annemans, MSc, PhD, Senior Professor of Health Economics, Ghent University, Belgium, past president ISPOR  
Univ. Prof. Dr. Heinrich Klech, MD, PhD, FACP, GFMD, Managing Director, VSCR, Vienna

## OPERATIONAL COURSE DIRECTOR:

Mag. Margarete Schreiner-Karner, MSc, Operational Manager, VSCR, Vienna

## ACADEMIC SUPERVISION AND QUALITY CONTROL:

Prof. Alfred Pritz, Univ-Prof, DDr.h.c., Rector Sigmund Freud Private University Vienna

## TECHNICAL SUPPORT/EQUIPMENT:

Martin Lachmair, creative director Lachmair GmbH

**MONDAY, 7 MARCH 2022****DAY 1**

12:30 p.m.	Vienna time	Opening platform – online chat for technical issues available
12:45–13:00	[15 min]	<b>OPENING &amp; INTRODUCTION</b>   Heinrich Klech & Margarete Schreiner-Karner
13:00–13:45	[45 min]	<b>PAYER AND BUYER ARCHETYPES</b>   Lieven Annemans
13:45–14:30	[45 min]	<b>THE VALUE STORY + EXERCISE: A RECIPE FOR A VALUE STORY</b>   Lieven Annemans
14:30–14:45	[15 min]	Break
14:45–15:30	[45 min]	<b>OPTIMAL INCENTIVES FOR COST-EFFECTIVE CARE</b>   Lieven Annemans
15:30–16:15	[45 min]	<b>CHALLENGING THE QALY + EXERCISE</b>   Lieven Annemans
16:15–17:00	[45 min]	<b>DEALING WITH UNCERTAINTY: OUTCOMES – BASED AGREEMENTS</b>   Lieven Annemans
17:00–17:15	[15 min]	<b>CLOSING AND PROCEDURE FOR DAY 2</b>   Heinrich Klech and Margarete Schreiner-Karner

**FRIDAY, 11 MARCH 2022****DAY 2**

12:30 p.m.	Vienna time	Opening platform – online chat for technical issues available
12:45–13:00	[15 min]	<b>OPENING &amp; INTRODUCTION</b>   Heinrich Klech & Margarete Schreiner-Karner
13:00–13:45	[15 min]	<b>STARTING EARLY FOR PATIENT ACCESS PLANNING: EARLY MODELS</b>   Lieven Annemans
13:45–14:30	[45 min]	<b>GETTING CROSS-FUNCTIONAL TEAM ALIGNMENT</b>   Lieven Annemans
14:30–14:45	[15 min]	Break
14:45–15:45	[60 min]	<b>THE SIGNIFICANCE OF A MEANINGFUL VALUE DOSSIER + CASE STUDY – PCSK-9 INHIBITORS</b>   Lieven Annemans
15:45–16:30	[45 min]	<b>FINAL RECOMMENDATIONS FOR SUCCESSFUL MARKET AND PATIENT ACCESS</b>   Lieven Annemans
16:30–17:00	[30 min]	<b>Q &amp; A “ASK ME ANYTHING”</b>   Lieven Annemans
17:00–17:15	[15 min]	<b>CLOSING AND KNOWLEDGE TEST PROCEDURE, FEEDBACK FORMS</b>   Heinrich Klech and Margarete Schreiner-Karner

## LEARNING OUTCOMES

### At the end of this 2-days module, participants will

- ↗ Understand how payers assess technologies depending on their own incentives and setting;
- ↗ See the opportunities in changing payment systems for hospitals and clinicians;
- ↗ Have insights into the weaknesses of the QALY and the opportunities of disease specific outcome measures;
- ↗ Understand the need for a tailored yet coherent value story
- ↗ Have a guidance how to best structure a submission for a HTA or reimbursement dossier building on facts and data together with a comprehensive value story
- ↗ See the options about how to deal via agreements with uncertain evidence
- ↗ Understand why health economic evaluations need to start early in the development of medicines/health technologies
- ↗ Understand the need to align strategies across functional teams for successful market and patient access of new health technologies
- ↗ Have insights in how the development program can anticipate on value – based strategies and access
- ↗ Be happy that they have participated at this module

## SCIENTIFIC COURSE DIRECTORS



**Lieven Annemans, MSc, PhD Senior Professor of Health Economics, Ghent University, 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. He has twenty-five years of experience in health economic research in more than 20 countries and published more than 320 papers on health economic evaluations for medicines, devices and diagnostics. He was advisor to the Belgian Minister of Health from 2001–2003 and president of the Flemish health council from 2003–2009. He was president of the International Society of Pharmaco-economics (ISPOR) in 2004–2005. He is author of books on health economic evaluations 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).



**Heinrich Klech, MD, PhD, FCCP, GFMD, Professor of Medicine, Medical University Vienna, Chief Executive Officer 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.

## OPERATIONAL COURSE 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 Med Uni 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.

## ACADEMIC SUPERVISION AND QUALITY CONTROL



**Alfred Pritz, PhD, Prof. of Psychotherapy**, has been engaged in many national and international research and educational projects and co-operations. He has been teaching psychotherapists in training at various levels, from different quarters and on many occasions for over 40 years. Alfred Pritz is also the founding father and principal of the Sigmund Freud Privat-Universität, which was accredited in 2005 and keeps expanding and growing (further SFU locations so far: Paris, Linz, Berlin, Milano, Ljubljana). Later on the SFU was enlarged by other faculties (Medicine, Law and Business). Since 2005 he is rector of the Sigmund Freud University. He is a founding member and president of the World Council for Psychotherapy, as well as a founding member and former general secretary of the European Association for Psychotherapy. The first three World Congresses of Psychotherapy in Vienna were organized by him and he was also a co-organizer for the World Congresses in Buenos Aires, Beijing, Sydney and Durban. He is an active editor and author of various books, book series and professional articles in journals and textbooks.

## TECHNICAL SUPPORT/EQUIPMENT



**Martin Lachmair**, graphic design, founded in 2004 as a graphics and illustration studio. Over the years photography and video production were added. Martin`s team consists of five employees, divided into the areas of graphics and / or video production. In the area of graphics, the focus is on magazine and book design, design of printed matter for companies and illustration. In video production, the focus is on: image film, webinars, interviews, recordings, spot production for social media and TV. Martin Lachmair also organizes practical workshops in small groups on the subjects of video production and photography.