



TEACHING THE FUTURE

VIENNA SCHOOL OF CLINICAL RESEARCH, PUBLIC HEALTH AND MEDICAL EDUCATION



! FROM CLINICAL EVIDENCE TO HTA – AN INTRODUCTION INTO THE BASICS OF HTA ASSESSMENTS

Deepening the knowledge & business case exercises

20th – 22nd April 2020

MISSION STATEMENT AND COURSE PROGRAM

The Vienna School of Clinical Research (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.



Heinrich Klech,
MD, PhD
Managing Director
of VSCR

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

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)

FACULTY

PROGRAM DIRECTORS



Jürgen Raths, MD

Lecturer VSCR; Managing Director of Cordée Consulting, Geneva

Jürgen Raths studied medicine and dentistry at the Universities of Heidelberg, Bonn and Cologne. He obtained his doctorate in medicine at the university of Bonn. He got 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. Jürgen served as CEO in assignments in public and private specialty pharma companies. Currently Jürgen Raths is managing director of Cordée, a pharma consultancy focussing on commercial models and market access in Geneva. He has leadership experience in: general management, company creation, M&A, change management and corporate restructuring situations, as well as in global business development.



Heinrich Klech MD, PhD

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 Lillys 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.

TECHNICAL 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 MedUni 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.

OTHER FACULTY

**Dominique Vandijck, MSc, PhD**

Professor of Healthcare Innovation, Health Economics, Healthcare Policy & Patient Safety at the Faculty of Medicine and Life Sciences of Hasselt University, and at the Faculty of Medicine and Health Sciences, and the Faculty of Pharmacy at Ghent University (Belgium)

Dominique is currently vice chief executive officer at KERTEZA, a management and advice office covering the (inter)national healthcare sector, with particular focus on quality management. Before, he was CEO at ICURO and director Quality & Safety at Zorgnet-Icuro (Flemisch Hospital Federation).

Besides, he is professor of Healthcare Innovation, Health Economics, Healthcare Policy & Patient Safety at the Faculty of Medicine and Life Sciences of Hasselt University, and at the Faculty of Medicine and Health Sciences, and the Faculty of Pharmacy at Ghent University (Belgium). He is visiting professor at Antwerp University, Antwerp Management School, European Management School, Ghent University College (HoGent – Vesalius), and Hasselt University College (PXL). He is also affiliated at the Department of Internal Medicine and Infectious Diseases of Ghent University Hospital.

His main research interests include quality & safety topics, from a health economic perspective, aimed at improving healthcare management performance. This research currently resulted in over 140 international peer-reviewed publications, of which a lot are published in high-ranked journals. He has an extensive experience in management and policy supportive research (Flemish government, Federal Services and European Commission) concerning the use and development of quality indicators, and the capacity of health care services on different levels of care. He is also frequently invited to act as an expert for several national and international regulatory agencies, and healthcare companies.

Prof. Dr. Dominique Vandijck holds a PhD in medical sciences (Ghent University). His background also includes a master degree in Medical and Social Sciences (option Healthcare Management & Policy), Biostatistics (both, Ghent University) and a master degree in Service and Healthcare Management at Vlerick Management Business School.

**Jörg Rustige**

Jörg studied physics in Kiel and Hamburg, and worked several years as a physicist in the field of high energy particles. He also completed Medical School in Hamburg, and practiced medicine more than 15 years in university and academic teaching hospitals specializing in internal medicine, interventional cardiology, emergency medicine and intensive care.

He participated in the design and conduct of clinical trials, and initiated one of the biggest real-life registries in myocardial infarction in Germany.

Jörg has also decades of experience in the pharma industry in Europe and North America, being responsible at different stages in senior positions for medical affairs, medical information, clinical research in all phases, regulatory, quality assurance and basic research laboratories.

Lately, he had supported European small pharma companies in Medical Affairs and Regulatory and he is now active with Cordée Consulting and VSCR.



Andrea Sobrio, MBA

International Management from the University of St. Gallen (HSG)

Andrea has a background in International Management, MBA in International Management from the University of St. Gallen (HSG).

During the last 20 years Andrea has focused on helping pharmaceutical companies improve and transform their commercial operations to become more customer-centric through the development of innovative strategies. During the last 10 years Andrea has specialized on Market Access and Policy, supporting the successful launch of best-in-class innovations. Andrea has been a speaker at various industry and academic conferences and has published several articles on the topics of innovative business models and value creation in the health care industry. Prior to founding of Executive Insight, he worked as a CRM and strategy consultant with Deloitte Consulting delivering several international assignments in the Health Care, Chemical and Life Sciences industries.

Andrea's selected experience is as follows. He wrote a positioning paper on HTA and trained the European leadership of a top Pharma company. Led and implemented several market access projects, aimed at identifying key stakeholders in influencing access to budget, held payer negotiation trainings and organizational capability assessments, supported best-in-class launches of highly specialized innovations including payer value communication, provided innovative pricing model development as well as detailed funding flow analysis. He developed and implemented an innovative global and regional business model for specialty and biotech products with best-in-class profitability and customer equity standards. Conceived, structured and delivered negotiation strategies for top launches in the industry and supported local pull-through facilitating payer negotiations in multiple European countries.

FROM CLINICAL EVIDENCE TO HTA – AN INTRODUCTION INTO THE BASICS OF HTA ASSESSMENTS

Deepening the knowledge & business case exercises

20th – 22nd April 2020 – VSCR HTA Course 2 (Building on the basic course)

LEARNING OBJECTIVES

- Understand EBM principles and the possibilities and limitations of controlled trials
- Understand key health outcome measures: QALYs and ICERs and their importance for reimbursement argumentation
- Understand health outcomes studies: analyze key publications and understand the various modelling techniques (Decision tree, Markov...)
- Appreciate the need for epidemiological data from regional/ national health statistics and the
- Importance to “localize” and adapt your health economic data to the needs of relevant stakeholders
- The 10 do’s & don’ts in HTA dossier preparation

FROM EVIDENCE TO HEALTH OUTCOME MODELS

DAY 1MONDAY 20TH APRIL 2020

13:00–13:15	(15 min)	OPENING & INTRODUCTION Heinrich Klech & Margarete Schreiner-Karner	
13:15–14:15	(60 min)	LECTURE EBM PRINCIPLES ➤ Key elements: EBM definitions; Systematic review techniques (Cochrane et al.); Usage in HTA; Clinical Guideline development ➤ Desired outcome: Understand the language of EBM	Jörg Rustige (GER)
14:15–15:15	(60 min)	LECTURE EBM GUIDELINES ➤ Key elements: Moderated business case: analysis of methodology and updates of clinical guidelines in Oncology – Cardiology – Neurology ➤ Desired outcome: Understand the impact of EBM logic in development of clin. guidelines	Jörg Rustige (GER)
15:15–15:45	(30 min)	Coffee break	
15:45–16:45	(60 min)	LECTURE MEASURING HO ➤ Key elements: Definitions of QALYs and ICERs – Application and relevance in HTA ➤ Desired outcome: Understand definition and application of standard HO measures	Jürgen Raths (CH)
16:45–18:00	(75 min)	EXERCISE AND GROUP WORK APPRAISING HO ➤ Key elements: Moderated business cases: HO data and budget consequences: Which data are relevant to who and why? ➤ Desired outcome: Stakeholder mapping: Understand the implications of HO data from various perspectives	Jürgen Raths (CH)
18:00–18:30	(30 min)	MULTIPLE CHOICE TEST ➤ Key elements: Multiple Choice Questions / Q&A with speakers? ➤ Desired outcome: Consolidate learnings	
19:30		GROUP DINNER	

FROM EVIDENCE TO HEALTH OUTCOME MODELS

DAY 2

TUESDAY 21ST APRIL 2020

09:00–09:15	(15 min)	WARM UP Heinrich Klech & Margarete Schreiner-Karner	
09:15–10:15	(60 min)	LECTURE HEALTH OUTCOMES ✦ Key elements: Decision trees – Markov Models – individual outcome modelling: the principles and their application ✦ Desired outcome: Understanding of the Health Outcome models	Dominique Vandijck (BE)
10:15–11:15	(60 min)	EXERCISE EXAMPLE DECISION TREE ✦ Key elements: Moderated group work; decision tree in example TA ✦ Desired outcome: Applying the learnings of day 1	Dominique Vandijck (BE)
11:15–11:30	(15 min)	Coffee break	
11:30–12:30	(60 min)	LECTURE THE CONTROLLED TRIAL vs. REAL WORLD EVIDENCE PARADIGM ✦ Key elements: Internal & external validity; HTA bodies and their usage of RWE for prevalence & incidence information as well as cost effectiveness and relative cost-effectiveness info; Appreciation of short and long-term effect & benefits ✦ Desired outcome: Understand the importance of different data sets for different HTAs. Why country HTAs look differently at identical data.	Dominique Vandijck (BE)/ Jörg Rustige (GER)
12:30–14:00	(90 min)	Lunch	
14:00–16:00	(75 min)	EXERCISE AND GROUP WORK APPRAISING HEALTH OUTCOMES ✦ Key elements: Moderated business cases: HO data and budget consequences: Which data are relevant to who and why? ✦ Desired outcome: Stakeholder mapping: Understand the implications of HO data from various perspectives	Jürgen Raths (CH)
16:00–16:15	(15 min)	Coffee break	
16:15–17:15	(60 min)	LECTURE WHAT WORKED AND DID NOT WORK IN HTA? ✦ Key elements: The different economic (and cultural) payer perspectives and their impact on HTA; short term vs long term info; registries and prospective HE trials ✦ Desired outcome: Understand “historic” cases: the reasons for successes and failures	Jürgen Raths (CH)/Andrea Sobrio (CH)
17:15–18:00	(45 min)	PRACTICAL USE CASES Q&A ON THE TOPICS RELEVANT TO THE AUDIENCE ✦ Key elements: Moderated Q&A session with experts ✦ Desired outcome: Discussion & resolution of practical business questions	
18:00–18:30	(30 min)	MULTIPLE CHOICE TEST ✦ Key elements: Multiple Choice Questions / Q&A with speakers ✦ Desired outcome: Consolidate learnings	



FROM EVIDENCE TO HEALTH OUTCOME MODELS

DAY 3

WEDNESDAY 22ND APRIL 2020

09:00–09:15	(15 min)	WARM UP Heinrich Klech & Margarete Schreiner-Karner	
09:15–10:30	(75 min)	LECTURE THE 10 GUIDING PRINCIPLES FOR HTA	Jörg Rustige (GER)/Jürgen Raths (CH)
		<ul style="list-style-type: none">Key elements: Considerations for internal organization HTA: What audience – what endpoint – what data – what narrativeDesired outcome: Understand the need for adequate internal organization and cooperation to adapt the HO narrative	
10:30–10:45	(15 min)	Coffee break	
10:45–11:30	(45 min)	BEST PRACTICE EXAMPLES Q&A ON THE TOPICS RELEVANT TO THE AUDIENCE	Andrea Sobrio (CH)/ Jörg Rustige (GER)
		<ul style="list-style-type: none">Key elements: Innovative technologies & HTA approachesDesired outcome: Understand recent HTA outcomes & reimbursement decisions	
11:30–11:45	(15 min)	MULTIPLE CHOICE TEST	
		<ul style="list-style-type: none">Key elements: Group work to respond to 10 multiple choice test questionsDesired outcome: Consolidate learnings	
12:00–13:00	(30 min)	WRAP UP	Heinrich Klech (AT)/ Margarete Schreiner-Karner (AT)
		<ul style="list-style-type: none">Key elements: Closing remarks, feedback forms, handover of certificates and awards, group photo	

For more information contact:

Margarete Schreiner-Karner

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PREVIEW 2020 HEALTH OUTCOME RESEARCH ADVANCED COURSES

FROM OUTCOME DATA TO VALUE DOSSIERS: AN INTRODUCTION INTO THE BASICS OF SUCCESSFUL HTA NEGOTIATIONS

21–23 September 2020

- ✎ Mapping stakeholders and arguments for reimbursement
- ✎ Negotiating for best possible reimbursement

LEARNING OBJECTIVES

- ✎ Understand health economic evaluation and reimbursement processes in key markets
- ✎ Mapping of the stakeholder landscape and their data needs
- ✎ Adapting the relevance of the HE narrative to the HTA assessment body and reimbursement decision makers
- ✎ Developing the value argument for successful pricing discussions with different stakeholders
- ✎ Building alliances for success: successful strategies to network with stakeholders
- ✎ The 10 do's and don'ts in reimbursement negotiations

TERMS OF PAYMENT

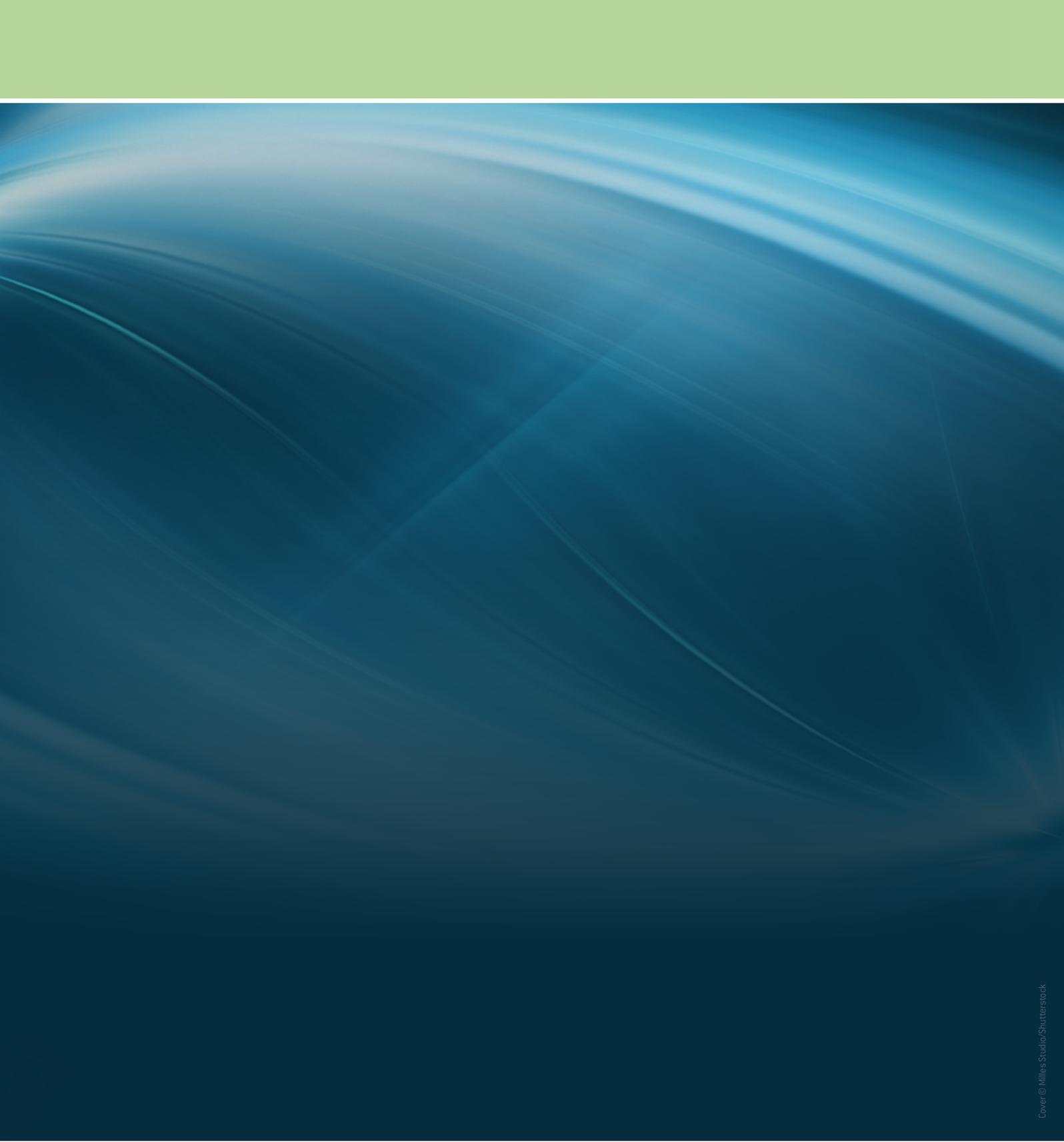
Tuition fees include course fee, study materials and refreshments during the course.

Price for 3 days (advanced course)		EUR	3,450.00
Early booking until 15 April 2020		EUR	2,990.00
Group discount for 3 days (advanced course) for industry:	Up to 3 employees (per person)	EUR	2,500.00
	Up to 7 employees (per person)	EUR	1,990.00
	Up to 10 employees (per person)	EUR	1,520.00
Price for 3 days per module for governmental, non profit- and academic institution		EUR	1,990.00

For registration contact office@vs-cr.at

Limited number of scholarships are available each year, please inquire at office@vs-cr.at.

The course fees are to be paid into the account of VSCR: **IBAN:** AT74 3818 6010 0036 7912 | **BIC:** RZSTAT2G186



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