

Center of Advanced Studies on Entrepreneurship in BioMedicine (CASE BioMed)



Università della Svizzera italiana

Faculty of Biomedical Sciences

Supported by



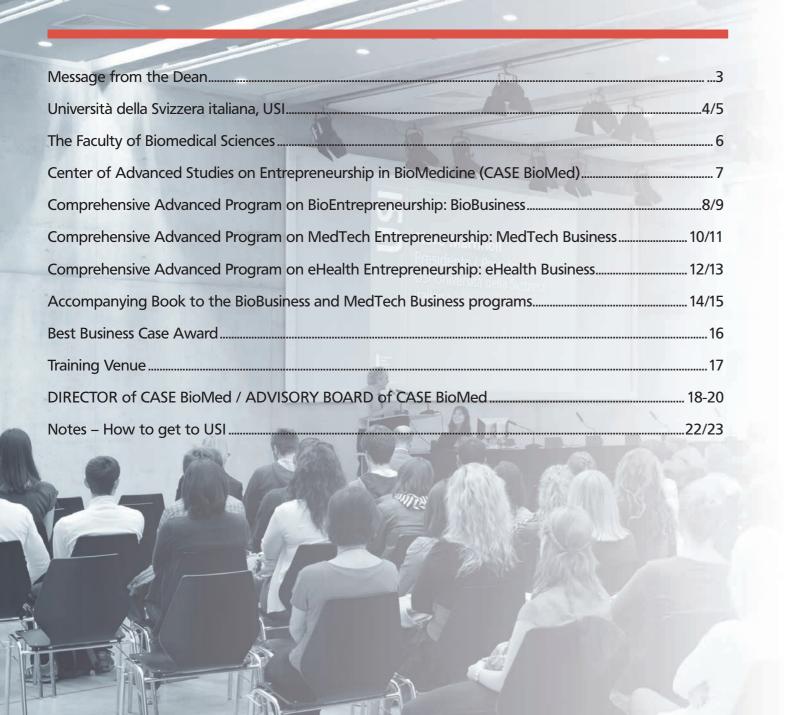
Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

Swiss Confederation

Innosuisse – Swiss Innovation Agency



Content





Message from the Dean

With an annual growth rate in excess of 10%, the life sciences are one of the strongest industrial sectors in Switzerland. It is driven by its innovative strength which enables healthcare systems to continuously improve their medical offer and services to address the unmet medical need.

Research results and inventions generated by universities can make a major contribution to the progress in medicine if they are transferred to industrial companies and developed into marketable products and services. In particular the establishment of new companies, spin-offs or start-ups, ensures that the results of research are turned into innovative medical products and that new jobs are created.

Università della Svizzera italiana (USI) was, in 2010, the first academic institution in Switzerland to offer a series of leading-edge comprehensive advanced programs in Bio- and MedTech Entrepreneurship, "BioBusiness" and "MedTech Business", providing young life sciences companies with the theoretical and project-based practical skills needed to develop, fund and market biomedical innovations.

With the creation of the Faculty of Biomedical Sciences, the programs are offered now through a Center of Advanced Studies on Entrepreneurship in BioMedicine (CASE BioMed) which, together with medical education at master level and biomedical research, is one of the pillars of the newly created Faculty of Biomedical Sciences at USI.

I encourage you to explore the life sciences entrepreneurship trainings we have to offer and hope that they will lead you to an educational and career path that makes a meaningful difference in your life.

We would be very pleased to welcome you to Lugano!

Prof. Dr. Mario Bianchetti

Dean, Faculty of Biomedical Sciences, USI

Università della Svizzera italiana, USI

The comprehensive advanced programs in life sciences entrepreneurship are held at the beautiful campus of the Università della Svizzera italiana (USI) in Lugano (www.usi.ch). USI is one of the 12 certified public universities in Switzerland and member of swissuniversities. It is organised in five faculties and is active in several study and research areas, among which: architecture, communication science, computational science, data science, economics, health studies, humanities, informatics, law, medicine and biomedicine.

USI is a young and lively university, a hub of opportunity open to the world where students are offered a quality interdisciplinary education in which they can be fully engaged and take centre stage, and where our researchers can count on having the space to freely pursue their initiative.

Around 2800 students and about 800 professors and researchers, hailing from over 100 countries, convene every day on the three campuses in Lugano, Mendrisio and Bellinzona. The relatively small size of the campuses encourages the free flow and open exchange of ideas within the academic community. USI encourages faculty, students and researchers to develop their potential, and appreciates their curiosity and willingness to experiment with new ways of thinking, learning, teaching and working.

Established in 1996, USI is in constant evolution, always taking on new challenges while remaining true to its three guiding principles: quality, openness and responsibility.



4 USITICASE BioMed USITICASE BioMed



The Faculty of Biomedical Sciences

The Faculty of Biomedical Sciences of Università della Svizzera italiana (USI) was established in 2014 with the main purpose to make a contribution towards the solution of an important national problem: the dearth of physicians trained in Switzerland.

To reach its goal, the Faculty will offer from 2020 a Master of Medicine (three years of clinical training), in cooperation with ETH Zurich, University of Basel, and University of Zurich regarding academics, and with EOC, clinics, and general practitioners regarding clinical training. The Master addresses the new challenges of medical practice by combining clinical and scientific training with communication skills.

The Faculty is already offering Doctoral Programmes (Medical Doctor Programme and PhD Programmes).

The Faculty (www.biomed.usi.ch/en) supports the following Institutes at an organisational level:

- the Institute of Human Medicine (IMU), responsible for medical studies:
- the Institute for Research in Biomedicine (IRB), affiliated and based on the Bellinzona
- the Institute of Oncology Research (IOR), affiliated and based on the Bellinzona campus;
- · the Institute of Public Health (IPH);
- the Institute of Computational Science (ICS).

The Center of Advanced Studies on Entrepreneurship in Bio-Medicine (CASE BioMed) adds to the medical and scientific education at the Faculty by offering advanced programs in biomedical innovation and life sciences entrepreneurship



Since 2010, the Center of Advanced Studies on Entrepreneurship in BioMedicine (CASE BioMed) at USI offers executive education in life sciences entrepreneurship and creates Public Private Partnerships to bring biomedical research results on the market for the benefit of the society in form of products, services and jobs.

CASE BioMed (www.biomed.usi.ch/en/study/center-advancedstudies-entrepreneurship-in-biomedicine) is an integrated, organizationally autonomous structure providing training that completes the medical and scientific education offered by the Faculty of Biomedicine at USI.

For the first time in Switzerland (Fig. 1), a Faculty of Biomedical Sciences provides an education that covers medical practice (IMU), scientific research (IRB) and biomedical innovation (CASE BioMed). The educational offer in biomedicine at USI therefore presents an added value compared with the programs at other Swiss universities - and this competitive advantage significantly improves the level of education and career prospects of the students and, at the same time, fosters the creation of biomedical innovations.



Fig. 1: The Faculty of Biomedical Sciences at USI

Three pillars of excellence					
Master in Medicine	Research	Innovation			
(IMU)	(IRB, IOR)	(CASE BioMed)			

6 USLI CASE BioMed 2019 USLI CASE BioMed 7



Comprehensive Advanced Program on BioEntrepreneurship: BioBusiness

The BioBusiness program was designed with ambitious objectives: to create an exclusive learning platform and network where academia, industry and venture capitalists interact fruitfully.

PROGRAM OBJECTIVES

The program (<u>www.biobusiness.usi.ch</u>) is aimed to promote entrepreneurship in the field of Biotechnology. It provides an indepth understanding of what it takes to set up successful biotech companies in Europe to train participants on how to start and finance a BioBusiness.

STRUCTURE AND CONTENT OF THE PROGRAM

This one-week comprehensive training is organized in modules with emphasis on Life Sciences, Entrepreneurship and Venture Finance.

These modules have been integrated in a progressive order of thematic clusters. With a common denominator — the creation and financing of BioEnterprises — they range from Basics in BioBusiness and Opportunity Recognition to Start-Up Creation, including Clinical Development, Intellectual Property Rights, Mandatory Regulatory and Legal Aspects as well as Financing, to end with an overview of possible Exit Strategies.

Lectures are complemented by case studies and extensive discussions.

Working in teams, participants are asked to design and develop a plan for a new business concept during the program week. Teams tackle an eminently interdisciplinary project, requiring contributions from various disciplines and offering excellent opportunities for knowledge and skills enhancement. Participants prepare and pitch an executive summary at the end of the program.

Participants constantly interact and network with biotechnology entrepreneurs and investors throughout the whole week.



WHO SHOULD ATTEND?

The program is tailored to the needs of individuals planning to create, finance or support successful biotechnology companies:

- Scientists, medical doctors and engineers wishing to commercialize drugs and technologies
- Entrepreneurs and managers from pharmaceutical or biotech companies who wish to explore and gain an insight into the global biotechnology.

TEACHING FACULTY

Lectures and seminars are held by a world-class team of 20 lecturers and instructors from industry, academia and venture capital.



BioBusiness Alumni Feedback

Our alumni attest that attending the BioBusiness program is a significant step towards professional career and personal development and representing a unique learning experience:

"My expectations were sky-high for Lugano - many founder-friends mentioned your program as the best-learning experiences in Switzerland (with a crazy amount of competition). You fully delivered - it was really a fantastic learning experience and I loved it!" Josua Jordi, Founder of EraCal

"This program is by far the best program I have ever attended. It gave me the courage and trust to really go the way with my own company. The quality of the speakers is just world class. The organization and the minds behind the program are brilliant. I highly recommend it."

Dr. Patrick Kugelmeier, Oberarzt, Chirurgie, Zurigo and Founder of Kugelmeiers

"Very few, if any, programs can achieve such balanced and comprehensive overview across pharma, biotech, start-ups and investment sectors within a short time of 5 days."

Maria Krestyaninova, Director, Uniquer Sarl

■ 8 USI I CASE BioMed 9

Comprehensive Advanced Program on MedTech Entrepreneurship: MedTech Business

The MedTech Business program takes the participant on a journey through the entire process of creating a medical device or diagnostic company from idea generation to venture financing.

PROGRAM OBJECTIVES

MedTech Business (<u>www.medtechbusiness.usi.ch</u>) provides existing and potential medtech entrepreneurs with the necessary network, tools and expertise to increase the chance for success whether they are exploring creating a venture or growing an existing business.

STRUCTURE AND CONTENT OF THE PROGRAM

The one-week comprehensive MedTech Business program covers the state of the medtech industry, assessing Market Opportunities, Product Development, Business Planning, the design of Preclinical and Clinical Studies, Intellectual Property Rights, Regulatory Affairs and Reimbursement as well as possible Capital Sources and Funding Opportunities for a medtech start-up.

Lectures are complemented by case studies and extensive discussions.

Participants are grouped into teams to work on their ideas or business cases and have the opportunity to present their work at the end of the program to a panel of experts in medical technology.

Access to a faculty of real-world business experts gives participants a chance to learn about and participate in the entrepreneurial process. Through these connections to seasoned entrepreneurial business executives, venture capitalists and service providers, the program can help build momentum for emerging ventures.

WHO SHOULD ATTEND?

The program is tailored to the needs of individuals who plan to create, finance and grow a medical device or diagnostic company:

- Scientists and engineers wishing to commercialize medical devices and diagnostic services
- Entrepreneurs and managers from medtech companies who wish to explore and better understand the global sector
- Scientists and engineers wishing to commercialize medical devices and diagnostic services
- Entrepreneurs and managers

TEACHING FACULTY

Lectures and seminars are held by a world-class team of 20 lecturers and instructors from industry, academia, and venture capital.

MedTech Business Alumni Feedback

MedTech Business participants highlight that the intense week-long experience led to a life-changing career transition and to a new professional path.

"I can highly recommend this program to any scientist planning to dive into the MedTech start-up world, as it gives an outstanding introduction to this field." Fabienne Hartmann-Fritsch, Founder, CUTISS

"Thousand thanks for the organization of this high-quality program. It was a tremendous experience, and valuable help to improve our business proposition and have it challenged by international experts!"

Davor Kosanic, Founder, SamanTree Medical

"This excellent and perfectly organized program provided great benefits for our company in the critical phase of making the step from proof of concept/prototype to building a device to be certified and placed on the market. The experts I had the opportunity to meet were able to answer crucial and very specific questions, while the intense discussions with other participants provided us with interesting points of view. The quality of the program was extraordinary and it provided the best overviews on critical topics within the successful development of a medical device I have ever heard."

Michael Peyer, Head of Electronic Development, Advanced Osteotomy Tools AG



Comprehensive Advanced Program on eHealth Entrepreneurship: eHealth Business

This comprehensive advanced program is aimed to promote entrepreneurship in the field of eHealth. It focuses on how eHealth services and products can be developed, financed, and commercialized.

PROGRAM OBJECTIVES

Young and future eHealth entrepreneurs are supported in getting a clear understanding of the relevant markets and the key problems that their business model will attempt to solve.

Participants will be given guidance in their leadership role, learn how to start and fund their own business.

STRUCTURE AND CONTENT OF THE PROGRAM

The comprehensive program is organized in course modules with emphasis on eHealth entrepreneurship. It covers a wide variety of the segments of the eHealth industry.

Participants will be trained on how to start, finance and grow an eHealth business. The teaching program also includes topics on health information technology, national strategies in eHealth, technology platforms, regulatory affairs, intellectual property rights and reimbursement. Extensive discussions and case studies emphasize the challenging issues that are critical to this new market opportunity.

Working in project teams participants are enabled to develop real business cases and to present this work at the end of the course to a panel of experts in eHealth.

WHO SHOULD ATTEND?

The course program is designed for:

- Medical doctors, scientists and engineers wishing to get eHealth products and services to market
- Entrepreneurs and managers from eHealth companies and start-ups who wish to explore and better understand the global sector
- · Investors interested in developing eHealth enterprises

The number of participants is limited to 30.

TEACHING FACULTY

Lectures and seminars are held by a world-class team of 20 lecturers and instructors from industry, academia, and venture capital.







Accompanying Book to the BioBusiness and MedTech Business programs

Designed to guide students that wish to set up a bio- or medtech start-up, the book offers 25 chapters written by 30 international authors, including start-up founders, experts and investors in the life sciences sector.



The compilation can be either read as a whole or used as a reference book by selecting individual chapters in the case of specific questions. It is a compendium rather than a classic textbook to deliver the knowledge at hand.

TARGET READERS

- Bio- or MedTech Entrepreneurs
- Managers
- Investors
- Technology Transfer Specialists
- Life Sciences students

KEY LEARNINGS

- Develop and successful market biomedical technology
- Increase the return of your investments in biomedical innovation
- Get ready for a new career in a life sciences start-up
- · Discover how to transfer a bioor medtech project from academia to industry
- Obtain a comprehensive overview of the innovation process in life sciences



OBJECTIVE

The book (<u>www.bioandmedtechentrepreneurship.ch</u>) allows the BioBusiness and MedTech Business participants better preparation and a retrospective review of the program weeks. In addition, it is to serve as a brief textbook to be used to gain a very first overview of what it takes to set up and finance bio- or medtech companies by highlighting crucial aspects on how to create a life sciences company.

CONTENT

The book contains a so far unique collection of life sciences sector-specific topics, fundamentally necessary to start and fund a start-up company. It includes chapters, divided into two distinct sections, on bio- and medtech entrepreneurship. Each chapter is written by a different author, most oft them are life sciences start-up founders, industry experts or venture capitalists. Each author prepared the content from an individual point of view based on experiences representing a multifaceted approach to life sciences entrepreneurship. The chapters begin with a short introduction leading into the specific theme. To familiarize the reader with the topic, in these short introductions particular emphasis was placed on providing some details from existing knowledge and information.

Cartoons illustrate the entrepreneurial challenges and add a touch of humor lending a lighter perspective to the challenging aspects of life sciences entrepreneurship.

PURPOSE

This book closes the educational gap in life sciences entrepreneurship and fills a market niche. It allows to understand, manage and successfully lead the innovation process in life sciences.

OPINION LEADER FEEDBACK

"Bio- and Medtech Entrepreneurship a must-companion of young Start-up entrepreneurs." Dr. Henri B. Meier, The Doyen of Swiss Venture Capital.

"Bio- and Medtech Entrepreneurship provides an invaluable and comprehensive resource for life science entrepreneurs."

Patrick Rivelli, Co-Director and Life Sciences Track Lead at MIT Angels, Investor and Serial Entrepreneur.

"The book provides excellent insights into the peculiarities of entrepreneurship in the life sciences." Mario Jenni, Co-founder & CEO, BIO-TECHNOPARK Schlie-

ren-Zürich Board Member, Gewerbe- und Handelszentrum Schlieren AG (GHZ).

"Extremely valuable, a must for students as well as managers!"

Jörg Meyer, former sales and marketing director, Siemens Healthcare.

"Bio- and Medtech Entrepreneurship by Heidrun Flaadt Cervini and Jörg Dogwiler is an enthusiasm-kick for timely jumps from academia to one's own business." Louis Schlapbach, Prof.em. ETH, former Director of Empa -Materials Science and Technology.

"Bio- and Medtech Entrepreneurship is, to my best knowledge, the only comprehensive guideline on how to master the exceptional challenges regarding the creation of a sustainable future enterprise."

Dr. med. Patrick Kugelmeier, Managing Partner Kugelmeiers

14 USLI CASE BioMed USLI CASE BioMed 15



The most promising start-up of the program week will have the opportunity to pitch to the MIT Alumni Life Science Angels, a group of private investors up until now only open to start-ups affiliated to the Massachusetts Institute of Technology.

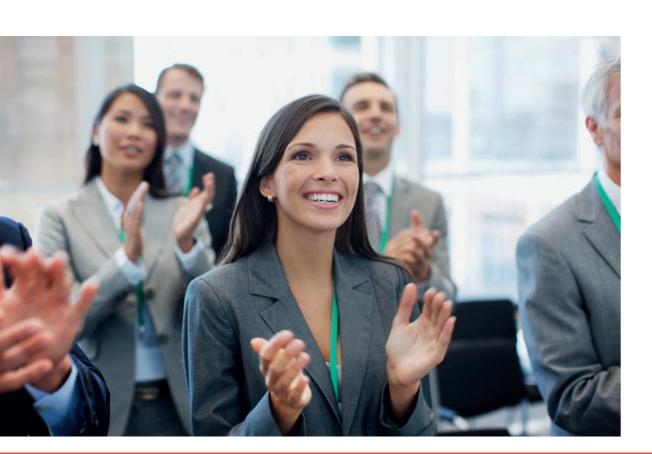
BioBusiness-MIT Alumni Life **Science Angels Award**

This award offers the BioBusiness program participants a direct access to an exclusive circle of business angels and top start-up hubs in the US.

The reason that the MIT Life Sciences Angels give for this decision say a lot about the international recognition of the BioBusiness program and its participants:

"The comprehensive advanced program on BioBusiness at Università della Svizzera italiana covers all the basics to start a business in life sciences. The program is known for its thor-

ough procedure for selecting the participating companies. The quality of the program and its participants has therefore atexperts at a leading university which is located in one of the tracted the attention of the MIT Alumni Life Science Angels"



TRAINING VENUE

The advanced training programs are held in the Executive Center at USI – a dedicated space set aside for executive education. Modern, air conditioned classrooms with high-quality audiovisual equipment prohigh level of interaction. The Center is also equipped with areas for group work, a lounge, wireless computer network and internet access.



Dr. Heidrun Flaadt Cervini

studied Biology at the University of Constance where she also completed her PhD. After her postdoctoral studies at Ecole Normale Supérieure in Paris, she attended Management Education in Zurich. She then served as COO of Diagene, a spin-off company at University of Basel. During that time, the company completed the first capital round. Driven by her interest for technology transfer she took over a position at the Office of Technology Transfer (OTT) at the University of Basel. In 2005, she started to build up a new OTT at EMPA in Dübendorf that she headed until end of 2007. In 2008, she moved to Ticino to join her husband and received a mandate from the Università della Svizzera italiana in Lugano to create new Executive Programs in the field of bio- and medtech entrepreneurship. Among others, she developed and implemented both "BioBusiness" and "MedTech Business" programs. Heidrun Flaadt Cervini is now the director of CASE BioMed, Center of Advanced Studies on Entrepreneurship in Biomedicine at USI.



Prof. Dr. Piero Martinoli Chairman of the Advisory Board

Piero Martinoli had been President of the Università della Svizzera italiana (USI) from September 2006 until August 2016. In this role, he fostered initiatives to develop supercomputing and computational sciences in Ticino through the establishment of the Institute of Computational Sciences, essential to guarantee the presence of the Swiss National Supercomputing Centre in Ticino. He also managed the project that lead to the establishment of a Faculty of Biomedical Sciences at USI. Martinoli studied at the Swiss Federal Institute of Technology of Zurich (ETH Zurich) where he earned a degree in physics and later a doctorate degree with an experimental-theoretical thesis on the proximity effect of superconductor-normal metal contacts exposed to a magnetic field. As visiting associate professor, he worked in the United States for one of the most prestigious research centres in the study of physics and matter: the Ames Laboratory of Iowa State University. Thanks to the research conducted overseas, he obtained professorship at the ETH Zurich and a chair in experimental physics at the University of Neuchâtel. In the latter, he developed an intense research programme (supported by the Swiss National Science Foundation, the European Union, and the European Scientific Foundation) on two-dimensional superconducting systems. The work resulted in over 120 publications in prestigious international journals. Two of Martinoli's studies were cited in the scientific background of the 2016 Nobel Prize in Physics, assigned to David J. Thouless, F. Duncan M. Haldane and J. Michael Kosterlitz. During his two sabbaticals, Piero Martinoli was visiting scientist at the IBM Research Lab in Zurich and visiting professor at the University of Geneva. He was president of the Division II of the Swiss National Science Foundation and recently he was appointed individual member of the Swiss Academy of Engineering Sciences.



Dr. Enrico Braglia

Enrico Braglia, M.Sc (Economics), ONELIFE founder and chairman, is a serial entrepreneur with over 25 years of top management experience in the healthcare and finance industry. Enrico is involved in many professional and non-profit international organizations and serves on the board of several innovative companies.



18 USI I CASE BioMed 19





Jörg Dogwiler

After graduating as Master of Engineering in electronics from ETH Zurich, Jörg Dogwiler joined ABB Power Systems as a system engineer in 1994 and later became group leader in systems engineering for combined cycle power plants. In 2000, he moved to Zühlke Engineering where he was project manager responsible for the development of various industrial products, including those for medical devices. During this period, he successfully filed for several patents to protect inventions in the field of infusion pumps. In 2006, he joined confinis ag as partner, and spent 10 years playing an active role in the successful development of the medical device consultancy company. During this period, he acted as senior consultant and senior project ma-

nager on various customer projects specialized in the field of medical devices working, amongst others, on the implementation of quality management systems, global product registrations and operative quality support. Since 2016, as founder and CEO of Congenius AG, he is in charge of the consultancy company that specializes in the field of medical devices, pharmaceuticals, diagnostics and biotechnology in Switzerland and abroad. In total, Jörg combines more than 20 years of experience in development and regulatory affairs of medical devices. He has supported several start-up companies, from a regulatory point of view, that are successfully marketing their medical devices.

Prof. Dr. Ruggero G. Fariello

Ruggero G. Fariello is a Board Certified Neurologist and Neuroscientist. Ruggero obtained Specialty Certification from the American Boards of Neurology and Psychiatry (Neurology, 1979) and in 1980 in Clinical Electrophysiology. In his academic career Ruggero was tenured Professor of Neurology at the University of Wisconsin (Madison), Texas (San Antonio), Jefferson (Philadelphia, as Vice Chair of the Dept. of Neurology) prior to being appointed Professor and Chair of Neurological Sciences at Rush University in Chicago. His work was devoted to the pathophysiological mechanisms of the epilepsies and neuro disorders. At the clinical level he led International clinical trials in epilepsy and movement disorders. In 1990 Ruggero be-



came Corporate R&D Director (from discovery to registration) for the CNS area at Farmitalia Carlo-Erba eventually merged into Pfizer (during the last mergings he retained a Senior Consultant position, supervising the development of drugs for Parkinson Disease, Depression and Epilepsy up to their registration). In 1998 Ruggero founded Newron Pharmaceuticals SpA, bringing it to a successful IPO to the Swiss Market and remaining on the Board of Director until 2005. Then he became CSO and CMO of Brane Discovery srl contributing to its acquisition by the Swiss Biotech Neurotune AG where he has been CMO until 2013. Ruggero runs also BioNeuroFar a consultancy firm advising private and public organizations and companies with biotechnological, scientific, industrial and educational needs in the area of brain science. In 2014 Ruggero was a cofounder of Pharmafox a Swiss Biotech devoted to the development of new proteins to treat neurological and muscular disorders. Ruggero acts as an advisor to VC firms, Universities, Pharma Industries and sits on the Board of Directors of Biotech companies and Foundations. Ruggero is an author of over 170 peer reviewed articles, several books on epilepsy and movement disorders and several patents.



20 USI I CASE BioMed 21

NOTES		

HOW TO GET TO USI

USI - Università della Svizzera italiana

Via Giuseppe Buffi 13, CH-6904 Lugano Tel.: +41 58 666 40 00 - Fax: +41 58 666 46 47 www.usi.ch



USI I CASE BioMed













