

siteminsel

MAS / DAS / CAS in Translation and Entrepreneurship in Medicine





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«SITEM-INSEL AG – BRINGING INNOVATION TO THE PATIENT»

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WELCOME TO SITEM-INSEL



sitem-insel is a future-oriented project. In the new institution, research findings and industrial products are developed into clinical application. This process is called «translation» and involves both industry, basic research, investors and physicians. They are all part of a network in which each member is relevant. Such networks are exactly in the focus of the innovation policy of the Swiss Confederation and in line with the support of the Swiss Commission for Technology and Innovation.

The Swiss innovation policy neither finances projects top-down nor pays direct subsidies to companies. This policy was successful in the past, a statement backed by Switzerland's continuous top position in international rankings. The pivotal role of innovation policy for today's economic policy is growing. Our policy calls for collaboration between partners from different industries and

research groups and, accordingly, for new models of cooperation. This brings us back to sitem-insel, a model project ensuring the involvement of all partners.

The strategy of sitem-insel opens new perspectives within the health care system. Please make use of that opportunity for your own profit in your research projects, as research is today more than ever interdisciplinary and benefits from exchange and cooperation. In the face of limited resources and international competition, a partnership approach is a must.

Johann N. Schneider-Ammann,
Federal Councillor

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From the perspective of the University of Bern, founding member of sitem-insel, the new institution offers a unique infrastructure to translate findings from basic research in biomedicine and medical technology into marketable products.

Basic research enjoys high priority at the University of Bern. In the biomedical field, for instance, the University of Bern hosts two National Centers of Competence in Research of the Swiss National Science Foundation – TransCure and RNA & Disease. Both centers aim to develop new treatments for previously untreatable diseases.

The University of Bern is also contributing to optimizing clinical operation technologies from an interdisciplinary perspective with the ARTORG Center for Biomedical Engineering Research involving engineers and surgeons. In this context, sitem-insel will complement and intensify existing activities for the benefit of our health care system.

A novelty at sitem-insel are the further training opportunities in the fields of translation, entrepreneurship, and regulatory affairs for medical products. These opportunities are unique in Switzerland's university landscape.

Overall, sitem-insel strengthens the position of the capital region of Bern in the medical sector to take a leading role in Switzerland and in Europe.

Prof. Dr. Christian Leumann,
Rector University of Bern

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**UNIVERSITÄT
BERN**





SITEM-INSEL SCHOOL IN A NUTSHELL

sitem-insel – the Swiss Institute for Translational and Entrepreneurial Medicine in Bern – has been created to establish, operate and develop a National Center of Excellence for Translational Medicine. Translational medicine is a new, process-oriented discipline that aims to translate new findings and products emerging from private-sector development and basic research into clinical applications.

A major criticism of the current translation process is the lack of professionalization. Therefore, the sitem-insel School aims to promote researchers and train executives in the fields of translational medicine and biomedical entrepreneurship. Lecturers and supervisors of the school are representatives from research and development-oriented private companies, scientists from universities, clinicians, collaborators from regulatory agencies and financial experts.

Participants are expected to acquire the necessary skills to initiate and implement the translation process from the stage of development in industrial or basic science institutions into clinical applications with the ultimate purpose of the latter's commercialization. The acquired theoretical knowledge is to be applied directly to the participants' own projects in order to provide specific solutions and strategies to each individual project.

The program is approved by the University of Bern and participants may obtain the degrees of «[Master of Advanced Studies](#)» (MAS), «[Diploma of Advanced Studies](#)» (DAS) or «[Certificate of Advanced Studies](#)» (CAS).



TEAM

Uyen Huynh-Do, Program director



Uyen Huynh-Do is Associate Professor at the Faculty of Medicine of the University of Bern. After receiving a Medical Degree at the University of Zurich Medical School, and various positions as research and clinical fellow at the Universities of Zurich and Bern, she joined the Division of Nephrology and the Center for Vascular Biology at the Vanderbilt University Medical Center as a Postdoctoral Research Fellow. She returned to the Department of Nephrology and Hypertension at the University Hospital in Bern, where she became an Assistant Professor in 2004, and Associate Professor in 2008.

As education and encouragement of young scientists have always been among her major priorities, she obtained a Master of Medical Education (MME) from the University of Bern and the University of Illinois at Chicago in 2009. These additional skills allowed her

to set up a research and teaching postdoctoral program in Integrative Kidney Physiology and Pathophysiology (IKPP), which has been funded by the European FP7 during two consecutive periods since 2010. As a member of the steering committee of the NCCR Kidney.CH, she set up a CAS/DAS in Translational Nephrology in 2015.

Uyen Huynh-Do has also a CAS in Entrepreneurship awarded by the University of Bern. Presently she is Principal Investigator in multiple research projects in basic sciences as well as translational and clinical nephrology.



Pascale Anderle, Program coordinator



Pascale Anderle graduated in pharmacy from the Swiss Federal Institute of Technology Zurich (ETHZ). After gaining her PhD in life science from the ETHZ, she worked at Covance CLS, Geneva, in the field of clinical trials. She then moved to the USA for a postdoctoral position at UCSF San Francisco and OSU, Ohio, concentrating on absorption and genomics in the intestine. Back in Switzerland she worked as postdoctoral fellow at the Swiss Institute for Experimental Cancer Research (ISREC/EPFL), partially in collaboration with the Nestle Research Center (NRC). The focus of her studies was on mucosal intestinal immunity, colon cancer and the use of genomics in silico analysis.

Being granted an EU project she moved to the Istituto Oncologico della Svizzera Italiana (IOSI, Bellinzona) as junior group leader, then joined the NCCR TransCure at the University of Bern. During this period, she was awarded a CAS in applied statistics.

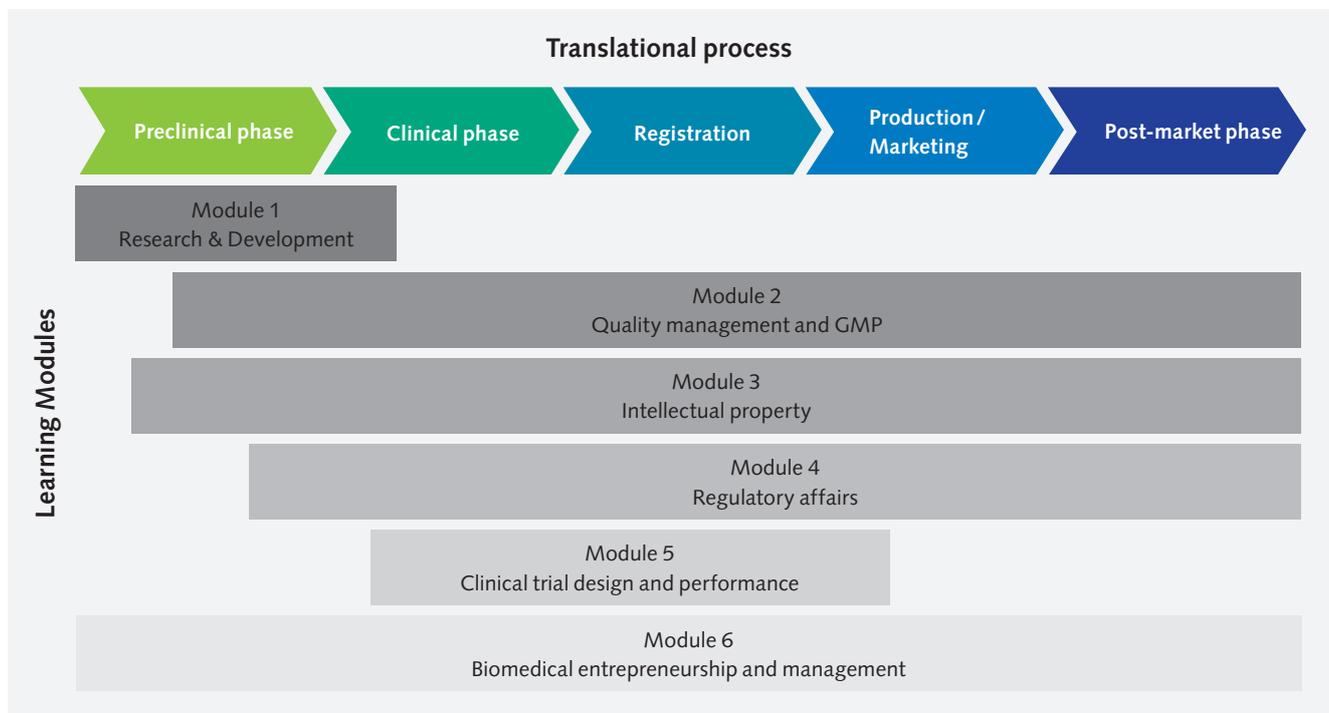
In addition to her activities at sitem-insel, she works as a project coordinator for statistics and translational medicine, is lecturer at the University of Lausanne and ETHZ as well as consultant for statistical and genomics data analysis.



POSTGRADUATE PROGRAM IN TRANSLATION AND ENTREPRENEURSHIP IN MEDICINE

The study program is designed to train professionals in scientific and medical knowledge, and simultaneously in entrepreneurship skills to enable them to successfully coordinate the development and commercialization of biomedical products.

Why selecting our program?



- comprehensive training in scientific/medical as well as entrepreneurial skills
- focus on medicinal products and medical devices
- practice-oriented study program
- modular structure with choice between CAS, DAS or MAS at the University of Bern
- blended learning allowing large flexibility



Personalized continuous education

Depending on your needs we offer a CAS, DAS or MAS. The program consists of 6 modules covering different aspects relevant for the development and commercialization of medicinal products and medical devices. The program is open for all academic disciplines. For academics without a background in natural science, engineering or medicine, a special module «Prerequisites» has been developed. It will allow those participants to acquire fundamental scientific-medical knowledge required for the program.

Project-focused and practice-oriented

The study program is embedded in siteminsel, which, in collaboration with partners, provides participants access to a vast amount of hightech facilities and services.

MAS students perform activities that are designed to specially address aspects relevant to their projects. This includes regular project discussions with peers and experts, the selection of applicable case studies and site visits at companies, which will give them the opportunity to apply knowledge, skill sets and techniques that they have gained from the classroom in real life situations.

Scientific and entrepreneurial translation

The program covers all relevant aspects of the translational process – i.e. entrepreneurial know-how in addition to all basic scientific, clinical and technical knowledge.

Expertise of teachers and supervisors

The teachers and supervisors of this program are from research and development oriented private companies, scientists from universities, ETHs and FHS, collaborators from regulatory agencies, financial experts and clinicians.

Academic requirements and benefits

The prerequisites for admission are the same as for entering the University of Bern. The program participants will be a group of postgraduate students at a high academic level. The program is approved by the University of Bern.

Flexibility

The study program offers «blended learning», i.e. e-learning complemented with face-to-face concept lectures, peer learning sessions and interactive discussions with specialists. Consequently, the program permits you to organize your daily workload and study time according to your background and your specific needs, while the face-to-face sessions allow networking with experts and personal contact with your peers.



Module 1: Research and Development

This module reviews basic heuristic principles related to the discovery and development of diagnostic and therapeutic biomedical products.

Learning objectives

- Understanding of the scientific and technical aspects of the R & D process
- Critical assessment of findings
- Strategic planning of scientific and economic aspects and risk management

Learning content

- Introduction to translational medicine
- Drugs: Drug discovery, bridging discovery and development, drug development
- Medical devices: Design process, design quality, design realization, evaluation
- Diagnostics: Biomarker discovery and validation, clinical test development
- Combination products

Module leaders

Prof. Uyen Huynh-Do, University of Bern
Dr. Andreas Wallnoefer,
Life Sciences Consulting, BioMed Partners

Lecturers

Various experts from industry (Behring SA, Bayer Pharma AG, Johnson and Johnson, Venture, BioMed Partners, Cellestia Biotech) and academia (Artorg, Inselspital)

Date and credits

21st April 2017 – 8th June 2017
3 ECTS

Module 2: Quality management and GMP

This module focuses on the understanding of the needs to establish and maintain the level of excellence required by regulatory agencies.

Learning objectives

- Understanding of manufacturing process & control strategy from lab to commercial scale manufacture
- Being familiar with the concept of a Target Product Profile
- Understanding of the manufacturing process based on risk management, experimental studies and small scale industrial experience
- Definition of a control strategy based on process and product understanding
- Understanding how the manufacturing process develops alongside within preclinical and clinical development

Learning content

- Virtual factory and general overview of regulated industry
- Manufacturing and control development
- Manufacturing and GMP
- Quality management

Module leader

Dr. Max Corbett,
Behring SA

Lecturers

Various experts from industry (UCB Farchim, Behring SA, meditec Consulting, Saq Qualicon, Cascination) and academia (University of Mainz)

Date and credits

9th June 2017 – 8th September 2017
5 ECTS

Module 3: Intellectual property

Intellectual property rights given to investigators are essential for the successful commercialization of biomedical products. The different types of intellectual property and specific legal aspects for biomedical products will be discussed.

Learning objectives

- Understanding of IP related topics
- Critical assessment of factors essential in IP
- Strategic planning of IP related aspects

Learning content

- History of IP rights
- International harmonization
- IP rights as assets
- Patents
- Copyrights, trademarks and design
- IP and ethics

Module leader

Prof. Dr. Heinz Mueller,
Swiss Federal Institute of IP

Lecturers

Various experts from industry (Swiss Federal Institute of IP, Keller and Partner) and academia (University of Basel, University of Zurich)

Date and credits

9th September 2017 – 25th Nov. 2017
3 ECTS

Module 4: Regulatory affairs

The role of the different regulatory authorities along the translational pathway and the product specific requirements are presented.

Learning objectives

- Understanding of the legal framework
- Understanding the elements relevant for the registration of biomedical products
- Basic understanding of new and innovative regulatory processes
- Strategic planning of regulatory activities

Learning content

- Legal framework for drugs and medical devices
- Regulation of drugs
- Certification of medical devices and diagnostic tools
- Regulation of particular medical products such as orphan drugs
- Regulation of combination products
- Pharmacovigilance and materiovigilance

Module leaders

Dr. Barbara Jentges, PhACT GmbH
Dr. Sandra Soniec, meditec Consulting GmbH

Lecturers

Various experts from industry (meditec Consulting, PhACT), academia and public institutions (University of Basel, WHO)

Date and credits

Spring 2018 – Summer 2018
5 ECTS

Module 5: Clinical trial design and performance

Clinical trials are designed to test how new medical approaches work in humans and how efficient, safe and economic they are. The prerequisites for such studies, the understanding of the pathophysiology of the underlying diseases, the definition of quantifiable endpoints by clinicians as well as data management and statistics are discussed.

Learning objectives

- Translation of preclinical data into clinics
- Design of a clinical study
- Identification of essential factors in trial conduct
- Understanding of the ethical and regulatory prerequisites for conducting clinical trials
- Completion of investigator-sponsor certificate

Learning content

- Review of R&D results
- Pharmacometrics
- Study design
- Trial conduct
- Ethical, regulatory and financial aspects of clinical trials

Module leader

PD Dr. Sven Trelle, Co-director Clinical Trial Unit, University of Bern

Lecturers

Various experts from the University of Basel and University of Bern

Date and credits

Summer 2018 – Autumn 2018
5 ECTS

Module 6: Biomedical entrepreneurship and management

The development and commercialization of a new biomedical product involves the coordination and leadership of a large multidisciplinary team. The module focuses on various aspects of entrepreneurship such as product management, business administration, and strategies to commercialize biomedical products.

Learning objectives

- Mastering of business models and related aspects
- Identification of critical success factors for start-ups
- Creation of a business plan
- Basic understanding of financial principles
- Training in team building and leadership
- Understanding of the health system and key players

Learning content

- Innovation and entrepreneurship
- Business modeling and planning
- New venture creation
- Fundraising strategies
- Principles of finance and accounting
- Project management
- Team building and leadership
- Structure of health systems

Module leader

Prof. Dr. Artur Baldauf, Director Department of Management and Entrepreneurship, University of Bern

Lecturers

Various experts from industry, academia and non-profit organizations (University of Bern, College M of Medicine, Commission for Technology and Innovation CTI, etc.)

Date and credits

October 2017 – Autumn 2018
13 ECTS

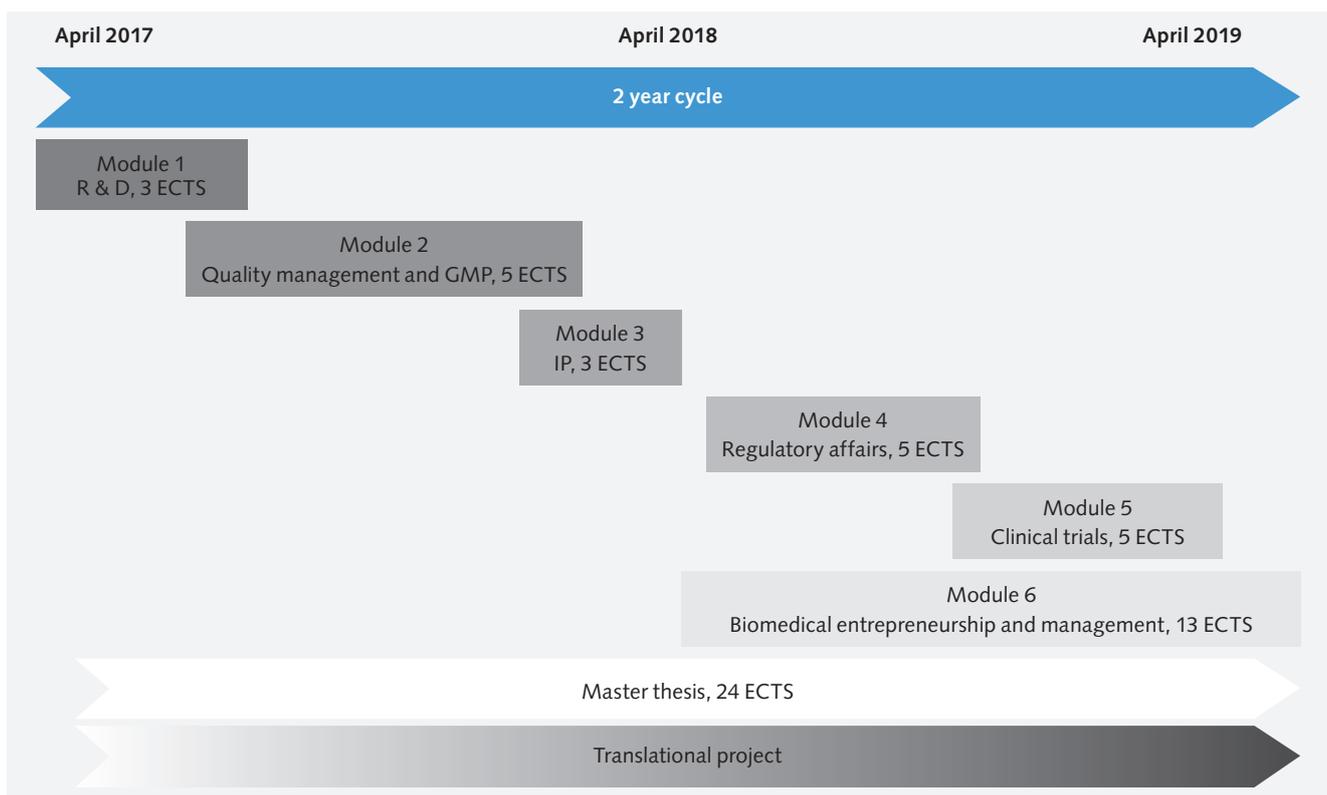


PROGRAM PLAN, FEES AND ADMISSION

Program plan

Modules 1 to 5 consist of a kick-off event, face-to-face lectures, peer discussions, round table discussions, a wrap-up session and an e-learning part. Module 6 predominantly consists of face-to-face lectures, workshops and round table discussions.

More than 70% of the contributors and speakers are experienced people from the private sector, who can share their practical knowledge during the face-to-face sessions and will accompany you throughout the e-learning part.





Different curricula

Depending on the curriculum selected, different numbers of ECTS points are required:

- CAS in Translational Medicine: Three modules of choice from modules 1 to 5 (min. 13 ECTS) and a certificate work (2 ECTS)
- CAS in Bio-entrepreneurship: Module 6 and a certificate work (2 ECTS)
- DAS: Combination of the 2 CAS mentioned above
- MAS: All 6 modules, Master thesis on a translational project and elective courses
- Single modules can be attended depending on available space

Admission requirements

CAS, DAS: Participants should have a MS or higher degree in life science, medicine, engineering science or equivalent.

MAS: Participants should have a MS or higher degree in life science, medicine, engineering science or equivalent and at least 2 years of experience in research and /or development. In addition, participants must submit a proposal for a translational medicine project on which they will work during the MAS to the MAS evaluation board.

Graduation

After successful participation and depending on the achieved ECTS points, the University of Bern awards the degree «Certificate of Advanced Studies» (CAS), «Diploma of Advanced Studies» (DAS) or «Master of Advanced Studies» (MAS). The corresponding certificates will disclose the content and achievements of the program.

Language and location

The course language is English. The University of Bern will be the location for all dates of presence (face-to-face sessions and audits).



Application

To apply for the MAS and for general questions contact uyen.huynh-do@insel-sitem.ch, to apply for the DAS, CAS or single modules contact pascale.anderle@sitem-insel.ch.

Registration and available services

Participants will be registered at the University of Bern. Upon successful registration, the participants will get a campus account, which includes an email account in the SWITCH network.

MAS students will receive a Unicard and have access to sports, childcare and counselling facilities offered by the University of Bern.

Program fees 2017

The fee for the MAS is CHF 31 500.–, for the DAS CHF 23 100.– and for each CAS CHF 12 600.–. The fee for single modules is between CHF 3 150.– and CHF 6300.–, depending on the size.

Insurance

Any type of insurance including health and accident insurance is each participant's own responsibility throughout the entire course.

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