

# Studienplan für das Studienprogramm Translational Medicine and Biomedical Entrepreneurship



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UNIVERSITÄT  
BERN

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Das Studienprogramm Translational Medicine and Biomedical Entrepreneurship ist eine universitäre Weiterbildung, welche Studiengänge in Translational Medicine and Biomedical Entrepreneurship beinhaltet. Es führt zur Erteilung der Abschlüsse „Certificate of Advanced Studies in Translational Medicine, Universität Bern (CAS TM Unibe)“, „Certificate of Advanced Studies in Biomedical Entrepreneurship, Universität Bern (CAS BE Unibe)“, „Diploma of Advanced Studies in Translational Medicine and Biomedical Entrepreneurship, Universität Bern (DAS TMBE Unibe)“, „Diploma of Advanced Studies in Translational Medicine, Universität Bern (DAS TM Unibe)“ sowie des Titels „Master of Advanced Studies in Translational Medicine and Biomedical Entrepreneurship, Universität Bern (MAS TMBE Unibe)“.

Die Rechtsgrundlage ist das Reglement der Medizinischen Fakultät für die Weiterbildungsstudiengänge in Translational Medicine and Biomedical Entrepreneurship vom 17.07.2019.

## 1. Ziele des Studienprogramms

Ziele

CAS TM: Die Teilnehmenden kennen grundlegende Aspekte in der Entwicklung eines medizinischen Produkts (z. B. regulatorische und produktionstechnische Aspekte).

CAS BE: Die Teilnehmenden sind mit wirtschaftlichen und unternehmerischen Gesichtspunkten der Entwicklung eines medizinischen Produkts vertraut.

DAS TMBE: Die Teilnehmenden sind mit den Inhalten des CAS TM und des CAS BE vertraut.

DAS TM: Aufbauend auf den im CAS TM vermittelten grundlegenden Aspekten der Entwicklung eines medizinischen Produkts vertiefen die Teilnehmenden ihr Wissen von der Forschung bis zum klinischen Einsatz. Dazu gehören forschungs- und entwicklungsspezifische Aspekte, produktionstechnische, regulatorische und ethische Gesichtspunkte, Fragen des geistigen Eigentums und klinische Versuche betreffende Aspekte.

MAS TMBE: Zusätzlich zu den Zielen des DAS TM und des CAS BE sind die Teilnehmenden in der Lage, im Rahmen ihrer MAS-Arbeit ein anspruchsvolles Projekt in translationaler Medizin in die Praxis umzusetzen und zu reflektieren.

Neben den technisch-wissenschaftlichen Fertigkeiten wird in den Modulen ein spezielles Augenmerk auf nicht-technische Fertigkeiten wie Kommunikation, Leadership und Teammanagement gelegt.

## 2. Umfang, Ziele und Inhalte der Studiengangselemente

Umfang	Alle Module bestehen aus Präsenzstunden und E-Learning-Elementen. Die durchschnittliche Präsenzzeit der Module 1 bis 5 ist 1.5 Tage pro Modul. Die Präsenzzeit von Modul 6 beträgt durchschnittlich 14–16 Tage (der totale Arbeitsaufwand beträgt 25 bis 30 Stunden pro ECTS-Punkt).
Inhalt	Das Programm zielt darauf ab, akademische Fachkräfte auf dem Gebiet der translationalen Medizin und des biomedizinischen Unternehmertums auszubilden. Von den Teilnehmern wird erwartet, dass sie die erforderlichen Fähigkeiten erwerben, um den Prozess des Übergangs biomedizinischer Produkte vom Entwicklungsstadium in industriellen oder grundlegenden wissenschaftlichen Einrichtungen in klinische Anwendungen mit dem Endziel ihrer Kommerzialisierung einzuleiten und umzusetzen. Der Schwerpunkt liegt sowohl auf diagnostischen als auch auf therapeutischen Produkten (Medizintechnik, Pharma).
Sprache	Die Unterrichtssprache in allen Modulen ist Englisch. Alle Leistungsnachweise (Leistungskontrollen, schriftliche Arbeiten, Präsentationen) werden in englischer Sprache durchgeführt.

## 3. Modulbeschreibung

Modul 1	<p><b>Research and development</b> Size: 4 ECTS points</p> <p>The first phase in the commercialization of a biomedical product is the discovery and identification of products that are worthwhile to be tested in clinical trials. The performance of a drug, medical device or diagnostic assay in the preclinical testing phase has to be sufficiently robust so that clinical trials can be considered and are likely to be granted by an ethics commission and an office of regulatory affairs. Module 1 focuses on research and development of drugs, medical devices and diagnostics.</p> <p>General learning objectives</p> <ul style="list-style-type: none"><li>• Basic understanding of R and D process (scientific and technical aspects)</li><li>• Critical assessment of findings</li><li>• Strategic planning (scientific and economic aspects) and risk management</li></ul>
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## Specific learning objectives

### Pharmaceutical products

- Know the principle steps in drug discovery and development
- Understand the concepts of question-based drug development
- Understand the requirements for a hit and for a lead compound
- Know the strategies applied in lead optimization
- Know the relevant parameters in pharmacokinetics, pharmacodynamics and toxicology
- Know what proof of principle studies are
- Be familiar with preclinical testing
- Know what ADME studies are and their purpose
- Be able to assess critically preclinical data
- Be familiar with the pharmacometrics strategies in preclinical studies

### Medical devices

- Know the principle steps in medical device design and validation
- Understand the process of prototyping
- Know the difference between prototype and produce
- Know the requirements for material selection
- Be familiar with criteria-based evaluation
- Know the difference between verification and validation
- Be familiar with risk management concepts

### Diagnostics

- Know the principle steps in biomarker discovery
- Understand the requirements for an appropriate biomarker
- Be familiar with technologies used in biomarker discovery
- Know the relevant processes in assay development and optimization

## Module 2

### **Good manufacturing practice and quality management**

Size: 5 ECTS points

The focus of this module is the understanding of aspects essential to ensure that all activities linked with a translational process maintain the desired level of excellence required by the regulatory agencies.

### General learning objectives

- Basic understanding of quality management processes
- Critical assessment of factors relevant for manufacture and process development

- Strategic planning (scientific and economic aspects) of quality and risk management

Although conceptually the development of drugs, medical devices and diagnostics is similar, there are nevertheless differences. Accordingly, for each type of product specific learning objectives were defined.

#### Specific objectives

- Understand the goals of process development
- Understand the steps for developing a robust manufacturing process
- Develop an awareness of the process development activities in relation to the clinical development program and product licensure
- Having read the “Four” and realize the big amount of details in these regulations
- Realize that the documents describing a product are of the same importance as the product itself
- Have an overview of the lifecycle of a medical device with its development process (pre-market) and product care process (post-market) and to comprehend the relation to the Quality Management System
- Understand what design control is
- Have an overview of manufacturing processes itself and facility considerations
- Understand the role of each key function: Production, Quality Control, Quality Assurance, and Technical Services, Supply Chain
- Understand how each function fits together to transform raw materials into a high-quality product, which may be applied to the patient
- Develop an understanding of GMP through practical examples
- Understand the purpose of a Quality Management System and how it fits into the manufacturing process
- Understand how these elements are deployed during the manufacturing process

#### Module 3

#### **Intellectual property**

Size: 3 ECTS points

Intellectual property rights given to investigators over the creations of their minds 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.

#### General learning objectives

- Basic understanding of IP related topics

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

#### Specific learning objectives

- Understand the economic rationale for intellectual property rights
- Name all intellectual property rights that can be protected with a protection right
- Define what each intellectual property right protects and what not
- List the maximal terms of all protection rights
- Understand the difference between the protections of software by copyright or patents
- Know what the general requirements for granting a patent right are
- Know the specific patent exclusion rights dealing with biological or medical matters
- Have a general understanding of the application procedures for each right
- Understand the importance of an IP strategy, in particular patent strategy
- Understand the differences of the parts of a patent document and their implications for the protection of the invention
- Understand some of the specificities in the patent rights of the US
- List some of the alternatives for patenting (and their advantages and disadvantages)

#### Module 4

#### **Regulatory Affairs**

Size: 5 ECTS points

Although, conceptionally, the requirements for medical products to be allowed to be tested in clinical trials and eventually be used for treatments in humans are similar, the regulatory processes involved are still very different. Consequently, the registration process for combination products adds another level of complexity. Module 4 focuses on regulatory affairs processes of drugs, medical devices (incl. diagnostics) and combination products. As the processes are in some aspects significantly different, the module has two tracks, one specific for drugs and one specific for medical devices. Combination products and general legal frameworks are common to both tracks.

#### General learning objectives

- Basic understanding of regulatory processes
- Critical assessment of findings
- Strategic planning (scientific and economic aspects) and risk management

## Specific learning objectives

### For pharmaceutical products:

- Being aware of the legal provisions and regulations organs/documentations that provide the legal basis for the regulation of therapeutic medicinal drug products and medical devices with focus on the European Union
- Becoming familiar with the EU legal provisions and regulations for licensing of medicinal products for human use
- Understanding the licensing procedures in the EU and the role of Health Technology Assessment (HTA) Bodies for pricing and reimbursement of medicinal drug products by public health systems
- Knowing the EU system of post-approval changes (PACs) and the categorization of PACs and the related measures to be taken by a marketing authorisation holder.
- Understanding the regulatory framework for non-clinical safety testing in pharmaceutical development and the requirements to conform with Good Laboratory Practices (GLP) provisions and how to present non-clinical study reports and study data in a regulatory submission dossier to be submitted to EU authorities.
- Being familiar with the EU provisions for clinical trials. the aspects for the application for a clinical trial and the presentation of clinical study reports and clinical data in an (initial) application for marketing authorisation and region-specific differences
- Knowing the basics of pharmacovigilance (PV) legislation in the EU

### For Medical Devices:

- Basic understanding of the Regulatory Affairs role and involvement in the life-cycle of a Medical Device / IVD
- Introduction to the EU / CH legal framework for Medical Device in the European Union and Switzerland including roles and responsibilities of Manufacturers, Notified Bodies and Competent Authorities
- Understanding how medical devices are CE-marked: Intended Purpose, Classification, Conformity Assessment, initial CE-marking, Post-market requirements
- Understanding the format and content of the Technical Documentation required for medical devices and IVDs
- Overview of key processes for demonstrating compliance with MDR / IVDR Annex I General Safety and Performance Requirements: Risk Management, Usability Engineering, Clinical Evaluation (Medical devices only) and Performance Evaluation (IVDs only)
- Overview of Labelling and Post-market surveillance requirements
- General introduction to international regulatory affairs and combination products

## Module 5

### **Clinical trial design and performance**

Size: 6 ECTS points

Clinical trials are designed to test how well new medical approaches work in humans. The prerequisites for such scientific studies, the understanding of the pathophysiology of the underlying diseases and the definition of quantifiable endpoints by clinicians as well as the analyses of data by statisticians will be considered.

#### General learning objectives

- Basic understanding of clinical trial design and performance process.
- Critical assessment of findings
- Strategic planning (scientific and economic aspects) and risk management

#### Specific learning objectives

- Understand relevant clinical endpoints and their differences
- Understand the different study designs, the prevention of bias and the basic principles of statistics
- Understand the structure of a study protocol
- Be familiar with the conduct of clinical trials
- Understand the principles of data acquisition, data quality and data monitoring
- Know how to report results of a clinical trial
- Know what regulatory and ethical issues need to be considered when requesting permission to perform a clinical trial
- Recognize the costs involved in a clinical trial and know how to estimate a budget
- Understand the basic concepts of pharmacometrics and its impact in clinical trial designs

## Module 6

### **Biomedical Entrepreneurship**

Size: 13 ECTS points

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

In order to successfully pass module 6, a Certificate/Project thesis (2 ECTS) has to be written within the MAS Translational Medicine and Biomedical Entrepreneurship. Details are provided in the document "Guidelines for the Certificate/Project Thesis of module 6 (Zertifikatsarbeit)"

### General learning objectives

- Basic understanding of processes important in biomedical entrepreneurship
- Critical assessment of findings
- Strategic planning of economic aspects

### Specific learning objectives

#### General

- learn the basics in how to identify market opportunities
- get an understanding of how to implement factors relevant in the innovation process

#### Business modeling and planning

- get familiar with the business canvas as a tool for business modeling
- understand the essential elements of a business plan and be able to write own business plan
- be aware of important factors of a successful pitch and be able to prepare and present an elevator pitch

#### Accounting and finance

- learn how to analyze financial statements
- be able to extract relevant information from accounting data for the purpose of decision-making in various business contexts, such as investment appraisal, performance evaluation, and performance-based compensation.
- basic understanding of portfolio analysis
- basic knowledge of relevant factors in short-term and long-term investments

#### Management

- be familiar with the basic principles of project management
- be aware of typical pitfalls in project management and contract negotiations
- be familiar with selected project management tools

#### New venture creation

- basic understanding of entrepreneurial strategies
- be familiar with factors influencing market chances of a product
- be familiar with the marketing process
- assess new business opportunities
- be able to plan a new venture
- be familiar of legal aspects when creating a new business
- basic understanding of financial requirements of a new venture
- be familiar with entrepreneurial financial strategies
- hands-on experience with valuation related factors



## Creativity and innovation

- understand the psychological principles of the creative thinking process
- learn tools and methods for design thinking
- Swiss and other international health systems
- learn about the organization and governance, health financing, health care provision, health reforms and health system performance of Switzerland and other countries

## Wahlkurse

### DAS TM:

Size: 3 ECTS points

The elective courses may include various presence lectures about medical topics (e.g. in the frame of colloquia) which include an examination or may include modules from other continuous education programs of the School (e.g. in the CAS Artificial Intelligence in Medical Imaging)

## Zertifikatsarbeiten

### CAS TM:

Size: 2 ECTS points

In the CAS TM thesis, students have to describe basic aspects related to the development of a medical product or project (e.g. regulatory or quality related aspects)

Before a CAS TM thesis can be submitted, the students have to successfully complete all activities of three selected modules from module 1-5 (i.e. achieved the minimum required points) and must have participated in at least 80 % of all activities (i.e. team works, site visits, peer discussion sessions and lectures).

The CAS TM thesis must have been approved by a referee. If the thesis is considered as "insufficient", a new version can be submitted within 3 months.

Details are provided in the document "Guidelines for the CAS TM UniBe Thesis (Zertifikatsarbeit)"

### CAS BE:

Size: 2 ECTS points

In the CAS BE thesis, students have to describe results and progress with respect to the development of a medical product or project in terms of entrepreneurial aspects e.g. in form of a business plan.

Before a CAS BE thesis can be submitted, the students have to successfully complete all activities and coaching sessions of module 6 "Biomedical Entrepreneurship and Management" and must have visited at least 80 % of all (i.e. team works, site visits, peer discussion sessions and lectures).

The CAS BE thesis must have been approved by a referee. If the thesis is considered as "insufficient", a new version can be submitted within 3 months.

Details are provided in the document "Guidelines for the Certificate/Project Thesis of module 6 (Zertifikatsarbeit)"

#### DAS TMBE:

Size: 4 ECTS points

In the DAS TMBE thesis, students have to describe basic aspects related to the development of a medical product or project (e.g. regulatory or quality related aspects) or their results and progress with respect to the development of their medical product in terms of entrepreneurial aspects e.g. in form of a business plan or a combination thereof.

As a basis for the DAS certificate thesis, the certificate thesis of the study that has been finished first (CAS TM or CAS BE) can be extended to include additional aspects. As an alternative, a new DAS certificate thesis can be provided.

The DAS TMBE thesis must have been approved by a referee. If the thesis is considered as "insufficient", a new version can be submitted within 3 months.

Details are provided in the document "Guidelines for the DAS TMBE UniBe Thesis (Zertifikatsarbeit)"

#### DAS TM:

Size: 4 ECTS points

In the DAS TM thesis, students have to describe basic aspects related to the development of a medical product or project (e.g. regulatory or quality related aspects).

As a basis for the DAS certificate thesis, the certificate thesis of the previous CAS TM study can be extended to include additional aspects. As an alternative, a new DAS certificate thesis can be provided.

The DAS TM thesis must have been approved by a referee. If the thesis is considered as "insufficient", a new version can be submitted within 3 months

Details are provided in the document "Guidelines for the DAS TM Unibe Thesis (Zertifikatsarbeit)"

#### Master thesis

#### MAS TMBE

Size: 24 ECTS points

In the MAS TMBE thesis, the students have to describe results and progress with respect to the development of a project related to translational medicine in terms of technical-scientific, but also entrepreneurial and strategic aspects.

Before a MAS TMBE thesis can be submitted, all 6 modules must have been successfully completed.

The thesis must have been approved by the referee, co-referee and a member of the study commission before a date can be defined for the final exam.

If the thesis is considered as "insufficient", a new version can be submitted within 6 months.

Details are provided in the document "Guidelines.MAS.Thesis")

#### 4. Leistungsnachweise im Studiengang

Leistungsnachweise

Die Leistungskontrollen für die Module 1-6 erfolgen entweder vor Ort oder mittels der E-Learning-Plattform. Die Leistungskontrollen umfassen folgende Elemente:

- Mündliche oder schriftliche Schlussprüfung und
- Quizze und/oder
- Übungen und/oder
- Präsentationen.

Die Leistungskontrolle für Modul 1 umfasst folgende Elemente:

- Progress Reports,
- schriftliche Arbeit und Präsentation.

Für jedes der Module 1-6 wird eine Endnote erteilt.

Die Studienkommission entscheidet aufgrund der Bewertung der Leistungsnachweise und der Erfüllung der weiteren Leistungsanforderungen über das Bestehen und die Erteilung des Zertifikats.

Das Nähere regeln die Richtlinien der Studienkommission zur Leistungskontrolle.

#### 5. Schlussbestimmungen

Inkrafttreten

Dieser Studienplan tritt auf den 1.8.2019 in Kraft.

*Von der Studienkommission beschlossen:*

24.06.2019

Der Vorsitzende



Prof. Dr. Jürgen Burger

*Von der Medizinischen Fakultät genehmigt:*

17.07.2019

Der Dekan



Prof. Dr. Hans-Uwe Simon