siteminsel
«Bringing Innovation to the Patient»
WELCOME TO SITEM-INSEL 4
Johann N. Schneider-Ammann
Federal Councillor 4
Christian Leumann,
Rector University of Bern 5

SITEM-INSEL IN A NUTSHELL 7

MISSION OF SITEM-INSEL 8
Operational definition of translational medicine 8
Structural problems in translational medicine 8
Contribution of sitem-insel 8

WHAT DOES SITEM-INSEL DO 9
sitem-insel School 9
sitem-insel Enabling Facilities 10
sitem-insel Promoting Services 11

LOCATION OF SITEM-INSEL 13
Comprehensive services in one building 13

ORGANIZATION OF SITEM-INSEL 14
Board of directors 15
Executive board 15
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

Translated from German with permission by sitem-insel
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
sitem-insel – the Swiss Institute for Translational and Entrepreneurial Medicine in Bern – was created to establish, operate and develop a National Center of Excellence for Translational Medicine. sitem-insel is organized as a non-profit oriented public private partnership. 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 application. The discipline seeks to professionalize the essential interaction between scientists conducting basic research in the private sector and universities, clinicians, regulatory bodies and investors.

The mission of sitem-insel is to create and foster an enhanced environment for translational medicine in Switzerland. The sitem-insel strategy rests on three pillars:

- The sitem-insel School offers university-level continuing professional development courses taught by university and private-sector lecturers.

- The sitem-insel Enabling Facilities provide infrastructure to foster cooperation between industrial partners, basic scientists and clinicians on the campus of the University Hospital of Bern (Inselspital) with the ultimate goal to bring novel diagnostic and therapeutic products towards clinical application.

- The sitem-insel Promoting Services aim to optimize the administrative-regulatory effort along the route from laboratory bench to commercial products.
Operational definition of translational medicine

sitem-insel considers translational medicine as a process-oriented discipline that aims to translate new findings and products resulting from industrial development and basic research to clinical application.

Structural problems in translational medicine

The number of innovative novel products reaching clinical application has been insufficient in the last twenty years. Given the unprecedented wealth of innovative discoveries from basic research and industrial development, the lack of transformation of these discoveries into practical applications appears as a paradox today. In Switzerland, the number of clinical studies declined steadily from 2004 to 2014, a decline not diminished by creating the Clinical Trial Centers or the Swiss Clinical Trial Organization by the Swiss National Science Foundation.

The sluggish interaction between industrial, laboratory and clinical investigators seems to be a main hindrance for fruitful translational developments. In addition, the regulatory obstacles steadily increased in the field of translational medicine.

Contribution of sitem-insel

The mission of sitem-insel is to improve the general environment for translational medicine in Switzerland. It seeks to professionalize the interaction between basic science researches from industries and universities, clinicians, regulatory bodies and investors. The strategy of sitem-insel comprises the school, the enabling facilities and the promoting services in one building to encourage cooperation.
WHAT DOES SITEM-INSEL DO?

sitem-insel School

A major criticism of the current translation process is the lack of professionalization. Therefore, the sitem-insel School aims to promote young 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 latters’ commercialization. The focus will be on both diagnostic and therapeutic products. The acquired theoretical knowledge will be directly applied 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).

For further information visit www.sitem-insel.ch and sitem.bio-med.ch.
sitem-insel Enabling Facilities

Investigations and products to be developed at sitem-insel are not dictated by the sitem-insel board of directors, but are based on the initiative of investigators from private companies, hospitals, basic research institutions and start-up companies.

To facilitate the transfer of research results into clinical practice and industrial production, a new building is currently under construction on the campus of the University Hospital of Bern. On a surface of approximately 20000 m², the building will be open for translation specialists from industry, academia and hospitals. The proximity of the new building to both the largest Swiss university hospital comprising all tertiary medical disciplines and the University of Bern is attractive for all partners.

To strengthen existing collaborations, key partners such as the ARTORG Center for Biomedical Engineering Research, the Institute for Surgical Technology and Biomechanics (ISTB), the Dental Translational Research Center, the Clinical Trials Unit Bern, Clinical Anatomy, Experimental Radiology and Investigative Neurology will be present in the new sitem-insel building.

Specific infrastructure will comprise open space for start-ups and spinoffs, 3-D printing, metabolomics, human cell therapy, 7 Tesla MRI, a diabetes research center, and a simulation center for novel surgical technologies, among others. As sitem-insel aims to account for disruptive developments, the infrastructural design guarantees flexibility.

For further information visit www.sitem-insel.ch and consult the additional leaflets in this folder.
sitem-insel Promoting Services

Complicated and slow regulation processes are relevant obstacles for translational projects. The promoting services therefore aim to optimize these processes with the ultimate goal of diminishing the administrative-regulatory effort. Based on the promoting services’ analyses, strategies will be developed as to how regulation requirements may be dealt with to facilitate translational efforts of medtech and pharmaceutical companies.

The services provided will include undergraduate and postgraduate teaching at the University of Bern and in private institutions. The director of the Promoting Services, Prof. Dr. Rudolf Blankart, was recruited by the Faculty of Business, Economics and Social Sciences of the University of Bern and the board of directors of sitem-insel.

The focus of the Promoting Services for 2017–2020 is as follows:

• Establish a consulting service in regulatory affairs
• Design a basic and advanced university training program in regulatory affairs in biomedicine and medical technology
• Analyze the economic importance of approval procedures in Switzerland
• Develop a strategy for the medium-term coordination of administrative-regulatory procedures
Comprehensive services in one building

sitem-insel will operate from dedicated, purpose-built facilities on the Campus of the University Hospital of Bern (Inselspital). This location is ideal to facilitate and promote sustainable medical innovation through efficient interaction between patients, competent clinicians, the private sector, regulatory authorities and legal counselors.

All three units of sitem-insel – sitem-insel School, sitem-insel Enabling Facilities, and sitem-insel Promoting Services – will operate under the same roof. sitem-insel is near the highway, the main railway station, the University of Bern’s main building and the city center.
sitem-insel is an independent, non-profit-oriented public private partnership. Government funding has been approved for the start-up phase. After that time, sitem-insel should become financially independent.
Board of directors

- **Gabor Székely**, Prof. em. ETH Dr., President sitem-insel AG, Zürich
- **Uwe E. Jocham**, dipl. pharm., Senior VP and General Manager CSL Behring Recombinant Facility AG, Vice President sitem-insel AG, Bern
- **Claudio L. Bassetti**, Prof. Dr. med., Chairman and Head of the Department of Neurology, University Hospital of Bern
- **Gerhard Bauer**, Dr. pharm., Head Research, Development & Operations, Institut Straumann AG, Basel
- **Michèle Etienne**, Dr. rer. pol., Co-owner Innopool AG, Co-Director GetDiversity, Schüpfen
- **Urs Gasche**, Attorney-at-law, Member of the Swiss National Council, Fraubrunnen
- **Daniel Odermatt**, Dr. rer. pol., Administrative Director of the University of Bern, Bern
- **Bruno Oesch**, Dr. phil. nat., Executive Chairman Neurotune AG, CEO Malcisbo AG, Founder Prionics, Zürich
- **Stephan Windecker**, Prof. Dr. med., Chairman of the Department of Cardiology, University Hospital, Bern

Executive board

- **Felix Frey**, Prof. em. Dr. med., Managing Director sitem-insel
- **Rudolf Blankart**, Prof., Dr. rer. pol., Director Promoting Services
- **Christian Rosser**, Dr. rer. soc., Director Centralized Services
- **Sabrina Ilgenstein**, Assistant to Executive Board

The Directors of the sitem-insel School and the sitem-insel Enabling Facilities will be appointed in 2018.