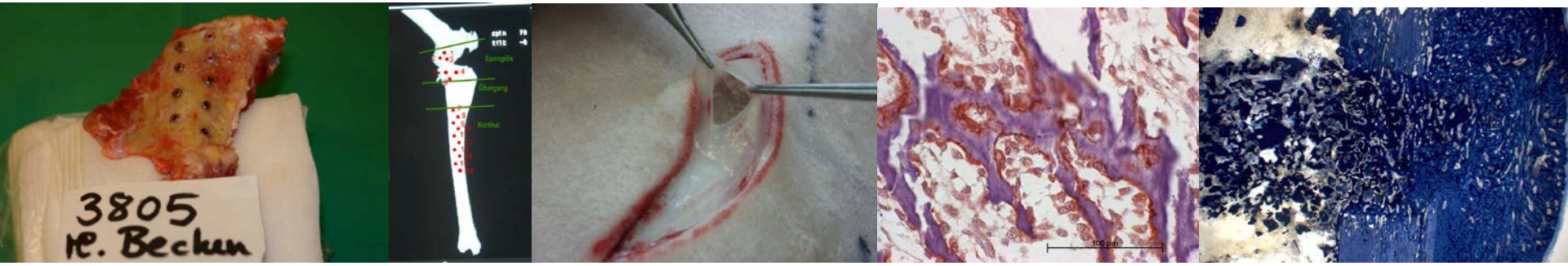
Workshop II : GLP Experiences



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Competence Center for Applied Biotechnology and Molecular Medicine (CABMM)

Vetsuisse Faculty ZH, University of Zurich, Switzerland

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- Why ?
- How ?
- Where?

Why: Quality accreditation

Status quo at (most) Universities

- Focus of Universities in teaching and/or research
- Positions mostly for teaching, soft money for research positions
- Basic research vs. applied research

Why: Quality accreditation

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- **Translational medicine**

Why: Quality accreditation

Translational medicine (also referred to as translational science)

Definition: is a discipline within biomedical and public health research that aims to improve the health of individuals and the community by "translating" findings into diagnostic tools, medicines, procedures, policies and education.

Translational medicine is a rapidly growing discipline in biomedical research and aims to expedite the discovery of new diagnostic tools and treatments by using a multi-disciplinary, highly collaborate, "bench-to-bedside" approach.

(Wikipedia:http://en.wikipedia.org/wiki/Translational_medicine)

Why: Quality accreditation

Status quo at (most) Universities

- Organization of research projects
  - Masters, doctorate or PhD students
  - Expertise by leader of the group (professors, senior researchers)
  - Development of technology project-oriented (animal models, *in vitro* models)
  - Ad-hoc documentation
  - Knowledge transfer questionable
  - No focus on registration of products
  - Limited to no knowledge of regulatory affairs

Why: Quality accreditation

Status quo at (most) Universities

- Accreditations non-existing
- OECD guidelines in medical devices (Europe more liberal)

- ISO….. Accreditation in reference laboratories, GCP seldom GLP, GMP
- Difference between US/Europe
  - Accreditation of projects vs. institutions
  - “GLP-like” documentation

- In Translational Medicine not adequate anymore…..

Why: Quality accreditation

Status quo of (most) Universities

- IP rights
- Spin-off companies
  - Success and survival difficult with limited portfolio
  - Transfer offices
- Step to industry difficult
  - Not enough data yet
  - Research not sufficiently documented
  - Risk too high for further development
  - Innovation disappears in desk drawer, “not-invented here syndrom”…….or worse is further developed without university ownership

Why: Quality accreditation

Industry perspective

- Need registration (CE-marked, TM-marked, FDA-approval) for marketing medical products
- Closing of *in house* research groups
- Outsourcing of research
  - University collaboration
  - GLP accredited private companies
  - No natural “flow” with several independent partners, multidisciplinary approach
  - Repetition of studies for accreditation purposes needed
  - Questionable results due to missing expertise

Why: Quality accreditation

Future of biotechnology: “From bench to bedside and back….”

- Attraction for collaboration with universities ?
  - Highly specialized medicine, especially in regenerative medicine
  - Interdisciplinary approach (engineers, pharmaceutics, (bio-)chemists, biologists, micobiologists, clinicians, veterinarians…)
  - Definition for product “needs” comes from clinicians
  - Industry needs academia for multi-centered approach (trials, etc.)
  - Different models for collaboration
    - In- kind contribution model with academic & industrial partners, focus-oriented *(Ref. Patel, PhD, Novartis @ symposium “Spitzenmedizin”)*

Why: Quality accreditation

Future of biotechnology: “From bench to bedside and back….”

- Stick to regulatory affairs
- True for translational medicine (regenerative medicine, tissue engineering)
- GLP for preclinical studies
- GMP for manufacturing and storage
- GCP for clinical trial phase

Studies need to be repeatable ! *(Ref. Heywood)*

- non biased studies
- preclinical and clinical results need critical review / documentation

How: Implementation

- **Adherence to strict protocol** ("Verordnung vom Bundesrat über die gute Laborpraxis" 813.112.1)
- **Documentation system** (Infrastructure, Equipment, Standard Operative Procedures animal experiments, Analytical Procedures, IT-Procedures, Administration, Quality Assessment)
- **Study plan** – signed by all partners
- **Documentation system** throughout the study (animal permission, surgeries, anesthesias, personnel, laboratory sheets, animal supervision, score sheets, amendments, deviations, etc.)
- **GLP schooling** of all people involved in the study
- **Personnel**: Facility director, study director, archive person, internal and external quality assessor
- **Personal folders** up-to date

How: Implementation

- Adherence to strict protocol (“Verordnung vom Bundesrat über die gute Laborpraxis” 813.112.1)
- Continuous up-dating of protocols/SOPs/ room lists / service /maintenance documentation, feed analysis
- Inspections by internal/ external quality assessors, Swissmedic
- Archiving of raw data, lab books, study plan, study reports (fire proof cupboards)
- Organigramm of GLP lab

- Site Visit by Swissmedic every three years

University of Zurich[UZH]

MSRU, CABMM

University of Bern | University of Zurich
Test Facility MSRU
Vetsuisse Faculty Zurich

GLP Organizational Chart
Version 24.03.2014

Test Facility Management
Brigitte von Rechenberg
Katja Nuss

Archivist
Flurina Clement
Aymone Lenisa

MSRU IT Manager
Karina Klein
IT Support specialist
Rainer Egle***

Quality Assurance
Sabine Koch
Iris Wüthrich****

Study Directors
Katja Nuss, Karina Klein,
Stefan Stübinger, Peter Kronen,
Agnieska Karol, Salim Darwiche

Study Personnel

BZL***
Margarethe Arras
Flora Nicholls
Nikola Cesarovic
Paulin Jirkof
Thea Fleischmann

Anesthetists
Peter Kronen
Isabelle Iff

Surgery Technicians*
Renè Kissling
Michael Bless
Jasmine Nauer
Urs Möri

Sacrifice Personnel*
Paul Müller
Peter Bänziger

Study Scientists
Flurina Clement
Ramon Bucher
Valentin Reichle
Maren Stempel
Julia Freudenhammer

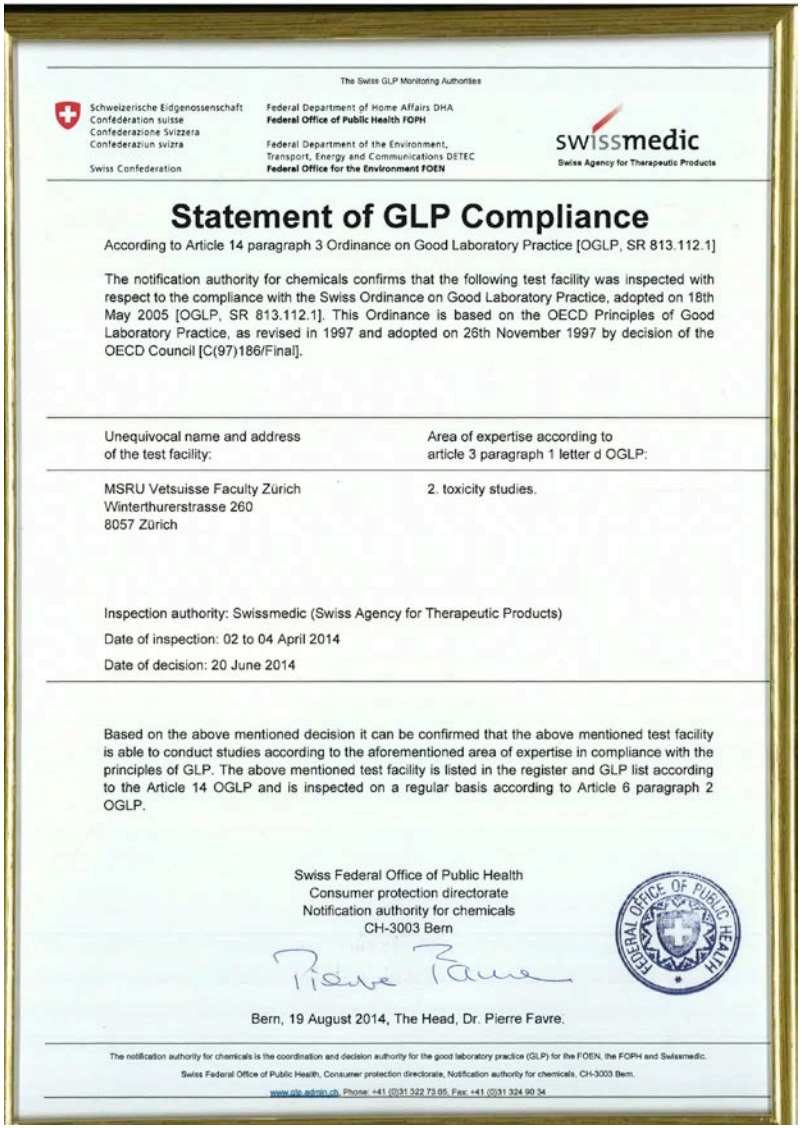
Animal Caretaker
Silvana Ressegatti

Radiology/CT Personnel*
Patrick Kircher
Claudia Di Giovanni
Henning Richter

Sheep housing**
Markus Knüsel
Gottfried Knüsel

Histology
Katharina Kämpf
Sabina Wunderlin
Katalin Zlinszky
Ladina Ettinger
Aymone Lenisa

* Tierspital
** Staffelegg AG, Küttigen
*** Egle Consulting, Russikon
**** QCW GmbH, Füllinsdorf
*****Unispital Zürich



The Swiss GLP Monitoring Authorities

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs DHA
Federal Office of Public Health FOPH

Federal Department of the Environment, Transport, Energy and Communications DETEC
Federal Office for the Environment FOEN

swissmedic
Swiss Agency for Therapeutic Products

Statement of GLP Compliance

According to Article 14 paragraph 3 Ordinance on Good Laboratory Practice [OGLP, SR 813.112.1]

The notification authority for chemicals confirms that the following test facility was inspected with respect to the compliance with the Swiss Ordinance on Good Laboratory Practice, adopted on 18th May 2005 [OGLP, SR 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted on 26th November 1997 by decision of the OECD Council [C(97)186/Final].

Unequivocal name and address of the test facility:	Area of expertise according to article 3 paragraph 1 letter d OGLP:
MSRU Vetsuisse Faculty Zürich Winterthurerstrasse 260 8057 Zürich	2. toxicity studies.

Inspection authority: Swissmedic (Swiss Agency for Therapeutic Products)

Date of inspection: 02 to 04 April 2014

Date of decision: 20 June 2014

Based on the above mentioned decision it can be confirmed that the above mentioned test facility is able to conduct studies according to the aforementioned area of expertise in compliance with the principles of GLP. The above mentioned test facility is listed in the register and GLP list according to the Article 14 OGLP and is inspected on a regular basis according to Article 6 paragraph 2 OGLP.

Swiss Federal Office of Public Health
Consumer protection directorate
Notification authority for chemicals
CH-3003 Bern

FEDERAL OFFICE OF PUBLIC HEALTH

Bern, 19 August 2014, The Head, Dr. Pierre Favre.

The notification authority for chemicals is the coordination and decision authority for the good laboratory practice (GLP) for the FOEN, the FOPH and Swissmedic.
Swiss Federal Office of Public Health, Consumer protection directorate, Notification authority for chemicals, CH-3003 Bern.
www.gle.admin.ch, Phone: +41 (0)31 322 73 05, Fax: +41 (0)31 324 90 34

Where: University of Zürich

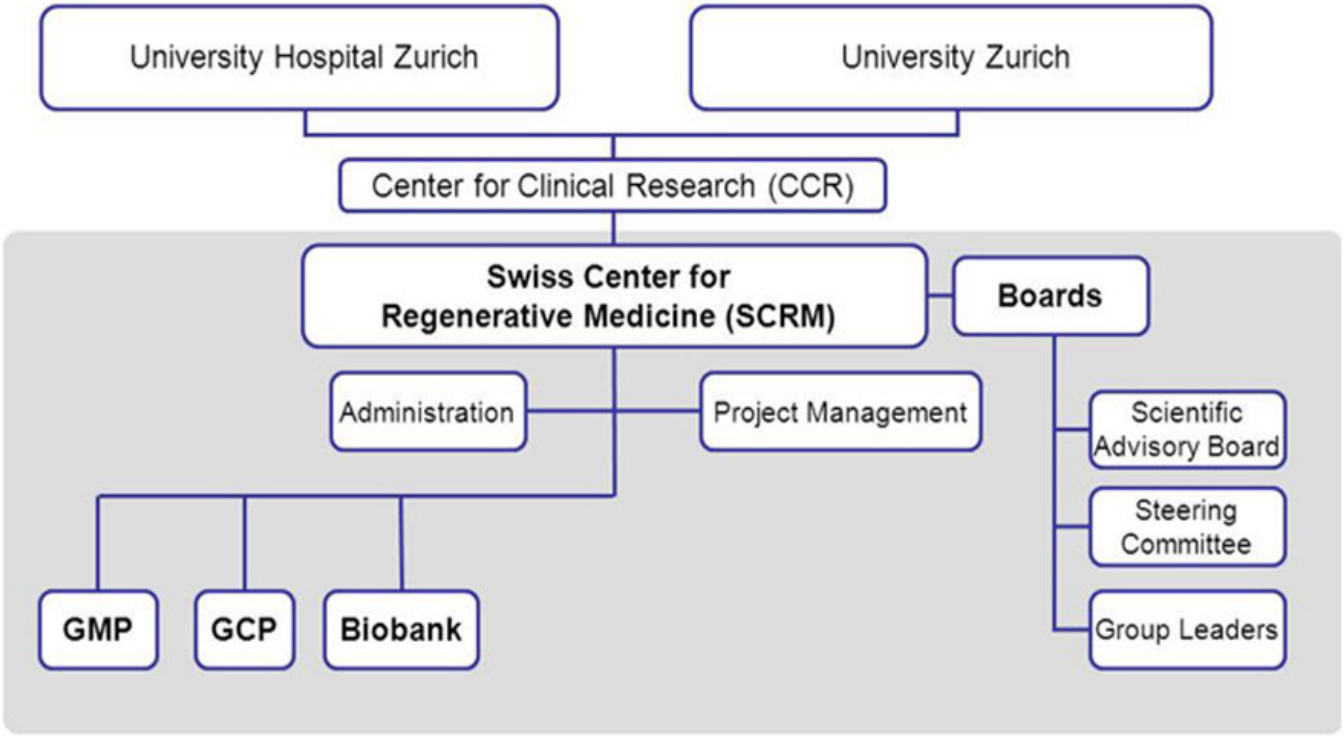
- Recognized the future
- Translational Medicine as Flaggship

- First Swiss Center for Regenerative Medicine (SCRM, *Prof. Simon Hoerstrup*)
- Competence Center for Applied Biotechnology and Molecular Medicine (CABMM)

- Provides GMP, GLP and GCP accreditation under one roof

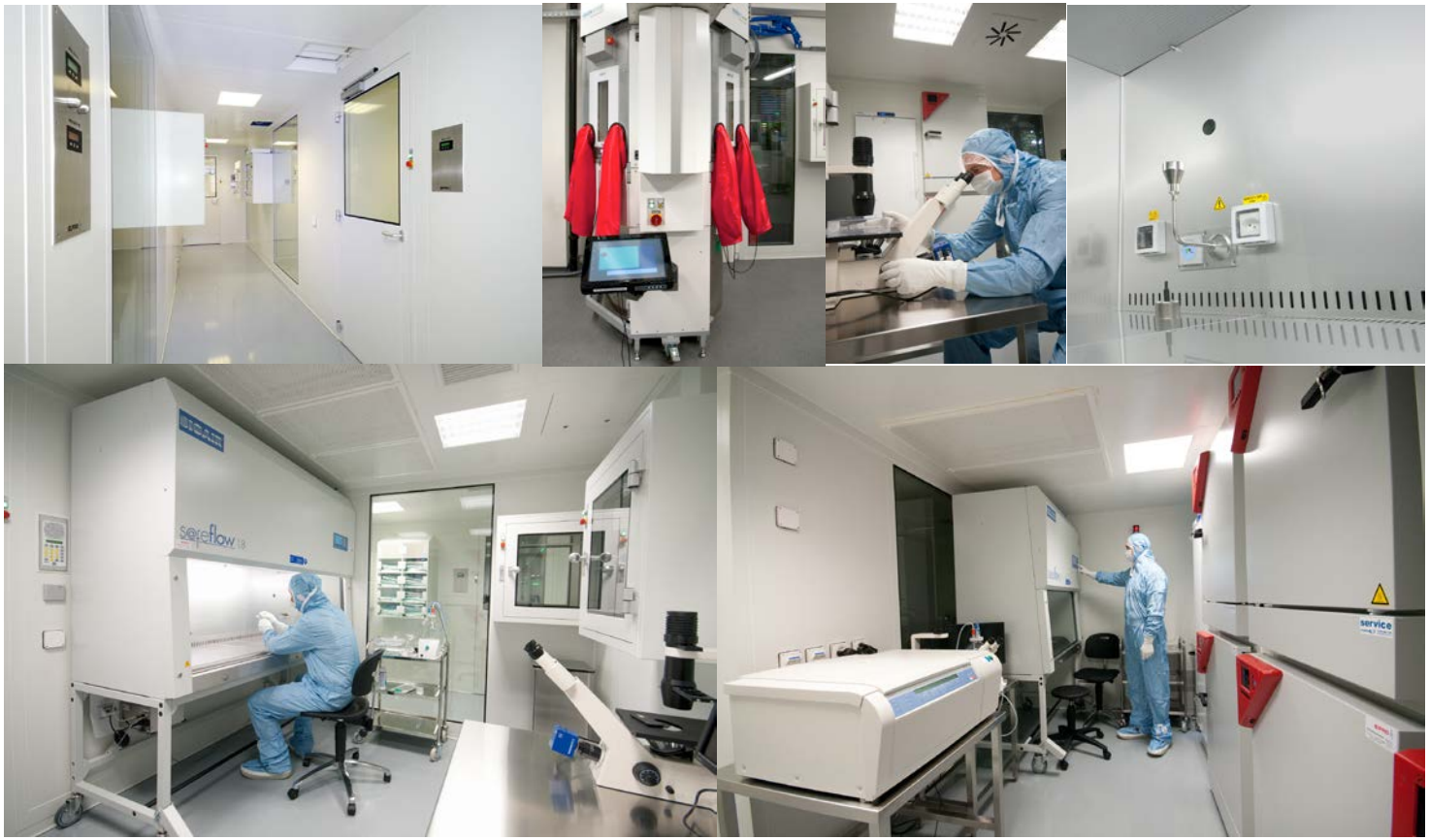
Where: University of Zürich

The *Swiss Center for Regenerative Medicine (SCRM)*



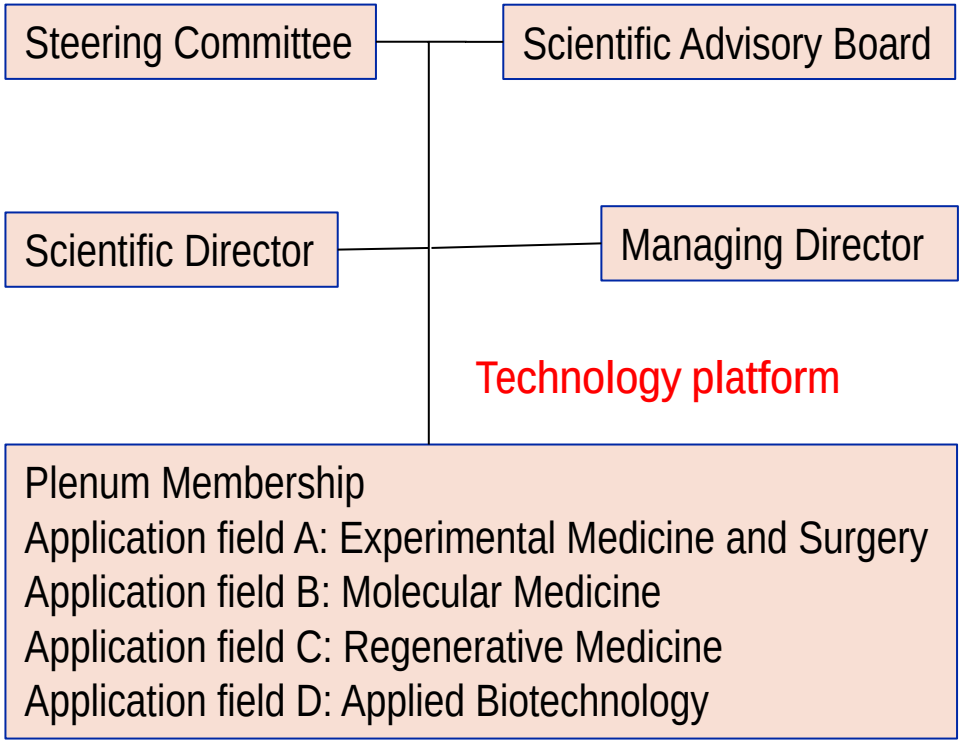
Where: University of Zürich

The *Swiss Center for Regenerative Medicine (SCRM)*



Where: University of Zürich

The *Center for Applied Biotechnology and Molecular Medicine (CABMM)*

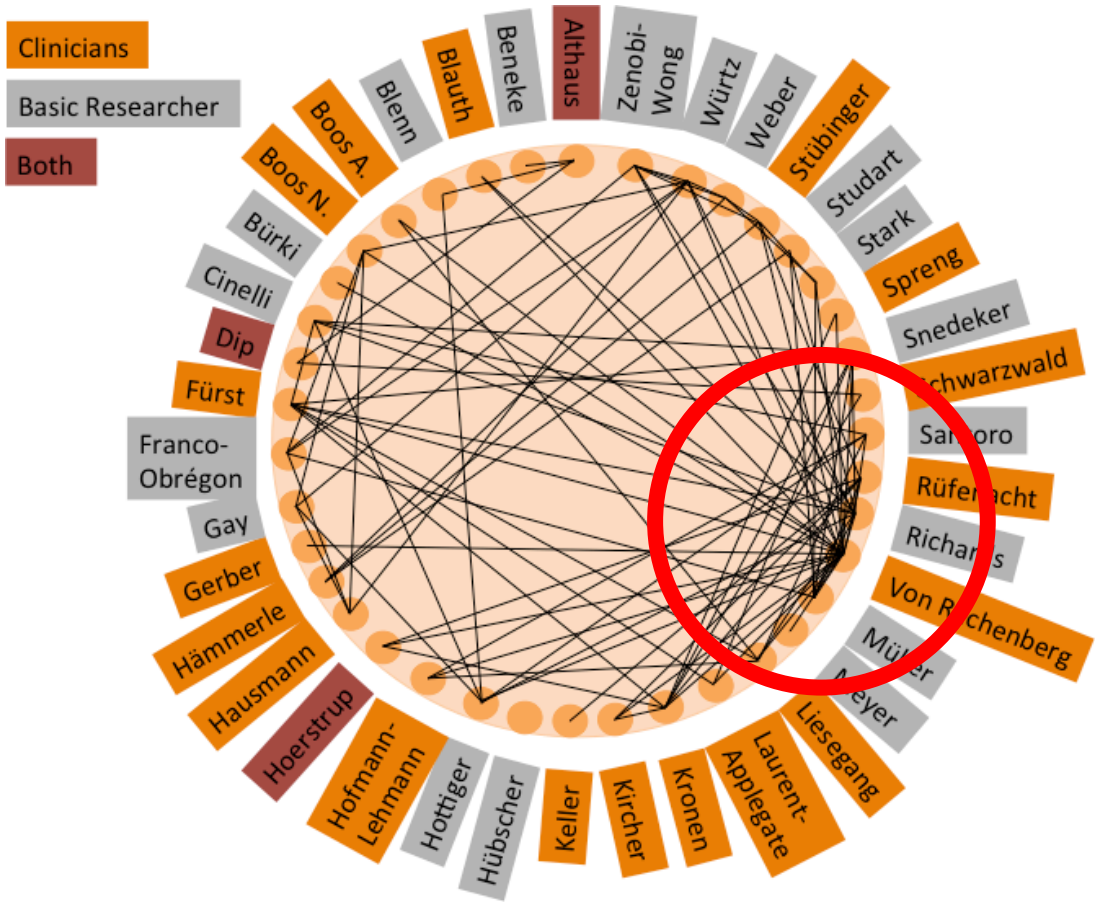


54 members
>150 PhD students

cabmm
center for applied biotechnology and molecular medicine

Where: University of Zurich

The *Center for Applied Biotechnology and Molecular Medicine (CABMM)*



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vetsuisse-faculty

Wyss Translational Center Zurich (WTZ)

ETH & UZH