



## Symposium Berlin 2012

*Infrastrukturen und Rahmenbedingungen für die medizinische Forschung*

### ***Strukturfragen der Organisation klinischer Forschung***

*Prof. Dr. med. PJ Meier-Abt,*

*Universität und Universitätsspital Basel*

*Schweizerische Akademie der Medizinischen Wissenschaften*

*Swiss Clinical Trial Organisation*





nature

the human genome

Vol 409  
813-958  
2001

16 February 2001  
**Science**

Vol 291 No 5507  
Pages 1145-1434 59

THE HUMAN GENOME

Vol 291  
1145-1434  
2001

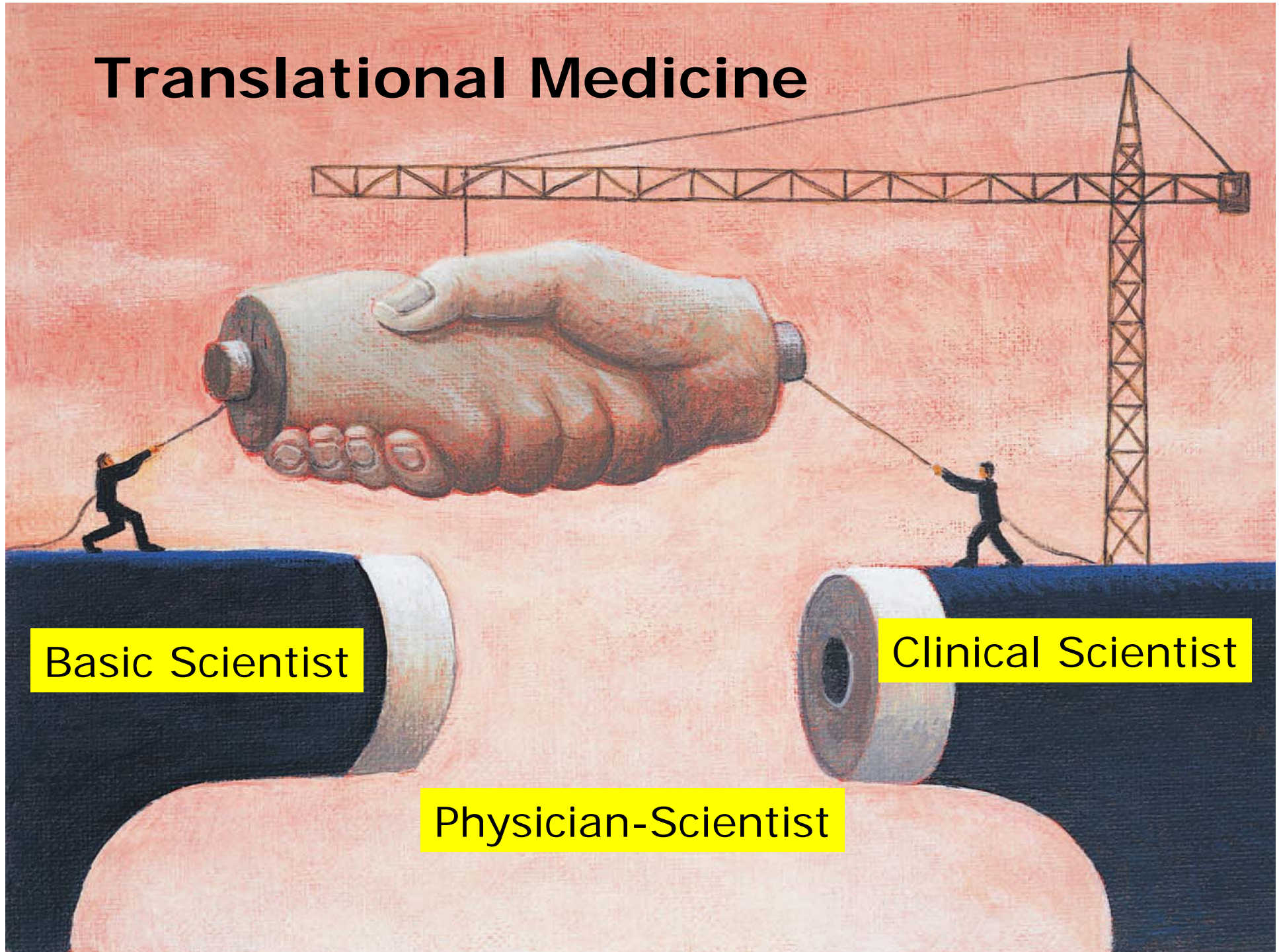
AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

«We simply cannot deliver the enormous promise of the genetics revolution without close attention to careers in clinical research».

D.G. Nathan & H.E. Varmus,  
National Institutes of Health USA,  
Nature Medicine 6, 1201-1204, 2000

Nature Medicine 6  
1201-1204, 2000

# Translational Medicine



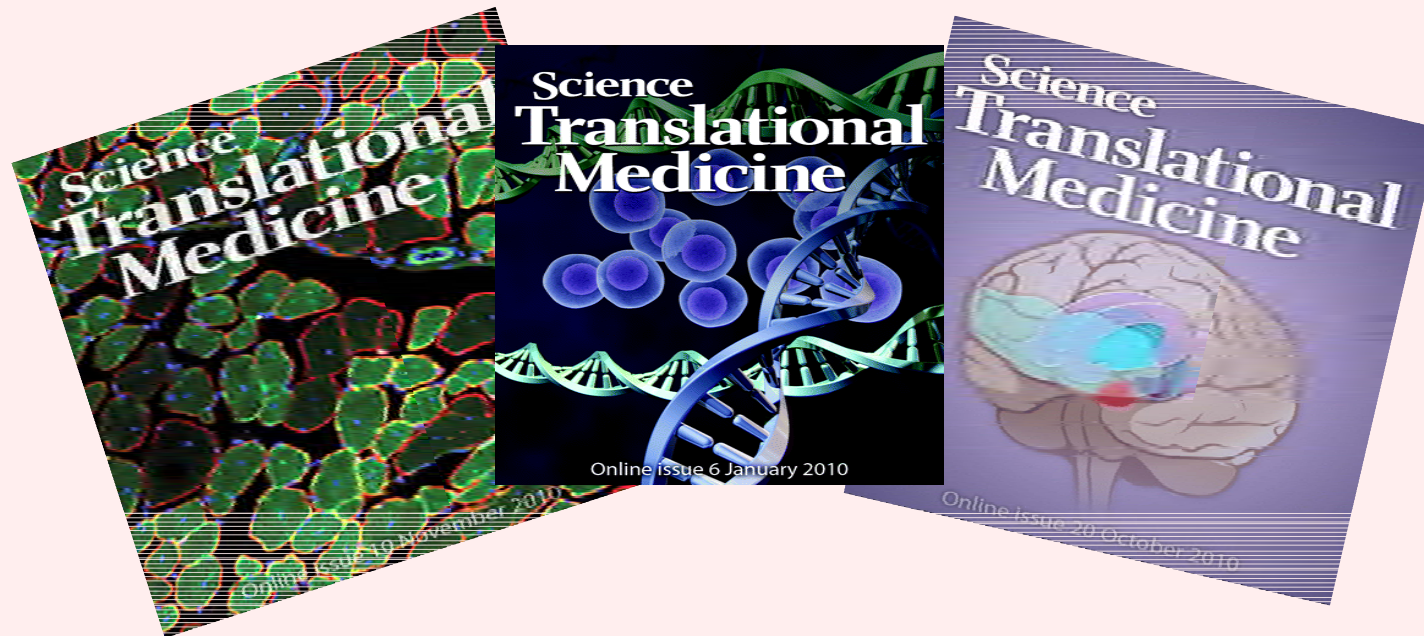
Basic Scientist

Clinical Scientist

Physician-Scientist

# „Changing Models of Biomedical Research“

*Crowley and Gisella, Sci. Transl. Med. 2; 1-3, 2010*



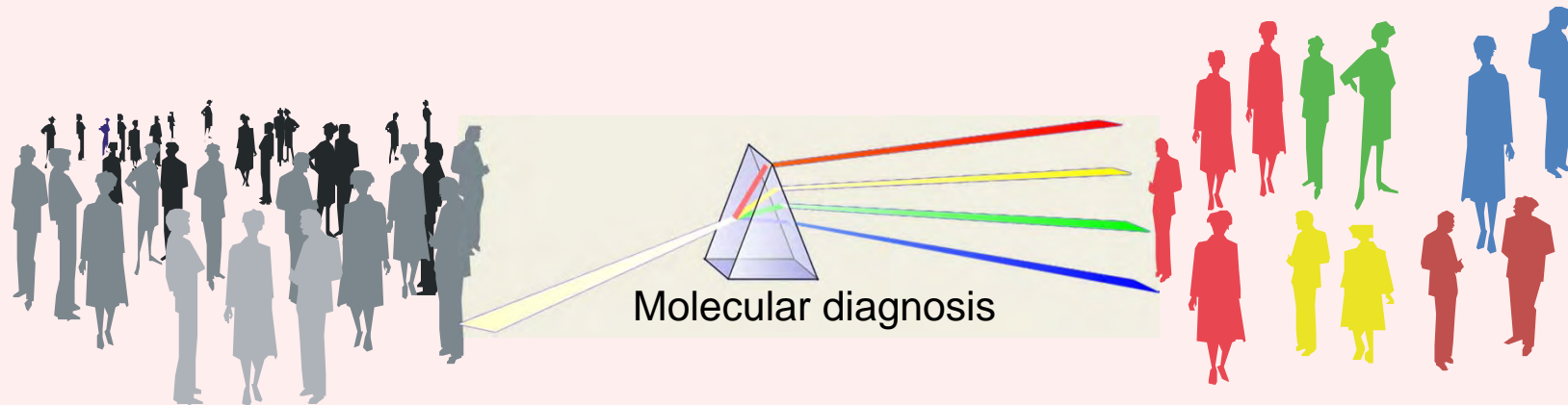
„Our country (USA) needs more and better translational research.....This is not to say, as many fear, that we should reduce our focus on basic research. On the contrary,.....But efforts to translate knowledge gained from experimental organisms will simply waste resources if scientists have not achieved a rich understanding of the fundamental properties of human physiology and pathophysiology....“

*Elis A. Zerhouni, AAAS, Sci. Transl. Med. 1; 1-2, 2009*

# The advent of Personalised Healthcare

## *Today and tomorrow*

**Personalised Healthcare:** use of new molecular insights and molecular diagnostic tests to better tailor medicines and better manage a patient's disease

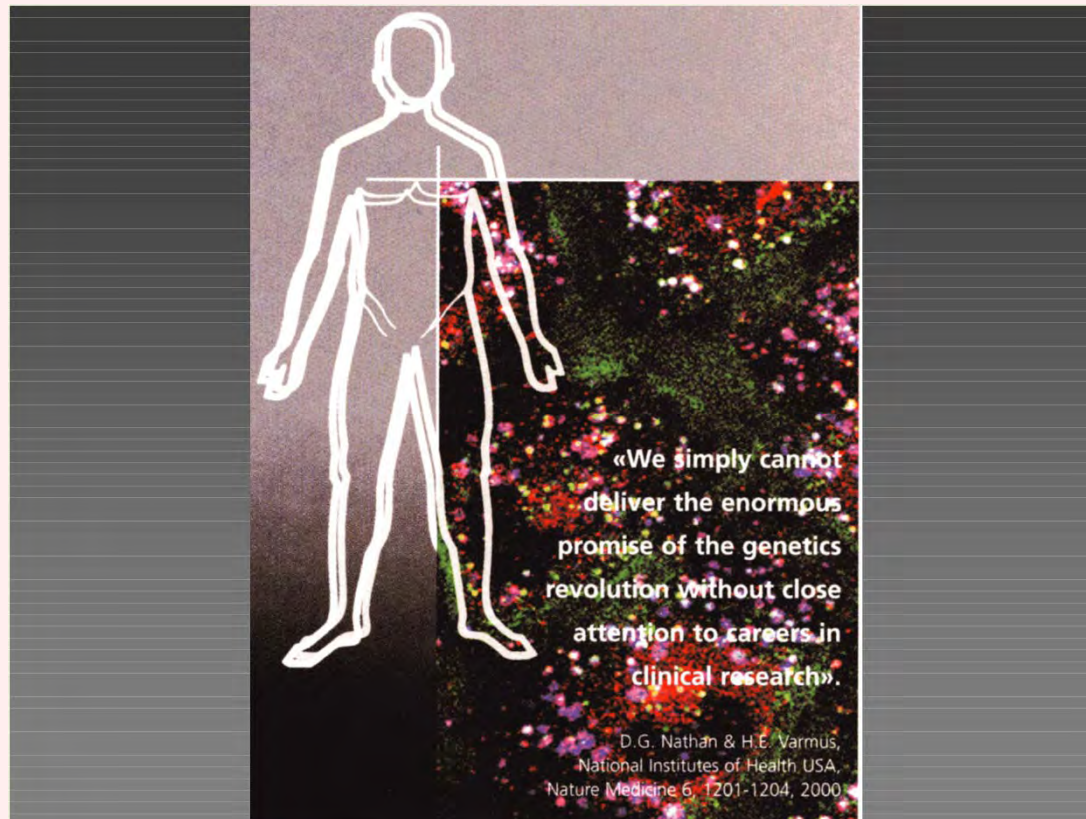


**Still today**, almost all patients are treated in a few similar ways

- Only 20-60 % of patients receive effective treatment\*
- Nearly 200.000 people die from adverse drug reactions\*

**Increasingly**, treatment will be tailored to **selected patient groups** defined by **molecular biomarkers**

# Effective Translational and Personalized Medicine needs good Clinical Scientists and a Professional Clinical Trial Organisation





# Was ist Klinische Forschung ?

## UK Medical Research Council:

- „research based primarily on patients or ex-patients, and designed to answer questions about disease“ (*aetiology, diagnosis, prevention, treatment*)

## USA:

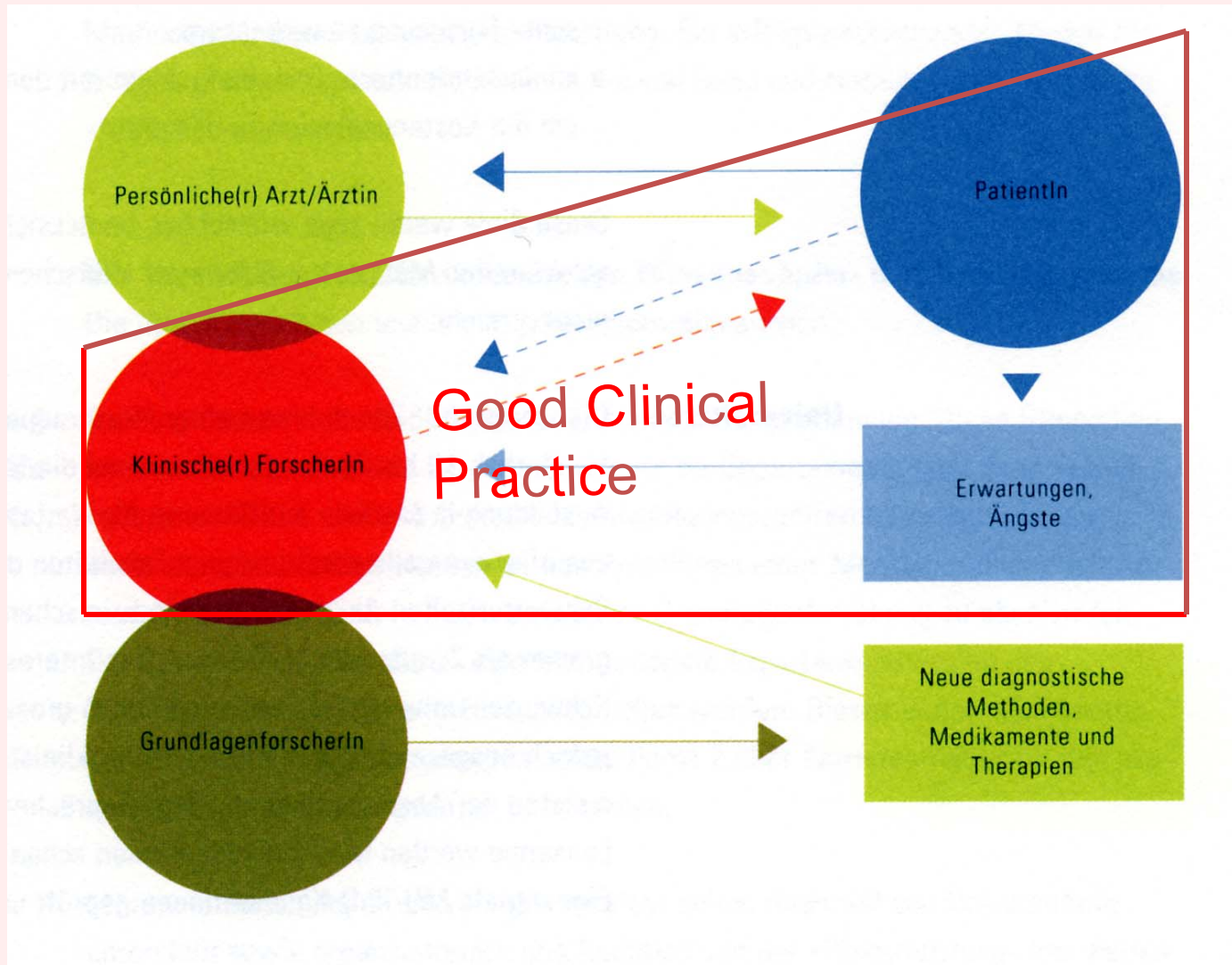
- „research conducted with human subjects or on material of human origin, for which an investigator directly interacts with human subjects“ (*patient-oriented research, epidemiological studies, outcome research, health services research*)





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SAMW Schweizerische  
Akademie der Medizinischen  
Wissenschaften

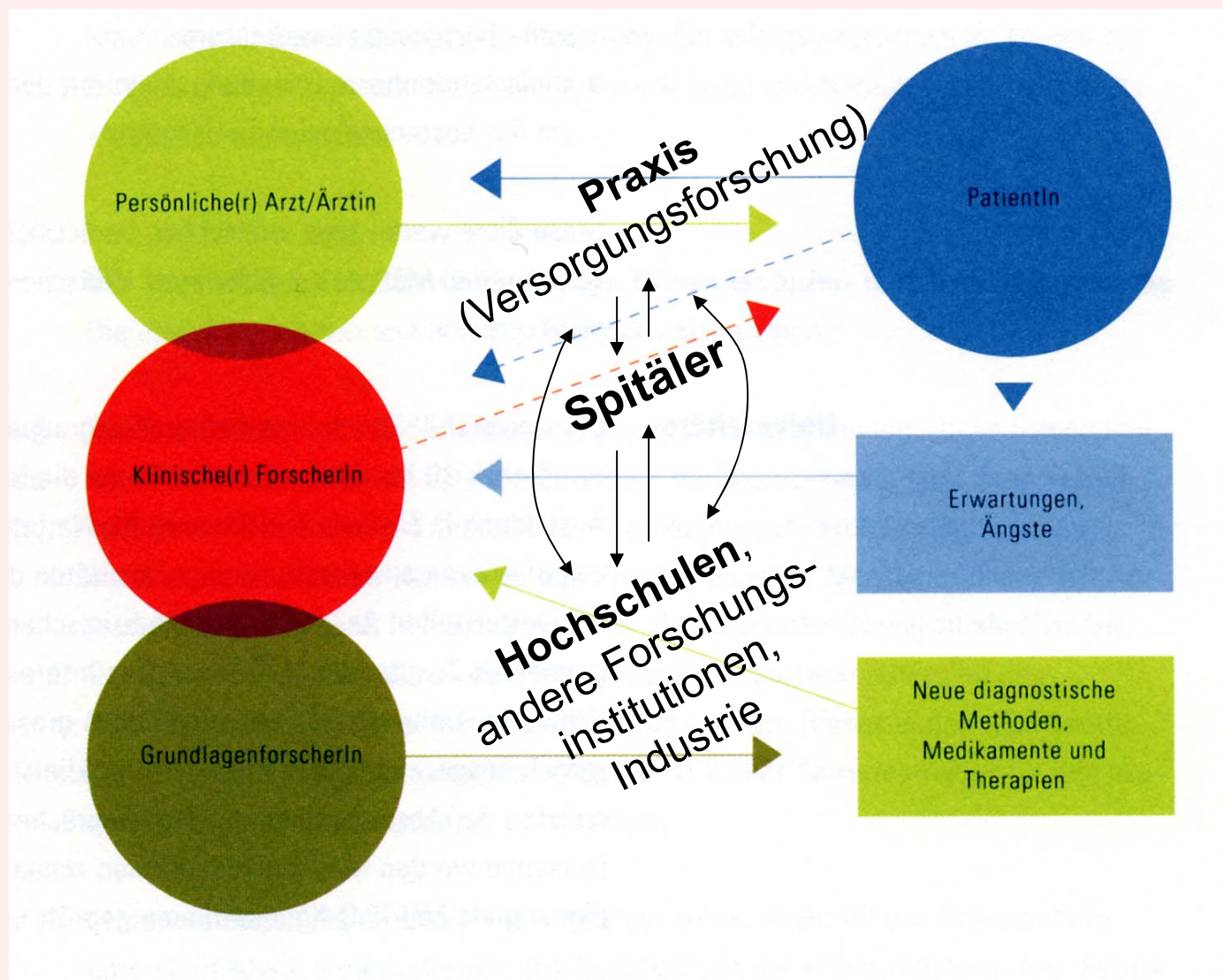


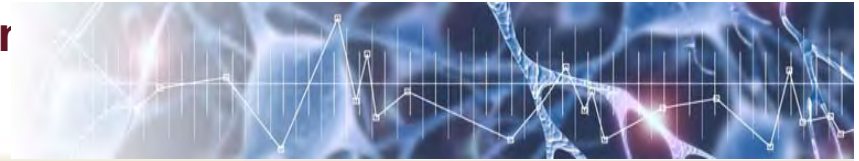




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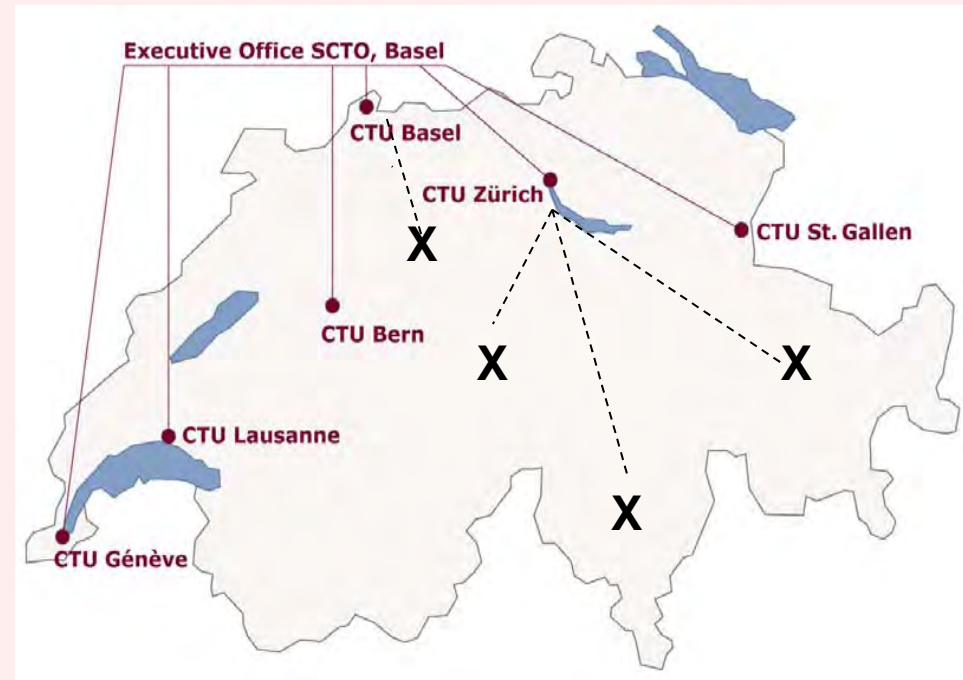
SAMW Schweizerische Akademie der Medizinischen Wissenschaften





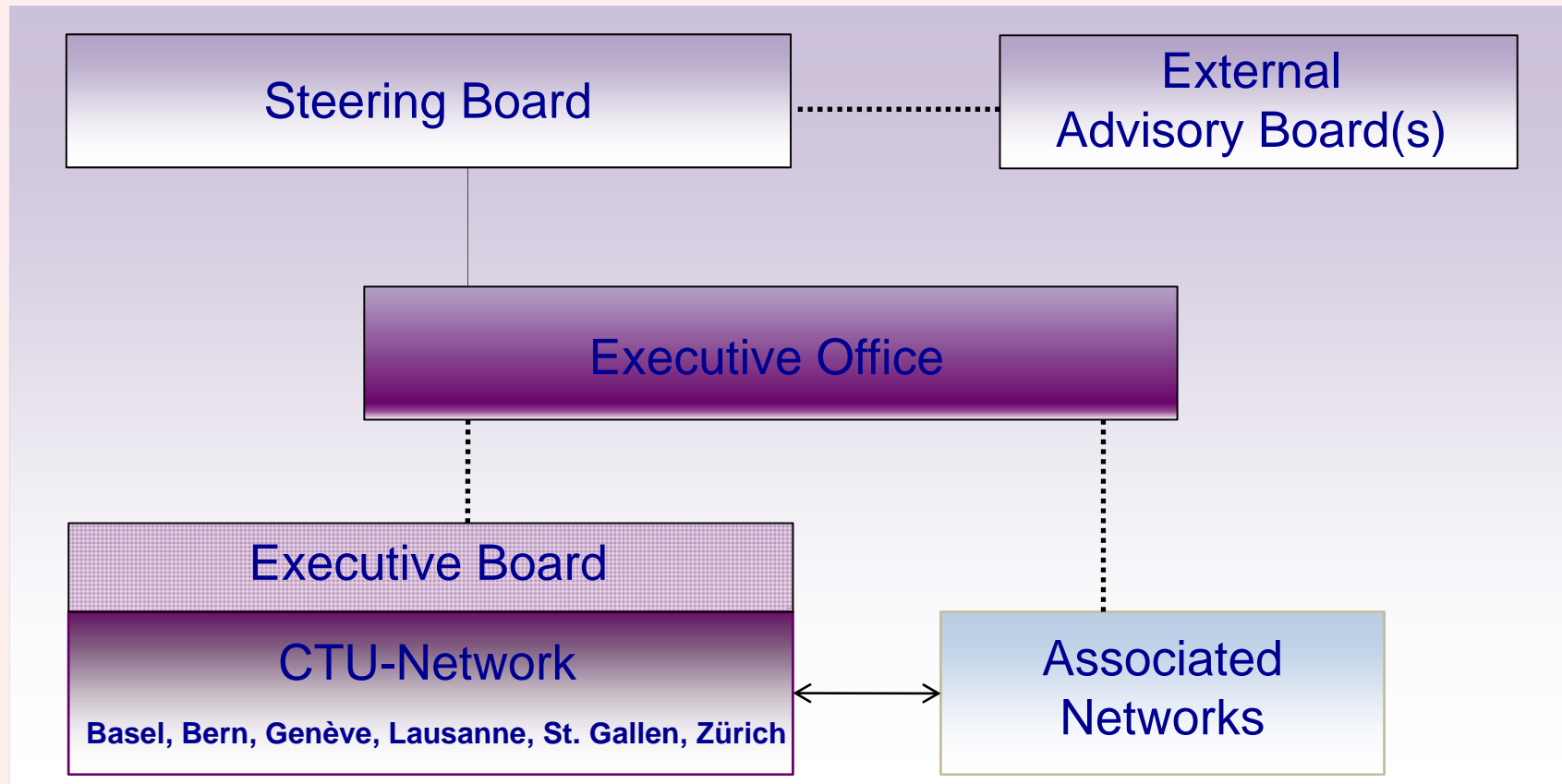
## Mission

- To improve quality and scientific profile of clinical research
- To support nationally efficient and well linked infrastructures and promote involvement of Swiss clinical research in international networks
- Building bridges between academia, industry and the authorities, as well as trade organisations and professional associations
- To advocate for favourable legal, political, and financial conditions in the field of clinical research

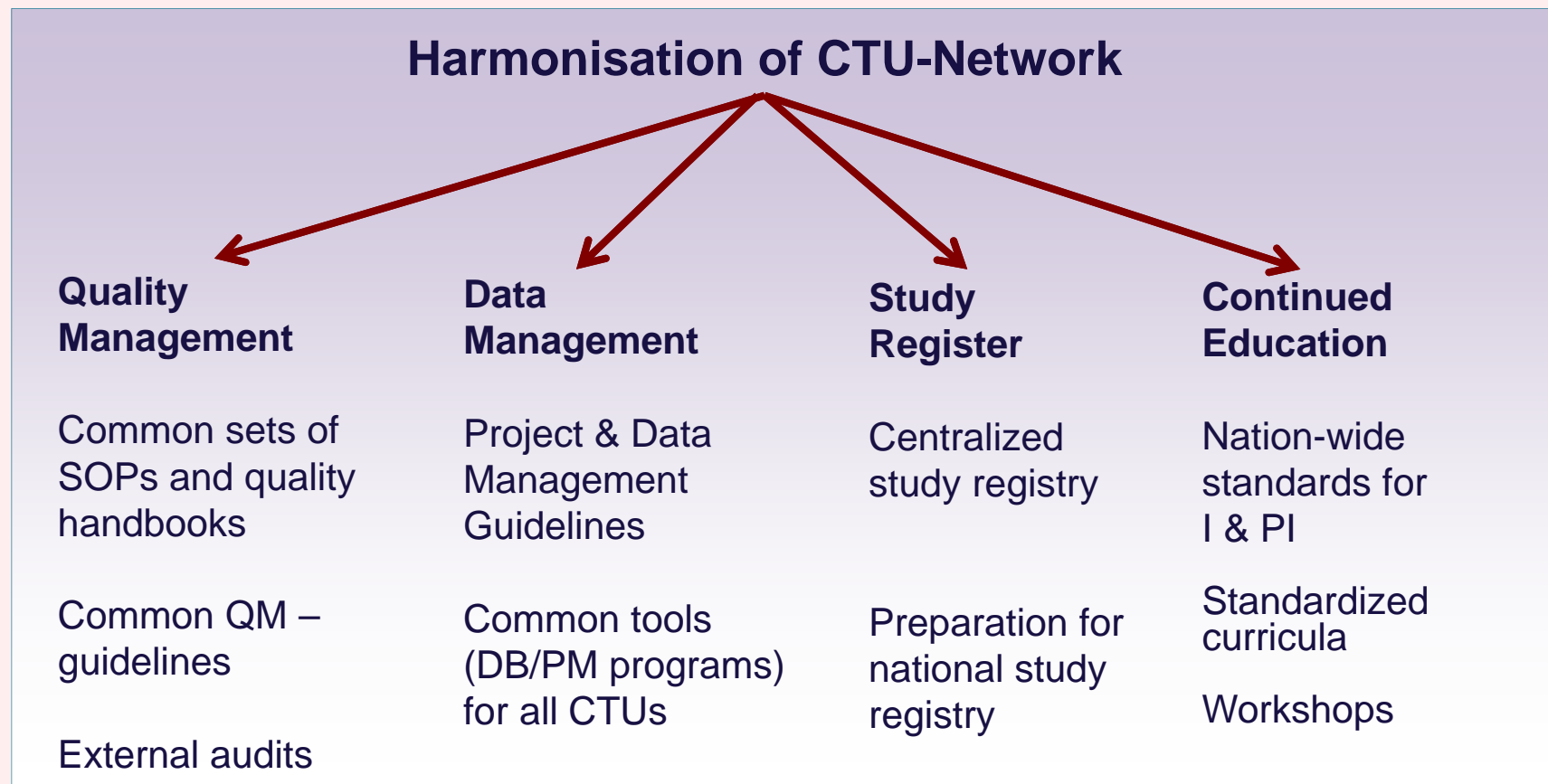


*(CTU = Clinical Trial Unit;  
X = with CTUs associated  
smaller study centers)*

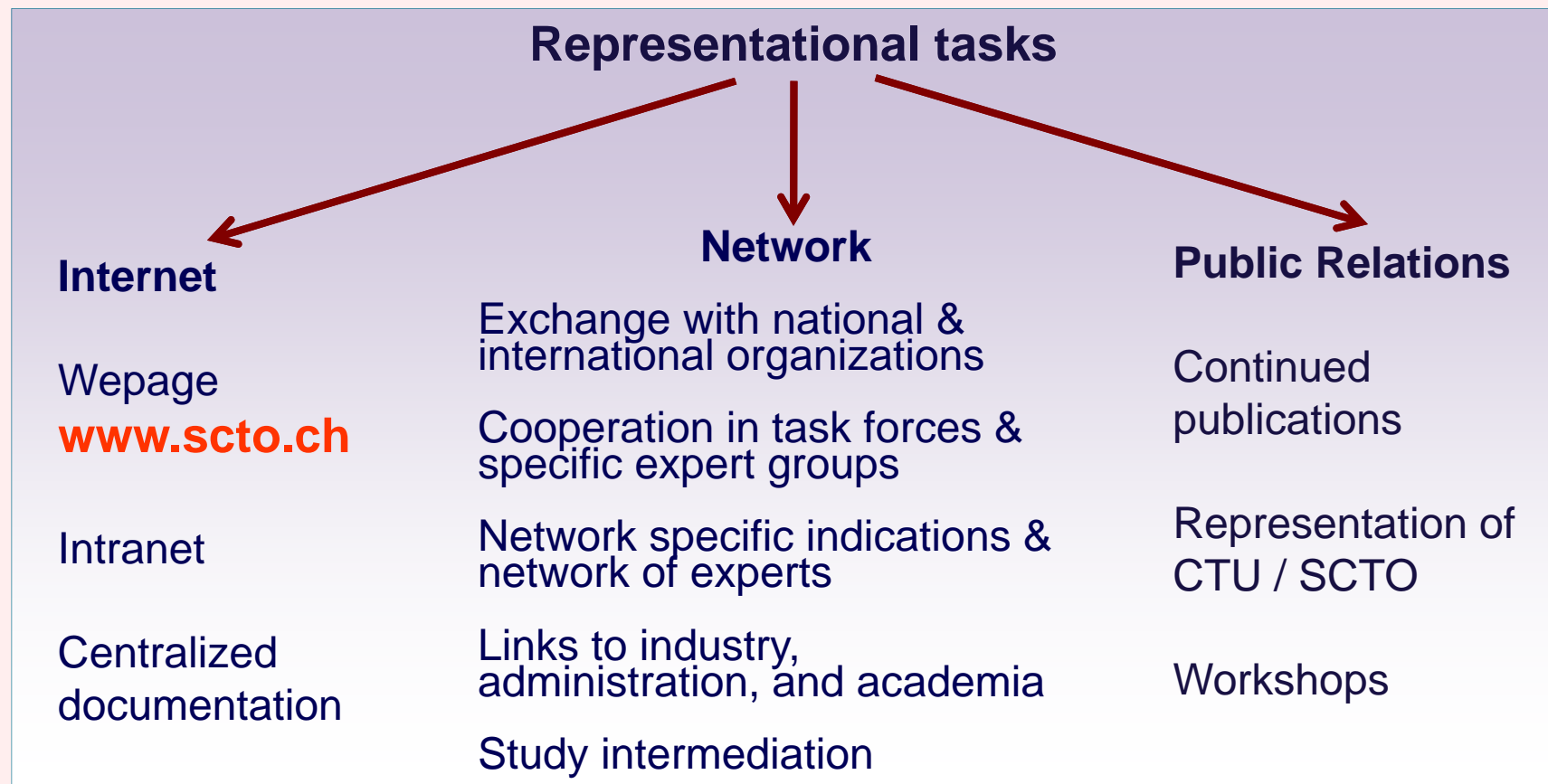
## Swiss Clinical Trial Organisation (SCTO) *Structure and Organization*



## Swiss Clinical Trial Organisation (SCTO) *Tasks and Activities*



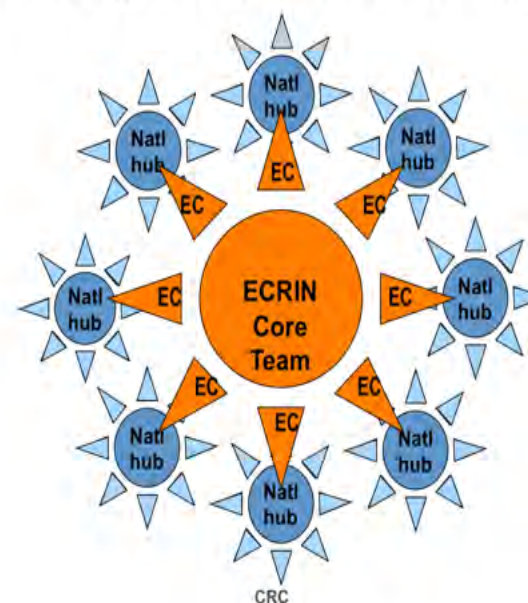
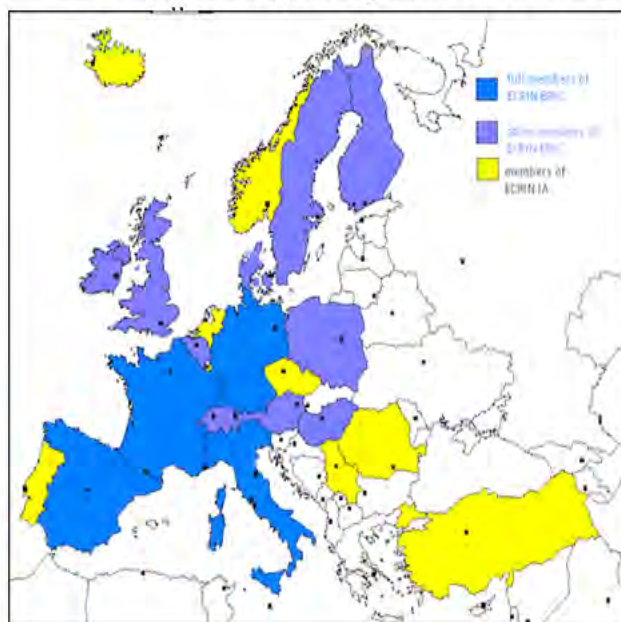
## Swiss Clinical Trial Organisation (SCTO)



## Partners and network structure

### 23 European countries in Consortium

- managed by ECRIN Core Team
- connected through the European Correspondents (EC, EuCo)
- with the participating national hubs (SCTO is national information hub, cooperation platform with CRC/CTU network)
- other participating institutions: research organisation, patient organisations or networks of



# „ WE MUST KEEP FIGHTING AGAINST RARE DISEASES“ *Orphanet Europe*



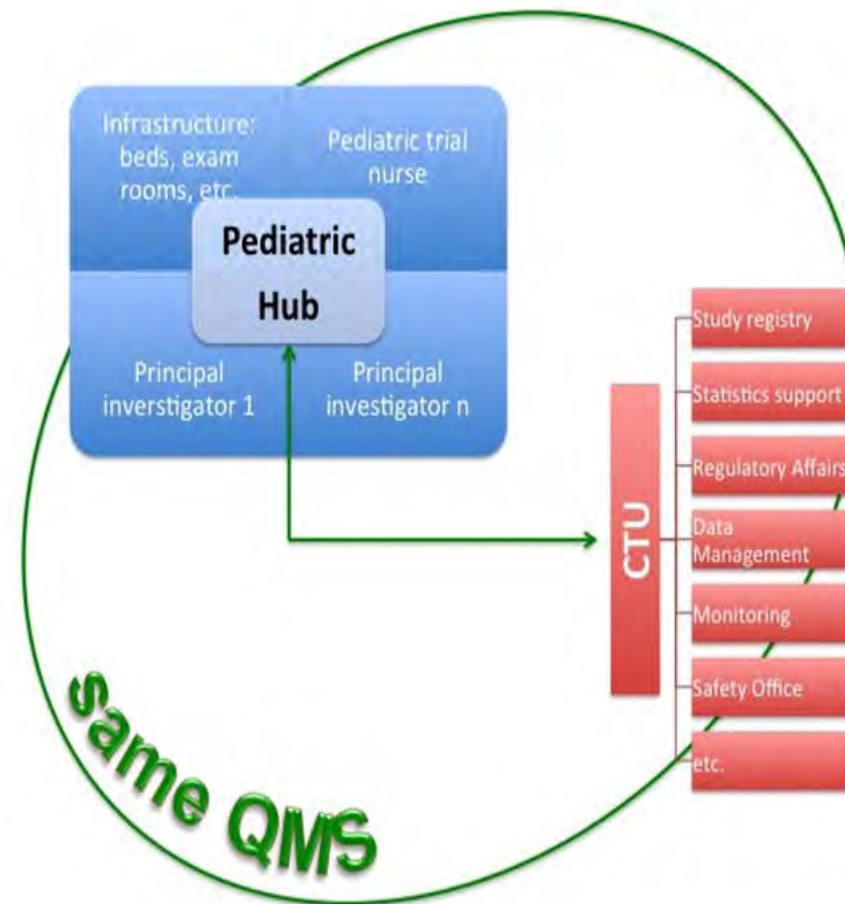
It is estimated that between 6 000 and 8 000 distinct rare diseases exist today, affecting between 6% to 8% of the population in total. In other words, 27-36 million people in the EU are affected or will be affected during their lifetime by rare diseases.

*“One of the problems with rare diseases is that no country alone can provide expertise on all of them. Knowledge has to be exchanged across Europe. It is important to have all the information in one place for both health professionals and patients.”*  
Ségolène Aymé, former Orphanet project leader



# Swiss PedNet coordinated by SCTO

## Local level







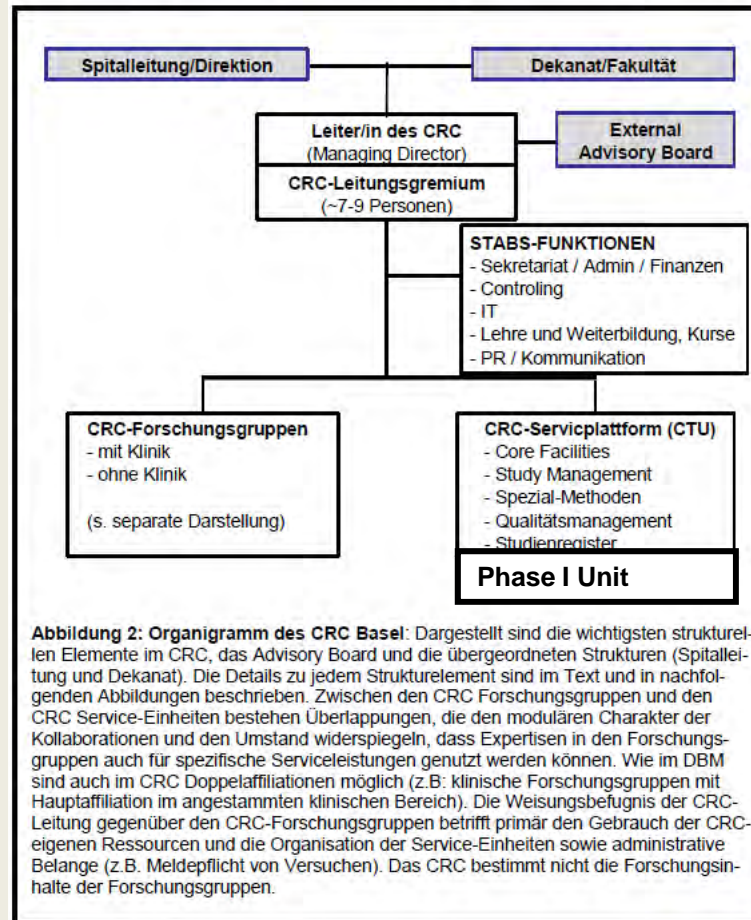
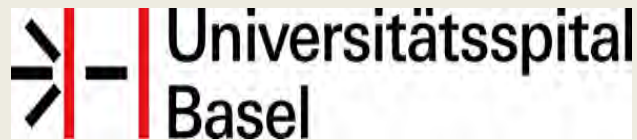
### Ausbau der CTUs in Departemente für Klinische Forschung (DKFs)\* an den Schweizer Universitätsspitälern



- Alternative Namen: Clinical Research Center (CRC) oder Clinical Trial Center (CTC)



## Organigramm des Clinical Research Center (CRC) bzw. Dept. Klinische Forschung (DKF) am Universitätsspital Basel

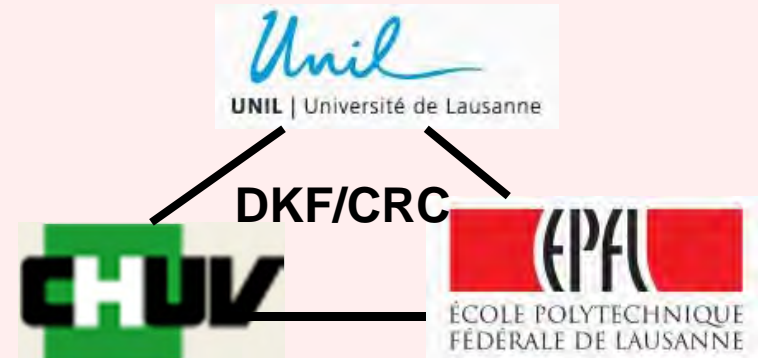
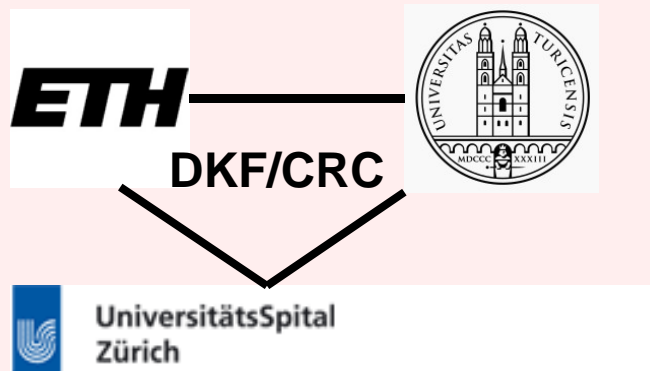




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### *DKFs bzw. CRCs als Plattformen für Netzwerke zur Förderung von Translationsforschung und Medizinischen Innovationen*

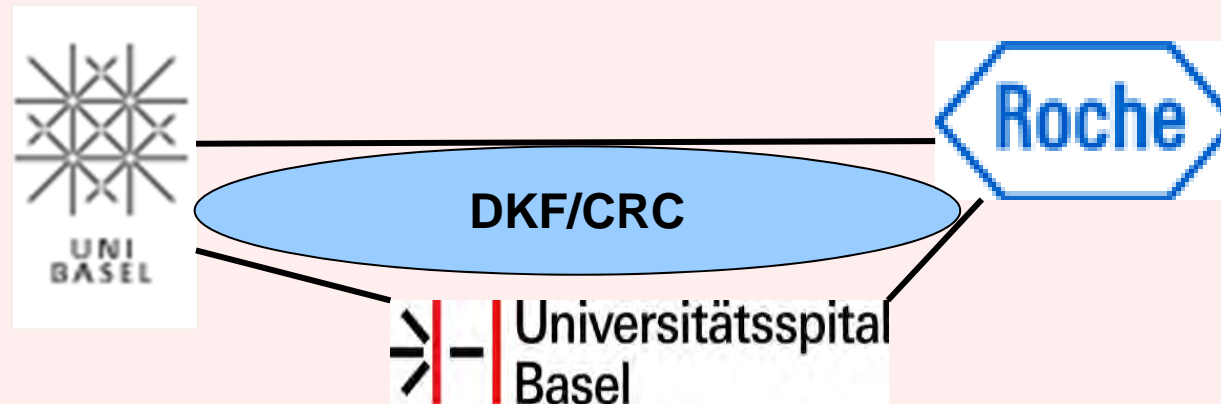




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*Academia-Industry Collaboration*

## Project: Basel Translational Medicine Hub

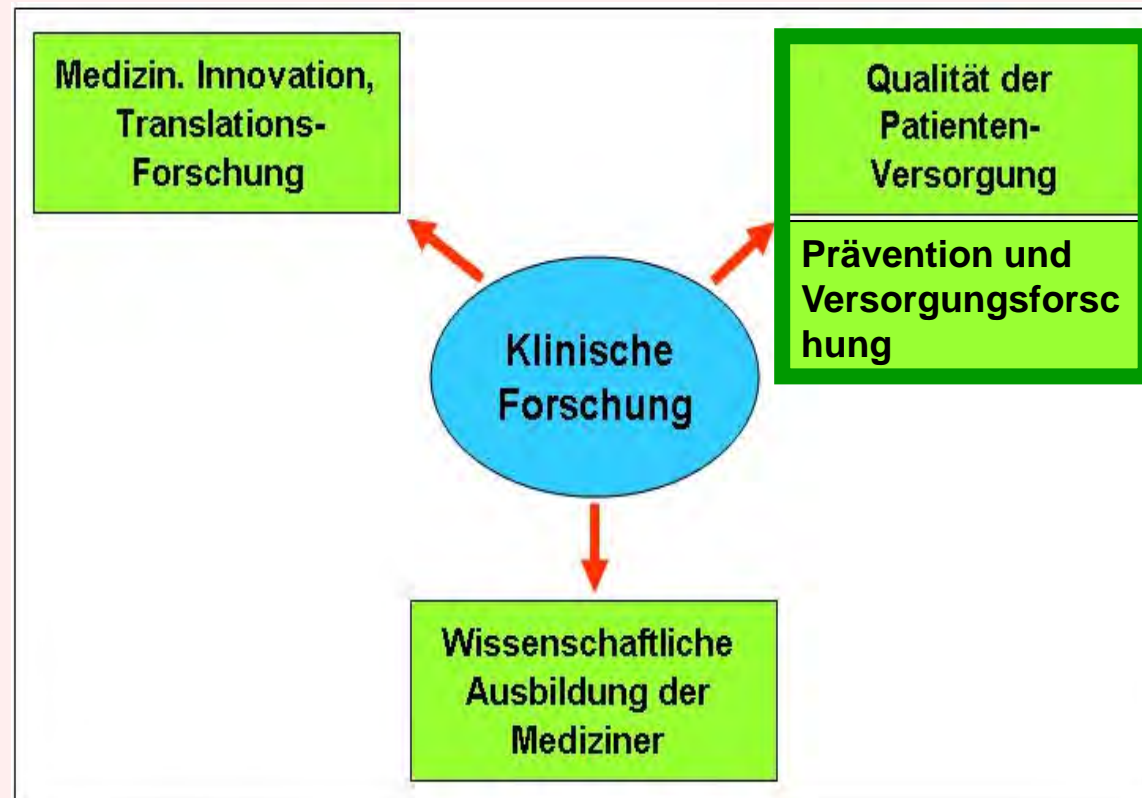


(2012: 40 gemeinsame Forschungsprojekte; Mehrzahl patientenorientiert)





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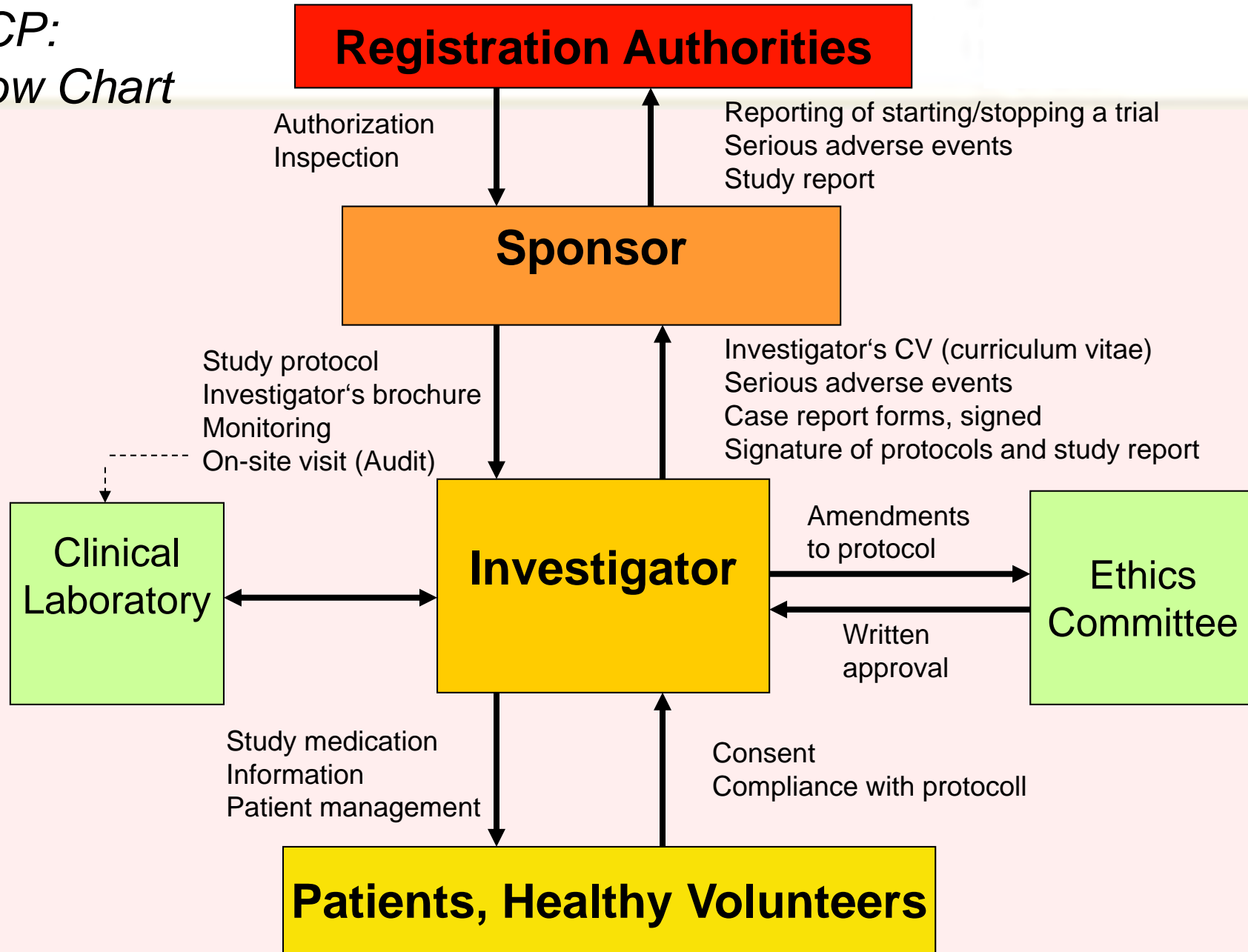


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*GCP:  
Flow Chart*





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DUW (Deutsche Universität für Weiter-  
bildung), Berlin

### Clinical Research & Regulatory Affairs

#### Abschluss

Hochschulzertifikat (15 ECTS)

#### Studienart

Fernstudium mit Präsenzen

#### Studiendauer

4 Monate (Regelstudienzeit)

#### Studienbeginn

individueller Einstieg jederzeit möglich

#### DUW-Fernstudium

Praxisnahes Curriculum

Flexibles Studienmodell

Modernes Lernen im Online-Campus

Individuelle Betreuung

### University of Liverpool

### Master of Science in Clinical Research



#### Modules

- Introduction to Clinical Research
- Ethical, Legal and Regulatory Considerations in Clinical Investigations
- Design and Conduct of the Clinical Protocol
- Good Clinical Practice in Managing and Monitoring of Clinical Trials
- Biostatistics
- Information and Data Management
- Product Development in the Pharmaceutical, Biotech and Medical Device Industries
- Health Economics and Financial Management in Clinical Research Administration

The programme takes on average 30 months to complete.



# The Translational Bridge from Basic To Clinical Research and Medicine

A conceptual painting with a textured, reddish-pink background. A large, realistic hand is shown from the palm side, holding a horizontal bridge structure. The bridge is supported by two large, dark blue cylindrical pillars. Two small figures in black are standing on top of these pillars, pulling ropes that connect to the bridge. A tall, lattice-structured crane stands on the right side of the scene. The overall scene is a metaphor for the translational bridge between basic and clinical research.

**Dept. Clinical Research**

**Basic Scientist  
(PhD)**

**Clinical Scientist  
(MD; Dr. sci. med.)**

**Physician-Scientist  
(MD-PhD; PhD/Dr. sci. med.)**



# Organisatorische Eckpunkte einer effizienten Klinischen Forschung an den Universitätsspitälern

## 1) Anpassung der Strukturen von Universitätsspitälern

- autonome und separat finanzierte **Dept. für Klinische Forschung** mit professionellen Kompetenzen in allen Belangen der KF und guter interner (Fachkliniken) und externer (Grundlagenforschung, Versorgungsforschung, Industrie u.a.) **Vernetzung**.
- Forschungsfreundliche Führungsstrukturen („**Dual Leadership**“)
- Klar definierte **Karrieretracks** für Klinische ForscherInnen
- **Nachwuchsförderung** (MD-PhD; PhD-MDsci.med.)

## 2) Aus- und Weiterbildung:

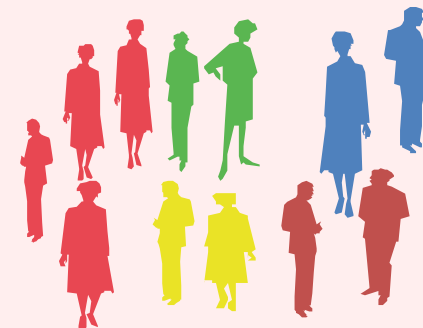
- Schaffung eines „klinischen Forschungstracks“ mit Kompetenzerwerb bereits im Studium (Medizin, Biologie, Ingenieurwissenschaften u.a.)



# Organisatorische Eckpunkte einer effizienten Klinischen Forschung an den Universitätsspitälern

### 3) Berücksichtigung vernachlässigter und neuer Trends der Medizin

- verstärkte Erforschung von „*rare diseases*“
- Einbezug der Prinzipien der „*Personalized Medicine*“



### 4) Bildung von Consortien zwischen Hochschul- und Industrieforschung

- zB „*Translational Medicine Hubs*“ mit gemischten Forschungsgruppen und gemeinsamen Aus- und Weiterbildungsprogrammen





## Organisatorische Eckpunkte einer effizienten Klinischen Forschung an den Universitätsspitalern

### 5) Kompetitive regulatorische und gesetzliche Rahmenbedingungen für die Förderung der klinischen Forschung und Innovation in der Schweiz

#### - Effizienzsteigerung der Ethikkommissionen

#### **CH-Humanforschungsgesetz (HFG) ab 2014:**

- bessere Kompetenzabgrenzung zwischen EK und Swissmedic;  
grössere Autonomie der EK
- Leitethikkommission für nationale Multizenterstudien
- kürzere Bearbeitungsfristen ( 30 Tage);
- „fast-track“ für qualitativ hochstehende Studien (v.a. Industrie-gesponserte  
internationale Multizenterstudien)
- **ABER:** Notwendigkeit der Entlastung der EK von mangelhaften  
Projekteingaben (Unterstützung durch **CTUs** und **DKFs**)



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