

# The role of patient organisations

Efficiency Strategies for Clinical Studies; April 28-30, 2015

PRORARIS



Alliance Maladies Rares – Suisse  
Allianz Seltener Krankheiten – Schweiz  
Alleanza Malattie Rare – Svizzera

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Jan. 2014**
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Switzerland?**
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# Some personal information

- Born with a rare disease
  - Characterized as a chronic condition
  - Irregular acute episodes
  - Health problems in childhood
  - „New“ health problems by getting older
- 
- Three decades of very few bone-related problems
- 
- Trained as an MD with an MPH



# Patient and consumer organisations in Switzerland

- Umbrella organisations of affected people
- Disease related patient organisations and support groups
- Supporting- and counselling organisations
- Ombuds centres for patients

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Association Enfance  
& Maladies Orphelines

**AIRG**  
Suisse

Association pour l'Information  
et la Recherche sur les maladies  
rénales Génétiques



Verein Schweiz



**ARFEC**



**BLACKSWAN®  
FOUNDATION**

SWISS FOUNDATION FOR RESEARCH ON ORPHAN DISEASES  
SCHWEIZERISCHE STIFTUNG FÜR DIE FORSCHUNG SELTENER KRANKHEITEN  
FONDATION SUISSE POUR LA RECHERCHE SUR LES MALADIES ORPHELINES  
FONDAZIONE SVIZZERA PER LA RICERCA SULLE MALATTIE ORFANE

Association **STB** Suisse



Sclérose tubéreuse de Bourneville  
Tuberöse Sklerose Komplex  
Sclerosi tuberosa complessa

Une rose bleue, un bleu entre eux,  
une face cachée ?



**aptcs**  
Association  
des personnes atteintes  
par le trépanement occipital



Schweizerische Gesellschaft für Cystische Fibrose  
Société Suisse pour la Mucoviscidose (CFCH)  
Società Svizzera per la Fibrosi Cistica (CFCH)



**CUORE MATTO**



ASSOCIATION ELA SUISSE  
WWW.ELA-ASSO.CH

*Fabrysuisse*

**lysosuisse**



FONDATION  
SANFILIPPO



**fraxas**

VEREIN FRAGILES-X SCHWEIZ  
ASSOCIATION X FRAGILE SUISSE  
ASSOCIAZIONE X FRAGILE SVIZZERA  
ASSOCIAZIUN X FRAGIL SVIZRA

**Morbus  
Wilson**



**Muskelgesellschaft**

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## NPSUISSE

Schweizerische Nemann-Pick Vereinigung  
Association Suisse Nemann-Pick  
Associazione Svizzera Nemann-Pick  
Associazione Svizzera Nemann-Pick  
Swiss Nemann-Pick Association



fsrmm

Fondation Suisse de Recherche sur les Maladies Musculaires

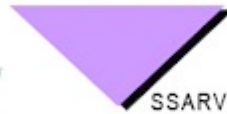


Schweizerische Alzheimervereinigung



SMCCV

Schweizerische Morbus Crohn /  
Colitis ulcerosa Vereinigung  
CH-5000 Aarau  
Telefon/Fax 041 670 04 87



SSARV - ASCS



svai

Schweizerische Vereinigung für Angeborene Immundefekte  
Association Suisse pour l'Immuno-Déficience Primitive  
Associazione Svizzera per l'Immunodeficienza Primitiva



Stiftung zur Förderung der  
Knochenmarktransplantation



tourette romandie  
Groupe d'échanges pour le syndrome Gilles de la Tourette



DRAVET  
Association Syndrome de Dravet Suisse  
Vereinigung Dravet Syndrom Schweiz  
Associazione Sindrome di Dravet Svizzera



VAINCRE LES  
MALADIES  
LYSOSOMALES



# Rare Disease Day, February 2015

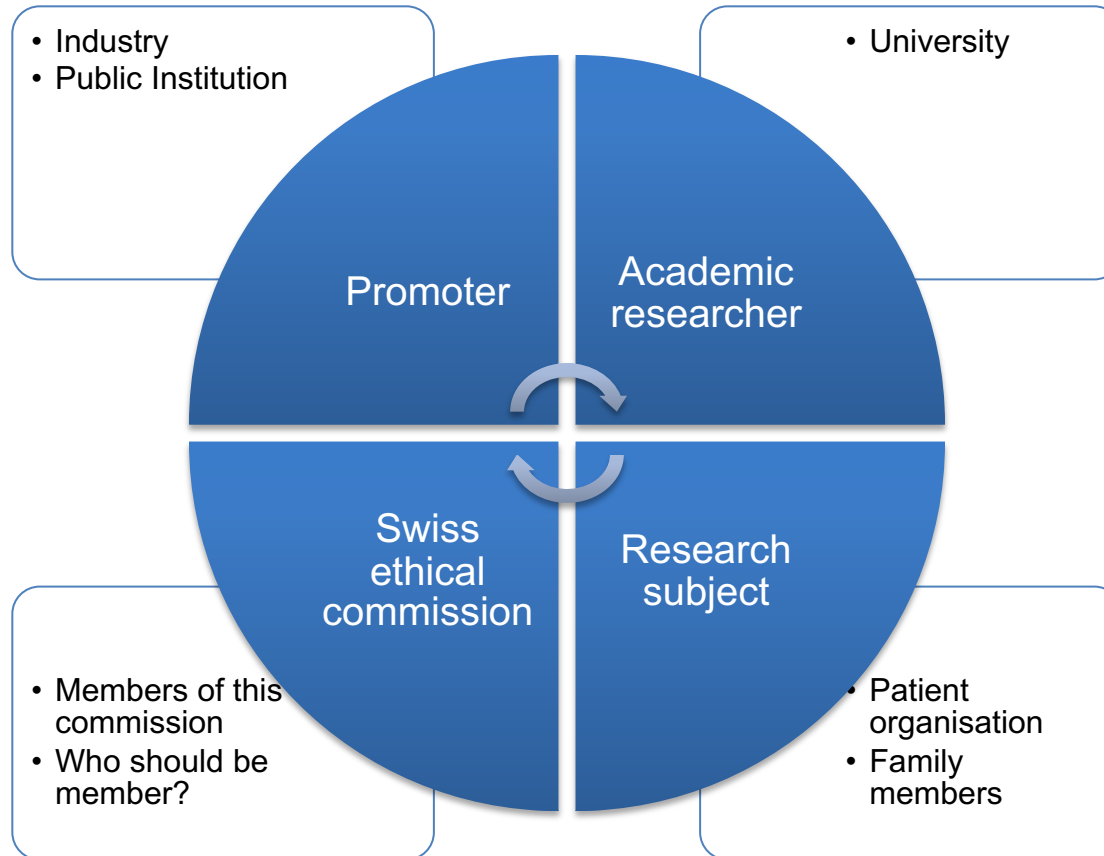


# Definitions (patients perspective)

- **Clinical trial:** a research project which aims to evaluate the effects of an intervention in connection with health
  - -> clinical research  $\neq$  clinical care
- **Role of the person in charge of care:** individual care of the patient by respecting his needs
- **Role of researcher:** to gain knowledge which can be disseminated. The interests of the patient are not always identical
- Céline Moret, representative of a patient organisation



# Partners in a clinical trial



# Benefits

No guarantee; the study is aimed at evaluating this topic

## To consider

- Study phase
- Study methodology (placebo)
- Existing data
- Discussion with other participants

Céline Moret, representative of a patient organisation

# Risks

## Some unexpected events can happen:

- in relation to the intervention
- in relation to the tests during the clinical study

## To take into consideration:



A clinical study has to evaluate the safety of a therapeutical intervention. Not all risks can be eliminated.

# Federal Act on Research involving Human Beings (Human Research Act, HRA)

## ■ **Art. 16 Informed consent**

- 1 Persons may only be involved in a research project if they have given their informed consent. Consent must be given in writing; the Federal Council may specify exemptions.
- 2 The persons concerned must receive comprehensible oral and written information on:
  - the nature, purpose and duration of, and procedure for, the research project;
  - the foreseeable risks and burdens;
  - the expected benefits of the research project, in particular for themselves or for other people;
  - the measures taken to protect the personal data collected;
  - their rights.

# Federal Act on Research involving Human Beings (Human Research Act, HRA)

## ■ **Art. 19 Liability**

- 1 Any person who carries out a research project involving persons shall be liable for damage suffered by them in connection with the project. The Federal Council may specify exemptions from liability.
- 2 Compensation claims become time-barred three years after the injured party has become aware of the damage and of the liable party, but no later than ten years after the completion of the research project. The Federal Council may specify a longer limitation period for particular research areas.
- 3 The provisions of the Code of Obligations<sup>4</sup> on tort are otherwise applicable; in the exercise of official duties, the Government Liability Act of 14 March 1958<sup>5</sup>, or cantonal government liability law, is applicable.

# SCTO Forum Clinical Research 2015: General consent – Yes but how?

*„Patients often have a huge interest in clinical research as they know first hand how life changes with a specific diagnosis. They need cures and hence, the majority of them has a positive attitude towards research. However patients want to become addressed and involved.“*

Karin Holm; representative of a patient organisation

## Some key elements, EU countries

- Kees Bob (April 2012): Exchanging knowledge on participation of health consumers and patients in research, quality and policy. The Netherlands Organisation for Health Research and Development.
- Thematic website for best practices: [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu)
- European Aids Treatment Group: Designing research protocols in collaboration with industry. Established relation with regulatory bodies
- Patient Partner (Dutch Genetic Alliance, EFGCP)
- Value+, Respect (EPF)
- EUROVISIONNET (Retina Suisse)

# Patient Involvement in Clinical Research

A guide for Sponsors and Investigators



## PATIENT INVOLVEMENT IN CLINICAL RESEARCH

A guide for Sponsors and Investigators



Produced by the PatientPartner project  
funded by the 7th Framework Programme  
of the European Commission



# Patient involvement: becoming an active partner in research

- Research subject
- Information provider
- Advisor
- Reviewer
- Co-Researcher
- Driving Force

# Patient involvement: professional perspective

- Representativeness
  - Quality
  - Bias
  - Influence
  - Consumer expectations,
  - Cost increase and research duration
  - Roles overlapping.
- 
- Consumer involvement in health research: a review and research agenda ; Jonathan Boote\*, et. Al. 2002

# Concluding discussion

- Is the Swiss health system ready for active patient involvement?
- Can Swiss patient organisations become active partners in research?
- Patient organisations as active partners: what do we need to lobby for or to do to get there?
  
- What is your experience in involving **patient partner organisations** in your research projects?

# Thank you for your attention

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## Special thanks

Céline Moret, Retina Suisse