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Société Suisse d'Informatique Médicale
Società Svizzera d'Informatica Medica
Swiss Society for Medical Informatics

**STADE DE SUISSE
BERN**
11.-12. SEPT. 2018

E-GeneralConsent Development and Implementation of a Nationwide Harmonized Interactive Electronic General Consent

Dr. Julia Maurer, Department of Clinical Research, University Hospital Basel

 @ Speaker twitter handle

In cooperation with



ehealthsuisse
Koordinationen: Plan & Politik
Organ de coordination: Confédération - cantons
Organi di coordinament: Confederaziun - Cantons

IHE
SUISSE
Integrating
the Healthcare
Enterprise

pharmaSuisse 

VGIch
Verbindung Gesundheitswirtschaft Schweiz

BACKGROUND TO GENERAL CONSENT.

Agreement of patients for the use of **health related data** (genetic and non-genetic) and **biological material**

- all data and leftover samples which have been and will be collected during hospital stay
- additional sampling for biobanking possible



BACKGROUND TO GENERAL CONSENT. ESTABLISHED PROCESSES

Delivery of **paper-based consent** information
mainly as part of regular **admission process** or by dedicated persons



BACKGROUND TO GENERAL CONSENT. ESTABLISHED PROCESSES

Collection of **signed consent** documents



BACKGROUND TO GENERAL CONSENT. ESTABLISHED PROCESSES

- Documentation of patient decision (consent/refusal) through **manual transfer** or **scanning**
- **Interfaces** to clinic information systems



DIFFICULTIES AND CHALLENGES.

National general
consent coverage
is less than 30%

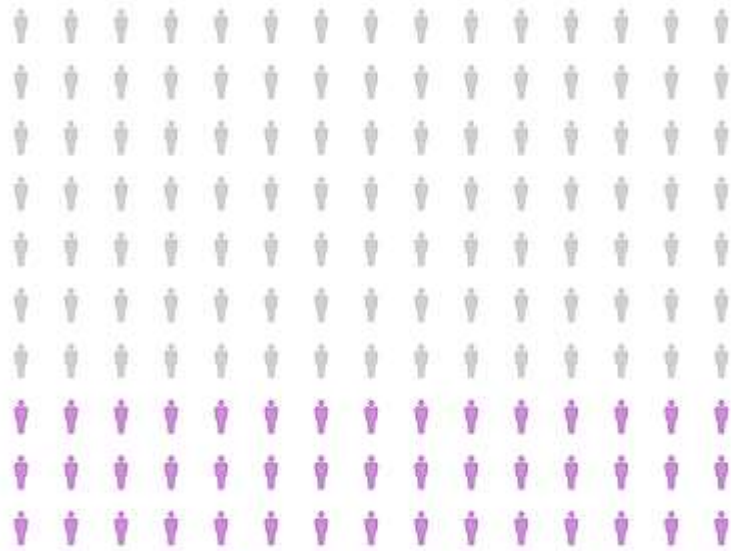
- ADMITTED: 100%



DIFFICULTIES AND CHALLENGES.

National general consent coverage is less than 30%

- ADMITTED: 100%
- RETURNED: 20-30%



DIFFICULTIES AND CHALLENGES.

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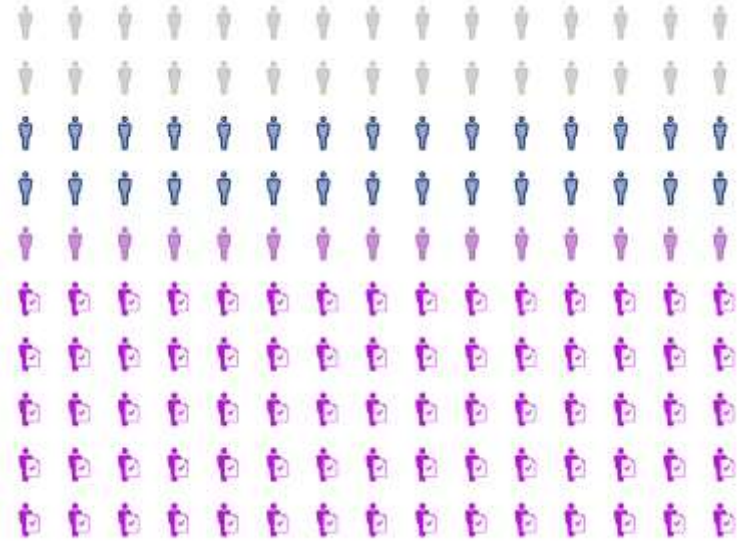
- ADMITTED: 100%
- RETURNED: 20-30%
- AGREED: 85%



SIGNIFICANCE OF THE PROJECT

Patients' consent as a **crucial basis** for the success of the personalized health initiative

More innovations are needed to enlarge the patient pool

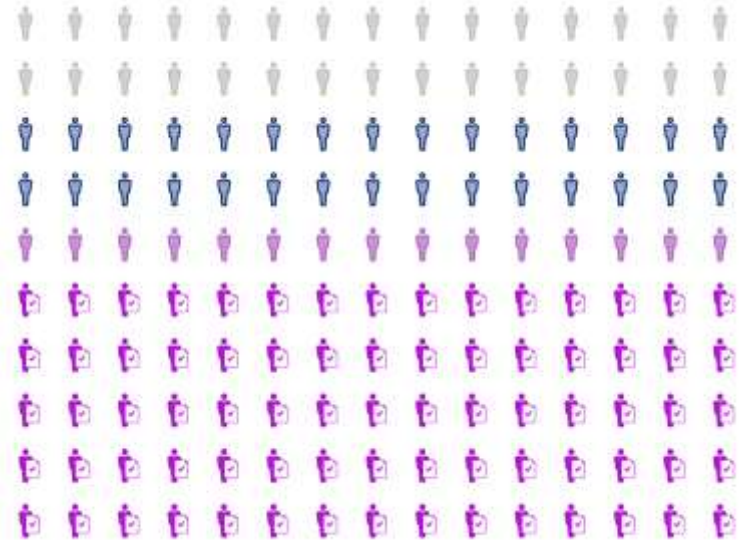


SIGNIFICANCE OF THE PROJECT

Patients' consent as a **crucial basis**
for the success of the personalized
health initiative

More innovations are needed to
enlarge the patient pool

ADMITTED:	100%
EXPOSED:	80%
RETURNED:	60%
AGREED:	85%



WHAT WE PROPOSE TO DO.

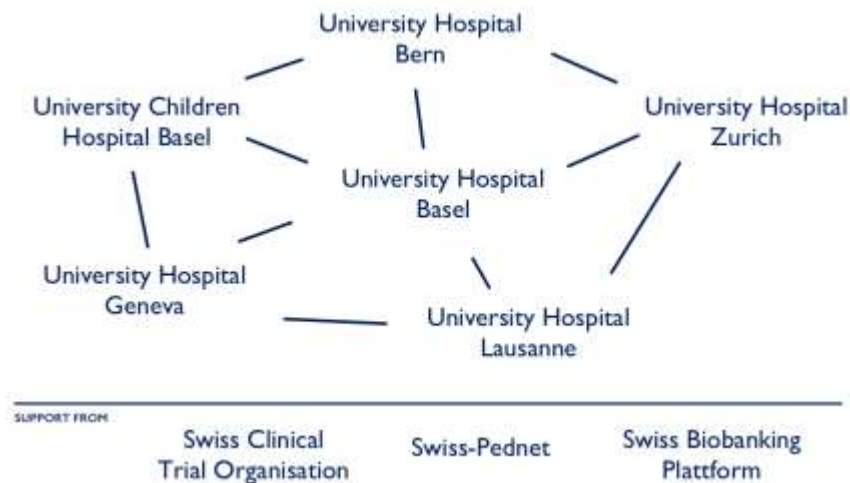
ADDITIONAL METHODS OF PROVIDING CONSENT DIGITALLY

To **increase** general consent coverage by establishing an **entirely digital** consent process that is paper-free and **independent of hospital admission**



PROJECT PARTNERS.

A NATIONWIDE PROJECT



PROJECT GOALS.

1. **Legal** requirements for electronic consent and the need of patient identification
2. **Interactive** general consent based on a **nationwide** harmonized content respecting patient needs
3. **Software** solution allowing the use of a digitalized general consent independent of hospital admission personnel



1 – LEGAL REQUIREMENTS

- According to Human research Ordinance (HRO) consent for further use of data and samples has to be given in a **written form** (Art.29 HRO)
- Written form means *Eigenhändigkeit* = **personal signature** (Art.14 OR)



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- According to Human research Ordinance (HRO) consent for further use of data and samples has to be given in a **written form** (Art.29 HRO)
- Written form means *Eigenhändigkeit* = **personal signature** (Art.14 OR)
 - No regulation according to “PostFinance”
 - Using “ipen” leads to controversial discussions





1 – LEGAL REQUIREMENTS

- But **exception** governed by **Art. 9**
- **Reference** is made to the **departure from written form** in the application to the responsible research **ethics committee**

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- But **exception** governed by **Art. 9**
- **Reference** is made to the **departure from written form** in the application to the responsible research **ethics committee**
→ Using a “**non-written form**” means checking a





1- LEGAL REQUIREMENTS - OUTLOOK

SEPTEMBER 2018

- **Preparation of a legal testimony by a legal expert**
- **Obtaining a consolidated statement regarding exception of written consent form by all Swiss Ethic Committees**



2 – INTERACTIVE HARMONIZED NATIONWIDE GENERAL CONSENT

- **First Draft Version** as basis between the University Hospitals provided
→ **further development** of harmonized GC under the guidance of **unimedsuisse**
- **Interactive presentation** of GC information
→ for **different population groups**
→ **publicly** available website



3 – INTERACTIVE SOFTWARE SOLUTION FOR E-CONSENT

- Prototype of the **user interface**
- Agreement on **system specifications** for an electronic general consent solution by all project partners
- Availability of a verified software solution

3 – VISION

Patient scans QR-code
or enters the url on the
mobile device



Patient agrees or declines
to provide any re-use
of data and samples



Decision is synchronized with a central information
system in the hospital and distributed from there to
other systems if necessary



THANK YOU FOR YOUR ATTENTION!

Project Team:

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- Julia Maurer, University Hospital Basel



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