SCTO PLATFORMS

**1 October 2025 | 12.00–13.00 | online seminar**

Facts and pitfalls of observational studies

# International multicenter HRO projects: Some kind of challenge

This session is a must for all researchers who want to take on the challenge of planning and conducting multicenter HRO projects in an international context. In the first part of the session, the regulatory and legal aspects will be addressed, while in the second part, practical experiences from managing an observational study across multiple sites in the DACH region will be shared.

## Registration and more information:

sctoplatforms.ch/hro-multicenter-projects.ch

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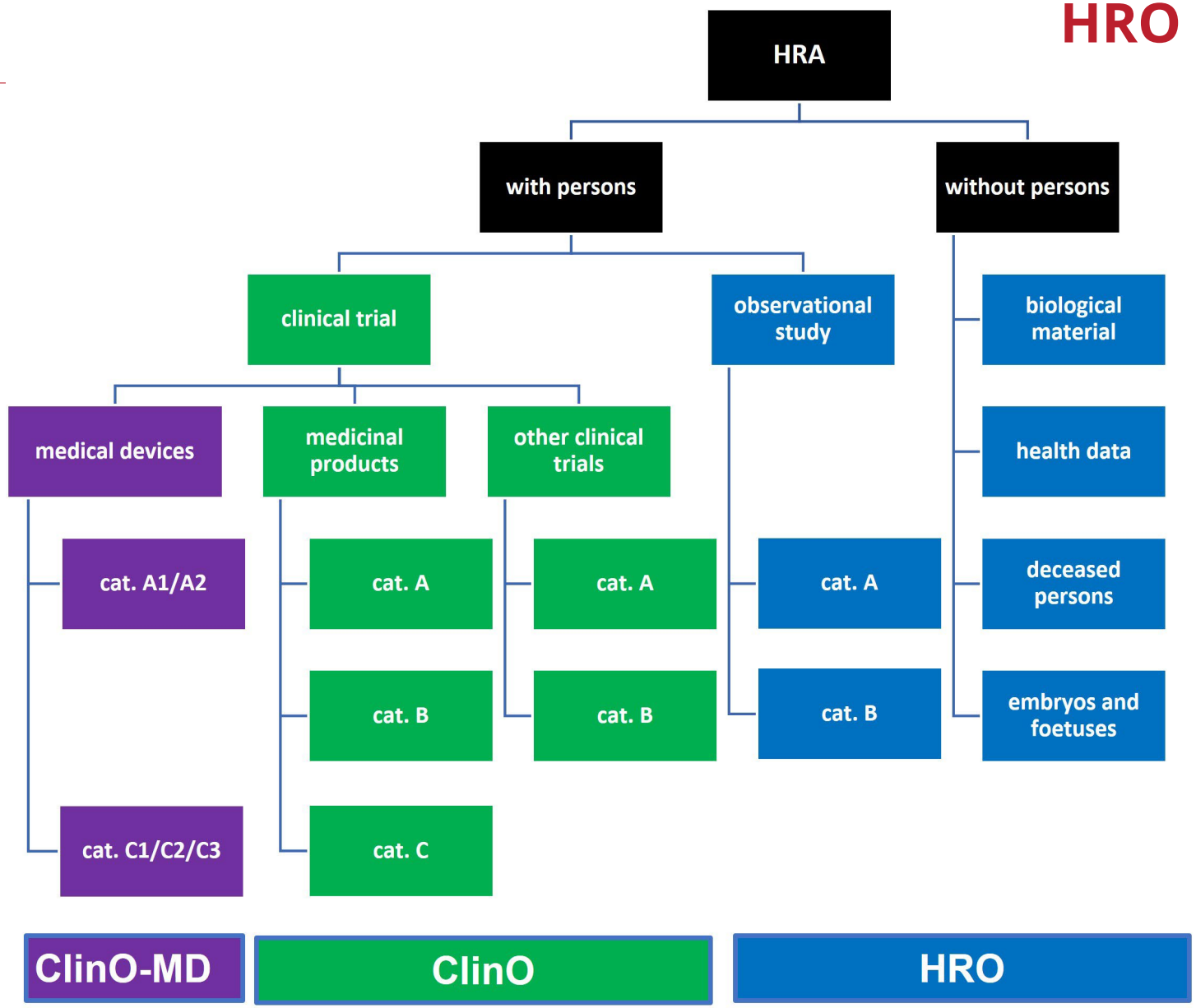
# HRO - Where are we?




according to Ch. Seiler, EC Bern

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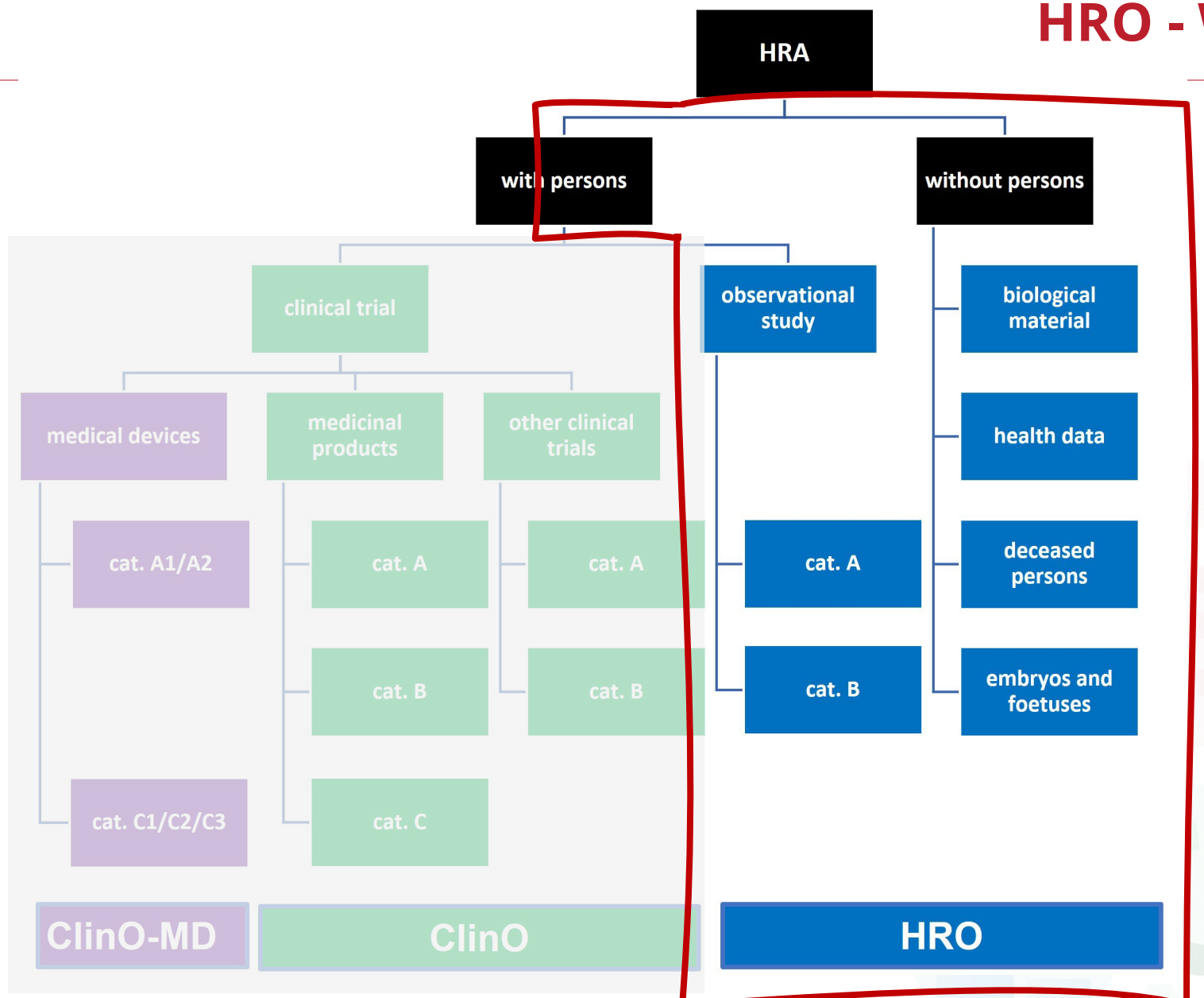
# HRO - Where are we?




according to Ch. Seiler, EC Bern

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# General information

- **Questions**:
  - **during presentation**: in the chat mentioning the part (I or II) of the session that it refers to (→ for Q&A session at the end)

- Presentation recorded

- Video, slides and Q&A provided after the session

- Feedback poll at end → please fill in!

- HRO lunch project team:
  - Claudia Fila (CTC Zurich)
  - Antoine Poncet (HUG)
  - Verena Golz (DKF Basel)

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# Presentation



## Dr. jur. Thomas Gruberski

*Member of the Ethics Committee of Northwest and Central Switzerland (EKNZ), Department of Clinical Research (DKF) Basel*

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## PD Dr. med. Jan Ebbing & Martina Becker-Seemann

*Senior Physician, Study coordinator SteamOne, Department Urology, University Hospital Basel (USB)*

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# HRO Lunch Session - Part I

## Legal and regulatory requirements

*Dr. jur. Thomas Gruberski*

Universitätsspital Basel

**Generalsekretariat**

Rechtsdienst

# International multicenter HRO projects – some kind of challenge

## Regulatory and Legal aspects (focus on GER/AUT)

Dr. iur. Thomas Gruberski

# Introduction

- Science is an international matter.
- Purely domestic research projects are the exception.
- Nevertheless - for purely domestic projects: https://swissethics.ch/assets/themen/swissethics_mult_konz_d.pdf

# Some basics (I)

Usual setting:

- Retrospective research project
- An institution analyzes data / biologic material…
- … originating from several hospitals / centers etc.
- some (or all) of them having their domicile outside Switzerland.

# Some basics (II)

Essential:

- DTA/DTUA: «Data Transfer Agreement / Data Transfer and Use Agreement»
- MTA: «Material Transfer Agreement»

- Increasingly requested by Ethics Committees…

- … and eventually by scientific journals (unless a CTA exists)

# Some basics (III)

- DTA / DTUA / MTA: Ideally to be checked by your trusted legal dpt.
- GDPR should be repealed whenever possible.

# Constellation I: Data transfer from EU to CH (I)

- According to an adequacy decision of the EU (01/2024), Switzerland's data protection level is comparable to the level in the EU.
- Meaning: Data import from EU to CH isn't a problem.
- (PM: Don't forget the DTA / DTUA / MTA)

# Constellation I: Data transfer from EU to CH (II)

Role of the Swiss ECs:

- project being led outside CH: ECs in general not competent
- project being led in CH: ECs competent
- The crucial question: **Where is the data being analyzed?**

# Constellation II: CH > EU (esp. GER, AUT) – Consent Issues (1)

Let’s lay back for a second….

- Focus lies on **retrospective** research projects.
- Whenever we talk about **routine data …**
- (… meaning data won by diagnostic or/and treatment interventions)
- … and therefore being stored in the medical / clinical records (“KG” / Krankengeschichte)

# Constellation II: CH > EU (esp. GER, AUT) – Consent Issues (2)

- So: whenever we say «routine data»…
- … key to happiness: General consent / «Generalkonsent»/ «Forschungskonsent»
- Meaning the patient consents à la:
- «I'm okay with my data and human samples being used in (many!) future research projects as long as I don't withdraw this consent.»

# Constellation II: CH > EU (esp. GER, AUT) – Consent Issues (3)

- But: If *additional* data or human samples needed (= for research purposes): GC not applicable; specific consent, please.
- K.I.M.: in these cases: ICFs might be necessary in additional languages (!)

# Constellation II: CH > EU (esp. GER, AUT)

- **Important to know: There is no HRA in AUT, GER etc.**
- Which means (1):
- By transferring data to other countries…
- … no issues as long as the **key** remains in CH (important clause in the corresponding DTA btw…)

# Constellation II: CH > EU (esp. GER, AUT)

**(Mantra): There is no HRA in AUT, GER etc.** (2)

- If you need to transfer **uncoded** data:
  - GC not applicable (even if routine data [!]) > specific consent needed
  - «Safe transfer to safe states»: List of states, territories etc. with adequate data protection: https://www.fedlex.admin.ch/eli/cc/2022/568/en (Swiss Data Protection Ordinance [DPO], Annex 1)

# EC's tasks @ EU (I)

**(Mantra): There is no HRA in AUT, GER etc.** (3)

- AUT/GER: The EC of a federal state («Bundesland») might not be / not see itself as competent
- (as retrospective data projects are not related to AMG/MPDG)

# EC's tasks @ EU (II)

**(Mantra): There is no HRA in AUT, GER etc.** (4)

- Key to happiness II: There are institutional ECs (ECs within the institution in question)…
- … happy to welcome you gratefully.
- Important to explain the concept of the GC (e.g. in the protocol)

# Thank you - questions?

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# HRO Lunch Session - Part II

Insights into the project management of SteamOne

*PD Dr. med. Jan Ebbing*

*Martina Becker-Seemann*

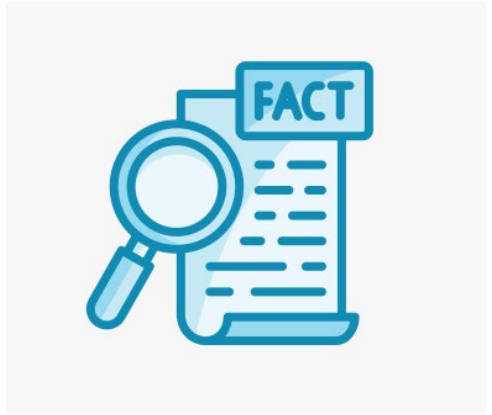
HRO- lunch

# SteamOne

unispital-basel.ch/SteamOne

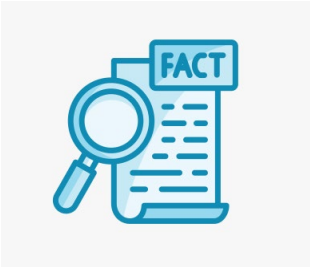

Universitätsspital Basel

# SteamOne – key facts




- Title: Prospective Database for Rezum water vapor therapy of the prostate
- Type: Research project involving human subjects
- Countries: D-A-CH (multicenter, maximum of 25 sites)
- Risk Categories:
  - CH: risk category A acc. to HRO Art. 7
  - D: non-interventional trial according § 15 Berufsordnung für die nordrheinischen Ärztinnen und Ärzte, Leitethik (Ethics Committee consultation)
  - A: prospective observational trial („sonstige Studie“), no clinical trial according to MDR (under discussion)
- Number of patients planned: 1000
- Medical devices used: REZUM® water vapor therapy of the prostate for BPH, EmanoFlow® (ad on tool to capture data on home-uroflowmetry)
- Data captured: CROMS (Clinical reported outcome measures) & PROMS (Patient reported outcomes)

# SteamOne – key facts cont.




- Aim of study: collecting real-world data to improve guideline recommendations
- Investigator initiated Trial (USB is sponsor)
  - Third-party funding application: Boston Scientific is funder

# SteamOne – challenges

- <u>Study set-up / requirements</u>:
  - Database design / Definition of features of the EDC: web-based, opportunitiy to send questionnaires by email (email notifications of PROMs)
    - Creation of additional questionnaires beside validated questionnaires
    - Creation of documents: study protocol, country specific documents e.g. informed consent forms etc.

5. Ich bin darüber aufgeklärt worden, dass meine Daten auch in Drittländer und an Empfänger weitergegeben werden, für die kein Angemessenheitsbeschluss der Europäischen Kommission und auch keine anderen, gleichwertigen Datenschutzgarantien vorliegen.

**<u>Ich bin darüber aufgeklärt worden, dass ich ohne meine Einwilligung in die Weitergabe r Daten in diese Länder nicht an dieser Studie teilnehmen kann!</u>**

**Ich willige** ausdrücklich **in eine Weitergabe meiner Daten in Länder außerhalb der Europä Union und des Europäischen Wirtschaftsraumes ein, in denen ein Schutz meiner Daten n vergleichbarer Weise garantiert werden kann.** Der erheblichen persönlichen Nachteile, di solche Datenübermittlung mit sich bringen kann, bin ich mir bewusst.

☐**Ja** ☐**Nein**

6. **Verarbeitung besonderer Kategorien personenbezogener Daten:**

Ich willige ausdrücklich ein, dass gemäß Art. 9 Abs. 2 Buchstaben a DSGVO personenbezogene besonderer Kategorien von mir erhoben und verarbeitet werden dürfen. Dies beinhaltet k Daten zu meinem Sexualleben, als auch meiner ethnischen Herkunft. **(Ohne Einwilligung Studienteilnahme möglich)!**

☐**Ja** ☐**Nein**

☐**Ja** ☐**Nein**

7. E-Mail-Versand Fragebögen (REDCap Datenbank):

Ich willige ein, dass die in der Patienteninformation genannten Fragebögen zur Studie per E-Mail durch REDCap an mich oder Angehörige von mir zugesandt werden dürfen. **(Ohne Einwilligung ist die Beantwortung der Fragebögen nur über ein Tablet in der Klinik/Praxis möglich).**

8. Emano Flow Mobile App: Falls ich die Emano Flow Mobile App für die Harnstrahlmessung benutzen möchte, bin ich darüber aufgeklärt worden und damit einverstanden, dass personenbezogene Daten von mir, wie in der Information unter „Sonstige Datenweitergabe" beschrieben an Emano Metrics. Inc. im Rahmen der Registrierung zur Nutzung der App weitergegeben werden. Die Datenschutzerklärung von Emano Metrics. Inc. habe ich schriftlich erhalten. **(Ohne Einwilligung, keine Nutzung der Emano Flow Mobile App möglich)**

☐**Ja** ☐**Nein**

# SteamOne – challenges cont.

- Site selection / site feasibility:
  - Experience of surgeons: Certified surgeons for Rezum intervention required
  - Experience of centers: Number of Rezum surgeries (at least experience in 50 cases before start of study)
  - Eligible patients: Understandig german language, willing to complete questionnairies, inclusion/exclusion criteria
  - Ressources within study centers: Availability of human ressources (study stuff) within study centers
- Site communication
  - Multiple stakeholders needed for subcenter contract: legal departments, data protection officers, Unitectra (Switzerland), outsourced service providers for scientific contracts (Germany)
  - Prolonged contract negotiations: (data sovereignty, data sharing (including to funders abroad, USA), employee invention)
- Regulatory
  - Different ethic commitees in different countries: different processes, different forms, (one study –one vote in Germany since 11/2024)*

*The procedural proposal for harmonizing professional legal advice according to § 15 MBO is implemented at the state level by the state medical associations adjusting their statutes and internal processes, training advisors, informing members, and continuously evaluating the process.

# SteamOne – challenges cont.

- External stakeholders
  - Home uroflowmetry: Kesem Heath, iUFlow → Emano Metrics, EmanoFlow
  - EDC-System: Heartbeat One → REDCap
  - Impacts:
    - New contracts with skakeholders
    - Amendment study protocol
    - Update PIC
    - Additional costs
    - Postponement of the planned timeline
    - Additional workload, e.g. re-training of sites

# SteamOne – challenges cont.

- Prolongation due to slow recruitment:
  - Complex and slow processes until finalization of site initiation
  - Multiple challenges in sites (small teams, finding eligible patients)

- Other issues / Further consequences:
  - Adjustment of the timeline for sponsor payments due to the delayed timeline, requiring a necessary amendment.
  - A precise overview of current and past expenses and costs is needed; accurate and forward-looking budget management is essential.

- Complexity:
  - Multiple roles & tasks for USB study team (as sponsor and also as site).

# Thank you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unispital-basel.ch/SteamOne

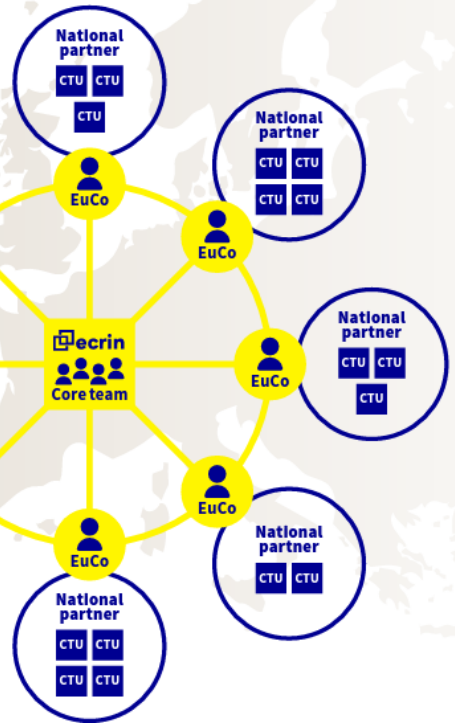
Universitätsspital Basel

# ECRIN
# European Clinical Research Infrastructure Network

Christina Huf, European Correspondent ECRIN, Switzerland

HRO Lunch meeting (online), 01st Oct 2025

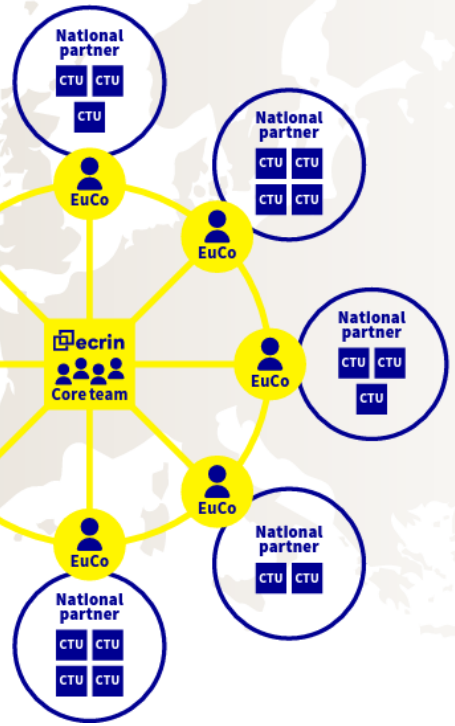
# European Clinical Research Infrastructure Network




MISSION: To support the conduct of multinational clinical trials in Europe

- European research infrastructure that **facilitates researchers to set up and conduct multinational clinical trials in Europe**.
- **ECRIN activities**
  - **Coordinated support to multinational study management**:
    - ⇒ Collaboration on study planning and design
    - ⇒ Operational study management services
  - **Development of tools, methods, and partnerships**
  - **Data Centre Certification**
- based in Paris (France), **ISO 9001:2015 certified**

# European Clinical Research Infrastructure Network




ECRIN is based on **country membership** and integrates its service with the existing national networks.

Currently there are **13 Member and Observer countries** (Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Slovakia, Spain, Switzerland).

– over **130 clinical trial units** (CTUs) in the network / specialized staff to provide:

⇒ Regulatory and ethical submissions; Project Management

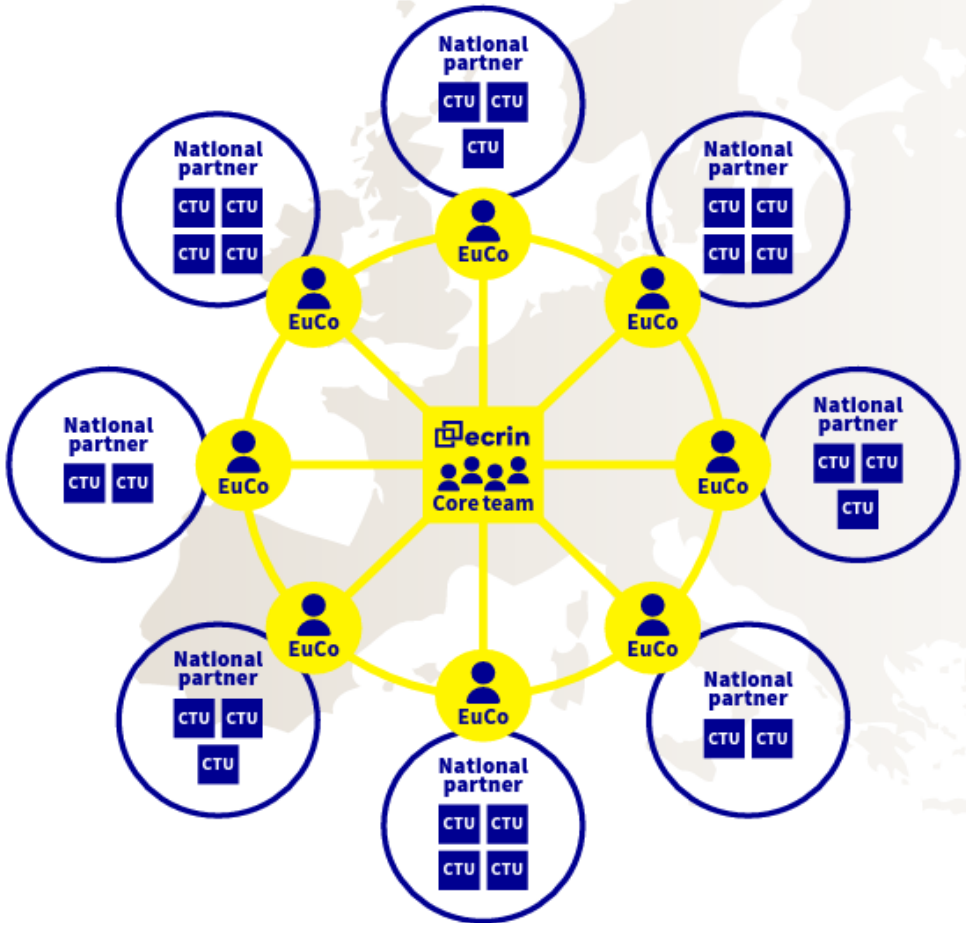
⇒ Monitoring & Vigilance

⇒ Data Management

⇒ Statistics

# ECRIN Structure and Clinical Trial Support

## Coordinated support to multinational study management




- National partners in each country = **node**
- **National CTUs** => linked to the node
- **European Correspondent** (EuCo) present at each national node
- ECRIN collaborates/ manages EuCos and projects via Core Team (Paris)

⇒ **Christina Huf** = ECRIN European Correspondent for Switzerland

⇒ **SCTO** = Swiss national node/ network

# Thank you!

**CONTACT: Christina Huf;  c.huf@scto.ch**

ECRIN office: **30 Boulevard Saint Jacques, 75014 Paris, France**

For further information about ECRIN: **contact@ecrin.org**
or to contact your local European correspondent: **www.ecrin.org/ecrin-staff**

Internet: **www.ecrin.org**
Twitter / X: **@ECRIN_ERIC**
LinkedIN: **@ecrin**
YouTube: **@ecrin-clinicalresearchinfra**

# Q&A session – questions?

Part1: Thomas Gruberski

Part 2: Jan Ebbing & Martina Becker-Seemann

# Thank you for participating!

Further questions to:

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Verena.Golz@usb.ch

**HRO lunch session 4**

- 19 November 2025 –

**«Research according to HRO chapter 4 and 5»**

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