Universität Basel

EU Clinical Trial Regulation and the Swiss Human Research Act

«EU Clinical Trial Regulation –
New Legal Framework for Multicenter Clinical Trials»
16 December 2016
University of Basel, Law Faculty, Center for Life Sciences Law (CLSL)

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Agenda

I. EU Clinical Trial Regulation 536/2014

II. Human Research Act and Clinical Trials Ordinance

III. Multicenter Studies in the EU and in Switzerland

IV. Remarks and Questions

V. Conclusion

EU Clinical Trial Directive 2001/20/EC

increasing percentage of multi-center clinical trials (CT) in EU

→ need for harmonisation and simplification

↓

EU Clinical Trials Directive 2001/20/EC (CTD)

↓

- alignment of regulatory requirements for CT only
- national notifications in all EU Member States (MS)

↓

need for harmonisation and further alignment of CT notification
(reduction of CT in the EU about 25% in the last few years)

Clinical Trials Regulatory Framework – Overview

until CTD

15 different approaches of EU MS

→ differences:

- notifications
- approval systems
- timelines
- languages
- documentations

CTD (2004 – 2014)

15/ 27 MS with same version of documents and same language (English)

BUT: no harmonisation on assessment
→ different notifications, approval systems, timelines, languages and documentations
→ time and cost consuming

(provisional) solution:
Voluntary Harmonisation Procedure (VHP)

after CTD: CTR

Clinical Trial Regulation 536/2014 (CTR)

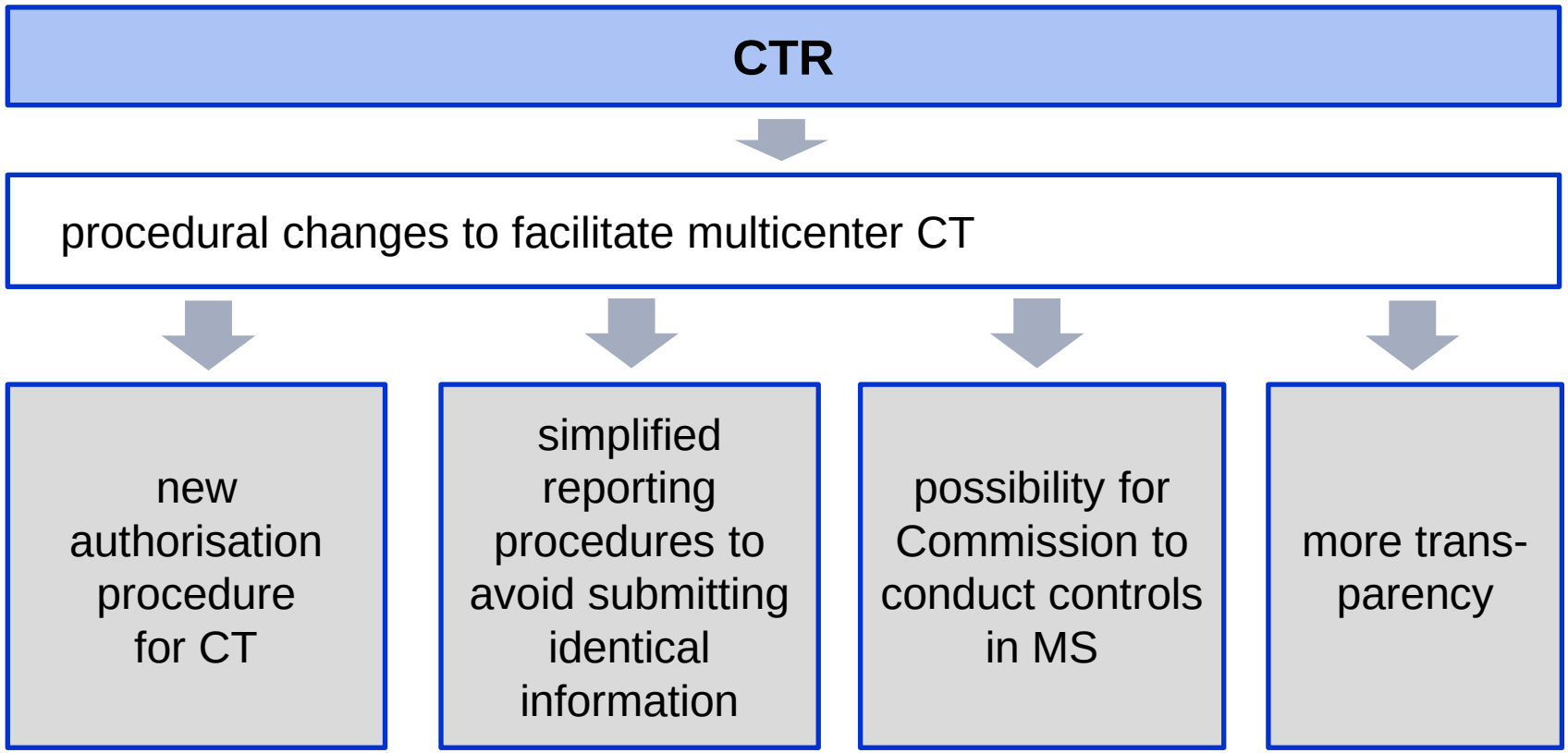
EU Clinical Trial Regulation 536/2014

from CTD to DTR

CTD	CTR
▪ only binding regarding results ▪ needs transcription into MS law ▪ form and method vary on MS level ▪ implementation period for MS	▪ no transcription into national law ▪ general applicable ▪ direct applicable ▪ immediately en-forecable in all MS ▪ simultaneously applicable

- change of quality of legislation
- new procedures and tools

EU Clinical Trial Regulation 536/2014



Clinical Trial Regulation – Key Elements

key elements

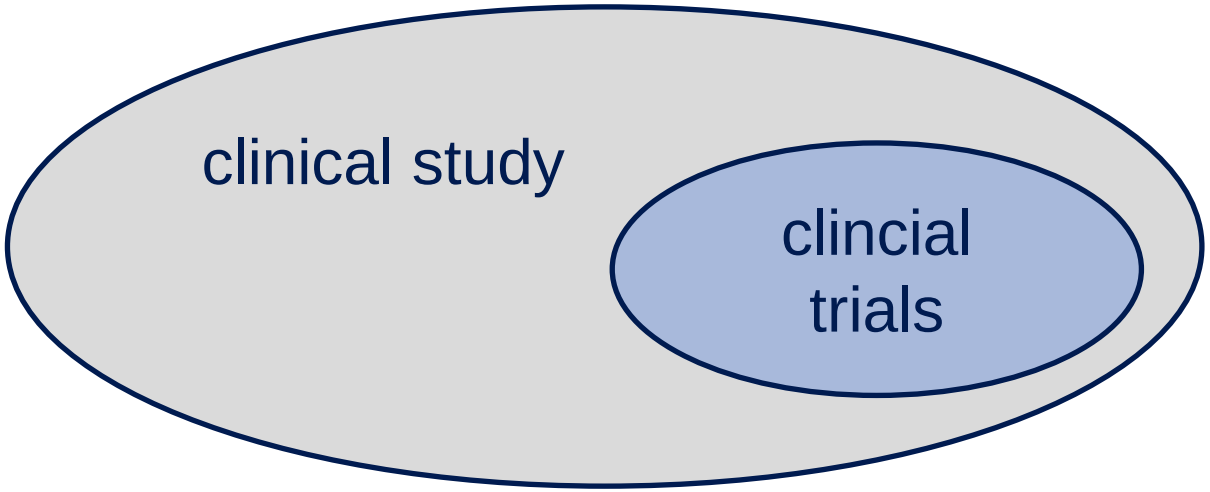
- single EU portal for notification
- single EU database + new transparency approach
- single national decision via EU portal
- coordination of assessment of CT by competent authorities of MS (instead of coordination by sponsor)
- 2-part assessment procedure amongst MS
- new structure for ethics committees (lead committee)
- risk based approach for documentation, approval, timelines, monitoring and liability
- revised and streamlined safety reporting

Clarification: Clinical Study instead of Clinical Trials

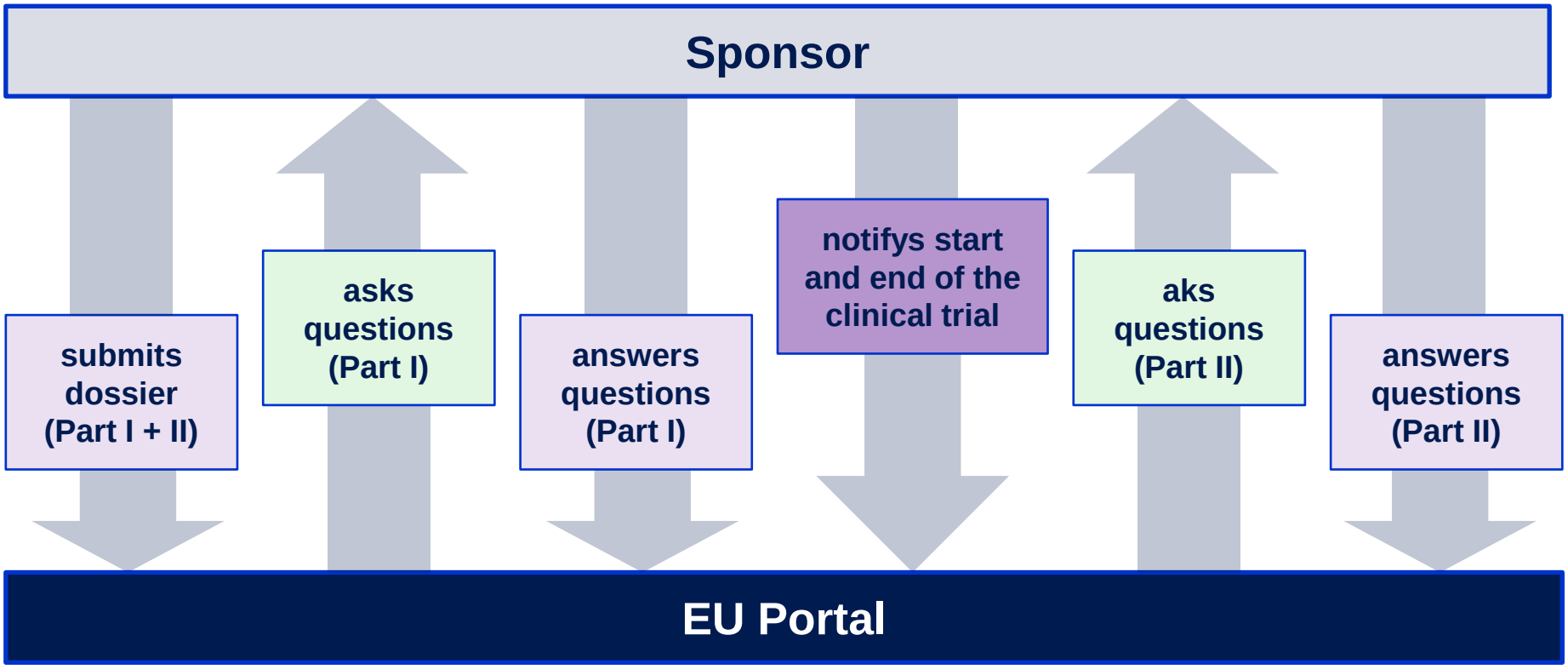
scope of the CTR

→ introduction of the new concept «clinical study» (Article 2 CTR)

→ «clinical trials» = one of several categories of a clinical study



Procedures and Workflow of the New System



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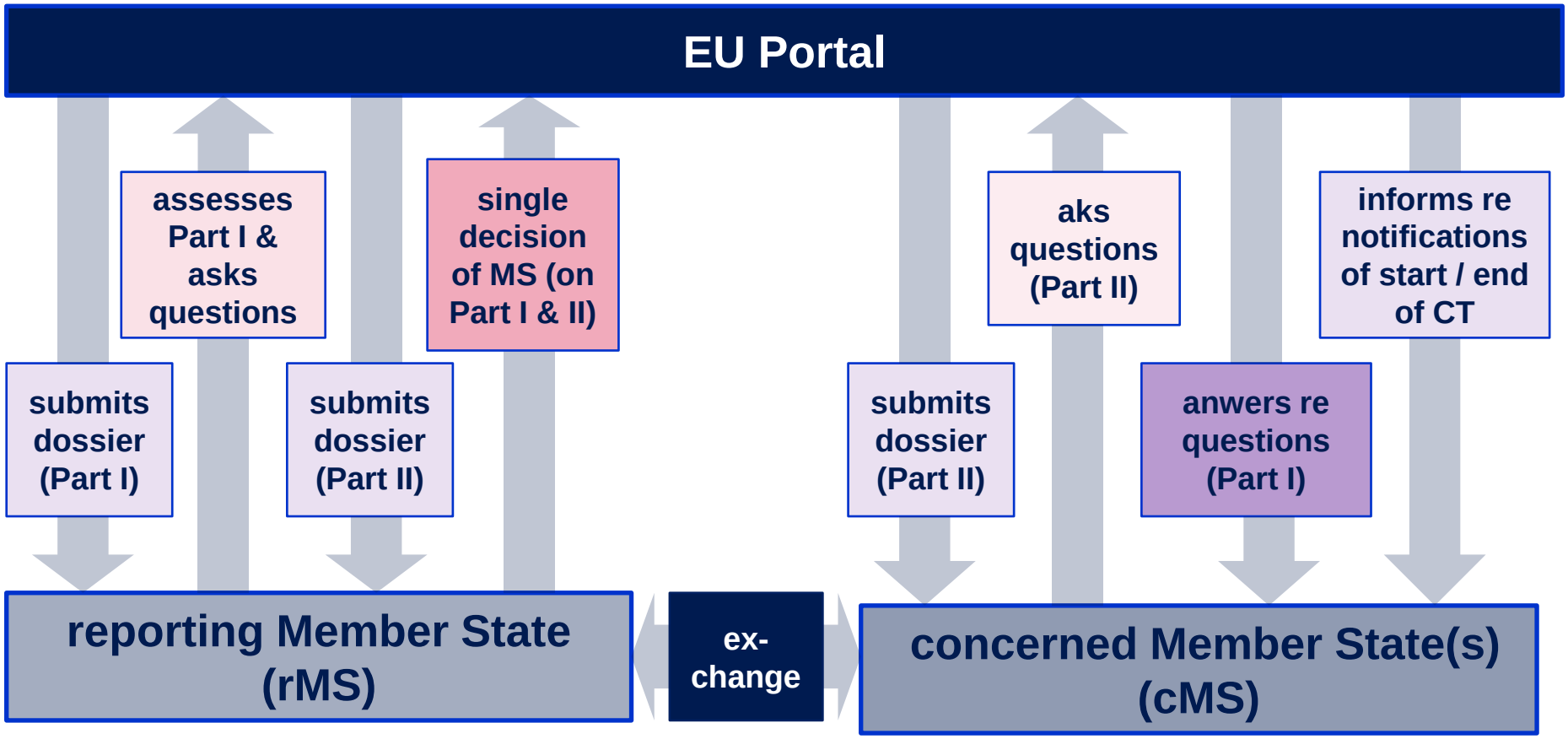

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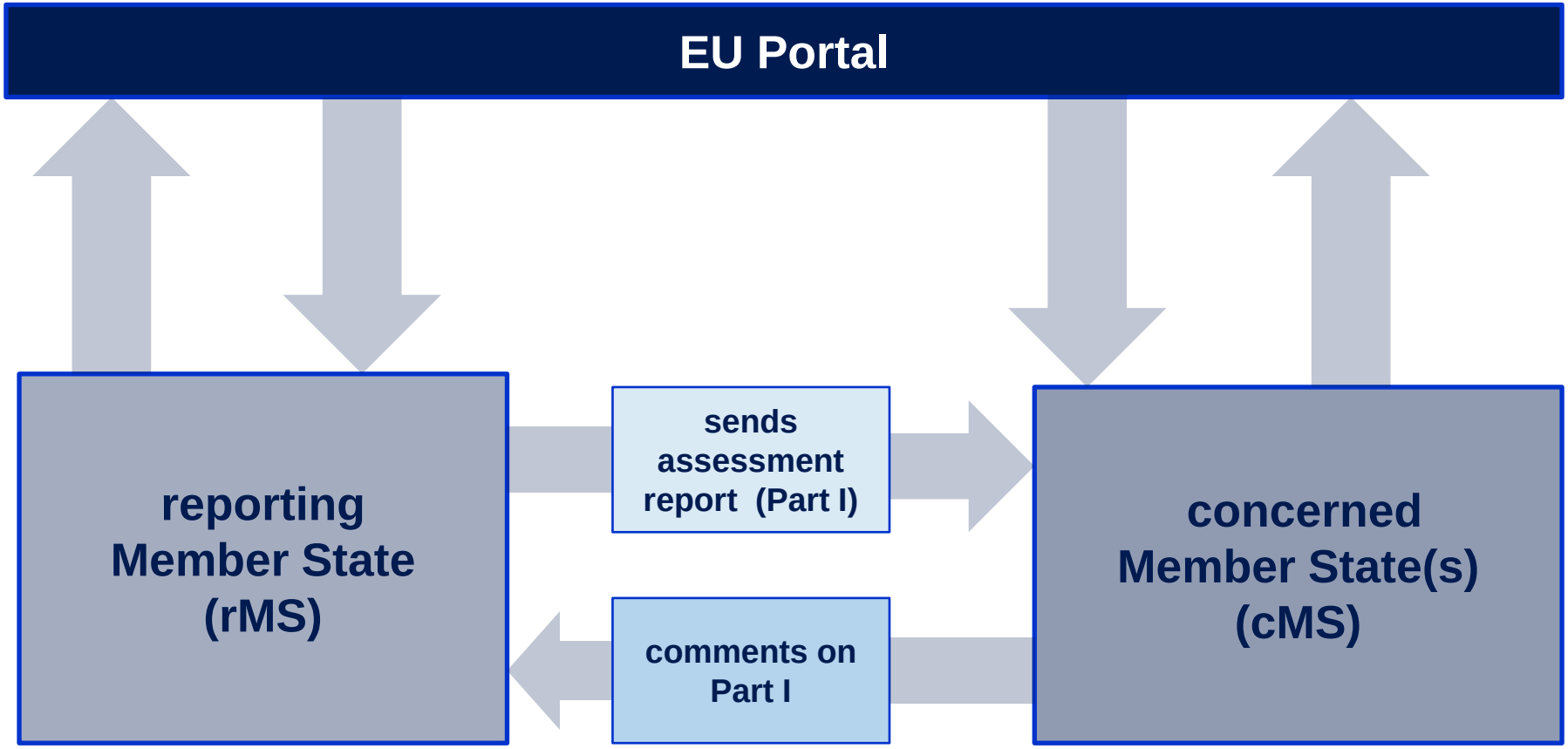

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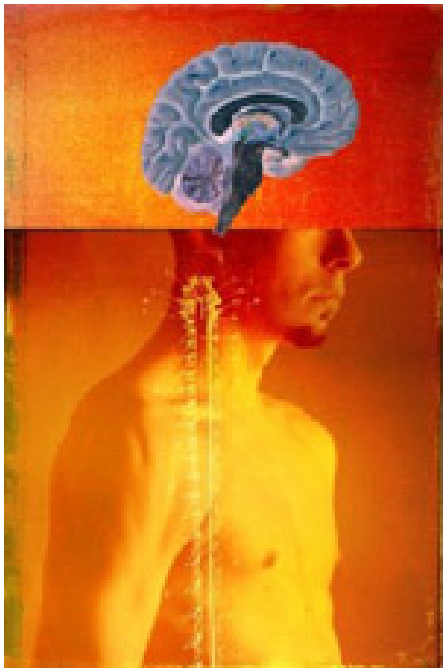
Swiss Human Research Act of 2014

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra



Bundesgesetz
über die Forschung am Menschen
(Humanforschungsgesetz, HFG)

vom 30. September 2011

Human Research Act (HRA), specified in

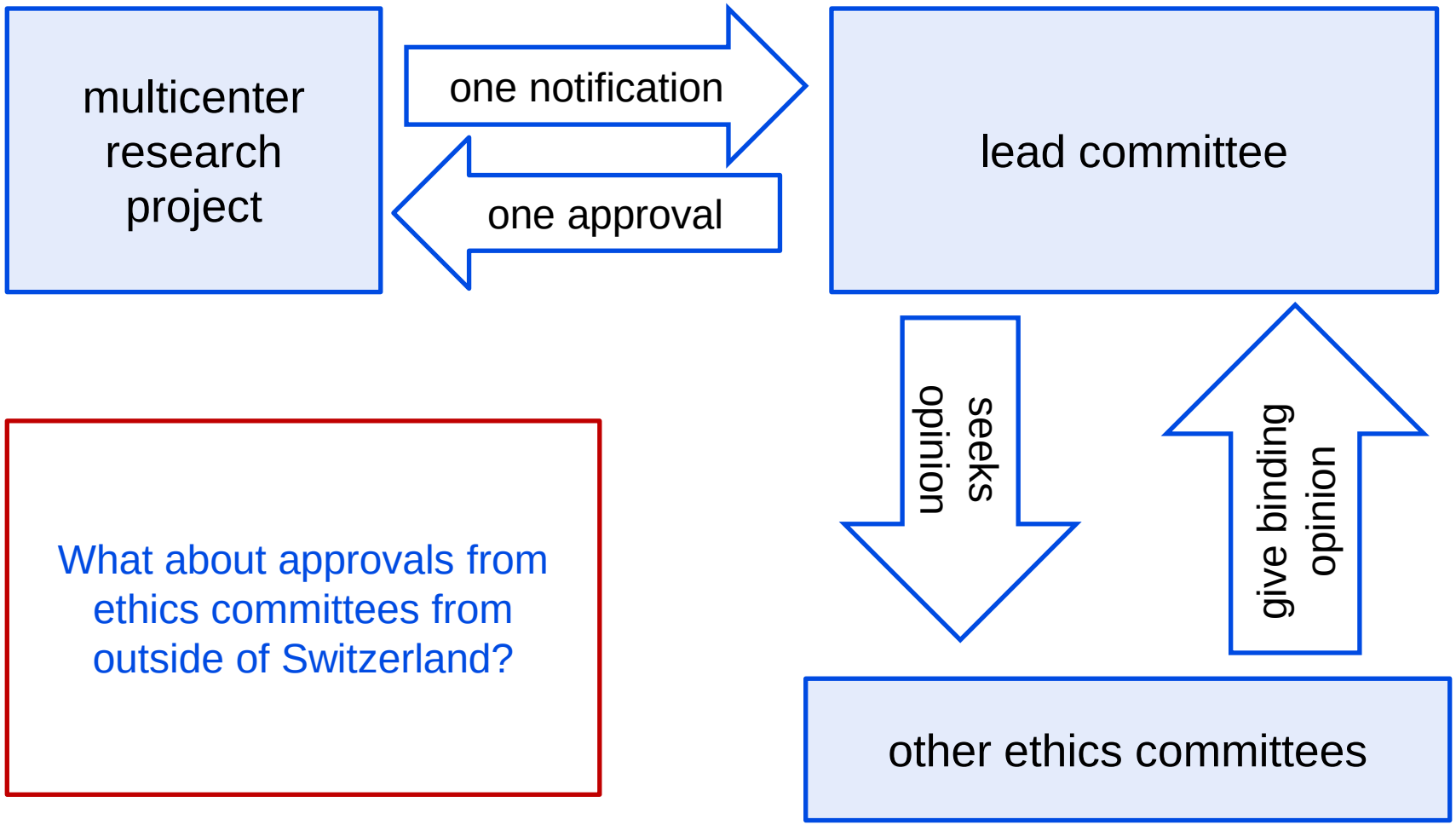
- Ordinance on Clinical Trials in Human Research («**Ordinance on Clinical Trials**», ClinO)
- Ordinance on Human Research with the Exception of Clinical Trials («**Human Research Ordinance**»)
- Organisation Ordinance on the HRA («**Organisation Ordinance**»)

Human Research Act – Key Elements

key elements

- applies to all areas of (non anonymised) research where humans may be exposed to a particular risk as a result of reseach
- regulates research with healthy, sick and deceased persons
- involves human body parts (biological material) and health-related personal data (as far as not anonymised)
- freedom of each person to decide whether to take part in a project or not
- authorisation by ethics committee for each research project

Human Research Act – Notification Procedure



What about approvals from ethics committees from outside of Switzerland?

Clinical Trial – Definition

Definition and Scope of Clinical Trial

«**clinical trial**» (HRA 3 lit. l)	«research project in which persons are prospectively assigned to **health-related interventions** in order to investigate its effects on health or in the structure and function of the human body»
«**health related intervention**» (ClinO 2 lit. a)	«preventive, diagnostic, therapeutic, palliative or rehabilitative measure investigated in a clinical trial»

Registration and Portal

Portal

ClinO 64	«**approved registries and data to be entered**» → registry: www.clinicaltrails.gov

ClinO 67	«**portal**»
	▪ public access to information on CT, conducted in Switzerland shall be guaranteed by a portal providing access to one or more registries
	▪ the portal shall enable in particular:
	  ▪ linking of data in the supplement federal database to data in the approved registry
	  ▪ searching for CT by keywords

ClinO, Annex 5	«**content of registration**» → data to be entered in a registry

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Multicenter Studies in the EU and in Switzerland

Comparison of EU and Swiss CT Regulation		
CTR	**HRA / ClinO**	**comparability?**
covers only trials for **medicinal products**	covers all **health-related interventions**	scope of HRA is broader than the CTR
comprises **detailed definitions** (CTR 2)	comprises less detailed definitions	applicability of CTR definitions if definition is missing in HRA/ClinO?
review areas of reporting MS (rMS) and concerned MS (cMS)	distinction between different **review areas** (ClinO 25 and 32): ethics committee + Swiss Agency for Therapeutic Products	consequences multicenter CT conducted in the EU and in Switzerland?

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Remarks and Questions

Some remarks ...

- CT conducted in Switzerland will not benefit directly from the simplified and centralized EU notification procedure of the new CTR
- Swiss system (HRA and ClinO) is not aligned to EU legislation

Some questions ...

- Could Swiss institutions (eg universities, pharmaceutical companies) profit also from the new EU system indirectly?
- Will there be ...
  - an adjustment of the Swiss system in the (near) future?
  - an «autonomous adaption» of EU law in Switzerland as far as possible (eg definitions?)
  - a decrease of clinical trials in Switzerland?

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Conclusion

The new EU Clinical Trial Regulation is a next step in harmonisation and simplification for clinical trials in the EU ...

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... but Switzerland will not benefit from the new EU approach under the existing legislation.

Thank you!

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