swissmedic
20 Jahre 2002 - 2022

Performance studies with IVDs

New requirements and changes to the legal requirements from 26 May 2022

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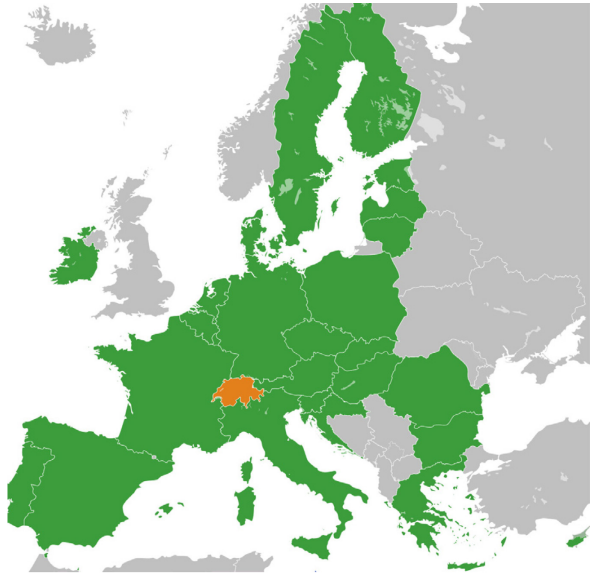
Medical Devices Clinical Investigations (MDCI) division

Harmonisation of Swiss medical devices legislation with EU IVDR

- EU IVDR requires evidence of clinical performance for in vitro diagnostic medical devices (Chap. VI)
- Amendment of the Ordinance on Clinical Trials with Medical Devices (ClinO-MD)

Now includes EU IVDR provisions for conducting performance studies with in vitro diagnostic medical devices (IVDs)



ClinO-MD: Trials with what products?

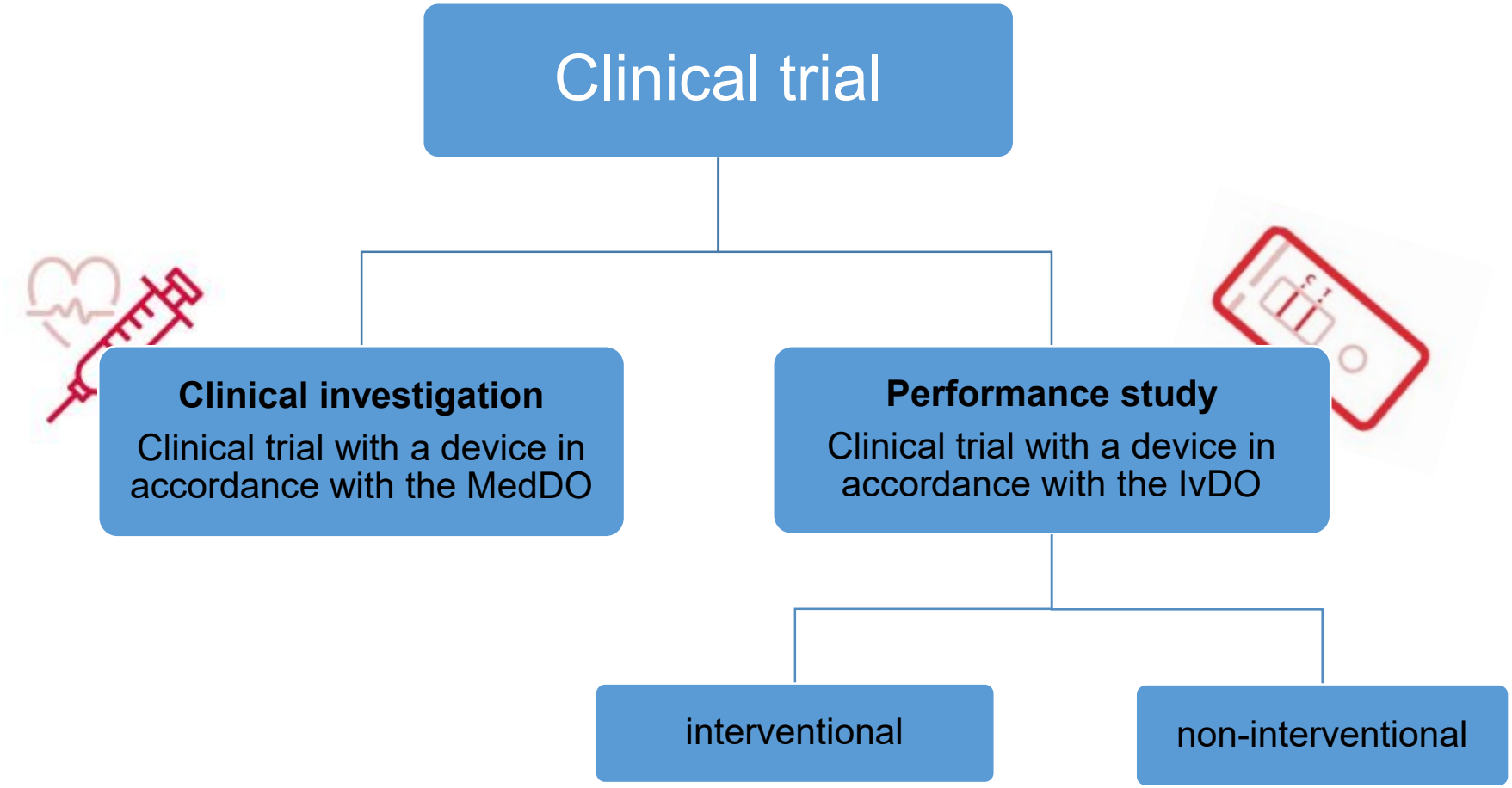
ClinO-MD	ClinO*

• All devices according to Art. 1 para. 1 IvDO
  • In vitro diagnostic medical devices and associated accessories
• All devices according to Art. 1 para. 1 MedDO
  • Medical devices and associated accessories
  • groups of products without an intended medical purpose in accordance with Annex 1 MedDO
• Devices that incorporate, as an integral part, a medicinal product or devitalised component that only has a supportive function
• Animal devitalised products incl. devitalised derivatives
• Human devitalised derivatives
	• Medicinal products, incl. combinations according to Art. 2 para. 1 let. f, g + j MedDO
	• Products according to Art. 2a para. 2 TPA (human devitalised products excluding devitalised derivatives)
	• Transplant products
	• Gene therapies, GMOs
	• Transplantation
	• Other

*Clinical Trials Ordinance; 810.305

New terminology

Art. 2 para. 1 let. a ClinO-MD



Definition: Performance study

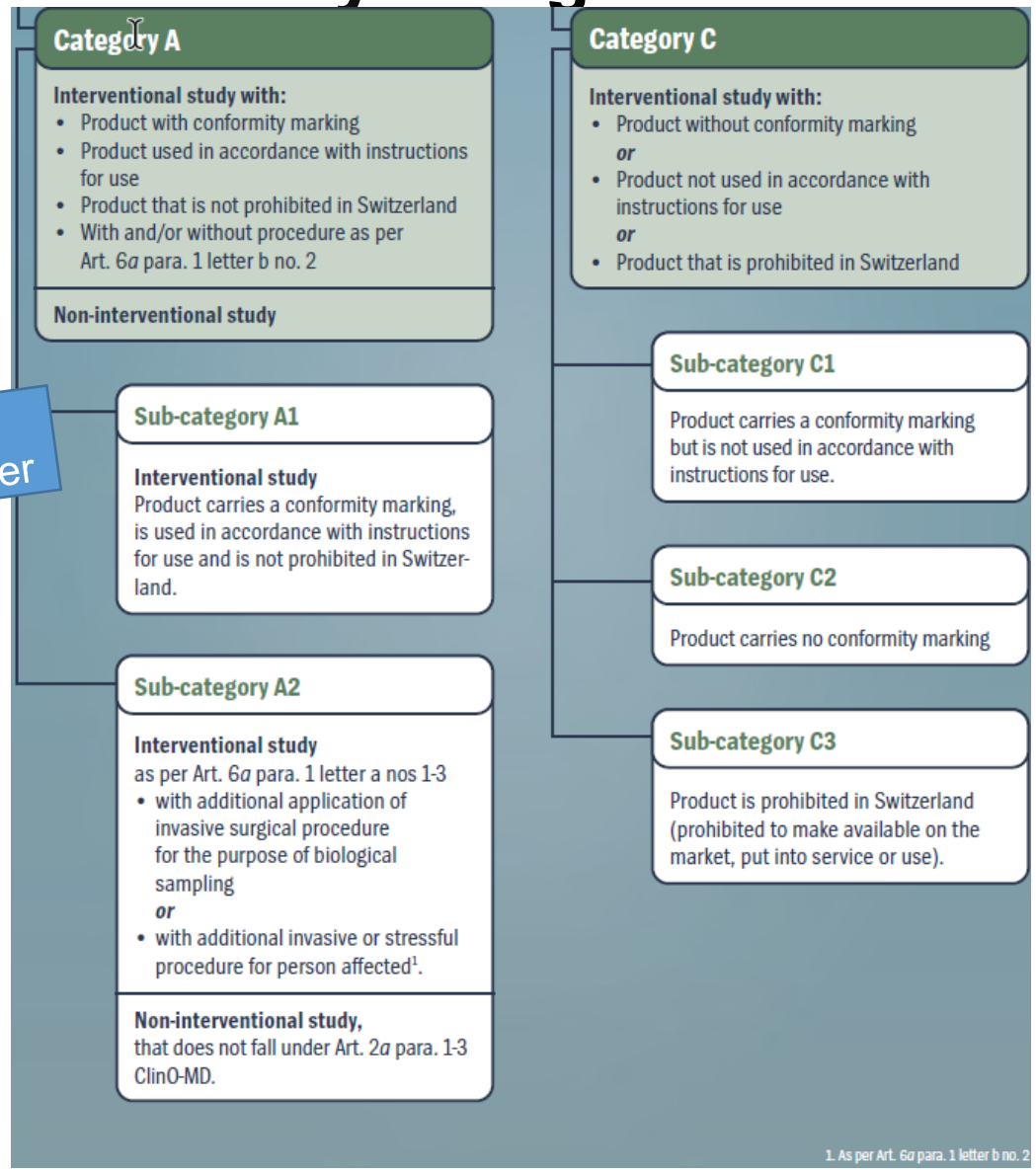
Art. 2 para. 1 let. a^{ter} ClinO-MD

- Study undertaken to establish or confirm the analytical or clinical performance of a device according to IvDO and the results of which:
  - *may influence patient management or treatment decisions (interventional performance study),*
  - *cannot influence patient management or treatment decisions (non-interventional performance study)*

Approval procedure: Performance study categorisation

Art. 6a ClinO-MD

KOFAM Categorizer IVD
www.kofam.ch/en/categorizer



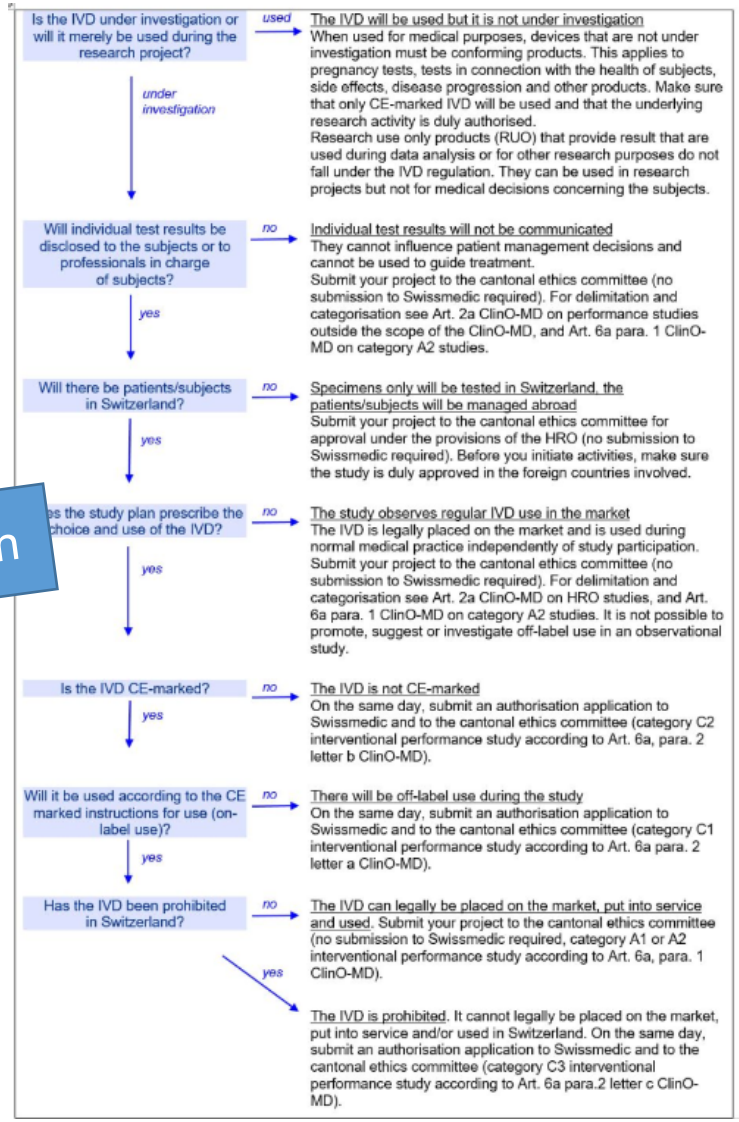
Infographic: KOFAM

Approval procedure: Decision tree for categorising performance studies

Art. 6a ClinO-MD

- Help for submitting performance studies with IVD

www.swissmedic.ch/performance-studies-en



Approval procedure: Parallel procedure in Switzerland

Art. 10-12, 16, 17, 19 ClinO-MD

- Parallel review of Cat. C performance studies by Swissmedic and ethics committee
- Submission on the same day via BASEC and *eMessage*
- Application documents according to Annex 1 ClinO-MD
- EU-compliant deadlines for authorities and sponsor
- Legal hearing and option for supplementary submission unchanged
- Start of the trial after approval by Swissmedic possible

Swissmedic website and information sheet: https://www.swissmedic.ch/performance-studies-en

Approval procedure: Simplified review by Swissmedic

Art. 17 para. 2 and 3 ClinO-MD

- Verification of completeness of the application and fulfilment of the conditions specified in Art. 17 para. 2 ClinO-MD:
  - Interventional performance study in sub-category C1 or C2 involving a class A or B IVD
  - Use entails minimal risks at most
  - Written agreement between investigator and sponsor on adverse events
  - Sponsor operates a risk management system incl. safety monitoring

NEW

Simplified review form:
BW610_10_025e_FO

Combined clinical trials with IVDs and medicinal products in Swiss trial centres

Compliant IVD	Authorised medicinal product	Submissions to and approval procedures by Swissmedic
☒	☒	• One submission with complete application documentation for interventional performance study with IVD and for clinical trial with medicinal product • Parallel procedure with ethics committee in accordance with ClinO-MD
☒	☑	• Complete application documentation for interventional performance study with IVD and additional information on medicinal product • Parallel procedure with ethics committee in accordance with ClinO-MD
☑	☒	• Complete application documentation for clinical trial with medicinal product and additional information on IVD • Procedure in accordance with ClinO
☑	☑	• No submission to Swissmedic

- If the clinical trial is conducted abroad using a central laboratory in Switzerland, does not have to be approved in Switzerland, but the central laboratory

Details in the Swissmedic information sheet:
"Performance studies with IVD"
www.swissmedic.ch/performance-studies-en

Substantial amendments

Art. 15, 20, 48 ClinO-MD

- Definition according to Art. 15 ClinO-MD

  "Modifications that are likely to have a substantial impact on the safety, health or rights of the participants or on the robustness or reliability of the clinical data generated by the study"

- Applies to Swissmedic and ethics committee
- Mandatory approval by ethics committee (Cat. A) or by Swissmedic and ethics committee (Cat. C), no “silent approval”
- Parallel approval procedure for Cat. C trials

Swissethics guidance document on ‘Substantial modifications’:
www.swissethics.ch

Safety reporting for Cat. C performance studies

Art. 33–36, 38 ClinO-MD

- Submission similar to guidance doc. MDCG 2020-10/1 and table MDCG 2020-10/2
- Reporting by the sponsor to Swissmedic and (lead) ethics committee:

Report / Event	**ClinO-MD**	**Deadline**
- SAE that is not unrelated - Device deficiency with SAE potential *in Switzerland and abroad*	Art. 33 para. 1	Without delay, max. 7d
Safety and protective measures *in Switzerland and EU/EEA states*	Art. 34, 36, 38	≤ 2d or ≤ 24h in case of termination or interruption for safety reasons
Annual Safety Report *with data from Switzerland and abroad*	Art. 35, 38	Annually

Swissmedic information sheet:
www.swissmedic.ch/md-clinicaltrials-en

Swissethics guidance document on safety reporting:
www.swissethics.ch

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Safety reporting for Cat. A performance studies

Art. 33–36 ClinO-MD

- Reporting by the sponsor to Swissmedic:

Report / Event	**ClinO-MD**	**Deadline**
Reports according to Article 59 IvDO (materiovigilance)	Art. 33 para. 7	

Swissmedic Materiovigilance: www.swissmedic.ch/md-materiovigilance-en

- Reporting by the sponsor to ethics committee:

Report / Event	**ClinO-MD**	**Deadline**
Sub-category A1 - SAE that is related, with test procedure **Sub-category A2** - SAE that is not unrelated - Device deficiency with SAE potential *in Switzerland and abroad*	Art. 33, para. 6 Art. 33 para. 1	- Without delay, max. 7d
Safety and protective measures	Art. 34, 36, 38	≤ 2d or ≤ 24h in case of termination or interruption for safety reasons
Annual Safety Report	Art. 35	Annually

Swissethics guidance document on 'safety reporting': www.swissethics.ch

Transitional provisions for approved performance studies

Art. 48 and 48a ClinO-MD

- Approvals remain valid until the expiry of the approval period
- Performance studies are subject to the new legislation
  - Reporting
  - Publication of the results in approved registries according to Art. 64 para. 1 ClinO and deadline in Art. 42 ClinO-MD
- Substantial amendment requires recategorisation according to Art. 6a ClinO-MD

Take-home messages and useful links

- Use the decision tree as an aid for submitting performance studies

- Swissmedic information sheet Performance studies with IVD provides detailed information on the approval process for performance studies, obligations while studies are in progress and end-of-study procedures

- www.swissmedic.ch/performance-studies-en

- Please send questions to: clinicaltrials.devices@swissmedic.ch

Laws and ordinances mentioned in the presentation

TPA:	Therapeutic Products Act; SR 812.21
ClinO-MD:	Ordinance on Clinical Trials with Medical Devices; SR 810.306
ClinO:	Clinical Trials Ordinance; SR 810.305
MedDO:	Medical Devices Ordinance; SR 812.213
IvDO:	Ordinance on In Vitro Diagnostic Medical Devices; SR 812.219
EU IVDR:	Regulation (EU) 2017/746 on in vitro diagnostic medical devices