Ordinance on Clinical Trials with Medical Devices (ClinO-MD)

of 1 July 2020 (Status as of 26 May 2021)

The Swiss Federal Council,

based on the Human Research Act of 30 September 2011[1] (HRA)
and on Articles 54 paragraphs 3, 6 and 8, 54*b* paragraphs 2 and 3 and 82
of the Therapeutic Products Act of 15 December 2000[2] (TPA),

ordains:

Chapter 1 General Provisions

Section 1 Subject matter, Definitions and Applicable Provisions

Art. 1 Subject matter

[1] This Ordinance shall regulate:

a. the requirements pertaining to clinical trials with medical devices and other devices in accordance with Article 1 of the Medical Devices Ordinance of 1 July 2020 (MedDO)[3];

b. the approval and reporting procedures for clinical trials involving the devices in accordance with letter a;

c. the duties and responsibilities of research ethics committees (Ethics Committees), the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Office of Public Health (FOPH) in connection with the approval and reporting procedures;

d. the registration of clinical trials involving devices in accordance with letter a;

e. public access to information concerning clinical trials.

[2] In this Ordinance, the term *devices* is used to designate all products defined in paragraph 1 letter a.

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2 SR **812.21**
3 SR **812.213**

Art. 2 Definitions

The following definitions shall apply in this Ordinance:

a. *clinical trial* means the systematic investigation of a device involving one or more persons for the purpose of assessing the safety or performance of the device;

b. *conformity-related clinical trial* means a clinical trial conducted to demonstrate the conformity of the device being investigated;

c. *contracting state* means any state that is bound to mutually recognise conformity assessments and conformity procedures for devices by an agreement with Switzerland under international law based on equivalent legislation;

d. *sponsor* means any individual or institution or organisation that takes responsibility for the initiation of a clinical trial – specifically its instigation, management and financing – in Switzerland;

e. *investigator* means any individual responsible for the conduct of a clinical trial and for the protection of the participants at a clinical trial site; any participant who assumes responsibility for initiating a clinical trial in Switzerland is simultaneously the trial's sponsor.

Art. 3 Applicable provisions

[1] The following provisions of the Ordinance of 20 September 2013[4] on Clinical Trials in Human Research (ClinO) apply to clinical trials with devices:

a. for scientific integrity and scientific quality: Articles 3 and 4 ClinO;

b. for participant information, consent and withdrawal of consent: Articles 7–9 ClinO;

c. for liability and indemnification: Article 10 paragraphs 1 letter c and 2 and Article 11–14 ClinO;

d. for the conduct of clinical trials in emergency situations: Articles 15–17 ClinO;

e. for the storage of personal health data and biological material: Article 18 ClinO;

f. for inspections and administrative measures: Article 46 paragraphs 1, 2, 4 and 5 and Article 47 and 48 ClinO.

[2] The powers exercised by Swissmedic and the duty to cooperate and provide information incumbent on the sponsor and investigator in the event of inspections and administrative measures are governed *mutatis mutandis* by Articles 77 and 78 MedDO[5].

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[3] Clinical trials with in vitro diagnostic devices, devices as specified in Art. 2*a* paragraph 2 TPA or combinations as specified in Article 2 paragraph 1 letters f and g MedDO are subject to ClinO.[6]

Section 2
General Obligations of the Sponsor and Investigator and Professional Qualifications

Art. 4 General obligations of the sponsor and investigator

[1] The sponsor and investigator must conduct clinical trials in accordance with Article 72 and Chapters I and III of Annex XV to Regulation (EU) 2017/745[7] on medical devices (EU-MDR).

[2] Compliance with the requirements of paragraph 1, specified in greater detail by designated technical standards[8] or common specifications in accordance with Article 9 paragraph 1 EU-MDR, is presumed if the clinical trial is conducted in accordance with those standards or specifications. Article 6 paragraph 5 MedDO[9] applies *mutatis mutandis*.

[3] If the sponsor is not domiciled in Switzerland and does not have a place of business there, it must designate an agent that is domiciled or has a place of business in Switzerland as an address for correspondence. This agent must ensure compliance with the sponsor's obligations.

Art. 5 Professional qualifications

[1] Clinical trial investigators must:

a. be entitled to practise independently as a doctor or in another profession that specifically qualifies them to conduct the clinical trial;

b. demonstrate adequate knowledge of the internationally recognised requirements for the conduct of clinical trials and the specialist knowledge and experience required for the clinical trial; and

c. possess knowledge of the legal requirements governing clinical trials or be able to guarantee the availability of such knowledge by recruiting appropriate expertise.

6 Amended by Annex No 1 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).

7 Regulation (EU) No 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117 of 5.5. 2017, p. 1; last amended by Regulation (EU) 2002/561, OJ L 130 of 24.4.2020, p. 18.

8 The electrical standards can be obtained from the industry association Electrosuisse, Luppmenstrasse 1, 8320 Fehraltorf, www.electrosuisse.ch, and the other standards from the Swiss Association for Standardization (SNV), Sulzerallee 70, 8404 Winterthur, www.snv.ch

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2 The remaining people conducting the clinical trial must possess the training or experience in the specialist field that is required to conduct clinical trials.

Chapter 2 Approval and Reporting Procedures

Section 1 General Provisions

Art. 6 Categorisation of clinical trials

1 Clinical trials fall into category A if:

a. the device to be investigated carries a conformity marking in accordance with Article 13 MedDO[10];

b. the device to be investigated is used in accordance with the instructions for use; and

c. it is not prohibited to make the device to be investigated available on the market, put it into service or use it in Switzerland.

2 Category A clinical trials are divided into sub-categories as follows:

a. if the participants do not undergo additional invasive or stressful procedures compared with the procedures applied when the device is used under normal conditions: sub-category A1;

b. if the participants undergo additional invasive or stressful procedures compared with the procedures applied when the device is used under normal conditions: sub-category A2.

3 Clinical trials fall into category C if:

a. the device carries a conformity marking in accordance with Article 13 MedDO but is not used in accordance with the instructions for use (sub-category C1);

b. the device does not carry a conformity marking in accordance with Article 13 MedDO (sub-category C2); or

c. it is prohibited to make the device available on the market, put it into service or use it in Switzerland (sub-category C3).

Art. 7 Exemption from mandatory approval

Category A clinical trials are exempt from the requirement to obtain approval from Swissmedic set out in Article 54 paragraph 1 TPA.

Art. 8 Data processing in electronic systems and information sharing

1–5 …[11]

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11 To come into force in due course (Art. 50 para. 2).

6 The medical devices information system in accordance with Article 62*c* TPA and the information system operated by the Cantons in accordance with Article 56*a* HRA may contain information on administrative or criminal proceedings or sanctions concerning the sponsor, investigator or manufacturer that Swissmedic and the competent Ethics Committee require in order to fulfil their duties under this Ordinance.

7 Swissmedic shall, upon request, forward the highly sensitive data in accordance with paragraph 6 to the Ethics Committees.

Art. 9 Information and coordination for approval procedures

The competent Ethics Committee and Swissmedic shall provide information to each other on the following aspects and coordinate their assessments:

a. categorisation of the clinical trial in accordance with Article 6;

b. aspects concerning the review areas in accordance with Article 11 and Article 17;

c. the conduct of the procedures set out in Articles 12 and 19 and in Chapter 3.

Section 2
Procedures to be performed by the Competent Ethics Committee

Art. 10 Application

1 The sponsor shall submit the application documents specified in Annex 1.[12]

2 The Ethics Committee may demand additional information.

3 The investigator may submit the application in place of the sponsor. In this case, it assumes the duties of the sponsor as set out in Articles 14 and 15 and the duty to notify and report to the competent Ethics Committee. The sponsor must co-sign the application documents.

Art. 11 Review areas

The areas to be reviewed by the Ethics Committee are governed by Article 25 ClinO[13].

Art. 12 Procedures and time limits

1 The Ethics Committee shall confirm receipt of the application to the sponsor within 10 days and notify the sponsor of any formal shortcomings in the application documents. It shall give the applicant 10 days to rectify the shortcomings and inform

12 Amended by Annex No 1 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
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