

Medical Devices - SWITZERLAND

Competent authority

Contact Details

Contact Name 1

Swissmedic - Schweizerisches Heilmittelinstitut / Swiss Agency for Therapeutics products

Contact Name 2

Medical Devices Department

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Email Department

clinicaltrials.devices@swissmedic.ch

Address

Hallerstrasse 7

ZIP/City

3000 Bern 9

Country

Switzerland (CH)

Web address

<http://www.swissmedic.ch/>

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)/ For certain types of MDs
Ethics committee(s)
Other

CA - Submission for authorisation mandatory for

Clinical trials on Medical Devices of category C (pursuant to Art 20 KlinV/ClinO)/
see also 'Additional Information'

CA - Registration/ notification without approval required for

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CA - Submission required to

—

CE-marked MD used within label are exempted from any notification obligation to CA

Yes

National trial registry - Registration mandatory

Yes

National trial registry

All clinical trials need to be registered in a national registry (Art. 64-67 KlinV/ClinO).

An official portal is expected to be available by the end of 2015; entries in www.clinicaltrials.gov will continue to remain acceptable in Switzerland.

More information is provided on the kofam website of FOPH (Email: [kofam\(at\)bag.admin.ch](mailto:kofam(at)bag.admin.ch))

Applicable national legal framework/ Reference

Art. 20 + 30 KlinV/ClinO

Additional Information

Clinical trials of medical devices are categorised into A or C according to Art. 20 KlinV/ClinO as follows:

Clinical trials of medical devices come under Category A if:

- a. the medical device bears a conformity marking; and
- b. it is used in accordance with the instructions.

2 They come under Category C if:

- a. the medical device does not have a conformity marking;
- b. it is not used in accordance with the intended purposes recognised in the conformity assessment and specified in the instructions; or
- c. use of the medical device is prohibited in Switzerland.

Category A trials are exempt from submission obligation (Art. 30 KlinV/ClinO).

NB! Special submission requirements apply to clinical trials on:

(1) Gene therapy/ GMO clinical trials: Additional application documents for Category B and C clinical trials of gene therapy and of genetically modified or pathogenic organisms are required and provided in Annex 4(4) KlinV/ClinO. Further respective guidelines, checklists and standard forms are provided on the Swissmedics website in section: Licenses > Clinical trials > Clinical trials on transplant products / gene therapy / genetically modified organisms.

(2) Radioactive substances, with regard to radiological protection for trial participants: The sponsor must submit the trial to the CA, the EC and, in addition, to the Radiological Protection Division of the Federal Office of Public Health (FOPH).

Additional application documents for clinical trials of therapeutic products capable of emitting ionising radiation are required and provided in Annex 4(5) KlinV/ClinO.

(3) Combination trials on IMP(s) and transplant products (organs, tissues, cells) must also be additionally submitted to the BAG. Details for submission can be found on their website.

Submission to CA and EC to be performed in the following order

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Responsible for study submission

Sponsor

Legal representative domiciled in the respective country

Entitled to study submission

—

Prerequisites for submission

—

Guidance on submission of application

A detailed "Medical Devices Information Sheet" (BW101_50_002e_MB Clinical trials of medical devices: Authorisation, notifications and reports) including the required documentation for submission is provided for sponsors, investigators and research institutions in various languages on the Swissmedic website in section:

Medical devices > Regulatory aspects and placing on the market > Clinical trials

Submission of
Application

	<p>Applicable national legal framework/ Reference</p> <p>Art. 31 and Appendix 4 (3) KlinV/ClinO.</p> <p>Additional Information</p> <p>NB! Combined trials (medical device & IMP) must be reviewed by Swissmedic as IMP/transplant product trials and also as MD trials. The requirements for both trials must be met and two separate dossiers (full documentation as well as the complete application form, including electronic copy) must be submitted to the corresponding department of the CA.</p> <p>The explicit submission procedure depends on the licensing status of both the IMP and MD and is specified in the "Information Sheet FAQ" (Q&A related to clinical trials with medicinal products), published on the Swissmedic website in section: Home > Licensing > Clinical trials > Clinical trials on medicinal products > Q&A and important links</p>
Submission Format	<p>Format option(s)</p> <p>Paper hardcopy Data carrier (CD-rom/DVD)</p> <p>Preferred format</p> <p>Paper (one copy), in a green ring binder. an additional electronic copy of the documentation can expedite processing and is accepted by Swissmedic.</p> <p>Standard application form</p> <p>Form BW101_50_001e_FO (Clinical trials of medical devices: Application for authorization)</p> <p>Guidance on submission format</p> <p>Standard form and detailed information sheet on submission format is available on the Swissmedic website in section: Medical devices > Regulatory aspects and placing on the market > Clinical trials</p>
Language of Submission	<p>Language(s) of application</p> <p>Regional language(s) English</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Partly, not for all documents</p> <p>Documents mandatory to be in official national language</p> <p>—</p> <p>Documents mandatory to be in local language of study site</p> <p>Protocol Summary Information material, Documents and Forms intended for study participants and patient information</p> <p>Documents mandatory to be in language of the study participant</p> <p>—</p>
Submission Fees	<p>Fees for trial submission mandatory</p> <p>Yes</p>

Fees

All-inclusive rate for evaluation of a clinical trial with medical device:
1000.- CHF

Additional workload caused by shortcomings regarding the documentation will also be invoiced if the amount is substantial: + 200.- CHF per hour).

Waiver for academic (non-commercial) studies possible

No

Applicable national legal framework/ Reference

Heilmittel-Gebührenverordnung, HGebV (Ordinance on Fees) levied by the Swiss Agency for Therapeutic Products (Appendix 3), version dated 01.01.2013

Timelines Authorisation**General timespan (max nr days)**

30

Mode of approval (General)

—

Clock-stop possible if complementary information requested

Yes

Timespan counted from

Confirmation of formal completeness

Applicable national legal framework/ Reference

Art. 33-34, 36 KlinV/ClinO

Additional Information

The CA shall notify the sponsor of receipt of application or of any formal deficiencies within 7 days.

Authorisation timelines: Extension to 60 days possible in specific cases: first-in-man trials, manufacturing using a new procedure, devices capable of emitting ionising radiation

Swissmedic notifies relevant ECs and other concerned CAs of its decision.

**Amendments/
Substantial
Amendments (SA)****Notification mandatory for**

—

Authorisation mandatory for

—

Responsible for submission of SA

—

Timeline for approval of SA (max nr days)

30

Applicable national legal framework/ Reference

34 KlinV/ClinO

Additional Information

The Agency informs the responsible EC and other competent cantonal authorities of its decision.

Other amendments must be declared to the CA, but do not require explicit approval by the CA.

Cave: Some of them require explicit approval by the EC according to Art. 29 KlinV/ClinO.

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

—

Reportable AEs

All serious and obviously not (device- or procedure-) unrelated AEs occurring in a Cat. C clinical trials with MD (observed in or outside Switzerland)

SUSAR being life-threatening or leading to death must be reported

—

All other SUSARs

—

SAE /SADE must be reported

Within 7 days + Within 2 days if the safety of other study participants is at stake

National standard reporting form available

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Standard Reporting Form

A standard reporting form for national incidents and serious and obviously unrelated AEs occurring in a Swiss trial center ("Safety issues and serious adverse events in Switzerland") is available on the website in various languages in section: Licensing > Documents and Forms > Clinical trials: SAE Clinical Trials MEP.

For SAEs in multi-center studies: the Excel table in accordance with the MEDDEV Guideline 2.7/3 must also be submitted.

Reporting format - Options

—

Preferred format

—

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA

Applicable national legal framework/ Reference

Art 42 + 43 KlinV/ClinO

	<p>Additional Information</p> <p>For SAEs occurring in clinical trials of Cat. A ('Vigilance cases'), the sponsor is subject to the notification requirements specified in Art. 42 (3) KlinV/ClinO and Art.15 (1) MepV. Detailed information is provided in MEDDEV 2.12/1 and on the Swissmedic website in section Medical Devices > Materiovigilance</p> <p>Investigator shall report SAE to</p> <p>—</p> <p>Reporting timeline</p> <p>—</p>
End of Trial	<p>End of trial declaration mandatory for</p> <p>All clinical investigations requiring authorisation by CA</p> <p>Responsible for End of trial declaration</p> <p>Sponsor</p> <p>Regular Termination - Declaration timespan (max nr days)</p> <p>90</p> <p>Timespan counted from</p> <p>—</p> <p>Early/premature Termination - Declaration timespan (max nr days)</p> <p>7 (interruption for safety reasons) / 15 (for other reasons)</p> <p>Applicable national legal framework/ Reference</p> <p>Art. 37 + 38 KlinV/ClinO</p> <p>Additional Information</p> <p>A fundamental definition for the end of the trial should be explicitly mentioned in the trial protocol. It is usually the date of the final visit by the final trial participant: LPLV (last patient, last visit).</p>
Additional Information & Specifics	<p>Additional Information</p> <p>Useful information for sponsors, investigators or research institutions conducting clinical trials with medicinal products in Switzerland is available in German, French, Italian and English on the Swissmedic website in section: Licences > Clinical trials > Clinical trials on Medical Devices</p>

Ethics committee

Contact Details	<p>Contact Name 1</p> <p>Swissethics- Schweizerische Ethikkommissionen für die Forschung am Menschen / Swiss Association of Ethics Committees for research on humans</p> <p>Contact Name 2</p> <p>Geschäftsstelle Swissethics/AGEK (Arbeitsgemeinschaft der Schweizer Ethikkommissionen)</p> <p>Address</p> <p>Haus der Akademien - Laupenstrasse 7</p> <p>ZIP/City</p> <p>3008 Bern</p> <p>Country</p> <p>Switzerland (CH)</p>
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E-Mail

info@swissethics.ch

Web address

http://www.swissethics.ch/eks_e.html

Additional Information

The Swiss Ethics Committees on research involving humans have formed a joint working group (swissethics). Swissethics is organised as an association, its members are all the recognised regional/cantonal ethics committees of Switzerland.

Ethical Review – General**Submission for Ethical review mandatory for**

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Submission to CA and EC to be performed in the following order

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Additional Information

A positive vote from the EC is mandatory for all clinical projects. Some of the recognized Cantonal ECs are competent for several cantons. The competent Cantonal EC can act as local EC in a single-centre trial or as lead EC in a multi-centre trial.

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)/ For certain types of MDs
Ethics committee(s)
Other

**Single-Centre Studies -
Ethical Review****Ethical approval (favourable opinion) to be obtained from**

Cantonal EC being competent for the respective trial site

Additional Information

The study dossier shall be submitted to the responsible Cantonal EC according to Art. 24 KlinV/ClinO.
The area of competence of the Cantonal ECs (EC can be competent for more than one Canton) are provided on the Swissethics website.

**Multi-Centre Studies -
Ethical Review****Ethical approval (favourable opinion) required from**

Lead EC (authorised to issue a single opinion)

Submission of application required to

Lead EC + All concerned local ECs for site-specific assessment

Additional Information

In multi-centre studies, the coordinating investigator or the sponsor submits the study dossier to the lead ethics committee (responsible ethics committee of the canton at the site of activity of the project coordinator (HRA Art. 47). The lead EC checks formal completeness and informs applicant. Applicant submits clinical trial dossier to all local Cantonal ECs responsible at other trial sites. The cantonal ECs evaluate local items only (e.g. adequate qualification of the investigator, infrastructural requirements, acceptance by the local community) and inform the lead EC on their decision. The lead ECs review the complete documentation, issues its final reasoned opinion on the clinical trial application and communicates its decision to the applicant, the local ECs concerned and to the CA (in case of Cat B and C trials). The local ECs can accept or refuse this decision or eventually add locally determined minor supplements.

Additional trial sites must be submitted to the local EC(s). (Art. 27 KlinV/ClinO).

Submission of Application

Responsible for study submission

Sponsor

Entitled to study submission

Sponsor
Principal Investigator

Prerequisites for submission / approval

—

Additional Information

The applicant (Sponsor or Coordinator) will be the primary contact person for further communication.

!NB: Specific submission requirements apply to clinical trials involving radiation sources pursuant to Art. 28 KlinV/ClinO:
Additional documents as specified in Annex 3 (5) KlinV/ClinO have to be submitted to the EC by the investigator.
The FOPH shall deliver an opinion on compliance with radiological protection legislation and on the dose estimation which have to be considered by the EC granting authorisation.

Submission Format

Format option(s)

Depending on the Cantonal EC: usually via post on data carrier (CD/USB stick) + x copies in paper format.

Preferred format

BASEC (new web portal): in use since November 2015; Mandatory from 1st of January 2016

Online portal

Starting from November 2nd 2015 all new projects should be submitted through the web-portal. As of January 1st 2016 the online-submission is mandatory and replaces all former submission methods (paper, CD, other storage devices). Please use these former submission methods for amendments and additions to old projects until December 31 2015; from January 1st 2016 the web-portal will also be compulsory for old projects.

Standard application form available

Yes

Standard application form

The standard form ("Basisformular") and checklist to be bindingly used for submission to the competent EC(s) is available on the Swissethics website in section "Templates".

Use of standard application form binding

Yes

Guidance on submission format

The required application documents for trials with medical devices are provided in Appendix 3 KlinV/ClinO.

They must always be co-signed by the investigator if the sponsor is the applicant.

Further relevant forms, guidelines and checklists for submission are published on the Swissethics website.

Additional Information**Language of Submission****Language(s) of application**

Regional language(s)

English

Preferred language of application

—

English accepted

Partly, not for all documents

Documents mandatory to be in official national language

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Documents mandatory to be in local language of study site

Protocol Summary

Information material, Documents and Forms intended for study participants and patient information

Documents mandatory to be in language of study participant

—

Additional Information

Regional languages in Switzerland: German, French and Italian.

Submission Fees**Fees for Ethical review mandatory**

Yes

Waiver for academic (non-commercial) studies possible

Yes

Fees for Ethical review

The fees charged by the EC for trial evaluation depend on the Cantonal EC concerned and the study type: e.g.

Lead EC review for industry sponsored projects: up to CHF 7,000

EC review for mono-centre, industry sponsored projects: up to CHF 6,000

Simplified procedure for Cat A trials: CHF 500, up to 5000

(for industry sponsored projects)

Amendments: CHF 200-3000

Non-commercial projects that are only sponsored by the investigator or by non-profit organisations: reduction or waiver is possible.

Additional Information

Each Swiss Canton regulates financing of its competent EC and, therefore, determines its separate charging rates, resulting in wider variations (Art 54 (5) HRA). The particular fees can be found on the websites of the respective ECs.

General timespan for single-centre studies (max nr days)

30

General timespan for multi-centre studies (max nr days)

45

External expert advice required: Timespan (max nr days)

—

Clock-stop possible if complementary information requested

Yes

Timespan counted from

—

Applicable national legal framework/ Reference

Single-centre studies: Art. 26 KlinV/ClinO

Multi-centre studies: Art. 27 KlinV/ClinO

Trials involving radiation sources: Art 28 KlinV/ClinO

Additional Information

The lead EC / local EC shall acknowledge receipt of the application within 7 days and notify the applicant (the (coordinating) investigator or sponsor) of any formal deficiencies.

1. Single-centre studies: Local EC informs applicant on its final decision (plus the CA in case of Cat C clinical trials).

2. Multi-centre studies:

the local ECs shall reach a decision on the trial sites within 15 days upon receipt of the application documents and communicate them to the lead EC. Lead EC informs applicant on its final decision (plus concerned local ECs in case of multi-centre trials as well as the CA in case of Cat C clinical trials).

3. Trials involving radiation sources:

Local EC shall issue a reasoned opinion within 45 calendar days of acknowledgement of receipt of the formally correct application dossier; local EC shall inform the FOPH of its decision.

Amendments/
Substantial
Amendments (SA)

Ethical review mandatory for

Any substantial amendments

Responsible for notification of SA

Investigator

Standard notification form available

Yes

Standard notification form

Submission via the new web portal BASEC

Timeline Ethical review of SA (max nr days)

30 (local EC) + 45 (lead EC)

Guidance on submission of SA available

Yes

Guidance on submission of SA

Detailed Guidance to the use of the new web portal BASEC is available on the website of Swissethics.

Please use these former submission methods for amendments and additions to old projects until December 31 2015; from January 1st 2016 the web-portal will also be compulsory for old projects.

Applicable national legal framework/ Reference

Art. 29 KlinV/ClinO

Additional Information

CAVE: The definition of substantial amendments for ECs is different to the definition for CA!

Other changes must be notified to the EC in the annual safety report.

Safety Reporting**Reportable AEs**

SAE + SADE occurring in a Cat. C clinical trial in Switzerland

Investigator shall report SAE to

—

Reporting timeline

—

Responsible for AE reporting to relevant EC(s)

Investigator

SUSAR being life-threatening or leading to death must be reported

—

All other SUSAR must be reported

—

SAE/SADE must be reported

Immediately (without delay)

Within a max of 2d upon first knowledge

Within a max of 7d upon first knowledge

National Standard Reporting form available

Via web portal BASEC (mandatory to use from 1st January 2016)

Reporting format - Options

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Preferred reporting format

Online portal

Online Safety Reporting Portal

Starting from November 2nd 2015 all new projects should be submitted through the web-portal. As of January 1st 2016 the online-submission is mandatory and replaces all former submission methods (paper, CD, other storage devices). Please use the former submission methods for amendments and additions to old projects until December 31 2015; from January 1st 2016 the web-portal will also be compulsory for old projects.

Provision of Annual safety report mandatory

Yes

Applicable national legal framework/ Reference

Art. 42 KlinV/ClinO

	<p>Additional Information</p> <p>SAE/ SADE must be declared within:</p> <ul style="list-style-type: none"> - 7 days if it cannot be excluded that the events are attributable to the MD or a trial-related intervention - 2 days if the safety of study participants is at stake. <p>In multi-centre trials, the Coordinating Investigator shall also notify all responsible ECs concerned.</p>
End of Trial	<p>End of trial Declaration mandatory</p> <p>Yes</p> <p>Responsible for End of trial Declaration</p> <p>Investigator</p> <p>Regular Termination - Declaration timespan (max nr days)</p> <p>90</p> <p>Timespan counted from</p> <p>—</p> <p>Early/premature Termination - Declaration timespan (max nr days)</p> <p>2 (interruption for safety reasons) / 15 (for other reasons)</p> <p>Reasons for early termination shall be clearly stated</p> <p>Yes</p> <p>Standard Declaration form</p> <p>A standard trial termination form to be used for declaration to the EC is available on the Swissethics website in section: Templates.</p> <p>Applicable national legal framework/ Reference</p> <p>Art 37 + Art. 38 KlinV/ClinO</p> <p>Additional Information</p> <p>A fundamental definition for the end of the trial should be explicitly mentioned in the trial protocol. It is usually the date of the final visit by the final trial participant: LPLV (last patient, last visit).</p> <p>Multi-centre trials: In case of an interruption or premature termination of at one of the trial site, the coordinating investigator informs the responsible EC concerned.</p>
Additional Information & Specifics	<p>Additional Information</p> <p>(1) Templates for EC: The use of the templates and standard forms provided on the Swissethics website in section Templates is binding for both applicants and ECs! (2) Since 1.1.2014, it is the AGEK's responsibility (used to be Swissmedic's) to validate GCP courses and to assess the required qualification of the Principal Investigator. A "List of recognized GCP course providers" is available on the Swissethics website in section: Aus-, Fortbildung.</p>

Study specific Requirements

Study Participants - Informed Consent (IC)	<p>Standard IC form (ICF) available</p> <p>Not specified</p> <p>Standard ICF - Additional Information</p> <p>A detailed guidance for the preparation of appropriate written patient information material and Informed Consent Forms are provided on the Swissethics website in section Templates > Study information and Informed Consent for Research Projects in Humans (HRA 7,16).</p>
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Informed Consent - Definition/ Requirements

Informed consent of study participants must be obtained in writing before (exemptions possible) the commencement of a clinical trial .
The persons concerned must receive comprehensible oral and written information on the nature, purpose, duration, procedures, foreseeable risks, burdens and expected benefits of the research project as well as the measures taken to protect the personal data collected and their rights.

The trial participants must be given an appropriate reflection period (Art 16 HRA; Art 7-9 KlinV/ClinO).

Applicable national legal framework/ Reference

Art 7-9 KlinV/ClinO, 16-18 HRA

Additional Information

Specific provisions apply to vulnerable groups of persons (Art 11 and 21-31 HRA; and 15-17 KlinV/ClinO) as well as for research on imprisoned persons (Art 28-29 HRA).

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

—

Specific provision

Studies with minors (children and adolescents < age of 18) are possible under special provisions (Art 11, 21-23 HRA).

Legal framework/Reference (Minors/Children)

Art 11, 21-23 HRA

A detailed guidance for research with minors, a related checklist and template for Informed Consent Form are provided on the Swissethics website in section Templates > Research with Children.

An interesting opinion on research involving children has been published by the Swiss National Advisory Commission on Biomedical Ethics NEC-CNE – Zur Forschung mit Kindern, Nr. 16/2009 (English: NEC-CNE - Research involving children (en), Nr. 16/2009).

Incapacitated persons - Studies allowed

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Specific provisions

Studies including incapacitated persons are possible under special provisions (Art 11, 21, 24 HRA)

Emergency situations - Studies allowed

—

Specific provisions

Studies with participants being in emergency situation are possible under special provisions (Art 11, 30, 31 HRA; Art 15-17 KlinV/ClinO).

Emergency situation without prior consent of patient or proxy - Studies allowed

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Conditions allowing trial participation in emergency setting without prior consent

Human Research Act: Art. 31 Post hoc or proxy consent

"1 The person concerned must be duly informed about the research project as soon as this becomes possible. He or she may subsequently give or withhold consent.

2 If the person concerned refuses to give post hoc consent, the biological material and data may no longer be used for the research project.

3 The Federal Council shall specify the procedure for the procurement of post hoc or proxy consent, in particular with regard to the involvement of children, adolescents and adults lacking capacity."

Pregnant or breastfeeding women - Studies allowed

—

Specific provisions

Studies with pregnant women (and IVF Embryos and Foetuses) are possible under special provisions (Art 11, 25-27 HRA).

No explicit provisions are provided for breast-feeding women.

Data Protection**Notification to DP Authority/ Ombudsmann is mandatory**

No

Approval/ authorisation required

Not specified

Specific notification timelines before operations start

—

Language of notification

—

Notification format

—

Data Protection Authority/ Agency - Contact Details

Federal Data Protection and Information Commissioner –FDPIC

Web address

<http://www.edoeb.admin.ch>

Additional Information

Data protection is safeguarded by the Federal Act on Data Protection (Bundesgesetz über den Datenschutz- DSG; SR 235.1).

Clinical trial related Data Protection issues are explicitly covered in Art. 57-61 HRA and Art 17-18 KlinV/ClinO.

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

—

Insurance**Liability insurance or alternative arrangements for damages mandatory for**

Investigator(s)
Study participants

Responsible for covering insurance

Sponsor

Minimum coverage sum

The defined policy values for liability coverage are at least: Cat A trials: Entire trial: CHF 3 000 000.- Per person: CHF 250 000.- All other clinical trials: Entire trial: CHF 10 000 000.- Per person: CHF 1 000 000.-

Applicable national legal framework/ Reference

19 (1) HRA;
Art 11-13, Annex 2 and 14 KlinV/ClinO

Additional Information

The liability coverage must cover damage occurring up to ten years after the completion of the clinical trial (extension of this period is attributable to the use of ionising radiation and GMOs).

Exemptions from liability coverage requirements in relation to clinical trials are attributable in special cases such as low- risk Cat A trials.

The insurance certificate needs to be sent to the EC.
The General Insurance Conditions (GIC) and a master Certificate of Insurance is provided on the Swissethics website in section Templates > Insurance.

Archiving & Data
Management

Study documents must be kept at least (in years)

15

Applicable national legal framework/ Reference

Art. 45 KlinV/ClinO

Additional Information

Clinical trials with transplant products and blood products: at least 20 years (according to Art 40(1) TPA)

National legislation

Investigations on
Medical Devices

Applicable national regulations

General Act(s) on Medical/Clinical Research in Humans
National Act on Medicinal Products and Medical Devices
Other

Act on Medical Devices (or comparable national legal framework)

1.
Heilmittelgesetz (HMG), Bundesgesetz über Arzneimittel und Medizinprodukte, SR 812.21 (2000)/
Therapeutic Products Act (TPA), Federal Act on Medicinal Products and Medical Devices (NB: en, non-official translation)

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

1. Humanforschungsgesetz (HFG), Bundesgesetz über die Forschung am Menschen, SR 810.30 (2011)
Human Research Act (HRA), Federal Act on Research involving Human Beings (NB: en, non-official translation)

2.
The Federal Council has approved three ordinances on the law on research involving humans, effective as from 01.01.2014:
(1) Verordnung über klinische Versuche (KlinV), Verordnung über klinische Versuche in der Humanforschung, SR 810.305 (2013) / Clinical Trials Ordinance; ClinO (NB: en, non-official translation)
NB: KlinV/ClinO is also applicable to Gene Therapy trials; however, it does not consider clinical trials on vital organs, tissues or cells of human or animal origin including ex-vivo gene therapy!
(2) Organisationsverordnung HFG (OV- HFG); Organisationsverordnung zum Humanforschungsgesetz; SR 810.308 (2013) / HRA Organisation Ordinance (OrgO-HRA) (en, non-official translation)
(3) Humanforschungsverordnung (HFV); SR 810.301 (2013) / Human Research Ordinance (HRO) (NB: en, non-official translation)

3.
Medizinprodukteverordnung MepV

Combination Studies (IMP&MD)**Applicable national regulations**

One legal act for both study types available

Legal act applicable to both study types

Heilmittelgesetz (HMG), Bundesgesetz über Arzneimittel und Medizinprodukte, SR 812.21 (2000)/
Therapeutic Products Act (TPA), Federal Act on Medicinal Products and Medical Devices (NB: en, non-official translation)
NB: HMG/TPA is also applicable to Gene Therapy trials

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

Humanforschungsgesetz (HFG), Bundesgesetz über die Forschung am Menschen, SR 810.30 (2011)
Human Research Act (HRA), Federal Act on Research involving Human Beings (NB: en, non-official translation)

Radiation & Radiotherapy**Use of radiation or radioactive compounds - Specific requirements**

Yes

Applicable legal framework

Applicable to trials with radioactive substances (in addition):
Strahlenschutzgesetz (StSG); SR 814.50 (2007)
Radiological Protection Act (RPA) (NB: en, non-official translation)
Strahlenschutzverordnung (StSV), SR 814.501 (1994, as amended)
Radiological Protection Ordinance (RPO) (en, non-official translation)

Additional Information

Radioactive substances, with regard to radiological protection for trial participants: The sponsor must submit the trial to the CA, the EC and, in addition, to the Radiological Protection Division of the Federal Office of Public Health (FOPH). Additional application documents for clinical trials of therapeutic products capable of emitting ionising radiation are required and provided in Annex 4(5) KlinV/ClinO.

Definition**MD/MD Investigation****MD - Definition available in national law**

Yes

MD - Definition

“Medical Devices” are defined pursuant to Art. 4 (1b) TPA as follows:

“...products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medical use and whose principal effect is not obtained with a medicinal product.”

Investigation of MD - Definition

Clinical Trial categories with MD pursuant to Art.20 KlinV/ClinO as of 01-01-2014:

- Cat A: Trials with medical devices bearing conformity marking and used in accordance with the instructions.
- Cat. C: Trials with medical devices not having a conformity marking and not used in accordance with the intended purposes recognised in the conformity assessment and specified in the instructions; or the use of the medical device is prohibited in Switzerland.

Additional Information

The website of KOFAM (Koordinationsstelle Forschung am Menschen) provides a tool for assessing the category of a trial. The EC (not Swissmedic!) is responsible to check if the category is correct.

KOFAM: <http://www.kofam.ch/en/home/>