Nutrition/Interventional - SWITZERLAND

Competent authority

Contact Details

Contact Name 1

Swissmedic - Schweizerisches Heilmittelinstitut / Swiss Agency for Therapeutics products Clinical Trials Division

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Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Institutional Ethics Committee
Regional Ethics Committee
National Ethics Committee

Regulatory and ethics bodies involved in approval process for trials including patients

–

Regulatory and ethics bodies involved in approval process for trials including including healthy participants

–

Regulatory and ethics bodies involved in approval process for trials including vulnerable population

–

CA - Registration/ notification without approval required for

–

CA - Registration requirements for clinical trials

Registration mandatory

Registration requirements for clinical trials including patients

–

Registration requirements for clinical trials including healthy participants

–

Registration requirements for clinical trials including vulnerable population

–

CA - Submission required to

Institutional CA

Studies including patients - submission required to

–

Studies including healthy participants - submission required to

–

Studies including vulnerable population - submission required to

–

Language of Submission

Language(s) of application

English

Language(s) of application for trials including patients

–

Language(s) of application for trials including healthy participants

–

Language(s) of application for trials including vulnerable population

–

Preferred language of application

–

English accepted

Yes

Documents mandatory to be in official national language

–

Documents mandatory to be in local language of study site

–

Documents mandatory to be in language of the study participant

–

Safety Reporting

Sponsor must declare reportable events to

–

Ethics committee

Contact Details

Contact Name 1

Swissethics- Schweizerische Ethikkommissionen für die Forschung am Menschen / Swiss Association of Ethics Committees for research on humans

Contact Name 2

Geschäftsstelle Swissethics/AGEK (Arbeitsgemeinschaft der Schweizer Ethikkommissionen)

	Phone 041 440 26 67 **Address** Haus der Akademien - Laupenstrasse 7 **ZIP/City** 3008 Bern **Country** Switzerland (CH) **E-Mail** info@swissethics.ch **Web address** http://www.swissethics.ch/ **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. List of all Ethics Committees in Switzerland: http://www.swissethics.ch/eks.html
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory for trials including patients** Yes **Submission of study mandatory for trials including healthy participants** Yes **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** Yes
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Institutional EC **Ethical approval (favourable opinion) for trials including patients to be obtained from** – **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** –

	Ethical approval in trials including patients obtained from – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** –
Submission of Application	**Entitled to study submission** – **Entitled to submission of trials including patients** Principal Investigator Investigator Physician PhD **Entitled to submission of trials including healthy participants** Principal Investigator Investigator Physician PhD **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** –
Language of Submission	**Language(s) of application** English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 2

	Time in weeks from submission to positive approval (maximum) 8 **Time in weeks from submission to positive approval (average)** 5
Safety Reporting	**Investigator shall report SAE to** Institution Sponsor **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Sponsorship mandatory in trials with patients** Yes **Sponsorship mandatory in trials with healthy participants** Yes **Co-sponsorship allowed in trials with patients** Yes **Co-sponsorship allowed in trials with healthy participants** Yes
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **Accepted format of Informed Consent (IC) form** – **Accepted format of IC form for studies including patients** Written consent **Accepted format of IC form for studies including healthy participants** Written consent **Accepted format of IC form for studies including vulnerable population** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** Yes

	Applicable ethical regulations –
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** – **Reimbursement for patients** Mandatory **Reimbursement for healthy participants** Optional **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** – **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** –
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Obligation to contract a liability insurance for trials including patients for** Patients/Volunteers **Obligation to contract a liability insurance for trials including healthy participants for** Patients/Volunteers **Obligation to contract a liability insurance for trials including vulnerable population for** – **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** – **Regularly performed methods in trials including patients** Audits Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF)

Regularly performed methods in trials including healthy participants

Audits
Monitoring
Standard Operating Procedures (SOP)
Case Report Form (CRF)

Regularly performed methods in trials including vulnerable population

–

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

–

Regularly performed audits in trials including vulnerable population

–

Additional Information

internal audits are regularly performed in interventional trials in patients and in healthy participants

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

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Applied regulatory conventions in studies including patients

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)

Applied regulatory conventions in studies including healthy participants

Declaration of Helsinki
ICH-GCP Guidelines
Other guidelines for good clinical practice (other than ICH-GCP)

Applied regulatory conventions in studies including vulnerable population

–

Applicable national laws

–

Applicable national laws for patients

–

Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

–

National regulations for volunteers exist for

–

Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted in trials including patients** Yes **Tissue samples permitted in trials including healthy participants** Yes