Essential Information on Clinical Studies

What interested people – patients, parents or friends – would like to know about clinical studies.
Introduction

Choosing whether to take part in a clinical study is an important personal decision. The following questions and answers provide some information that may help you. Before deciding whether to take part in a study, you may want to discuss personally with your treating physician, family, friends or with a representative of a patient association. The next step is for you and your treating physician to contact the study doctor and ask for more specific information.

This brochure is meant for people either patients, parents or friends, men or women, interested in learning more about clinical trials on drugs in Switzerland.
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1 | What would make me consider a participation of a clinical study?

Taking part in a **clinical study** means playing an active role with regard to your health and potentially having access to new treatments before they are made available to anyone else. It also means contributing to scientific research and helping people who are affected by the same disease not only in Switzerland but also all around the world. You should consider that the benefits of the experimental treatment may not have been demonstrated before and you may therefore not take any personal benefit in participating in the study.
2 | Where can I find information on clinical studies in Switzerland?

Sponsors of studies report essential information on publicly available websites meant for interested people and health care professionals.

http://kofam.ch is the Federal Office of Public Health’s (FOPH) portal for human research in Switzerland.¹ On this website you will find information on all conducted studies in Switzerland as well as on the regulation of human research in Switzerland.

Another website https://clinicaltrials.gov is an international registry and results database of publicly and privately supported clinical studies of human participants conducted around the world owned by the American National Institute of Health.²

On both websites, the information is regularly updated. It is therefore recommended to perform regular searches. Your treating physician will support you in addressing any question you might have. If needed, your physician may reach out directly to the sponsor of the study for further information.
3 | What is a clinical interventional study?

According to the Federal act on research involving human beings (HRA), a clinical study is a research project on persons requiring the participants to have an active role toward the study. Clinical studies can also be called interventional studies as they aim at assessing the effect of the health-related intervention (medicinal product, medical device, irradiation or surgery) on a medical condition.

Clinical studies are opposed to two other types of research studies:

1) observational studies in which persons are observed during routine management in the health care system and

2) research projects that are based on health-related data and/or biological material with no involvement of the people they belong to.

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<tr>
<th>Clinical study</th>
<th>Observational study</th>
<th>Research project</th>
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<td>Evaluation of health-related intervention</td>
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<td>Evaluation of routine disease management</td>
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<td>Evaluation of collected health-related data and/or sample</td>
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4 | What are the aims of an interventional clinical study?

Clinical research is the second step of the development path which leads to the validation of a new treatment. Research starts in laboratories (basic research), where a compound is studied in cell lines and animals in order to assess its efficacy and safety. Only when this phase is successfully completed, the experimental treatments with the most promising laboratory results may go to the second step consisting in clinical interventional studies in humans. Over the clinical development, increasing amounts of information are collected on the experimental treatment, its risks and how effective (or ineffective) it is. While the safety of a drug is measured by laboratory tests, imaging tests and functional tests, the efficacy of a drug is assessed via different measures that are specific to the medical indication in which the drug is developed.

When a compound enters clinical development, limited information is available. Therefore the development of a medicine requires a stepwise progression through four different phases. Each phase has a different purpose and helps researchers to answer different questions.

The study aims at answering scientific questions such as:

- What is the dose of the experimental treatment associated with a change in the disease?
- Does the experimental treatment affect a given aspect of the disease (improving or worsening)?
- How tolerable is the experimental treatment?
- Is the experimental treatment associated with adverse events?
5 | What are the different phases of clinical development?

The clinical development of a drug in a common disease is the following:

In **phase I** studies, researchers study an experimental treatment for the first time on a small group of people (20–80) to evaluate how it is absorbed, distributed, transformed and eliminated by the body, in order to identify the optimal route of administration and dose. At this stage, the subjects of the study are usually healthy volunteers.

In **phase II** studies, the experimental treatment is administered to a larger group of people (100–300) to check the efficacy and further evaluate the safety of use. From this phase onwards, the subjects of the study are patients who suffer from the disease for which the medication is being developed.

In **phase III** studies, the experimental treatment is administered to much larger groups of patients (1000–3000) to confirm its efficacy, monitor the side effects, compare it to a comparator, commonly-used treatments or placebo, if there are no available treatments in clinical practice, and collect information that will allow the medicine or treatment to be used in the most beneficial way to the patient.

**Phase IV** studies are conducted after marketing authorization has been granted and are used to obtain additional information on the risks, benefits or optimal use of the medicine.
The clinical development of a drug in a rare disease may be slightly different. Phase I studies may be conducted in patients and not in healthy volunteers as the balance of the risks and benefits may be different for patients affected by an invalidating chronic disease with no therapeutic option. In clinical trials conducted in patients with rare diseases, the number of participants may be lower and some phases may be combined.
6 | Who are the authorities assessing if the study can be conducted in humans?

Clinical research in Switzerland is subjected to obligations stipulated by international guidelines and by federal and cantonal regulations. These regulations provide public assurance that the rights, safety and well-being of participants are protected and that data collected are reliable. All involved parties are obliged to strictly adhere to these regulations.


The same principles have been implemented in the federal legislation. The Swiss law regulating clinical research in human beings (Federal act on research involving human beings, HRA) and its applicable ordinance were introduced in 2011 and reviewed in 2014.

The ordinance on organisational aspects of the human research act regulates the functioning of the independent bodies, named...
ethics committees. Ethics committees are constituted of medical/scientific professionals and other non-medical/non-scientific professionals, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial.

In Switzerland, ethics committees are under the responsibility of the cantons and exercise their authority in their respective canton/region in coordination with the other involved ethics committees for multicentric clinical studies.

Swissmedic, the Swiss agency for therapeutic products, is the Swiss authority attached to the Federal Department of Home Affairs, responsible for the authorization and supervision of therapeutic products, assessing the quality, safety and efficacy of medicinal products and medical devices. Swissmedic registers, validates and monitors all the clinical studies.

A clinical study can only be conducted in Switzerland when both, relevant ethics committees and Swissmedic approve the clinical trial application. Since the introduction of the new online portal for submission to ethics committees, BASEC (Business Administration System for Ethics Committees) in 2016, approved studies are automatically published on the Federal Office of Public Health’s portal for human research in Switzerland http://kofam.ch.
7 | What information should I know about the study?

Important information concerns all aspects of the study as the patient has an active role. A clinical study is a unique research project defined by specific objectives, study design, study drug (including its risks and benefits – please see question 15), study assessments (please see question 9), study population (inclusion and exclusion criteria – please see question 12). All study specific information is found in a document called study protocol available to the physician and his study team members. In order to allow a potential candidate to learn and understand about the study and formally decide on participating or not, essential information on the study, called informed consent form, is developed for the patient (please see question 11).
What are study designs?

Study design refers to the structure of the clinical study. It is determined to define the best conditions to achieve the objectives of the study answering the study questions.

The assessment of the effects of a compound may require the comparison to an inactive compound (placebo) or another drug (active comparator). In order to allow the comparison without the influence of any other factor, the patients will be randomly distributed to a treatment arm. Randomisation is the process in which patients participating in a study are randomly assigned to the experimental treatment or to a control group, placebo or active drug.

Blinded treatment is a procedure where the clinical study staff or participating patients or both do
not know which treatment has been assigned. **Single-blind** means that only the patients do not know the assigned treatment, while **double-blind** means that both the patients and investigators and, in some cases, also the data analysts, do not know the assigned treatment.

**Open label** treatment is a procedure where the clinical study staff and participating patients know which treatment has been assigned.
9 | What are study assessments?

Study **assessment** is the name of the measure assessing the effect of the study drug, such as its safety and its efficacy. Assessments comprise measures of biological parameters in the blood, in the urine or in any other biological samples. It also comprises signs collected during the physical examination, such as the blood pressure and the pulse, information collected during imaging tests such as the size of a bone, or functional tests, such as the measurement of the gait speed. The rational to use a given assessment to evaluate the efficacy of a drug in a given medical condition may be either already demonstrated or currently being investigated. The assessments and their schedule along the study are defined in the study protocol and summarized in the informed consent form developed for the patient.

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<th>Day 1</th>
<th>Day 8</th>
<th>Day 15</th>
<th>Day 22</th>
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<tr>
<td><strong>Weight</strong></td>
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<td><strong>Height</strong></td>
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<td><strong>Blood pressure</strong></td>
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<td><strong>Blood sugar levels</strong></td>
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Who are the people I am facing as participant of the study?

The study team includes the responsible physician for the study, also called the principal investigator, and his collaborators, i.e. physicians, nurses, coordinators, technicians, health care workers and social workers. The principal investigator can delegate part or all his tasks to other members of the study team but he remains responsible for the correct conduct of the trial at the site. Each of them performs specific tasks delegated by the principal investigator and act under his supervision.

The conduct of a clinical study is determined by the study protocol. The study team evaluates your state of health at the beginning of the study, provides you with specific instructions, carefully monitor and inform you during the study and may remain in contact with you even after the study has ended. Some studies require more exams and visits than you would normally undergo for your disease or specific condition. During the clinical study, you must closely collaborate with the study team to ensure the protocol is carefully followed.

An important role is played also by your treating physician who is not directly part of the study team but contributes to the correct conduct of the trial. In fact, clinical studies provide treatments for a specific period of time and for a certain disease or condition, but do not provide an extended or full health care assistance. The treating physician might see you during the duration of the trial and prescribe treatments and therapies, which should be in compliance with the study protocol. In addition, he could detect safety issues which are important for the study team to know.
Therefore, it is recommended that you discuss your participation in a trial with your treating physician and keeps him up to date on progresses of the study.

11 | How do I access key information on the study that will help me decide if I want to participate or not?

Like for any other medical procedure, the decision to participate in a study belongs uniquely to the patient capable of discernment after receiving the appropriate information. The Association of Swiss Ethics Committees on research involving humans (http://www.swissethics.ch) provides a patient information and consent form template that can be used by the sponsor and the investigator to write an informed consent form which is compliant with Swiss law. The information is developed for the potential participant, using a language that he can understand, with no technical wording, covering the following points:
Like all material related to the study, the informed consent form is reviewed and approved by the ethics committee of the canton or the region.

It is very important you take the time to address any question or doubt with the study physician or any other trustful person, treating physician, family, friends or representatives of patient organisations. If you accept to participate in the study, will you sign the informed consent form.
Can children and adolescents take part in clinical trials?

Yes, children (defined as persons up to 13 years of age) and adolescents (defined as persons from 14 to 17 years of age) can participate in clinical trials. However, they are considered as vulnerable population. In this context, the expected direct benefits as well as risks and burdens of the trials should be taken into consideration while designing the study and special attention should be paid in obtaining the consent.\(^3\)

In the case of children who are not capable of exercising judgement (neonates, infants and toddlers), the consent to participate is given by their legal representative (usually the parents or legal guardian appointed by law). The legal representative signs the informed consent form on behalf of the child.

Children up to 10 years of age, who are capable of judgement, should be verbally briefed about the study and agree to take part in the study and/or show no sign of resistance to participation, before the legal representative consents to their participation and signs the informed consent form.

Children from 11 to 13 years, who are capable of exercising judgement, should be given a verbal briefing and also written information that has been adapted to this age group’s comprehension level. Their legal representative receives all the information about the trial and signs the consent form, if the child agrees to take part in the study and/or shows no sign of resistance to participation.
Adolescents aged 14 and above receive a verbal briefing and a written information with the same content as that the one given to their legal representative, but using a more familiar form and are required to provide their consent in writing. Also the signature of their legal representative is required, if the trial entails more than minimal risks and burdens.

Can adults lacking discernment capacity participate in clinical trials?

Yes, adults lacking discernment capacity can participate in clinical trials. However, they are considered a vulnerable population, therefore, the expected direct benefits as well as risks and burdens of the trials should be taken into consideration while designing the study and special attention should be paid in obtaining the consent.³

The trial can be carried out if the concerned person has given his consent, granted while in a state of capacity and duly documented or the informed consent has been given in writing by the legal representative, a designated trusted person or the next of kin, if no documented consent of the person concerned is available. In any case it is required that the person concerned does not visibly express opposition to the trial.
12 | Am I eligible to participate in the study?

For each study, it is clearly defined in the protocol and in the informed consent form who are the eligible patients that could potentially participate. The factors that allow some people to take part in a study are called **inclusion criteria**, while those that do not allow a person to take part are called **exclusion criteria**. These criteria are based on factors such as age, sex, type and stage of the disease, previous treatments, other medical conditions and values of laboratory tests. All together inclusion and exclusion criteria define the study population. The use of inclusion/exclusion criteria is an important principle of medical research which helps protect the safety of participants and obtain reliable results. For this reason, before taking part in a trial, the criteria must be checked by the study physician.

It is important to note that inclusion and exclusion criteria are not used to discriminate participants but, instead, they are used to identify the people most suitable for the study and to protect their health. The study physician will be discussing these criteria with you in order to assess your eligibility.
13 | Can I enter a study at any time?

The entry to a clinical study is not only determined by defined inclusion and exclusion criteria but also conditioned to a given period of time. This period of time is called recruitment period. The recruitment period may depend on the sample size, the study population characteristics and on the development phase. Therefore, the recruitment period of a study with patients affected by a common disease may be shorter than the recruitment period of a study with patients affected by a rare disease. Similarly the recruitment period of a study in 65-year and older patients with decreased locomotor function may be shorter that the recruitment period of a study in 65-year and older patients with increased locomotor function. Finally, the recruitment period of a phase 3 study with thousands of participants may be longer that the recruitment period of a phase 1 study with dozens of participants. After this period is passed, entering the clinical study is no more possible.
14 | What are my rights and obligations as a participant?

Like for any medical procedure, the decision to participate belongs to the patient. No one can force you or influence you in any way. If you do not wish to participate in a study, your treating physician will inform you on the best available treatment. You can always change your mind, if you decide to participate. No explanation is required if you do not give your consent or withdraw it. You have the right to information, before the study begins, during its conduct and after its completion. It is your right to ask questions at any time to the responsible physician. His contact details are listed in the information.

If you decide to participate in the study, you will be asked to document your decision by signing the informed consent form specifically developed for that particular study. By giving your consent, you are expected to follow guidelines for your safety and your health. The study team will support you as much as possible. As a study participant, you are expected to:
• Follow the medical recommendations provided by the responsible physician and adhere to the study plan.

• Inform the responsible physician on the status of your condition and any new symptoms or new signs, until the study completion.

• Inform the responsible physician on your current treatment, including any other medication purchased without prescription.

15 | What are the benefits and risks to participate in a clinical study?

The benefits and risks to participate in a clinical study are specific to a given trial, depending on the study design, the study drug, the study population and the study assessments. The benefits of the experimental treatment may not have been demonstrated and you may therefore not take any personal benefit in participating in the study. It is however expected, that the experimental treatment may improve given aspects of your disease based on prior preclinical or clinical studies. The study might also impact other patients with the same medical condition not only in Switzerland, but also around the world.

As participant, you do not only consider the benefits but also the risks associated with the experimental treatment and any study-related procedures. The experimental treatment may be associated with an insufficient or lack of efficacy. It may also have been
associated with adverse effects reported in past human or animal studies. As the clinical development progresses, new information may become available. You will be informed in due time of any change in benefits and risks that may impact your decision to maintain your participation in the study. It is very important that you inform the study team of any change in your condition and any new symptoms or new signs. The study team will take action for you and all participants, if needed. If you suffer any damage or injury as a result of the investigational product or study related procedures, the liabilities would be covered by the sponsor’s insurance company.
16 | How is the confidentiality of my personal information ensured?

During the conduct of the study, your personal information such as your medical history and laboratory test results, will be collected. The sponsor is responsible for complying with national and international data protection directives. All personal and medical information as well as samples collected in the context of the study are encoded, which means that they are identified only by a number. It is the responsibility of the sponsor to maintain the same data protection standards for personal data and samples sent to other countries as in Switzerland.

The study may be reviewed by the approving authorities, Swissmedic or the ethics committee or by the sponsor to assess the processes ensuring your safety are respected. In case of a review, the investigator may need to grant access to your personal and medical data to the approving authorities and to the sponsor. All personnel involved in the study must observe strictest confidentiality.
17 | How are the study’s experimental and other procedures being covered?

In the light of the risks and benefits of a clinical trial, to ensure that the decision to participate is a free one, the participant is not remunerated and is not participating to the costs.

No fees can be demanded from your involvement with the study.

During the time of the study, all medical procedures that are both approved and reimbursed that are part of standard disease management, will be covered by your health insurance company or the Disability insurance (DI). All other study specific procedures will be covered by the sponsor of the study.

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<th>All treatments and procedures</th>
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<tr>
<td>Standard disease management</td>
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<td>Costs covered by the health insurance or the DI</td>
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<tr>
<td>Study specific disease management</td>
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<tr>
<td>Costs covered by the sponsor</td>
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18 | What happens if the study drug is affecting my condition?

During the time of the study treatment and until the study is completed (some include a follow up period), any change you might observe, related to your condition or not, must be reported to the study team as stated in your obligations (please see question 14). If the study drug is being administered in a blinded randomized clinical study, you will be informed of your treatment only after its completion unless a health-related event requires the unblinding of your treatment (please see question 9).

If your condition changes, the study physician may adapt your study treatment depending on the protocol, for example, by introducing rescue medications.
19 | What happens after all study data is collected?

At the end of a study, statisticians analyze the data collected during the study and establish the treatment efficacy and and safety. This information remains confidential until the study results have been publicly communicated. To learn more about study results, you may want to reach out to the study physician.

The results of the study must be submitted to the authorities (Ethics Committee and Swissmedic) which approved the study, and registered on public websites such as https://clinicaltrials.gov.

In addition, the results of the studies are published in scientific journals. Once the safety and efficacy have been demonstrated by the clinical studies, an application for market authorization can be submitted to Swissmedic, the Swiss agency for therapeutic products.
20 | What is a genetic substudy?

In DNA, genes contain information about the composition of all living organisms. DNA is identical in the majority of all human beings. However, small variations in our DNA are responsible for the differences between individuals, eye color, for example, is such a variance. The variations of DNA could also explain the different responses to any given drug, the individual risks of developing a given disease or the diverse evolutions of a given disease. Through genetic research, the sponsor studies the relationship between DNA and these individual characteristics. If a genetic substudy is conducted in a clinical trial, you will be provided with specific information on the genetic tests in the informed consent form for the genetic substudy. Therefore you will decide specifically if you want to participate or not in the genetic substudy.

Some genetic investigations are approved tests which results may lead to the diagnosis of a disease, the assessment of a risk or the modification to your current treatment. In this context, the patient will have the opportunity to discuss the results with the study doctor.

Some other genetic investigations are only research tests without clinical implication. In this context, patients are not expected to derive personal benefit from these genetic tests. However, participating in a genetic substudy will help better understand the disease, along with its treatment and on how to improve the management of all patients affected by the same medical condition.

During and after the study you remain the owner of the genetic samples. This gives you the right to request the destruction of the sample materials at any time, if you revoke your consent. If
you want the samples to be destroyed, you should contact the doctor responsible for the study. The medical data that have been collected until that time will still be evaluated, as well as the biological samples, to ensure that the validity of the study is preserved.

The sponsor is responsible for the destruction of the samples at the end of the retention period as stated in the informed consent form.
What kind of treatment do I receive after the completion of the study?

As a principle, after the completion of the study, a patient cannot be treated with the study medication any longer. The study doctor will explain you what the available treatment options are and guide you in identifying the right treatment for you.

However, some trials already foresee in the initial protocol an extension phase which allows patients given their consent to stay on the study drug, often but not necessarily, in open label until it is on the market. This is usually described in the patient information that you receive before participating in the study. You might want to ask the study doctor for information about this particular point during the informed consent process.

The study doctor might also consider that it is appropriate for you to continue the treatment with the drug (compassionate use). Upon authorization by Swissmedic, the study doctor asks the sponsor to provide the study drug.
Notes
Testimonials of participants to clinical trials
Benefiting from the positive effect of the treatment observed during the study

“I took part in a pilot study investigating the efficacy of a combination of dietary supplements in the context of an exercise program for adults with a muscle disease. The trial consisted of a 12-week long treatment during which two drugs were taken each for six consecutive weeks.

Over the course of this period, I came to the hospital for three visits, during which the following exams were completed: physical exam, vital signs, blood and urine, bone density measurement, calorimetry, muscle strength measurement and MRI.

During the trial none of the study-related costs were covered by the trial participants.

During the study I had mild side effects from the drugs such as reduced appetite and diarrhea. I felt stronger and recovered faster from exercise. After the trial completion, the drugs were discontinued and after a brief period of time, I felt like before the trial.

The main problem of the trial participants was the transportation of the drugs, which were provided in larger quantities (bottles) that were almost impossible to carry in public transportation.

After the trial was over, I could continue the treatment with the prescription of the same drugs. Thus I am still benefiting from the positive effect of the treatment observed during the study.”

Anonymous, 2017
Help others affected by the same disease

“Following an open call at a conference, I signed up to participate in this trial. Two incentives were decisive for me:

1. It will help a doctoral student graduate.

2. It will help to better understand rare diseases that are difficult to study. Even if I do not have any personal benefits in the trial, it will still help others affected by the same disease in the long run.

As participant, I was told to come twice to the university hospital in order to complete different exams on my ear. I was told I could experience short adverse events such as dizziness and similar reactions. The trial had neither positive nor negative effects on me.

I personally appreciated learning that inflammatory nerve diseases do not affect the vestibular system. Obviously I was very happy about this.”

Anonymous, 2017
Participation was and still is very demanding

"Of course I performed a Google search on the Internet. Far too many. And, fortunately, I did do these Google searches! This is how I was able to learn about a study a couple of months later that slowed down the progression of the disease.

Full of hope, I sent the report to the doctor at the Children’s Hospital and requested in writing the inclusion of my son in the study, if the mutation responsible for his disease would allow it. The answer was very disappointing. As at that time there was no patient registry, he wrote back among other things that we, the parents, are responsible for finding the studies.

So, this is what I did.

When I found a study conducted on the medical condition of my son, we wanted to celebrate! But the study was delayed and it was more and more difficult to wait.

Finally we received the call we had been waiting for, for so long. The study was about to commence. We were asked if we could come to the trial hospital the week after. Obviously, we dropped everything and took off!

The participation in the trial, was and remains very demanding. During the first 10 months we travelled every week. After a night at a hotel, the treatment was provided the following morning. We would have lunch and then head back home. At 7:30 p.m. we would arrive.

If no one takes part in a trial, no drug can be developed! Every time we take off, we feel hope. Even if participation is still difficult and arduous, we have to carry on. Because the last thing you lose is hope!”

Anonymous, 2017
Glossary

Assessment
Study assessments are ways to measure disease activity and therefore study drug effect on the disease. Study assessments can be routine assessment of standard disease management or study specific disease management. Examples: blood test, CT-scan, patient questionnaire.

Clinical study
Research project involving humans in which participants are submitted to health intervention (such as a drug) in order to assess its effect on health or human body function. Examples: randomised study, open label study.

Comparator
Active drug that already demonstrated a clinical effect in a given medical condition. Comparator is meant as a reference to compare the investigated study drug to, to assess the relative effect of the investigated study drug.

Design
A study design describes the study course of action. The study design is determined by the hypothesis to be tested in the study. Example: Hypothesis: is drug “A” more efficient in treating condition “X” than drug “B”? Study design: two treatment arms to compare the effect of drug “A” with drug “B” in patients affected by “X”.

Discernment
Discernment refers to the capacity of any person capable of rational decision, that is not too young, affected by cognitive deficit, psychiatric condition, drug abuse or any other conditions that may impair discernment.

Double-blinded
Type of study or study period during which the participant received a study drug which identity (investigated drug, placebo or active comparator per study protocol) is hidden to the participant and to the physician to prevent any bias from psychological factors.

Drug
Study drug refers to any drug used in a clinical trial. Examples: active drug, placebo, active comparator.
Ethics committee

Independent committee composed by different experts including physicians, biologist and legal counselor that review the scientific, ethical and legal aspects of the study to secure the protection of the study participants.

Exclusion criteria

Criteria excluding potential study participants. Exclusion criteria are meant to protect participants that could potentially be at higher risk of adverse events in participating to the study.
Example: age below 20 as exclusion criteria means that volunteers/patients below age 20 cannot participate in the study.

Inclusion criteria

Criteria defining the eligibility of potential study participants. Inclusion criteria are meant to identify participants that could potentially take a benefit in participating to the study.
Example: patients with diabetes mellitus as inclusion criteria means that patients with diabetes mellitus can participate in the study.

Informed consent

As for any other health-related intervention, informed consent is required before study participation. It refers to the process during which the patient is informed on all key information to judge if he wants to participate. After receiving information, the patient is provided with a specific informed consent form developed by the sponsor, for him to document his consent.

Intervention

In clinical studies, the intervention is a health-related action, meant to prevent, diagnose, treat or cure a medical condition.
Examples: medical device, treatment, medicinal product, surgery, irradiation.

Open label

Type of study or study period during which the participant received a study drug which identity (investigated drug, placebo or active comparator per study protocol) is known to the participant.

Placebo

Inactive drug meant as a reference to compare the investigated study drug to, to assess the relative effect of the investigated study drug.
**Population**

The study population is defined by the inclusion and exclusion criteria.

**Principal investigator**

Person responsible in Switzerland for the conduct of a clinical trial and for the protection of the participants at the trial site; an investigator who takes responsibility for organising a clinical trial in Switzerland is also a sponsor.

**Protocol**

Study plan containing all information on study objectives and conduct.

**Randomisation**

Process of random distribution of the study participant into the different treatment arms (at least two to allow comparison).

**Recruitment**

Study period during which the participants enter the study. While the study is in preparation, the recruitment of participant is not yet open. After the recruitment is closed, no additional patient can enter the study.

**Single-blinded**

Type of study or study period during which the participant receives a study drug which identity (investigated drug, placebo or active comparator per study protocol) is hidden to the participant to prevent any bias from psychological factors.

**Sponsor**

Person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial, and in particular for the initiation, management and financing of the trial in Switzerland.

**Study team**

Group of people involved in the study conduct under the leadership of the principal investigator. The study team can comprise physicians, nurses, biologists, physiotherapists and other health care professionals. These are the people the participant will regularly met with during the time of the clinical trial.

**Treatment arm**

Study treatment defining the group of participant receiving this particular treatment. Examples: placebo arm, comparator arm.
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