swissmedic swissethics

Position Paper
Decentralised clinical trials (DCTs) with medicinal products in Switzerland

(Version 4.0, 9 March 2026)

1. Introduction

1.1. Aim of the Position Paper

This position paper reflects the current state of thinking of swissethics and Swissmedic on decentralised clinical trials (DCTs) with medicinal products in Switzerland interpreting their respective areas of responsibility. The aim is to encourage and invite stakeholders to intensify the dialogue on this innovative way in conducting clinical trials and to find relevant information on the interpretation of the current legal situation in Switzerland. This paper describes a broad variety of topics starting from the recruitment, trial conduct, sponsor- and investigator responsibilities and how oversight should be ensured in decentralised clinical trials. Guidance is also provided on content requirements for drafting the trial protocol, conduct of monitoring visits and task delegation. As this type of clinical trial is relatively new, changes to existing laws and regulations may be required over time and will be included in this guidance on an ongoing basis.
In general, the developing practices associated with DCTs require careful scrutiny on a case-by-case basis for compatibility with applicable law.

1.2. Content and objectives of DCTs

When conventional clinical trials are performed with medicinal products, trial participants are sometimes required to commit a considerable amount of time and are also often expected to have a high degree of mobility since they have to travel to a trial site for trial-related visits. One objective of “decentralised clinical trials” (DCTs) is to partly transfer the trial-related visits or assessments from the trial site to the participant’s home in order to reduce the practical obstacles to trial participation and to integrate the visits more smoothly into the participant’s daily routine.

DCTs are clinical trials in which the digital recording and/or transmission of data in the context of trial-related interventions play a significant role. They may involve, for example, digital recruitment of trial participants, trial visits performed using telemedicine in the patient’s home or digital recording and transmission of data using wearables (computer technology worn on the body) or smart devices such as tablets or smartphones. Other aspects such as informed consent of participants, monitoring and the associated verification of the source data are also affected by digital technologies.

A further characteristic element of DCTs is the direct delivery of the investigational medicinal product (IMP) to the trial participant at home, where it is stored, and in some cases administered by qualified trial nurses or the patient himself. Wherever possible, trial-related interventions are performed and documented in the patient’s home by trained trial nurses.

In “hybrid DCTs” some of the interventions are performed in the conventional setting at a trial site, and others are performed in a decentralised setting in the trial participant’s home. Whether or not parts of a clinical trial can be performed in a decentralised way depends on many factors – including the type of disease, the phase of the trial and the type of IMP, and on the prevailing legal framework.

There is great interest, both internationally and in Switzerland, in performing clinical trials in a decentralised way. The ICH (International Council for Harmonization) has developed a comprehensive update on the global GCP (Good Clinical Practice) Guideline, ICH E6 (R3). Annex 1[1] contains considerations for interventional clinical trials and has been supplemented compared to ICH E6 (R2) with regard to DCTs by the following aspects (list not exhaustive): selection of service providers (e.g., for home nursing care) and associated agreements,

[1] ICH Harmonised Guideline, Guideline for Good Clinical Practice, E6(R3), Step 4. The principles and Annex 1 have been endorsed by the Regulatory Members of the ICH Assembly on 6 January 2025.

qualifications of home nurses, remote consent, supply of investigational medicinal products to the patient, timely access and review by the investigator of data collected remotely, etc. Annex 2[2] addresses the GCP considerations that arise from the increased use of a wider range of design elements and data sources. It provides additional GCP considerations, focusing on examples of trials that incorporate decentralised elements, pragmatic elements and/or real-world data (RWD). It furthermore provides a definition of DCTs:

> *"Decentralised elements in a clinical trial are those trial-related activities conducted outside the investigator's location (e.g., trial visit is conducted in the trial participant's home, local healthcare centre or mobile medical units or when data acquisition is performed remotely using digital health technologies (DHTs))."*

On 4 May 2021, the Danish Medicines Agency published guidance on the implementation of decentralised elements of clinical trials with medicinal products.[3] These guidelines explain the opportunities of the new trial setting and challenges while ensuring patient safety and data integrity during DCTs. On 14 December 2022, the European Commission Directorate-General for Health and Food Safety published the recommendation paper on decentralised elements in clinical trials and updated it in October 2025[4]. The recommendation paper addresses the roles and responsibilities of the sponsor and investigator, electronic informed consent, IMP delivery, trial related procedures at home, data management and monitoring in a decentralised clinical trial setting. It also provides an overview of the current national provisions applicable in each Member State (MS) in relation to the topics addressed in the paper. This overview is included in Appendix 1 of this position paper and is supplemented by the Swiss provisions.

The stakeholders involved in clinical trials in Switzerland are convinced that DCTs are set to play an increasingly important role in the future. At the *Swissmedic Round Table Innovation* event held in October 2019 the stakeholders emphasised their wish to support innovation in Switzerland in this context.[5]

In an introductory summary they stated their intention of giving potential participants in Switzerland the opportunity to take part in DCTs. The anticipated advantages are the following:

- rapid, digital recruitment through new channels;
- trial implementation that can be better integrated into trial participants' day-to-day routine by reducing the time and mobility required;
- digital automation of data capture with a possible improvement in data quality;
- possibility of performing clinical trials for rare diseases.

1.3. Legal framework in Switzerland

In Switzerland, clinical trials with medicinal products are regulated in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA [SR 812.21]) and in the Federal Act on Research involving Human Beings (Human Research Act, HRA [SR 810.30]) and the associated ordinances[6]. The ICH GCP Guidelines E6 (R3) are also applicable in Switzerland (art. 5 para. 1 ClinO). The requirements of the Federal Act on Data

[2] ICH Harmonised Guideline, Guideline for Good Clinical Practice, E6(R3), Annex 2, Step 3 (status on 1 July 2025)
[3] The Danish Medicines Agency's guidance on the implementation of decentralised elements in clinical trials with medicinal products (version 2.0; September 2021)
[4] Recommendation paper on decentralised elements in clinical trials (version 02 dated 01.10.2025)
[5] Proceedings of the 1st Round Table Innovation "Innovative Methods and Technologies in Clinical Trials" Monday, 7 October 2019 (Version 1.0 dated 05.12.2019)
[6] Ordinance on Clinical Trials with the exception of Clinical Trials with Medical Devices, Ordinance on Clinical Trials, ClinO [SR 810.305]; Organisation Ordinance to the Human Research Act, Organisation Ordinance HRA, OrgO-HRA [810.308]

Protection (FADP [SR 235.1]) and the Ordinance to the Federal Act on Data Protection (OFADP [SR 235.11]) must also be fulfilled.

The existing legal framework already regulates many aspects of DCTs with medicinal products in Switzerland, although researchers are recommended to liaise closely with Swissmedic and the responsible Ethics Committee beforehand in order to clarify specific questions relating to the conduct of DCTs. The aim of prior consultation/clarification is to identify ways in which DCTs can comply with the ethical and legal standards mandated by the existing regulatory environment and can therefore be carried out in Switzerland.It is not possible to assess definitively on the basis of this document which provisions of national and international law are affected, and to what extent, and whether or how the required compliance of clinical trials with the legislation can be achieved by the modalities of different DCT settings. The document does not prejudice the necessary case-by-case examination of applications for approval of a clinical trial, nor does it set out the elements of a DCT which are permissible under current law. Furthermore, DCT elements will be examined on a case-by-case basis to establish whether they can be made compatible with the currently applicable legal provisions.

2. DCT aspects

In regulatory and ethical terms there are four main aspects related to DCTs, which are considered in detail below.

1. Optimal medical care, the rights and safety of participants must be ensured at all times.
2. The IMP must be safely dispensed, ingested/administered and returned.
3. The data recorded during the clinical trial must be credible and reliable.
4. The data protection requirements must be met in full.

Re 1: Since the clinical trial is performed virtually or partly virtually, there is a risk that the personal relationship with the physician, which is the basis of mutual trust, cannot be established as personally and in the same way as in conventional clinical trials. The optimal care and treatment of participants in the trial setting is a fundamental ethical requirement for any form of research involving human beings and is therefore essential in the performance of DCTs, too. Optimal patient safety must also be ensured, even if participants are not regularly physically present at the trial site.

Re 2: The IMP must be suitable for delivery to the participants and for being ingested/ administered at and returned from their homes. All the requirements regarding the quality of the IMP must be fulfilled during delivery and storage.

Re 3: Given the modalities of recruitment and selection, there is a risk that it will mainly be technically-versed individuals who decide to take part in the trials. A representative sample of trial participants must be ensured in order to avoid a selection bias. The data-recording tools (e.g. wearables) must generate correct and valid data.

Re 4: Data protection: Special attention must be paid to ensuring the highest security standards during data transfer, for example within a larger network and between all participants. This means that health-related data must be protected from unauthorised access at all time.

2.1. Recruitment through digital channels

In case potential trial participants are informed about a trial through electronic media, swissethics draws attention to the guidance for producing and using electronic patient information (without or with electronic consent (eIC)) in accordance with ClinO (link: Guidance document on the development and use of an Electronic Informed Consent (eIC)).

If the discussion about participation between the investigator, i.e., the trial physician, and the patient during the informed consent process is done via electronic platforms, several additional aspects have to be considered. Ethical principles such as autonomy and ethical requirements such as time to reflect about trial participation must be addressed. The requirements of the Swiss Data Protection Act, e.g., with respect to server location, must be fulfilled (art. 7 FADP). The protection of personal data from unauthorised or accidental disclosure must be safeguarded, in particular by ensuring that during any data transmission these personal data are adequately protected from unauthorised or accidental disclosure to the sponsor or companies involved in this process (ICH GCP II. 1.6; art. 7 para. 1 and para. 2, art. 24 FADP).

Under the Ordinances relating to the HRA in force until 31 October 2024, a handwritten ("wet-ink") signed consent was required in Switzerland, unless the trial participant could provide a qualified electronic signature that meets the legal requirements of the Federal law on electronic signatures (ZertES, SR 943.03). Under the amended Ordinances that came into force on 1 November 2024, researchers can obtain the consent from research participants electronically (so-called e-consent). For the requirements on the use of an electronic patient information and on the electronic consent refer to the guidance document on e-consent of swissethics[7], and to the document "eConsent Study Documents Recommendations" published by EFCGP (link: EFGCP - European Forum for Good Clinical Practice).

The original signed consent form or the certified proof of the e-signature signed by the trial participant must be retained (ICH GCP C3.3).

If new information important for the participating trial participants emerges while a clinical trial is in progress, it is necessary to ensure – also when electronic media are used – that the participants are informed in a timely manner and, where applicable, receive an updated consent form. Such changes include, for example, the occurrence of new side effects that are relevant for safety and may alter the participant's willingness to take part in the trial. swissethics draws attention to the guidance and the template for supplementary concise information on consent in clinical trials available at swissethics.ch.

It is also necessary that, even when using electronic media, the information and consent process as well as the respective versions of the patient information and declaration of consent used are documented in a GCP-compliant manner and are available for monitoring, audits and inspections. The statutory archiving obligation for these source data must be observed (art. 45 para. 2 ClinO).

2.2. Performance of trial-related interventions outside the trial site

If trial-related interventions are performed outside the trial site with the trial participants' consent, e.g., in their homes, these tasks may be performed by commissioned service providers who supply the corresponding trial nurses, known as "mobile nurses". Each person who performs these interventions – at the responsibility of the investigator as part of the study team – must have appropriate training and proven knowledge and experience with regard to the relevant specialist field and the conduct of a clinical trial (art. 6 para. 1 let. c, art. 4 ClinO, ICH GCP III. 2.3.2).

In this situation it is the responsibility of the investigator in Switzerland to monitor that the trial nurses carry out and document the study-specific interventions on the patients at home in accordance with the protocol. Some medical examinations cannot be performed by the trial nurses or at home (e.g., specific neurological examinations, computed tomography). These

[7] The guidance document is published on the swissethics.ch website under: Topics, Position papers, Conception and application of an electronic informed consent (eIC)

must be performed at the trial site or at a suitably equipped facility by qualified personnel or in the course of a personal visit to the patient's home by the investigator or a delegated physician. The sponsor must ensure that the trial participants' needs are taken into account in respect of doctors' visits carried out using telemedicine. The trial participants should be given the opportunity to see the doctor in person if needed. The investigator in turn must also be able to pay a personal visit if they consider it to be necessary for the optimal medical care of trial participant s (art. 2 let. e ClinO).

The investigator must ensure adequate medical care if adverse events occur outside the trial site and the standardised documentation and protocol-compliant reporting of adverse events (art. 39 – 41 ClinO, ICH GCP III. 2.7.1. let. c).

If the investigator in Switzerland instructs or performs the trial-related interventions in patients' homes using digital platforms, e.g., video calls (telemedicine), compliance with the Swiss Data Protection Act must be guaranteed by end-to-end encrypted communication. If cloud systems are used, these must comply with the requirements of this Act.

The trial nurses who perform the trial-related interventions outside the trial site have access to uncoded personal data by virtue of their activities in the trial participants' homes. Suitable technical and organisational measures must therefore be taken to ensure that these personal data are protected from unauthorised or accidental disclosure to the sponsor or, when data are transmitted to involved companies (art. 18 para. 1 ClinO; art. 5 let. c no. 2, art. 7 para. 1 FADP).

Source data recorded in the context of trial-related interventions outside the trial site must be documented in compliance with GCP and available for monitoring, audit and inspection purposes (ICH GCP III. 2.3.5). The statutory archiving obligation for these source data must be observed. Source data recorded directly in the CRF must be identified as such in the protocol (ICH GCP B.14.2).

2.3. Trial Oversight and responsibilities

If the sponsor intends to delegate certain tasks and functions to third-party service providers (home nurse services or other health care providers), the roles and responsibilities must be defined in appropriate service agreements and must be well understood by all parties involved (sponsor, investigators and third-party service provider) (ICH GCP III. 3.6.4). Like in all clinical trials, the roles and responsibilities of all involved personnel must be defined in a site-specific delegation log (ICH GCP III. 2.3.3). A decentralised study sets higher demands on the oversight on both the investigator but also the sponsor to ensure the safety and well-being of the trial participants as well as the credibility of the data collected. It must be ensured by design, how the sponsor and the investigator can fulfil their duties and responsibilities as stated in HRA, in the Ordinances and ICH GCP E6 (R3) at all times (art. 4 HRA), and in particular to ensure compliance with the Swiss Data Protection Act (FADP). It must also be clearly indicated how the investigator will be informed in a timely manner about relevant changes in the health status of the trial participants (art. 15 para. 1 HRA). In addition, it must be described how the investigator will review the data entered by the participant in diaries or reported via various platforms/ electronic patient-reported outcomes (ePRO) in a timely manner.
The requirements of decentralised elements should meet those of regular clinical trial settings in terms of e.g., IMP storage conditions and temperature control, pregnancy testing etc. – it should thus be considered as an extension of the clinical trial site.

2.3.1 Sponsor responsibilities

Since data collected in DCT trials is coming in from various sources, a carefully designed Data Management Plan (DMP) is essential to clearly identify the origin and data flow for all involved parties and to outline how data is being processed. Special focus should be put on remote data acquisition (i.e., diaries, ePRO, online questionnaires, laboratory, Health Care Professionals (HCP), trial personnel, vendors etc). The DMP should furthermore include a list or refer to a list of vendors who are responsible for data collection, handling and management ICH GCP III. 3.16.1 let. x (i)).

The sponsor is responsible for selecting third-party service providers who are qualified by experience in their intended field of activity (art. 10 para. 1 let. d HRA; art. 6 para. 1 let. c ClinO). This should be reflected in the contract between the sponsor and the investigator so that the investigator knows the qualifications of the service provider and can agree or disagree with them if the delegated tasks fall within the investigators area of responsibility (ICH GCP III. 3.6.5). The investigator must ensure, that all third-party service providers are properly trained on the trial-specific tasks they are delegated for and which relate to the medical care of the trial participant or fall within the investigators area of responsibility (ICH GCP III. 2.3.1 and 2.3.2).

The sponsor must ensure adequate oversight of the clinical trial (ICH GCP III. 3.6.4). The decentralised nature requires effective lines of communication which are more complex compared to traditional trials and must be thoroughly defined in a concise Communication Plan as also requested by the EMA in their recommendation paper on decentralised clinical trials, distributed to all involved parties including investigators, third-party service providers, and also trial participants. If applicable, the communication plan should also cover emergency situations, so that all involved parties can act accordingly without delay. The communication plan must be established and trained *before* trial start. A high degree of attention should also be paid to informing the study participants; they should receive specific contact information for all possible situations so they and/ or the legal guardians or household member know who to contact in acute cases (unforeseen reactions, exacerbations etc.), device failures, overdosing, product complaints, questions on home visits etc. The participants should furthermore be instructed what is considered an adverse event/ a serious adverse event and who they need to report such events, within which timeframe. Furthermore, if applicable they should also be instructed how to manage such events (i.e., use of predefined medication by investigator and protocol for pain etc.) (art. 15 HRA).

2.3.1.1 Trial Protocol

The sponsor must describe in the clinical trial protocol the operational aspects of the clinical trial, which should cover the following (list not exhaustive) ICH GCP B.4.2; B.7; B.9; B.12; B.14:

a) A description of all scheduled and unscheduled visits
b) The tasks planned to be performed by external nurses, HCPs (including general practitioners), external laboratory, imaging providers etc.
c) How the visits are to be held (in person or remotely)
d) Locations where the visits are taking place (investigator site, medical office, imaging facility, patients' home, other HCP location)
e) Responsibilities (who performs which task)
f) How the oversight by the sponsor and the investigator is achieved
g) The information flow and workflow of different tasks should be described in detail in the protocol or in a referenced document.
h) How are reports and data (i.e., from HCP, laboratory, imaging data etc.) on activities performed at different locations are being transmitted – this must also be specified in a concise communication plan.
i) For handling of IMP at the study participant's home a clear handling and storage guidance should be handed out to the participant. Handling and storage conditions must be supported by in use stability data laid down in the quality dossier (Investigational Medicinal Product Dossier) or instructions provided in the SmPC

(Summary of product characteristics). Handling and storage information in participants instructions, quality dossier, SmPC and Pharmacy manuals must be identical. The protocol must contain a statement on whether the IMP is taken to the patient's home or applied at the trial site and a reference to the documents containing the information and instructions.

j) Handling of adverse events including how patients can contact site personnel in case they experience any adverse events

2.3.1.2 Monitoring

Sponsors must ensure monitoring, according to a predefined Monitoring Plan (ICH GCP III. 3.11.4). The monitoring strategy should be based on a thorough risk-based approach, regardless of whether it is a DCT trial, and should cover the following aspects (list not exhaustive):

- How is monitoring implemented in order to determine if the trial is conducted in accordance with the protocol and all applicable local regulations.
- The frequency and type of monitoring (on site or remote). In case of remote monitoring how is data protection ensured? The measures must be described in detail in the monitoring plan or another referenced document.
- The monitoring plan should furthermore take the design of the DCT into account, and must also outline how HCPs and other service providers (nurses, general practitioners etc.) are being monitored if they perform study related tasks that require specific knowledge of the trial protocol.

2.3.2 Investigator responsibilities

As with all other clinical trials, the investigators of DCTs are responsible for the conduct of the clinical trial and the protection of the participants at their trial site. The investigator must thus have oversight of all individuals who perform trial-related activities (art. 2 let. e ClinO; ICH GCP III. 2.3.1 and 2.3.2).
Investigators may delegate tasks to local HCPs if this is permitted by the protocol. Visits can take place at trial participant's home, decentralised doctor's office or other location, as specified by the protocol.
Investigators must have adequate resources to conduct the trial and should only enrol as many participants as they can appropriately manage (art. 4 let. c ClinO; ICH GCP III. 2.2, 2.3.1 and 2.3.2). The high volume of incoming data from various sources (ePRO, diaries, wearables etc.) should not be underestimated. It is the investigators responsibility to ensure a timely review of all those data. The review frequency should be proportionate to the relevance of the data concerned for the safety and well-being of the participants and for the efficacy and data integrity.
The primary aim is to record and assess SAEs in a timely manner without placing an excessive burden on the investigator and/ or the trial participant. If digital tools are to be used to generate critical safety data that requires immediate medical attention, this should be set out in an appropriate plan and emphasised during training.
Depending on the design it is possible that adverse events are received via several routes (ePRO, wearables or other digital tools, external HCP or the trial participant); it is therefore essential to have adequate oversight of all those events and identify and avoid duplicates.

2.3.3 Delegation of tasks

The delegation of tasks in a DCT is of key importance and requires thorough oversight of all parties involved as well as a careful and precise definition of tasks (ICH GCP III. 2.3.3). Although some tasks might be delegated to third-party service providers, the ultimate responsibilities as stated in Art. 2 let. d and e ClinO and ICH GCP III. 3.6.6 remain with the sponsor and the investigator.

If tasks are delegated to service providers, a high-level rationale and extent of their involvement should be included in the protocol and a more detailed description should be given in a referenced document.
If a service provider is selected by the sponsor and the investigator is not involved in the contractual agreement, the contract between the investigator and the sponsor should clearly define the contractual arrangements with the third-party service provider for tasks that fall within the investigator's area of responsibility (ICH GCP III. 3.6.4 and 3.6.5). Due to the complex nature of the involvement of various parties it is recommended to involve investigators at an early stage of trial design.
All local HCPs and other personnel involved in *trial-related tasks*, that require detailed knowledge of the protocol, IMP(s), Investigator Brochure or other trial-related documents, should be *listed in the delegation log*. The delegation log should include the following:

- Names and affiliations of the person to perform trial-related tasks.
- Location where the tasks are performed/ name of the institution/ medical office.
- Start and end dates of delegations.
- Signature/ initials of the PI and date of signature for initial assignments, amendments of delegations and end of delegations.
- All changes in delegations and roles must be made by the PI only.

Other health care professionals who deliver basic care and *non-study related services* (emergency room personnel, family physicians, nurses, patients' pharmacists etc.), that is not related to the trial, need *not to be listed in the delegation log*.
Technicians and other personnel of clinical laboratories, image providers etc. need *not to be listed in the delegation log*.

2.4. Dispensing and administration/ingestion of the IMP outside the trial site

IMP whose stability and safety profile has not yet been adequately characterized due to an early stage of development is unsuitable for dispensing and administration to the trial participants at home. IMPs which require preparation, e.g., in a sterile environment, before administration or those that are associated with a high risk of possible adverse reactions (e.g., anaphylactic shock) are also not suitable. Precautions must be taken to ensure the medical care of trial participants should adverse reactions occur during or after the administration/ingestion of the IMP by the trial participant at home (ICH GCP III. 2.7.1. let. c).

If the IMP is dispensed outside the trial site, the requirements of Good Manufacturing Practice (GMP) must be fulfilled (Annex 1 of the Ordinance on Licensing in the Medicinal Products Sector, MPLO [812.212.1]; art. 32 para. 1 let. d ClinO). Moreover, the requirements of the Good Distribution Practice (GDP) for the IMP and the applicable national provisions in Switzerland must be fulfilled. It is furthermore recommended that the details of a planned implementation in Switzerland are discussed in advance with Swissmedic and the competent Ethics Committee and, if applicable, the competent cantonal authorities.
The following models are being discussed at the international level for the dispensing of IMP in DCTs:

a. Direct delivery of the IMP to trial participants by the trial site.
b. Delivery of the IMP directly to trial participants by a central pharmacy.
c. Delivery of the IMP by a central pharmacy to a local pharmacy near the trial participant's home. The trial participants or trial nurses pick up the IMP in person.
d. Delivery of the IMP directly to the trial nurses by a central pharmacy.

If trial participants are supplied directly, they must be given appropriate information and agree to the personal data necessary for this being passed on. Steps must be taken to ensure that personal data are protected from unauthorised or accidental disclosure (art. 18 para. 1 ClinO).

If the trial participants are supplied directly, they must be instructed in advance about the correct storage and use of the IMP.

Until it is administered/ingested, the IMP must demonstrably be stored in such a way that its quality (protocol-compliant storage, shelf-life) is not impaired (ICH GCP III. 2.10.5). Care must also be taken to ensure that the IMP is used only in accordance with the approved protocol ("compliance", ICH GCP III. 2.10.6).

The sponsor must provide suitable means (e.g., using electronic tools) for performing the regular review of quality and compliance. The investigator in Switzerland is responsible for this review and must therefore be able to access these data at all times (ICH GCP C.1). The investigator may delegate the review to the mobile trial nurses. Like the return of unused IMP to the sponsor and its disposal, the review of quality and therapy compliance must be documented in compliance with GCP and the documentation must be available for monitoring, audit and inspection purposes.

2.5. Data capture outside the trial site using mobile devices

If mobile devices are intended to be used for data collection outside the trial site, it must be ensured that the trial participants have been fully informed and agreed (consented) to data being recorded by the device (e.g., wearables) or entered by the trial participants, e.g., ePRO. Moreover, patients must also be informed how data is transmitted via the used tools, ePROs, wearables etc. It should be emphasised that the investigator may not be able to review all data in real time and who patients should contact in the event of safety concerns or serious health problems/ Serious adverse events. This information is included in the main written study informed consent form. The trial participants must also be trained in the correct use of the mobile devices. If source data are recorded directly in the CRF, this must be identified as such in the protocol (ICH GCP B.14.2). If data are recorded automatically, e.g., by wearables, it should be ensured that only trial-specific data are recorded by the mobile devices being used. The data which are considered to be source data must be stated in writing before the clinical trial begins, e.g., if data are only stored for a short time on the mobile device.

It is the sponsors responsibility that the mobile devices are demonstrably validated use save (encrypted) transmission of all trial related data and comply with the relevant standards for accuracy, precision, reproducibility, reliability and responsiveness (sensitivity to technological changes over time, ICH GCP III. 3.16.1 let. x). A Risk Mitigation Plan should describe the procedure in place in the event the electronic system is not available, or e.g., under maintenance.

Furthermore, the equivalence of the mobile devices used across various data-collection platforms or methods must be ensured. It must be possible to trace data entry and data changes by means of an audit trail. If the data generated this way are source data, the sponsor must ensure that they are documented in compliance with the legislation and that the statutory archiving obligation is observed. Continued access to this documentation must be guaranteed (ICH GCP C.2.4).

The sponsor must define measures in order to ensure that the recorded data actually originate from the trial participants or were generated by the trial participants (and not, for example, by a third person). Here it must be ensured that the sponsor has no access to personal or identifiable information relating to the trial participants.

To ensure the protection of personal data from unauthorised or accidental disclosure, the sponsor must protect these data from any form of intervention from outside, whether accidental or intentional. This protection applies to all personal, identifiable information, to all personal

health-related data and mobile devices used to collect, store or transmit data. Compliance with the Swiss Data Protection Act must be guaranteed.

2.6. The question of CE certification of the technology employed

A distinction must be made for mobile devices according to whether they are used solely for research purposes or whether they have an additional medical purpose. Mobile devices with an additional medical purpose (i.e., medical devices) are regulated by the medical devices legislation. A medical purpose exists if the data generated by the medical device influence medical decisions. It is forbidden to dispense non-compliant devices for a medical purpose (art. 1, art. 6. para. 1, art. 8 para. 2, art. 14, art. 21 para. 2, art. 23 of the Medical Devices Ordinance (MedDO) [SR 812.213]).

If the medical devices employed, including apps and software, are marked with a CE label for medical devices and are employed according to the approved intended use (not off-label use), the trial is purely a trial of a medicinal product (IMP). If, on the other hand, the medical devices employed do not bear a CE label for medical devices, or if they are employed for an off-label use, Swissmedic will assess both the IMP and the investigational medical device as part of the approval procedure. Information on submissions can be found in an information sheet (BW600_00_015e_MB > Combined trials with multiple types of products).

If the mobile devices are not medical devices, the data are not considered to be trustworthy for individual medical purposes. The sponsor must ensure that such data does not erroneously influence medical decisions by mistake. In particular, these data must not be filed in patients' records, nor should they be communicated to trial participants, treating doctors, therapists or trial nurses without a compelling reason.

2.7. Remote source data verification (rSDV)

If persons commissioned by the sponsor ("monitors") review uncoded personal data of trial participants (e.g., medical records) as part of source data verification and if this review is not performed in person at the trial site, but by means of electronic tools outside the trial site (remotely), suitable technical and organisational measures must be taken to ensure compliance with the Swiss Data Protection Act.

If the trial site sets up separate electronic access for the monitors to the trial patients' source data for the purpose of verifying the source data, measures must be taken to ensure that the transmission of data is adequately protected. The following must be taken into account when rSDV is planned to be used in the framework of a clinical trial (regardless if it is a DCT or not):

a) Procedures should be in place to ensure that the operating system software of the computer used for rSDV is regularly updated.
b) The use of up-to-date antivirus software is recommended
c) The login to the medical records system should be done via two-factor authentication (e.g., by sending a SMS code, using Microsoft Authenticator, security token or similar)
d) VPN (virtual private network) should be used to ensure encrypted communication
e) The access of the monitor to the medical records must be restricted to the study participants of the respective trial and should include read-only rights
f) Any kind of export functions or printing should be blocked in the medical records software interface (if possible)
g) Signed agreements by monitors to confirm the following (list not exhaustive):
    I. rSDV should not be performed in public areas where third parties could have insight in the data
    II. No screenshots should be taken
    III. No printout via web browser function should be performed

h) Patients must be informed and give their consent as part of the informed consent process that monitors can access their medical data remotely.

The Human Research Act regulates the export of health-related data to foreign countries and distinguishes between export of non-genetic data versus genetic data/biologic material. Swiss law allows the export of non-genetic data without a written informed consent when the requirements of art. 16 and art. 17 FADP are met (art. 42 HRA). In contrast, a written informed consent is obligatory for the export of genetic data/biological material. However, since most clinical trials process both non-genetic and genetic data, a clear-cut distinction between the two is not satisfying and therefore not really possible from a practical perspective. Moreover, there are ethical justifications to inform the persons in a transparent manner according to ethical standards that are higher than the legal minimum. Therefore, whenever uncoded personal data, regardless of whether non-genetic or genetic, are reviewed (monitored), the trial participants must be informed about this and provide their written consent by signing the main informed consent form.

DCTs must comply with the applicable law, in particular the provisions of the HRA, TPA and FADP. In clinical trials, personal data or health data requiring special protection are regularly processed as clear data, coded or anonymised. In the latter case there is no need to qualify as personal data or to be subject to the HRA and FADP, provided that the requirements for anonymisation are met. The Federal Data Protection and Information Commissioner, FDPIC, explains the law to be complied with and publishes guidelines, e.g., on the transfer of personal data abroad (cf. Transborder data flows (www.edoeb.admin.ch)). The area of health data processing is subject to rapid technical, economic, political and legal changes nationally and internationally, which may have an impact on the assessment of DCT.

2.8. Organisational aspects for regulatory GCP inspections

If Swissmedic performs an on-site inspection, the inspected party must ensure that all documents and data (i.e., medical records including those of Health Care Professionals (HCP), reports of mobile nurses, diaries, ePRO, online questionnaires, laboratory, etc.) for patients of the respective site are available at the inspected location.

3. Summary and outlook

There is great interest, both internationally and in Switzerland, in performing fully decentralised clinical trials, or clinical trials that incorporate decentralised elements. Both Swissmedic and swissethics are committed to support researchers and sponsors in this innovative step. This guidance paper focuses on clinical trials with medicinal products and is intended for sponsors and researchers who are planning DCTs and want to perform them in Switzerland.

This document considers the major challenges relating to DCTs and is based on the current position of Swissmedic and swissethics interpreting their respective areas of responsibility (art. 25 and art. 32 ClinO). The continuation of the present dialogue will identify areas in which further action or adaptation is required. The intention in general is not to communicate additional regulatory hurdles but rather to remove obstacles and to facilitate further innovation in clinical research in Switzerland. Swissmedic and swissethics are open for further mutual exchange regarding DCTs in Switzerland.

This position paper contains information from existing EMA[4] and FDA[8] publications to DCTs, supplemented with additional content and requirements form Swissmedic and swissethics.

[8] Conducting Clinical Trials With Decentralized Elements – Guidance for Industry, Investigators, and Other Interested Parties; September 2024

Appendix 1: Overview of DCT regulation in the EU and Switzerland

The tables of appendices 1 and 3 are based on the appendix of the "Recommendation Paper on Decentralised Elements in Clinical Trials" (Version 02 from 01 October 2025) supplemented with the legislation in Switzerland.

Please see relevant footnotes for responses marked with an asterisk. A footnote may be raised even though no response is given.	**AT**	**BE**	**BG**	**CY**	**CZ**	**DE**	**DK**	**EE**	**EL**	**ES**	**FI**	**FR**	**HR**	**HU**	**IE**	**IS**	**IT**	**LI**	**LT**	**LU**	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SE**	**SI**	**SK**	
The delivery of IMPs from sponsor/site, in relation to RP section 4.																															
Q1: Is it possible to deliver IMPs directly to trial participants from their associated trial site?	No *	No *	Yes *	No *	Yes *	Yes *	Yes	Yes	*	Yes *	Yes	*	No *	Yes	Yes *		Yes		Yes *	Yes *	Yes *	Yes *	Yes *	Yes	Yes	Yes *	Yes	Yes *	No *	Yes	Yes *
Q2: Is it possible to deliver IMPs directly to trial participants from the pharmacy associated with the trial site?	No *	No *	Yes *	No *	Yes *	Yes *	Yes	No *	*	Yes *	Yes *	*	No *	Yes	Yes *		Yes		No *	No *	Yes *	Yes *	Yes *	Yes	Yes	Yes *	No *	Yes *	*	Yes	Yes *
Q3: Is it possible to deliver IMPs directly to trial participants from any delegated pharmacy?	No *	No *	No	No	Yes *	Yes	Yes *	No *	No *	No *	No *	Yes	No *	Yes	Yes *		Yes *		No *	No *	Yes *	No	Yes *	Yes	No *	Yes *	No *	Yes *	No *	Yes	Yes *
Q4: Is it possible to deliver IMPs directly to trial participants from the IMP manufacturer with a MIA license?	No	No *	No	No	No *	No	*	No *	No *	No *	No *	No *	No *	Yes	No *		Yes *		No *	No	Yes *	No	No	No *	No *	Yes *	No	No	No *	No	No
Q5: Is it possible to deliver IMPs directly to trial participants from the trial sponsor (sponsors intermediaries/depots)? If yes, footnote states if a licence is required for the depot to carry out this task and how to obtain this licence.	No	No *	No	No	No *	No	*	No *	No *	No *	No *	No	No *	No	Yes *		Yes *		No	No	Yes *	No	No	No *	No *	No *	Yes *	No	*	No	No
The shipment of IMPs from sponsor/site across boarders within the EU, in relation to RP section 4.																															
Q6: Is it possible to deliver IMPs directly to trial participants from e.g. distribution/manufacturing/pharmacy licence holders located in other EU MSs if legally allowed to carry out this task in the country of origin?	No *	No *	No	No	No *	No *	Yes	No *	No *	No *	No *	No *	No *	Yes	Yes *		Yes *		No *	No	Yes	No	No *	No *	No *	No *	Yes	No *	No *	No	No
Q7: Is it possible to deliver IMPs directly to investigators from e.g. distribution/manufacturing/pharmacy licence holders located in other EU MSs if legally allowed to carry out this task in the country of origin?	Yes *	Yes *	No	*	Yes	Yes *	Yes	Yes	Yes *	No *	No *	Yes *	Yes *	Yes	Yes *		*		Yes	No	Yes	Yes	No *	No *	No *	Yes *	Yes	No *	No *	Yes	Yes *
Labelling of IMP, in relation to RP section 4.																															
Q8: Is it possible for any delegated pharmacy to label IMP or is this restricted to the pharmacy associated with the trial site?	No	No *	No	*	Yes *	*	Yes	*		Yes *	No *	No *	No *	Yes	Yes *		Yes		Yes *	No		No	*	No *	No *	No	No	Yes *	*	Yes	Yes *

Please see relevant footnotes for responses marked with an asterisk. A footnote may be raised even though no response is given.	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	
The shipment and hand-out of IMPs from pharmacies. This is currently not included in the recommendation paper but may be relevant in next version of the RP.																															
Q9: Is it possible to deliver or dispense <u>authorised</u> IMPs directly to trial participants from pharmacies not associated with the clinical trial sites? This includes authorised investigational medicinal products <u>not</u> used according to their SmPC.	Yes *	No *	No	No	No *	Yes	Yes *	No *	No *	No *	No *	No *	No *	Yes	Yes *		Yes *		No *	No	Yes	No	Yes *	Yes *	No *	No *	No *	Yes *	*	Yes *	*
Q10: Is it possible to deliver or dispense <u>non-authorised</u> IMPs directly to trial participants from pharmacies not associated with the clinical trial sites?	No	No *	No	No	No *	Yes	No *	No *	No *	No *	No *	No *	No *	Yes	No		Yes *		No *	No		No	Yes *	Yes *	No *	No *	No *	Yes *	*	Yes *	*
The eConsent process, in relation to RP section 3.																															
Q11: Is a physical face to face meeting between the trial participant and the PI or a member of the research team always mandatory during the consent procedure (even if the rest is conducted remotely)?	No	No	Yes *	Yes	No *	Yes *	No *	*	*	No *	No	No *	No *	Yes *	No		No *		No	Yes	No	No	No *	No	No	Yes *	No	No	*	No	No *
Q12: Is it possible to use electronic signatures instead of wet ink? If yes, please specify in the footnotes which eIDAS category is expected for the electronic signature.	Yes *	Yes *	Yes *	Yes	Yes *	Yes *	Yes *	Yes *	*	Yes *	Yes *	Yes *	Yes *	Yes *	Yes		Yes *		Yes *	No	Yes *	Yes	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	*	Yes *	Yes *
Trial participant oversight and home visits, in relation to RP section 2 and 5.																															
Q13: Is it possible for the PI to delegate tasks under their responsibility to a qualified (for the delegated task) external healthcare provider?	Yes	Yes *	Yes *	*	Yes *	Yes *	Yes	Yes *	Yes *	Yes *	Yes	Yes *	Yes	Yes *	Yes		Yes		Yes *	No	Yes	Yes	Yes *	Yes *	Yes *	Yes *	Yes *	Yes *	Yes	Yes	Yes *
Q14: Certain tasks/procedures carried out at home may require supervision of the investigator (a physician). Is it allowed for the physician to supervise remotely?	Yes	Yes *	Yes *	*	No *	Yes *	Yes	*	*	*	Yes	*	Yes *	Yes *	Yes *		Yes		Yes	Yes *	*	Yes	Yes *	Yes	*	Yes *	No *	Yes *	*	No	Yes *
Trial Monitoring using remote access to source data, in relation to RP paper section 7																															
Q15: Is remote access to the medical records allowed by the monitor or auditor?	Yes *	No *	Yes *	*	Yes *	Yes *	Yes *	*	No	*	Yes	Yes *	No *	Yes *	Yes *		Yes *		Yes *	No	*	Yes	Yes *	*	*	Yes *	No	No	No *	No	Yes *

Appendix 2: Footnotes to the DCT Provision Overview by Switzerland

	CH
Q1	Sponsor must be compliant with ICH GCP E6, national law and GDP.
Q2	see Q1.
Q3	see Q1.
Q4	-
Q5	-
Q6	-
Q7	An import license for the duration of the clinical trial is issued with the authorisation letter (art 19 para. 1 MPLO)
Q8	A manufacturing license for labelling of Investigational medicinal Products according to art. 5 para.1 let. a TPA from Swissmedic has to be in place.
Q9	Currently under investigation
Q10	Currently under investigation
Q11	If the study participant requests a face-to-face meeting with the PI, this must be respected. The eIC can make use of electronic media (e.g., video, podcasts, interactive websites, applications for tablets and smart phones, etc.) to convey the information.
Q12	According to Art. 7c para. 1 ClinO the informed consent can be given either by signature or in electronic form. Consent given in electronic form is according to Art. 7c para. 3 ClinO permissible provided that: a. it has been granted using a method which unequivocally identifies the person concerned; b. the chosen method prevents an overhasty decision; c. it is protected against modification in accordance with the state of the art; d. it is described in the application documents how the requirements specified in letters a - c are met. Please consult the electronic informed consent guidance and checklist of swissethics, which is published on the swissethics.ch website under: Topics, Position papers, Conception and application of an electronic informed consent (eIC)
Q13	The PI has the overall responsibility and the staff must be listed on the delegation log. Medical tasks and decisions must be performed by physicians.
Q14	That depends on the type of medical intervention and will be evaluated on a case-by-case basis. The safety and the well-being of the participant is the main priority.
Q15	Separate electronic access for the monitor with read-only rights and appropriate data protection measures (e.g., with two-factor authentication and a VPN [virtual private network]). In addition, the monitor must sign a confidentiality agreement promising not to take screenshots or printouts of medical records and not to access such data remotely if unauthorised persons can view them (especially in public areas). Further guidance can be found above in section 2.7 “Remote source data verification (rSDV)” of this document.

Appendix 3: Footnotes to the DCT Provision Overview by EU Member States

	AT
Q1	§57, §59(1), (9) AMG (Austrian Medicines Act) Change in national legislation/guidelines is ongoing
Q2	§57 AMG (Austrian Medicines Act), exception: Authorised or registered, non-prescription medicinal products could be delivered directly to patients as per §59(10) AMG (Austrian Medicines Act). Change in national legislation/guidelines is ongoing
Q3	§57 AMG (Austrian Medicines Act), exception: Authorised or registered, non-prescription medicinal products could be delivered directly to patients as per §59(10) AMG (Austrian Medicines Act).
Q4	-
Q5	-
Q6	§57 AMG (Austrian Medicines Act), exception: Authorised or registered, non-prescription medicinal products could be delivered directly to patients as per §59(10) AMG (Austrian Medicines Act).
Q7	§57, §59(1), (9) AMG (Austrian Medicines Act)
Q8	-
Q9	(For non-prescription medicinal products only), packaging and labelling must not be changed, IMP must be from trial stock
Q10	-
Q11	-
Q12	The use of advanced and qualified electronic signatures is accepted. Integrity and authenticity of the signature must be undisputable.
Q13	-
Q14	-
Q15	Allowed for original electronic medical records only. The electronic medical record system must be validated for that purpose.

	BE
Q1	Not allowed, unless specified in the CTA why a waiver should be authorized, referring to the Q&A n°10: https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/qa-good-clinical-practice-gcp [Change in national legislation ongoing]
Q2	Same approach as in Q1 and according to the RD of 21 January 2009, a pharmacy in Belgium must deliver each medication in person to a patient, with the exception in art. 29 of medication free of prescription. [Change in national legislation ongoing]
Q3	According to the RD of 21 January 2009, a pharmacy in Belgium must deliver each medication in person to a patient, with the exception in art. 29 of medication free of prescription. [Change in national legislation ongoing]
Q4	According to the RD of 21 January 2009, a pharmacy in Belgium must deliver each medication in person to a patient, with the exception in art. 29 of medication free of prescription. An investigator can also provide the trial participant in person with an amount of medication (IMP). [Change in national legislation ongoing]
Q5	Same as Q4
Q6	Same as Q4
Q7	According to art. 43 of the RD 9/10/2017
Q8	Labelling is a manufacturing operation. Labelling is only possible if the site/pharmacy has a GMP licence.
Q9	Only a delegated pharmacy (delegated by the PI) can deliver or dispense IMPs.
Q10	Only a delegated pharmacy (delegated by the PI) can deliver or dispense IMPs.
Q11	-
Q12	According to the national guidance on e-ICF, for remote signing, only an advanced or a qualified electronic signature as defined in the eIDAS regulation (Ref. 3) should be used as they uniquely identify the individual signing. Only a qualified electronic signature has the equivalent legal effect of a handwritten signature (eIDAS, art 25. §2.). Signatures via e-ID (Ref. 4) or itsme® (Ref. 5) are qualified electronic signatures. The advanced signature should comply with the defined requirements as described in the article 26 of the eIDAS Regulation that give guarantees of the identification of the individual signing. More information is available on the website of the FPS Economy (Ref. 6). References are available in https://consultativebodies.health.belgium.be/en/e-ICF%20guidance%20Belgium_30-09-2020
Q13	Provided that the delegated tasks fall under the qualification of the study personnel according to the Belgian legislation.
Q14	Provided that the delegated tasks fall under the qualification of the study personnel according to the Belgian legislation.
Q15	Remote source data verification is as such not allowed. This is only possible in specific cases, approved during the CTA process under the following conditions: - An agreement has been setup describing rSDV which is approved by all parties (institution, principal investigator and the sponsor or the CRO assigned). - The rSDV can be organized by the investigator's site and is therefore technically feasible without compromising the confidentiality of the Electronic Medical Records data.

	BG
Q1	It is possible, but it will be assessed on a case by case basis with respect to the character of the particular IMP and the medical condition.
Q2	It is possible, but the pharmacy must be part of the approved trial site. It will be assessed on a case by case basis with respect to the character of the particular IMP and the medical condition.
Q3	-
Q4	-
Q5	-
Q6	-
Q7	-
Q8	-
Q9	-
Q10	-
Q11	Face to face meeting between the trial participant and the PI or a member of the research team is always mandatory during the consent procedure.
Q12	It is possible to electronically sign the Informed consent form (ICF), as the only permissible method is using qualified electronic signature (only qualified electronic signature issued by a licensed provider), replacing the handwritten signature but without fully digitalizing the entire informed consent process.
Q13	It is possible, but it will be assessed on a case by case basis. In case that clinical trial activities will be carried out outside the trial site, the location outside the site shall be indicated with the name of the medical institution, the structure therein and the exact address of the activity, as well as the names and qualifications of the relevant person carrying out the activity, where applicable. The information should be present in the Site Suitability Form and in the ICF. Home visits are generally not allowed, except in limited cases after assessment.
Q14	-
Q15	in certain cases- Information should be provided and assessed.

	CY
Q1	Any exemption is subject to a justified request and a case-by-case assessment and approval.
Q2	Any exemption is subject to a justified request and a case-by-case assessment and approval.
Q3	-
Q4	-
Q5	-
Q6	-
Q7	IMP delivery to investigational sites is possible upon a case-by-case assessment and approval.
Q8	Not addressed in the national pharmaceutical legislation. Case by case assessment and approval.
Q9	-
Q10	-
Q11	-
Q12	-
Q13	Case-by-case assessment. Comprehensive documentation and adherence to GCP guidelines is expected
Q14	Case-by-case assessment. Comprehensive documentation and adherence to GCP guidelines is expected
Q15	Case by case assessment. Comprehensive documentation and adherence to GDPR rules and GCP guidelines is expected.

	CZ
Q1	It is possible, but it will be assessed on a case by case basis with respect to the character of the particular IMP and its pharmaceutical form (tablets, infusion etc.) It would not be possible in case of IMPs that need to be diluted or reconstituted before administration, because these operations have to be carried out by healthcare professionals appointed by the healthcare service provider (Section 79 (10) of Act no. 378/2007 Coll., on Medicinal Products). The sponsor must then proceed in accordance with national guideline VYR-44, available on SUKL's website.
Q2	It is possible if the pharmacy is closely connected with the trial site. It is possible then to deliver IMPs directly to trial participants from the pharmacy based on investigator´s request. But it will be assessed on a case by case basis with respect to the character of the particular IMP and its pharmaceutical form (tablets, infusion etc.) It would not be possible in case of IMPs that need to be diluted or reconstituted before administration, because these operations have to be carried out by healthcare professionals appointed by the healthcare service provider (Section 79 (10) of Act no. 378/2007 Coll., on Medicinal Products). The sponsor must then proceed in accordance with national guideline VYR-44, available on SUKLS's website.
Q3	It is possible if the pharmacy is connected with the trial site per contract. It is possible then to deliver IMPs directly to trial participants from the pharmacy based on investigator´s request. But it will be assessed on a case by case basis with respect to the character of the particular IMP and its pharmaceutical form (tablets, infusion etc.) It would not be possible in case of IMPs that need to be diluted or reconstituted before administration, because these operations have to be carried out by healthcare professionals appointed by the healthcare service provider (Section 79 (10) of Act no. 378/2007 Coll., on Medicinal Products). The sponsor must then proceed in accordance with national guideline VYR-44, available on SUKLS's website.
Q4	In general, the trial site pharmacy or PI is responsible for IMP handling. (Section 75 (5) and section 77 Act no. 378/2007 Coll., on Medicinal Products). Also, in line with the GCP the sponsor must not know trial participant's identification.
Q5	In general, the trial site pharmacy or PI is responsible for IMP handling. (Section 75 (5) and section 77 Act no. 378/2007 Coll., on Medicinal Products) Also, in line with the GCP the sponsor must not know trial participant's identification.
Q6	In general, the trial site pharmacy or PI is responsible for IMP handling. (Section 75 (5) and section 77 Act no. 378/2007 Coll., on Medicinal Products)
Q7	-
Q8	Delegated pharmacy can label IMP, but it must be treated contractually in case that delegated pharmacy and trial site are not the same legal entities.
Q9	In general, the trial site pharmacy or PI is responsible for IMP handling. (Section 75 (5) and section 77 Act no. 378/2007 Coll., on Medicinal Products)
Q10	In general, the trial site pharmacy or PI is responsible for IMP handling. (Section 75 (5) and section 77 Act no. 378/2007 Coll., on Medicinal Products)
Q11	But in accordance with Act no. 378/2007 Coll., on Medicinal Products, an investigator must always be a physician and only the investigator is responsible for dialogue with the participant during the consent procedure.
Q12	In our view, it is possible to use a qualified electronic signature in accordance with Regulation (EU) no. 910/2014 of the European Parliament and of the Council of 23 July 2014 on Electronic Identification and Trust Services for Electronic Transactions in the Internal Market and Repealing Directive 1999/93/EC (the „eIDAS regulation"). However, given that the acceptability of electronic signatures concerns all EU member states and the approach should be harmonised, we recommend to confirm with the European Commission should there be any differing views.
Q13	Home care is possible in the CZ, but with certain limits – please see more information on the website here https://sukl.gov.cz/en/en-reg-kh-doplnujici-informace/home-care-3/
Q14	Due to safety of patients. Supervision of a physician is necessary due to situations where potential action from a physician would be required in case of any urgent emergency (risk procedure etc.) In such case remote supervision can put the participant in danger (connection loss, misunderstanding in communications etc.)
Q15	As the medical records are currently available in the paper form at the trial sites, the remote access is not allowed. With the ongoing digitization of healthcare systems at the trial sites, the remote access to the medical data will be reviewed case by case.

	DE
Q1	Not subject to CT legislation
Q2	Certain restrictions for e.g. hospital pharmacies may apply.
Q3	-
Q4	In principle: Not allowed. According to Section 47 (1) sentence 1 number 2 letter g German Medicinal Product Act pharmaceutical entrepreneurs and wholesalers may only supply pharmacy only medicinal products only then directly and only to hospitals and doctors if the medicinal products are labelled "Intended for clinical trials", provided they are supplied free of charge. Exceptions: According to an exemption valid until 31. December 2023, the NCA may, by way of derogation from Section 47 (1) sentence 1 number 2 letter g AMG, permit pharmaceutical entrepreneurs (also: sponsors) and wholesalers to make medicinal products labelled for clinical trials available free of charge to participants in a clinical trial if, after an assessment to be carried out by the sponsor on a case-by-case basis, the safety of the persons participating in the clinical trial and the validity of the data collected in the clinical trial are guaranteed and the pseudonymisation of the data is ensured by appropriate measures that the trial participants have the right to contact the sponsor. This should be reflected in the protocol
Q5	
Q6	See explanation to Q4; only for pharmacy licence holders
Q7	Section 47 (1) sentence 1 number 2 letter g and section 73 (2) number 2 German Medicinal Product Act.
Q8	It is crucial, that the manufacturer or the pharmacy has a manufacturing license
Q9	-
Q10	-
Q11	Face to face meeting not subject to German Medicinal Product Act. According to Model Professional Code for Physicians of the German Medical Association exclusive counselling or treatment via communication media is permitted in individual cases if this is justifiable from a medical point of view and the required medical care is observed, in particular by the way in which the findings are ascertained, counselling, treatment and documentation are carried out and the patient is also informed about the special features of exclusive counselling and treatment via communication media.
Q12	Only possible, when qualified electronical signature (eIDAS)
Q13	Possible in principle, but medical activities must be carried out by a physician
Q14	„In principle, yes, subject to the qualification requirements under national law for the medical personnel to whom a task is assigned; a number of medical tasks may according to national law only be performed by physicians (with a medical license to „In principle, yes, subject to the qualification requirements under national law for the medical personnel to whom a task is assigned; a number of medical tasks may according to national law only be performed by physicians (with a medical license to practice medicine
Q15	In principle, yes, provided that the investigators can and does comply with their obligation to maintain the confidentiality of his patients' health records; therefore, the responsibility for answering this question is with the respective investigator

	DK
Q1	-
Q2	-
Q3	Yes, for hospital pharmacies.
Q4	A framework is being developed and will be provided in national guidance.
Q5	A framework is being developed and will be provided in national guidance.
Q6	-
Q7	-
Q8	-
Q9	If dispensed and then delivered according to normal prescription practice and taken by pharmacy standard stock of medicinal products.
Q10	-
Q11	The physical face-to-face meeting is the primary expectation, but video-based communication can be accepted in certain situations, as per decision of the ethical committee.
Q12	Currently both NemID (OCES standard) and MitID (eIDAS-compliant) is accepted.
Q13	-
Q14	-
Q15	Please consult the DKMA DCT guidance for specific requirements if utilised for rSDV.

	EE
Q1	-
Q2	Not allowed for hospital pharmacies
Q3	The conditions and procedure for the issue of prescriptions for medicinal products and for the dispensation of medicinal products by pharmacies and the format of the prescription
Q4	Medicinal Products Act
Q5	Medicinal Products Act
Q6	Medicinal Products Act
Q7	-
Q8	Re-labelling is restricted to associated pharmacy
Q9	The conditions and procedure for the issue of prescriptions for medicinal products and for the dispensation of medicinal products by pharmacies and the format of the prescription
Q10	The conditions and procedure for the issue of prescriptions for medicinal products and for the dispensation of medicinal products by pharmacies and the format of the prescription
Q11	If justified. Remote authentication and facial recognition.
Q12	Qualified electronic signature (Smart ID, Mobile ID and ID card)
Q13	-
Q14	Case by case
Q15	Remote SDV not allowed

	EL
Q1	Direct shipment to the patient is not addressed in CT legislation. In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q2	Direct shipment to the patient is not addressed in CT legislation. In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q3	In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q4	In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q5	In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q6	In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q7	Yes, however IMPs are shipped to the trial site (not to specific investigators).
Q8	-
Q9	In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q10	In general, the trial site Head of hospital pharmacy or PI is responsible for IMP handling. Ministerial Decree O.J. 4131/2016, Art 6.
Q11	Although not specifically addressed in CT legislation, a face-to-face meeting is implied. Ministerial Decree O.J. 4131/2016, Art. 9. In addition, the National Ethics Committee interpretation is that a face-to-face meeting is required for the provision of Informed Consent.
Q12	In general, electronic signatures are acceptable in Greece. However, CT specific legislation does not address the issue. The National Ethics Committee requires wet ink signatures.
Q13	Ministerial Decree O.J. 4131/2016, Art. 3
Q14	Not specifically addressed in current CT legislation
Q15	-

	ES
Q1	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ) (however this activity should be managed by the Pharmacy Department [unless the site has no Pharmacy]).
Q2	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ)
Q3	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ). It is covered by Autonomous Communities legislation (e.g., Law 19/1998 the organization of pharmaceutical services in Madrid)
Q4	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ)
Q5	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ)
Q6	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ). It is covered by Autonomous Communities legislation (e.g., Law 19/1998 the organization of pharmaceutical services in Madrid)
Q7	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ). Except if the trial site has no Pharmacy Department.
Q8	Regulation 536/2014 article 61.5 a). If the delegated pharmacy is taking part in the same clinical trial in the same Member State.
Q9	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ)
Q10	Real Legislative Decree 1/2015 article 3.6 c) and Royal Decree 1090/2015 article 39 ñ)
Q11	Physical face to face is not specifically established by any national provisions.
Q12	If high level of eIDAS and if the confidentiality of the personal data, data security and secure access to the data is ensured. See national Guidelines for undertaking decentralised items in clinical trials
Q13	If an adequate investigator oversight and proper contractual arrangements between sponsor, trial site and investigator is ensured. Data protection aspects should also be considered.
Q14	Certain tasks/procedures should be defined in order to provide proper assessment. General Data Protection Regulation (GDPR) should be addressed in this regard.
Q15	There are no specific national provisions; GDPR covers this aspect in the entire EU and should be considered.

	FI
Q1	-
Q2	In special and justified circumstances only
Q3	Medicinal Act §15 b. Fimea Administrative Regulation 2/2016
Q4	Medicinal Act §15 b. Medicinal Act §31
Q5	Medicinal Act §15 b
Q6	Medicinal Act §17. Medicinal Act §15a
Q7	Medicinal Act §17
Q8	Medicinal Act §15a
Q9	Fimea Administrative Regulation 2/2016
Q10	Fimea Administrative Regulation 2/2016
Q11	-
Q12	The national Client Data Act 703/2023 8 and 22§: the participant should be identified reliably (authentication. for example suomi.fi or respective) and the signature method must be advanced or qualified.
Q13	-
Q14	-
Q15	-

	FR
Q1	The shipment to patient home by PUI (hospital pharmacy) are allowed by 'retrocession' (article L. 5126-6 CSP). For experimental drugs in the context of a CT and in absence of any legal specification, ANSM and Ethics Committees may accept it.
Q2	The shipment to patient home by PUI is allowed by 'retrocession' (article L. 5126-6 CSP). For experimental drugs in the context of a CT and in absence of any legal specification, ANSM and Ethics Committees may accept it.
Q3	-
Q4	In accordance with art R 5124-2 and -3 of CSP
Q5	-
Q6	As per French legislation.
Q7	Yes, but under conditions for the shipping to the investigators as per article L 5126-7 of CSP. PUIs are allowed to provide investigators of the same CT or professionals with similar activities outside of France (article R 5124-4 of CSP), with experimental drugs. In the same way dispensers of experimental drugs who are based outside of France, may be allowed to provide French investigators of the same CT with experimental drugs. However, these deliveries should be in conformity with articles L5121-108 and L5124-13 of CSP and customs code (importation authorization if clinical trial is not already authorized). Under these conditions the ANSM may agree. The labelling should be in French language.
Q8	The community pharmacy is not allowed to label experimental drugs. The labelling of experimental drugs should be performed either by a pharmaceutical entity with a GMP manufacturing authorization, or by a PUI pharmacy with authorization of preparing products needed for clinical trials (article R.5126-9 CSP).
Q9	Not possible for a PUI pharmacy in a hospital that is not involved in the given clinical trial (article L. 5126-1 CSP). Possible for a community pharmacy under conditions of article D. 5125-45-1 of CSP - if specified in the protocol, the ANSM may agree.
Q10	Not possible (article L. 5126-1 and D. 5125-45-1 of CSP)
Q11	Not mandatory
Q12	Based on the following legal references: - Article L1122-1-1 paragraph 1 of CSP & article 1367 of Civil code. - The European regulation (UE) number 910/2014 of European Parliament and of the Council of 23 July 2014 concerning the electronic identification does distinguish three types of electronic signatures: the simple electronic signature, the advanced signature (article 26 of regulation) and qualified signature. The e-consent is legal (via these 3 categories of signature) but not yet used in France under this scope.
Q13	Provided that the delegation is appropriately planned in the study protocol and validated by competent authorities. This possibility allows to involve the private physicians who work outside the hospitals in clinical studies.
Q14	As of today, it is not forbidden in the regulation. As a consequence, it is allowed for a given trial provided that there is no opposition from ANSM or from the Ethics Committees.
Q15	Fulfilling the recommendations of the CNIL (French DPA) about regulation and sensitive data protection. cf. provisional recommendations during the Covid crisis (https://www.cnil.fr/fr/recommandations-provisoires-controle-qualite-essais-cliniques-crise-sanitaire)”

	HR
Q1	The IMP must be managed by trial site pharmacy or PI.
Q2	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q3	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q4	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q5	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q6	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q7	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q8	According to the Medicinal Product Act only wholesale distributors with a manufacturing authorisation are allowed to perform labelling of IMPs.
Q9	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q10	According to the Medicinal Product Act only wholesale distributors can distribute medicinal products and the IMP is dispensed to the participant by the trial site pharmacy or PI.
Q11	Physical face to face meeting between the trial participant and the PI or a member of the research team is yet mandatory in Croatia.
Q12	Although not specifically addressed in CT legislation, the use of qualified electronic signatures is accepted.
Q13	-
Q14	It depends on the task/procedure.
Q15	If on-site SDV is not possible, remote SDV is allowed if EU (EC, EMA, HMA) GUIDANCE ON THE MANAGEMENT OF CLINICAL TRIALS DURING THE COVID-19 (CORONAVIRUS) PANDEMIC is respected. Remote SDV must be submitted as substantial protocol amendment to CEC/RA and must be precisely specified in the protocol as to how it will be carried out. Permission to perform remote monitoring should be previously carefully considered with clinical trial site and prior permission and agreement must be reached between the site and the sponsor/CRO.

	HU
Q1	-
Q2	-
Q3	-
Q4	-
Q5	-
Q6	-
Q7	-
Q8	-
Q9	-
Q10	-
Q11	35/2005. (VIII. 26.) Health Ministry Decree
Q12	e-IDAS Art. 6., 7. , 26. , 27. , 36. , 37.
Q13	Consent of the trial participant to the home visits does not reduce in any aspect the responsibilities of the PI.
Q14	Consent of the trial participant to the home visits does not reduce in any aspect the responsibilities of the PI.
Q15	In case of emergency remote SDV should be allowed if EMA „GUIDANCE ON THE MANAGEMENT OF CLINICAL TRIALS DURING THE COVID-19 (CORONAVIRUS) PANDEMIC (most recent version)" is respected with special attention to paragraph 11. d) and Annex 1. In general, the prerequisite of RSDV may not be less stringent.

	IE
Q1	Could be allowed on case-by-case basis, when justified and clearly described in the clinical trial application. Generally recommended to speak with the HPRA.
Q2	Could be allowed on case-by-case basis, when justified and clearly described in the clinical trial application. Generally recommended to speak with the HPRA.
Q3	Could be allowed on case-by-case basis, when justified and clearly described in the clinical trial application. Generally recommended to speak with the HPRA.
Q4	An MIA in itself does not provide for direct distribution to clinical trial participants
Q5	Could be allowed on case-by-case basis, when justified and clearly described in the clinical trial application. Generally recommended to speak with the HPRA.
Q6	Could be allowed on case by case basis, when justified and clearly described in the clinical trial application. Generally recommended to speak with the HPRA. The IMP should comply in all respects with details which have been approved as part of the clinical trial application in Ireland e.g. labelling.
Q7	The IMP should comply in all respects with details which have been approved as part of the clinical trial application in Ireland e.g. labelling.
Q8	In accordance with the terms of CTR Art 61.5, S.I. No. 99/2022 and the HPRA Guide to Registration of Processes Exempted under Article 61(5) of the CTR. Generally recommended to speak with the HPRA.
Q9	When justified and clearly described in the clinical trial application. Generally recommended to speak with the HPRA
Q10	-
Q11	-
Q12	-
Q13	-
Q14	Dependant on task
Q15	There are no provisions in national legislation which prohibit remote access to medical records. However, such access can only be permitted by the institution / persons responsible for control of the data, in consideration of application data protection requirements.

No footnotes for: IS

	IT
Q1	-
Q2	-
Q3	National guideline published on Aug 2024 allowing direct delivery
Q4	National guideline published on Aug 2024 allowing direct delivery
Q5	National guideline published on Aug 2024 allowing direct delivery
Q6	National guideline published on Aug 2024 allowing direct delivery
Q7	Not according to the current provisions for CT according to Directive; national provisions for CT according to CTR are to be made available shortly
Q8	-
Q9	National guideline published on Aug 2024 allowing direct delivery
Q10	National guideline published on Aug 2024 allowing direct delivery
Q11	(CTR art.29 does not foresee a face to face interview, no additional national provision exists on this aspect)
Q12	PADES electronic signature on pdf files is surely accepted; other formats (e.g., CADES) to be confirmed
Q13	-
Q14	-
Q15	In compliance with the GDPR

No footnotes for: LI

	LT
Q1	National legislation does not foresee the delivery of IMP directly to trial participants. Nevertheless, the IMP delivery from trial site to trial participant could be allowed on case by case basis, when justified and clearly described in the clinical trial application.
Q2	Law of pharmacy https://www.e-tar.lt/portal/lt/legalActEditions/TAR.FF33B3BF23DD
Q3	Law of pharmacy https://www.e-tar.lt/portal/lt/legalActEditions/TAR.FF33B3BF23DD
Q4	Law of pharmacy https://www.e-tar.lt/portal/lt/legalActEditions/TAR.FF33B3BF23DD
Q5	-
Q6	Law of pharmacy https://www.e-tar.lt/portal/lt/legalActEditions/TAR.FF33B3BF23DD
Q7	-
Q8	Re-packing and re-labelling can be performed in the hospital pharmacy, associated with the clinical trial site: The Order of the Minister of Health of the Republic of Lithuania No V-571 regarding the procedure of re-packing and re-labelling of IMPs at the clinical trial sites
Q9	Law of pharmacy https://www.e-tar.lt/portal/lt/legalActEditions/TAR.FF33B3BF23DD
Q10	Law of pharmacy https://www.e-tar.lt/portal/lt/legalActEditions/TAR.FF33B3BF23DD
Q11	-
Q12	Qualified electronic signature should be used.
Q13	Delegation of specific functions is possible, contract needed with the relevant and licensed Health care institutions.
Q14	-
Q15	Yes, if electronic medical records are used and access to medical records of particular patient is feasible.

	LU
Q1	It is delivered by the hospital pharmacist to the investigator who then delivers it to the patient.
Q2	The delivery is coordinated by the hospital pharmacy. The pharmacist provides the investigator with the IMP.
Q3	Clinical trials are only performed in hospitals in Luxembourg, and there are no delegated pharmacies for IMPs. IMPs can only be managed by hospital pharmacies.
Q4	-
Q5	-
Q6	-
Q7	-
Q8	-
Q9	-
Q10	-
Q11	-
Q12	Not applicable as not yet done in practice.-
Q13	Delegated tasks are performed by qualified research team members.
Q14	It depends on the clinical trial and task/procedure modalities
Q15	-

	LV
Q1	No restrictions in national legislation
Q2	No restrictions in national legislation
Q3	No restrictions in national legislation
Q4	Delivery to patients is acceptable if patient's confidentiality is ensured.
Q5	Licensed depot is deemed acceptable for IMP delivery directly to the trial participants. Not specifically mentioned in national legislation.
Q6	-
Q7	-
Q8	-
Q9	-
Q10	-
Q11	The physical face-to-face meeting is the primary expectation, but video-based communication can be accepted in certain situations, as per decision of the ethical committee.
Q12	-
Q13	-
Q14	Case-by-case evaluation
Q15	As the medical records are currently mainly available in the paper form at the trial sites, the remote access is possible only if justified. For electronic records access is possible if justified. On site SDV is preferred option.

	MT
Q1	Activity has to be approved so a request should be made to the Medicines Authority
Q2	Activity has to be approved so a request should be made to the Medicines Authority
Q3	-
Q4	-
Q5	-
Q6	-
Q7	-
Q8	-
Q9	-
Q10	-
Q11	-
Q12	-
Q13	-
Q14	-
Q15	-

	NL
Q1	Only in specific circumstances, see Medicines Act (Geneesmiddelenwet), 61.2.
Q2	Medicines Act (Geneesmiddelenwet), article 61.2.
Q3	Medicines Act (Geneesmiddelenwet), article 61.2.
Q4	Medicines Act (Geneesmiddelenwet), article 34.2 and 61.2.
Q5	-
Q6	Medicines Act (Geneesmiddelenwet), article 61.2, 61.5 and 61.6.
Q7	Medicines Act (Geneesmiddelenwet), article 34.2 and 61.2.
Q8	Medicines Act (Geneesmiddelenwet) article 18.1 and 18.7.
Q9	Under the conditions mentioned in Medicines Act (Geneesmiddelenwet) articles 18.1, 34.2 and 61.2.
Q10	-
Q11	However, see requirements in article 6 of the Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen), especially 6.5, 6.6 and 6.7.
Q12	Article 6.2 of the Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen). Guidance on electronic signature (in Dutch): https://www.ccmo.nl/onderzoekers/publicaties/publicaties/2022/08/31/handreiking-elektronische-toestemmingsverlening
Q13	Taking into account the requirements mentioned in the Healthcare Professionals Act (Wet op de beroepen in de individuele gezondheidszorg).
Q14	Taking into account the requirements mentioned in the Healthcare Professionals Act (Wet op de beroepen in de individuele gezondheidszorg).
Q15	Taking into account the requirements mentioned in the General Data Protection Regulation (GDPR).

	NO
Q1	NoMA defines "deliver" as physical delivery to patient, and not shipment. Shipment to patient must be applied for and approved by NoMA.
Q2	-
Q3	-
Q4	Forskrift om tilvirkning og import av legemidler § 3-2/Forskrift om grossistvirksomhet § 13
Q5	Forskrift om tillvirkning og import av legemidler § 3-2 /Forskrift om grossistvirksomhet § 13
Q6	Forskrift om tillvirkning og import av legemidler § 3-2/forskrift om grossistvirksomhet § 13
Q7	Forskrift om tillvirkning og import av legemidler § 3-2/forskrift om grossistvirksomhet § 13
Q8	Pharmacies with a “pharmacy manufacturing license” are allowed to re-label IMP. Only pharmacies with an ordinary MIA can label IMP.
Q9	Provided agreement with the sponsor (Apotekforskriften § 27 g)
Q10	Provided agreement with the sponsor (Apotekforskriften § 27 g)
Q11	-
Q12	Qualified electronic like for instance BankID is acceptable.
Q13	Provided contractual arrangement
Q14	-

Q15	No national legislations regulating such activities. However, compliance with GDPR is a prerequisite as well as adherence to local procedures.

	PL
Q1	Poland indicated acceptance of this solution in 2022 but it is not specifically addressed in current PL legislation
Q2	-
Q3	Public pharmacies do not IMPs. 68.1 pharmaceutical law (u.p.f). Retail trade in medicinal products is carried out in generally accessible pharmacies, subject to the provisions of para. 2, art. 70 sec. 1 l art. 71 sec. 1. When Art. 86 par. 2a upf pharmaceutical services referred to in art. 4 sec. 3 points 5 and 7 of the Act of 10 December 2020 on the pharmaceutical profession and professional tasks referred to in art. 4 sec. 4 points 1, 2, 5-7, 15 and 16 of this Act, may be provided only in a hospital pharmacy, company pharmacy or hospital pharmacy separated from these pharmacies" (Article 4 paragraph 4 point 2 of the Act - "Examination in auxiliary tests including research conducted in the hospital as a member of the research team." Thus, community pharmacies cannot provide IMP for research.
Q4	No. Annex 13 of the Regulation GMP defines the obligations of the manufacturer of investigational medicinal products, including the points below are as follows: point 44. The distribution of investigational medicinal products is carried out in accordance with the instructions given by or on behalf of the sponsor in the distribution order. 46. Detailed inventory records of shipments of investigational product sent by the manufacturer or supplier shall be maintained. In particular, it includes data identifying recipients. Currently, the PF Act, art. 42 par. 2 point 2 defines to which entities the manufacturer/importer may distribute medicinal products, there is no direct recipient - study participant listed there.
Q5	-
Q6	No, in relation to generally available pharmacies - they cannot participate in clinical trials, they can only trade medicinal products - Art. 68 sec. 1 u.p.f.
Q7	No, in relation to generally available pharmacies - they cannot participate in clinical trials, they can only trade medicinal products - Art. 68 sec. 1 u.p.f.
Q8	Not. Any delegated pharmacy may not label the IMP, this is limited to the pharmacy associated with the study site. Article 38b upf
Q9	Pharmaceutical services referred to in Art. 4 sec. 3 points 5 and 7 of the Act of 10 December 2020 on the profession of a pharmacist, and the professional tasks referred to in art. 4 sec. 4 points 1, 2, 5-7, 15 and 16 of this Act, may be provided only in a hospital pharmacy, company pharmacy or a hospital pharmacy department established instead of these pharmacies" (Article 4 paragraph 4 point 2 of the u.o.z.f - "participation in research clinical trials, including trials conducted in a hospital as a member of the research team". Thus, generally accessible pharmacies cannot provide IMPs to trial participants. This is the task of a hospital pharmacy, an in-house pharmacy, a medical entity where a clinical trial is conducted
Q10	as above
Q11	In accordance with the Act on the professions of physician and dentist Art. 42. 1. A physician shall rule on the health status of a given person after previously examining him personally or examining him via teleinformatic systems or communication systems (...)
Q12	Qualified electronic signature is acceptable
Q13	Poland indicated acceptance of this solution in 2022 but it is not specifically addressed in current PL legislation
Q14	Poland indicated acceptance of this solution in 2022 but it is not specifically addressed in current PL legislation
Q15	Not forbidden

	PT
Q1	as long as shipping conditions are kept under control
Q2	as long as shipping conditions are kept under control
Q3	to be assessed on a case-by-case basis; IMP circuit should be clearly and in detail described in the CT protocol
Q4	to be assessed on a case-by-case basis; IMP circuit should be clearly and in detail described in the CT protocol
Q5	Article 32nd, Law 21/2014, from the 16th of April, current version
Q6	Article 32nd, Law 21/2014, from the 16th of April, current version
Q7	to be assessed on a case-by-case basis; IMP circuit should be clearly and in detail described in the CT protocol
Q8	Pharmacies with a “pharmacy manufacturing license” are allowed to re-label IMP. Only pharmacies with an ordinary MIA can label IMP.
Q9	Article 32nd, Law 21/2014, from the 16th of April, current version; the pharmacies must be included on the IMP circuit described in detail in the CT protocol
Q10	Article 32nd, Law 21/2014, from the 16th of April, current version
Q11	Dialogue is mandatory
Q12	On a case-by-case basis; wet ink use should also be possible, along with e-signatures; according to the EC website, reuse of CEF eID sample implementation software is described as being implemented in Portugal; please refer to Autenticacao.gov.pt
Q13	Healthcare provider must be in direct dependency of the IP

Q14	Should be clearly specified in the CT protocol
Q15	This should be approached under the EU GDPR. Remote monitoring may be performed using video or by sending the de-identified data via email using secure means. Direct remote access to the site´s patient records computer systems is not allowed

	RO
Q1	-
Q2	In Romania, authorizes activities for pharmacies are explicitly mentioned in the Pharmacy Law nr 266/2008 which permit shipping activities only for OTC medicines
Q3	In Romania, authorizes activities for pharmacies are explicitly mentioned in the Pharmacy Law nr 266/2008 which permit shipping activities only for OTC medicines
Q4	-
Q5	Based on authorisation issued by ANMDMR
Q6	-
Q7	-
Q8	-
Q9	In Romania, authorizes activities for pharmacies are explicitly mentioned in the Pharmacy Law nr 266/2008 which permit shipping activities only for OTC medicines
Q10	In Romania, authorizes activities for pharmacies are explicitly mentioned in the Pharmacy Law nr 266/2008 which permit shipping activities only for OTC medicines
Q11	-
Q12	Advanced electronic signature/ Qualified electronic signatures
Q13	Only if it is an accredited medical service provider
Q14	Not yet. National provisions are under development
Q15	-

	SE
Q1	If relevant national legislation (for example "Lag (2009:366) om handel med läkemedel") is followed.
Q2	If relevant national legislation (for example "Lag (2009:366) om handel med läkemedel") is followed. Any pharmacy that is handling IMPs for a clinical trial site should have a CT specific delegation (either from site or sponsor/CRO) and established routines for handling IMP.
Q3	If relevant national legislation (for example "Lag (2009:366) om handel med läkemedel") is followed. Any pharmacy that is handling IMPs for a clinical trial site should have a CT specific delegation (either from site or sponsor/CRO) and established routines for handling IMP.
Q4	-
Q5	-
Q6	Current interpretation of "Lag (2009:366) om handel med läkemedel"
Q7	Current interpretation of "Lag (2009:366) om handel med läkemedel"
Q8	Labelling of IMPs in pharmacies is restricted to e.g. auxiliary labelling of authorised IMPs, if performed in accordance with relevant national pharmacy legislation. Please refer also to national legislation HSLF-FS 2021:109. Any pharmacy that is handling IMPs for a clinical trial site should have a CT specific delegation (either from site or sponsor/CRO) and established routines for handling IMP.
Q9	If relevant national legislation (for example "Lag (2009:366) om handel med läkemedel") is followed. Any pharmacy that is handling IMPs for a clinical trial site should have a CT specific delegation (either from site or sponsor/CRO) and established routines for handling IMP.
Q10	If relevant national legislation (for example "Lag (2009:366) om handel med läkemedel") is followed. Any pharmacy that is handling IMPs for a clinical trial site should have a CT specific delegation (either from site or sponsor/CRO) and established routines for handling IMP.
Q11	-
Q12	The system used (level of category) is the responsibility of the sponsor.
Q13	If relevant national healthcare legislation and hospital practices allows for it.
Q14	If relevant national healthcare legislation and hospital practices allows for it.
Q15	-

	SI
Q1	In case the trial site is a Hospital, the IMP must be managed by Hospital pharmacy Art 62, Par 3 and Par 7 of Pharmacy Practice Act
Q2	Always under supervision of the investigator of the trial site
Q3	In case the trial site is a Hospital, the IMP must be managed by Hospital pharmacy article 67 point 7 (1)
Q4	In case the trial site is a Hospital, the IMP must be managed by Hospital pharmacy article 67 point 7 (1)
Q5	Only in exceptional situation (IMP shortage due to for example COVID-19 lock-down and should be on the basis of a risk assessment with patient safety as utmost priority and only after agreement with the investigator and on the basis of the investigator's prescription.
Q6	In case the trial site is a Hospital, the IMP must be managed by Hospital pharmacy article 67 point 7 (1) Only after agreement with the investigator and on the basis of the investigator's prescription.
Q7	In case the trial site is a Hospital, the IMP must be managed by Hospital pharmacy article 67 point 7 (1) Only after agreement with the investigator and on the basis of the investigator's prescription.
Q8	Delegated pharmacy must comply with special requirements in accordance with Article 13 Par 2.
Q9	It is not appropriate if IMP is blinded. Under oversight of investigator of trial site. The trial drug must be marketed and used within the approved indication (according to the SmPC).
Q10	It is not appropriate if IMP is blinded. Under oversight of investigator of trial site. The trial drug must be marketed and used within the approved indication (according to the SmPC).
Q11	In accordance to ICH GCP The investigator, or a person designated by the investigator, should fully inform the participant or the participant's legally acceptable representative, of all pertinent aspects of the trial & and should answer all participant questions. The communication of this information should be documented.
Q12	Currently, there is no established practice.
Q13	-
Q14	depending on the procedure/task
Q15	If on-site SDV is not possible for a longer period of time due to for example lock-down due to pandemic, remote rSDV must be submitted as substantial protocol amendment to EC/RA and must be precisely specified in the protocol as to how it will be carried out, so that the rights of the participants will be protected and will not unnecessarily burden the staff at the trial site who must agree to such a method of data verification. Monitors should sign a written confidentiality agreement committing to securely destroy any copy of redacted documents, whether paper or electronic, as soon as they have been used for source data verification and committing not to make any copy (or recording in the case of video access) of any non-pseudonymised document.

References from SI:
(1) Pharmacy Practice Act (Official Gazette of the RS, no. 85/16, 77/17, 73/19 and 186/21)
(2) Regulation on the implementation of the Regulation (EU) on clinical trials of medicinal products for human use (Official Gazette of the Republic of Slovenia, No. 132/22)

	SK
Q1	
Q2	
Q3	
Q4	
Q5	
Q6	
Q7	
Q8	
Q9	Pharmacist must be delegated by PI.
Q10	Pharmacist must be delegated by PI.
Q11	
Q12	Qualified electronic signature for investigator and participant is required according to the Act No. 272/2016 on credible services for electronic transaction for domestic trade. According to the EU regulation, the new forms of eIDAS are AsiC-E, AsiC-S and are acceptable.
Q13	
Q14	According to § 2(46) of Act No. 576/2004 Coll. on Health Care, Services Related to the Provision of Health Care, and on the Amendment and Supplementation of Certain Acts
Q15	