

Form

Terms of use Master CT contract

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Terms

The following definitions apply

Swissmedic	Swiss Agency for Therapeutic Products, Hallerstrasse 7, CH-3000 Bern 9
eGov service	All electronic services offered by Swissmedic within the navigation structure and visual framework of the eGov system in question, including access-protected electronic services provided on the swissmedic.ch domain that are directly linked to the respective eGov system.
eGov CT service	The web-based eGov CT service enables eGov CT parties to electronically submit legally binding entries relating to approval procedures and the implementation of clinical trials (e.g. scientific documentation, and correspondence, notifications and reports, including Development Safety Update Reports [DSUR]) and to receive corresponding legally opened decisions from Swissmedic. The service can also be used to track the current status of applications submitted to Swissmedic and of ongoing clinical trials.
Master CT contract	Contract containing all the provisions governing the use of the eGov CT service and concluded by the eGov CT party.
Terms of use of the master CT contract	The provisions of the master CT contract for using the Swissmedic eGov CT service.
eGov CT party, also referred to as eGov party	Contracting party of Swissmedic in the master CT contract, including the natural persons working for a contracting party who use the eGov CT service of Swissmedic on behalf of the contracting party. The contracting party is the sponsor referred to in Article 2 letter d of the Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices (ClinO; SR 810.305), who can be headquartered or domiciled in Switzerland or abroad.
Representative in Switzerland	If the eGov CT party has to state a representative in Switzerland according to Article 2 letter d ClinO, this representative should be specified with the required details in the contract. The representative in Switzerland is the address for service for the opening of decisions sent by post (any further obligations are based on the applicable legislation and the published interpretation guide dated 22.04.2014: Obligations of representatives of foreign sponsors).
Account management by the eGov CT party	The eGov party shall designate a maximum of two account administrators. They may designate additional individuals who can be authorised to use the respective eGov CT service on behalf of the eGov CT party.
Account administrators	Individuals designated by the eGov CT party who are able to designate additional individuals, authorise them to use the eGov CT service and manage their accounts on behalf of the eGov CT party. A maximum of two account administrators can be appointed per eGov CT party.
Account	Access authorisation for an access-restricted eGov CT service or the underlying system. The eGov CT party must use the appropriate credentials to authenticate itself during log-in.
Credentials	The eGov CT party must authenticate itself during log-in using the appropriate credentials, i.e. log-in ID, personal password, SMS codes or other criteria used to authenticate the eGov CT party during log-in.
Electronic legal transactions	Official communications by means of legally binding electronic messages, i.e. the electronic transmission of data submissions arising from the issuing of a decision by Swissmedic and decisions issued by Swissmedic as defined in the Ordinance of 18 June 2010 on electronic transmissions in connection with an administrative procedure (ECAPO, SR 172.021.2).

1. Subject matter

These terms of use of the master CT contract set out the legal framework and the terms for using the eGov CT service. They apply to eGov CT parties.

In the event of discrepancies between the various language versions, the German version is definitive in each case.

2. Contract

2.1 Contracting party

The master CT contract applies to an eGov CT party in order to conduct electronic administrative procedures relating to clinical trials with medicinal products.

Swissmedic concludes the master CT contract with the sponsor who, according to Article 2 letter d of the Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices (ClinO; SR 810.305), takes responsibility for organising a clinical trial. If a representative in Switzerland is required, this representative should be specified in the contract. Any change to the representative in Switzerland must be reported promptly to Swissmedic in a written, signed document.

2.2 Conclusion of the contract

Registration for the eGov CT service takes place by means of a master CT contract that has to be signed by hand. The contractual relationship comes into being when the master contract sent to Swissmedic has been signed, when any representative in Switzerland has been correctly designated, when the eGov CT party has accepted the terms of use and when the account has been activated.

The master CT contract should be signed by an authorised signatory of the eGov CT party. If a power of attorney for exercising the rights and obligations relating to the eGov CT service contractual relationship has been submitted, an authorised representative of the eGov party may sign the contract. To this end, the eGov party may authorise the representative in Switzerland according to Article 2 letter d ClinO or a person with a valid postal address in Switzerland. Swissmedic shall provide the eGov CT party with a form, the original or a copy of which must be signed (Form: Power of attorney for exercising the rights and obligations relating to the eGov CT service contractual relationship). The eGov CT party or authorised representative must notify Swissmedic promptly of any change (incl. deletion) to this power of attorney in a written, signed document.

3. Services and responsibility of Swissmedic

3.1 General

A description of the eGov CT service can be found in the information sheet "eSubmissions – Standard functions".

3.1 Services of Swissmedic

Swissmedic shall provide the eGov CT parties with online support (instructions, information sheets, FAQ), eGov-specific access to support sites and training. These support services apply exclusively to questions and problems arising in connection with the eGov CT service.

Swissmedic shall endeavour, but cannot guarantee, to make the eGov CT service available to the eGov parties at all times and in fault-free condition. The eGov party will be informed of any imminent maintenance operations. Swissmedic reserves the right, at any time and without consulting the eGov parties, to interrupt, modify, supplement or restrict the processes, structure or functions of the eGov service it provides. Swissmedic may also modify or supplement the credentials at any time. Swissmedic shall provide the eGov party with appropriate details as necessary.

Swissmedic shall make every effort to rectify any loss of service quickly, particularly where such losses of service fall within its area of responsibility. While Swissmedic will make every effort to troubleshoot serious problems quickly, it shall determine the time

at which troubleshooting takes place at its own discretion. Depending in each case on the duration of the failure or interruption, and depending on the complexity of the fault or problem, Swissmedic shall inform the eGov party via its official website www.swissmedic.ch.

Swissmedic is under no obligation to store content or to transmit unread or unsent messages to the eGov party or third parties. After a certain period of time, Swissmedic will delete all messages, regardless of whether they were received or not. This does not affect Swissmedic's statutory storage and archiving obligations.

eGov parties may use the eGov CT service free of charge.

The Swissmedic eGov CT service and the eGov services servers will be operated exclusively in Switzerland. The eGov CT service will only be provided in Switzerland and only for eGov parties with a domicile, registered office, branch or legal representative in Switzerland.

3.2 Electronic legal transactions

Swissmedic provides internet-based eGov CT services for electronic legal transactions and information and data sharing. These services extend and supplement the communication channels for individual business transactions. Electronic legal transactions with Swissmedic are authorised for administrative procedures after the contract has been concluded and the terms of use accepted. In the event of pending administrative procedures, Swissmedic shall decide on the timing and the procedural step from which the switch to electronic legal transactions takes place.

Legally binding data submissions to Swissmedic and decisions issued by Swissmedic are not usually transmitted via an acknowledged delivery platform as defined in Art. 2 of the Ordinance on Electronic Communication in Administrative Proceedings (ECAPO; SR 172.021.2), but via the Swissmedic eGov CT services. In the context of electronic legal transactions, these services constitute a "different transmission method" as defined by Art. 9 para. 2 ECAPO.

Swissmedic attaches a digital signature to e-mails sent in connection with electronic data submissions or decisions. The following arrangements apply in particular.

a. Data submissions to Swissmedic

The list published on the internet by the Federal Chancellery (www.bk.admin.ch) provides information about the specific communication channels and data formats that are approved for electronic submissions to Swissmedic (see Art. 4 ECAPO).

Data submitted electronically will be rejected in the following cases:

The e-mail or documents contained in the e-mail

- are not machine readable or processable or
- contain harmful software (viruses, malware, etc.)

In such cases, the eGov CT party will receive an error message.

Calculation of Swissmedic's time limit then begins on the next working day.

b. Decisions issued by Swissmedic, postal address for service

If the eGov CT party has declared its consent by checking the corresponding checkbox in the contract, all future decisions will be opened electronically for it as part of the eGov CT service. In justified exceptions, Swissmedic may deviate from this arrangement and issue decisions by post. Consent to accept electronic delivery can be withdrawn by sending written notification by post or via the eGov CT service.

Decisions are considered to have been legally delivered when they are opened within a period of 7 days after upload. The time of uploading that determines the 7-day time limit is communicated to

the eGov party as an information component of the delivery receipt. If it is not opened within the 7-day time limit, the decision will be delivered by registered mail.

In the event of the repeated failure to acknowledge receipt of decisions on time, Swissmedic can revert from electronic opening to postal opening.

The address for service of the eGov CT party according to Art. 11b para. 1, sentence 2 of the Administrative Procedure Act (APA; SR 172.021) and Art. 2 letter d of the Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices (ClinO; SR 810.305), whereby parties undertake to designate a representative in Switzerland if they have a place of residence or registered office abroad, corresponds to the representative in Switzerland stated in the contract by the eGov party.

3.2 Responsibility of Swissmedic

Swissmedic does not guarantee the availability and reliability of the eGov CT services or the completeness, authenticity and integrity of the stored data or the data transmitted via its system or the internet. Swissmedic tests the eGov CT services with the browsers and operating systems stated on its website. It cannot guarantee that the eGov CT services will function with other browsers or operating systems.

Despite taking the appropriate protective measures and responding to relevant signs, Swissmedic cannot rule out the possibility of the eGov CT services or associated web applications being used for improper purposes. Furthermore, Swissmedic cannot – despite taking appropriate protective measures – provide any guarantee or warranty that the eGov CT services are safe from hackers, viruses or other attacks. Swissmedic will accept no responsibility for losses arising from improper use by the eGov CT party or third parties.

In connection with e-mail notifications sent via open e-mail services, the eGov CT party also explicitly accepts the risk of data possibly being intercepted or disclosed by third parties during transmission, and understands that, to this extent, confidentiality cannot be guaranteed.

Swissmedic cannot guarantee that e-mails showing Swissmedic as the sender were actually sent by Swissmedic, or that e-mails sent by Swissmedic will be received by the correct recipient unaltered and on time. Swissmedic accepts no responsibility for the content or correct operation of external sites accessed via hyperlinks, or for hyperlinks published on non-Swissmedic websites that can be used to access the eGov services.

Swissmedic shall not be liable for losses arising from the improper use, or use in breach of contract, of the eGov CT services, particularly losses attributable to the failure of the eGov CT party or third parties to exercise their due diligence obligations. Swissmedic shall not be liable for losses suffered by the eGov CT party as a result of transmission errors, technical shortcomings, interruptions, faults or errors in data. In the event of claims, regardless of their legal basis, Swissmedic shall only be liable for losses caused by its own actions or those of its employees, either intentionally or through gross negligence. Swissmedic excludes any liability for its auxiliaries and individuals mandated by it, where legally permissible. Liability for indirect and consequential losses is also excluded, where legally permissible.

If Swissmedic may nevertheless be considered liable, such liability shall be subject to Article 80 of the Therapeutic Products Act (TPA, SR 821.12) in conjunction with Article 19 of the Government Liability Act (GLA, SR 170.32).

4. Obligations and responsibility of the eGov CT party

4.1 General

In this connection see, in particular, the MB-Information sheet "eSubmissions – Standard functions".

4.2 General obligations of the eGov CT party

The eGov CT party is obliged, when it registers and in other usage operations (e.g. address changes), to provide complete and accurate information and to ensure that all information is correct and up to date. The eGov CT party undertakes to use the eGov CT services in compliance with Swiss law and in accordance with the relevant provisions. The eGov CT party also undertakes to safeguard the rights of third parties and to check data prior to transmission to ensure they are correct and free from viruses. eGov parties are responsible for ensuring that their hardware and software satisfy Swissmedic's technical requirements. The eGov CT party is responsible for taking appropriate measures to protect its IT infrastructure and the terminals used to access the eGov services against unauthorised access and misuse by third parties. The account administrator must inform Swissmedic, promptly and in a written, signed document, of any changes to the account administrator information, including deletions.

If the eGov CT party has doubts about the accuracy of particular transmitted information and data, it must contact Swissmedic without delay. If the eGov party has doubts about whether an e-mail or SMS message was actually sent by Swissmedic, the e-mail or SMS message should be opened and the information contained therein followed only after consultation with Swissmedic. If the eGov CT party notices an error (e.g. including unauthorised access by third parties) in use, it shall notify Swissmedic immediately. If, as a result of an error, the eGov CT party gains access to confidential and legally protected information, it shall not be allowed to distribute, reproduce or use said information in any other way.

4.3 Obligations of the eGov CT party concerning electronic legal transactions

The eGov CT party is responsible for storing messages and receipts on its system for evidential purposes in such a way that their content and the exchange of messages that took place can, if necessary, be accurately reconstructed. Swissmedic reserves the right to request the original information, data or documents, or paper copies, from the eGov CT party.

It is the responsibility of the eGov party to ensure that it has a functioning internet connection with sufficient bandwidth to open messages and receipts.

a. Data submissions to Swissmedic

The eGov CT party uses Swissmedic eGov CT services entirely at its own risk, particularly for the purpose of observing time limits. Accordingly, the eGov CT party is solely responsible for delivering or collecting data in good time such that any time limits can still be observed even in the event of any planned or unplanned system interruption.

Data can be submitted electronically at any time. However, for the purpose of observing time limits, business hours are considered to be 8.00 a.m. – 5.00 p.m. CET. The next working day is therefore regarded as the time limit for data submitted after these business hours.

Electronic data submissions to Swissmedic do not require an electronic signature. The master contract on the use of Swissmedic eGov CT services ensures sender identification and transmission integrity by an alternative suitable method in accordance with Art. 6 para. 2 ECAPO. A recognised electronic signature in accordance with Art. 21a para. 2 APA is therefore not required. The eGov party undertakes to preserve signed originals of submission documents that, according to federal law or international standards, have to be signed so that these can, if necessary, be presented or sent by post to Swissmedic (see Art. 4 para. 2e ECAPO).

b. Decisions issued by Swissmedic

The eGov CT party undertakes to check the electronic mailbox associated with the party account at regular intervals, but at least once every 5 working days.

4.4 Responsibility of the eGov CT party

The eGov CT party bears full responsibility for protecting the confidentiality of and securely managing personal passwords and the other credentials. The eGov party is responsible for protecting credentials against misuse by third parties. Swissmedic will hold the eGov party responsible for any use of accesses by employees or third parties and for the content of the information that is transmitted for processing by the eGov party (including its employees) or third parties. Swissmedic regards users who access the system using valid credentials as being authorised to do so by the legitimised eGov CT party. Transactions by such users and data transmitted by them are considered by Swissmedic to have been authorised by the legitimised eGov CT party and therefore legally binding.

The eGov CT party shall be liable for all losses arising from the violation of its contractual obligations.

5. Exclusion from use

5.1 Blocking at the request of the eGov CT party

If the eGov CT party has any indications that unauthorised individuals have gained or could gain access to an account, the eGov party or its administrators shall block the account in question immediately. If the eGov party is unable to block the account in question itself, it shall immediately arrange for the account to be blocked by Swissmedic. Blocking can cover single or all accounts, complete access or individual eGov services. Until Swissmedic is able to block the account at the eGov party's request, the latter shall bear full responsibility for any losses arising from the unauthorised access, regardless of Swissmedic's reaction time.

Contact details for account blocking by Swissmedic:

during business hours	+41 58 462 06 00
outside business hours (Emergency Operations Centre of the Federal Administration, ask to be connected to Swissmedic)	+41 58 465 88 88

5.2 Blocking by Swissmedic

If Swissmedic or its mandated system operators notice any irregularities in the use of the eGov services, Swissmedic can, at its own initiative, temporarily block individual accounts, all eGov services or affected eGov services without notice.

In particular, blocking may occur if:

- the Gov CT party fails to comply with the terms of use,
- the access credentials are improperly used or distributed or
- a threat from malicious software is identified.

Blocking usually results in termination of the contract with the affected eGov party.

6. Contract termination

The eGov CT party can terminate the use of the eGov CT service subject to a notice period of one month to the end of the following month. Notice must be given in writing.

Swissmedic reserves the right to unilaterally terminate the master contract at any time, particularly as a result of account blocking due to irregularities in use, inactivity or preconditions no longer being met (e.g. an eGov party no longer has a legal representative in Switzerland). Swissmedic is not obliged to store content or to otherwise forward unread content. After a certain period of time, Swissmedic will delete all content, regardless of whether it was received or not. This does not affect Swissmedic's statutory storage and archiving obligations.

Swissmedic can temporarily or permanently exclude eGov CT parties that fail to comply with the master contract from using the eGov CT service. Swissmedic may cease operating the eGov CT service at any time and without entitling the eGov CT party to any further claims against it.

7. Validity and modifications to the terms of use

Swissmedic reserves the right to modify or supplement the terms of use as required. eGov CT parties shall be informed of any modifications and additions appropriately and well before they come into effect, i.e. in writing, by e-mail or online, the next time they log in.

The modified terms of use are deemed to have been approved if the eGov CT party does not submit a written objection (e.g. by e-mail) within one month. Objections count as notice of termination and automatically lead to immediate termination of the contract. The customer will be informed of these rights and consequences in the change notification.

8. Data protection and archiving

Unless otherwise provided for, Swissmedic shall treat in confidence information that is not generally known and that is disclosed to it during the provision of the eGov CT services. Such information will not be forwarded to third parties without the consent of the eGov CT party. Swissmedic will only process personal data provided by eGov CT parties in connection with the use of the eGov CT services, and only where this is necessary to provide the services and to safeguard the security of operation and infrastructure. The following data are saved to logfiles when eGov CT services are used: IP address, date, time, browser request and the information on the operating system and browser normally transmitted in such circumstances, log-in ID, time of the last successful and failed log-in attempt, plus changes to user master data, credentials, access rights and user status. For the eGov CT service, other data may be saved in compliance with the legal provisions in Art. 57i et seq. of the Federal Act on the Organisation of the Government and the Administration (GAOA; SR 172.010).

Documents that are relevant to proceedings will be retained until the legally binding conclusion of the administrative proceedings. This does not affect Swissmedic's statutory storage and archiving obligations.

9. Jurisdiction and applicable law

The contractual relationship is subject solely to Swiss law. The place of jurisdiction is Bern.