

## Swissmedic eSubmissions platform for applications for the approval of clinical trials

The eSubmissions platform is used for the electronic submission of applications for the approval of clinical trials with medicinal products and ATMP products, for variations and notifications relating to clinical trials with medicinal products and ATMP products, and for the electronic delivery of correspondence from Swissmedic. This information sheet provides information about key issues.

- **Electronic submission of applications**

Since applications are submitted in the eDok format (KLV structure) via a web portal, locally installed software is not necessary. To upload documents, you will need to use the 'Microsoft Edge' or 'Mozilla Firefox' web browser. Submitting documents via the web application is a user-friendly process. Users very quickly receive a response concerning their delivered data.

- **Customised granting of permissions up to clinical trial level**

Using the platform, it is possible to grant permissions up to the level of the individual clinical trial. Access rights to the data can be managed individually.

- **Overview of ongoing applications**

The processing status of ongoing applications can be tracked. The milestones for the next 30 days are presented in a specific view. The latest status can be exported as a PDF file using the integrated function.

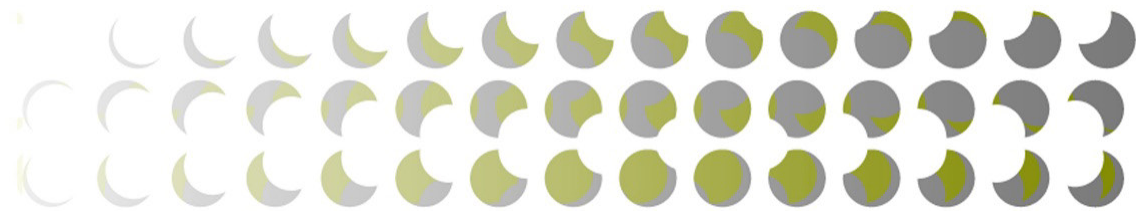
- **Central inbox for mail from Swissmedic**

Correspondence from Swissmedic sent to the company is saved in a central inbox and can be searched according to various filter criteria.

Depending on the contractual agreement (the company can choose from two options), the submission can take place in 'fully electronic' or 'semi-electronic' mode:

- 'Fully electronic' (see Master CT contract, Special provisions)

With this option, the company submits its documentation electronically and also receives all correspondence from Swissmedic in electronic form. Official decisions come with a legally valid digital signature.



- **'Semi-electronic'** (see Master CT contract, Special provisions)

With this option, the company submits its documentation via the platform and receives all correspondence that is not connected with official decisions electronically. Documents with the nature of an official decision, e.g. preliminary decisions, Further Information Requests or official decisions, are sent to the company in paper form by post.

- **CT contractual partners (Sponsor – Swiss Representative relationship)**

A separate registration and a separate Master CT contract is required for each Sponsor – Swiss Representative relationship. In practical terms this means, for example, that sponsors who collaborate with several Swiss Representatives will use separate portal relationships with individual contracts and account IDs.

The terms of use of the Master CT contract can be found on the Swissmedic website.

- **Delivery of the contracts for signing after registration**

Interested companies can register using the online form on the Swissmedic website.

Swissmedic then sends the required contract documents (Master CT contract for the use of eGov, a power of attorney form and the terms of use) by post to the Swiss Representative in all cases for signing.

- **Waiving the sending of the confirmation of receipt and acknowledgements**

As soon as Swissmedic has received the documents with valid signatures, the parties will be authorised to use the portal as contractual partners. Thereafter, confirmations of receipt and conclusive acknowledgements relating to CT applications will no longer be sent by Swissmedic, with the exception of 'Confirmations of receipt with a list of formal deficiencies' and 'Acknowledgements of the fulfilment of conditions'.

- **Further information on eGov and support**

Further information on the use of eGov for CT applications can be found on the Swissmedic website.

If you need help with any technical or procedural issues relating to eGov or eDok, please contact us during the pilot phase via "esubmission@swissmedic.ch".