

## Manual no. 4 – Clinical Investigations

In compliance with Section 15, paragraph 1 of Act No [268/2014](#) Coll., on Medical Devices and Amendments to Act No [634/2004](#) Coll., on Administrative Fees, as amended (hereinafter referred to as the “Act on Medical Devices”), clinical investigations may be conducted only if authorised by the Institute. An application for authorisation of a clinical investigation shall be filed by the sponsor of the clinical investigation electronically, via the Registry of Medical Devices (“RZPRO”). In addition to the particulars set forth by the Code of Administrative Procedure, the application shall, moreover, contain the clinical investigation dossier as referred to under Section 21, paragraph 1(a), except for items 1, 2, and 6.

The Clinical Investigations Module is available only to those persons who are registered in the Registry of Medical Devices and, concurrently, have notified their activity of a “Clinical Investigation Sponsor” (user role Notifier), in compliance with Section 26, paragraph 5 of the Act on Medical Devices. Furthermore, the module is available to the Agency (authorised representative of the clinical investigation sponsor) to which the Notifier granted Power of Attorney via the Registry of Medical Devices – instructions for “Granting Power of Attorney to the Agency” refer.

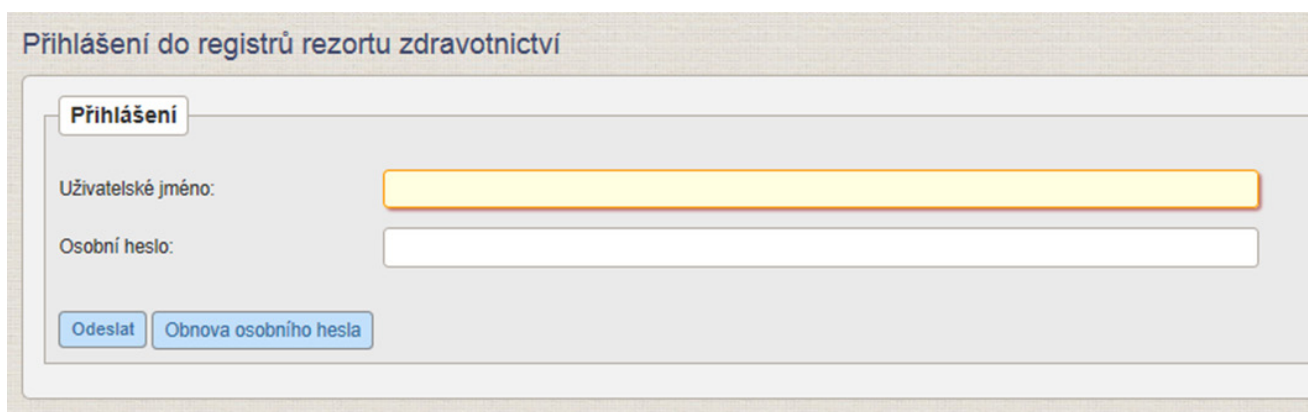
In case any act in respect of a clinical investigation is to be performed, you shall proceed as outlined below:

### 1. Login to the Registry of Medical Devices

- 1) In your internet browser (the system is supported by the following browsers: Internet Explorer, versions 8-10, and Firefox, versions 4-17), open [www.rzpro.cz](http://www.rzpro.cz).
- 2) In the middle section of the page, you will see a hyperlink called “Access to RZPRO for experts and notifiers”. Mouse-click the heading.

[Access to RZPRO for experts and notifiers](#) (the “Login” in the upper left corner)

- 3) The following page, asking you to log into your user account, will be displayed. Enter your user name (usually composed of the first six letters of your surname and the first letter of your name) and password, i.e. the data you have received in the e-mail for access to the Registry of Medical Devices.



Přihlášení do registrů rezortu zdravotnictví

**Přihlášení**

Uživatelské jméno:

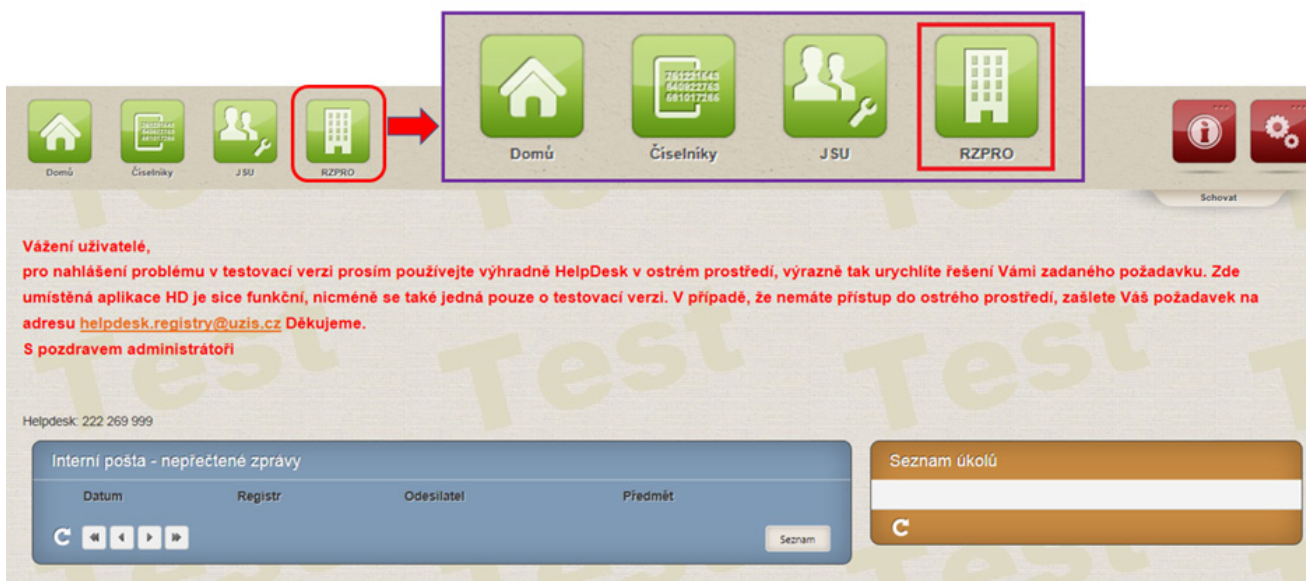
Osobní heslo:

- 4) Once you complete the required data, click on the “Odeslat” (Submit) button. At that moment, check your mobile phone (or e-mail) where a one-time code will be sent. The one-time code is of limited validity. Should it expire, it would be necessary to click on the “Zpět na odeslání jednorázového kódu” (Back to one-time code sending) button.

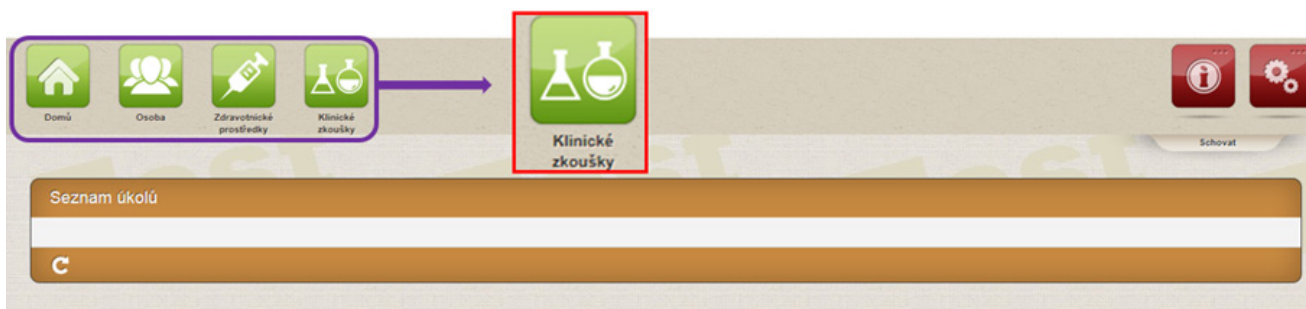
- 5) The following screen will be displayed:

In the green field, the word “SMS” may be replaced by the word “e-mail”, depending on what login option you have set up.

- 6) Shortly, a one-time code will be delivered to your phone number/e-mail. Type the code in the “Jednorázový kód” (One-time code) field and click the “Odeslat” (Submit) button.
- 7) A page with an upper bar will be displayed. On this page, click on the green frame reading “RZPRO”.

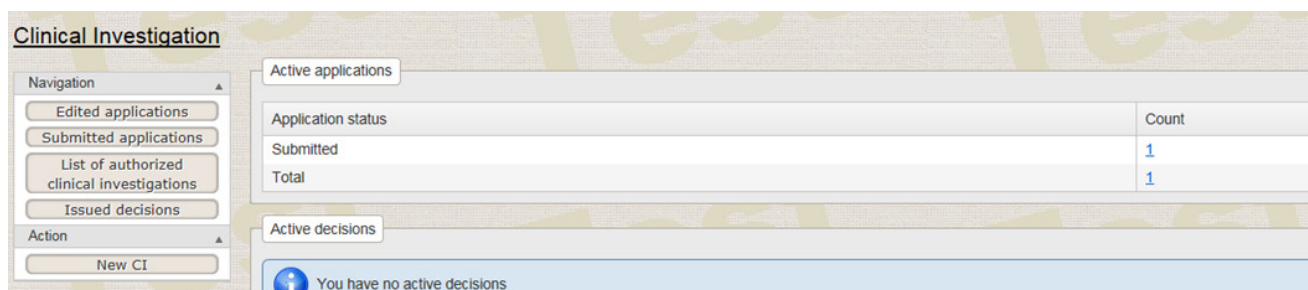


- 8) The screen displayed below will come up. Click on the green frame reading “Klinické zkoušky” (Clinical investigations) (the frame is displayed only after the notified activity of a “clinical investigation sponsor” has been confirmed for the person or upon receipt of a power of attorney via the JSU module in the RZPRO from a person having a confirmed notification of the “Clinical investigation sponsor” activity).



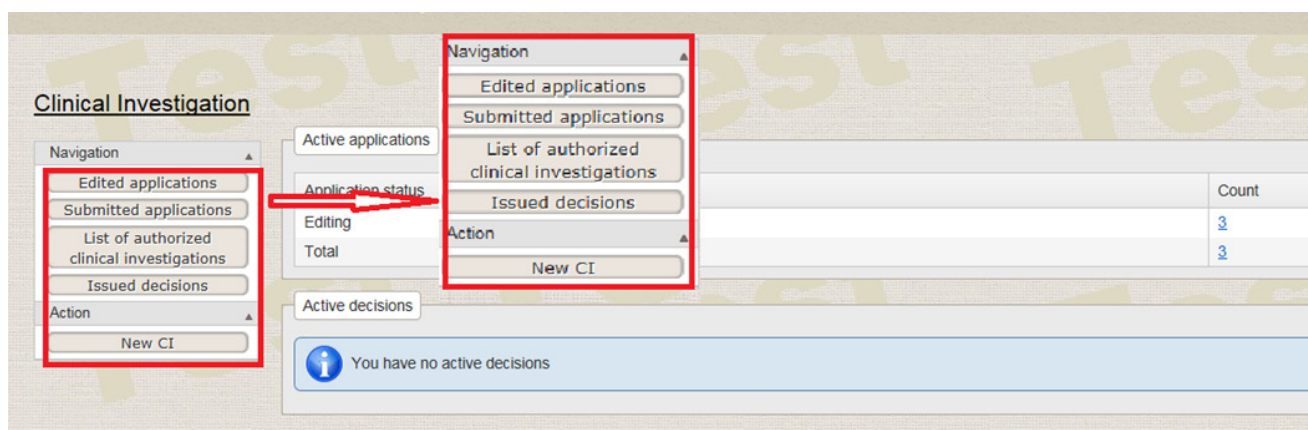
## 2. Clinical Investigation Module

Once you enter the Clinical Investigation Module (hereinafter referred to as the “CI” module) as per the instructions outlined above, the main window with the options menu and a dashboard will be displayed, providing a recap of the active processing status of applications, notifications, and delivered decisions. When the module is accessed for the first time and there is no application in the system, the dashboard is not displayed.



### 2.1. CI Module Main Menu

#### 2.1.1. Options Menu Window



#### Navigation:

- **Edited (unfiled) applications** – a list of all unfilled applications of the respective person will come up together with the option to search and display the detail of the application. If you click on the application detail, the option allowing to submit the application will come up.
- **Submitted applications** – a list of all submitted applications of the respective person will come up, together with the option to search and display the detail of the application, and to run options allowing to manage the application as per the Code of Administrative Procedure (application withdrawals, appeals, etc.).
- **List of authorised CIs** – a list of all authorised clinical investigations of the respective person will come up together with the option to search and display the detail of the CI.
- **Issued decisions** – a list of all decisions issued by administrative authorities regarding filed applications of the respective person will come up together with the search option. The list of decisions is common for several modules.



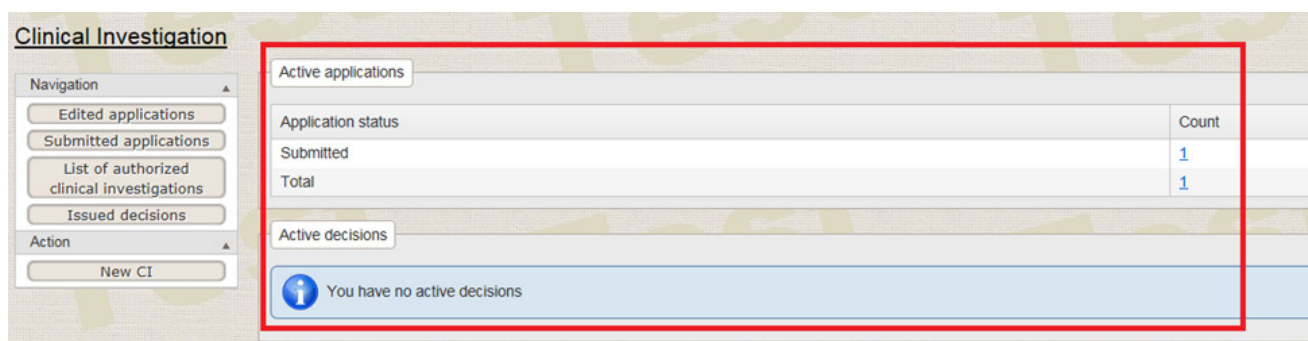
### Actions:

- **New CI** – generates a form for completion of an application for a new CI authorisation and its submission.

### 2.1.2. Main Window Dashboard

The dashboard is split into the following sections:

- **Active applications** – displays the list of active pending applications for clinical investigations in individual stages of the administrative procedure. If you click on the field showing the number of applications (column “count”), a filtered list of the person’s applications will be displayed.
- **Active decisions** – displays an overview of the issued decisions that have not yet become final by action type and status. If you click on the field showing the number of actions (column “count”), a filtered list of entities for detailed display will come up.



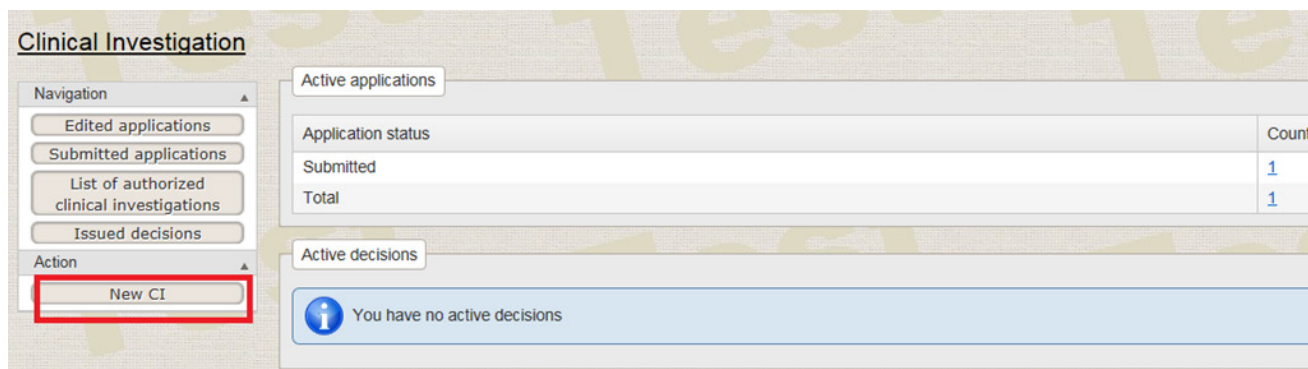
Application status	Count
Submitted	1
Total	1

Active decisions

You have no active decisions

### 2.2. New application for Clinical Investigation Authorisation

To submit a new application for CI authorisation, click on the “New CI” button in the main window of the “Clinical Investigation” module.

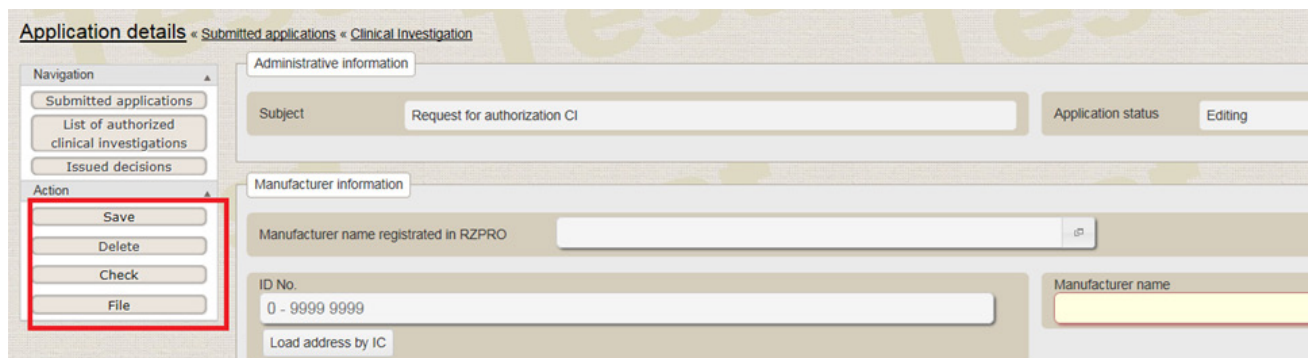


Application status	Count
Submitted	1
Total	1

Active decisions

You have no active decisions

The form for the submission of a new application for clinical investigation authorisation will be displayed.



Application details « Submitted applications « Clinical Investigation

Administrative information

Subject: Request for authorization CI

Application status: Editing

Manufacturer information

Manufacturer name registered in RZPRO: [Field]

ID No.: 0 - 9999 9999

Manufacturer name: [Field]

Load address by IC: [Field]

Action:

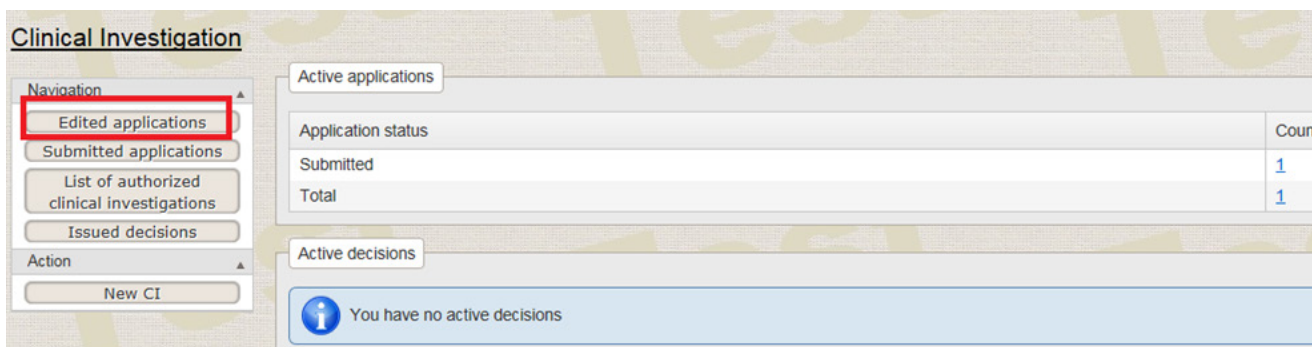
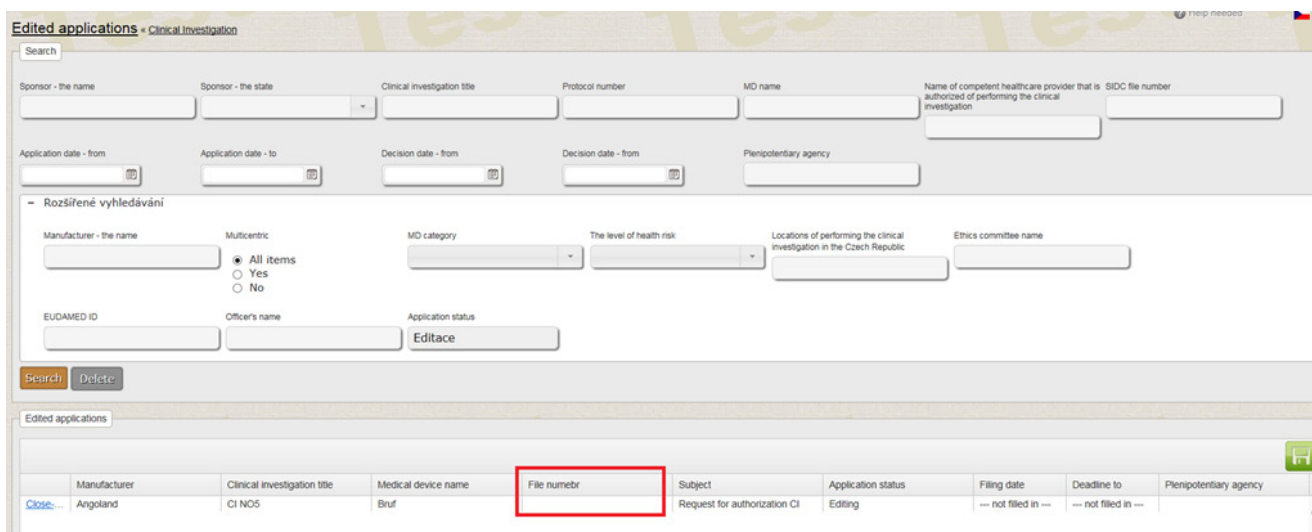
- Save
- Delete
- Check
- File

If you open the form for the submission of a new CI, the Registry of Medical Devices will enable you to perform the following with the application:

- **Save** – saves the content of the completed form and the saving is confirmed by a message in the information bar below the navigation icons. It is possible to save also partially filled-in forms and to get back to them later for completion.
- **Delete** – irreversibly deletes the currently opened application form. It is possible to delete forms in the “Edited” status only.
- **Check** – saves the content of the form and checks it for completeness of mandatory fields to be filled in and for attachments to be inserted. The result of the check is displayed in an information message.
- **File** – this option will submit the application to the Institute for processing. Prior to submission, the form completion will be checked and in case errors are identified, the submission will not be made and the user will be asked to eliminate the errors. The status of the application will change to „Submitted“.

### 2.2.1. Application Prior to Submission to the State Institute for Drug Control

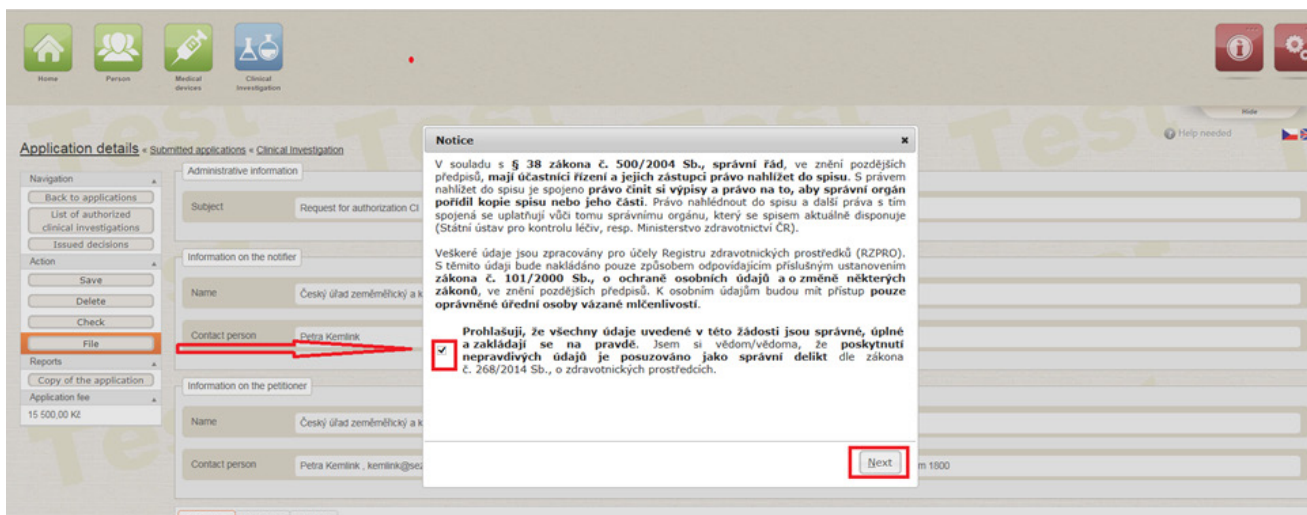
An application which has not been submitted to the State Institute for Drug Control (hereinafter referred to as the “Institute”) yet, is in the status of being edited and does not have an Institute reference number (sukls) allocated. The list of unfilled applications is available from the navigation field in the “Clinical Investigations” module main window.

## 2.2.2. Submission of a New Clinical Investigation

For a detailed description of the application form for CI authorisation please, refer to the Registry of Medical Devices User Manual, chapter “*New Application for Clinical Investigation Authorisation*”, which can be found in the Registry of Medical Devices under the red “**I**” icon in the right upper corner under the “*Documents*” tab. The fields in the form may dynamically change to reflect the values entered in switches. Detailed instructions for form completion (for all alternatives) are available also in the Registry of Medical Devices User Manual.

If you have completed all of the mandatory fields (highlighted in yellow) and uploaded all of the mandatory attachments, the application may be filed with the Institute by pressing the “**File**” button. When you press the “**File**” button, and your submission is confirmed (see figures below), the application is already on the side of the Institute and **it may no longer be edited**. Following submission, the application may be edited only upon the delivery of the **Call for completion of the application** issued by the Institute.



The screenshot shows the 'Application details' page for a submitted application. The 'File' button is highlighted in the left sidebar. A 'Notice' dialog box is open, displaying legal information in Czech. The 'Next' button is highlighted in the bottom right corner of the dialog box.

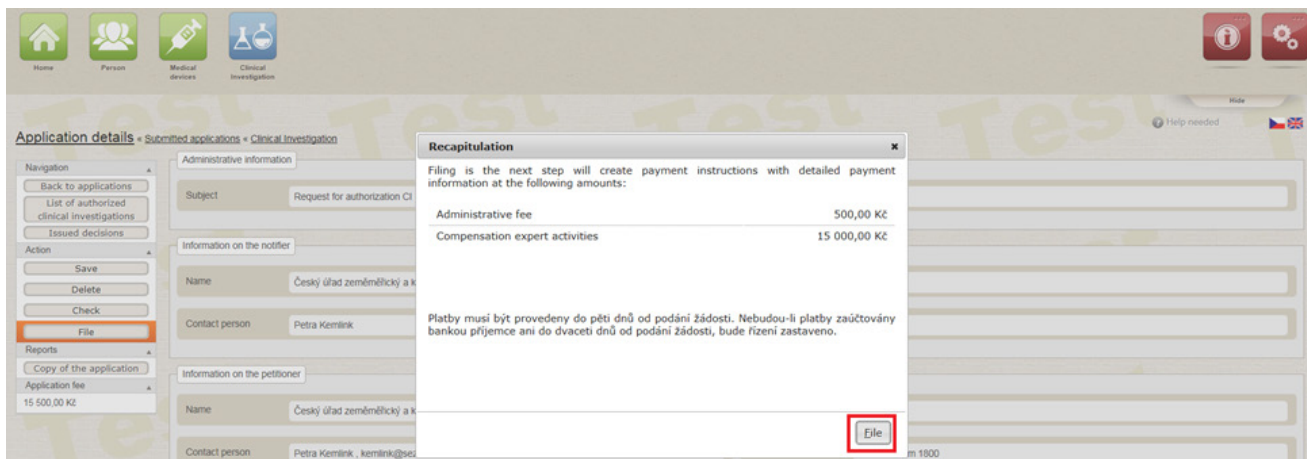
**Notice**

V souladu s § 38 zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů, mají účastníci řízení a jejich zástupci právo nahlížet do spisu. S právem nahlížet do spisu je spojeno právo činit si výpisy a právo na to, aby správní orgán pořídil kopie spisu nebo jeho části. Právo nahlédnout do spisu a další práva s tím spojená se uplatňují vůči tomu správnímu orgánu, který se spisem aktuálně disponuje (Státní ústav pro kontrolu léčiv, resp. Ministerstvo zdravotnictví ČR).

Veškeré údaje jsou zpracovávány pro účely Registru zdravotnických prostředků (RZPŘO). S těmito údaji bude nakládáno pouze způsobem odpovídajícím příslušným ustanovením zákona č. 101/2000 Sb., o ochraně osobních údajů a o změně některých zákonů, ve znění pozdějších předpisů. K osobním údajům budou mít přístup pouze oprávněné úřední osoby vázané mlčenlivostí.

☒ Prohlašuji, že všechny údaje uvedené v této žádosti jsou správné, úplné a zakládají se na pravdě. Jsem si vědomý/vědoma, že poskytnutí nepravdivých údajů je posuzováno jako správní delikt dle zákona č. 268/2014 Sb., o zdravotnických prostředcích.

**Next**



The screenshot shows the 'Application details' page for a submitted application. The 'File' button is highlighted in the left sidebar. A 'Recapitulation' dialog box is open, displaying payment information in Czech. The 'File' button is highlighted in the bottom right corner of the dialog box.

**Recapitulation**

Filing is the next step will create payment instructions with detailed payment information at the following amounts:

Administrative fee	500,00 Kč
Compensation expert activities	15 000,00 Kč

Platby musí být provedeny do pěti dnů od podání žádosti. Nebudou-li platby zaúčtovány bankou příjemce ani do dvaceti dnů od podání žádosti, bude řízení zastaveno.

**File**

## 2.3. Filed Applications for Clinical Investigations

### 2.3.1. Searching for and Filtering of Filed Applications

In the main window of the CI module, click on the “Submitted applications” option.

**Clinical Investigation**

Navigation

- Edited applications
- Submitted applications**
- List of authorized clinical investigations
- Issued decisions

Action

- New CI

Active applications

Application status	Count
Submitted	1
Total	1

Active decisions

You have no active decisions

A list of all applications you have submitted will be displayed.

**Submitted applications** • Clinical Investigation

Search

Sponsor - the name:  Sponsor - the state:  Clinical investigation title:  Protocol number:  MD name:  Name of competent healthcare provider that is SIDC file number authorized of performing the clinical investigation:

Application date - from:  Application date - to:  Decision date - from:  Decision date - to:  Plenipotentiary agency:

+ Rozšířené vyhledávání

Submitted applications

	Manufacturer	Clinical investigation title	Medical device name	File number	Subject	Application status	Filing date	Deadline to	Plenipotentiary agency
<a href="#">Close...</a>	Angoland	CI NOS	Bruf	sukis271/2018	Request for authorization CI	Submitted	20. 03. 2018	19. 05. 2018	
<a href="#">Close...</a>	Black Hole, Ltd	MDxc	wtf	sukis16429/2017	Request for authorization CI	Accepted	27. 09. 2017	26. 11. 2017	

You can search using a filter by filling one or more of the filter fields and clicking on the “Search” button; the applications will be filtered as appropriate.

### 2.3.1.1. Submitted Application Status

In the list of submitted applications, under the “Application status” column, it is possible to find the current status of individual submitted applications within the administrative procedure.

**Submitted applications** • Clinical Investigation

Search

Sponsor - the name:  Sponsor - the state:  Clinical investigation title:  Protocol number:  MD name:  Name of competent healthcare provider that is SIDC file number authorized of performing the clinical investigation:

Application date - from:  Application date - to:  Decision date - from:  Decision date - to:  Plenipotentiary agency:

+ Rozšířené vyhledávání

Submitted applications

	Manufacturer	Clinical investigation title	Medical device name	File number	Subject	Application status	Filing date	Deadline to	Plenipotentiary agency
<a href="#">Close...</a>	Angoland	CI NOS	Bruf	sukis271/2018	Request for authorization CI	Submitted	20. 03. 2018	19. 05. 2018	
<a href="#">Close...</a>	Black Hole, Ltd	MDxc	wtf	sukis16429/2017	Request for authorization CI	Accepted	27. 09. 2017	26. 11. 2017	

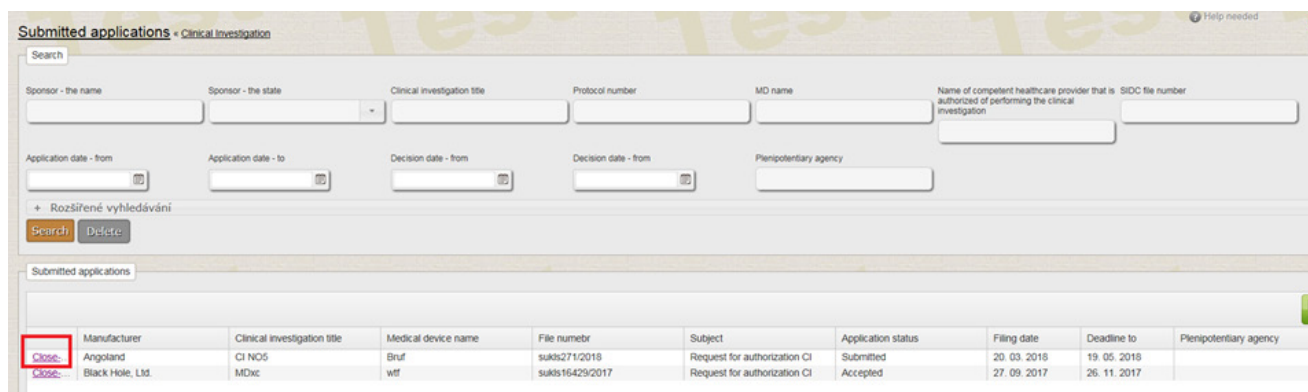


## Overview of application statuses:

- **EDITED** – an Institute reference number has been assigned – the application contained shortcomings, upon which you were asked by the Institute to amend the application. You have opened the application detail and the edited application may be completed/amended.
- **SUBMITTED** – the application or its amendment required by the Institute has been submitted with the Institute.
- **UNDER PROCESS** – the application/required amendment is being assessed by an officer of the Institute.
- **PROCESSED** – the application/required amendment has been assessed and the outcome forwarded for signature.
- **ACCEPTED** – the application meets all of the particulars set forth by law and the Institute has issued a decision on CI authorisation.
- **CALL FOR COMPLETION** – you have received a call to amend the application; it is necessary to respond to the call **within the timeline set forth by the resolution**, which forms part of the call for completion.
- **TERMINATED** – the Institute has issued a resolution on termination of the administrative procedure regarding your application.
- **REJECTED** – the Institute has issued a decision on rejection of the submitted application.
- **APPLICATION WITHDRAWN** – you have withdrawn your application. On the basis thereof, the Institute will issue a resolution on termination of the administrative procedure. Once the resolution is issued, the status of the application will change to “Terminated”.

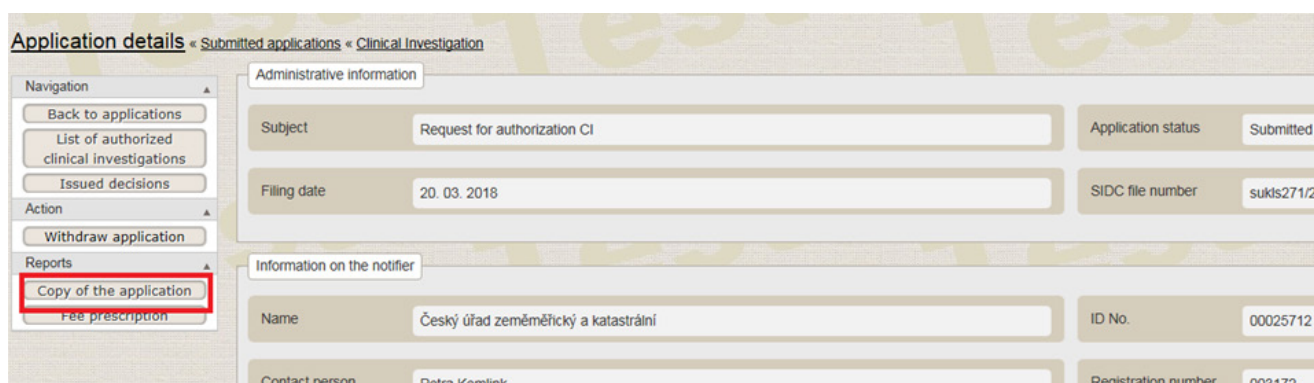
### 2.3.1.2. Submitted Application Detail

To display the detail of any submitted application which has been created, saved, and submitted, click on the **“Close-up”** button in the list of filed applications.



Manufacturer	Clinical investigation title	Medical device name	File number	Subject	Application status	Filing date	Deadline to	Penipotentiary agency
Angostad	CI NOS	Bruf	sukis271/2018	Request for authorization CI	Submitted	20. 03. 2018	19. 05. 2018	
Black Hole, Ltd.	MDxc	wtf	sukis16429/2017	Request for authorization CI	Accepted	27. 09. 2017	26. 11. 2017	

The completed application in the pdf format will be generated by clicking on the **“Copy of the application”** button.



**Application details** » Submitted applications » Clinical Investigation

**Administrative information**

Subject: Request for authorization CI

Application status: Submitted

Filing date: 20. 03. 2018

SIDC file number: sukis271/2

**Information on the notifier**

Name: Český úřad zeměměřický a katastrální

ID No.: 00025712

Contact person: Petra Kemlink

Registration number: 003172

**Navigation**

- Back to applications
- List of authorized clinical investigations
- Issued decisions
- Withdraw application
- Reports
  - Copy of the application**
  - Fee prescription



## 2.4. Acts to Be Taken with Regard to the Institute's Response to a Filed Application

With regard to the Institute's response, it is possible to carry out the following actions in the **detail of a submitted application** (see above):

- **Withdraw an application** – upon application withdrawal, the Institute will stop the administrative procedure and will no longer work with the submitted application.
- **File an appeal** – the submitter of the application files an appeal from the decision issued by the Institute. The filed appeal shall comply with the Code of Administrative Procedure.
- **Abandonment of Appeal** – the submitter waives their right to appeal, which means the decision comes into force on the given date; in case of clinical investigation authorisation, the CI may be commenced on the day following the date the decision comes into force.
- **Append an application** – allows to amend/edit the application with regard to the "call for completion" issued by the Institute.

The screenshot shows the 'Application details' page for a submitted application. The 'Action' menu on the left contains the following options: 'Withdraw application', 'File an appeal', 'Abandonment of appeal', 'Append an application', 'Copy of the application', and 'Fee prescription'. The 'Withdraw application' option is highlighted with a red box. The main content area displays administrative information, including the subject 'Request for authorization CI', filing date '20. 03. 2018', application status 'Call for completion', and SIDC file number 'sukds271/2018'. It also shows information on the notifier, including name 'Český úřad zeměměřický a katastrální', ID No. '00025712', and contact person 'Petra Kemlink'.

### 2.4.1. Withdrawal of a Filed Application

A filed application may be withdrawn by pressing the **"Withdraw application"** button. An advice will be generated. In this Advice, please tick the Declaration of taking note of withdrawal of the submitted application. Thereafter, click on the **"Withdraw application"** button (see Fig. below). A withdrawn application may no longer be edited and the Institute, having regard to the withdrawal, will issue a resolution on terminating the administrative procedure.

The screenshot shows the 'Application details' page with a 'Notice' dialog box open. The dialog box contains the following text: 'V souladu s § 38 zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů, mají účastníci řízení a jejich zástupci právo nahlížet do spisu. S právem nahlížet do spisu je spojeno právo činit si výpisy a právo na to, aby správní orgán pořídil kopie spisu nebo jeho části. Právo nahlédnout do spisu a další práva s tím spojená se uplatňují vůči tomu správnímu orgánu, který se spisem aktuálně disponuje (Státní ústav pro kontrolu léčiv, resp. Ministerstvo zdravotnictví ČR). Veškeré údaje jsou zpracovány pro účely Registru zdravotnických prostředků (RZPRO). S těmito údaji bude nakládáno pouze způsobem odpovídajícím příslušným ustanovením zákona č. 101/2000 Sb., o ochraně osobních údajů a o změně některých zákonů, ve znění pozdějších předpisů. K osobním údajům budou mít přístup pouze oprávněné úřední osoby vázané mlčenlivostí. Prohlašuji, že podanou žádost beru zpět. Jsem si vědom/vědoma, že případné nesplnění povinnosti zadavatele klinické zkoušky je posuzováno jako správní delikt dle zákona č. 268/214 Sb., o zdravotnických prostředcích.' The 'Withdraw application' button is highlighted with a red box. The 'Application details' page in the background shows the same administrative information as the previous screenshot.

## 2.4.2. Appeal from Institute's Decision

It is possible to file an appeal from a decision by clicking on the **"File appeal"** button. A form for the entry of the text specifying the reasons for appeal will come up together with the **mandatory** upload of a document containing the submitter's appeal in the form of an attachment (click on the **"Select"** button). An appeal is filed by clicking on the **"File"** button.

## 2.4.3. Abandonment of Right to Appeal

In case the applicant needs the decision issued by the administrative authority to come into force earlier than upon the timeline specified for appeals from the decision in question, it is possible to waive the right to appeal from the decision. The right to appeal may be waived by clicking on the **"Abandonment of appeal"** button and subsequently confirmed by clicking on the **"Ano"**(Yes) button.

## 2.4.4. Amendment of a Submitted Application

To amend an application on the basis of requirements specified in the call for completion, click on the **“Append an application”** button. A form identical to the one for submission of a new CI will come up, with fields from the previous submission of the concerned CI completed. These may be amended or new attachments may be uploaded.

The screenshot shows the 'Application details' form for a submitted application. The left sidebar contains a 'Navigation' menu with buttons: 'Back to applications', 'List of authorized clinical investigations', 'Issued decisions', 'Withdraw application', 'File an appeal', 'Abandonment of appeal', 'Append an application' (highlighted with a red box), 'Copy of the application', and 'Fee prescription'. The main form area contains fields for 'Administrative information' (Subject: Request for authorization CI, Application status: Call for completion, Filing date: 20. 03. 2018, SIDC file number: suks271/2018), 'Information on the notifier' (Name: Český úřad zeměměřický a katastrální, ID No.: 00025712, Contact person: Petra Kemlínek, Registration number: 003172), and 'Information on the petitioner' (Name: Český úřad zeměměřický a katastrální, ID No.: 00025712).

The application may be amended item-by-item. To save your changes gradually, always click on the **“Save”** button. Once you complete all of the particulars required by the call for completion, click on the **“File”** button to file the amended application with the Institute. To verify whether the application has been filed, check whether the application status has changed from **“Edited”** to **“Filed”**.

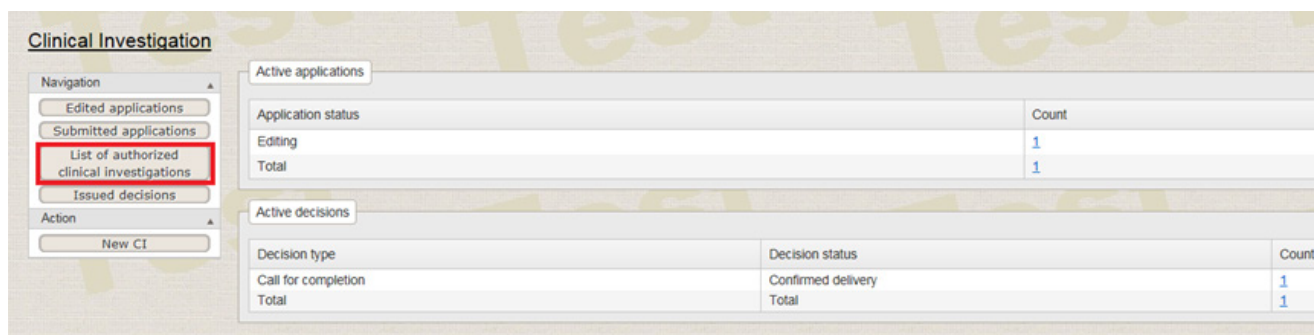
The screenshot shows the 'Poučení' (Notice) dialog box overlaid on the 'Application details' form. The dialog box contains text regarding the application and a declaration. The 'File' button in the left sidebar is highlighted with a red box. The 'Poučení' dialog box has a title bar 'Poučení' and a close button. The text inside the dialog box states: 'V souladu s § 38 zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů, mají účastníci řízení a jejich zástupci právo nahližet do spisu. S právem nahližet do spisu je spojeno právo činit si výpisy a právo na to, aby správní orgán pořídil kopie spisu nebo jeho části. Právo nahližet do spisu a další práva s tím spojená se uplatňují vůči tomu správnímu orgánu, který se spisem aktuálně disponuje (Státní ústav pro kontrolu léčiv, resp. Ministerstvo zdravotnictví ČR). Veškeré údaje jsou zpracovávány pro účely Registru zdravotnických prostředků (RZPRO). S těmito údaji bude nakládáno pouze způsobem odpovídajícím příslušným ustanovením zákona č. 101/2000 Sb., o ochraně osobních údajů a o změně některých zákonů, ve znění pozdějších předpisů. K osobním údajům budou mít přístup pouze oprávněné úřední osoby vázané mlčenlivostí. Prohlašuji, že všechny údaje uvedené v této žádosti jsou správné, úplné a zakládají se na pravdě. Jsem si vědom/vědoma, že poskytnutí nepravdivých údajů je posuzováno jako správní delikt dle zákona č. 268/2014 Sb., o zdravotnických prostředcích.' There is a red checkmark in a box next to the declaration. The 'OK' button is highlighted with a red box.

## 2.5. Authorised CI Administration

### 2.5.1. List of Authorised CIs

In case you desire to display the list of approved applications for clinical investigations, use the **“List of authorised clinical investigations”** option.





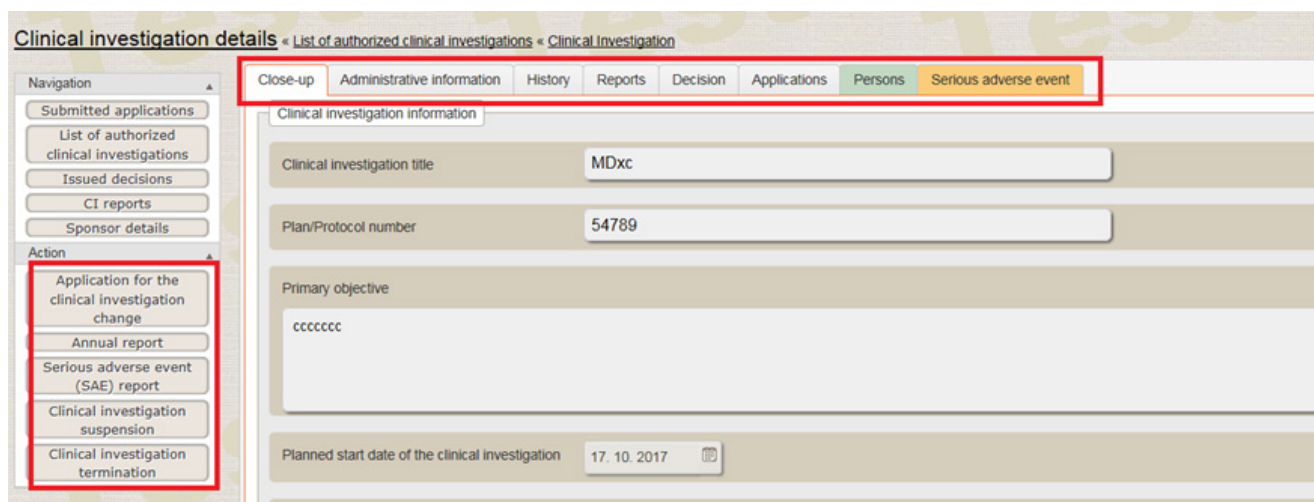
Active applications	
Application status	Count
Editing	1
Total	1

Active decisions		
Decision type	Decision status	Count
Call for completion	Confirmed delivery	1
Total	Total	1

A list with the possibility to apply filters will be displayed, just as described under section “2.3.1. Searching for and Filtering of Filed Applications”. The description of the individual fields of the search filter is available from the Registry of Medical Devices User Manual.

For more details on the clinical investigation, the possibility to submit reports on CI commencement, submission of the annual report, etc., and the conduct of other acts (application for CI modification, application for continuation of a CI suspended by the sponsor or by the Institute), click on the **“Close-up”** of the respective CI **in the list of authorised CIs**. The CI detail will come up with individual tabs containing detailed information on the CI and a panel of buttons for the submission of individual reports and applications which may be submitted in respect of the authorised CI.



## 2.6. Acts Conducted in Respect of Authorised CIs

Acts conducted in respect of authorised CIs (reports, applications for CI modification) may be carried out in the Registry of Medical Devices only if you click on the **“Close-up”** of the respective CI in the **“List of authorised clinical investigations”** option!

When you click on the button for individual reports, it is possible to go back by clicking on the **“Close-up”** button.

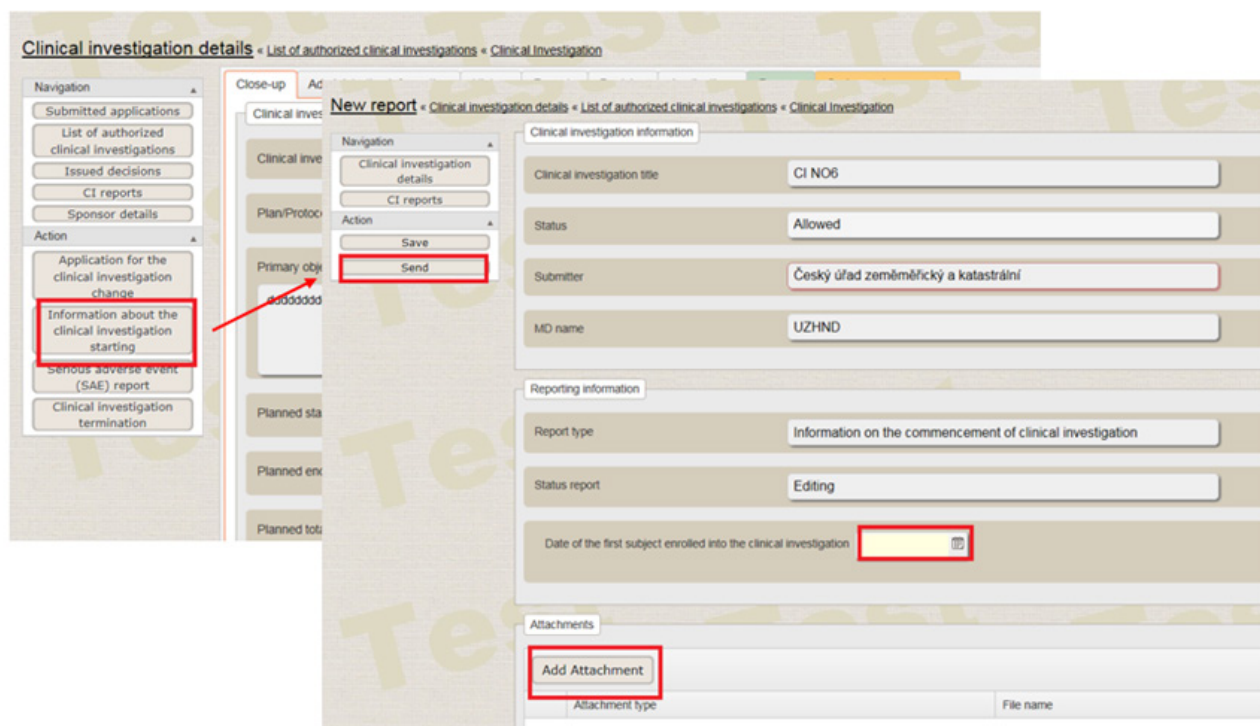


The following acts may be carried out under the Detail of an authorised CI:

- **Application for CI change (modification)** – may be filed also prior to the start of the CI
- **Information on Clinical investigation starting (commencement)** – following the submission of the report on the CI starting (commencement), this act is no longer available and the original report cannot be edited.
- **Annual report** – the button for its submission will be displayed only after the submission of the Information on CI commencement.
- **Serious adverse event (SAE) report** – this serves for the purposes of reporting a SAE; the list of SAEs reported via the Registry of Medical Devices is available from the “Serious adverse event (SAE) report” tab.
- **Clinical investigation suspension** – the button for notifying suspension of a CI will be displayed only after the information on CI starting (commencement) has been submitted.
- **Clinical investigation termination** – after the report on the termination of the clinical investigation is submitted, the only options available are SAE reporting and submission of the final report.
- **Final report** – the button for the submission of the final report will be displayed only after the report on clinical investigation termination has been submitted.

### 2.6.1. Commencement of a Clinical Investigation

The sponsor is obliged to forthwith report the commencement of the clinical investigation in compliance with Section 19, paragraph 2(i) of the Act on Medical Devices. To report the commencement of the CI, click on the “**Information about the clinical investigation starting**” (CI commencement) button in the Detail of the authorised CI. It is necessary to enter the date of CI commencement in the displayed form and it is possible to insert attachments (optional). If you click on the “**Send**” button, the report for the Institute will be displayed. The report on CI commencement may only be submitted once. The submitted report may no longer be edited.



The screenshot displays the 'Clinical investigation details' page with a sidebar menu on the left. The menu includes options like 'Submitted applications', 'List of authorized clinical investigations', 'Issued decisions', 'CI reports', 'Sponsor details', and 'Action'. The 'Action' section is expanded, showing 'Application for the clinical investigation change', 'Information about the clinical investigation starting' (highlighted with a red box and an arrow), 'Serious adverse event (SAE) report', and 'Clinical investigation termination'.

The main content area shows the 'New report' form for 'Information about the clinical investigation starting'. The form includes the following fields:

- Clinical investigation information:**
  - Clinical investigation title: CI NO6
  - Status: Allowed
  - Submitter: Český úřad zeměměřický a katastrální
  - MD name: UZHND
- Reporting information:**
  - Report type: Information on the commencement of clinical investigation
  - Status report: Editing
  - Date of the first subject enrolled into the clinical investigation: [Yellow highlighted field]
- Attachments:**
  - Add Attachment button (highlighted with a red box)

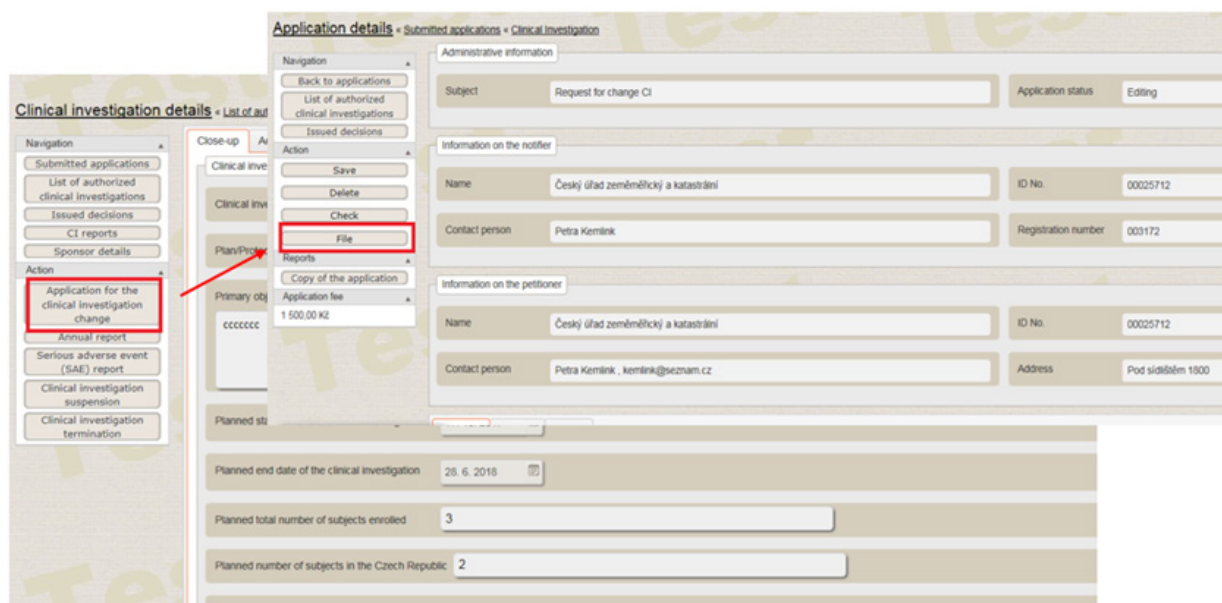
At the bottom of the form, there is a table for attachments with columns for 'Attachment type' and 'File name'.

### 2.6.2. Application for the change (modification) of a Clinical Investigation

If the sponsor wishes to make amendments to the conditions of the clinical investigation, they shall be obliged to apply for the Institute's approval of such changes in compliance with Section 15, paragraph 4 of the Act on Medical Devices.

In the CI detail, click on the **"Application for the clinical investigation change"**. A new **"Application for CI change"** will be automatically created and saved with the "Edited" status and fields from the latest effective version of the CI registration will be populated in the application. The application requires editing – completion of the field **"Justification for application of the clinical investigation change"** and insertion of the necessary attachments (the mandatory attachments being the "A proposal of changes in clinical investigation documentation" and a „written approval of the ethics committee with changes of clinical investigation documentation"). Thereafter, save the application using the **"Save"** button. If the application is complete, it is possible to submit it for the Institute's approval of the modification of the clinical investigation (through the **"Send"** button). Following submission, the status of the application will be changed to "Submitted" and it may be displayed in the list of applications. The subsequent options available are the same as those outlined under section 2. 2. 2. *"Submission of a New Clinical Investigation"*.

If you have created the application for clinical investigation change by mistake, it may be deleted by clicking on the **"Delete"** button, if it has not been submitted.



The screenshot displays the 'Application details' form for a clinical investigation change. The form is divided into several sections:

- Navigation:** Includes links for 'Back to applications', 'List of authorized clinical investigations', and 'Issued decisions'.
- Action:** Contains buttons for 'Save', 'Delete', 'Check', and 'File'. The 'Delete' button is highlighted with a red box.
- Administrative information:** Includes fields for 'Subject' (Request for change CI) and 'Application status' (Editing).
- Information on the notifier:** Includes fields for 'Name' (Český úřad zeměměřičský a katastrální), 'ID No.' (00025712), 'Contact person' (Petra Kemlínek), and 'Registration number' (003172).
- Information on the petitioner:** Includes fields for 'Name' (Český úřad zeměměřičský a katastrální), 'ID No.' (00025712), 'Contact person' (Petra Kemlínek, kemlink@seznam.cz), and 'Address' (Pod sídlištěm 1500).
- Planned start/end date:** Includes fields for 'Planned end date of the clinical investigation' (28. 6. 2018) and 'Planned total number of subjects enrolled' (3).
- Planned number of subjects in the Czech Republic:** Includes a field for 'Planned number of subjects in the Czech Republic' (2).

### 2.6.3. Serious Adverse Event (SAE) Reporting

In compliance with Section 19, paragraph 2(n) of the Act on Medical Devices, the sponsor is obliged to inform the Institute of arising SAEs immediately upon their occurrence.

To report an arising SAE or modification thereof, click on the **"Serious adverse event (SAE) report"** option in the Detail of the authorised CI. The mandatory fields are the text description of the SAE and the SAE report form as per MEDDEV 2.7/3 uploaded as an attachment.

**Clinical investigation details** » List of authorized clinical investigations » Clinical Investigation

Close-up Administrative information History Reports Decision Applications Persons Serious adverse event

Clinical investigation information

Clinical investigation title CI NO6

Status Interrupted authority

Submitter Český úřad zeměměřický a katastrální

MD name UZHND

Reporting information

Report type Reporting serious adverse events (SAE)

Status report Editing

Serious adverse events reports

**SAE description**

Attachments

Add Attachment

Attachment type File name

**SAE shall be attached**

#### 2.6.4. Annual Report

The annual report on the course and safety evaluation of the clinical investigation has to be submitted by the sponsor by 31 January of the following year in compliance with Section 19, paragraph 2(j) of the Act on Medical Devices.

To submit the annual report, click on the **“Annual report”** button in the detail of the authorised CI. This button is available only after the Information on CI starting (commencement) has been submitted via the Registry of Medical Devices (section 2.6.1. “Commencement of a Clinical Investigation” refers).

**Clinical investigation details** » List of authorized clinical investigations » Clinical Investigation

Close-up Administrative information History Reports Decision Applications Persons Serious adverse event

Clinical investigation information

Clinical investigation title MDxc

Status Launched

Submitter Český úřad zeměměřický a katastrální

MD name wtf

Reporting information

Report type Yearly Report

Status report Editing

Annual report for the year:

2018

Attachments

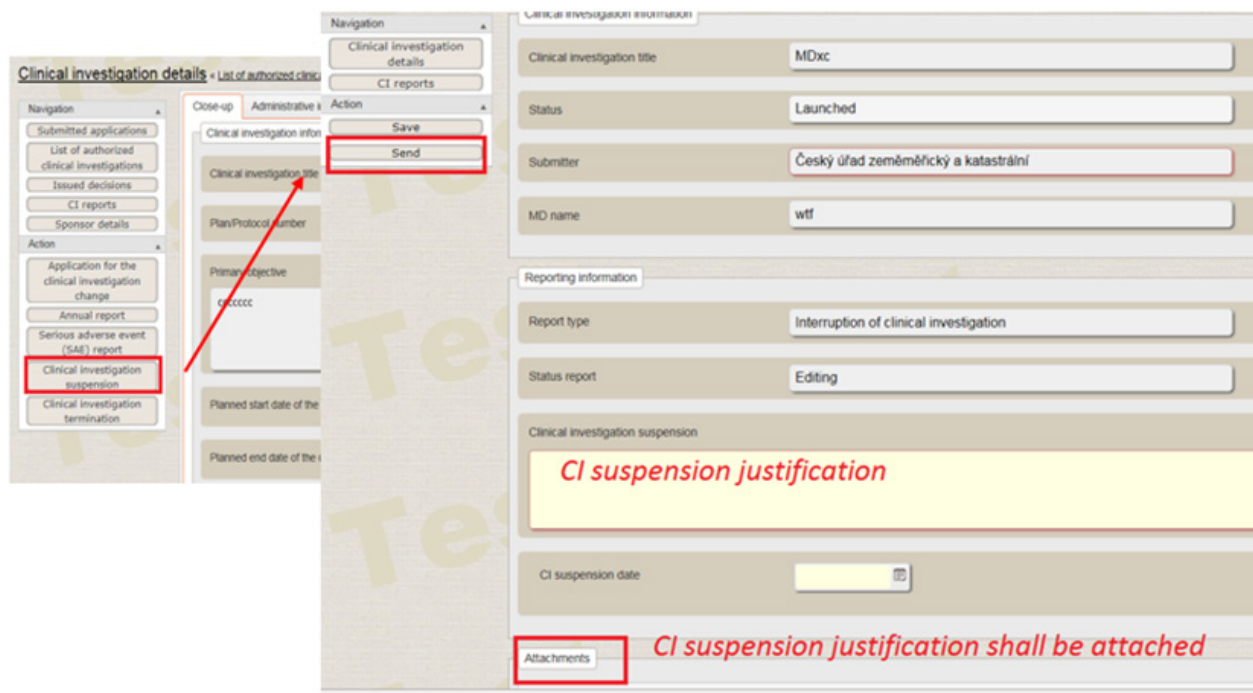
Add Attachment

**The annul report shall be attached**

### 2.6.5. Suspension of a Clinical Investigation

A suspension of a clinical investigation has to be reported by the sponsor within the timeline of 30 days of the suspension in compliance with Section 19, paragraph 2(k) of the Act on Medical Devices.

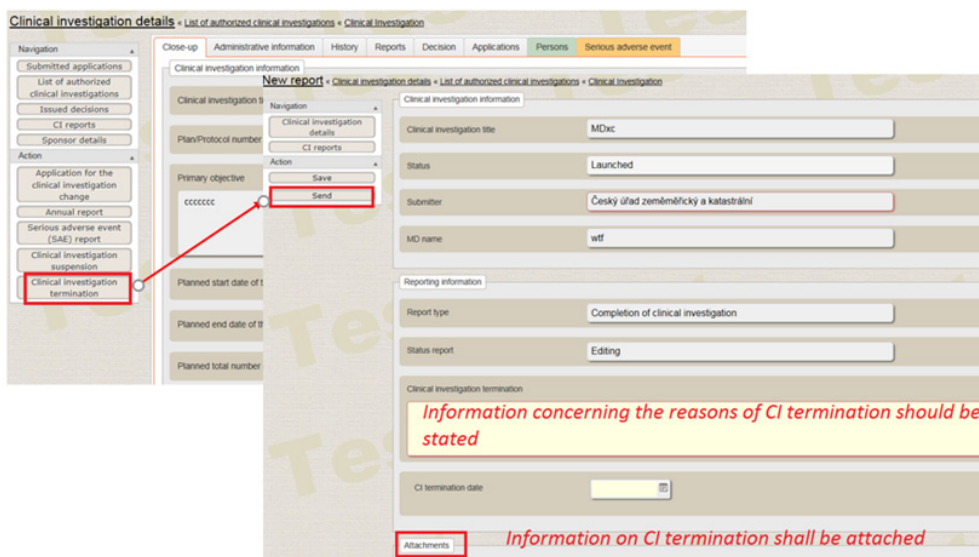
To report a clinical investigation suspension, click on the **“Clinical investigation suspension”** button. To resume a suspended CI, proceed as outlined under section 2.7.1 *“Continuation of a Clinical Investigation Suspended by the Sponsor or by the Institute”*.



The screenshot shows the 'Clinical investigation details' form. On the left, the 'Action' menu has 'Clinical investigation suspension' highlighted with a red box. A red arrow points from this button to the 'Send' button in the 'Action' section of the 'Clinical investigation information' tab. The main form area shows fields for 'Clinical investigation title' (MDxc), 'Status' (Launched), 'Submitter' (Český úřad zeměměřický a katastrální), and 'MD name' (wtf). The 'Reporting information' section shows 'Report type' (Interruption of clinical investigation) and 'Status report' (Editing). The 'Clinical investigation suspension' section has a yellow box with the text 'CI suspension justification' and a date field for 'CI suspension date'. At the bottom, there is an 'Attachments' button and a red text box stating 'CI suspension justification shall be attached'.

### 2.6.6. Termination of a Clinical Investigation

Termination of a clinical investigation has to be reported by the sponsor within the timeline of 30 days of CI termination in compliance with Section 19, paragraph 2(k) of the Act on Medical Devices. To report clinical investigation termination, click on the **“Clinical investigation termination”** button.



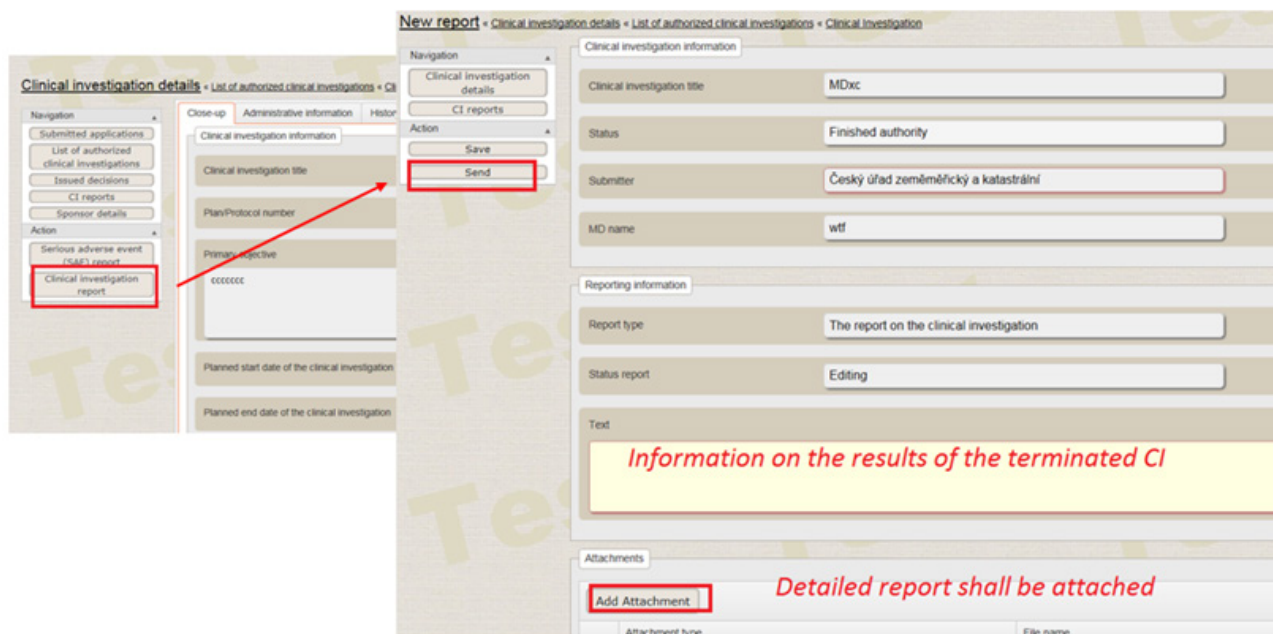
The screenshot shows the 'Clinical investigation details' form. On the left, the 'Action' menu has 'Clinical investigation termination' highlighted with a red box. A red arrow points from this button to the 'Send' button in the 'Action' section of the 'Clinical investigation information' tab. The main form area shows fields for 'Clinical investigation title' (MDxc), 'Status' (Launched), 'Submitter' (Český úřad zeměměřický a katastrální), and 'MD name' (wtf). The 'Reporting information' section shows 'Report type' (Completion of clinical investigation) and 'Status report' (Editing). The 'Clinical investigation termination' section has a yellow box with the text 'Information concerning the reasons of CI termination should be stated' and a date field for 'CI termination date'. At the bottom, there is an 'Attachments' button and a red text box stating 'Information on CI termination shall be attached'.



### 2.6.7. Final Report on the Clinical Investigation

The final report on the clinical investigation has to be submitted by the sponsor to the Institute following termination of the CI in compliance with Section 19, paragraph 2(l) of the Act on Medical Devices.

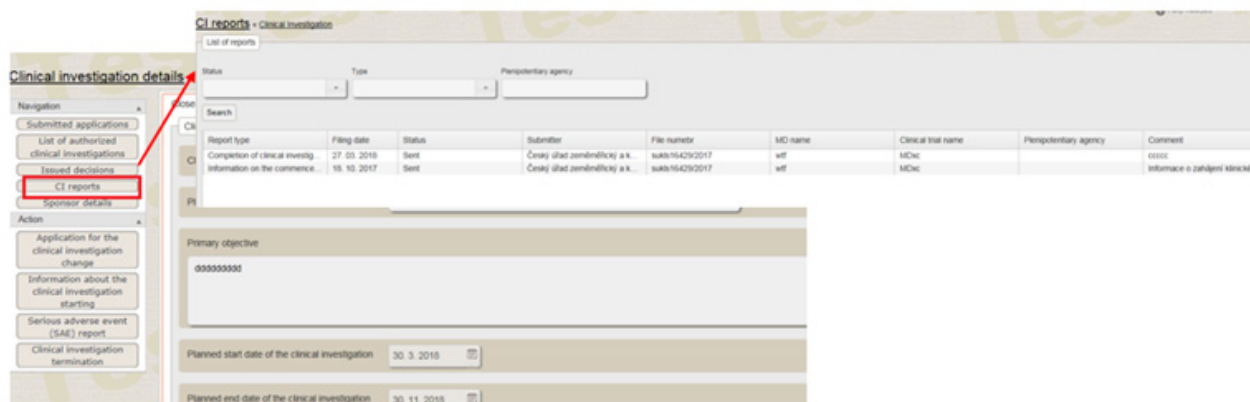
To submit the final report, click on the **“Clinical investigation report”** button.



### 2.6.8. List of Individual Reports

If you wish to display the list of reports for individual CIs, click on the **“CI reports”** button. The list is designed to display a listing of individual reports from all authorised clinical investigations.

It is possible to search the list using filters, to sort the reports in ascending/descending order by one of the columns. The report detail may be opened by clicking on the row of the respective report.



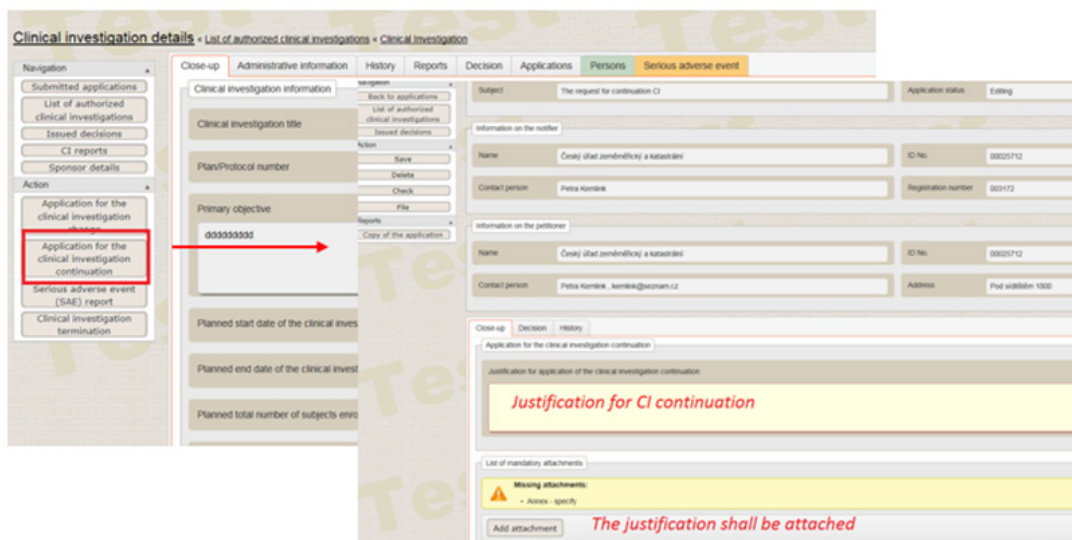
## 2.7. Suspension of an Authorised Clinical Investigation by the Institute

The Institute may temporarily suspend conducting of an authorised clinical investigation thereby in compliance with Section 15, paragraph 5 of the Act on Medical Devices.

You will be informed of the suspension of the clinical investigation by means of a delivered resolution issued by the Institute.

### 2.7.1. Continuation of a Clinical Investigation Suspended by the Sponsor or by the Institute

Once the reasons for suspension cease to exist, it is possible to file an application for CI continuation in respect of a suspended CI by means of a report and to apply for Institute's resolution on authorisation to resume the CI.



### 2.8. Ex-officio Halting of an Authorised Clinical Investigation by the Institute

The Institute may halt conducting of an authorised clinical investigation thereby in compliance with Section 15, paragraph 5 of the Act on Medical Devices.

The decision on halting an authorised clinical investigation by the Institute will be displayed on the dashboard in the main window of the CI module and will be available from the **"Issued decisions"** list in the main window or in the Detail of a specific CI.

It is possible to file an appeal from the decision on halting an authorised clinical investigation by the Institute via the Registry of Medical Devices (*section 2. 4. 2. "Appeal from Institute's Decision" refers*). If the decision on the halting of a clinical investigation comes into force, it shall be permanent and an application for CI continuation may no longer be submitted.

Should you encounter any **unclearities regarding the procedures to be followed in the Clinical Investigation Module**, please contact SÚKL at:  
email: [SZP\\_RZPRO\\_dotazy@sukl.cz](mailto:SZP_RZPRO_dotazy@sukl.cz)  
tel. 272 185 704

Should you encounter **technical problems** when filing your application, please contact ÚZIS:  
tel: 222 269 999 – general ÚZIS helpline  
[helpdesk.registry@uzis.cz](mailto:helpdesk.registry@uzis.cz)

**Generals questions** should be addressed to SÚKL at: 272 185 333