
SÚKL

APPLICATON FOR THE CLINICAL INVESTIGATION CHANGE

Medical Devices Branch

31.8.2020

Section 15 par. 4 of the Act No. 268/2014 Coll., on Medical devices

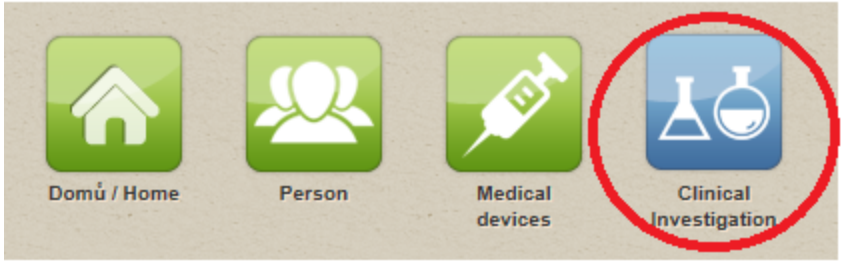
Where the sponsor of the clinical investigation the conduct of which has been authorised by the Institute intends to implement changes to the conditions of the clinical investigation, the sponsor shall apply with the Institute for approval of such changes and shall submit to the Institute **the proposed changes in the clinical investigation dossier** and a **written approval of the proposed changes by the ethics committee.** The Institute shall inform the sponsor whether it agrees with the changes within the period of 30 days.

SÚKL

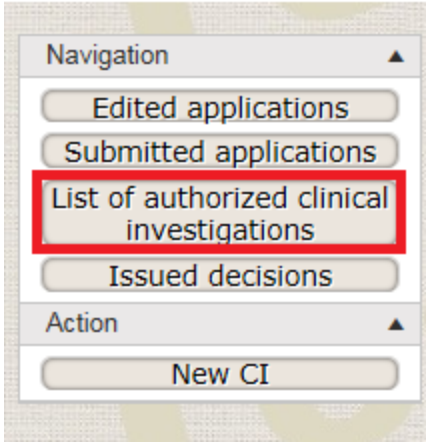
Principle of submitting applications for the clinical investigation (CI) change

Once an application for CI change is submitted, it is not possible to change it in the Registry of Medical Devices (RZPRO). Next application for CI change of the particular CI may be submitted only after the previous application has been fully reviewed by the Institute and the decision has been issued and has come to legal force.

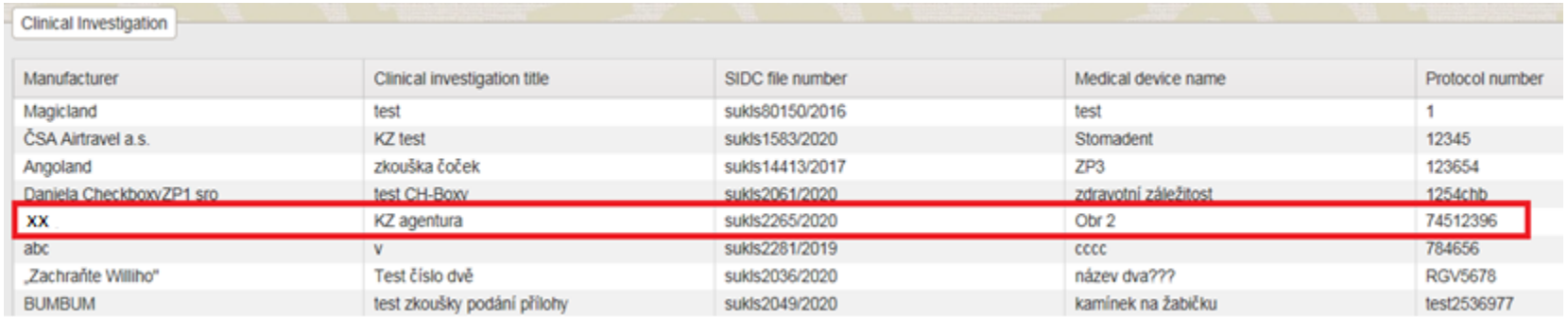
If you are registered as Sponsor, log in the RZPRO and access Clinical investigations module.



Select the CI you intend to change in the list of authorised clinical investigations



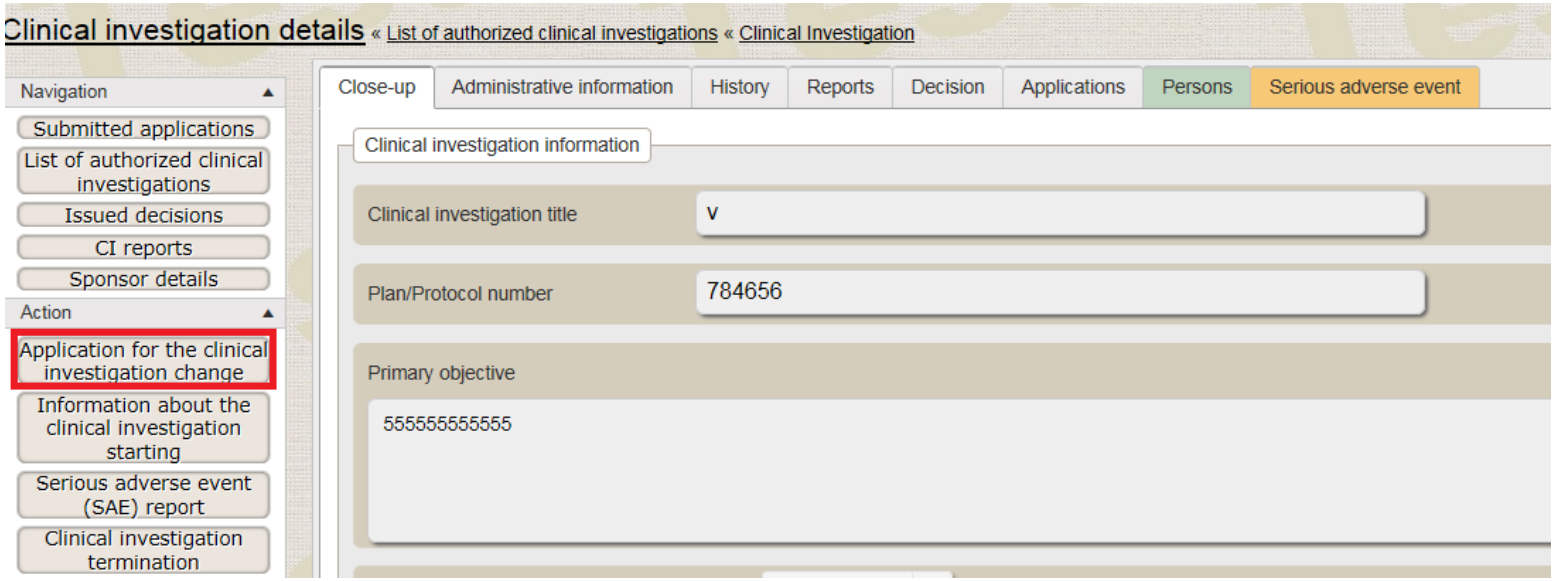
Go to the CI detail



Clinical Investigation

Manufacturer	Clinical investigation title	SIDC file number	Medical device name	Protocol number
Magicland	test	sukls80150/2016	test	1
ČSA Airtravel a.s.	KZ test	sukls1583/2020	Stomadent	12345
Angoland	zkouška čoček	sukls14413/2017	ZP3	123654
Daniela CheckboxyZP1 sro	test CH-Boxy	sukls2061/2020	zdravotní záležitost	1254chb
xx	KZ agentura	sukls2265/2020	Obr 2	74512396
abc	v	sukls2281/2019	cccc	784656
„Zachraňte Williho"	Test číslo dvě	sukls2036/2020	název dva???	RGV5678
BUMBUM	test zkoušky podání přílohy	sukls2049/2020	kamínek na žabičku	test2536977

Click Application for the CI change to open the application form

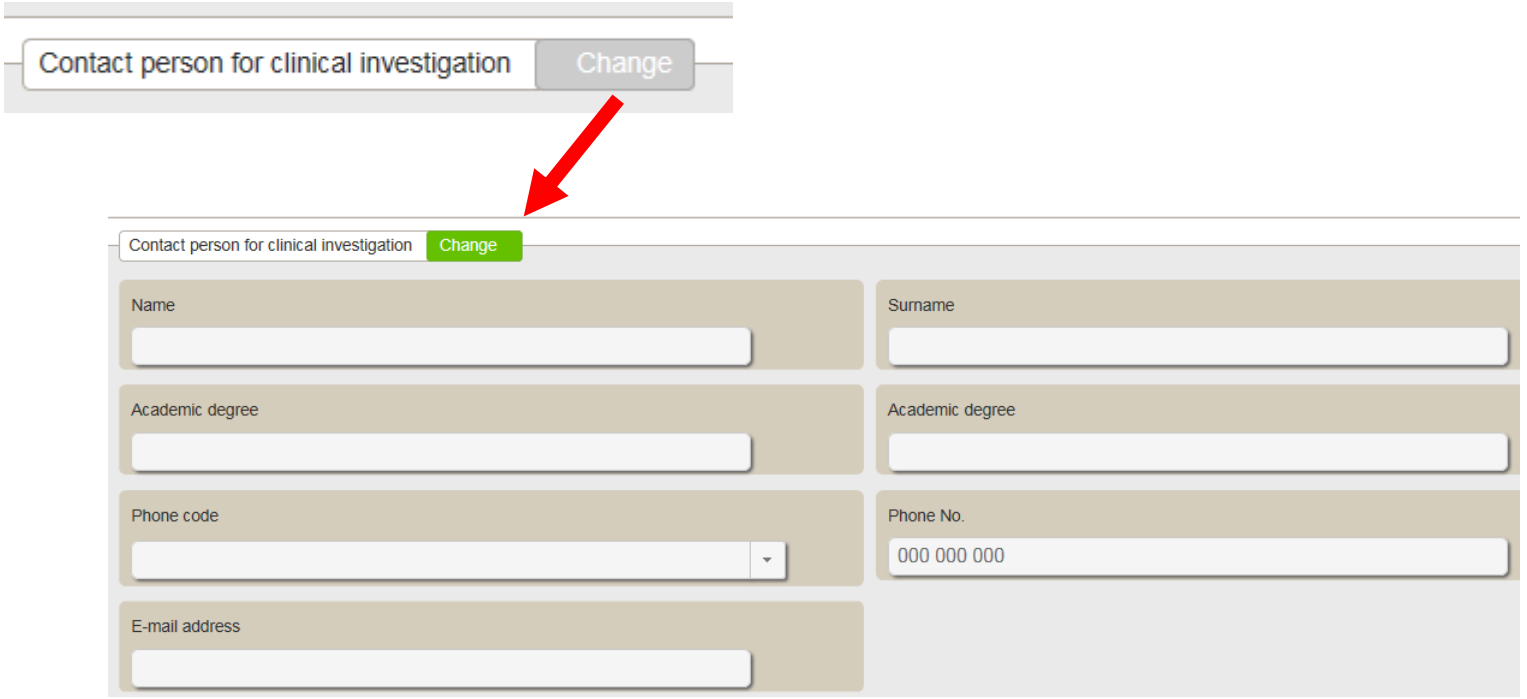


Fill in the application form. Enter the summary of changes in the field Justification for application.

Items that could be changed within the applicatin for CI change are marked by gray Change icon. If you wish to change the item, click Change button, it will turn green and enable you to carry out the change of the item.

When you click the icons Manufacturer information, Contact person for CI, European countries involved in the CI, Locations of the CI in CZ with the relevant ethics committee and List of mandatory attachments a new sub-form opens.

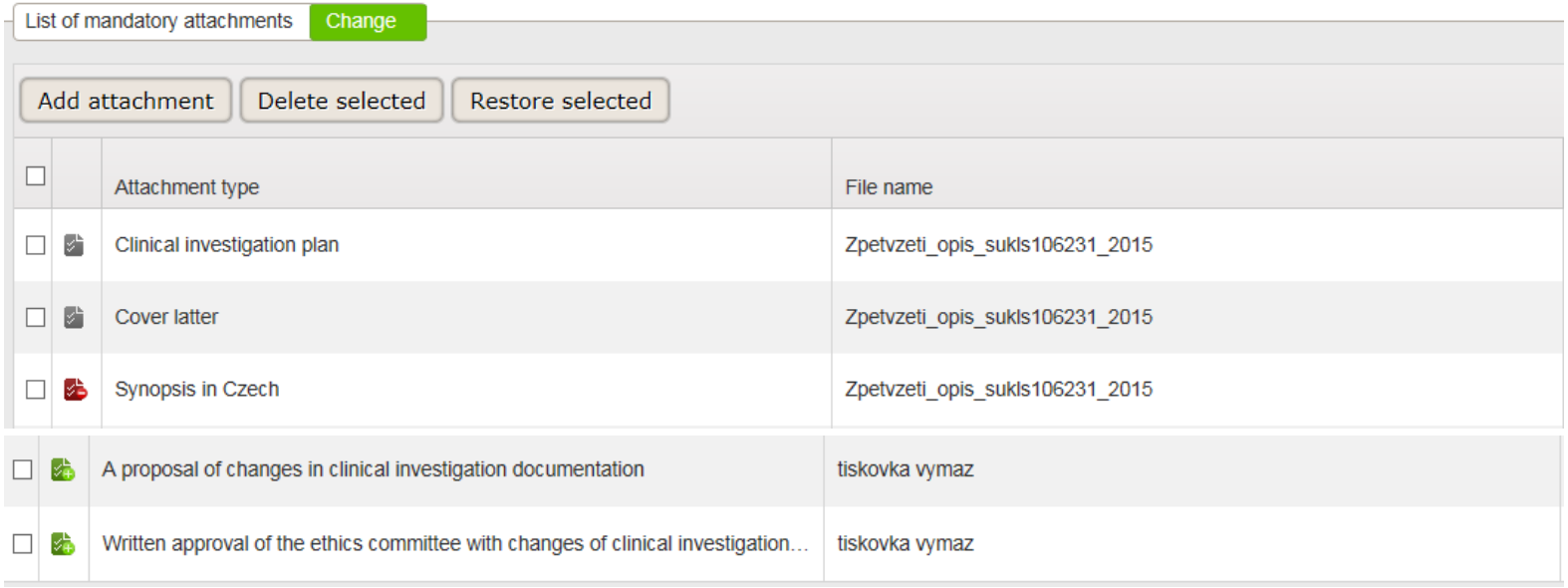
E.g.



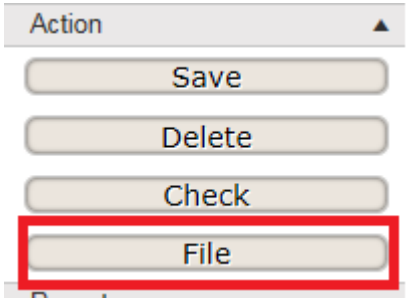
It is not possible to edit the item Locations of the CI in CZ with the relevant ethics committee. The item can be either deleted or added. The deleted items are marked red and the added ones green .

The mandatory attachments of an application for CI change are:
- the proposal of changes in the CI dossier and
- written approval of the proposed changes by the ethics committee

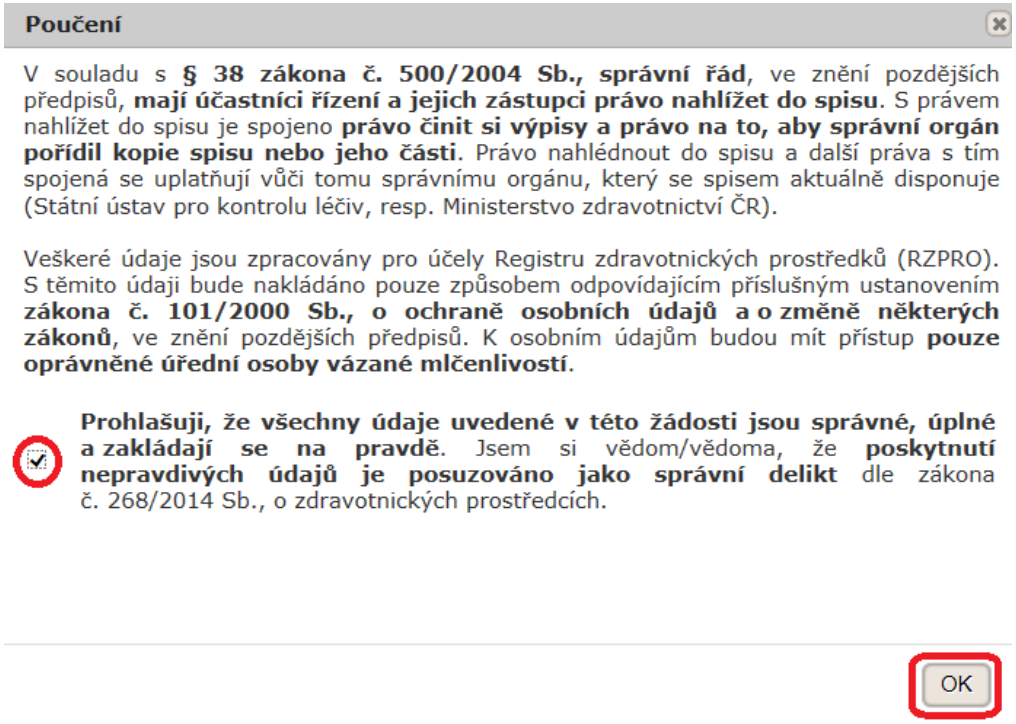
Attachments, that are subject to the change, may be deleted and added.



To file the application click „File“

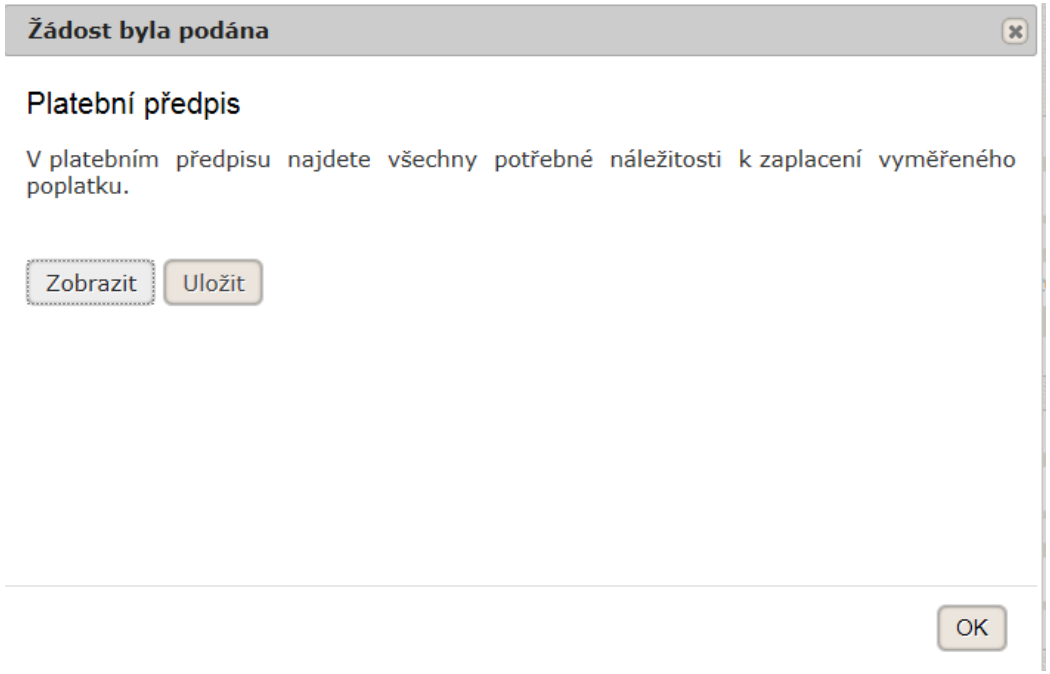


An informative notice is displayed. Confirm and click OK



Note: There is no English version of the notice. By clicking the notice you confirm that all data provided within the application is true, correct and fact based.

Payment receipt is generated upon filing the application. Make the payment according to the receipt immediately after the submission. Do not forget to enter variable symbol (variabilní symbol) to identify the payment.

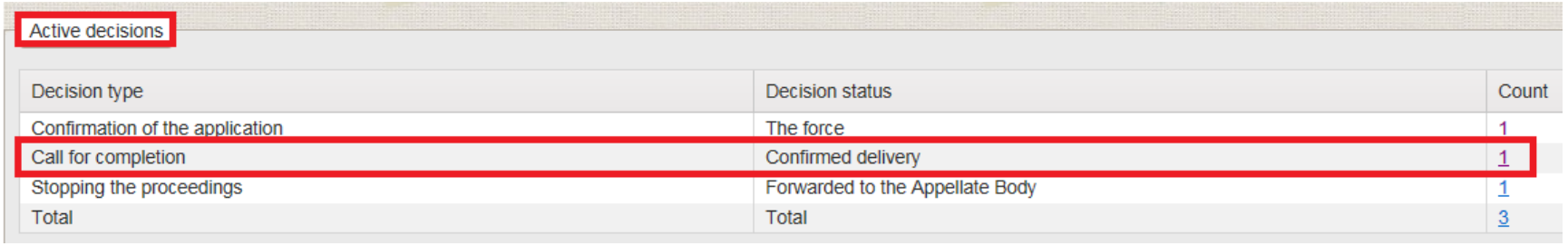


Your application has been filed

Call for completion

Should the application fail to meet the particulars stipulated by Administrative Code or Section 15 par. 4 of the Act on Medical Devices, you will be invited to eliminate the shortcomings within a reasonable timeline.

Call for completion will be displayed in the Clinical Investigations module under „Active decisions“

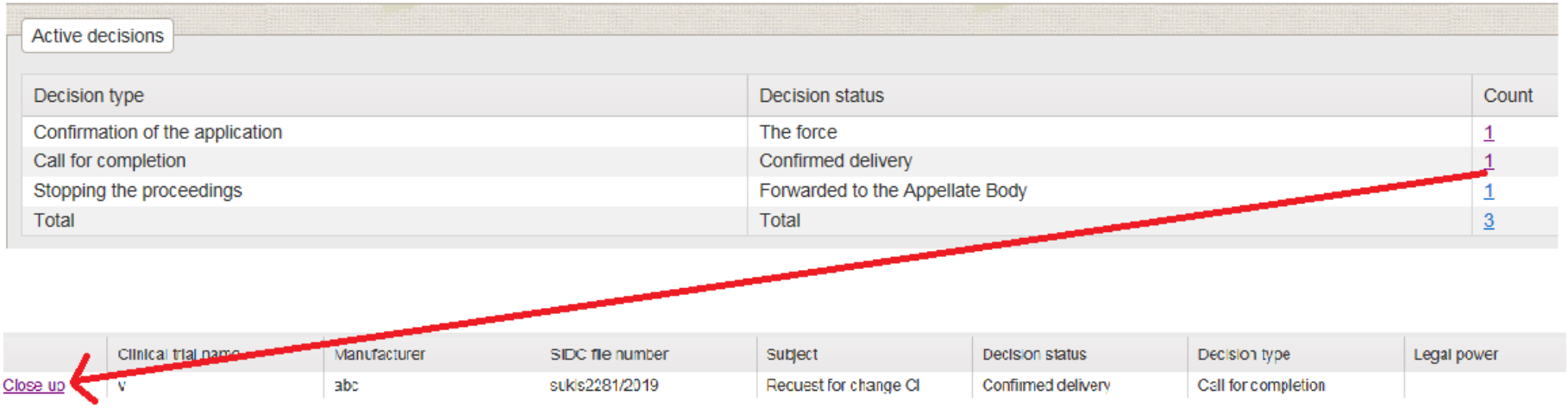


Active decisions

Decision type	Decision status	Count
Confirmation of the application	The force	1
Call for completion	Confirmed delivery	1
Stopping the proceedings	Forwarded to the Appellate Body	1
Total	Total	3

How to append the application upon call for completion

To append the application when you have received the call for completion, go to the detail of the application

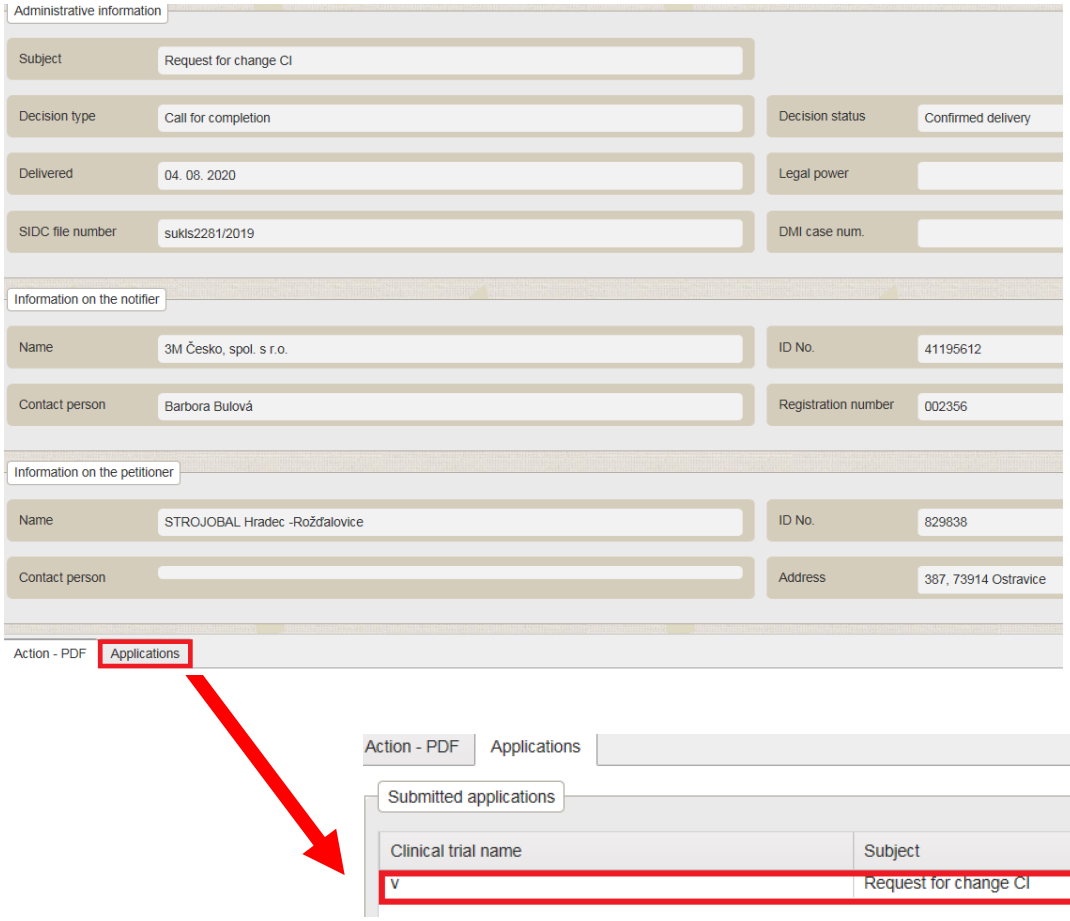


Active decisions

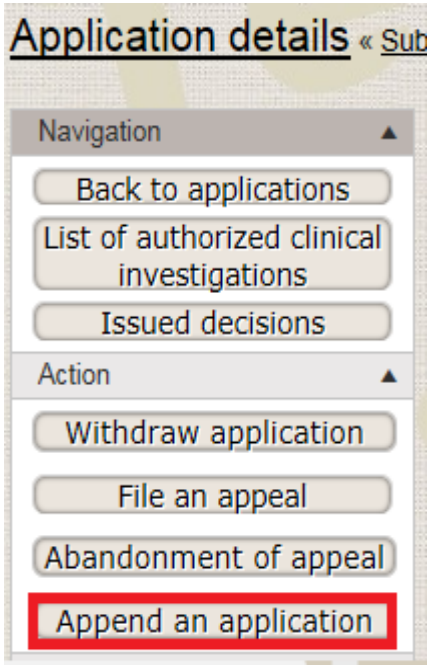
Decision type	Decision status	Count
Confirmation of the application	The force	1
Call for completion	Confirmed delivery	1
Stopping the proceedings	Forwarded to the Appellate Body	1
Total	Total	3

	Clinical trial name	Manufacturer	SIDC file number	Subject	Decision status	Decision type	Legal power
Close up	v	abc	sukls2281/2019	Request for change CI	Confirmed delivery	Call for completion	

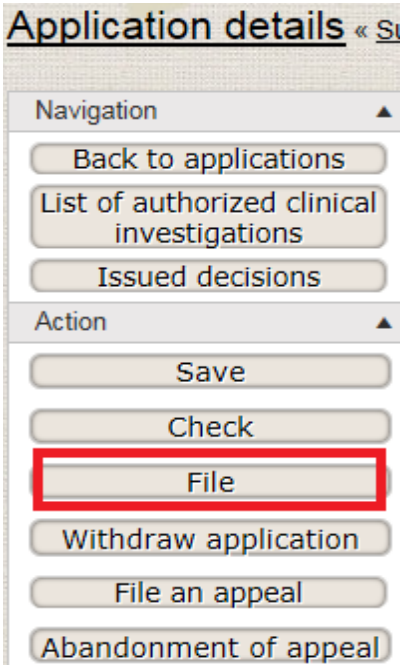
Press Applications button to access the application.



1. Click „Append an application“



2. To file the completed application, press „File“



Confirmation of the application

In case the application meets the particulars stipulated by Section 15 par. 4 of the Act on Medical Devices, the Institute issues the Decision on changes to the conditions of the clinical investigation.

SÚKL

Termination of the procedure

In case, the applicant e. g.:

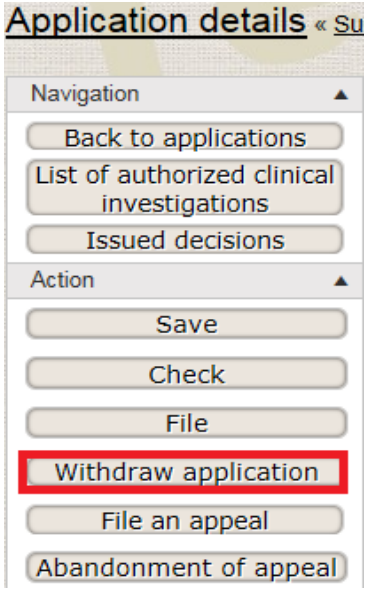
- fails to eliminate the substantial defects of the application within the predefined timeline
- Fails to pay the fee
- takes the application back (withdraws)

The Institute terminates the procedure according to Section 66 par. 1 od the Administrative Code. In such case, the applicant is delivered resolution on procedure termination.

Withdrawal of the application

The applicant may take the application back at any time until the decision is issued.

Attention – this step is not reversible!



Status in RZPRO

- **EDITING** – (reference number issued) you may edit (modify) the application
- **SUBMITTED** – the application has been filed or appended to the Institute
- **PROCESSED** – the application is being assessed by the assessor
- **ACCEPTED** – the application meets the legal requirements and the Institute has issued the decision
- **CALL FOR COMPLETION** – you have been delivered call for completion, it is necessary to append the application within the predefined timeline set forth by the resolution, which is part of the call for completion
- **STOPPED** – you have not appended the application within the predefined timeline, the Institute cannot confirm the application, you will be informed thereof by a letter sent via post or data box.
- **THE APPLICATION WAS WITHDRAWN** – you have taken your application back. The decision cannot be issued. You shall be informed on this fact by a resolution sent via the data box or post. After the resoulution has been issued, the application status changes to „cancellation administration“.
- **CANCELLATION ADMINISTRATION – see THE APPLICATION WAS WITHDRAWN.**

You may find only status Editing in the list of **EDITED APPLICATION**:

- **EDITING** – (no reference number issued) the application has not been filed, you may edit it.

SÚKL

In case of confusion, contact the Institute:

Technical and methodology requests:
email: SZP_RZPRO_dotazy@sukl.cz or
tel. 272 185 262 on Wednesdays 9:00 a.m. - 12:00 a.m.

Expert requests:
email: khv@sukl.cz