



APPLICATON FOR THE CLINICAL INVESTIGATION CHANGE

Medical Devices Branch

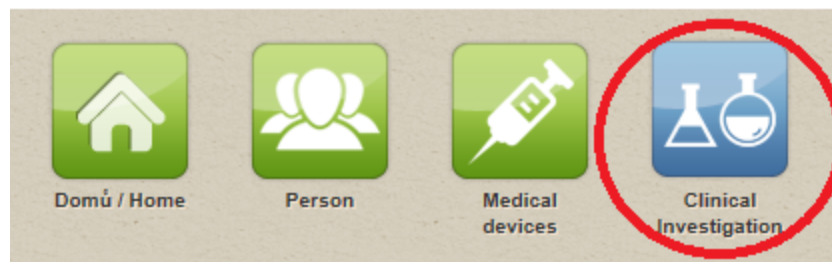
Section 15 par. 4 of the Act No. 268/2014 Coll., on Medical devices

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.

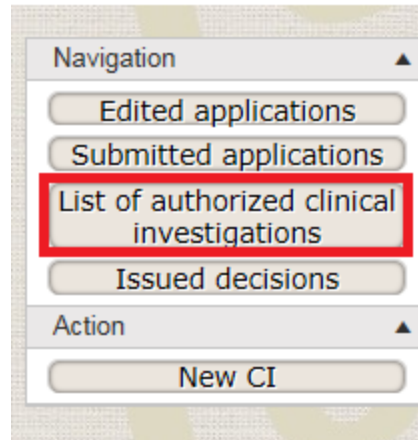
Principle of submitting applications for the clinical investigation (CI) change

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 CheckboxZP1 sro	test CH-Boxy	sukls2061/2020	zdravotní záležitost	1254cbb
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 žabíčku	test2536977

Click Application for the CI change to open the application form

Clinical investigation details « List of authorized clinical investigations « Clinical Investigation

Navigation ▲

- Submitted applications
- List of authorized clinical investigations
- Issued decisions
- CI reports
- Sponsor details

Action ▲

- Application for the clinical investigation change**
- Information about the clinical investigation starting
- Serious adverse event (SAE) report
- Clinical investigation termination

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

Clinical investigation information

Clinical investigation title v

Plan/Protocol number 784656

Primary objective

555555555555

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

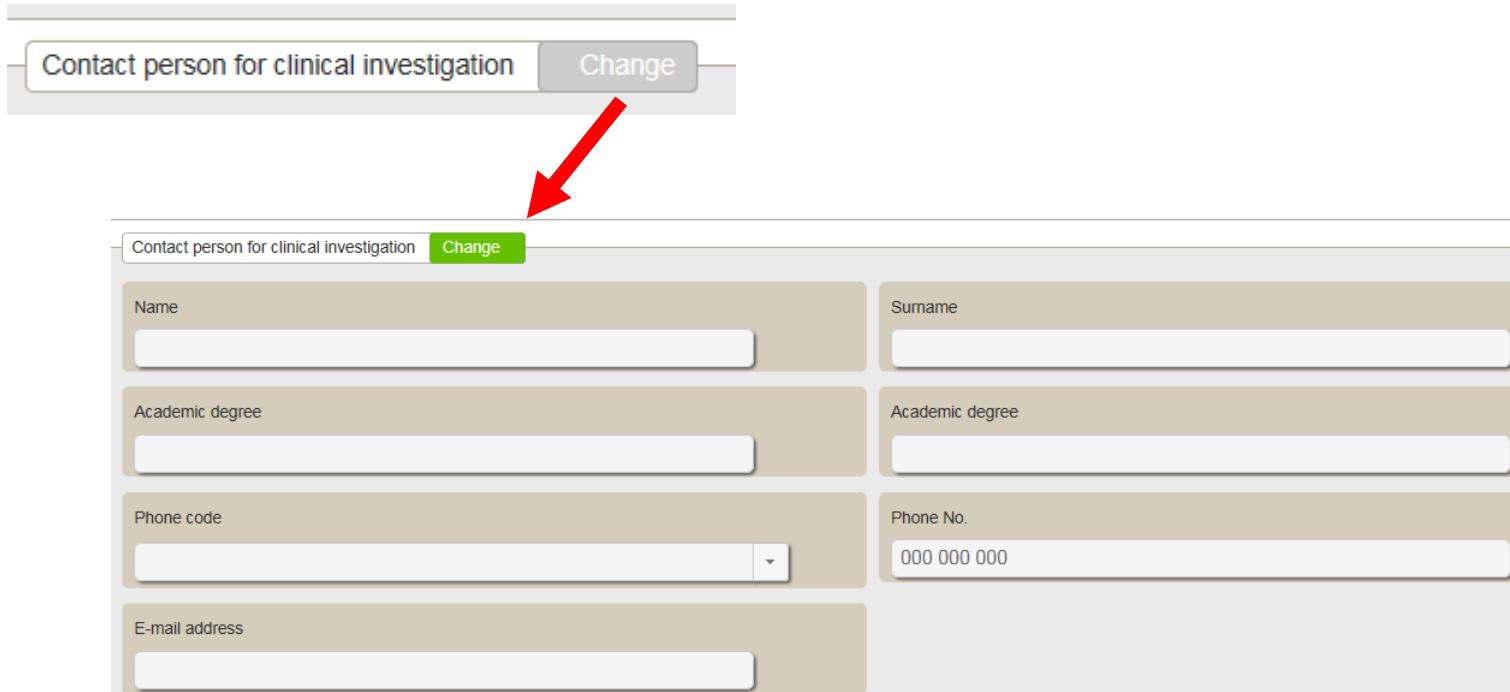
Justification for application of the clinical investigation change

Items that could be changed within the application 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.








The image shows a sequence of two screenshots from a web application. The top screenshot shows a button labeled "Contact person for clinical investigation" with a "Change" button next to it. A red arrow points from the "Change" button to the top of a larger form below. This larger form has a header with "Contact person for clinical investigation" and a green "Change" button. The form contains several input fields: "Name" and "Surname" (text boxes), "Academic degree" (text boxes), "Phone code" (a dropdown menu), "Phone No." (a text box with "000 000 000" pre-filled), and "E-mail address" (a text box).

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 .

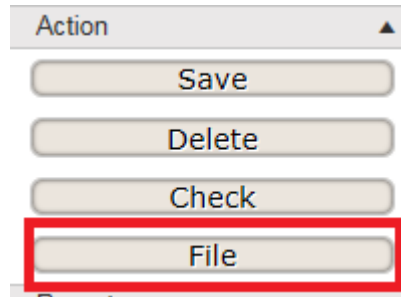
Locations of the clinical investigation in CZ with the relevant ethics committee Change					
Add site of conducted clinical investigation in CZ and the relevant ethics committee					
<input type="checkbox"/>		Ethics committee name	City	Phone No.	E-mail address
<input type="checkbox"/>		FN XX...	Plzeň		
<input type="checkbox"/>		FN Tests	Praha		

- 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.

List of mandatory attachments		Change
<input type="button" value="Add attachment"/> <input type="button" value="Delete selected"/> <input type="button" value="Restore selected"/>		
<input type="checkbox"/>	Attachment type	File name
<input type="checkbox"/>	 Clinical investigation plan	Zpetvzeti_opis_sukls106231_2015
<input type="checkbox"/>	 Cover letter	Zpetvzeti_opis_sukls106231_2015
<input type="checkbox"/>	 Synopsis in Czech	Zpetvzeti_opis_sukls106231_2015
<input type="checkbox"/>	 A proposal of changes in clinical investigation documentation	tiskovka vymaz
<input type="checkbox"/>	 Written approval of the ethics committee with changes of clinical investigation...	tiskovka vymaz

To file the application click „File“




An informative notice is displayed. Confirm and click OK

Poučení ✕

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 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.

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.

Žádost byla podána ✕

Platební předpis

V platebním předpisu najdete všechny potřebné náležitosti k zaplacení vyměřeného poplatku.

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	suk's2281/2019	Recuest for change CI	Confirmed delivery	Call for completion	

Press Applications button to access the application.

Administrative information

Subject	Request for change CI		
Decision type	Call for completion	Decision status	Confirmed delivery
Delivered	04. 08. 2020	Legal power	
SIDC file number	suks2281/2019	DMI case num.	

Information on the notifier

Name	3M Česko, spol. s r.o.	ID No.	41195612
Contact person	Barbora Bulová	Registration number	002356

Information on the petitioner

Name	STROJOBAL Hradec -Rožďalovice	ID No.	829838
Contact person		Address	387, 73914 Ostravice

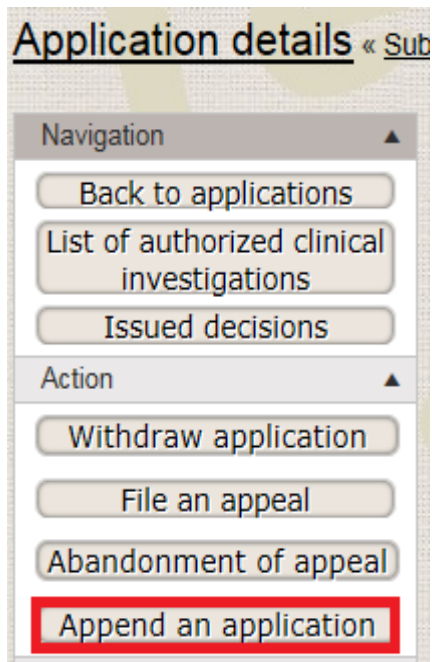
Action - PDF **Applications**

Action - PDF Applications

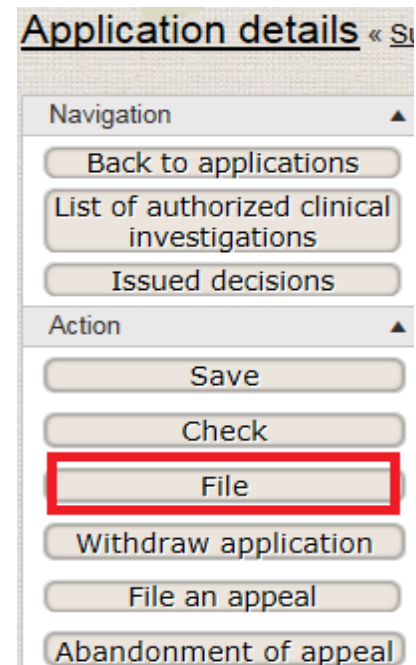
Submitted applications

Clinical trial name	Subject	Application status
v	Request for change CI	Call for completion

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.

Termination of the procedure

In case, the applicant e. g.:

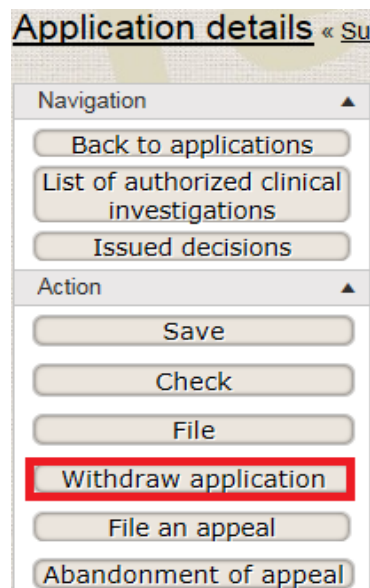
- fails to eliminate the substantial defects of the application within the predefined timeline
- Fails to pay the fee
- takes the application back (withdraws)

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

- ⑥ **EDITING** – (reference number issued) you may edit (modify) the application
- ⑥ **SUBMITTED** – the application has been filed or appended to the Institute
- ⑥ **PROCESSED** – the application is being assessed by the assessor
- ⑥ **ACCEPTED** – the application meets the legal requirements and the Institute has issued the decision
- ⑥ **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
- ⑥ **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.
- ⑥ **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 resolution has been issued, the application status changes to „cancellation administration“.
- ⑥ **CANCELLATION ADMINISTRATION** – see **THE APPLICATION WAS WITHDRAWN**.

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

- ⑥ **EDITING** – (no reference number issued) the application has not been filed, you may edit it.



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