

Manual No. 13 – Performance Study Module

On 26 May 2022, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter referred to as the “IVDR”) and the related Act No. 375/2022 Coll., on Medical Devices and In Vitro Diagnostic Medical Devices (hereinafter referred to as the “Act on MD and IVD”) governing the area of in vitro diagnostic medical devices took effect. With regard to the postponed EUDAMED database go-live date to no earlier than Q4 2023, in its transitory provisions, the Act on MD and IVD reflects the use of the RZPRO medical device registry for agendas that are to be covered by the EUDAMED database in the future.

This document describes the module for the submission of performance study (hereinafter referred to as the “performance study” or “SFE”) notifications. Pursuant to the IVDR, PERFORMANCE STUDY / SFEs are to be notified via EUDAMED. The Act on MD and IVD contains transitory provisions according to which the RZPRO registry is to be used for the submission of applications for performance studies, their notifications and record-keeping, notification of substantial changes and reporting of serious adverse events arising in the course of performance studies until the full performance study module is available. As of the IVDR effective date, performance study reporting shall be conducted in compliance with the IVDR. The particulars of a performance study application are governed by Art. 66(1) of the IVDR and related Annex XIII (sections 2 and 3) and Annex XIV. The particulars of notifications of performance studies or substantial changes thereto are governed by the respective articles of the IVDR.

To gain access to the performance study / SFE module, it is necessary to register the operation of a “clinical investigation sponsor”. The process is described in Manual No. 1.

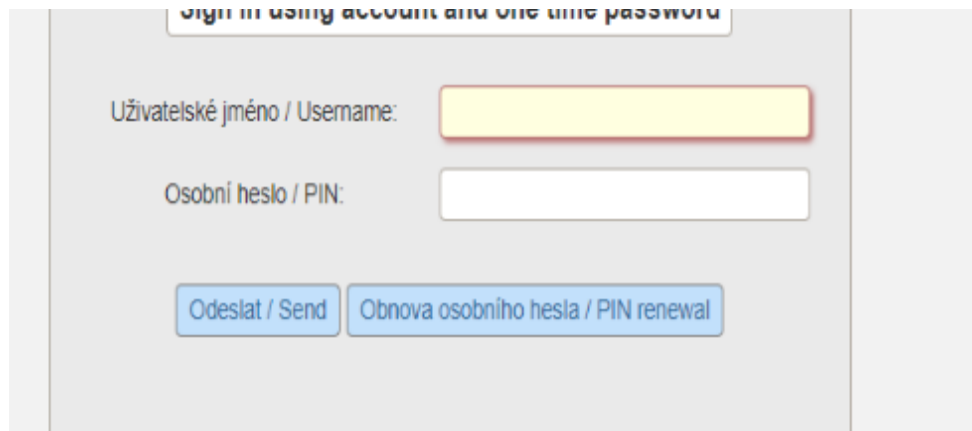
If you wish to perform any action associated with a performance study, please proceed as explained below:

1. Log in to RZPRO Registry

- 1) In your web browser, open the following site: www.rzpro.cz.
- 2) Approximately in the middle of the page, you can see a link called “Access to RZPRO for experts and notifiers”. Click the title with your mouse.

[Access to RZPRO for experts and notifiers](#)

- 3) The following page will come up and prompt you to log into your user account. Enter your username (typically composed of the first six letters of your surname and the first letter of your first name) and password, i.e., the data you have received in the RZPRO access e-mail.



Sign in using account and one time password

Uživatelské jméno / Username:

Osobní heslo / PIN:

- 4) When you complete the required data, click on the “Send” button. At that moment, check your mobile phone/e-mail, where a one-time password will be sent. The validity of the one-time password is limited. Should it expire, please click the “Back” button.

5) The following page will come up:

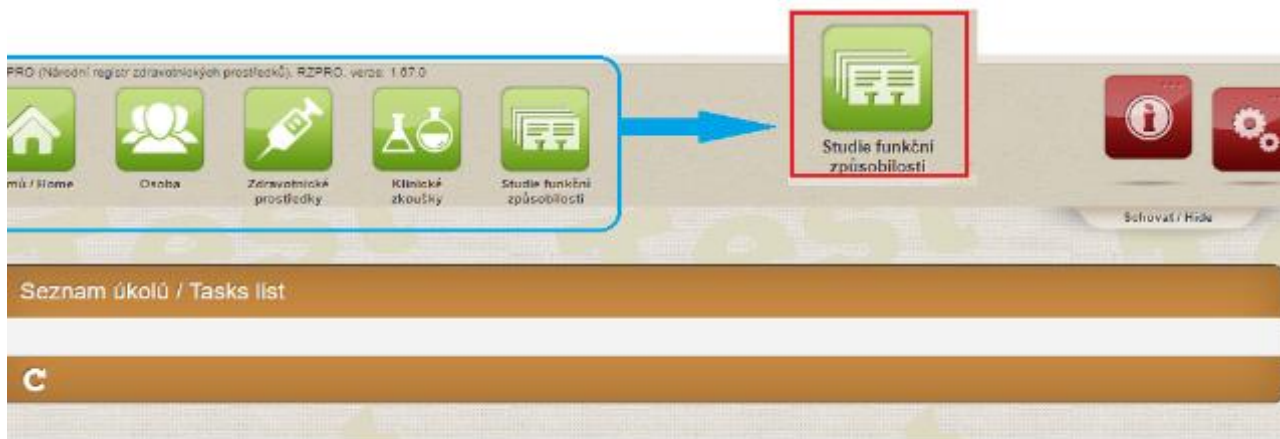


The word “SMS” in the green field may be also replaced with the word “e-mail” – it depends on which login option has been set up.

- 6) In a moment, a one-time password will arrive on your mobile phone/e-mail. Please enter the code in the “One-time password” field and click the “Send” option.
- 7) A page showing an upper bar will be displayed. On this page, click on the “RZPRO” green field.

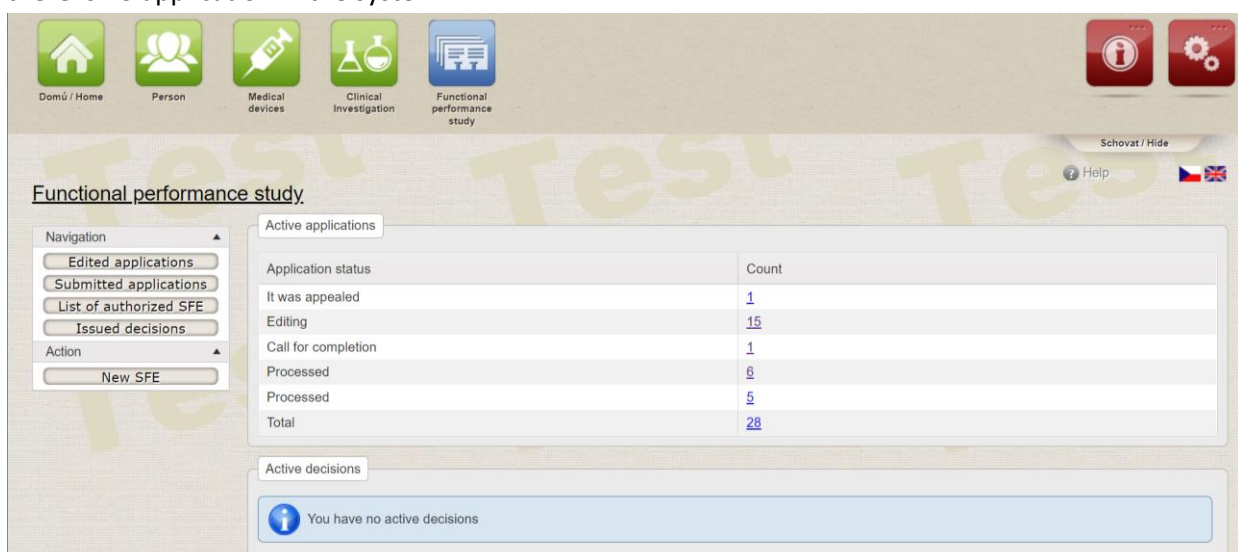


- 1) The page displayed in the picture below will appear (the English version is unavailable). On this page, click the “Studie funkční způsobilosti”(performance study)” green field (it will be displayed only in case of a previously confirmed notification of operation of a “clinical investigation sponsor” or upon receipt of a power of attorney via JSU from the person for whom the notification of operation of a “clinical investigation sponsor” has been confirmed.



2. Performance Study Module

When you enter the Performance Study module (hereinafter referred to as the “PERFORMANCE STUDY / SFE module”) as per the instructions, the homepage with a menu of options and a dashboard will come up, showing a recapitulation of the active status of handling of applications, reports, and delivered decisions. The dashboard is not displayed when you run the module for the first time and there is no application in the system.



Functional performance study

Navigation

- Edited applications
- Submitted applications
- List of authorized SFE
- Issued decisions

Action

- New SFE

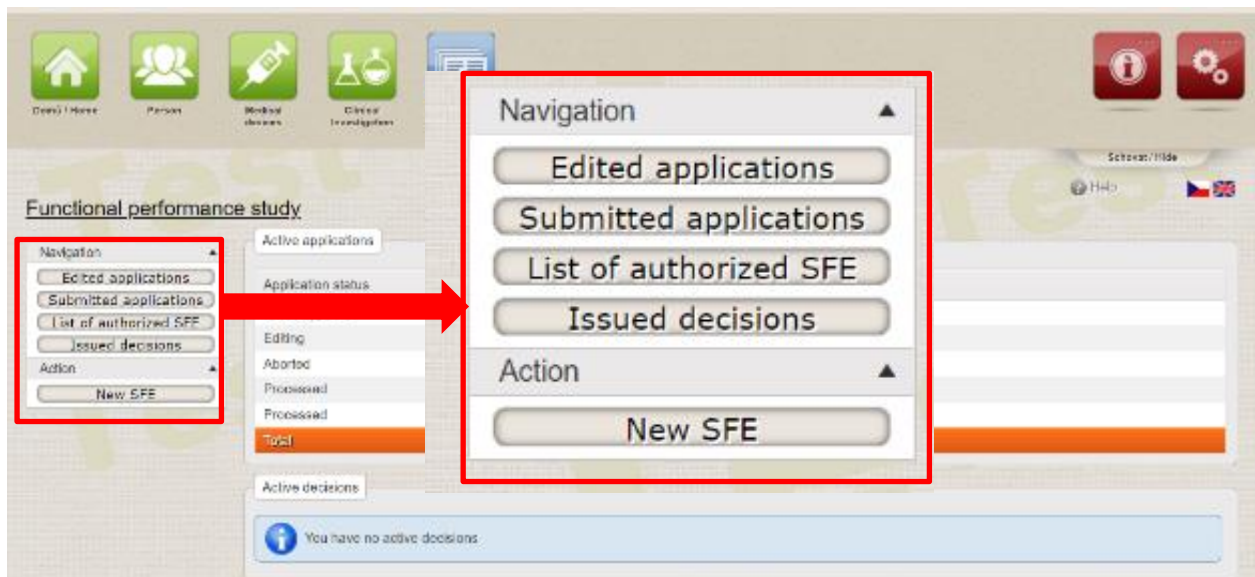
Application status	Count
It was appealed	1
Editing	15
Call for completion	1
Processed	6
Processed	5
Total	28

Active decisions

You have no active decisions

2.1. PERFORMANCE STUDY / SFE Module Main Menu

2.1.1. Options menu window



Navigation:

- **Edited applications** – displays a list of all not yet submitted applications of the respective sponsor, with the option to search and display the application detail. When you click on the application detail, the option allowing you to apply will come up.
- **Submitted applications** – displays a list of all submitted applications of the respective sponsor, with the option to search and display the application detail, to run the options to process the application in terms of the Code of Administrative Procedure (application withdrawal, appeal, etc.).
- **List of authorised PERFORMANCE STUDY / SFE** – displays a list of all authorised performance studies of the respective person with the option to search and display the PERFORMANCE STUDY / SFE detail.
- **Issued decisions** – displays a list of all decisions issued by administrative authorities regarding the submitted applications of the concerned sponsor with the option to search. The list of decisions is common for several modules at the same time.

Action:


- **New PERFORMANCE STUDY / SFE** – generates a form for the completion of an application for the authorisation of an PERFORMANCE STUDY / SFE conduct and its submission.

2.1.2. Homepage dashboard

Active applications

Application status	Count
It was appealed	1
Editing	15
Call for completion	1
Processed	6
Processed	5
Total	28

Active decisions

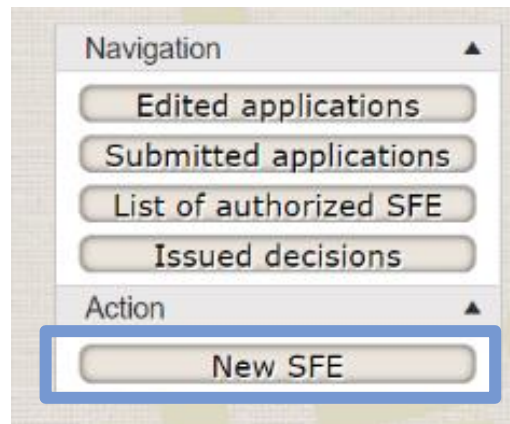
 You have no active decisions

The dashboard is split into the following overviews:

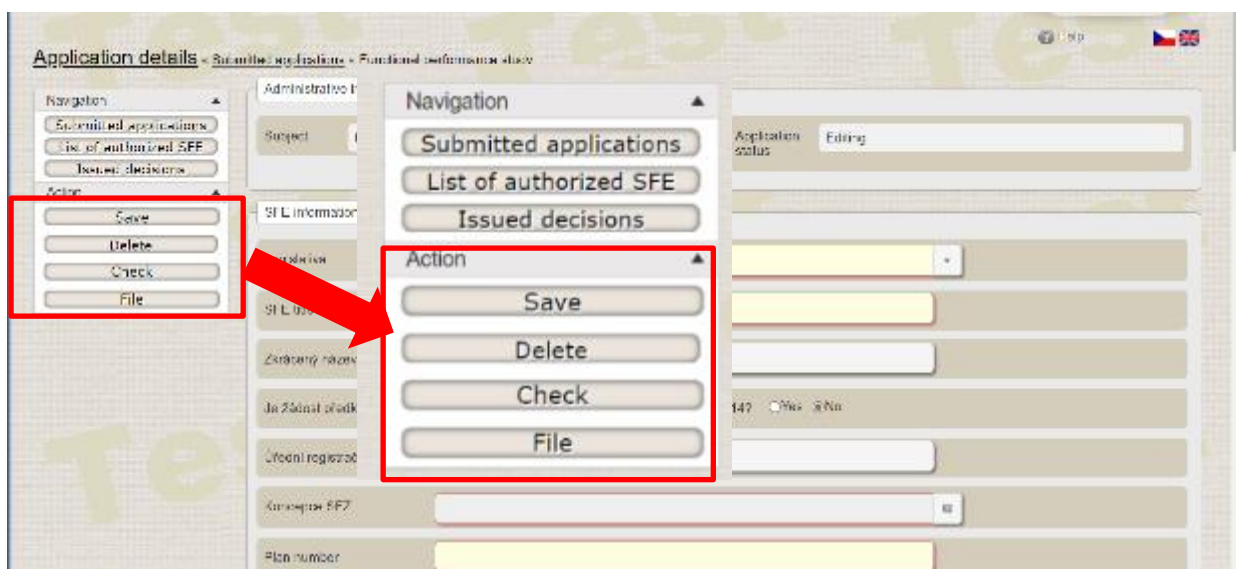
- **Active applications** – displays the number of active pending applications for performance studies at various stages of the administrative procedure. If you click on the application count field, the filtered list of the sponsor's applications will be displayed.
- **Active decisions** – displays an overview of the number of decisions by types and action status, which have been issued by the Institute and have not become final as yet. If you click on the Count field, a filtered list of entities for detailed display will come up.

2.2. New Application for the Conduct of a Performance Study

To submit a new application for the authorisation of a PERFORMANCE STUDY / SFE conduct, please click the “New SFE” button on the homepage of the “Performance study / SFE” module.



The form for the submission of a new application for the authorisation of a performance study conduct will come up.



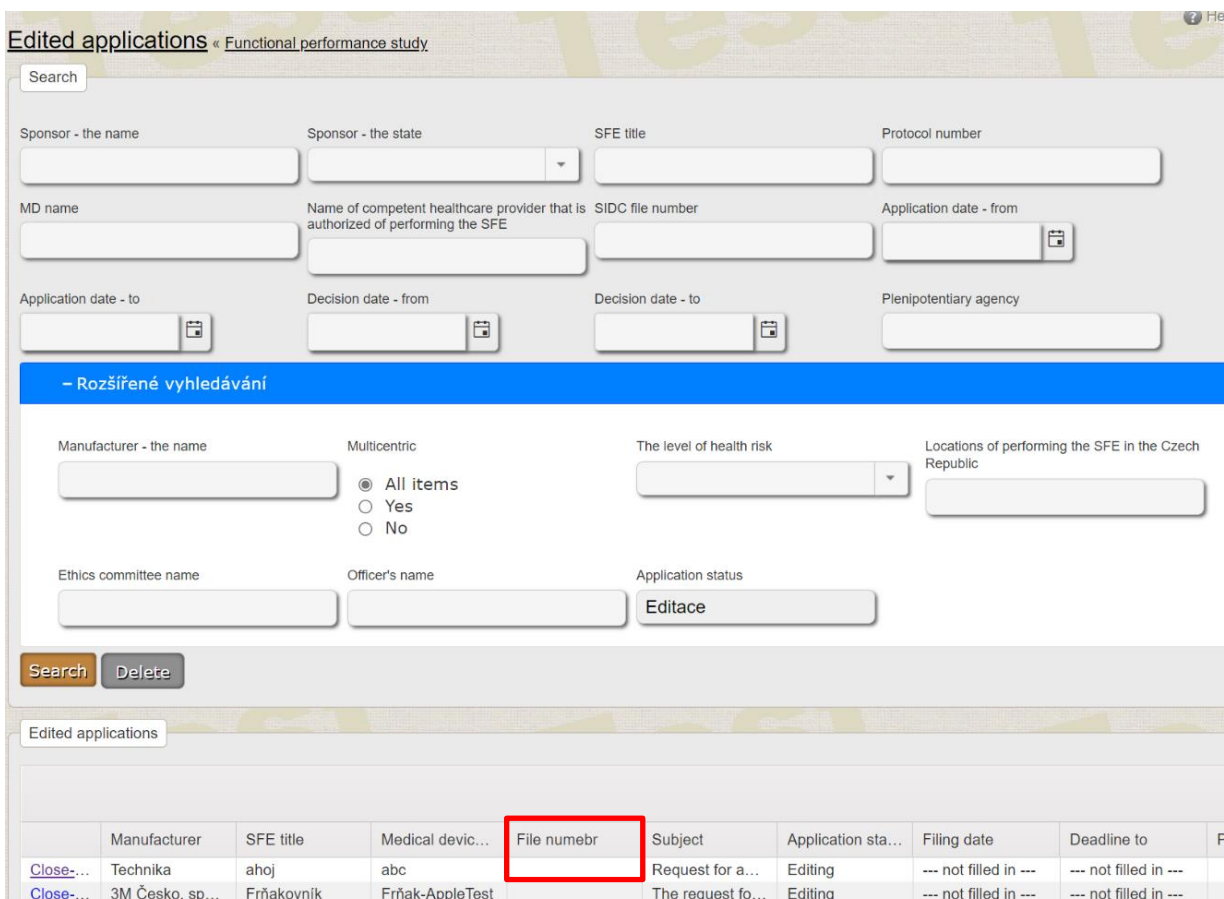
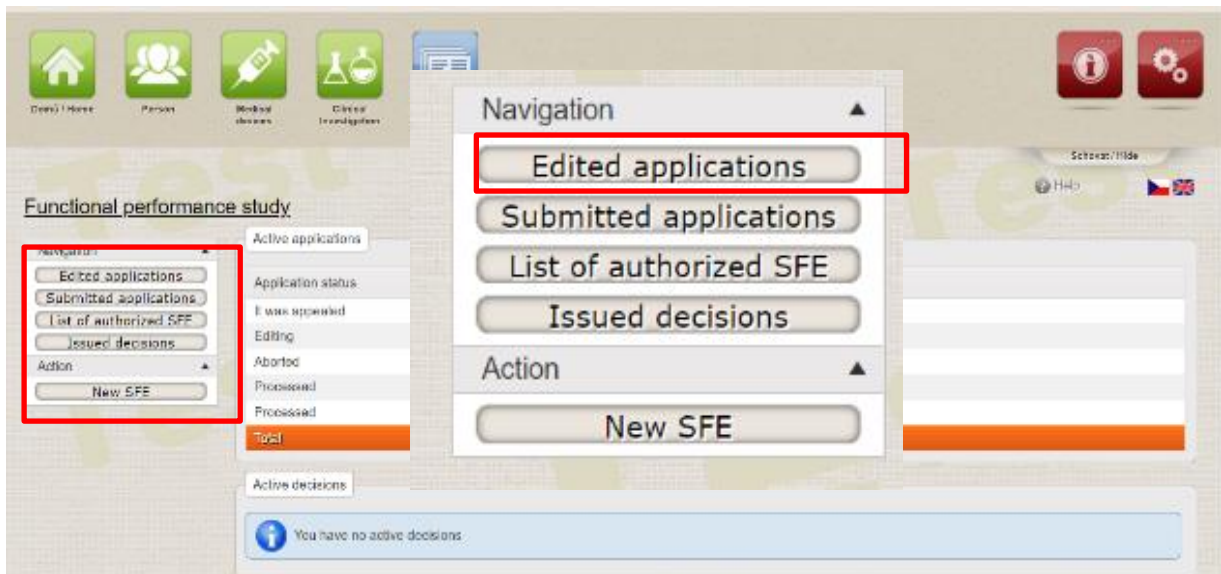
Upon opening the form for the submission of a new PERFORMANCE STUDY / SFE, the RZPRO registry allows for the following actions:

- **Save** – saves the content of the completed form and the saving is confirmed by a message in the info bar under the navigation icons. It is possible to save also forms that have not been fully completed and you still work on them.
- **Delete** – irreversibly deletes the currently opened application form. Forms may be deleted only if in the “Editing” status.
- **Check** – saves the content of the form and checks the completeness of the mandatory fields and included attachments. The result of the check is displayed in an information message.

- **File** – this option will apply for processing to the Institute. Before the submission, the **form** completeness check is performed and, if errors are detected, the submission is not completed, and the user is invited to eliminate the errors. The application Status changes to “Submitted”.

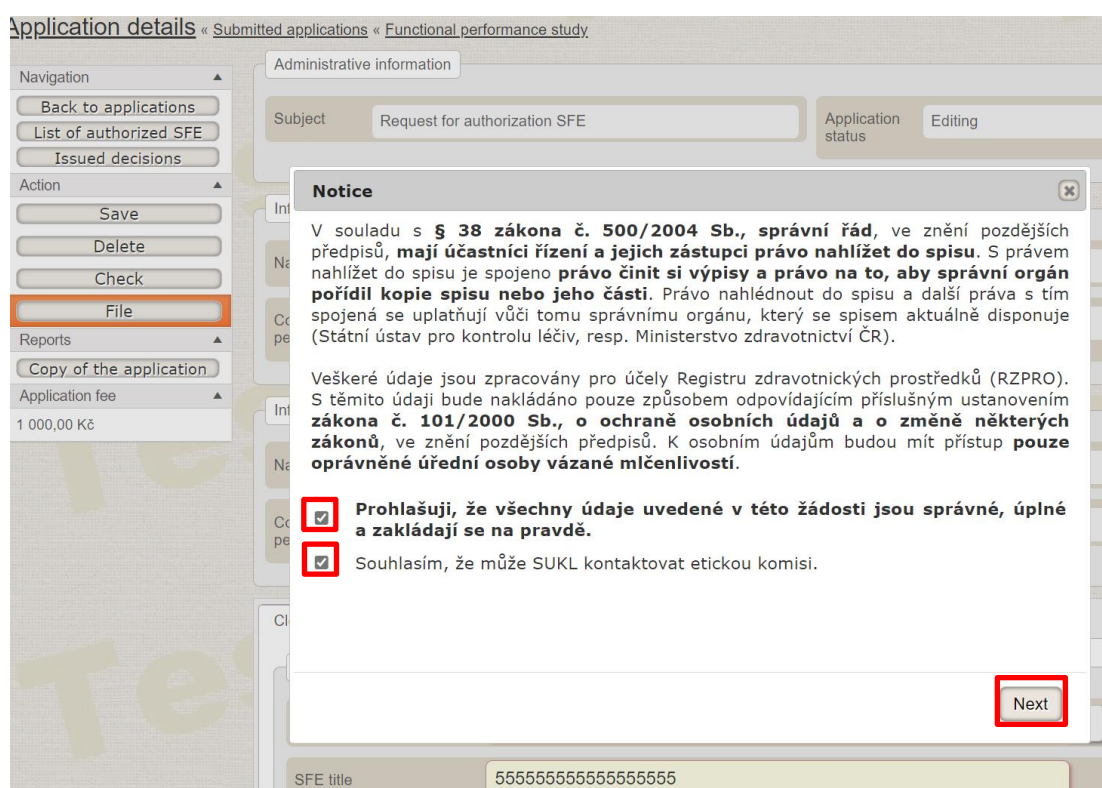
2.2.1. Application before submission to the State Institute for Drug Control

An application that has not yet been submitted to the State Institute for Drug Control (hereinafter referred to as the “Institute”) is in the edited status and does not have any allocated file number. The list of not yet submitted applications is available from the navigation field on the homepage of the “Performance Study” module.



2.2.2 Submission of a new functional performance study

If you have completed all of the mandatory fields (highlighted in yellow) and uploaded all of the mandatory attachments, the application may be submitted to the Institute by pressing the “File” button. When you press the “File” button and confirm the submission of the application (see pictures below), the application is forwarded to the Institute and **may no longer be edited**. Editing an application after its submission is possible only if a **request for amendment of the application** issued by the Institute is delivered.



Application details « Submitted applications « Functional performance study

Administrative information

Subject Request for authorization SFE Application status Editing

Navigation

- Back to applications
- List of authorized SFE
- Issued decisions

Action

- Save
- Delete
- Check
- File**
- Reports
- Copy of the application

Application fee

1 000,00 Kč

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).

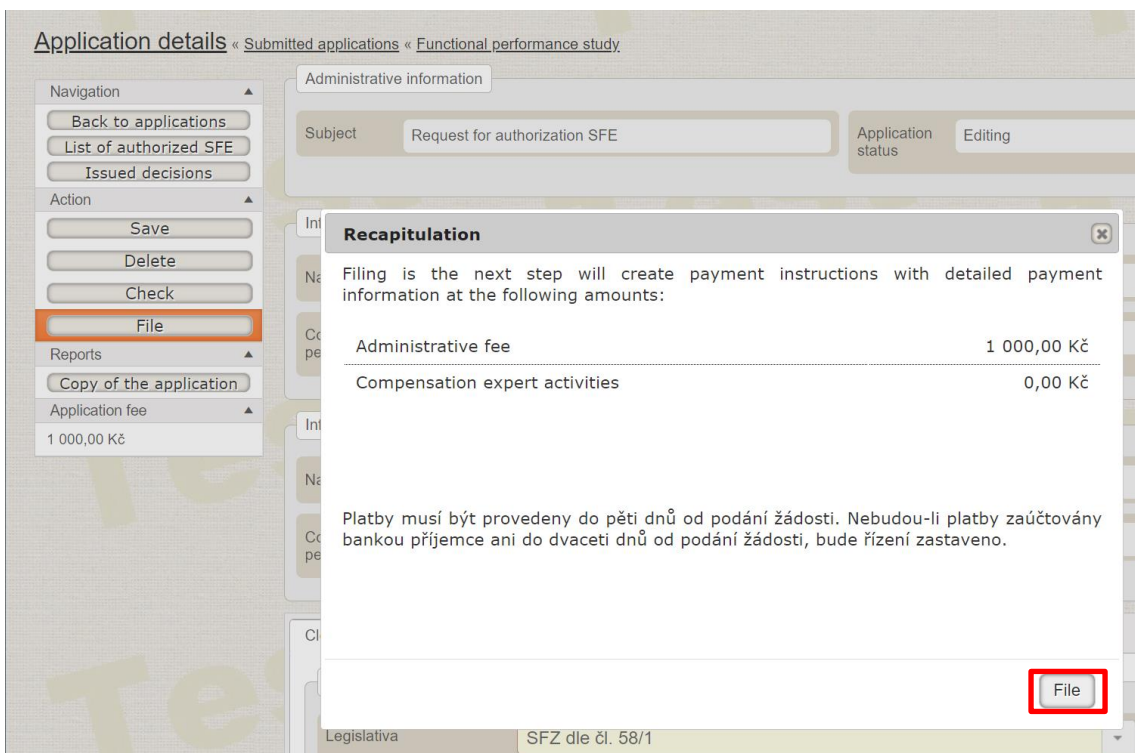
Veškeré údaje jsou zpracovány pro účely Registru zdravotnických prostředků (RZPRO). S těmito údaji bude nakládáno pouze způsobem odpovídajícím příslušným ustanovením **zákona č. 101/2000 Sb., o ochraně osobních údajů a o změně některých zákonů**, ve znění pozdějších předpisů. K osobním údajům budou mít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

Prohlašuji, že všechny údaje uvedené v této žádosti jsou správné, úplné a zakládají se na pravdě.

Souhlasím, že může SUKL kontaktovat etickou komisí.

Next

SFE title 55555555555555555555



The screenshot shows the 'Application details' page for a 'Submitted application' in the 'Functional performance study' module. The subject is 'Request for authorization SFE' and the application status is 'Editing'. A 'Recapitulation' dialog box is open, displaying the following information:

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

Administrative fee	1 000,00 Kč
Compensation expert activities	0,00 Kč

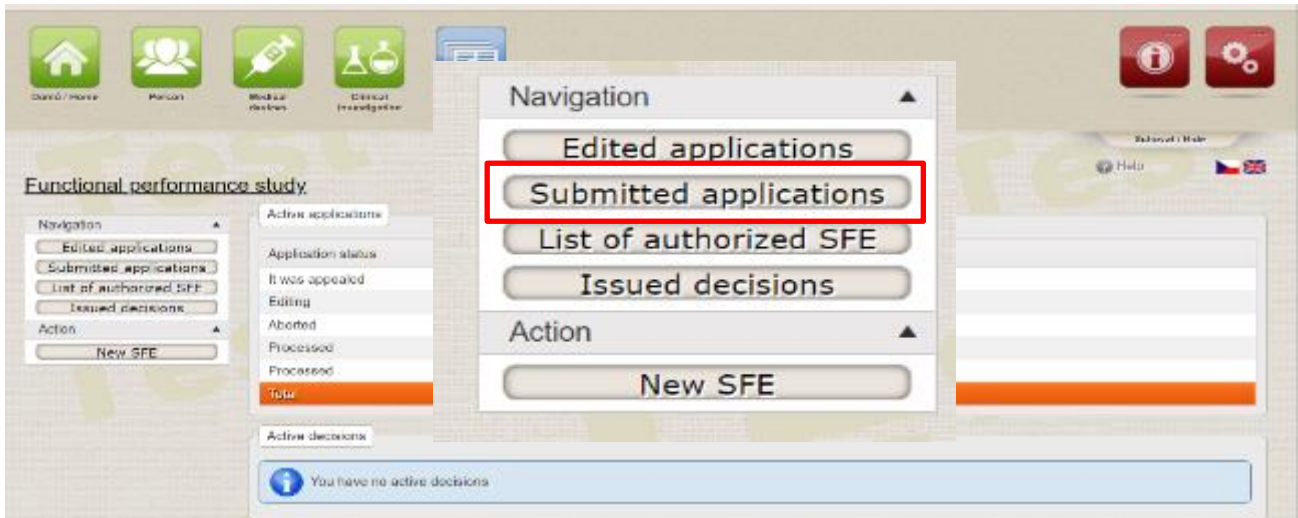
Below the table, the text reads: 'Platby musí být provedeny do pěti dnů od podání žádosti. Nebudou-li platby zaúčtovány bankou příjemce ani do dvaceti dnů od podání žádosti, bude řízení zastaveno.'

The 'File' button in the dialog box is highlighted with a red rectangle. In the background, the 'File' button in the left-hand navigation menu is also highlighted with a red rectangle.

2.3. Submitted Applications for Performance Studies

2.3.1. Searching and filtering submitted applications

On the PERFORMANCE STUDY / SFE module homepage, click on the “Submitted applications” button.



Submitted applications « Functional performance study

Search

Sponsor - the name Sponsor - the state SFE title Protocol number

MD name Name of competent healthcare provider that is authorized of performing the SFE SIDC file number Application date - from

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

Registration number

+ Rozšířené vyhledávání

Search Delete

Submitted applications

	Manufacturer	SFE title	Medical devic...	File numebr	Subject	Application sta...	Filing date	Deadline to	Plenipotentiari...
Close...	Abbott Labora...	55555555555...	Spalničkytest	sukls7827/2022	Request for a...	Submitted	29. 12. 2022	27. 02. 2023	
Close...	" E & B Pharm...	Studie M	Trišt	sukls6997/2022	Request for a...	Accepted	07. 12. 2022	05. 02. 2023	

A search using a filter can be done by completing one or more filter fields and pressing the "Search" button, which will retrieve the filtered submitted applications.

Overview of statuses:

- **EDITING** – a file number has been allocated – the application contained shortcomings based on which the Institute invited you to amend the application and you have already opened the application detail; you can amend/supplement the application in the editing status.
- **SUBMITTED** – the application or requested application amendment has been submitted to the Institute

- **VALIDATED** – the application is at the validation stage until verified application issuance is notified.
- **UNDER PROCESSED** – the Institute’s officer assesses the application/requested application amendment in the assessment stage
- **PROCESSED** – the application or requested application amendment has been assessed and the outcome forwarded for signature
- **ACCEPTED** – the application contains all of the particulars required by law and the Institute has issued a decision on PERFORMANCE STUDY / SFE conduct authorisation.
- **CALL FOR COMPLETION** – you have received a request to amend the application, which has to be responded to **within the timeline established by the resolution** which forms part of the request for amendment.
- **TERMINATED** – the Institute has issued a resolution to stop the administrative procedure concerning your application.
- **REJECTED** – the Institute has issued a decision to decline the submitted application.
- **APPLICATION WITHDRAWN**– you have withdrawn your application. Based on this action, the Institute will issue a resolution to stop the procedure. When the resolution is issued, the application status will change to “Terminated”.

2.3.1.2. Submitted application detail

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

Submitted applications « Functional performance study

Search

Sponsor - the name Sponsor - the state SFE title Protocol number

MD name Name of competent healthcare provider that is authorized of performing the SFE SIDC file number Application date - from

Application date - to Decision date - from Decision date - to Plenipotentiary agent

Registration number

+ Rozšířené vyhledávání

Search Delete

Submitted applications

	Manufacturer	SFE title	Medical devic...	File numebr	Subject	Application sta...	Filing date
Close-...	Abbott Labora...	5555555555...	Spalničkytest	sukls7827/2022	Request for a...	Submitted	29. 12. 2022
Close-...	" E & B Pharm...	Studie M	Tříšť	sukls6997/2022	Request for a...	Accepted	07. 12. 2022

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

Application details « Submitted applications « Functional performance study

Administrative information

Subject Application status

Filing date SIDC file number

Information on the notifier

Name ID No.

Navigation

- Back to applications
- List of authorized SFE
- Issued decisions

Action

- Withdraw application

Reports

- Copy of the application**
- Fee prescription

2.3.1.3. PERFORMANCE STUDY / SFE registration number

For an authorised PERFORMANCE STUDY / SFE, a unique identifier (registration number) will be generated – these are displayed in the list of authorised PERFORMANCE STUDY / SFEs.

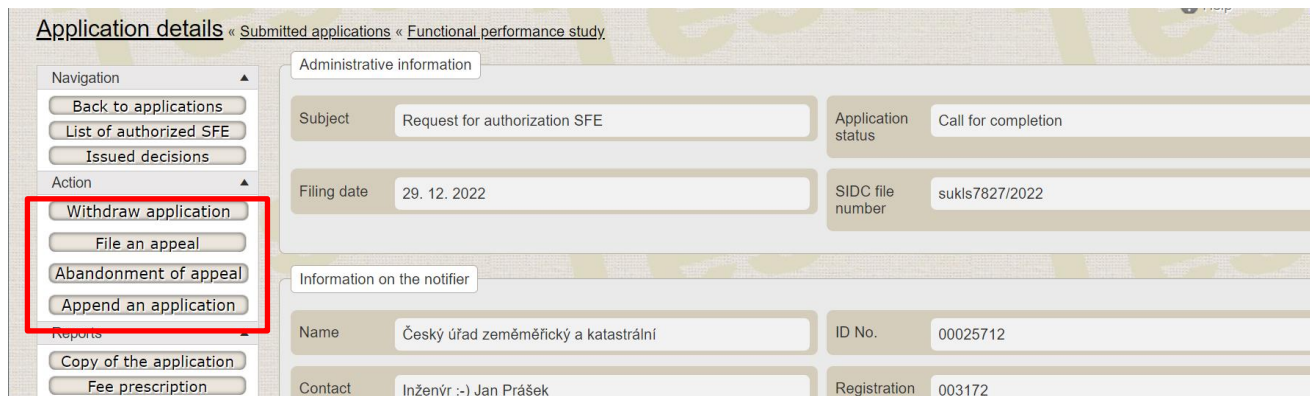
Search

Functional performance study

Manufacturer	SFE title	SIDC file number	Registration number	Medical device name	Protocol number
Český úřad zeměměřický ...	testujeme	sukls862/2022	0106	test	1234
Český úřad zeměměřický ...	spalňičky2	sukls737/2022	0112	Spalňičkytest	123456789
Český úřad zeměměřický ...	evidenční číslo oprava	sukls1178/2022	0116	evidenční číslo	3005

2.4 Actions in Response to the Institute's Reaction to the Submitted Application

Based on the Institute's reaction, it is possible to perform the following actions in the **Detail of a submitted application**:



The screenshot shows the 'Application details' page for a 'Submitted application' under 'Functional performance study'. The 'Action' menu is highlighted with a red box, containing the following options: 'Withdraw application', 'File an appeal', 'Abandonment of appeal', and 'Append an application'. The main content area displays administrative information: Subject (Request for authorization SFE), Application status (Call for completion), Filing date (29. 12. 2022), and SIDC file number (sukls7827/2022). Below this, information on the notifier is shown: Name (Český úřad zeměměřický a katastrální), ID No. (00025712), Contact (Inženýr :-) Jan Prášek, and Registration (003172).

- **Withdraw application** – based on an application withdrawal, the Institute stops the administrative procedure and no longer considers the submitted application.
- **File an appeal** – the application submitter files an appeal from the decision issued by the Institute. The filed appeal must comply with the Code of Administrative Procedure.
- **Abandonment of appeal** – the submitter abandons their right to appeal, which makes the decision final upon that moment; if the conduct of the performance study is authorised, the study may be commenced on the day following the date of the decision becoming final.
- **Append an application** – allows to amend/edit an application based on the Institute's request for amendment.

2.4.1. Withdrawal of a submitted application

The submitted application may be withdrawn by pressing the **“Withdraw application”** button. This generates a Notice within which it is necessary to tick the declaration confirming that you are withdrawing the application. Thereafter, click the **“Withdraw application”** button (the picture below refers to). A withdrawn application may no longer be edited and based on the withdrawal; the Institute shall issue a resolution to stop the administrative procedure. This action is irreversible, and should the applicant thereafter wish to conduct the respective performance study, they will have to apply with the Institute for the PERFORMANCE STUDY / SFE authorisation again.

Action

- Withdraw application**
- File an appeal
- Abandonment of appeal
- Append an application
- Reports
- Copy of the application
- Fee prescription

Filing date: 29. 12. 2022

SIDC file number: sukls7827/2022

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).

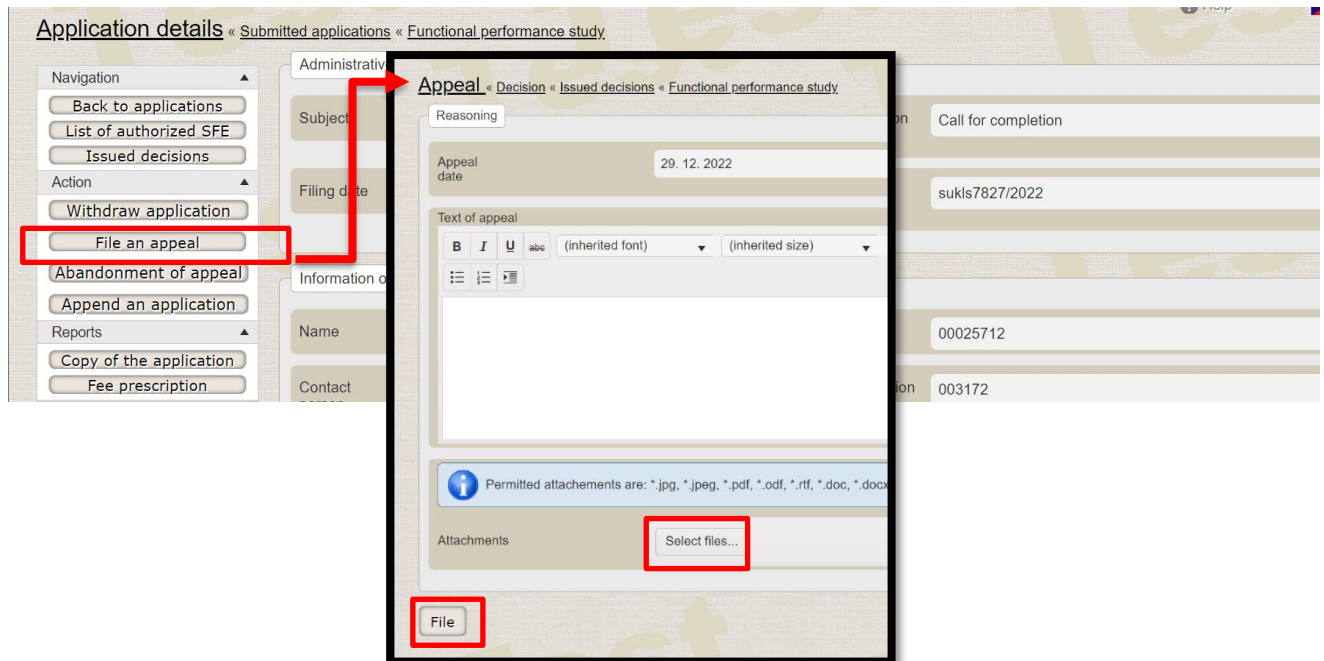
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Prohlašuji, že podanou žádost beru zpět.

Withdraw application

2.4.2. Appeal from the Institute's decision

It is possible to file an appeal from a decision by pressing the **“File an appeal”** button. This brings up a form to enter the text on the appeal rationale and it is **mandatory** to attach the document containing the submitter's appeal (click on the **“Select”** button). The appeal may be submitted by pressing the **“File”** button. Appeals are heard by the Ministry of Health of the Czech Republic.

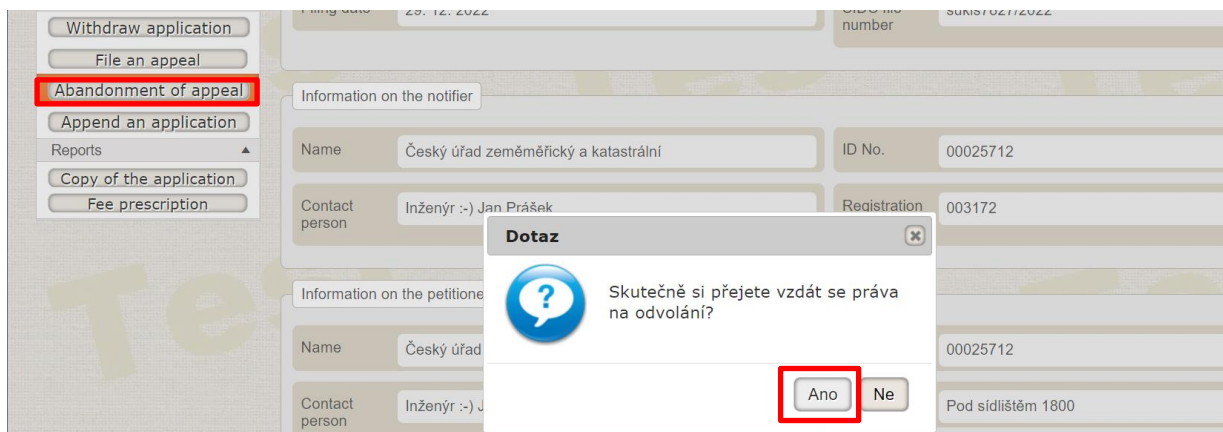


The screenshot shows the 'Application details' page for a 'Functional performance study'. In the left-hand navigation menu, the 'File an appeal' button is highlighted with a red box. A red arrow points from this button to the 'Appeal' form. The 'Appeal' form contains the following elements:

- Reasoning** section with a breadcrumb: Appeal » Decision » Issued decisions » Functional performance study.
- Appeal date** field: 29. 12. 2022.
- Text of appeal** field: A rich text editor with formatting options (B, I, U, abc) and font/size dropdowns.
- Attachments** section: A 'Select files...' button is highlighted with a red box.
- File** button: Located at the bottom of the form, highlighted with a red box.

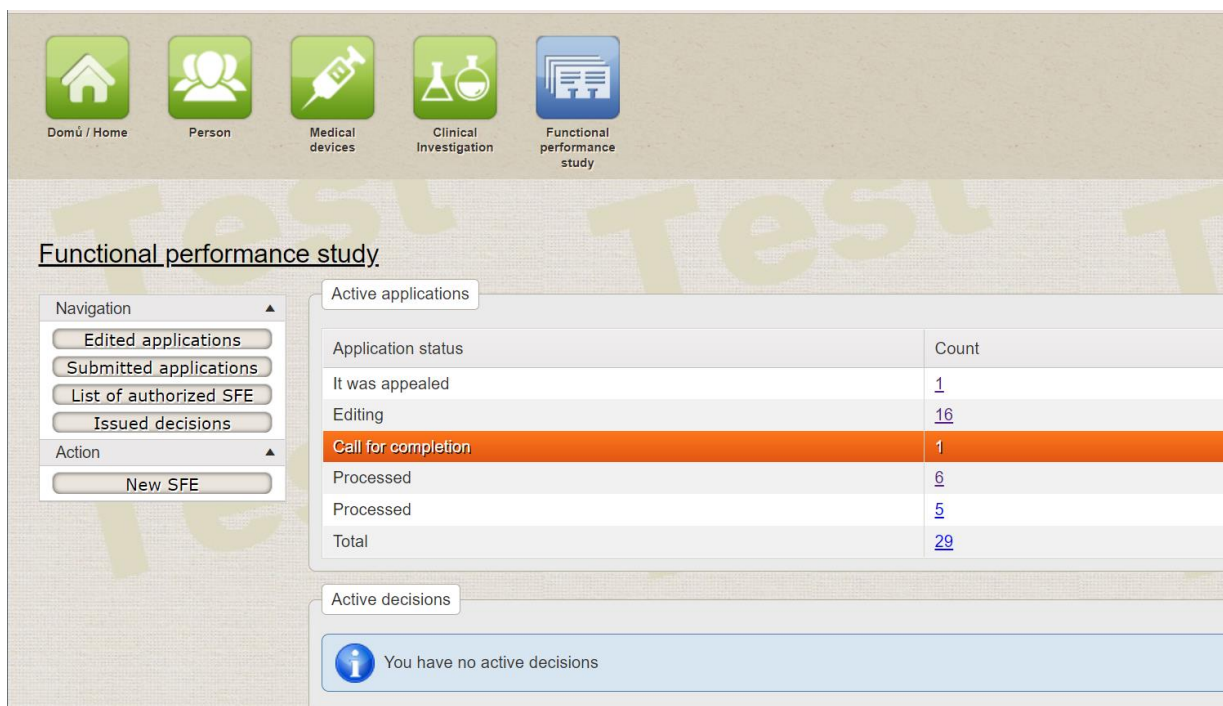
2.4.3. Abandonment of appeal

In case the applicant needs the decision issued by the administrative authority to become final earlier than upon the expiry of the timeline for appeals from the respective decision, they may abandon their right to appeal from the decision. The right to appeal may be abandoned by clicking the **“Abandonment of appeal”** button and subsequent confirmation by pressing the **“Ano” (Yes)** button.



2.4.4. Amendment of a previously submitted application

The active applications on the homepage contain also requests for amendment (“Call for completion” status). Click on the active numeral in the “Count” column.



Domů / Home Person Medical devices Clinical Investigation Functional performance study

Functional performance study

Navigation

- Edited applications
- Submitted applications
- List of authorized SFE
- Issued decisions


Action

- New SFE

Active applications

Application status	Count
It was appealed	1
Editing	16
Call for completion	1
Processed	6
Processed	5
Total	29

Active decisions

 You have no active decisions

This will bring you to your submitted applications for which a request for amendment is available. Click on the “Detail” section for an application which is in the “Append an application” status – i.e., click the “**Close-up**” button for an application with SÚKL’s file no. `sukls.....`, which is specified in the request for amendment that you have received in your data mailbox or via a postal delivery service. The detail of the application will then come up.

If you wish to display the document that you have received in your mailbox or via a postal delivery service, i.e., the request for amendment of the application – click on the “Decision” tab. The “Decision” tab cannot be used to amend the application.

To amend the application as requested, it is necessary to go back to the application (i.e., the “Detail” tab.).

To amend the application as requested by the request for amendment, click on the “**Append application**” option. This will bring up the same form as that for the submission of a new PERFORMANCE STUDY / SFE, with defaulted data from your previous submission of the concerned PERFORMANCE STUDY / SFE, which may be amended, or it is possible to enclose new attachments.

Application details « Submitted applications « Functional performance study

Administrative information

Subject: Request for authorization SFE Application status: Call for completion

Filing date: 29. 12. 2022 SIDC file number: sukl57827/2022

Information on the notifier

Name: Český úřad zeměměřický a katastrální ID No.: 00025712

Contact: Inženýr -) Jan Prašek Registration: 003172

Navigation:

- Back to applications
- List of authorized SFE
- Issued decisions
- Action
- Withdraw application
- File an appeal
- Abandonment of appeal
- Append an application**
- Reports
- Copy of the application
- Fee prescription

The application may be amended in stages; always click on the “Save” button to save your changes. As soon as you amend all the particulars of the requested amendment, click on the “File” button to submit the amended application to the Institute. To make sure that the application has been submitted, please check that the application status has been changed from “Editing” to “Submitted”.

Application details « Submitted applications « Functional performance study

Administrative information

Subject: Request for authorization SFE Application status: Editing

Notice

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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.

Souhlasím, že může SUKL kontaktovat etickou komisi.

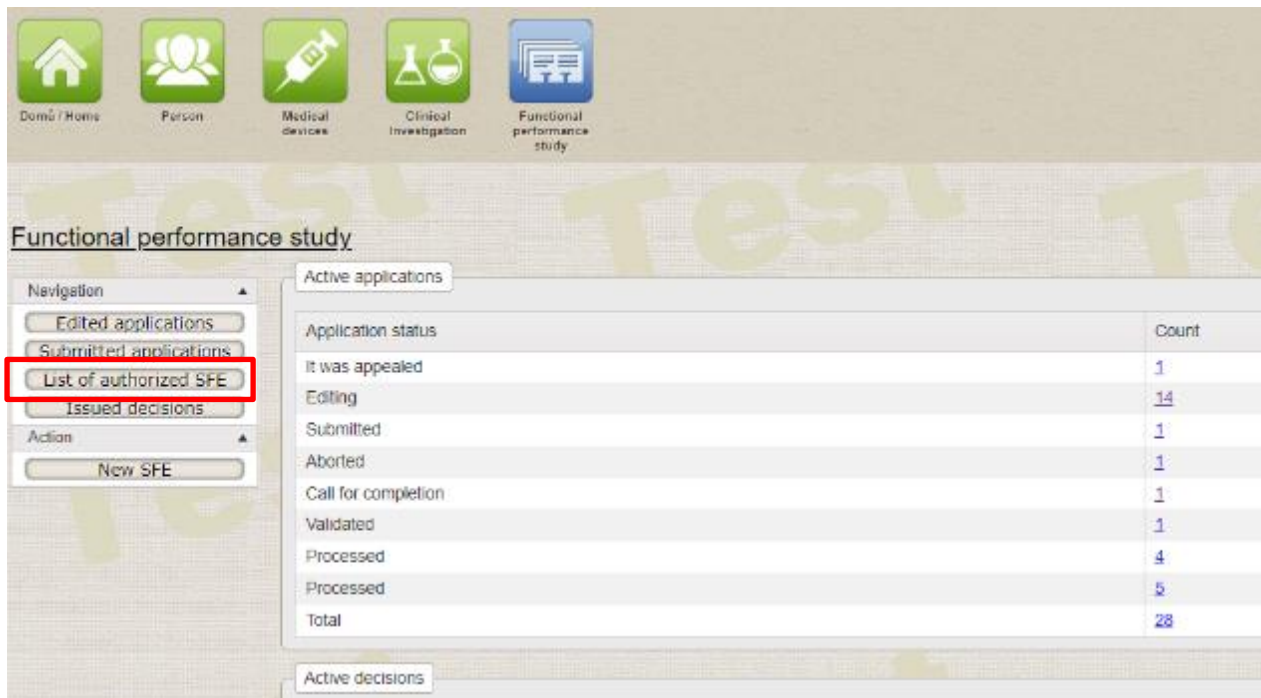
Next

SFE title: 55555555555555555555

2.5 Management of Authorised PERFORMANCE STUDY / SFEs

2.5.1. List of authorised PERFORMANCE STUDIES / SFEs

If you wish to display the list of authorised applications for performance studies, use the “**List of authorised SFE**” option.

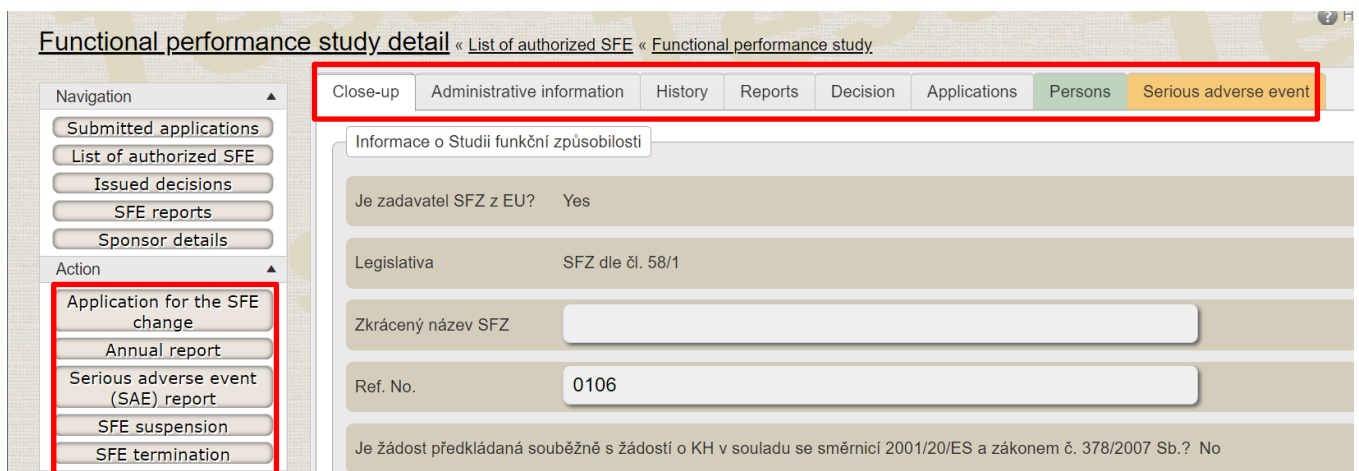


The screenshot shows the 'Functional performance study' section of the SÚKL web application. In the navigation menu on the left, the 'List of authorized SFE' option is highlighted with a red box. The main content area displays a table of application statuses and counts.

Application status	Count
It was appealed	1
Editing	14
Submitted	1
Aborted	1
Call for completion	1
Validated	1
Processed	4
Processed	5
Total	28

This will bring up a list with the option to apply filters, just as described in chapter “2.3.1. Searching and filtering submitted applications”. The description of individual fields of the search filter is available from the RZPRO user manual.

For more detailed information on the performance study, the possibility to submit a report on PERFORMANCE STUDY / SFE initiation, submitting an annual report, etc., and the conduct of other actions (application for change to PERFORMANCE STUDY / SFE, application to continue a PERFORMANCE STUDY / SFE previously suspended by the sponsor or the Institute), click on the **“Close-up”** of the concerned PERFORMANCE STUDY / SFE in the list of authorised PERFORMANCE STUDIES / SFEs. This will bring up the PERFORMANCE STUDY / SFE detail with individual tabs containing detailed information on the PERFORMANCE STUDY / SFE and a panel with buttons for the submission of individual reports and applications that may be filed for the authorised PERFORMANCE STUDY / SFE.



Functional performance study detail < List of authorized SFE < Functional performance study

Navigation

- Submitted applications
- List of authorized SFE
- Issued decisions
- SFE reports
- Sponsor details

Action

- Application for the SFE change
- Annual report
- Serious adverse event (SAE) report
- SFE suspension
- SFE termination

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

Informace o Studii funkční způsobilosti

Je zadavatel SFZ z EU? Yes

Legislativa SFZ dle čl. 58/1

Zkrácený název SFZ

Ref. No. 0106

Je žádost předkládána souběžně s žádostí o KH v souladu se směrnicí 2001/20/ES a zákonem č. 378/2007 Sb.? No

2.6. Actions conducted in Respect of an Authorised PERFORMANCE STUDY / SFE

The actions that may be conducted for authorised PERFORMANCE STUDIES / SFEs (reports, application for change of PERFORMANCE STUDY / SFE) may be carried out in the RZPRO only after you click on the “Close-up” of the concerned PERFORMANCE STUDY / SFE in the “List of authorised PERFORMANCE STUDY / SFE”!

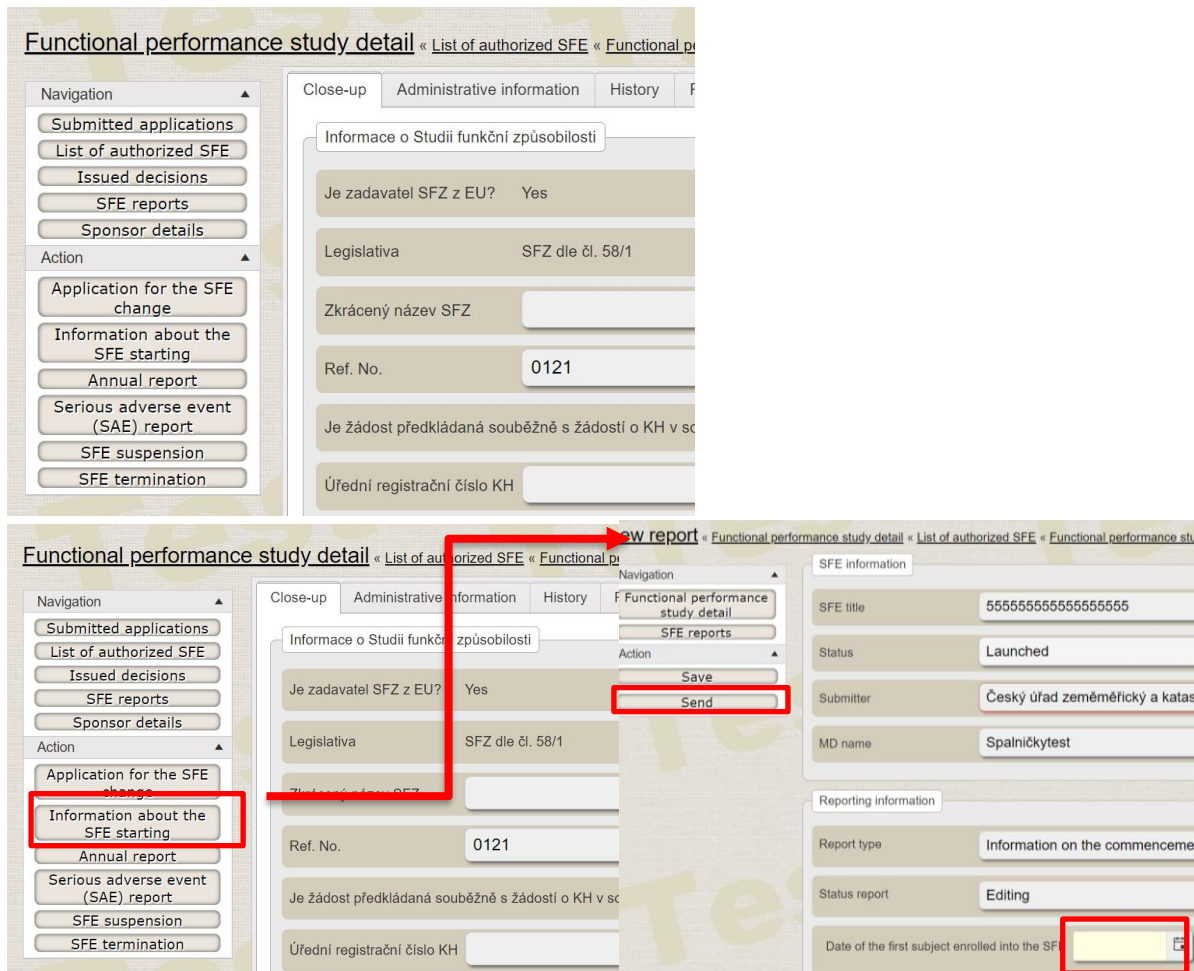
When you click the button for individual reports, it is then possible to go back by clicking on the “performance study detail”.

The following actions may be carried out under the detail of an authorised PERFORMANCE STUDY / SFE:

- **Application for the PERFORMANCE STUDY / SFE change** – may be submitted also before the start of the PERFORMANCE STUDY / SFE.
- **Information about the PERFORMANCE STUDY / SFE starting** – once the PERFORMANCE STUDY / SFE initiation report has been submitted, this option is no longer available, and editing the original report is no longer possible.
- **Annual report** – the button for its submission will be displayed only after the “Information about the PERFORMANCE STUDY / SFE starting” report is submitted.
- **Serious adverse event (SAE) report** – serves for SAE reporting; the list of SAEs reported via RZPRO is available from the “Serious adverse event” tab.
- **PERFORMANCE STUDY / SFE suspension** – the button for the notification of a PERFORMANCE STUDY / SFE suspension will be displayed only after the “Information about the PERFORMANCE STUDY / SFE starting” report is submitted.
- **PERFORMANCE STUDY / SFE termination** – when the report on performance study termination is submitted, the only options available is a SAE report submission and final report submission.
- **Final report** – the button for the submission of the final report will be displayed only when the PERFORMANCE STUDY / SFE termination report is submitted.

2.6.1. Performance study initiation

To report a PERFORMANCE STUDY / SFE initiation, click on “**Information about the SFE starting**” in the detail of the authorised PERFORMANCE STUDY / SFE. This will bring up a form where it is necessary to enter the date of performance study initiation and where attachments may be enclosed (optional). If you click on the “Send” button, the report will be displayed to the Institute. The PERFORMANCE STUDY / SFE initiation report may only be submitted once. A submitted report may no longer be edited.



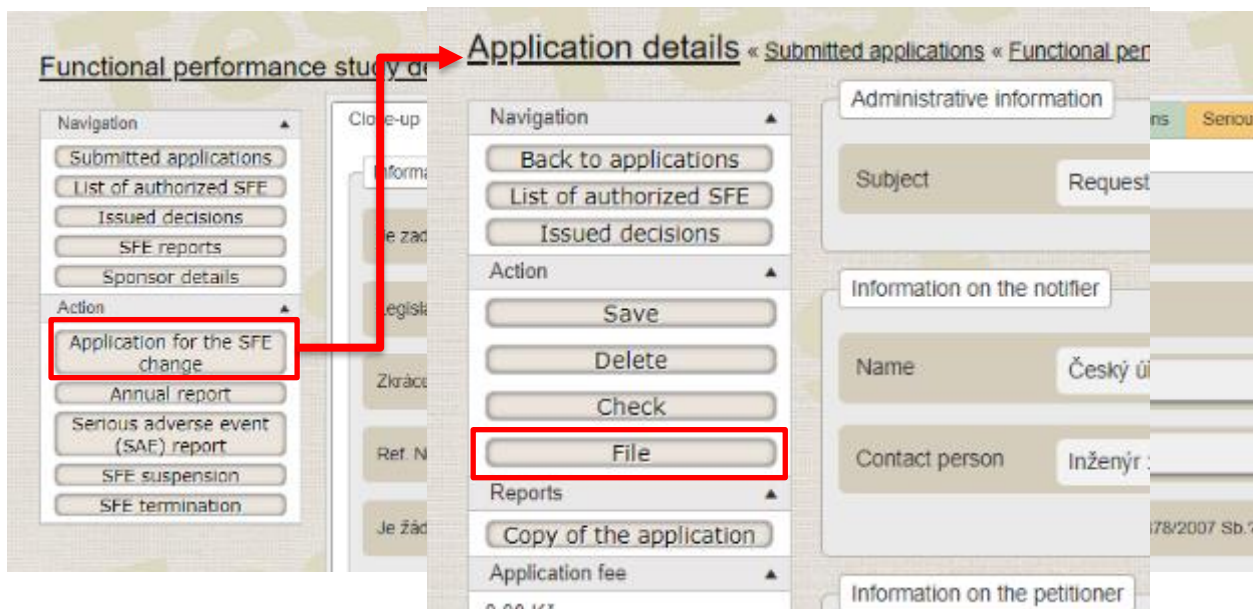
The screenshot displays the 'Functional performance study detail' page in the SÚKL system. The page is divided into two main sections: 'Administrative information' and 'SFE information'. The 'Administrative information' section includes fields for 'Je zadavatel SFZ z EU?' (Yes), 'Legislativa' (SFZ dle čl. 58/1), 'Zkrácený název SFZ', 'Ref. No.' (0121), and 'Úřední registrační číslo KH'. The 'SFE information' section includes fields for 'SFE title' (5555555555555555), 'Status' (Launched), 'Submitter' (Český úřad zeměměřický a katastr), 'MD name' (Spalníkytest), 'Report type' (Information on the commencement), 'Status report' (Editing), and 'Date of the first subject enrolled into the SF' (empty). The left navigation menu contains buttons for 'Submitted applications', 'List of authorized SFE', 'Issued decisions', 'SFE reports', 'Sponsor details', 'Application for the SFE change', 'Information about the SFE starting', 'Annual report', 'Serious adverse event (SAE) report', 'SFE suspension', and 'SFE termination'. The 'Action' menu contains buttons for 'Save' and 'Send'. Red boxes highlight the 'Information about the SFE starting' button in the left navigation menu, the 'Send' button in the 'Action' menu, and the 'Date of the first subject enrolled into the SF' field.

2.6.2. Application for the performance study (SFE) change

If the sponsor wishes to perform a change to an authorised performance study, they are obliged to report the change to the Institute in compliance with Article 71 of the IVDR and MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR.

In the performance study detail, click on the **“Application for the SFE change”** option. This will automatically generate and save a new application of the *“Application for the PERFORMANCE STUDY / SFE change”* type in the *“Editing”* status and fields from the latest effective PERFORMANCE STUDY / SFE authorised version will default in the application. The application must be edited as follows: complete the *“Justification”* field and enclose the necessary attachments (attachments *“Proposal of changes in PERFORMANCE STUDY / SFE documentation”* and *“Written approval of the ethics committee with changes of PERFORMANCE STUDY / SFE documentation”* are mandatory); thereafter, save the application (use the **“Save”** button). If the application is complete, it may be submitted to the Institute for approval of the change to the performance study (use the **“File”** button). After the submission, the status of the application will change to *“Submitted”* and the application may be displayed in the list of applications. The subsequent options available are the same as those described in chapter 2. 2. 2. **“Submission of a new performance study”**.

In case you have generated the application for a PERFORMANCE STUDY / SFE change by mistake, it may be removed by clicking on the **“Delete”** button, unless it has been submitted.



2.6.3. Different file numbers of applications for performance study (PERFORMANCE STUDY / SFE) authorisation of changes and applications for continuation

In case of submission of an application for the authorisation of changes to the PERFORMANCE STUDY / SFE and PERFORMANCE STUDY / SFE continuation, separate file numbers are generated. In case of submission of an application for PERFORMANCE STUDY / SFE authorisation or PERFORMANCE STUDY / SFE continuation, a new file number is generated in the procedures. In the sphere of performance studies, it is necessary to distinguish individual procedures from each other and for each, a separate file must be kept.

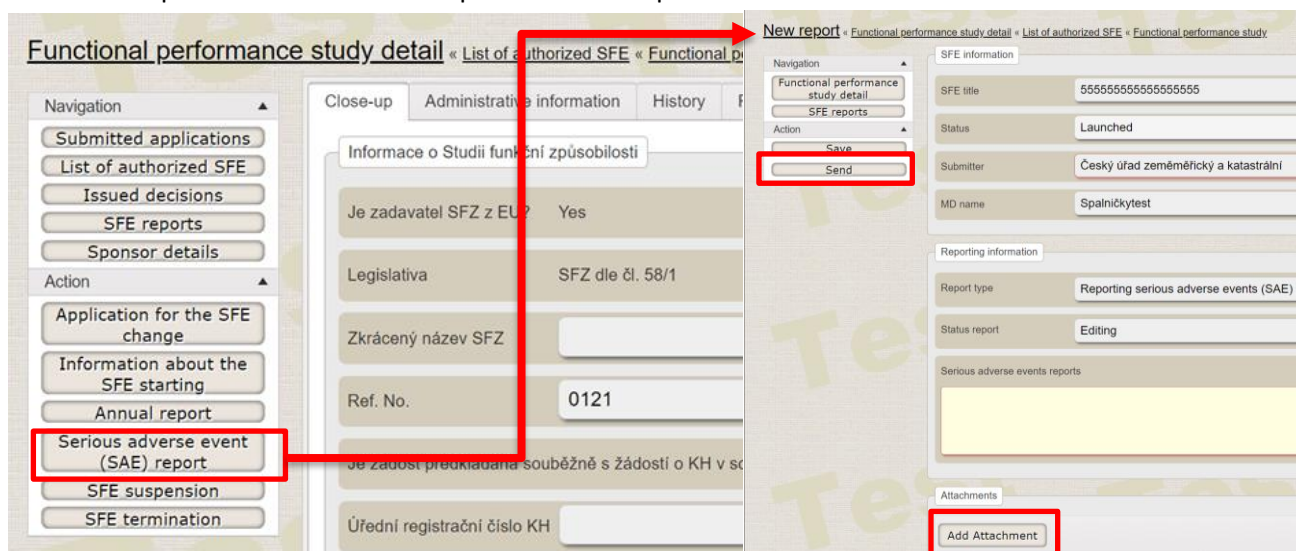
In the beginning, there is always the PERFORMANCE STUDY / SFE authorisation procedure, which is concluded by a decision. During the conduct of an authorised PERFORMANCE STUDY / SFE, however, a need to change it may arise. The Institute must be notified of any such change, and the change must be approved by the Institute.

Each change hence represents a new matter which is to be addressed by a separate file and under a unique file number. The initiation document that triggers the establishment of a new file is in this case the notification of the change to the performance study.

2.6.4. Serious adverse event (SAE) reporting

The sponsor is obliged to inform the Institute about arising SAEs immediately as they arise, in compliance with Article 76 of the IVDR.

To report an arising SAE or a modification thereof, click on the **“Serious adverse event (SAE) report”** button in the detail of the authorised PERFORMANCE STUDY / SFE. It is mandatory to provide a text description of the SAE and to upload the SAE report form as an attachment.



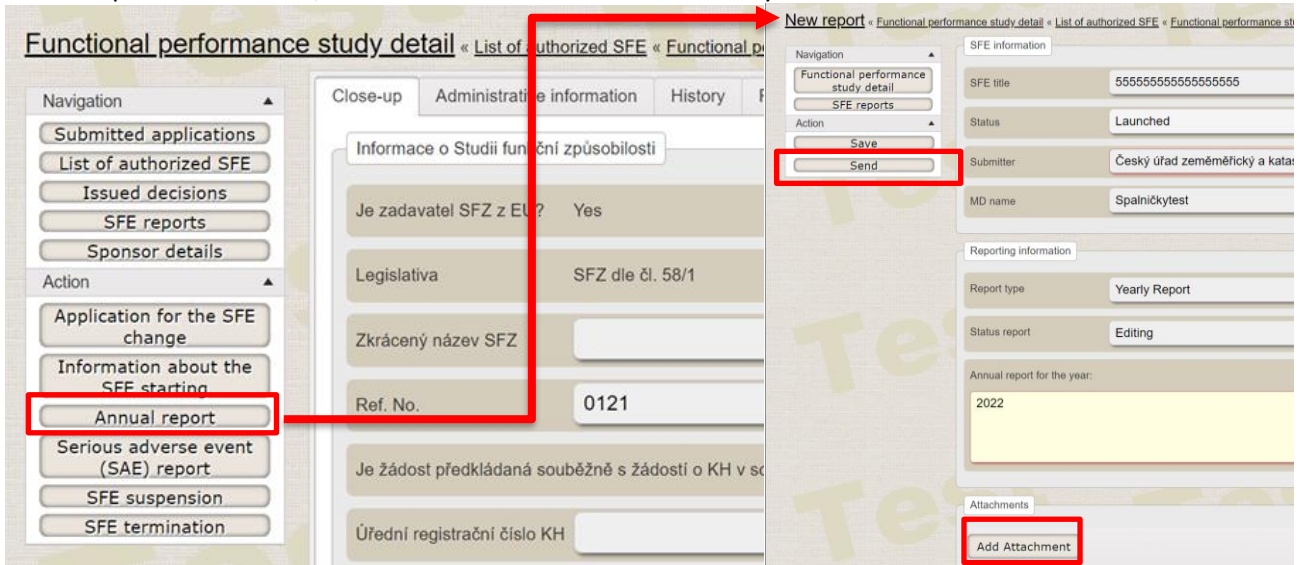
The screenshot displays the 'Functional performance study detail' page. In the left-hand navigation menu, the 'Serious adverse event (SAE) report' button is highlighted with a red box. A red arrow points from this button to the 'New report' form on the right. The form contains the following fields:

- SFE information:** SFE title (55555555555555555555), Status (Launched), Submitter (Český úřad zeměměřický a katastrální), MD name (Spalnicový test).
- Reporting information:** Report type (Reporting serious adverse events (SAE)), Status report (Editing).
- Attachments:** Add Attachment button (highlighted with a red box).

Other visible fields include 'Je zadavatel SFZ z EU?' (Yes), 'Legislativa' (SFZ dle čl. 58/1), 'Zkrácený název SFZ', 'Ref. No.' (0121), and 'Úřední registrační číslo KH'.

2.6.5. Annual report

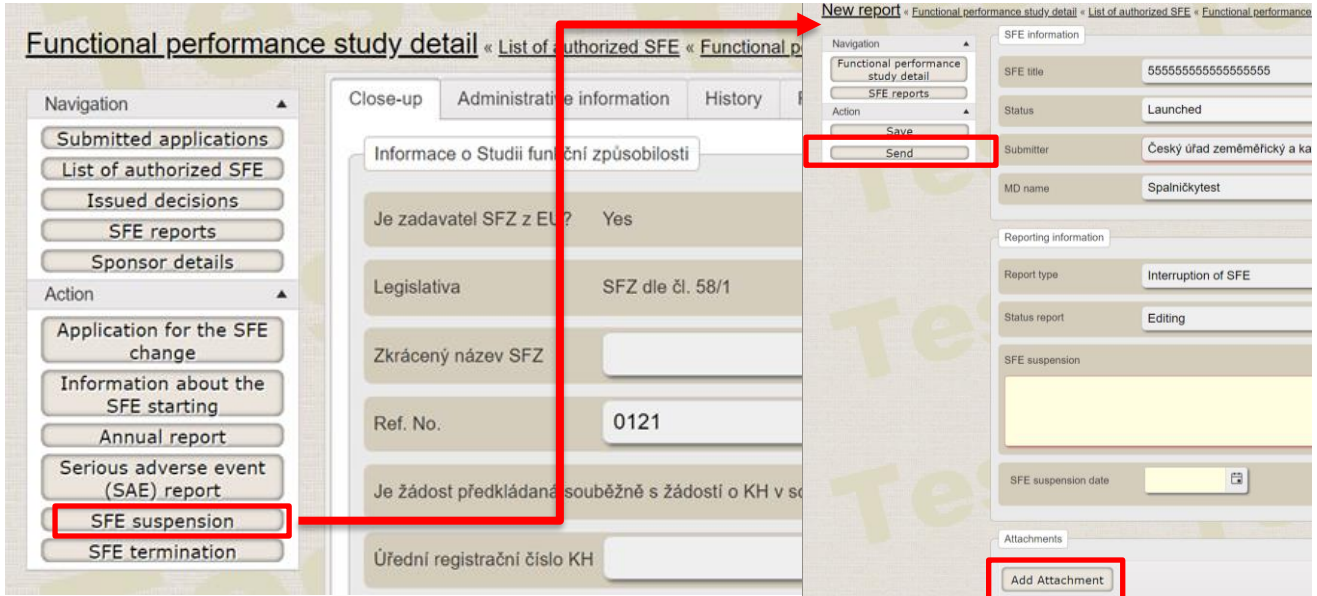
To submit the annual report, click on the “**Annual report**” button in the detail of the authorised PERFORMANCE STUDY / SFE. This button is not available until the PERFORMANCE STUDY / SFE initiation report is submitted; see section 2.6.1. “Performance study initiation”.



The screenshot displays the 'Functional performance study detail' page. On the left, a navigation menu includes buttons for 'Submitted applications', 'List of authorized SFE', 'Issued decisions', 'SFE reports', 'Sponsor details', and an 'Action' menu. The 'Action' menu contains buttons for 'Application for the SFE change', 'Information about the SFE starting', 'Annual report', 'Serious adverse event (SAE) report', 'SFE suspension', and 'SFE termination'. The 'Annual report' button is highlighted with a red box. A red arrow points from this button to the 'Send' button in the 'Action' menu of the main form area. The main form area has tabs for 'Close-up', 'Administrative information', and 'History'. It contains fields for 'Informace o Studii funkční způsobilosti', 'Je zadavatel SFZ z EU?', 'Legislativa', 'Zkrácený název SFZ', 'Ref. No.', and 'Úřední registrační číslo KH'. The 'Ref. No.' field contains the value '0121'. On the right side, there is a 'New report' section with a 'Send' button highlighted in a red box. Below it, there are sections for 'SFE information', 'Reporting information', and 'Attachments'. The 'Reporting information' section shows 'Report type' as 'Yearly Report' and 'Annual report for the year' as '2022'. The 'Attachments' section has an 'Add Attachment' button highlighted in a red box.

2.6.6. Performance study suspension

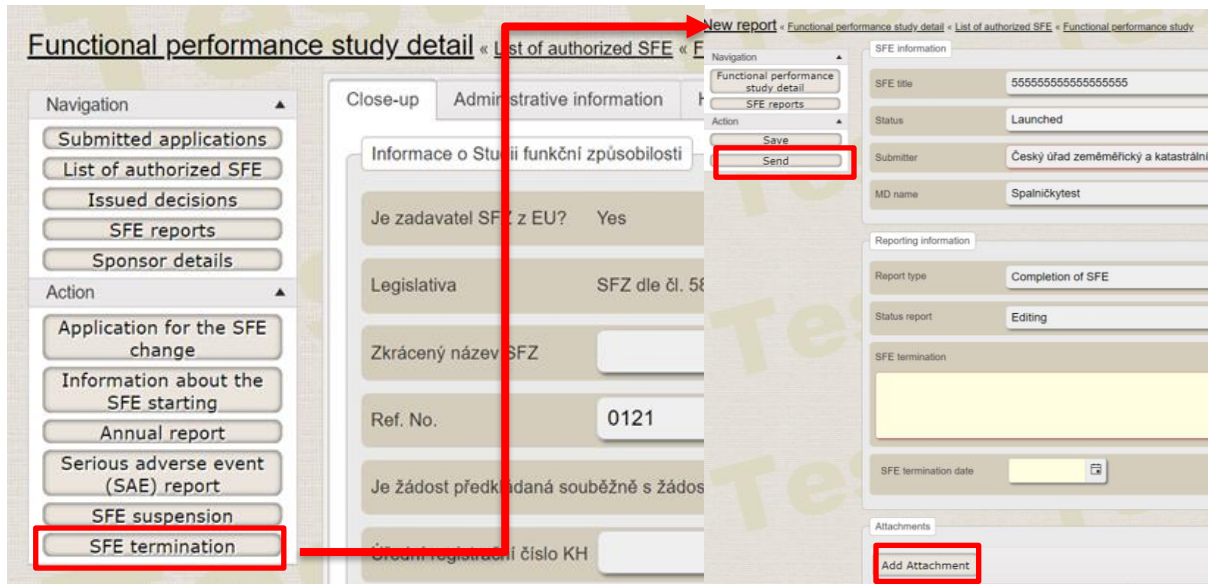
To report a performance study suspension, click on the “**SFE suspension**” button. To resume a suspended PERFORMANCE STUDY / SFE, please proceed as explained under section 2.7. 1 “Continuation of a performance study suspended by the Institute or sponsor”.



The screenshot displays the 'Functional performance study detail' page. On the left, a navigation menu contains several buttons, with 'SFE suspension' highlighted in a red box. In the top right corner, a 'Send' button is also highlighted in a red box. A red arrow points from the 'SFE suspension' button to the 'Send' button. The main content area shows various fields for the study, including 'Je zadavatel SFZ z EU?' (Yes), 'Legislativa' (SFZ dle čl. 58/1), 'Zkrácený název SFZ', 'Ref. No.' (0121), and 'Úřední registrační číslo KH'. On the right side, there is a form for 'SFE Information' with fields for 'SFE title', 'Status' (Launched), 'Submitter', and 'MD name'. Below this, there is a 'Reporting information' section with 'Report type' (Interruption of SFE) and 'Status report' (Editing). At the bottom right, there is an 'Attachments' section with an 'Add Attachment' button highlighted in a red box.

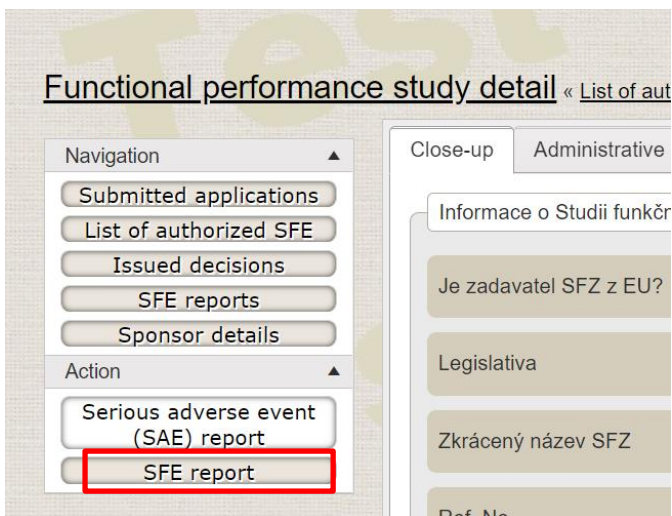
2.6.7. Performance study termination

To report the termination of a performance study, click on the “SFE termination” button.



2.6.8. Performance study final report

To submit the final report, click on the “SFE report” button.



2.6.9. List of all reports

If you wish to display the list of reports for individual PERFORMANCE STUDIES / SFEs, click on the “**SFE reports**” button. The list is designed to display a listing of individual reports from all authorised functional performance studies.

You can search the list using filters and sort the list in ascending/descending order by individual columns. The report detail may be opened by clicking on the row of the required report.

Functional performance study detail « List of authorized SFE « Functional performance study.

Navigation

- Submitted applications
- List of authorized SFE
- Issued decisions
- SFE reports**
- Sponsor details

Action

- Application for the SFE change
- Annual report
- Serious adverse event (SAE) report
- SFE suspension
- SFE termination

Close-up Administrative information History Reports Decision Applications Persons Serious adv

Informace o Studii funkční způsobilosti

Je zadavatel SFZ z EU? Yes

Legislativa SFZ dle čl. 58/1

Zkrácený název SFZ

Ref. No. 0121

Je žádost předkládaná souběžně s žádostí o KH v souladu se směrnicí 2001/20/ES a zákonem č. 378/2007 Sb.? No

SFE reports « Functional performance study.

List of reports

Status Type Plenipotentiary agency

Search

Report type	Filing date	Status	Submitter	File numebr
Information on t...	30. 12. 2022	Sent	Český úřad zem...	sukls7827/2022
Interruption of SFE	23. 05. 2022	Processed	Český úřad zem...	sukls792/2022
Completion of SFE	23. 05. 2022	Sent	Český úřad zem...	sukls737/2022
Information on t...	13. 05. 2022	Sent	Český úřad zem...	sukls862/2022
Information on t...	10. 05. 2022	Processed	Český úřad zem...	sukls873/2022
Interruption of SFE	10. 05. 2022	Processed	Český úřad zem...	sukls869/2022
Reporting seriou	04. 05. 2022	Sent	Český úřad zem...	sukls792/2022

2.7. Suspension of an Authorised Performance Study by the Institute

The Institute may temporarily suspend a performance study previously authorised thereby. You will be informed about the suspension of an ongoing performance study using the delivery of a resolution issued by the Institute.

2.7.1. Continuation of a performance study suspended by the Institute or sponsor

In case of a suspended investigation, it is possible to apply for PERFORMANCE STUDY / SFE continuation when the reasons for the suspension no longer exist, requesting a resolution authorising the continuation of the PERFORMANCE STUDY / SFE from the Institute. If it is necessary to update the documentation, it is also necessary to apply for a change to the PERFORMANCE STUDY / SFE (section 2.6.2. refers). It is necessary to **first submit the application for continuation and only then the application for change to the PERFORMANCE STUDY / SFE.**

2.8. Discontinuation of an authorised Performance Study by the Institute (ex officio)

The Institute may stop an ongoing performance study the conduct of which it has authorised.

The decision on the discontinuation of the performance study by the Institute will be displayed on the dashboard, which is provided on the PERFORMANCE STUDY / SFE module homepage, or it will be available from the “**Issued decisions**” list on the homepage or in the detail of the concerned PERFORMANCE STUDY / SFE.

It is possible to file an appeal from the Institute’s decision on the discontinuation of an authorised performance study via the RZPRO (section 2. 4. 2. “Appeal from the Institute’s decision” refers).

Once the decision on the discontinuation of the performance study becomes final, the decision is permanent, and it is no longer possible to submit an application for PERFORMANCE STUDY / SFE continuation.

Should you encounter any **unclearities regarding the procedures to be followed in the Performance Study Module**, please contact SÚKL at:
email: SZP_RZPRO_dotazy@sukl.cz
tel. +420 272 185 933

Should you encounter **technical problems** when filing your application, please contact ÚZIS:
Tel.: +420 222 269 999 – general UZIS helpline
helpdesk.registry@uzis.cz

Generals questions should be addressed to SÚKL at: +420 272 185 333