|  |  |
| --- | --- |
| **Method and requirements for submission of an application for authorisation of a performance study (hereinafter referred to as "PS") or for notification of the PS, via the RZPRO Registry** | The application or notification shall be submitted via the RZPRO Registry of SÚKL (hereinafter referred to as “RZPRO”), see [Manuals | NISZP](https://www.niszp.cz/index.php/en/registration-and-notification-registry-medical-devices/manuals)  Please note that before submitting an application/notification, the sponsor must be verified and have access to the RZPRO. If the applicant is a legal representative of the sponsor (which is usually a CRO), the application/notification shall be submitted via the RZPRO from this applicant's account, see [How to register and submit application for clinical investigation\_0.pdf (niszp.cz)](https://www.niszp.cz/sites/default/files/dokumenty/How%20to%20register%20and%20submit%20application%20for%20clinical%20investigation_0.pdf)  Practical remark: after logging in to the RZPRO, the PS module (the icon in the form of a card file) and the type of performance study is to be selected. Please do not confuse the PS icon (highlighted in blue below) with the icon for clinical evaluation of medical devices.  Obsah obrázku text, snímek obrazovky, Písmo, číslo  Popis byl vytvořen automaticky  All documents should be submitted in PDF format to enable text search. |
| **A list of documents for an application for authorisation /notification of the PS** | **Remarks** |
| Cover Letter by the applicant | It is strongly recommended that the applicant set up a data box, for more information see: [Data Mailbox Set-up for Foreign](https://www.sukl.eu/medicines/data-mailbox-set-up-for-foreign-entities) [Entities, State Institute for Drug Control (sukl.eu)](https://www.sukl.eu/medicines/data-mailbox-set-up-for-foreign-entities). Please note that if the applicant fails to do so, they will be communicated via postal services, which creates significant barriers in communication and extends the application processing time.  In the cover letter, provide the applicant's contact information in as much detail as possible. |

|  |  |
| --- | --- |
| Power of attorney for the legal representative of the sponsor, including power of attorney for the acting employee (multiple files can be added) - principal/legal representative/date | Without the correct power of attorney duly documented in accordance with the provisions of the Administrative Code of the Czech Republic, the proceedings will not be initiated. Please pay attention to the information on requirements for powers of attorney. We remind you that, in the case of companion diagnostics, the power of attorney must also cover conducting the PS. We highly recommend that you follow the general instructions for drawing up powers of attorney [here](http://www.niszp.cz/index.php/cs/otazky-odpovedi-tykajici-se-klinickych-zkousek/shrnuti-zakladnich-informaci-k-podavani-klinickych#faq-PLN%C3%81-MOC---obecn%C3%A9-informace).  Important! It must be clear from the wording of the power of attorney that the subject of the power of attorney is conducting the PS pursuant to the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5, 2017 on in vitro diagnostic medical devices and on the repeal of Council Directive 98/ 79/EC and Commission Decision 2010/227/EU (hereinafter also referred to as "IVDR"). |
| How to fill out the form in the RZPRO | The form contains mandatory data and annexes. In the form, among other things, it is necessary to fill in the details of the PS sponsor (there is always only one sponsor who bears full responsibility for all companies they share responsibility with).  In the case of sponsors not established in the Union, a natural person or legal entity representing the sponsor and established in the Union must be appointed, and this fact duly documented. The sponsor must be verified and have access to the RZPRO. Without that, the application cannot be submitted. |
| Clinical Performance Study (CPSP) - indicate the number/version/ date (mandatory) | Performance evaluation plans (hereinafter referred to as “CPSP) shall be prepared in accordance with the requirements laid down in Annex XIII of the IVDR, setting the minimum content requirements for the document and determining its structure. It must contain numbered pages including annexes, detailed table of contents with marked page numbers and must be subject to the standard requirements for controlled documents.  Some annexes of the plan can exceptionally be submitted as a separate file, but in no case is it possible to submit a CPSP as a folder of several loosely related documents.  SÚKL points out that in the case of companion diagnostics, the plan of clinical trials in human medicines cannot replace the CPSP, even though it may contain some of the data required in Annex XIII of the IVDR. The structure of the plan of clinical trials in human medicinal products does not correspond to the requirements of Annex XIII of the IVDR, is prepared based on different requirements and for another purpose than CPSP. Therefore, the CPSP must have a different identification number than that of the plan of the clinical trial in the respective medicinal product (as referred to in Article 66(1)).  Note: it is necessary to submit a version of the CPSP that has been approved by the ethics committee.  The sponsor listed in the document must be identical to the sponsor in the application/notification and must also match the information in the submitted powers of attorney. |
| Overall synopsis of the CPSP  in Czech | Czech version of the overall synopsis of the CPSP can be part of the study plan and, if available, should also be provided (for the purpose of submission to the ethics committee). |
| Investigator´s Brochure (multiple files can be added) - number/version/date | The structure of the Investigator's Brochure (IB) must comply with the requirements laid down in Annex XIV of the IVDR. IB pages shall be numbered, including annexes, the document must contain detailed table of contents with marked page numbers and be subject to the standard requirements for controlled documents. Some annexes to the IB can be provided, in exceptional cases, as a separate file, but in no case is it possible to submit the IB as a set of loosely related documents.  Practical remark: with regard to point 2.2 of chapter 1 of Annex XIV IVDR *"Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available,* ***information to be placed on the product label*** *and instructions for use to be provided with the device when placed on the market, to the extent that this information is available. In addition, information relating to any relevant training required.",* SÚKL also recommends that the documentation containing product label samples or an overview of the information to be placed on the product label, incl. pictograms, is also submitted. It is required to provide a version of the IB approved by the ethics committee.  The sponsor listed in the document must be identical to the sponsor in the application/notification and must match the information in the submitted powers of attorney. |
| Proof of insurance cover or indemnification of subjects for the entire duration of the PS for compensation in case of damage, injury or death - name of the insurance company/insurance period | An insurance contract or a guarantee can be accepted; such documents must contain at least an accurate identification of the CPSP (ideally, also with the title of the performance study) and information that the PS insurance meets the requirements of the IVDR and other relevant legislation. |
| Informed consent (multiple files can be added) - version/date | Where the individual informed consents differ (e.g. in relation to individual centres) or are separated (e.g. for the PS and GDPR), all current versions approved by the ethics committee must be attached.  Practical remark: it is recommended to provide separate informed consents for the clinical evaluation in medicinal products and for the PS to facilitate necessary changes to the wording. Ethics committees for medicinal products and for medical devices follow different rules and may differ (and certainly will differ in the future). The sponsor listed in the document must be identical to the sponsor in the application/notification and must match the information in the submitted powers of attorney. |
| Statement on whether the product contains substances of human or animal origin, including human blood derivatives or plasma, or on whether the product is manufactured using tissues or cells of human or animal origin or their derivatives (multiple files can be added) | Such a statement is useful and welcome. Within the IB, at a minimum, data on the presence of given substances should be provided.  In the statement box, insert the document indicating the respective page number where the information can be found in the IB or the information that the IVD does not contain any of the given substances. It is possible to use one statement for all given substances and insert it into individual boxes. |
| Declarationt that the respective medical device complies with the general safety and performance requirements laid down in IVDR Annex XIV point 4.1. | Mandatory statement, pursuant to IVDR Annex XIV point 4.1. |
| Instructions for use/application /manual of the tested device (multiple files can be added) - number/version/date | Mandatory attachment, in case the manual (containing all essentials) is not included in the IB.  English version is acceptable. |
| Administrative fee payment | It refers to submissions following the entry into force of Act No. 375/2022 Coll., on medical devices and in vitro diagnostic medical devices (as of 22 December 2022).  Payment requests are generated via the RZPRO.  When paying, you must always enter the variable symbol. Problems can arise with payments from abroad. In that case, follow the instructions below, see:  <https://www.niszp.cz/sites/default/files/dokumenty/Variable>  [\_Symbol\_Payment\_from\_abroad%20(002).pdf](https://www.niszp.cz/sites/default/files/dokumenty/Variable) |
| Application assessment fee payment | It refers to submissions following the entry into force of Act No. 375/2022 Coll., on medical devices and in vitro diagnostic medical devices (as of 22 December 2022). The payment requests must be generated via the form on the SÚKL website, see below:  <https://www.sukl.cz/modules/payment2/index.php?id_oblast> [i=21&token=.php](https://www.sukl.cz/modules/payment2/index.php?id_oblasti=21&amp;token)  When paying, it is always necessary to enter a variable symbol into the system. Problems may arise with payments from abroad. In that case, follow the instructions below, see:  <https://www.niszp.cz/sites/default/files/dokumenty/Variable>  [\_Symbol\_Payment\_from\_abroad%20(002).pdf](https://www.niszp.cz/sites/default/files/dokumenty/Variable).  Applicants are required to provide SÚKL with a confirmation of the payment made. This will speed up the processing of the application. |
| Evidence by the sponsor that the investigator meets the requirements laid down in point 1.13 in Chapter I of Annex XIV of the IVDR | Practical remark: referring to the requirements laid down in point 1.13 Chapter 1 of Annex XIV of the IVDR *"evidence from the sponsor that the clinical investigator and the* ***investigational site*** *are capable of conducting the clinical performance study in accordance with the performance study plan"*, not only a CV and GCP confirmation by the investigator are required, but also confirmation that the samples are processed by a certified laboratory is mandatory. |
| Ethics Committee Opinion (multiple files can be added) | Following the entry into force of Act No. 375/2022 Coll., on medical devices and in vitro diagnostic medical devices (as of 22 December 2022), the opinion of the ethics committee must be issued as stipulated by this law. The opinion shall contain a list of approved documentation corresponding to the current versions submitted to SÚKL. The ethics committee is established by the health care provider and issues opinions in accordance with the provisions stipulated by the legal act. Each provider either has their own ethics committee or can use the ethics committee of another health care provider. In such a case, the respective health care provider must sign a supervision agreement with the latter (the ethics committee established by another provider).  Note: Ethics committees for human medicines and for medical devices and IVD are governed by different rules and laws and may not (and certainly will not be in the future) be the same. |
| Additional attachments | Not mandatory |