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| **Submission of notification****of the performance study (hereinafter referred to as "PS") pursuant to Article 58, paragraph 2, second and third sentences 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 referred to as****"IVDR")** | Notifications can be submitted either via SÚKL data box or via postal services to the SÚKL filing office, always also in electronic format (e.g. on CD or DVD in the case of submission via postal services).All documents should be submitted in PDF format to be text searchable. |
| **List of documents for the simplified submission of notification of PS pursuant to Article 58, paragraph 2, sentence two of the IVDR** | **Remarks** |
| Cover letter by the applicant | SÚKL strongly recommends applicants to set up a data box, for more information see: [Data Mailbox Set-up for Foreign Entities, State Institute for Drug Control (sukl.eu)](file:///C%3A%5CUsers%5Ckostalovad%5CDesktop%5CJob%5CZP_SYS%5CP%C5%99eklady%5CDoprovodn%C3%A9%20dokumenty%20pro%20p%C5%99eklad%20k%20SFZ%20do%20EN%5CWord%5CData%20Mailbox%20Set-up%20for%20Foreign%20Entities%2C%20%20%20%20State%20%20%20%20Institute%20%20%20%20for%20%20%20%20Drug%20%20%20%20%20Control%20%20%20%20%20%28sukl.eu%29). 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. The cover letter should include as much detailed contact information as possible and a summary of the content of the application. See also the point “Filled-in form”. The document is to be submitted in PDF format to enable text search.  |
|  Power of attorney for the legal representative of the sponsor, including the power of attorney for the acting employee (multiple files can be added) - principal/authorized 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 PS.Important! It must be evident 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 IVDR. |
| ”Filled-in form” | The form (if not yet available, the following information must be clearly stated in the Cover Letter) must contain:* The name, address and contact details of the sponsor. There is always one sponsor bearing full responsibility for all the companies they share responsibility with.
* In the case of sponsors not established in the Union, their legal representative established in the Union must be appointed and duly documented in the form, including the name, address and contact details.
* The name, address and contact details of the manufacturer of the companion diagnostic to be subjected to a performance evaluation (similarly as in the case of sponsors, there is always one manufacturer only).
* In addition, it is necessary to indicate the ultimate legal representative of the sponsor who will submit the notification on the basis of a power of attorney, including the name, address and contact details.
* Accurate identification and description of a companion diagnostic, including its type and version. If analytical software is part of the IVD, its version shall also be documented.
* The name of the PS, its single identification number and the dated version of its plan.
* In particular, it is necessary to unequivocally and thoroughly document the fact that only left-over samples will be used within this specific PS (including, for example, a citation from the respective human medicine clinical trial plan). The origin of the samples must be described in detail, with clear justification by the sponsor as to why the samples can be classified as left-over.
* At the same time, information on the use of data from left-over sample banks describing the reliability and representativeness of the respective samples, incl. a specification of the statistical analysis method, or the provision of the relevant method for determining the actual clinical status of samples from patients, respectively, must be documented.
* The study centers must also be listed (including detailed contact addresses).
* Identification of the clinical trial in human medicines in which the companion diagnostic will be used must be documented, including ID number of its plan, its version and synopsis. The assessment status of the clinical trial at the time of submission of the PS notification in which the companion diagnostics are to be used must be indicated and duly documented.
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| Clinical Performance Study Plan (CPSP) must indicate the number/version/date of drafting the document  | Clinical Performance Study Plans (hereinafter referred to as CPSP) shall be prepared in accordance with the requirements laid down in Appendix XIII of the IVDR setting the minimum content requirements for the document and determining its structure. It must contain numbered pages including annexes, a detailed table of contents with marked page numbers and must meet the standard requirements for controlled documents. Some annexes to CPSPs can exceptionally be submitted as a separate file, but in no case can the CPSP be submitted as a folder of several loosely related documents. SÚKL points out that in the case of companion diagnostics, the protocol of clinical trials in human medicines will not be accepted instead of the CPSP, even though it may contain some data required in Annex XIII of the IVDR. The structure of the CT Plan does not correspond to the requirements of Annex XIII of the IVDR, is prepared based on different requirements and for another purpose than the CPSP. Therefore, the CPSP shall have a different PS identification number than that of the clinical trial in the respective human medicines (as referred to in Article 66(1)) The sponsor listed in the document must be identical to the sponsor in the application/notification and must also match the information in the powers of attorney submitted. |
| Overall synopsis of the CPSP in Czech | The 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). |
| Instructions for use/application /manual of the tested device (multiple files can be added) - number/version/date  | Mandatory attachment. English version is acceptable.  |
| Payment for application assessment  | Free of charge. |