**Information for sponsors and applicants/payers of administrative fees for clinical trial applications under Regulation No. 536/2014 submitted via CTIS**

The State Institute for Drug Control (SIDC) informs sponsors and applicants of clinical trials that after joining the system of central fee registration, the method of payment of administrative fees for administrative proceedings and actions of the SIDC will be available from 1 September 2024 through the **eKolok** payment system, which is operated by **Slovenská pošta a.s.**

Administrative fees for clinical trials applications under Regulation No. 536/2014 paid via the previous payment method of the administrative fees, which will be transferred to account No. SK34 8180 0000 0070 0013 3673 **as of 1.9.2024, will be automatically returned to the payer**.

The eKolok system has been designed with modern technology and user needs in mind to make payments simpler, faster, and more secure. It offers various payment methods and an intuitive interface. The system allows payments of administrative fees as defined in Act No. 145/1995 Coll. on administrative fees.

More information about the service, as well as a detailed description of the recommended payment options, can be found [HERE](https://www.posta.sk/sluzby/platobny-system-ekolok).

For sponsors and applicants of clinical trials, we would like to draw your attention in particular to the method of payment of the administrative fees based on the issued payment order (in addition to the legal options). This payment order is issued by the SIDC only after the application has been received.

Based on the information provided in the application, SIDC will determine the exact amount of the administrative fee. The administrative fees for procedures related to clinical trials of medicinal products, where Regulation No. 536/2014 applies, are defined in **Act No. 145/1995 Coll.** on administrative fees, **item 152, letter ad**. The amount of the administrative fees for clinical trial procedures is determined for the joint assessment by the SIDC and the Ethics Committee for Clinical Trials, so for each procedure, there **is only one administrative fee for the assessment by both organizations**. The administrative fees for clinical trial applications are also listed in the table, which can be found [HERE](https://www.sukl.sk/buxus/docs/SUKL_zoznam_poplatkov_-_SIDC_List_of_Fees.xlsx).

Further, the submission of a clinical trial application via CTIS is considered a fully electronic submission (not a paper submission). On this basis, it is possible to claim a fee reduction, which is determined by **paragraph 2 of Article 6 of Act No 145/1995 Coll. on administrative fees**.

Once the application is received and validated, a notification of the creation of a payment order is entered into the CTIS system within the RFI, requesting the applicant toupload the payment order and the proof of payment.

The notification will be as follows:

„We are sending you a  Payment Order - e-kolok (in the attachment of e-mail) for EU CT (initial, SM) XXXX-XXXXXX-XX-XX from e-mail [trial-sukl@sukl.sk](mailto:trial-sukl@sukl.sk) (xxxx eur). In the RFI response please upload the Proof of Payment and the Payment Order e-kolok (in the attachment of e-mail) to CTIS field.

From e-mail [trial-sukl@sukl.sk](mailto:trial-sukl@sukl.sk) was sent a  Payment Order - e-kolok to email xxxxxxxxx.„

Subsequently, the issued payment order is sent to the sponsor/applicant of the clinical trial via email.

**Sponsors and applicants of clinical trials are requested to include in the cover letter the email address to which the payment order should be sent. If such an address is not provided in the cover letter, the payment order will be sent to the email address provided in the CTIS.**

The payment order will contain the Procedure No. (EU CT number) and the application ID (a numerical code consisting of one or two numbers). The first number in the case of an initial submission will be 1. The first number for a substantial amendment will be 2. The second number in the case of a substantial amendment will be the serial number of the amendment, e.g., in the case of SM-1, it will be No. 1).

**The expiration date of the payment order is 30 days.**

The payment order can be paid by bank transfer with the given payment details or by scanning the QR code according to the PAY by square standard. You can also scan the QR code and pay for the payment order via a kiosk or the eKolok mobile application. The eKolok web application can also be used to make payments. When paying the payment order by bank transfer, care must be taken to ensure that the IBAN and variable symbol are filled in correctly.

Clinical trial sponsors and applicants have the option to purchase an eKolok to accompany their clinical trial application to CTIS. eKolok can be purchased via the eKolok mobile app (Android or iOS) or via the eKolok web application. An eKolok purchased through this method can be used within 30 days from the date of purchase.

For further information, please refer to the document [Guidline for Applicants/Payers in regard of Fee Collection using the „eKolok“ system](https://www.sukl.sk/buxus/docs/MP_149-2024_METODICKY_POKYN_PRE_ZIADATELOV_POPLATNIKOV_SPRAVNYCH_POPLATKOV_V_NADVAZNOSTI_NA_ZAPOJENIE_SUKL_DO_CENTRALNEHO__SYSTEMU_VYBERU__EVIDENCIE__A_ZUCTOVANIA_POPLATKOV__TZV._SYSTEMU_eKOLOK.pdf).