Form for submitting clinical trial documents to the State Institute for Drug Control

The Clinical Trials Department of the State Institute for Drug Control (SIDC) informs about the form for submission of certain clinical trial documents:

- **Delivery address:**

Štátny ústav pre kontrolu liečiv (State Institute for Drug Control)
Oddelenie klinického skúšania liekov (Clinical Trials Department)
Kvetná 11
825 08 Bratislava 26

We kindly ask not to state the name of the SIDC employee in the delivery address.

- **Proof of delivery to SIDC:**
  - In case of personal delivery, please confirm the receipt directly in the filing office.
  - In case of courier delivery, request an acknowledgment of receipt from the courier.
  - In case of delivery by post, use letter with a proof of delivery, addressed to SIDC, not to a particular person.
  - In case of delivery to the e-mail address – trial-sukl@sukl.sk, select "**Request a delivery receipt**" and "**Request a read receipt**". (Always include the clinical trial identification number Eudra CT).

Any documentation which is delivered to SIDC goes through its central registry. Employees of the clinical trials department do not issue certificates proving documents delivery.

- **Form for submitting documents**
  - Amendments to protocol and the like, and updates on informed consent always require a version with highlighted changes as well as a clean version;
  - Electronic documents such as (IB, IMPD, CT protocol etc.) shall be sent in pdf file, which allows searching the document for information; scanned pdf document is not acceptable;
  - All documents shall be sent in electronic form on a CD and in printed form as shown in the table below.
  - In case of an approved clinical trial, send the cover letter in printed form and all the other documents in accordance with the instructions in the table below.

Table no. 1

	Document	Form for submitting the document	Link to a relevant regulation, guideline or recommendation of EU
1.	**Initial** CTA (pdf + XML file on a CD)	With the original signature from the authorized person Printed Electronic	https://eudract.ema.europa.eu/ (must include a validation letter)
2.	CTA **update** (pdf + XML file on a CD)	With the original signature from the authorized person Printed – only the signature page Electronic	https://eudract.ema.europa.eu/
3.	Cover letter with a list of submitted documents in Slovak	With the original signature from the authorized person Printed	Detailed guidance (CT-1)* Section 2.3
4.	Confirmation (e-mail) about receiving the EudraCT number	Printed Electronic	Detailed guidance (CT-1)* section 2.2
5.	Proof of payment of the administrative fee (from the bank)	Printed Electronic	Detailed guidance (CT-1)* section 2.9
6.	Written power of attorney entitling the authorized representative to act on the behalf of the sponsor, indicating scope of the power, for instance in case the applicant is not the sponsor	With the original signature from the authorized person (constituent) Printed	Act No. 362/2011 Coll., § 29 section 10
7.	Protocol, amendments and changes to the protocol	Printed Electronic (with updates only electronic)	http://ec.europa.eu/health/files/eudralex/vol-10/substantial_amendment_notification_form_.pdf
8.	IB with all the current amendments	Electronic	http://ec.europa.eu/health/files/eudralex/vol-10/substantial_amendment_notification_form_.pdf
9.	IMPD with all the current amendments	Electronic	http://ec.europa.eu/health/files/eudralex/vol-10/substantial_amendment_notification_form_.pdf
10	Reference Safety Information	Electronic	http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2013_CTFG_Ref_Safety_Info.pdf
11	Information for participant /Informed consent document + updates with amendments in Slovak	Printed Electronic (with updates only electronic)	Act No. 362/2011 Coll. § 29 section 14, § 31, 32
12	License to operate the healthcare facility where the clinical trial workplace is situated	Officially certified copy, printed form	Act No. 362/2011 Coll. § 34 section 2
13	Written consent of the ministry of environment for cases with genetically modified microorganisms	Electronic	Act No. 362/2011 Coll. § 34 section 2; Act No. 355/2007 Coll. § 45 section 2 m)
14	Written consent of the Public Health Authority for cases with exposure of participants	Electronic	Act No. 355/2007 Coll. § 45 section 2 m)
15	Ethics Committee decision of the clinical trial, in case it was issued	Electronic	Act No. 362/2011 Coll. § 34 section 2
16	Sponsor's response to reasoned objections raised by SIDC	Printed with the original signature from the authorized person Printed	Act No. 362/2011 Coll. § 35 section 7
17	Cover letter to a change to the clinical trial application form	Printed with the original signature from the authorized person Printed	Act No. 362/2011 Coll. § 35 section 7
18	Change to the clinical trial	Printed with the original	https://ec.europa.eu/health/sites/health/files/files/e

	Document	Form for submitting the document	Link to a relevant regulation, guideline or recommendation of EU
	application form Annex II.	signature from the authorized person Electronic	udralex/vol-10/2010_c82_01/2010_c82_01_en.pdf
19	DSUR presents a report on the safety of participants	Electronic	ICH guideline E2F on development safety update report Act No. 362/2011 Coll. § 43 section 2 n) article 8
20	Information about suspension of the clinical trial and reasons for the suspension	Printed or Electronic	Act No. 362/2011 Coll. § 43 section 2 n) article 3
21	Any new event relating to the conduct of the trial or the development of the investigational medicinal product for human use, and the measures taken to protect the participants against any immediate hazard.	Immediately by phone or e-mail, then adding the documentation in a printed or electronic + submission letter with the original signature of the authorized person	Act No. 362/2011 Coll. § 43 section 2 n) article 4
22	Information about the termination of the clinical trial in the Slovak Republic	Printed with the original signature from the authorized person	Act No. 362/2011 Coll. § 43 section 2 n) article 7
23	Global termination of the clinical trial (submitting the End of Trial Notification Form)	Printed with the original signature from the authorized person	End of Trial Notification Form

Abbreviations:
CTA – Clinical Trial Application (Annex 1)
IB – Investigator`s Brochure
IMPD – Investigational Medicinal Product Dossier
DSUR – Development Safety Update Report

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