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SÚKL

F-I-H, Sponsor, Investigator, Clinical Trial Site

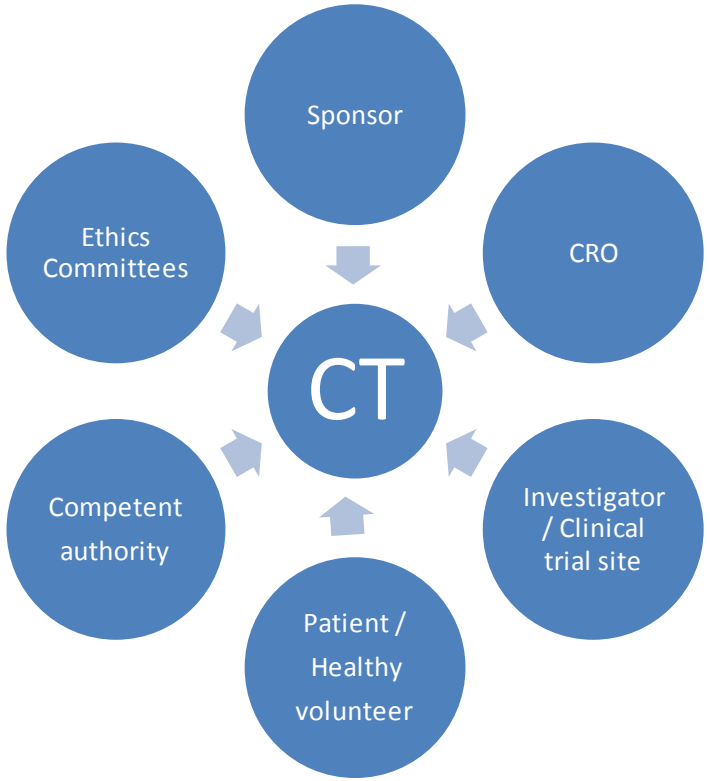
Eva Hruskova Reinova

Day 1 – 23. 2. 2021

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

Content of presentation

- Clinical trial – definition, distinction of interventional vs. non-interventional study, basic terminology of clinical trials
- Legal framework
- Clinical trial phase I, F-I-H
- Essential documentation of the CT
- Sponsor – duties and responsibilities
- Investigator – duties and responsibilities



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Clinical Trial

Definition

Any investigation in human subjects

- ✓ intended to **discover or verify the clinical, pharmacological and/or other pharmacodynamic effects** of **an investigational product(s)**
- ✓ **identify any adverse reactions**
- ✓ **study absorption, distribution, metabolism, and excretion**

of an investigational product(s) with **the object of ascertaining its safety and/or efficacy**.

All studies with a non-authorised drug product are CTs

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Clinical trial on pharmaceuticals vs. other studies

Rapid identification of the interventional clinical trial

Drug product

- Administration of a medicinal product or active substance
- Non-authorised / Authorised medicinal product

Trial subject

- Healthy volunteer
- Patient

Intervention

- Anything that is beyond normal medicinal practice
- Everything that trial subject undergoes for research, not for routine medicinal practice (treatment)

3x YES = CLINICAL TRIAL

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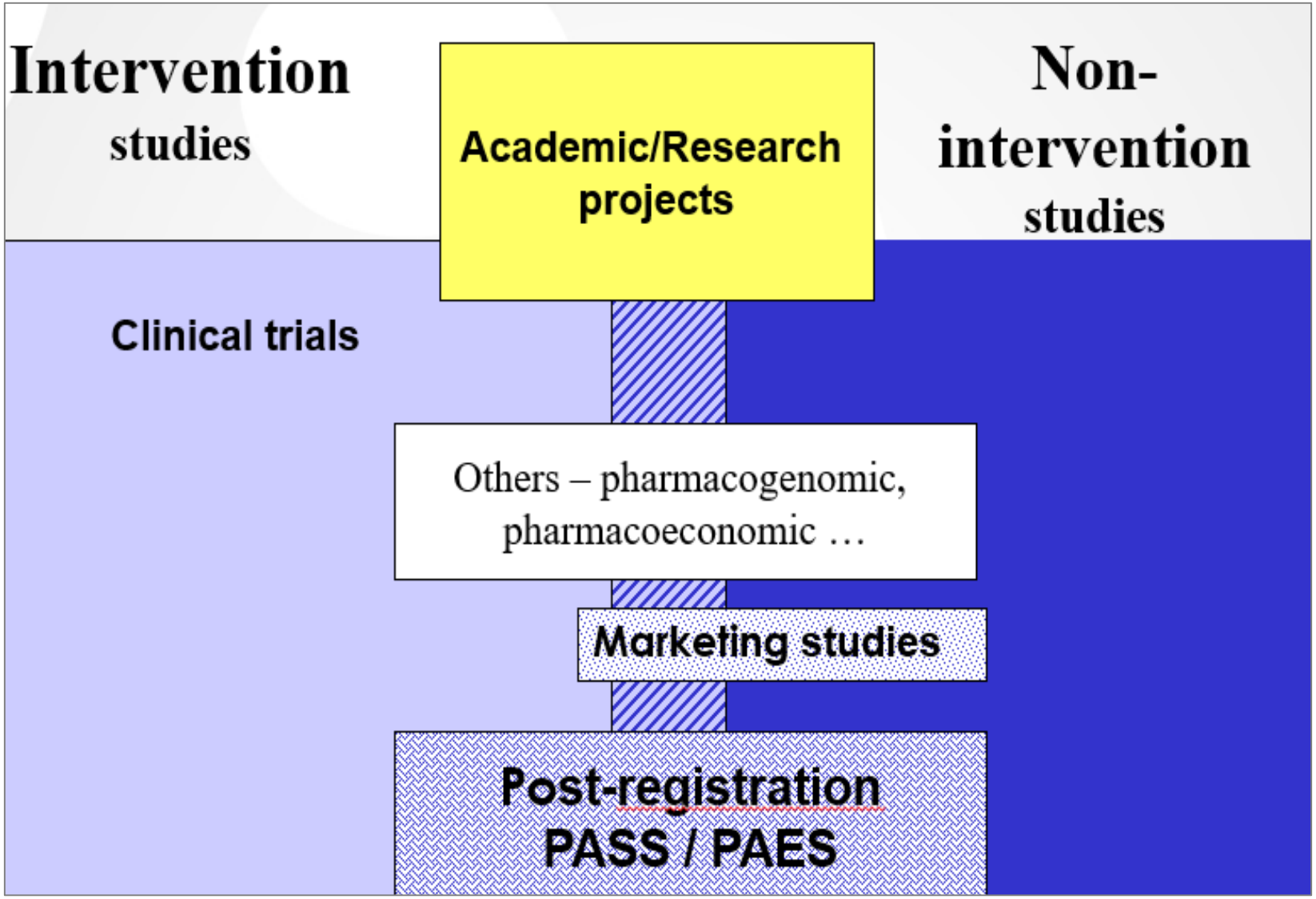
Clinical Trial

Elements of intervention

- ✓ Randomization
- ✓ Blinding
- ✓ Use of placebo
- ✓ Another medicinal product dosing
- ✓ Another route of administration medicinal product
- ✓ Another dosage form
- ✓ Performing the examination for study purposed only
- ✓ A sampling of biological material (blood, urine, tumour tissue…) for research purposes


Intervention studies
Academic/Research projects
Non-intervention studies
Clinical trials
Others – pharmacogenomic, pharmacoeconomic …
Marketing studies
Post-registration PASS / PAES

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- **PAES** - Post-authorisation efficacy studies
  - EMA Guidance – Post-Authorisation Efficacy Studies: Questions and Answers
- **PASS** - Post-authorisation safety studies
  - More information - ema.europa.eu
- PAESs and PASSs can either be **clinical trials** or **non-interventional studies**.

Intervention CTs

Approved by Regulatory Authorities and Ethics Committee

Non- intervention studies

Approved by Ethics Committee

PASS –PRAC assesses the study protocol and the final study report

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Legal Framework

✓**Directive 2001/20/EC** of the European Parliament and of the Council, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use – *link*

✓**National legislation (Law, Decree)** – implementation of the Directive, but there are also national specific requirements

✓**Regulation (EC) No 1394/2007** of the European Parliament and of the Council, on advanced therapy medicinal products specifically governs gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products.

✓**Regulation (EC) No 1901/2006** (32006R1901), of the European Parliament and of the Council on medicinal products for pediatric use.

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Legal Framework

✓**ICH E6 (R2) - Guideline for good clinical practice**

✓GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

✓Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

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ICH E6 (R2
Guideline for GCP

1. CT - should be conducted in accordance with the **ethical principles** (*Declaration of Helsinki, GCP ICH E6 and regulatory requirements*)
2. Risks and inconveniences should be weighed → **benefits justify the risks**
3. The **rights, safety**, and **well-being of the trial subjects** > interests of science and society
4. Adequate **nonclinical** and **clinical information** on an IMP
5. CT - scientifically sound, and described in a clear, detailed protocol
6. A CT should be conducted in compliance with the protocol
7. A qualified physician or a qualified dentist (when appropriate) – is responsible of the medicinal care
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)
9. Freely given informed consent – obtains prior to clinical trial participation

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Legal Framework

✓**Regulation (EU) No 536/2014** of the European Parliament and of the Council, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

- A streamlined application procedure via a single entry point - an EU portal and database
- A single authorisation procedure by all Member States concerned
- Strengthened transparency for clinical trials data

✓Regulation has not taken effect - cannot be applied

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Legal framework

✓**CT-1** Detailed guidance for the request for authorisation of a Clinical trial on medicinal product for human use to the competent authorities, notification of subtantial amendments and declaration of the end of the trial.

✓**CT-3** Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use

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Legal framework

- ✓ **EudraLex - Volume 10 - Clinical trials guidelines**
  - ✓ **Chapter I - Application and application form**
  - ✓ **Chapter II - Safety reporting**
  - ✓ **Chapter III - Quality of the investigational medicinal product**
  - ✓ **Chapter IV - Inspections**
  - ✓ **Chapter V - Additional information**
    - ✓ Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products (F-I-H)
    - ✓ Guideline for Good Clinical Practice – ICH E6(R2)
    - ✓ Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products
    - ✓ …
  - ✓ **Chapter VI – Legislation**

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Drug Development

MARKETING AUTHORISATION

Phase I
Human Pharmacology
'First in Human'

Phase II
Therapeutic
Exploratory

Phase III
Therapeutic
Confirmatory

Phase IV
Post-approval

* Safety
* Tolerance
* FK / FD
* Starting dose for phase II

* Verification of effectiveness
* Drug dose selection
* Further monitoring of safety data

* Demonstration of efficacy in a large number of patients
* Important data for authorisation
*Safety

*Post marketing authorisation study
* Interaction
* Long-term administration of the drug product

Clinical Trial

Phase I

- ✓Investigational Medicinal Product (IMP) in humans for the first-time use
- ✓Study the human pharmacology, tolerability and safety of the IMP
- ✓F-I-H is often undertaken in healthy volunteers but can also include patients
- ✓Starting dose determination - based on the non-clinical studies

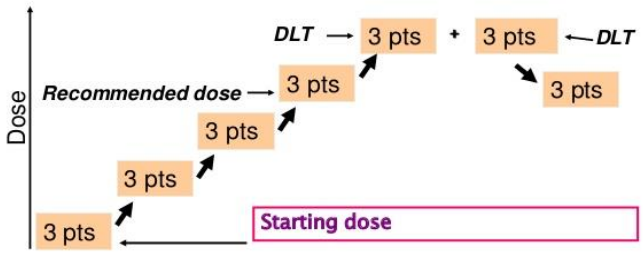
Clinical Trial

Phase I

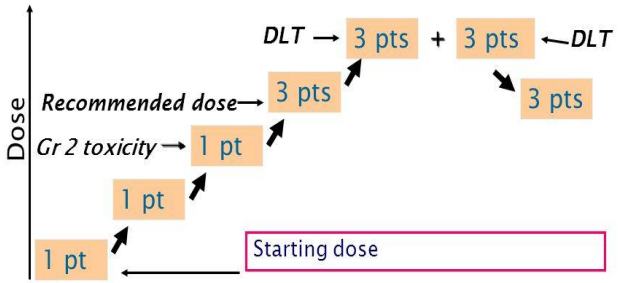
✓FIH and early phase CTs with integrated protocols that combine a number of different study parts (e.g. single ascending dose (SAD), multiple ascending dose (MAD), food effects, pharmacokinetic (PK),

✓pharmacodynamic (PD) and human safety data…)

Phase I Standard 3 + 3 Design



Phase I trial design: accelerated titration



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Clinical Trial – Phase I

Key aspects of design

- ✓ Population selection - clearly and unambiguously defined inclusion and exclusion criteria
- ✓ Healthy volunteers (preferable 18-65 years) / patients (phase I/II)
- ✓ Open design, unblinded
- ✓ Initial dose, maximum dose and exposure, and maximum duration of treatment
- ✓ Number of subjects in the cohort - transition period between cohorts with a new dose
- ✓ Stopping rules
- ✓ Monitoring of safety parameters

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Clinical Trial

Phase II

- ✓ Pilot Clinical trials
- ✓ Therapeutic exploratory
- ✓ Evaluate efficacy (and safety) in selected populations of patients with disease or condition to be treated, diagnosed, or prevented
- ✓ Objectives - dose-response, type of patient, frequency of dosing, or other characteristics of safety and efficacy

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Clinical Trial

Phase III, Therapeutic Confirmatory

- ✓ CTs conducted before submitting the application for marketing authorization
- ✓ Generate additional data of both efficacy and safety
- ✓ Large numbers of patients in selected populations of patients with disease or condition to be treated, diagnosed, or prevented

- ✓ **Phase IIIb** – CTs conducted after marketing authorization of medicinal products – different formulations, dosages, durations of treatment, new age groups, new indication, different route of administration…

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Clinical Trial

Phase IV

- ✓ CT conducted after marketing authorization
- ✓ IMP - must be used in accordance with SmPC
  - ✓ dose,
  - ✓ route of administration,
  - ✓ diagnosis,
  - ✓ age groups…
- ✓ Additional details about the medicine´s efficacy or safety profile
- ✓ Possibility of simplified labelling for open CT

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Clinical Trial

Essential documents of the CTA

- ✓Cover letter
- ✓Protocol and all amendments
- ✓CTA form, confirmation of assignment EudraCT number
- ✓Investigator´s Brochure
- ✓IMPD
- ✓Case Report Form (if required)
- ✓Patient Information Sheet / Informed Consent Form

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Cover Letter

It is necessary to submit a cover letter with the CTA

Cover letter should contain the following information:

- ✓a complete lists of documentation, including version numbers and version dates
- ✓in the case of a resubmission of CT application → mention in a cover letter any changes to the previous application submission in the text.
- ✓If the CT has been rejected in any member state by a regulatory authority or ethics committee.

Cover Letter

✓Cover letter should contain the following information:

✓ Where an Integrated Protocol Design is concerned (a protocol including two separate parts of a clinical trial, where different trial subjects are to be enrolled in part one and part two), it shall be mentioned whether both parts of the protocol are to be conducted in the cMS. In case only one part is to be conducted in the cMS, it shall be specified which one and where the other part of the protocol will be/has been conducted.

✓A medical device supplied by the sponsor is to be used within the scope of the CT for the purposes of the CT

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Clinical Trial Protocol

document that describes the objective(s), design, methodology, statistical considerations and organisation of a clinical trial

General Information

✓Protocol title
✓Protocol identifying number (Protocol code)
✓Version number and date
(the numbering of each page is important and identification of CT is necessary /protocol number or EudraCT number/, version number and date)
✓Sponsor - name and address
✓Phase of CT

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Clinical Trial Protocol

- ✓Name and description of the IMPs
- ✓Summary of findings from nonclinical studies and from CTs that are relevant to the trial
- ✓Evaluation of Benefit/Risk profile
- ✓Detailed description of the objectives and the purpose of the trial
- ✓Primary endpoints and secondary endpoints
- ✓Description of the trial design (e.g. double-blind or open, randomised, placebo-controlled, parallel design) and a schematic diagram of trial design,

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Protocol

- ✓Subjects population - inclusion and exclusion criteria, including stopping rules or discontinuation criteria from the trial
- ✓Treatment of subjects - names of all the products (IMP, AMP), dose, route of administration, treatment period, follow-up period
- ✓Concomitant treatment - permitted and prohibited, including regimen measures
- ✓Schedule of procedures - flowchart – time of visits, investigations, blood samples, compliance, adverse event/reaction
- ✓Pharmacovigilance - reporting adverse event, SAE, SUSAR
- ✓Statistics
- ✓Parameters of efficacy / safety
- ✓Other info – substudies; DSMC ect.

Investigator`s Brochure

- ✓Data file of the clinical and nonclinical data on the IMP
- ✓IB provides investigators with available data on IMP
- ✓(according the section 7 ICH E6 (R2))

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7.3.7 Summary of Data and Guidance for the Investigator 42

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Investigator`s Brochure

RSI – Reference Safety information

- ✓ Separate section in IB
- ✓ Includes a list of expected serious adverse reactions (SARs), e.g. in the form of a table (preferable)
- ✓ All related serious adverse reactions are listed by nature and severity including frequency (see CT-1 section 2.3. (32.), CT-3 section 7.2.3.2. (51 to 53))
- ✓ Any change to an RSI is considered a substantial amendment and it requires to be justified with supportive data

http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2017_11_CTFG_Question_and_Answer_on_Reference_Safety_Information_2017.pdf

Investigator`s Brochure

RSI – Reference Safety information - examples

Right

SOC	SARs	Number of subjects exposed (N) = 328		
		All SARs	Occurrence of fatal SARs	Occurrence of life-threatening SARs
		n* (%)	n (%)	n (%)
Gastro-intestinal disorders	Diarrhoea	25 (7.6)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	ALT increase	12 (3.6)	0 (0.0)	0 (0.0)
	AST increase	9 (2.7)	0 (0.0)	0 (0.0)
Cardio vascular disorders	Myocarditis	33 (10.0)	0 (0.0)	2 (0.6)

n = number of subjects who have experienced the SAR

Wrong

Preferred Term[a]	SOC	[redacted] (n=1873)	Blinded Study Treatment[c] (n=491)	Combined [redacted] Blinded (n=2364)	Frequency[d]
Cardiac Failure Congestive	Cardiac Disorders	13 (0.7%)	1 (0.2%)	14 (0.6%)	Uncommon
Hypoglycaemia	Metabolism And Nutrition Disorders	8 (0.4%)	0 (0%)	8 (0.3%)	Uncommon
Non-Cardiac Chest Pain	General Disorders And Administration Site Conditions	4 (0.2%)	1 (0.2%)	5 (0.2%)	Uncommon
Cardiac Failure	Cardiac Disorders	3 (0.2%)	0 (0%)	3 (0.1%)	Uncommon
Renal Failure Acute	Renal And Urinary Disorders	3 (0.2%)	0 (0%)	3 (0.1%)	Uncommon
Dyspnoea	Respiratory, Thoracic And Mediastinal Disorders	3 (0.2%)	0 (0%)	3 (0.1%)	Uncommon
Oedema Peripheral	General Disorders And Administration Site Conditions	2 (0.1%)	1 (0.2%)	3 (0.1%)	Uncommon
Pneumonia	Infections And Infestations	2 (0.1%)	1 (0.2%)	3 (0.1%)	Uncommon
Fluid Overload	Metabolism And Nutrition Disorders	2 (0.1%)	1 (0.2%)	3 (0.1%)	Uncommon

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Patient Information Sheet/Informed Consent Form

PIS/ICF

- ✓document safeguarding the provision of information about the basic principles of the concerned CT
- ✓about the voluntary nature of participation therein to the aforementioned persons
- ✓the objective of which is to inform the trial subject about the CT in which he/she is offered participation
- ✓the text of the PIS/IC shall be clear and in a language the trial subject well understands
- ✓it should not contain foreign expressions, specialised terminology, unexplained abbreviations and complicated definitions

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Patient Information Sheet/Informed Consent Form

PIS/ICF

- ✓the text should be written in a friendly and sensitive manner
- ✓it is advisable to avoid words like “you have to” “you must not”, “you suffer” etc.
- ✓pages shall be numbered (e.g. “1/6“ or “1 (of 6)“, etc.) and each page should be identified by the relevant version number, date of issue and CT identification (protocol number or EudraCT number)
- ✓the written informed consent form should be signed by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion

PIS/ICF: ICH E6 (R2), section 4.8.10

Include explanations of the following:

4.8.10.

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

a) That the trial involves research.

b) The purpose of the trial.

c) The trial treatment(s) and the probability for random assignment to each treatment.

d) The trial procedures to be followed, including all invasive procedures.

e) The subject's responsibilities.

f) Those aspects of the trial that are experimental.

g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

j) The compensation and/or treatment available to the subject in the event of trial-related injury.

k) The anticipated prorated payment, if any, to the subject for participating in the trial.

l) The anticipated expenses, if any, to the subject for participating in the trial.

m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

s) The expected duration of the subject's participation in the trial.

t) The approximate number of subjects involved in the trial.

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CTA form
(Clinical Trial Application form)

✓is available on website of the European Medicines Agency (EMA) at **https://eudract.ema.europa.eu**

✓contains a detailed instruction how to complete the application

✓Each CTA for CT must contain the EudraCT number as an identifier ➡ may be obtained on the same website

https://eudract.ema.europa.eu/ → EudraCT number, CTA & Login for posting results → Create → initially, generate the EudraCT number; thereafter, using this number, generate the application (Clinical trial protocol)

✓EudraCT number must be stated on all documents

http://eudract.eudra.org/

EudraCT

Help

Hosted on behalf of the European Commission

- Home
- What's new
- FAQs
- Login to EudraCT
- EudraPharm EU CTR
- Protocol documentation
- Results documentation
- Technical documentation
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Welcome to the community clinical trial secure home page

The European Medicines Agency has launched a new version of the European Clinical Trials Database (EudraCT). This new version, EudraCT V10, marks the final step of a process through which summary clinical trial results will be made publicly available through the EU Clinical Trials Register (EU CTR).

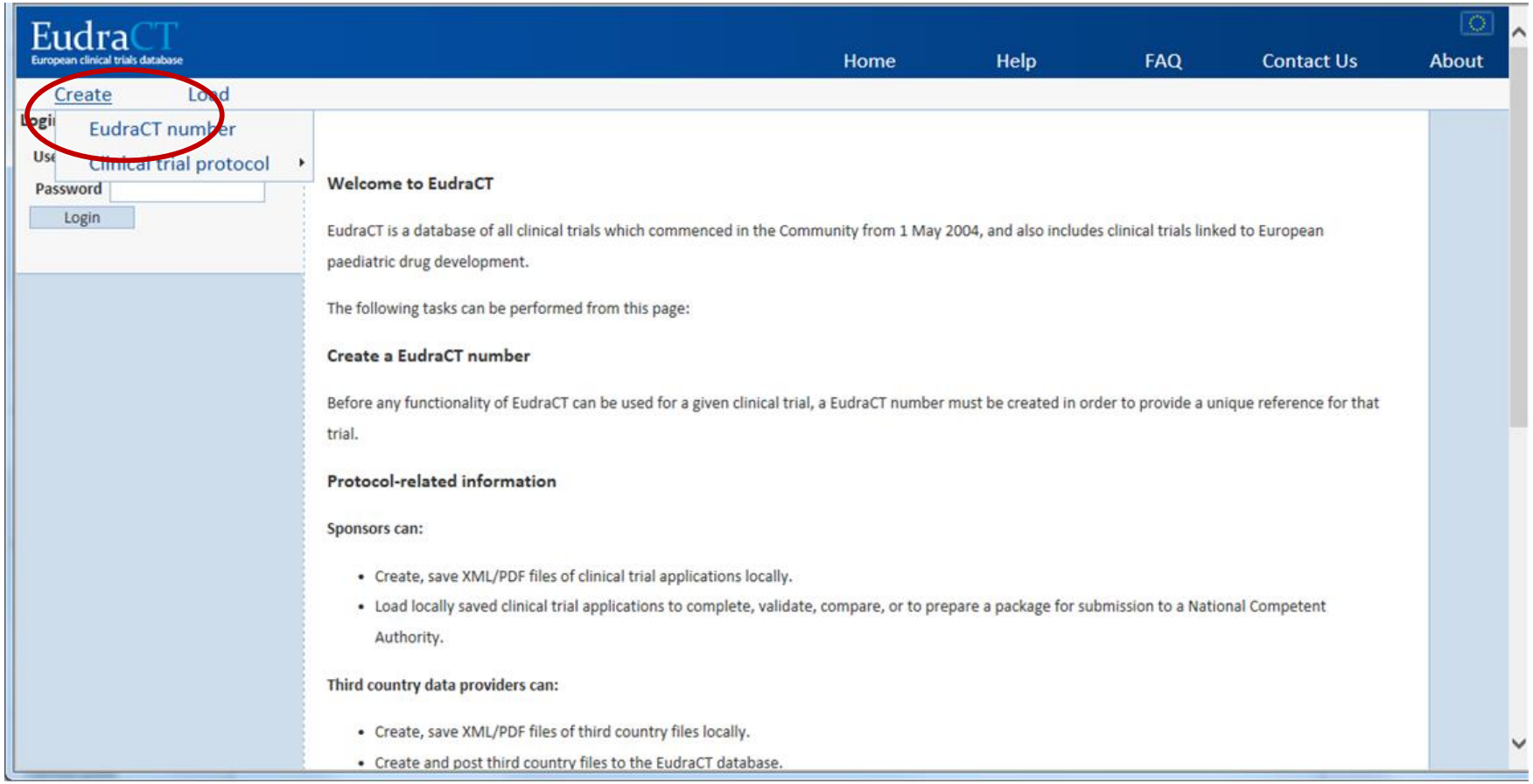
Sponsors' representatives are recommended to register with EudraCT in order to become results users and before they can log into EudraCT. The registration process is described in the help and is accessed on the login page.

RSS

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Last Updated: September 21, 2018 11:14
European Medicines Agency © 1995-2018
For technical support, please visit the EMA Service Desk portal using your user credentials for a system hosted by EMA (except Eudravigilance). If you do not have an account or have forgotten your credentials, please click here

CT number must be generated first



EudraCT
European clinical trials database

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Login

Username
Password
Login

Get EudraCT Number

Requestor's organisation name:	Hospital Praha
Requestor's organisation town/city(*):	Praha
Requestor's organisation country(*):	Czech Republic
Sponsor's protocol code number(*):	ABC101
Requestor name(*):	Kamila
Requestor last name(*):	Nováková
E-mail to which the EudraCT number will be sent (*):	alena.truneckova@sukl.cz
Enter the characters shown(*):	dnjx2y

d n j x 2 y

New Image

Is it anticipated that this EudraCT Number will be used for a Clinical Trial contained in a Paediatric Investigation Plan (PIP)? (*) ○ Yes ◉ No

Is it anticipated that this EudraCT Number will be used for a Clinical Trial conducted in a third country (outside of the EU/EEA)? (*) ○ Yes ◉ No

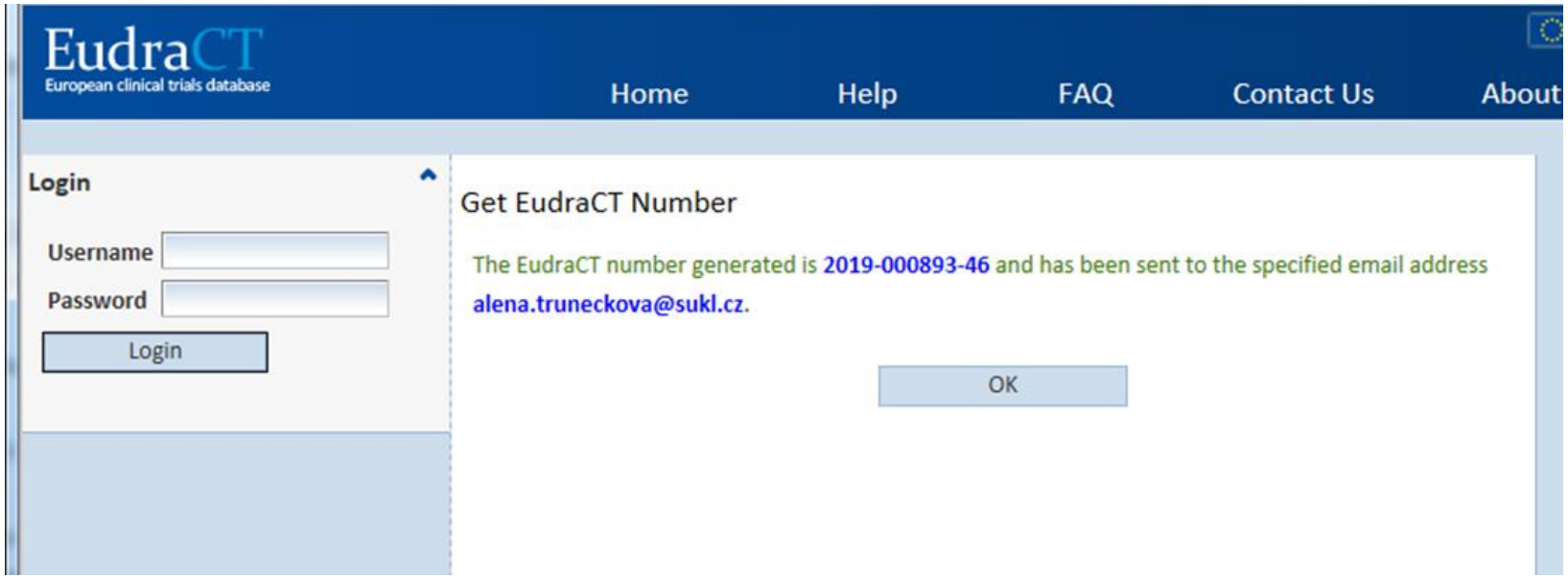
Please select the Member States where it is anticipated that the trial will be run:

Cyprus
Denmark
Estonia
Finland
France

Copy
Remove
Remove All

Czech Republic

Get EudraCT Number | Cancel



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N

noreply@eudract.ema.europa.eu

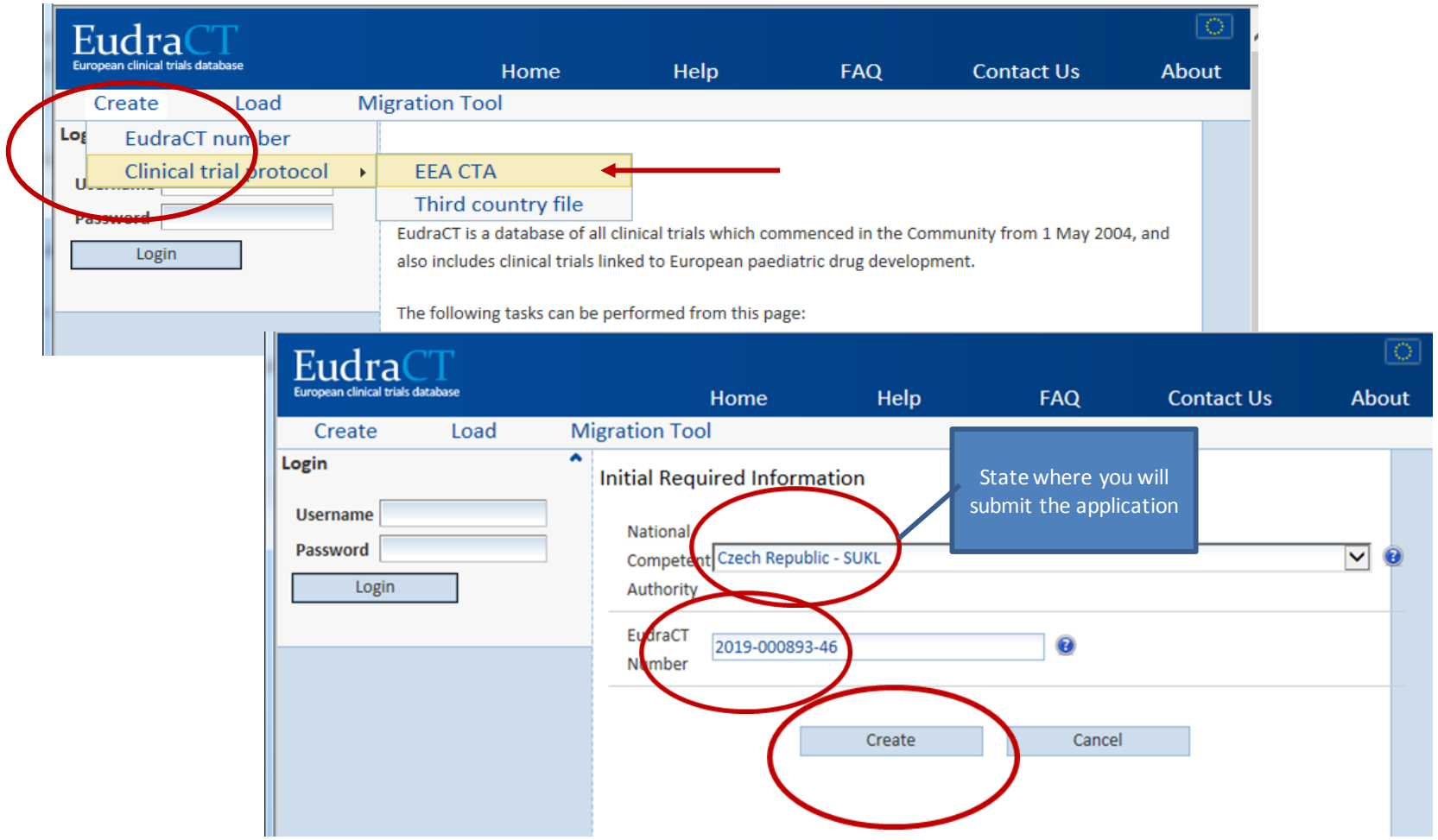
Application for EudraCT Number

Komu Trunečková Alena

The EudraCT number 2019-000893-46 has been issued for your Sponsor's Protocol Code Number ABC101.

THIS IS AN AUTOMATED EMAIL - PLEASE DO NOT REPLY AS EMAILS RECEIVED AT THIS ADDRESS WILL BE AUTOMATICALLY DELETED.

Then create an application in the system



Now this is the workspace of Clinical Trial Application form (CTA)

EudraCT
European clinical trials database

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Create Load Migration Tool

CTA Information

EudraCT Number
2019-000893-46

Sponsor's Protocol Code Number

NCA
Czech Republic - SUKL
update XML identifier

CTA Sections
- Sections Index
- Section A
- Section B
- Section C
- Section D
- Section D.8
- Section D.9
- Section E
- Section F
- Section G
- Section H

Validate Compare Save as XML Switch XML Save PDF Package

Clinical Trial Application Menu

A. Trial Identification
B. Sponsor Identification
C. Applicant Identification
D. IMP Identification
D.8 Placebo Information
D.9 Site(s) where the qualified person certifies batch release
E. General Information on the Trial
F. Population of Trial Subjects
G. Clinical Trial Sites/Investigators in the Member State
H. Competent Authority/Ethics Committee Information

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CTA form
(Clinical Trial Application form)

If you are going to interrupt the work on filling in (even if only for a few minutes), download the completed form to a PC (in xml format) to be sure

You always have to load it back and you can continue working

Follow the instructions for filling provided in the CTA

How to continuously save the pending application:

EudraCT
European clinical trials database

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Create Load Migration Tool

CTA Information

EudraCT Number
2019-000893-46
Sponsor's Protocol Code Number
ABC101
NCA
Czech Republic - SUKL
update XML identifier

CTA Sections
Sections Index
Section A

Validate Compare Save as XML Switch XML Save PDF Package

Clinical Trial Application Menu

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D.8 Placebo Information
D.9 Site(s) where the qualified person certifies batch release
E. Gener
F. Popula
G. Clinic
H. Comp

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CTA Information

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ABC101
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Return

Save to PC

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Clinical trial protocol
EEA CTA
Third country file

Login

Username
Password
Login

Welcome to E

EudraCT is a database of all clinical trials which commenced in the Community from 1 May 2004, and also includes clinical trials linked to European paediatric drug development.

The following tasks can be performed from this page:

Create a EudraCT number

Before any functionality of EudraCT can be used for a given clinical trial, a EudraCT number must be created in order to provide a unique reference for that trial.

Protocol-related information

Sponsors can:

To continue working, we will upload to the system again

EudraCT
European clinical trials database

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Create Load Migration Tool

Login

Username

Password

Login

Load an XML file for an EEA Clinical Trial Application

Add...

File path of locally saved XML file to load

Upload Return

Application hosted on behalf of the European Commission http://ec.europa.eu

EudraCT
European clinical trials database

Home Help FAQ Contac

Create Load Migration Tool

Login

Username

Password

Login

Load an XML file for an EEA Clinical Trial Application

Add... Clear All

C:\fakepath\2019-000893-46 CZ 20190215 CTA (7).xml Clear

Done

File path of locally saved XML file to load

Upload Return

Section H. Competent Authority/Ethics Committee Information

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Sponsor's Protocol Code Number

ABC101

NCA

Czech Republic - SUKL

update XML identifier

CTA Sections

- Sections Index
- Section A
- Section B
- Section C
- Section D
- Section D.8
- Section D.9
- Section E
- Section F
- Section G
- Section H

H. National Competent Authority

H.2.1 National Competent authority name	SÚKL
H.2.2 Address	
H.2.2.1 Street address	Šrobárova 48
H.2.2.2 Town/ city	Praha 10
H.2.2.3 Post code	100 41
H.2.2.4 Country	Czech Republic
H.2.3 Date of submission	2019-02-19
H.3 Authorisation/Opinion	
H.3.1 / H.3.2 / H.3.3 What is the status of the National Competent Authority's authorisation?	Pending
If 'Given' specify:	
H.3.3.1 Date of authorisation	
H.3.3.2 / H.3.3.3 Indicate whether accepted or not	

Validation of the completteness of the CTA form

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EudraCT Number
2019-000893-46

Sponsor's Protocol Code Number
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XML File Identifier
0rw8bTopThb9D5Hq2pfQCLE0s1w=

Validate Compare Save as XML Switch XML Save PDF Package

Application Validation Results

Validation Date and Time: 2019-02-15 15:23:00 GMT

This is the list of inconsistencies found in your application. Please go back and correct the inconsistencies before submission.

Expand All / Collapse All

Total: 1 **Failed**

Section C

FIELD: C.2 Request for Opinion of the Eth

RULE ID: FEAT6.2.2.06

DESCRIPTION: This section is not mandatory. It sh those Member States where the E completed then all fields mandato

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Validate Compare Save as XML Switch XML

Application Validation Results

Validation Date and Time: 2019-02-15 12:05:04 GMT

The Clinical Trial (EEA CTA) has passed all validation rules.

Submission package = .xml + .pdf. + Validation Report

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Validate | Compare | Save as XML | Switch XML | Save PDF | Package

Prepare Clinical Trial Application Package

NOTE: These options refer to the PDF rendition of the Clinical Trial Application Form, that will be included in the submission package.

Select Language: English

Create Submission Package for National Competent Authority

Create Submission Package for Independent Ethics Committee

2019-000893-46 CZ 20190215 CTA Package.zip - WinRAR

Soubor | Příkazy | Nástroje | Oblíbené | Možnosti | Nápověda

Přidat | Extrahovat do | Otestovat | Zobrazit | Smazat | Vyhledat | Průvodce | Informace | Antivirus | Komentář | SFX

2019-000893-46 CZ 20190215 CTA Package.zip - Archiv ve formátu ZIP, dekomprimovaná velikost 215 252 Bytů

Jméno	Velikost	Komprim. ...	Typ
..			Složka soubo
2019-000893-46 CZ 20190215 Form.pdf	136 301	118 888	Adobe Acrob
2019-000893-46 CZ 20190215 Validation Report.pdf	22 521	20 738	Adobe Acrob
2019-000893-46 CZ 20190215.xml	56 430	7 132	Dokument v

2019-000893-46 CZ 20190215 Validation Report.pdf - Adobe Acrobat Reader DC

Soubor | Úpravy | Zobrazení | Okna | Nápověda

Domovská stránka | Nástroje | 2019-000893-46 ... ×

1 / 1

Validate Application Results

EudraCT Number:	2019-000893-46
Sponsor's Protocol Code Number:	ABC101
National Competent Authority:	Czech Republic - SUKL
Validation Date and Time:	2019-02-15 12:11:03 GMT

The Clinical Trial (EEA CTA) has passed all validation rules.

Sponsor

✓can be an individual, company, institution or organization, which takes responsibility for the initiation, management and/or financing of a CT

✓must be located in an EU Member State or has a „legal representative“ in the EU

✓may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor

STARS
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SCIENCE

Sponsor`s Responsibilities

- ✓full responsibility for performing the CT
- ✓preparation and continuous updating of documentation
- ✓standard procedures introduction (SOP)
- ✓selection of investigator and clinical trial site
- ✓GCP assurance
- ✓risk management plan
- ✓pharmacovigilance during CT (*SUSAR, DSUR*)
- ✓ongoing reporting (*initiation of the CT, Urgent Safety Restriction, Deviation of protocol, notification of the end of CT in MS and global, Clinical Study Report*)

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Investigator

Person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Person who has:

✓relevant qualifications

✓training and experience for the proper conduct of the clinical trial

✓experience in performing CT

He/she knows and obeys GCP and the applicable regulatory requirements (national legislation of MSs concerned)

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Investigator`s responsibilities

- ✓full responsibility for carrying out the CT on trial site
- ✓compliance with GCP principles and MS regulations by all team members
- ✓selection of investigator´s staff (*sufficient experience and adequate qualifications*) – Delegation log (*the tasks entrusted to the individual members of the study team are indicated; their training is recorded - everyone confirms with their signature*)
- ✓being in charge of IMP
- ✓conducts interviews with patients/healthy volunteers, obtain a signed IC by SH and signs IC itself if required by national law

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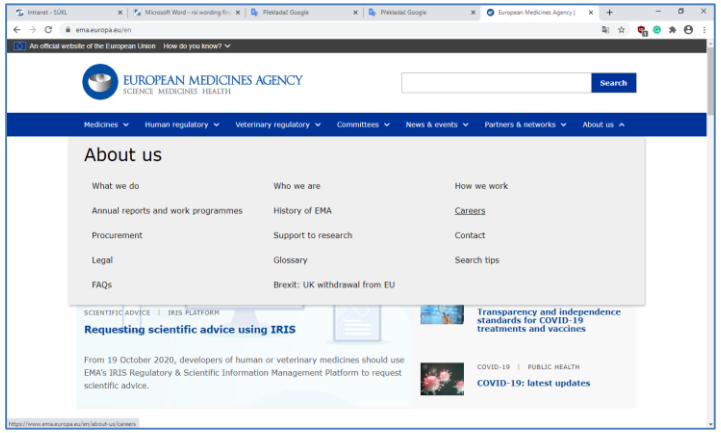
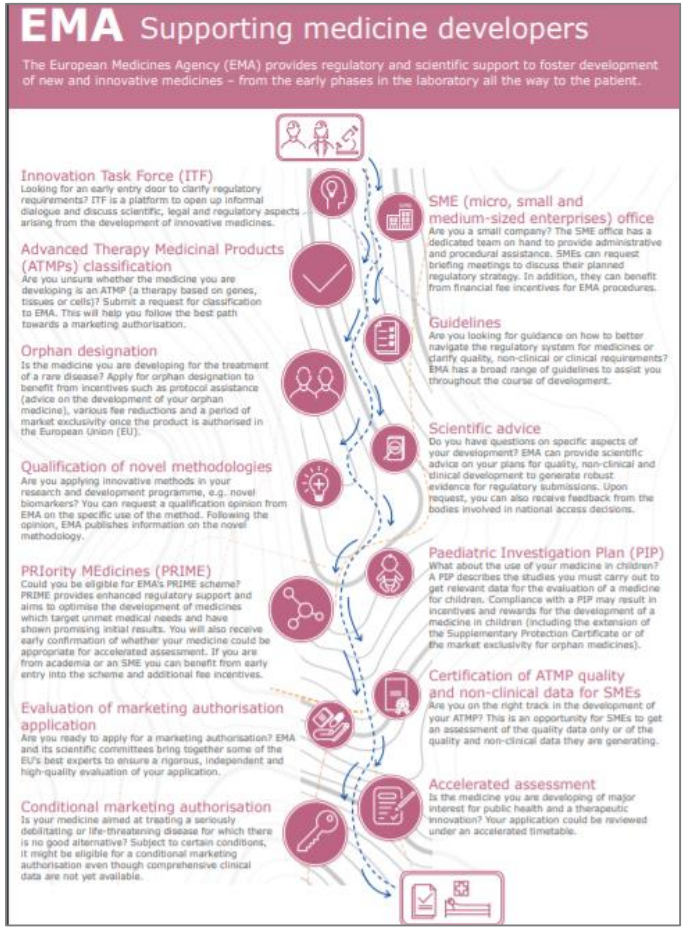
Regulatory support to the development of clinical research and/or of new medicines

- ✓ **Scientific advice for CTs** (documentations, legislations, GCP principles, duties and responsibilities of the sponsor and the investigator…)
- ✓ **Consultations** (written or face to face)
- ✓ Provide:
  - ✓ Competent authority of the Member States
  - ✓ European Medicines Agency (EMA)
  - ✓ Clinical Trial Facilitation and Coordination Group (CTFG)

EMA Groups involved in Scientific Advice

https://www.ema.europa.eu/en





Regulation of CTs – the main reason

- ✓ Testing in standard conditions
- ✓ Obtaining objective and valid data
  - Documentation for the registration
  - Documentation for the application asking for variations in registration
- ✓ Balanced risk/benefit ratio
- ✓ Legal protection of human subjects
  - Protection of vulnerable human subjects
- ✓ Drug product quality

Quality and safety of marketing authorisation of medicinal products

STARS
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Abbreviations

AMP	Auxiliary Medicinal Product
CRO	Contract research organization
CT	Clinical trial
CTA	Clinical Trial Application form
DSMC	Data and Safety Monitoring Committee
DSUR	Development Safety Update Report = Annual Safety Report (ASR)
EC	European Commission
EMA	European Medicines Agency
F-I-H (FIH)	First-in-human
GCP	Good Clinical Practice
HMA	Heads of Medicines Agencies
IB	Investigator's brochure
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
MAD	Multiple Ascending Dose
MS	Member State
PASS	Post-Authorisation Safety Study
PAES	Post-Authorisation Efficacy Study
PRAC	Pharmacovigilance Risk Assessment Committee
PD	Pharmacodynamic
PK	Pharmacokinetic
PIS	Patient Information Sheet
RSI	Reference Safety Information
SAD	Single Ascending Dose
SmPC	Summary of product characteristics
SUSAR	Suspected Unexpected Serious Adverse Reaction
SÚKL	State Institute for Drug Control
VHP	Voluntary Harmonisation Procedure

Acknowledgement

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