Details on the electronic clinical trial application via CESP

The CESP portal can be reached via the link http://cesp.hma.eu/Home .

This link takes the user to the CESP homepage, where he or she can log in to the input system for his/her submissions. New users can access a registration form via this page. The operation is implemented with a so-called "self-service model for user management". This means that each company appoints its own administrator, who sets up access to CESP and looks after its employees.

Please refer to the following instructions for submitting clinical trial application documents:

PLEASE NOTE:
The procedural step/subject line has to be given in the COMMENTS field!
e.g. **Resp. Val. Req /2904/2015-0045450-99**

Category	Sub-Category	Subject line in COMMENTS
Initial CTA		**Initial CTA/EudraCT-No./ Abbreviation study code; VHP-No. if applicable**
	response to validation requests	**Resp. Val. Req. / Vorlage-No.: / EudraCT-No.**
	response to address grounds for non-acceptance	**Resp. GNA /Vorlage-No.: /EudraCT-No.**
substantial amendment		**Subst. Amend., Vorlage-No.: / EudraCT-No.**
Non substantial amendment		**Non-SA/ Vorlage-No.: / EudraCT-No.**
summary report/results		**Sum. Report, Vorlage-No.: / EudraCT-No.**
annual Safety report/DSUR		**DSUR ,DSUR Number; Reporting period; Vorlage-No.: / EudraCT-No., if possible**
Interruption, Temp Hold, restriction of recruiting, etc		**Temp. Hold or Interrup. recruit., Vorlage-No.: / EudraCT-No.**
Urgent Safety Measures		**USM/, Vorlage-Non.: / EudraCT-No.**

1. Login

2. New Delivery File.

a. Create your "Delivery File" here, which is required to upload your application documents to the CESP server.

b. Step 1

i. Fill in all fields marked with an asterisk (*).

1. select "Regulatory Activity":

a. Clinical Trial

b. Development Safety Update Reports

2. select "Sub Activity":

a. H002 Initial Application

i. New applications

b. H003 Answers to Questions during Validation

i. Submissions of subsequent submissions on formal deficiencies or references to new applications

c. H004 Answers to Questions during Procedure

i. Submissions of subsequent submissions to substantive objections (deadline 90) to new applications

d. H005 Closing Documents

i. Completion of studies (§ 13 (8) GCP-V, national and global)

e. H001 Not Applicable:

i. substantial amendment (§ 10 GCP-V)

ii. non-substantial amendment (§ 12 GCP-V)

iii. Safety communication (§ 13 (4) GCP-V)

iv. Termination or interruption of studies (§ 13 (8)

v. Final reports (§ 13(9) GCP-V, BUT NOT according §42b AMG)

vi. Other notifications

c. Step 2

i. Under "Procedure Type", select "national".

d. Step 3

i. Select the competent authority (e.g. DE (PEI)).

e. Step 4

i. You can enter additional e-mail addresses for correspondence.

ii. The names of the investigational medicinal products and, if available, the Vorlagenummer. Also, if applicable, the registration number can be entered.

iii. Further investigational products can be entered via "add Product

iv. Submit" creates the "Delivery File", which must be downloaded in the next step.

3. under "Web Upload" the application documents as well as the "Delivery File" can now be uploaded

a. Select "Integrated Upload

i. A new window opens.

ii. First you have to upload your zip file with the application documents.

iii. Then the "Delivery File" must be uploaded.

iv. After successful upload you will find both files under "completed".

v. You will receive an e-mail confirming the upload.

vi. You will receive another e-mail confirming the delivery of the files to the selected authority.

If you have any questions regarding registration or technical details, please contact the following e-mail address: cesp@hma.eu