

## Common European Submission Platform – CESP

The new CESP system has been designed to allow for a single, electronic submission for Clinical Trials, to all European regulatory agencies, as required. The single-platform submission aims reduce the administrative burden of set-up in multi-national trials through automated-distribution of the application with no CD/DVD or 'hard copy' requirement.

As of February 1<sup>st</sup> 2016, the MHRA will no longer be accepting physical submissions, all future clinical trial applications will be required to be made through CESP. This also applies to amendments and DSURs.

### Initial registration

To submit via CESP you will require access to the system. At this point, you should considering who within your Department will require access in order to submit new applications, amendments, DSURs etc. as well as ensuring contingencies are in place should staff members be unavailable for any reason.

To register with CESP, please contact [ctrig@admin.ox.ac.uk](mailto:ctrig@admin.ox.ac.uk) in the first instance to request a CESP account. We will require registration name (first name, last name) and preferred email address; this can be a generic email address monitored by multiple users and the name of the individual user or clinical trial. Currently, all University of Oxford users will be registered under a single 'Company' – we may in future, dependent on the functionality and development of the CESP system, register each Department as individual 'sub-companies' under the University umbrella.

Following your registration you will receive an email to the registered address. This will include:

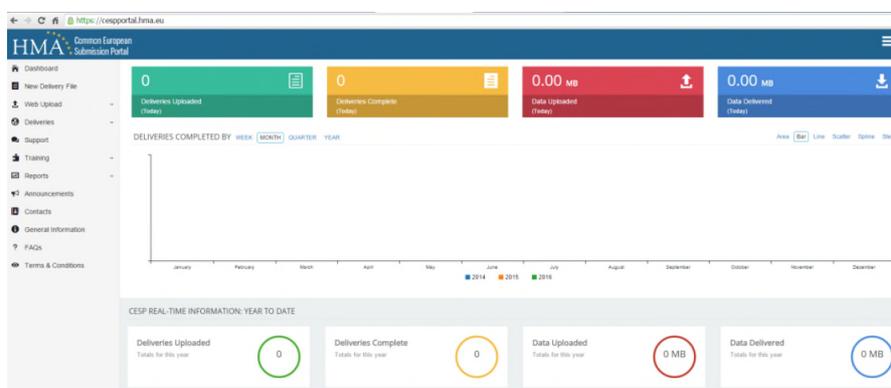
- A link to the CESP web platform
- Contact details and opening hours for the CESP support team
- Your CESP username (formatted as: c3716-surname/first initial – for example, c3716-bloggsj).

In order to complete your registration, follow the link in the email to the CESP log-in page where you will be required to set your password. **If you do not receive this email please check your Junk email folder, the password link will time-out and demands prompt action.**

**CESP 2.0 requires:** Internet explorer 10+, Google Chrome, Mozilla Firefox or Safari.

Upon log-in you will be presented with your 'Dashboard' (shown below). This will currently appear empty, however, following CESP uploads this will allow you to track the number and size of submissions from your account through the system.

Figure 1



### Using CESP to submit

CESP allows for electronic submission of Clinical Trial applications to the appropriate regulatory agency, Europe-wide.

The submission should be a **single .zip file**. Within this package should be all the required documentation for the submission. CESP offer guidance on the creation of .zip folders using standard Windows compression [here](#).

When naming your .zip file, and the files within the .zip package, please use the standard ASCII character set. **Do not use any special characters**. Additionally, please note that file names and paths should not exceed **240 characters**.

All submissions will now also *require* a covering letter; this letter *must* include the **CESP submission number**. *This is the number of the downloaded .xml file* (Your Delivery File, see below).

Figure 2

### Delivery Files

The first step in the submission process is to create a new 'Delivery File'. Please select this option from your sidebar and proceed through the four Steps. Step 1 will require you to indicate the 'Area', 'Activity' and 'Sub-Activity' of the submission from the drop-down list provided. This should largely be intuitive based on the type of submission you are intending, however, you are *required* to enter these fields so please contact either the CESP support team or CTRG for further guidance if you are unsure of your activity. Step 2 will ask for your 'Procedure Type', this is in reference to the method by which you will be gaining marketing authorisation, should that be your intention. You will also be asked to select your 'Submission Type', unless you are aware this is not the case, please select 'Other eSubmission Type' (which would not have been '*Technically Validated*'). Finally you can select the relevant competent authorities to receive your submission and any additional email address to be included in the submission verification. Following the completion of these steps, a .xml file will be available for download. Save this to a safe location as it will need to be uploaded alongside your .zip file.

Please note, **Delivery files cannot be renamed and each is unique to a single submission**. The number in the file name is your *CESP submission number* and should be included in your covering letter.

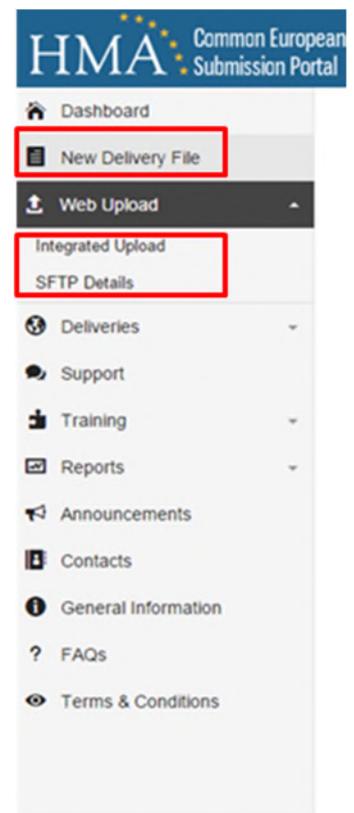
The FAQs section of the website has a specific section for Delivery Files should you require support. As CESP is designed for a variety of applications outside of clinical

trials, there will be numerous acronyms and options which will not be relevant to your research. If you require further support, please contact CTRG.

### Upload

There are two methods by which a submission can be made:

1. Via the online 'Integrated Upload' option.
2. Via the 'SFTP' or Secure File Transfer Protocol.

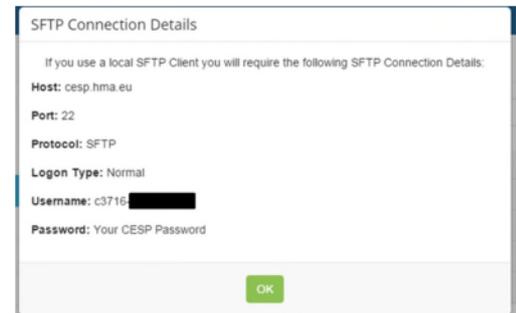


### Secure File Transfer Protocol (SFTP).

The Integrated Upload option is based in the web platform whereas the SFTP option requires the installation of File Transfer Protocol software. For the majority of University of Oxford computers, the Oxford Applications installer will have 'FileZilla' freely available, FileZilla is compatible with CESP. There are other compatible FTP programs, details of which are available on the CESP FAQs ('Software' section).

Figure 3

Selecting the SFTP details from the sidebar will produce a pop-up with the required information for use with your chosen FTP software.



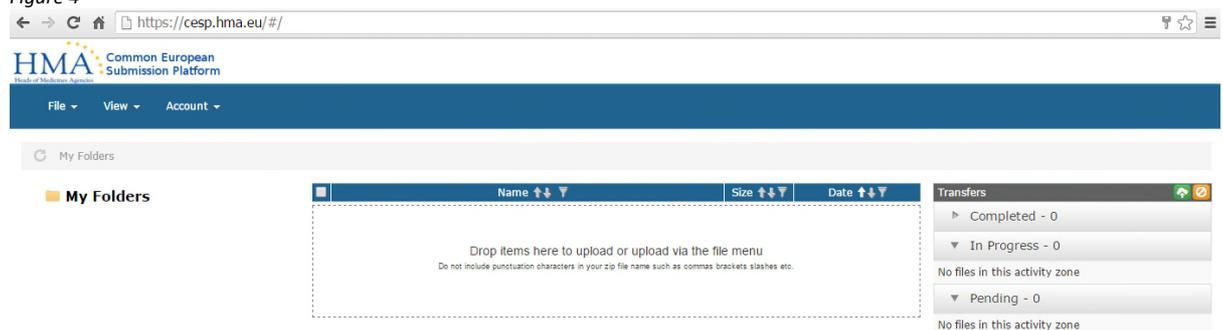
The advantage of this method is that, for extremely large uploads, SFTP is somewhat more reliable and quicker than the Integrated Upload platform.

### Integrated Upload

CESP has the option to upload online via the built-in upload platform.

1. Select the 'Integrated Upload' option from the sidebar; this will open a new tab in your browser, as below.

Figure 4



2. Select 'File> New Folder', naming the folder appropriately for your submission.
3. Within the newly created folder, **first upload your .zip package**. The upload progress is shown in the right hand 'Transfers' panel.
4. Once the .zip upload is **fully complete, upload the relevant Delivery File**.

### Post-upload

Following your upload, regardless of your method of choice, the registered email address will receive a message advising your submission has been received on the CESP Server. This will be followed by delivery receipts from each Agency indicated in your Delivery File.

Please be aware, these emails simply indicate successful delivery they **do not** equate to validation of your submission by the relevant agency.

The submission should now appear on your dashboard, which will confirm its delivery status.

Figure 5

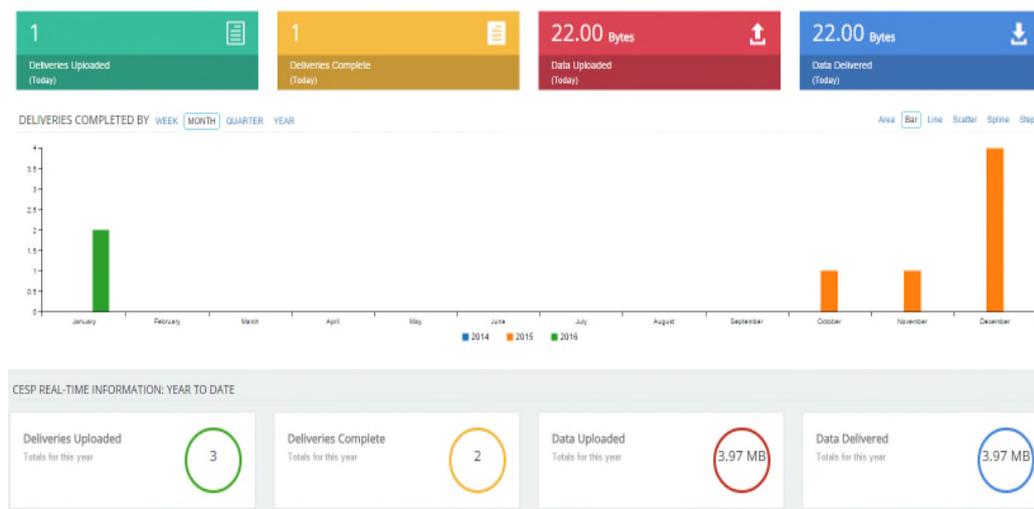
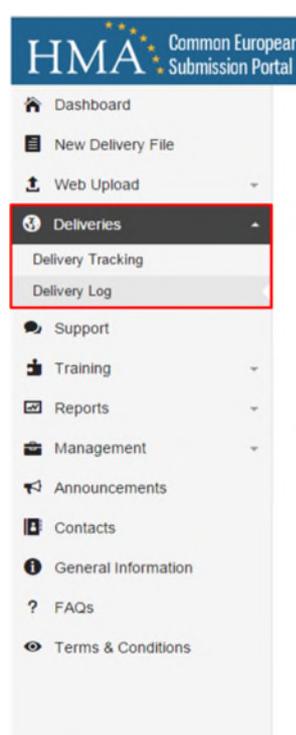


Figure 6



You may also check the status of your submission (and any previous submissions) via the Deliveries tab on the sidebar.

### **Support and Training**

The CESP support team offer interactive Webinars. In order to register for these, check the 'Announcements' tab in the CESP sidebar for the date of the next demonstration. Additionally, via the 'Training' tab on your sidebar, there are a number of short video tutorials freely available on demand. These are also available as downloadable PowerPoint slide shows.

Furthermore, a comprehensive FAQs section is available, accessible via the sidebar. This is divided into 7 sub-sections:

- Delivery Files
- eSubmissions
- General
- Security
- Setup
- Software
- Training Guides

Should you have a technical issue the 'Support' section allows for call-logging. Here you can raise your issue and a member of the CESP support team will respond in due course. You will be notified of their response via email and on the sidebar of CESP next time you log in.