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1  LOG IN DETAILS

Link received via email
Login = User name = your email

Password (PW): received by email, change upon first login

GDPR approval: only when logging into Dyco Flow for the first time

2  PASSWORD FORGOTTEN

1. Complete username: email and choose forgot password
2. Complete next window:

![Complete next window screenshot]

3. A warning is sent out:

![A warning is sent out screenshot]

4. A notification is sent out:

![A notification is sent out screenshot]
5. Reset the password:
REQUEST TO CREATE A NEW PROJECT

Before a new study can be submitted, a new project has to be created in Dyco Flow by the Clinical Trial Center (CTC). In order to create this project, the following information has to be provided via the webform: https://vub.fra1.qualtrics.com/jfe/form/SV_cvxoo1kGKjODNs

- Project name: use up to 10 characters; a code with year and sequential number will be assigned by the Central Study office
- Project title Dutch
- Project title English
- Is this project part of a CTR procedure or an MDR procedure? CTR (Clinical Trial Regulation) and MDR (medical device regulation) are new European regulatory frameworks to replace the previous directives.
- Will human body material be used as part of the project?
- Information Principal Investigator (PI)
  E-mail address: please provide a business e-mail address only, private e-mail addresses are not allowed
  Surname
  First name
  Profile: *see list below
  - End date validity of Principal Investigator’s GCP certificate: the GCP certificate is valid for a maximum of 3 years
  - Department/research group of UZ Brussel/VUB where the study is performed: the signature of the head of the department is required for approval of all study-related actions in the department for which the head of the department is responsible (e.g. using posters for recruitment in the department). The Medical Ethics Committee cannot approve a study without the signature of the Head of Department.
  - Is the principal investigator part of this department/research group?
  - Information Head of Department:
    E-mail address: please provide a business e-mail address only, private e-mail addresses are not allowed
    Surname
    First name
    Profile: *see list below
  - Is the PI also a submitter?
  - Are there other persons who will be submitters for this project? If the sponsor is not VUB/UZ Brussel, it is recommended to foresee a submitter role for both the sponsor and VUB/UZ Brussel.

All other members of the study team will be notified in the registration form when completing the documents for submission.

*Profile: Medical doctor in training – General Physician or Medical Doctor (specialist) – Dentist (specialist) – (Hospital) Pharmacist – Nurse/Midwife – Physiotherapist – Clinical psychologist with a visum - Paramedic° – (being in possession of a degree (in a healthcare profession) is a prerequisite; master students cannot fulfil the role as PI, the promotor of the master thesis can be submitted as PI)

° Paramedic professions include audiologist, audiologist, dietician, occupational therapist, pharmaceutical technician assistant, speech therapist, medical laboratory technologist, dental hygienist, podiatrist, medical imaging technologist, orthoptist - optometrist, prosthetist
In the system 3 main roles are defined: Submitter-Principal Investigator-Head of Department. Next to their viewing rights, following actions can be carried out by the different roles:

<table>
<thead>
<tr>
<th>Action</th>
<th>Submitter</th>
<th>Principal Investigator</th>
<th>Head of Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fill in registration form</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open/Read registration form</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Change registration form</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sign registration form</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Submit documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove documents</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documents correction</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>View documents</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Complete folder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Add comments</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Send dossier to CTC</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Important: in case the Principal Investigator also performs the tasks of the Submitter, the 2 roles (Submitter and Principal Investigator) need to be assigned to this person.

Once the project is created by the CTC, an email from Dyco Flow will be sent to the Submitter who can then start uploading the project.
1. Select the registration form:

Click on “Select Registration form “in the light grey bar:

Now the type of registration form can be selected as well as the Central and Local Ethics Committees. Click on “Open registration form”.

Important: In case the study has been evaluated according to CTR or MDR procedures with an external ethics committee performing the review, the name of the Central Ethics Committee is mentioned on the approval letter.
2. **Complete the registration form:**

Complete each tab of the registration form with the correct information:

![Registration form](image)

**Important:** it is mandatory to fill in ALL the data.

To add a sub-investigator: click on ![add_sub_investigator](image) and complete the required information.

Don’t forget to add the requested information for the contact person.

Extra supporting documents are available at the bottom of each window and in the tab “Support”

![Support tab](image)
In case the wrong registration form has been chosen, the Submitter can click on “Return to form selection” in the light grey bar.

When the form has been completed, the Submitter needs to click on “Send for signature” in the light grey bar to send the registration form to the PI for signature. Once the PI has signed the form, the form is automatically sent to the Head of Department for signature.
The PI and the HD receive an email from Dyco Flow to invite them to sign the registration form.

In order to sign the registration form, the PI/HD has to go to “Tasks” where the document can be selected to open the task. After review the document can be signed.

Important: the order for signing is fixed: first the PI and then the HD
Login User: Principal Investigator

The Principal Investigator can choose to sign the form or to refuse the form.

To sign the form:

PI clicks on “Sign”. A pop up screen will appear requesting the reason for signing. After having entered user name and password, the signature will appear on the form.

Important: The following reason is chosen by the PI when signing the registration form:

- Reviewed and approved → PI signs the registration form

Now the form is sent to the HD to sign.
To refuse the form:
PI refuses the form and fills in the reason for rejection.

In case the reject comment box is too small to add all the remarks, a comment can be added via the text symbol.
The registration form is then returned to the Submitter who can make the necessary changes before sending it again for signature to the PI and HD.

→ Login User: HD

The Head of Department can choose to sign the form or to refuse the form.

To sign the form:
HD clicks on “Sign” the form.

Important: The following reason is chosen by the HD when signing the registration form:

- Signed for approval → HD signs the registration form

HOOFDONDERZOEKER
Voor gezien en akkoord,

| Titel, Naam, Voornaam | Handtekening | Datum |

Electronically signed by Catherine PI on 23/08/2019 17:26:45 (reviewed and approved)

DIENSTHOOFD(EN) of VERANTWOORDELIJKE(EN)
Voor gezien akkoord,

| Titel, Naam, Voornaam | Handtekening | Datum |

Electronically signed by HD UZB on 17/12/2021 11:35:53 (document signed for approval)
To refuse the form

HD clicks on “Refuse” and fills in the reason for rejection (see part “To refuse the form” by PI):

![Reject dialog box]

The document is then returned to the Submitter who can make the necessary changes before sending it again for signature.

**Important:** the PI and the HD both have to sign the document again! After the PI has signed, the form will be sent for signature to the HD.

Once all signatures are in place, the folder 01 Registration form turns **PURPLE**.

![Folder structure]

**Important:** in case the PI is also the HD, this process has to be performed twice by the same person (once as PI and once as HD).
Once the registration form has been sent for signature to the PI and HD, folders 02-13 are displayed and are ready for upload of the submission documents.

1. **To upload documents/information:**

Click on a folder from 02-13 to upload documents.

Do not forget to consult the supporting documents

- "Required documents for the EC submission per study type”
- “Documents per folder”

To add a file in a folder the Submitter clicks on “Add file” in the light grey bar.

**Important:** the file to be uploaded has to be saved on your computer; e.g. it is not possible to upload documents from Sharepoint.
Once all the documents have been uploaded in their relevant folder, click on “Set complete”. The folder will turn PURPLE.

Once all the documents have been uploaded in their relevant folder, click on “Set complete”. The folder will turn PURPLE.
In case an extra document needs to be uploaded the Submitter can click on “Set incomplete” and add the extra file. Do not forget to click again on “Set complete” afterwards (folder turns PURPLE).

In case a folder is not applicable for the study and remains empty, select “Set not applicable”. The folder will then turn BROWN.
In case additional information needs to be provided, click “Add comment”. These comments will be read by the CTC.
2. Special folders

- Folder 03: Supporting departments.

In this folder the (internal) supporting departments participating in the study can be identified.

For an upload of documents (e.g. a collaboration agreement with the supporting department) in folder 03 supporting departments, the Submitter can select “Add file”.

To add a supporting department the Submitter can click on “Select/update supporting departments”.

Here the Submitter can either select one of the supporting departments from the scroll list or can add an extra supporting department.
Folder 04: ICF

Before adding files, select one of the subfolders. Then click on “Add file” and upload the document.

After upload go back to main folder 04 ICF and click on “Set complete”. The main folder will turn PURPLE.
When all folders have turned either PURPLE or BROWN, click on the main project folder and then on “Send to CTC for review” in the grey folder menu.

The project is ready for review by the CTC.

After review by the CTC, the study will either be returned to the Submitter with some comments or items that need to be modified/uploaded. Or the study will be sent directly to the EC when it is validated as complete by the CTC.
Click on the RED folders.

1. Read the comments on the top of the window, comply with the request.
   
   a. **To respond to the comments**: click on “Add comment”.
   
   b. **To upload a new document**:
   
      - Click on “Add file” in the folder menu (grey).
      - Click on “Select” to select your document.
      - Click on “Add”.
      - Click on “Save & Close”.

   c. **To replace a document**:

      - Click on the original document.
- Click on “Document correction”.

![Document correction screen]

- Click on “Select” to upload the new version.
- If necessary, you can rename the document.
- Click on “Save”.

![Save screen]

Don’t forget to click again on “Set complete” after uploading the new documents. This folder will now turn BLUE.
d. **To replace the registration form**

In case of multiple comments on the content of the registration form, or in case the wrong type of registration form has been used, a new registration form has to be completed and signed by the Principal Investigator and the Head of the Department.

First the Submitter must remove the old registration form via “Remove registration form”.

- The Submitter clicks on “Select registration form”

  ![Select Registration form](image1)

- The Submitter selects, opens, completes the new form and can then “Send for signature”

  ![Select Registration form](image2)

- Folder 01 Registration form turns YELLOW.

  ![Select Registration form](image3)

- After completion of the signing process, the folder 01 Registration form turns PURPLE.

  ![Select Registration form](image4)

- The Submitter can select “Set complete” or “Set incomplete”.

  ![Select Registration form](image5)

- After selection “Set complete”, folder 01 Registration form turns GREEN and not BLUE!
2. Repeat this operation for all the RED folders until all the folders are GREEN, BROWN, or BLUE.

3. Click on your project.

Click on “Send to CTC for review”.

The project is ready for a second review by the CTC.
Once your study has been validated by the CTC, the study will be sent to the Ethics Committee. An email with the EC reference number of the study will be sent.

The folder of the study now turns YELLOW/LIGHTGREEN.

Important: always use this reference number to refer to your study.
In case the EC considers the study not valid, the folder of the study will turn RED and an email with a link to the project will be sent. Please check the RED folders, make the necessary changes and provide an answer to the comments that were made (see section “Returned to Submitter for action”).

When all the necessary changes are made, the Submitter clicks on “Send to EC for review” and the study folder will now turn BLUE.
10 STUDY VALIDATED BY EC

Once the study has been validated by the EC, an email specifying the meeting date will be sent. The folder of the study has now turned LIGHT GREEN.

At that time, a new folder 14 EC opinion is created. In this folder, the AoR specifying the documents received for review are listed.

Once the review has been performed by the Ethics Committee, the opinion/advice will be uploaded in the folder 14 EC opinion.
11 PRELIMINARY ADVICE

In the preliminary advice, the remarks from the Ethics Committee are described.

The folders in the project can have different colours, depending on the status of the content:

- **RED** folders: these are the folders/documents with remarks from the EC. To provide the requested answers and changes please follow the instructions as described in the section “Project returned to Submitter”.

- **DARK GREEN** folders: the documents in these folders have been evaluated and are approved without remarks.

- **BROWN** folders: these folders were set not applicable.

The Submitter can upload a document with answers to the remarks of the EC in folder 12 Correspondence (this folder will also be RED).

Once all the necessary changes have been made, the Submitter can click on “Send to EC for review” for a second review.

Important: in case the study team/sponsor disagrees with (one of) the remarks of the EC, a reason needs to be provided via “Add comment”.

![Image of file management system interface with highlighted options for sending to EC for review and adding comments.](attachment:image_file.png)
12 SINGLE OPINION ADVICE

In case no remarks were made by the Ethics Committee, a single opinion advice, electronically signed by the president/vice-president, is uploaded in folder 14 EC opinion. The main folder of the project will be DARK GREEN.

When the “Wet signed” single opinion is uploaded by the EC, the Green Light procedure can be started.
Login User: Principal Investigator

After authorization of the “EC Single opinion positive advice” the Principal Investigator receives a notification to complete the Green Light template.

The main folder is DARK GREEN/LIGHT GREEN

1. The PI opens the tasks:

2. The window opens and the PI completes:

When signing the PI choses the following reason: I take responsibility and approve
After completion the PI signs the Green Light according to part 11.

Now a notification is sent to the CTC. The CTC refuses or gives approval. In case of refusal, the task will be sent to the PI who can read the comment, make the necessary modifications and send back to the CTC for signature.

When the CTC approves the Green Light checklist, the project status changes to project open for enrolment.

The main folder of the project turns now DARK GREEN/YELLOW 🟢.

An email from Dyco Flow will be sent to confirm that the study can start at the study site.
CONTINUING REVIEW

For ongoing studies, the submission of an amendment, upload of a new insurance certificate or other documents like annual progress report, safety reports, audit reports,… can be done via folder 17 EC Continuing review. As soon as the green light procedure is completed folder 17 EC Continuing review will become available.

Different types of documents can be uploaded here:

1. Upload documents

To upload a document in folder 17 EC Continuing review, choose the type of action and click on the + button next to the type of action in the grey field.

The system automatically creates a sequence number. The first amendment will be coded AM-A, the 2nd amendment will be called AM-B. Following this sequence the name of this new subfolder (e.g. the version of the Amendment) can be indicated. After adding the name, click on create.

A new subfolder will be created under the folder 17 EC Continuing review (e.g. subfolder AM-A-Amendment 1).
For the upload of documents in these folders: see section “6. Uploading documents in the folders”.

When all documents have been uploaded in a folder, click on “Set complete”. The folder will now turn PURPLE. When all the documents are uploaded, click in the light grey bar on “Send to EC for review”.

When the EC has validated the submission of the amendment and has determined on which meeting it will be reviewed, the folder will turn LIGHT GREEN.

Once the amendment has been reviewed and approved by the EC a notification by email will be sent.
The advice regarding the amendment can be consulted in the folder containing the documents for the amendment. This folder now has a DARK GREEN colour.

If the EC did not validate/approve the amendment, the folder will turn RED. A comment with the reason for the no validation/disapproval will appear on the folder.

New/modified documents can be uploaded in the RED folder and resubmitted to the EC for review, or a new amendment can be submitted.
15 GENERAL TOOLS

1. SEARCH TOOLS:

The search tool provides the opportunity to search on different topics. If you have several project running in DycoFlow you can search on project details. Also, you can search for specific documents and comments. Finally, there is a possibility to check the project status (e.g. at ctc for review of returned to submitter)
2. SUPPORT TAB

Supporting documents in the application: a number of documents that are requisite in obtaining an advice of the EC are provided here. To have an overview of the documents required per type of study or per folder, you can consult the corresponding documents in this section.

3. TASK

This tab enables you to have an overview of tasks that are open for action. If you receive an email with an open task, the link in the mail will lead you to this task. Click on the task to be referred to the corresponding page in DycoFlow.
APPENDIX I: DOCUMENTS PER FOLDER

Protocols, ICF’s, questionnaires, posters, etc. should have a version number and a version date; please also put this version number and version date in the file name of the document in DycoFlow.

* Mandatory for every type of protocol

01 Registration form (to be completed in DycoFlow) (“adviesaanvraagformulier”)*

02 Study team
   o signed and dated CV PI*
   o valid GCP certificate of PI (TransCelerate approved certificates are valid for a period of 3 years)*

03 Supporting department
   o Agreement(s) with supporting department(s)

04 ICF
   o ICF Dutch, French, English,…
   o Assent document (if applicable)

05 Protocol
   o Protocol or Clinical Investigation Plan (signed and dated by PI )* 
   o Protocol Synopsis
   o Administrative changes letter
   o GDPR checklist*

06 Product information
   o Summary of Product Characteristics (SmPC)
   o CE marking Medical Devices
   o Investigator’s Brochure (IB)
   o Instruction/manual Medical Devices

07 Patient related
   o Questionnaires/interview /guidance/instructions
   o Brochures
   o Diaries
   o All patient related documents (e.g., patient card)

08 Regulatory
   o Signed Clinical Trial Application (FAGG)

09 Insurance
   o Insurance certificate
   o Technical data sheet (if insurance certificate is not available at the time of submission - only for academic projects with UZ Brussel or VUB as the sponsor)

10 Miscellaneous
   o Approval Central EC /Leading EC (if project has already been approved)
   o Site list
   o Invoice details
   o Acknowledgement of receipt (if applicable)
APPENDIX II: COLOURS FOLDERS

Main folders

- Project in upload by submitter
- Project at CTC for initial review
- Project returned to submitter for action
- Project at CTC for new review
- Project at EC for validation
- Validated project at EC for initial review
- Green light ongoing
- Project ongoing