# Dyco Flow - User Instructions

**UZ Brussel**

## Contents

1. Log in details ........................................................................................................................................... 2
2. Password forgotten .................................................................................................................................... 2
3. Request to create a new project ............................................................................................................. 5
4. Project in upload by Submitter ............................................................................................................... 7
5. Signing process Principal Investigator / Head of Department ................................................................. 10
6. Uploading documents in the folders ........................................................................................................ 14
7. Project returned to Submitter for action ................................................................................................. 20
8. Study sent to EC by CTC ...................................................................................................................... 24
9. Study not validated by EC ..................................................................................................................... 25
10. Study validated by EC .......................................................................................................................... 26
11. Preliminary advice ............................................................................................................................... 27
12. Single opinion advice ............................................................................................................................ 28
13. Green light ............................................................................................................................................ 29
14. Continuing review ............................................................................................................................... 31
15. General Tools ...................................................................................................................................... 34
   1. Search tools ........................................................................................................................................ 34
   2. Support Tab ........................................................................................................................................ 35
   3. Task ................................................................................................................................................... 35
16. Appendix I: documents per folder ....................................................................................................... 36
17. Appendix II: colours folders .................................................................................................................. 37
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
2. Complete next window:

![Complete next window](image1)

3. A warning is sent out:

![A warning is sent out](image2)

4. A notification is sent out:

![A notification is sent out](image3)
5. Reset the password:
3. Request to create a new project

Before you can submit a new study, a new project has to be created in Dyco Flow by the Clinical Trial Center (CTC). In order to create your project, the following information has to be provided via email:

- Project number:
- Project short name (not mandatory):
- Title project Dutch:
- Title project English:
- External department (if applicable):
- Department:
- Head of Department:
  - Email:
  - First name:
  - Name:
  - Profile (e.g. physician: choose from list below)**
  - GCP certificate valid until:

- Users (indicate at least the Principal Investigator and Submitter)
  - Email:
  - First name:
  - Name:
  - Profile (e.g. master student: choose from list below***)
  - GCP-certificate valid until:
  - Role in the project (e.g. sub-investigator: choose from list below****)

* Project number: Identifier to easily retrieve your project in the system (at your own choice e.g. 2021_JAN_VUB_Name of initials of PI). For commercial studies a project name has usually already been assigned by the sponsor.


*** Principal investigator - Study administrator - Study coordinator - Study nurse - Sub-investigator Submitter

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

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Dyco Flow - INPUT REQUIRED: you have been assigned as Submitter of Project test1201

Dear Kira Godderis,

Your Project test1201 is ready for your input.

Instructions:
1. Open your project on the left panel (by clicking on “+”) to display the 01 REGISTRATION FORM folder.
2. Click on “Select Registration form”.
3. Fill in the questionnaire (select the registration form type and the central EC and local ECs) and click on the button “Open registration form”.
4. Complete ALL fields in the registration form.
5. Click on “Send for signature”

An e-mail notification will be sent when the registration form has been signed/rejected by PI/Head of Department.

Project title:
test

Follow this Dyco Flow link to access the project.

Kind regards,

The Central Study office/Clinical Trial Center
4. Project in upload by Submitter

Login User: Submitter

1. Select the registration form:

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

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

Important: In case your study has been evaluated in the CTR pilot project, you will find the name of the Central Ethics Committee 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.**

In case you want to add a sub-investigator: click on ![Add Sub-Investigator](image) and complete the required information.

![Sub-Investigator](image)

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

![Contact Information](image)

Extra supporting documents are available at the bottom of each window.

![Extra Documents](image)
In case the wrong registration form has been chosen or additional information needs to be given regarding the Ethics Committees, 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 and the Head of Department for signature.
5. **Signing process Principal Investigator / Head of Department**

The Principal Investigator (PI)/Head of Department (HD) are invited to sign the registration form. The PI and the HD will receive an email from Dyco Flow to invite them to sign the registration form.

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**Dyco Flow** - Input: the registration form of test1201 is waiting for your signature

Dear UZB PI,

You are invited to sign off the registration form of project test1201.

To sign, open the registration form and follow the instructions in orange.

- Project title: test
- Please follow this Dyco Flow link, go to your task list and select the project specific registration form.

Kind regards,

The Central Study office/Clinical Trial Center

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The PI and the HD go to “Tasks”. They select the document and click to open the task.
After review they will sign for approval.

**Important**: The first person to sign is the PI after having reviewed the form. Afterwards the HD is asked to sign.
→ Login User: Principal Investigator

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

To sign the form:
P1 clicks on “Sign”. A pop up screen will appear requesting the reason for signing. After having entered username and password, the signature will appear on the form.

**Important:** The *following reason* is chosen when the PI signs the registration form:

- **Reviewed and approved → PI signs the registration form**

Now the form is sent to the HD to sign.

![Sign Form](image)

To refuse the form:
P1 refuses the form and fills in the reason for rejection.

In case the reject comment box is too small to fill in all the remarks, a comment can be added via the text symbol. This will be read by the Submitter.
The registration form is sent back to the Submitter who makes changes and sends it back for signature to the PI and HD.

→ Login User: HD

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

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

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

- Signed for approval → HD signs the registration form
To refuse the form

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

The document is sent back to the Submitter who makes changes and sends 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.

**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).
6. Uploading documents in the folders

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. Consult supporting document “Required documents for the EC submission per study type” to know which documents are needed for your study.

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 a certain folder, click on “Set complete”. The folder will turn PURPLE.

In case the Submitter has forgotten to upload a document, click on “Set incomplete” and add an extra file. Do not forget to click again on “Set complete” afterwards (folder turns PASSIVE). 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 supporting departments participating in your study can be identified.

For an upload of documents (for example 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 you can either select one of the supporting departments from the scroll list or you can add an extra supporting departments.
• **Folder 04: ICF**

Before adding files, select one of the subfolders. Click then 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 your project and then on “Send to CTC for review” in the grey folder menu.

The project is ready for review by the CTC.

Either the study will be sent back to the Submitter with some comments or items that need to be adapted/uploaded. Or the study can be sent directly to the EC when it is validated as complete by the CTC.
7. **Project returned to Submitter for action**

→ **Login User: Submitter**

1. Click on the RED folders.

2. Read the comments on the top of the window, comply with the request.

   a. **To respond to the comments**: click on “Add comment”.

   **Important**: Please provide answers to ALL comments made by the CTC. In case only an upload/replacement of a document is required, please add “OK” to the comments.

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”.

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

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”

- The Submitter selects, opens, completes the new form and “Send for signature”
- Folder 01 Registration form turns YELLOW.

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

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

4. Click on your project.

Click on “Send to CTC for review”.

The project is ready for a second review by the CTC.
8. **Study sent to EC by CTC**

Once your study has been validated by the CTC, the study will be sent to the Ethics Committee. You will receive an email with the EC reference number for the study. The folder of your study now turns YELLOW/LIGHTGREEN.

**Important:** always use this reference number to refer to your study
9. **Study not validated by EC**

In case certain documents are missing or incorrect in your application, your study will not be validated by the EC and will turn RED. You will receive an email with a link to the system. 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, you can click on “Send to EC for review” to send your study back to the EC. Your study folder will now turn BLUE.
10. **Study validated by EC**

Once your study has been validated by the EC you will receive an email from Dyco Flow. In this email the meeting date will be specified on which your study will be discussed.

The folder of your study has now turned LIGHT GREEN.

Now a new folder 14 EC opinion has been created. In this folder you will find the AoR in which the Ethics Committee lists all the documents they received for the study and will be discussed during the meeting.

When your study has been reviewed by the Ethics Committee, you will be able to find your advice in the folder 14 EC opinion.
11. Preliminary advice

You can open the preliminary advice and read the remarks from the Ethics Committee.

In your project a number of folders have changed colour.

- 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 and still are.

The document with your answers to the remarks of the EC, can be uploaded in folder 12 Correspondence (this folder will also be RED).

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

Important: in case you disagree with one of the remarks of the EC you need to provide a reason via “Add comment”.
12. Single opinion advice

In case there were no remarks from the Ethics Committee you will find a single opinion advice, electronically signed by the president/vice-president, in folder 14 EC opinion. Your project will be DARK GREEN.

When the “Wet signed” single opinion is uploaded by the EC, the Green Light procedure can be started.
13. **Green light**

→ 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.

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, adapt and send back to CTC to sign.

When the CTC approves the Green Light the project status changes to project ongoing. The project turns now DARK GREEN/YELLOW.

You will receive an email from Dyco Flow to confirm that the study can start at the study site.
14. Continuing review

For ongoing studies, the submission of an amendment, a new insurance certificate or other documents can be done via folder 17 EC Continuing review.

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 you can put the name of your new subfolder (e.g. the version of the Amendment). When you have filled in the name of the subfolder, you can 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 “Uploading documents in the folders”.

When all documents have been uploaded in a folder, you can 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”.

Dyco Flow - User Instructions
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 you will receive an email.

You can find the advice regarding your amendment in the folder in which you uploaded the documents for your amendment. This folder has now 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.

You can either upload new/adapted documents in the RED folder and resubmit them to the EC for review, or submit a new amendment.
15. **General Tools**

1. **Search tools:**

   ![Search Projects](image1)

   ![Search documents](image2)

   ![Search comments](image3)
2. Support Tab

Supporting documents in the application

3. Task

- My work:
16. **Appendix I: documents per folder**

1. Registration form (to be filled in)

2. Study team
   - CV PI
   - GCP certificate

3. Supporting department
   - Agreement with supporting department

4. ICF
   - ICF Dutch, French, English and other
   - Assent document (if applicable)

5. Protocol
   - Protocol
   - Protocol Signature Page
   - GDPR information register data processing

6. Product information
   - Summary of Product Characteristics (SmPC)
   - CE certification for Medical Devices
   - Investigator’s Brochure (IB)
   - Manual Medical Devices

7. Patient related
   - Questionnaires/Guidance interview
   - Brochures
   - Diaries
   - All patient related material (e.g. patient card)

8. Regulatory
   - Signed Clinical Trial Application (FAGG)

9. Insurance
   - Certificate
   - “Technische fiche” (for academic studies; in case certificate is not yet available)

10. Miscellaneous
    - Approval Central EC (in case the study has already been approved)
    - Site list
    - Invoice details
11. Legal
   o Clinical Trial Agreement (draft is allowed)
   o Other agreements (e.g. Data transfer agreement, material transfer agreement)
   o Budget

12. Correspondence
   o Previous communication with CTC/CME
   o Correspondence between parties involved in the study

13. Advertisement
   o Flyer/poster (recruitment documents)

17. 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