

DYCO FLOW USER INSTRUCTIONS

Version May 2022



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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

Settings:
- Preferred browser is Google Chrome.
- Disable the pop-up blocker (for instructions go to tab Support after login).

GDPR.pdf

Dear User,

You have been assigned as new user in Dyco Flow (DigiDyco), an interactive platform-based application to facilitate the document collection and shared management of clinical projects. Before you proceed, we like to make you aware that the system captures some of your personal data. Please read the following GDPR statement and indicate your choice on consent.

Dyco Flow is GDPR compliant

Subject-matter and objectives

I declare that I have read the above paragraphs regarding GDPR and approve on the processing of my personal data in Dyco Flow, with the limitations mentioned above ☒ Yes ☐ No

[Continue](#)

Application developed by ARCO Information 8/2000-2019. Loaded in 0.0882 seconds.

2 PASSWORD FORGOTTEN

1. Complete username: email and choose forgot password


Dyco Flow

User name

Password

[Forgot username](#) [Forgot password](#)

[Login](#)



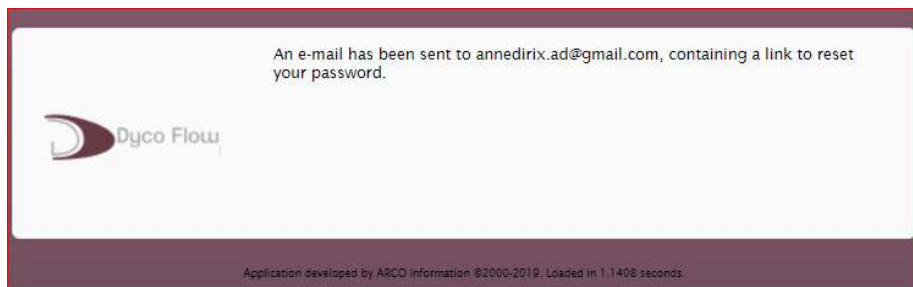
Application developed by ARCO Information 8/2000-2019. Loaded in 0.0110 seconds.

2. Complete next window:



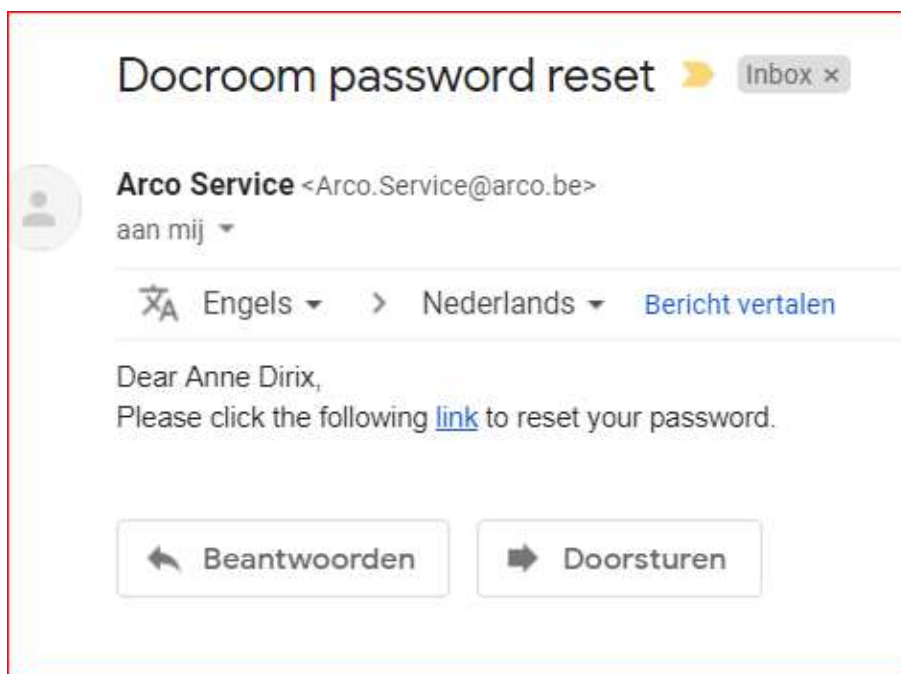
The image shows a login window for Dyco Flow. It features the Dyco Flow logo on the left. The main area contains a 'User name' field with the email 'annedirix.ad@gmail.com', a 'Code' field with a refresh button and a captcha image showing '91THL', and a 'Request' button at the bottom. A footer note states: 'Application developed by ARCO Information ©2000-2019. Loaded in 0.0444 seconds.'

3. A warning is sent out:



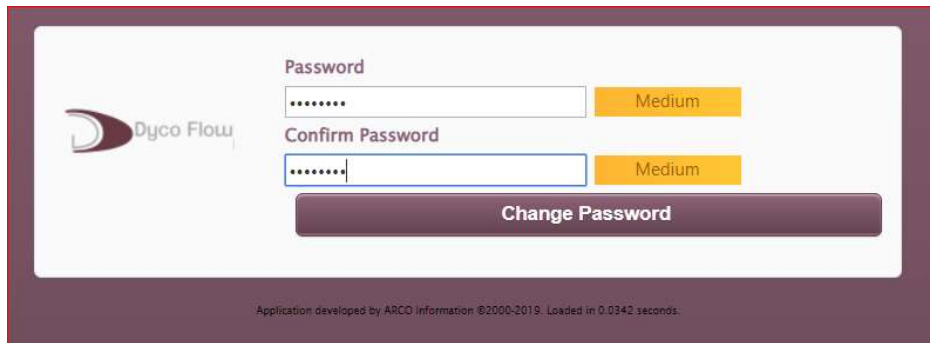
The image shows a warning message window. It contains the text: 'An e-mail has been sent to annedirix.ad@gmail.com, containing a link to reset your password.' The Dyco Flow logo is on the left. A footer note states: 'Application developed by ARCO Information ©2000-2019. Loaded in 1.1408 seconds.'

4. A notification is sent out:



The image shows an email notification window titled 'Docroom password reset'. It is from 'Arco Service <Arco.Service@arco.be>' to 'aan mij'. The email body says: 'Dear Anne Dirix, Please click the following [link](#) to reset your password.' At the bottom are two buttons: 'Beantwoorden' and 'Doorsturen'. The window also shows language options: 'Engels' and 'Nederlands', and a 'Bericht vertalen' link.

5. Reset the password:



The screenshot shows a web interface for resetting a password. On the left is the 'Dyco Flow' logo. The main form has two input fields: 'Password' and 'Confirm Password', both containing six dots. To the right of each field is a yellow button labeled 'Medium'. Below these fields is a large, dark purple button labeled 'Change Password'. At the bottom of the interface, a small line of text reads: 'Application developed by ARCO information ©2000-2019. Loaded in 0.0342 seconds.'

3 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_cvxoo1kGKJjODNs

- 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:

Action	Submitter	Principal Investigator	Head of Department
Fill in registration form	X		
Open/Read registration form	X	X	X
Change registration form	X		
Sign registration form		X	X
Submit documents	X		
Remove documents	X		
Documents correction	X	X	
View documents	X	X	X
Complete folder	X		
Add comments	X	X	X
Send dossier to CTC	X		

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.

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

 **UZB Dyco Flow** <no_reply_uzb_Dyco_Flow@digidyco.com> di 12 jan. 08:28 (23 uur)
aan klara.godderis, DycoFlowUZB ▾

Engels ▾ > Nederlands ▾ [Bericht vertalen](#)

Dear Klara 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

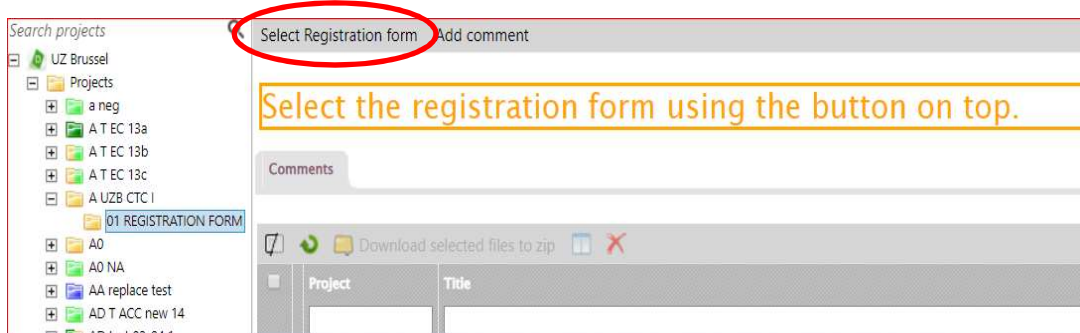


4 PROJECT IN UPLOAD BY SUBMITTER

→ Login User: Submitter

1. Select the registration form:

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



Now 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:

The screenshot shows the registration form with tabs: 0. Project info A, 1. Project info B, 2. Medical Ethics Committee, 3. Participants, 4. Recruitment and informed consent, 5. Project progress. The main content area is titled "Fill in all fields and click Send for Signature". It includes sections for "Registration Form type" (Interventional with medical product/medical device), "Principal investigator (project responsible)" (UZB PI, UZB HO), "Sub-investigator" (Name, Profile, GCP certificate (valid till)), "Contact for the study" (Name, E-mail, Phone number), "Project short name", "Project number", "Medical device?" (Yes/No), "Where is this project registered?" (a) clinicaltrialsregister.eu, (b) ClinicalTrials.gov, (c) Other, "Does one of the (co-) investigators involved in this research have a direct or indirect (financial) interest in this research?" (Yes/No), "Does any of the other employees involved in this research (eg study coordinators, data managers,...) have a direct or indirect (financial) interest in this research?" (Yes/No), "Goal of the experiment (maximum 2000 characters)", and "Summary of the project (maximum 2000 characters)".

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

To add a sub-investigator: click on  and complete the required information.

The screenshot shows the "Sub-investigator" form with fields for Name (Danny Vinck), Profile (Physician), and GCP certificate (valid till) (30-08-2020).

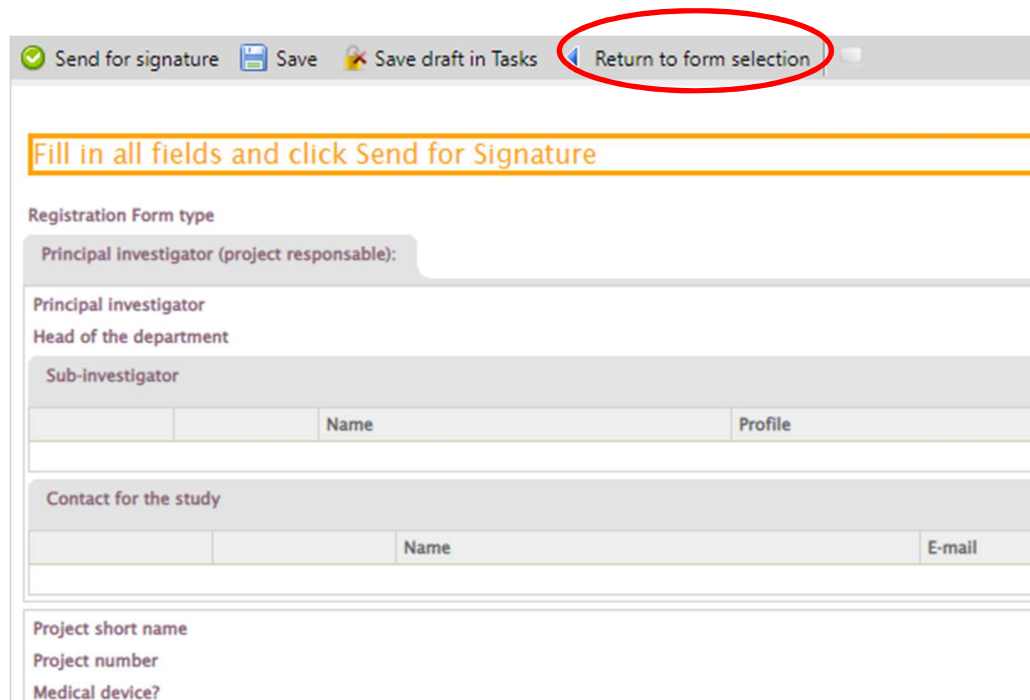
Don't forget to add the requested information for the contact person.

The screenshot shows the "Contact for the study" form with fields for Name (Klara), E-mail (klara.godderis@uzb.be), and Phone number (001).

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

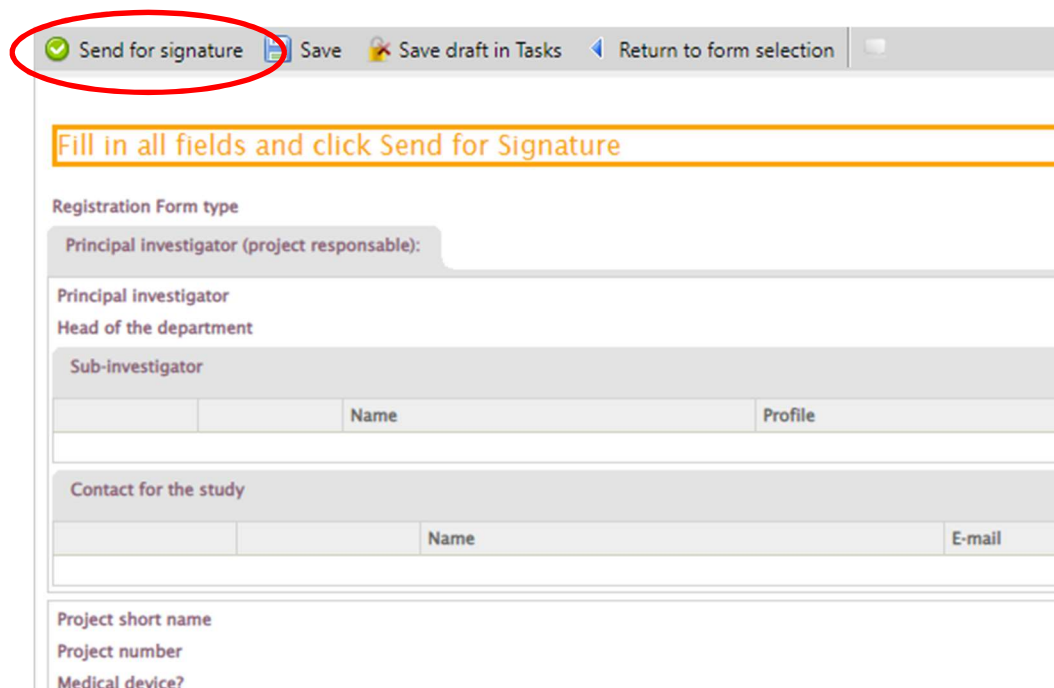
The screenshot shows the "Extra documents" section with a "Title" field and a "Required document for the EC submission per study type" section. Below this, the "Support" tab is highlighted in the navigation bar, and the "Support" section is visible at the bottom of the window.

In case the wrong registration form has been chosen , the Submitter can click on “Return to form selection” in the light grey bar.



The screenshot shows a web interface for a registration form. At the top, there is a light grey bar containing four buttons: "Send for signature" (with a green checkmark icon), "Save" (with a floppy disk icon), "Save draft in Tasks" (with a red X icon), and "Return to form selection" (with a blue left-pointing arrow icon). The "Return to form selection" button is circled in red. Below this bar is an orange banner with the text "Fill in all fields and click Send for Signature". The form itself is titled "Registration Form type" and contains several sections: "Principal investigator (project responsible):" with a sub-section for "Principal investigator" and "Head of the department"; "Sub-investigator" with a table for "Name" and "Profile"; "Contact for the study" with a table for "Name" and "E-mail"; and a bottom section for "Project short name", "Project number", and "Medical device?".

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.

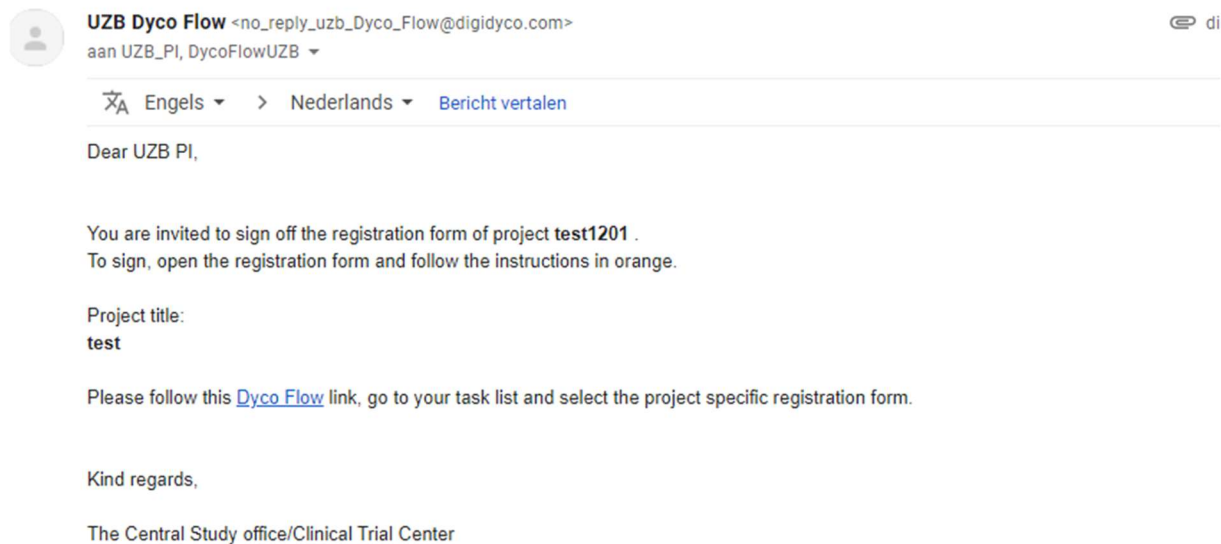


This screenshot is identical to the one above, showing the same registration form interface. However, in this version, the "Send for signature" button in the top light grey bar is circled in red, indicating the next step in the process.

5 SIGNING PROCESS PRINCIPAL INVESTIGATOR / HEAD OF DEPARTMENT

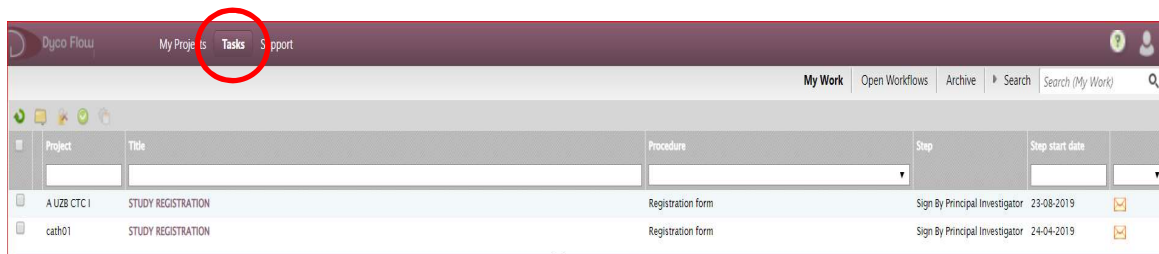
The PI and the HD receive an email from Dyco Flow to invite them to sign the registration form.

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



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.

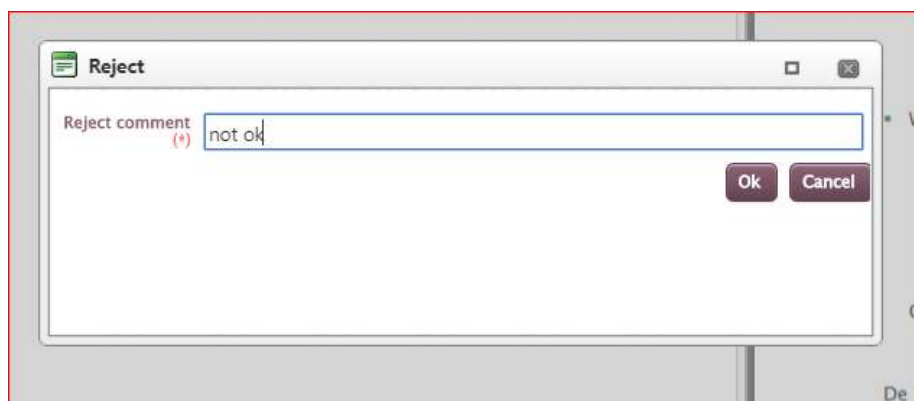
Important: The **following reason** is chosen by the PI when signing the registration form:

- **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(N)
Voor gezien en 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

The screenshot shows a web browser window with the URL `vmdevdona6.arco-information.com/DocRoomDycoFlow_UZB/dm_detail.aspx?RTCASE_TECH_ID=133256&folderid=0&caselist=133256;69304;69277;23128;20421&fromarchive=N&mode=2&SITE=Default&rnd_str=0...`. The browser's address bar shows 'Not secure'. The page has a top navigation bar with 'Sign', 'Refuse', and 'Save draft in Tasks' buttons. A yellow box highlights a message: 'You are invited to review and sign the registration form. If you approve, use the sign button. If you don't approve, insert a comment via the refuse button on top.' Below this is a 'Comments' section with a text area and a 'Sign By Department Responsible' button. The main content area shows a PDF document titled 'STUDY REGISTRATION.pdf' with the VUB logo and text: 'ADVIESAANVRAAG AAN DE COMMISSIE MEDISCHE ETHIEK WET BETREFFENDE HET ONDERZOEK OP EMBRYOS IN VITRO'. At the bottom, it says: 'Enkel volledig ingevulde formulieren worden aanvaard Gelieve in te vullen of aan te klikken in de grijze zones'.

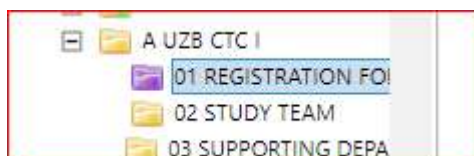
HD clicks on “Refuse” and fills in the reason for rejection (see part “To refuse the form” by PI):

The screenshot shows a 'Reject' dialog box with a title bar. Inside, there is a text field labeled 'Reject comment (*)' with the text 'not ok' entered. To the right of the text field are two buttons: 'Ok' and 'Cancel'.

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.

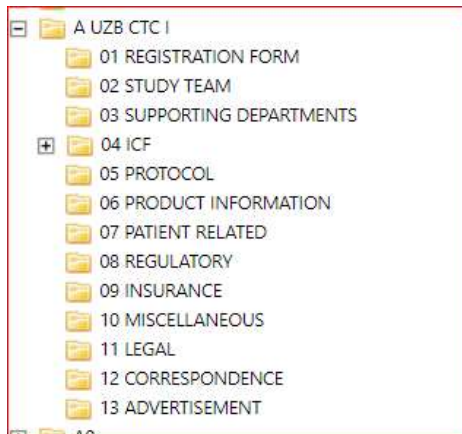
Once all signatures are in place, the folder 01 Registration form turns PURPLE .



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:

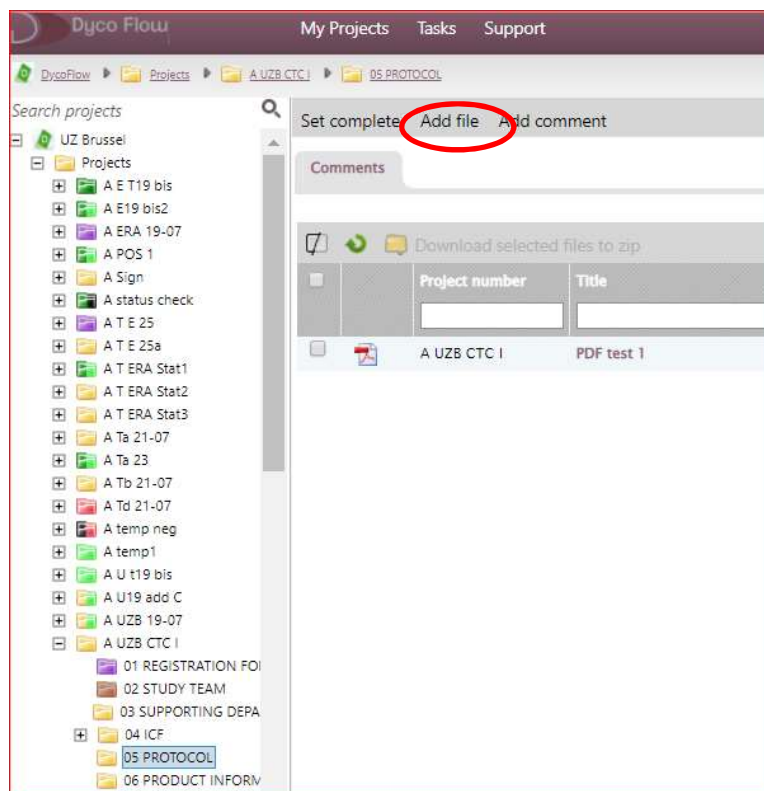
Click on a folder from 02-13 to upload documents.


Do not forget to consult the supporting documents

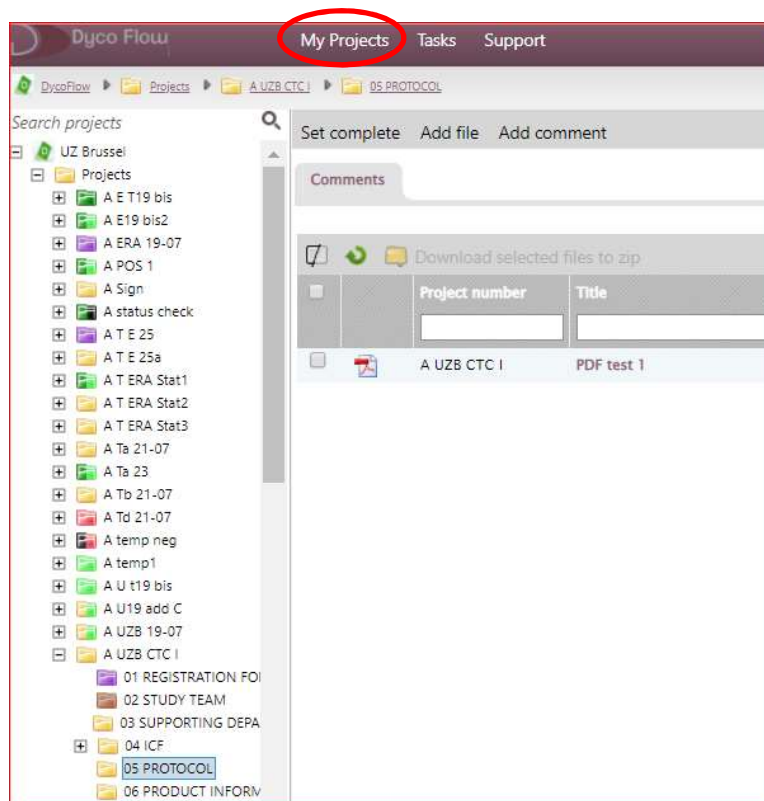
- “Required documents for the EC submission per study type”
- “Documents per folder”

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.

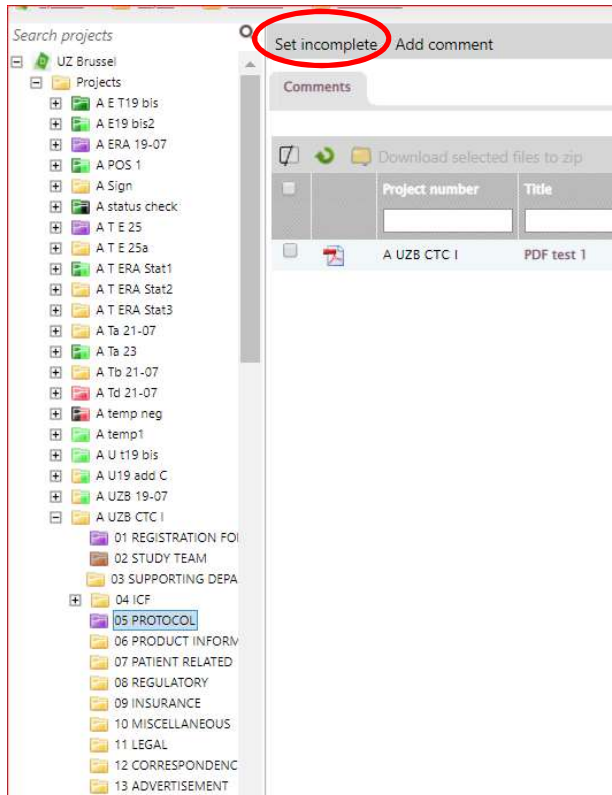



Once all the documents have been uploaded in their relevant folder, click on “Set complete”. The folder will turn PURPLE .

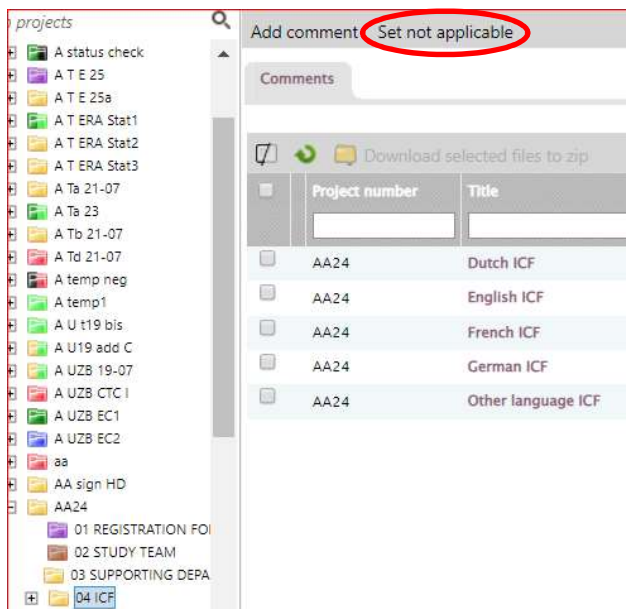


In case an extra document needs to be uploaded the Submitter can click on “Set incomplete” and add the extra file.

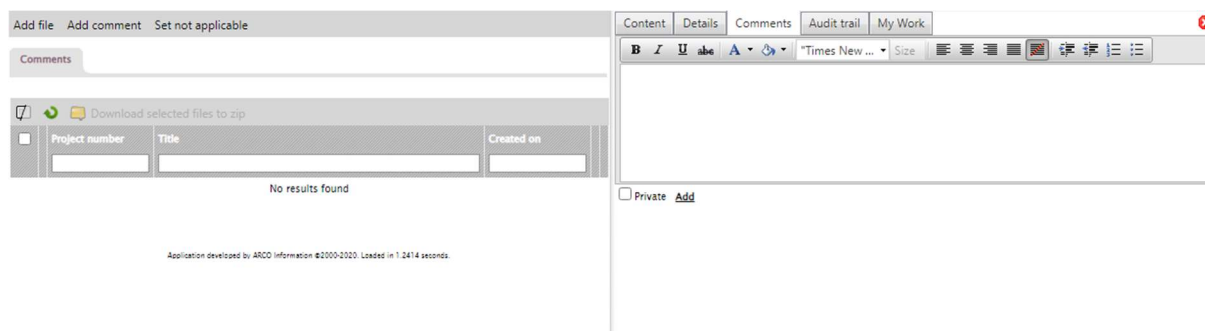
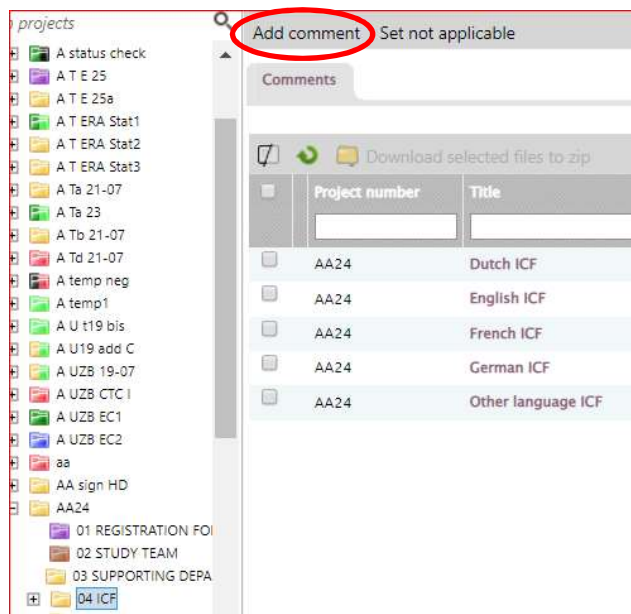
Do not forget to click again on “Set complete” afterwards (folder turns PURPLE ).



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.

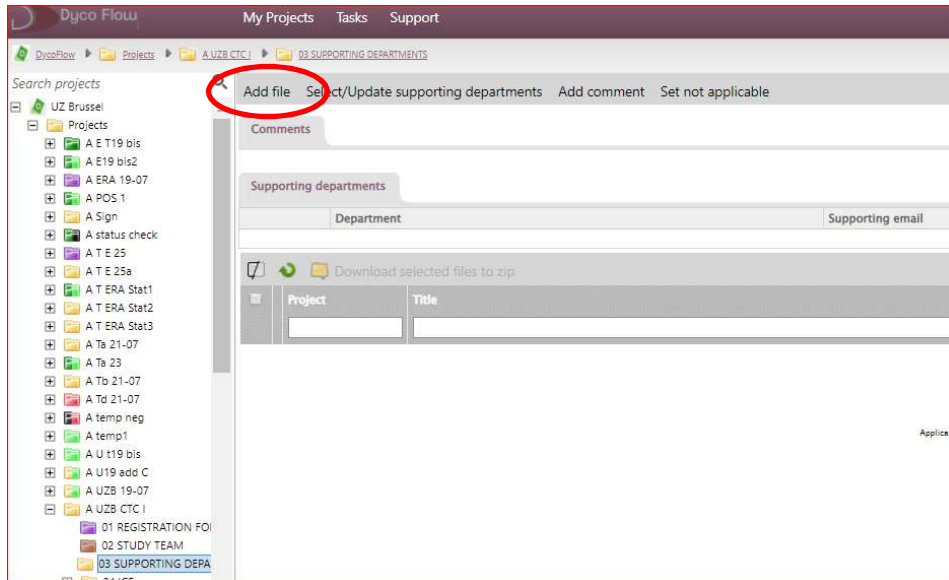


2. Special folders

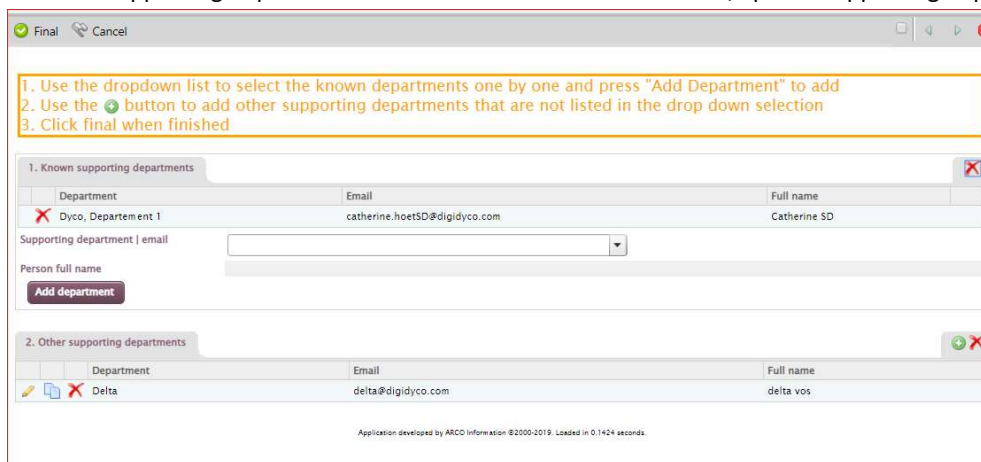
- Folder 03: Supporting departments.

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”.



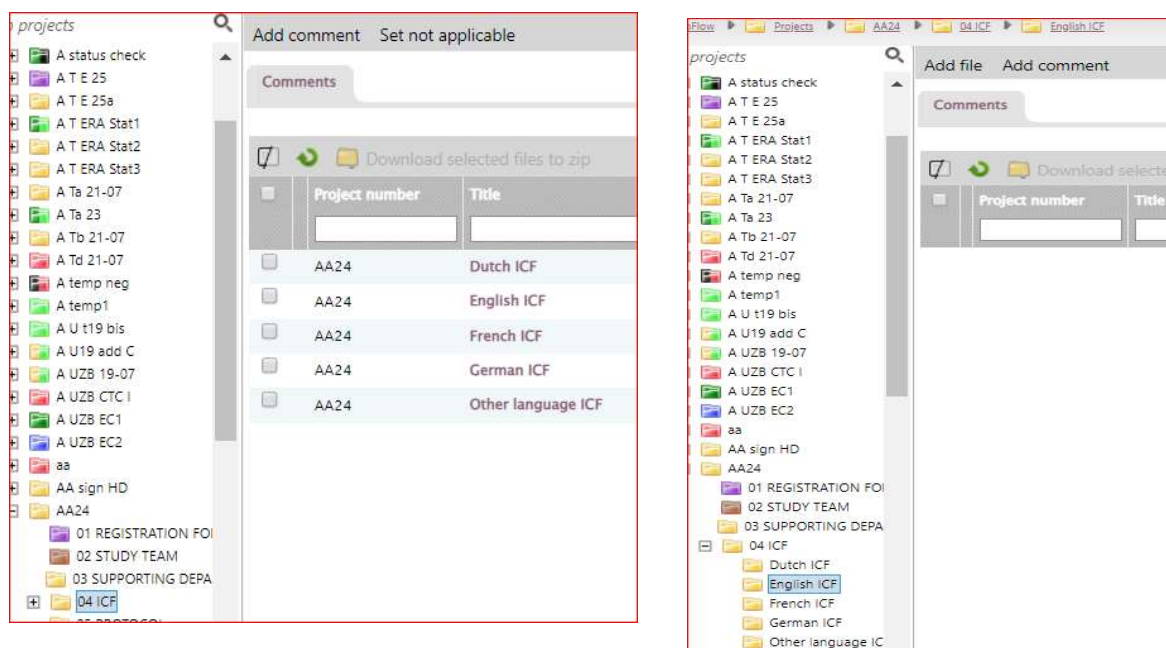
To add a supporting department the Submitter can click on “Select/update supporting departments”.




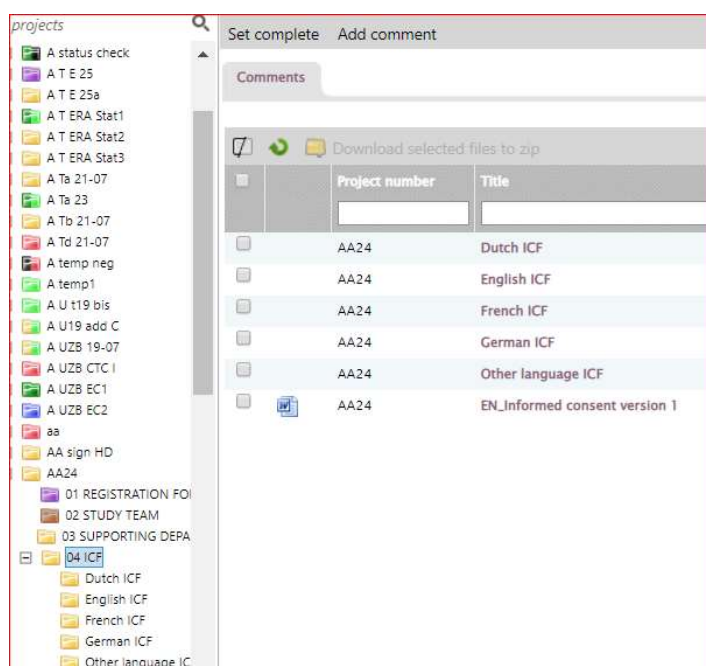
Here the Submitter can either select one of the supporting departments from the scroll list or can add an extra supporting department.



- Folder 04: ICF

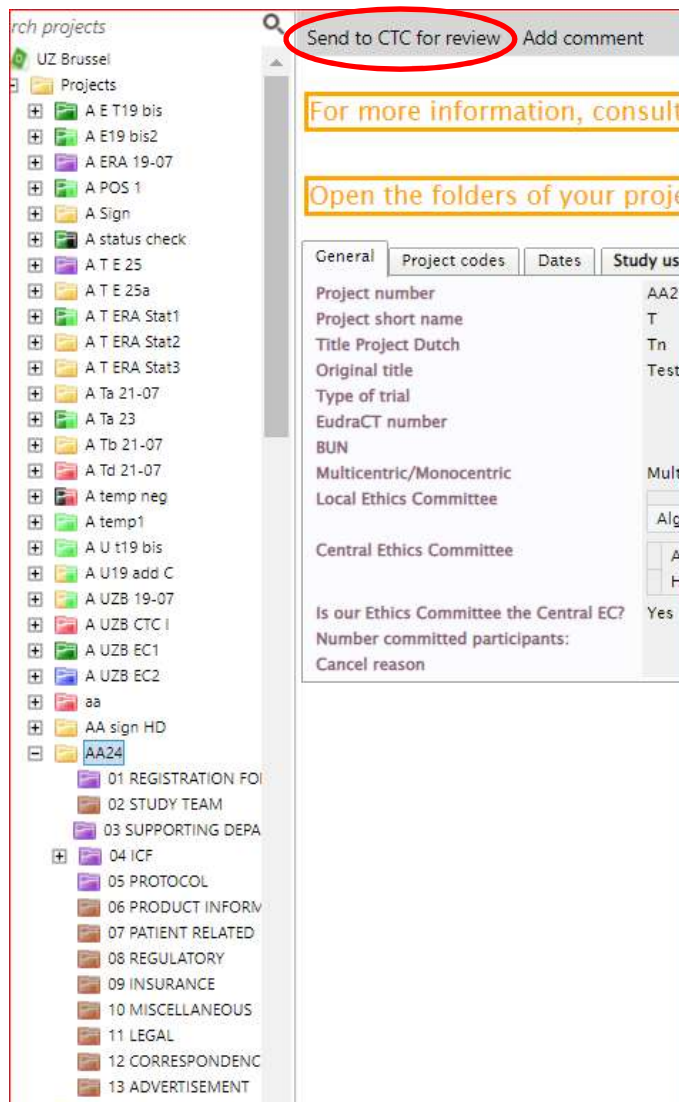
Before adding files, select one of the subfolders. Then click on “Add file” and upload the document.



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.

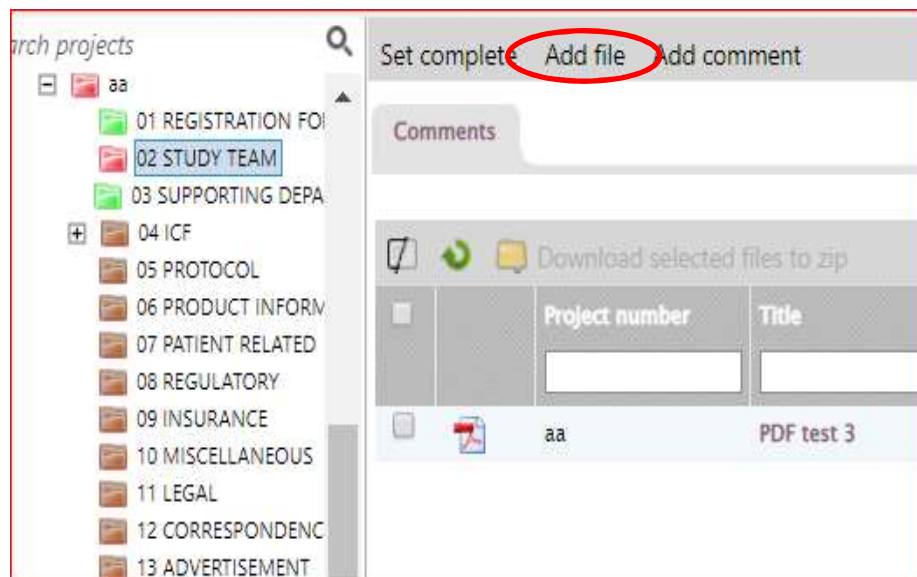
After review by the CTC the study will either be returned to the Submitter with some comments or items that need to be modified/uploaded. Or the study will be sent directly to the EC when it is validated as complete by the CTC.

7 PROJECT RETURNED TO SUBMITTER FOR ACTION

→Login User: Submitter

Click on the RED  folders.

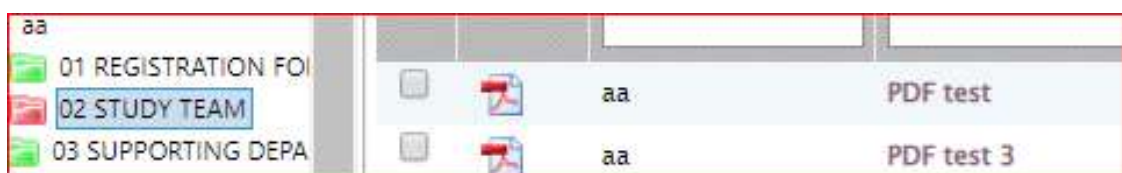
1. Read the comments on the top of the window, comply with the request.
 - a. **To respond to the comments:** click on “Add comment”.
 - b. **To upload a new document:**



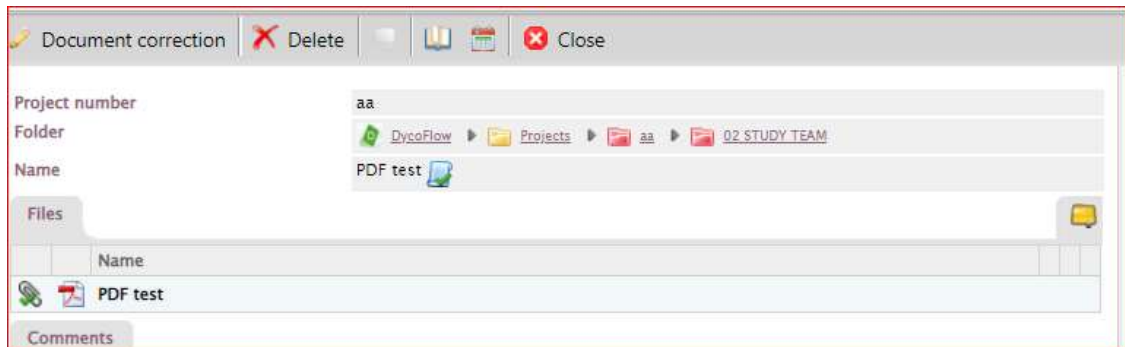
- Click on “Add file” in the folder menu (grey).
- Click on “Select” to select your document.
- Click on “Add”.
- Click on “Save & Close”.

- c. **To replace a document:**

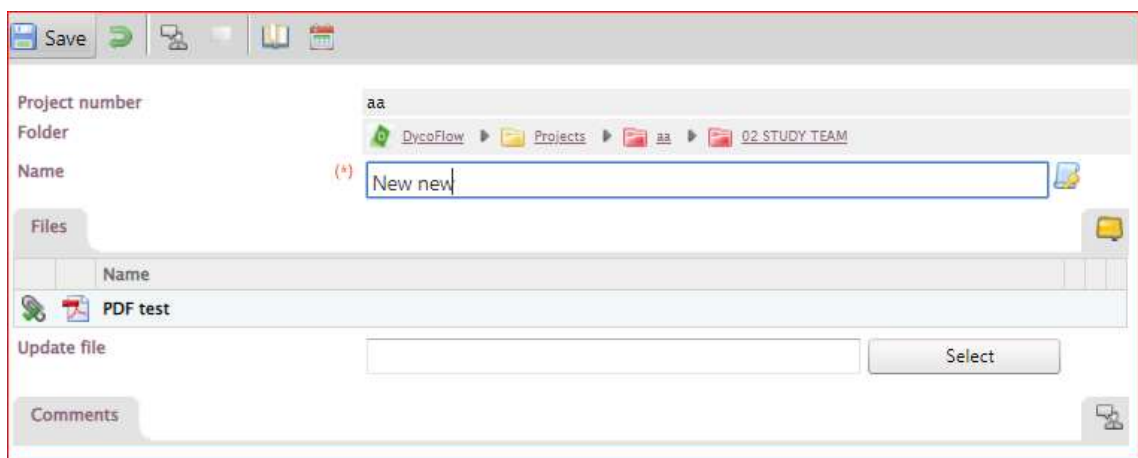
- Click on the original document.




- Click on “Document correction”.



- 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 .

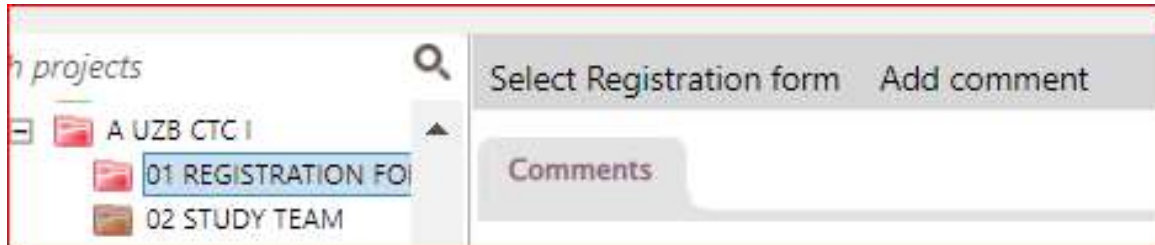


d. **To replace the registration form**


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.

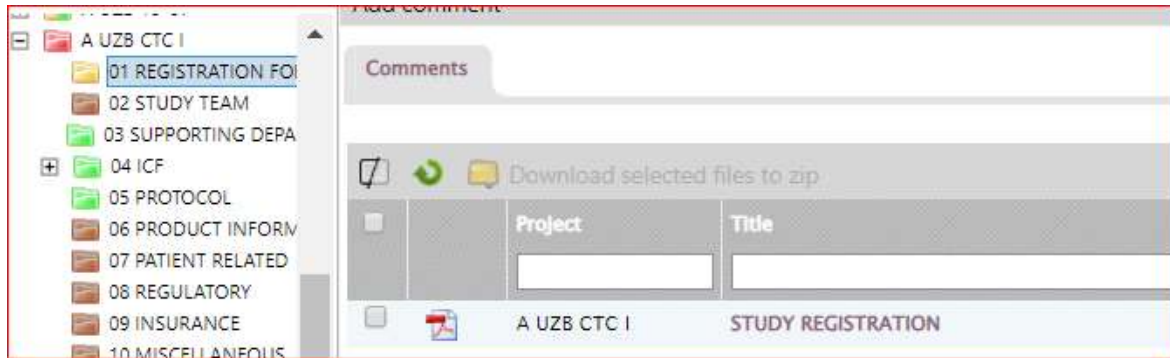
First the Submitter must remove the old registration form via “Remove registration form”.


- The Submitter clicks on “Select registration form”

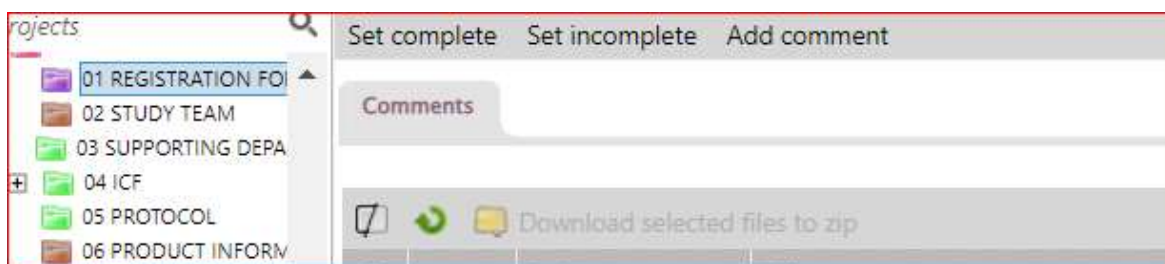


- The Submitter selects, opens, completes the new form and can then “Send for signature”



- Folder 01 Registration form turns YELLOW .

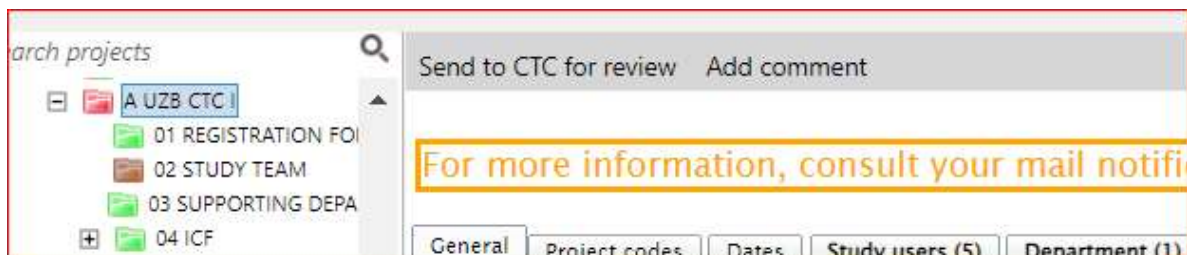






- After completion of the signing process, the folder 01 Registration form turns PURPLE .



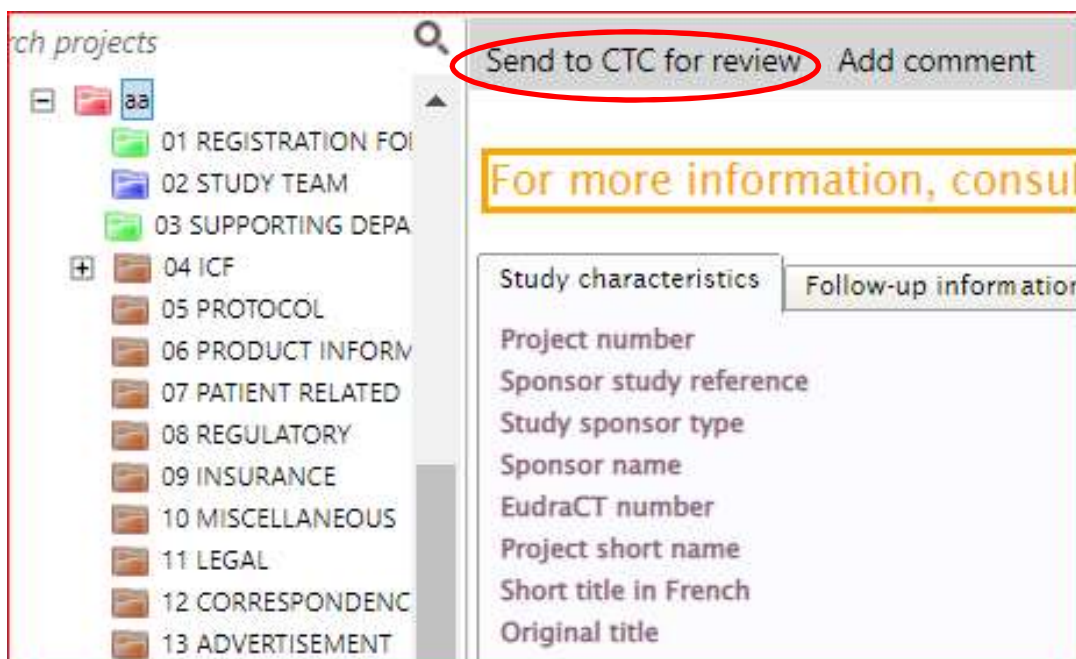
- The Submitter can select “Set complete” or “Set incomplete”.

- After selection “Set complete”, folder 01 Registration form turns GREEN  and not BLUE .



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.

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. 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

Dyco Flow-INFO: project test0812 was reviewed by CSO and sent to EC for review.



UZH Dyco Flow <no_reply_uzb_Dyco_Flow@digidyco.com>
aan klara.godderis, DycoFlowUZH ▾

vr 8 jan

 Engels ▾ > Nederlands ▾ [Bericht vertalen](#)



Dear Klara Godderis,

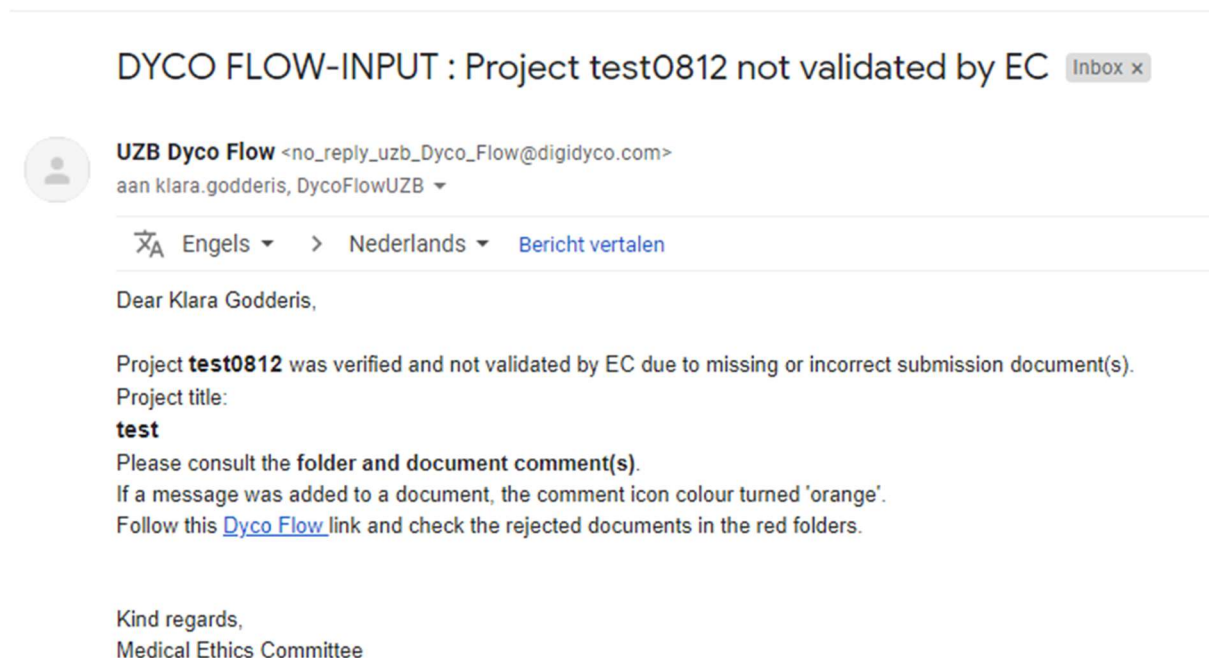
The Central Study office has validated the documents of Project **test0812** and the dossier has been sent to the EC for review.


Project title:
test
Reference number: test0801

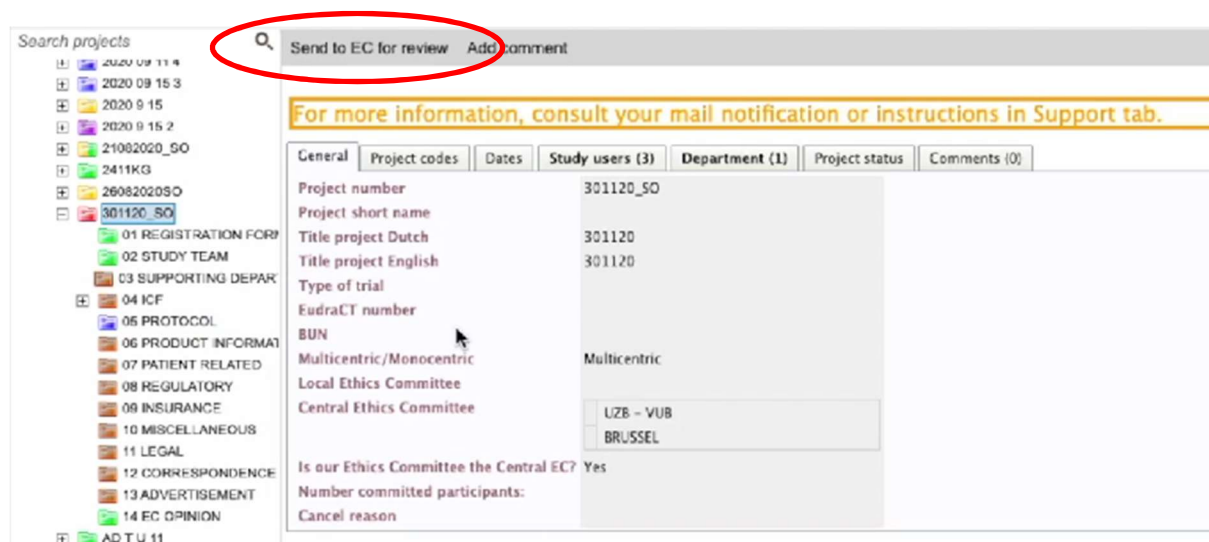
Kind regards,

The Central Study office/Clinical Trial Center


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 .

DYCO FLOW-INPUT : Project test0812 validated by EC – AOR uploaded

 **UzB Dyco Flow** <no_reply_uzb_Dyco_Flow@digidyco.com>
aan klara.godderis, DycoFlowUzB ▾

🌐 Engels ▾ > Nederlands ▾ [Bericht vertalen](#)

Dear Klara Godderis,

Project **test0812** has been validated.

EC meeting date: 2021-01-12

Please consult the Acknowledgement of Receipt in folder 14 EC OPINION.

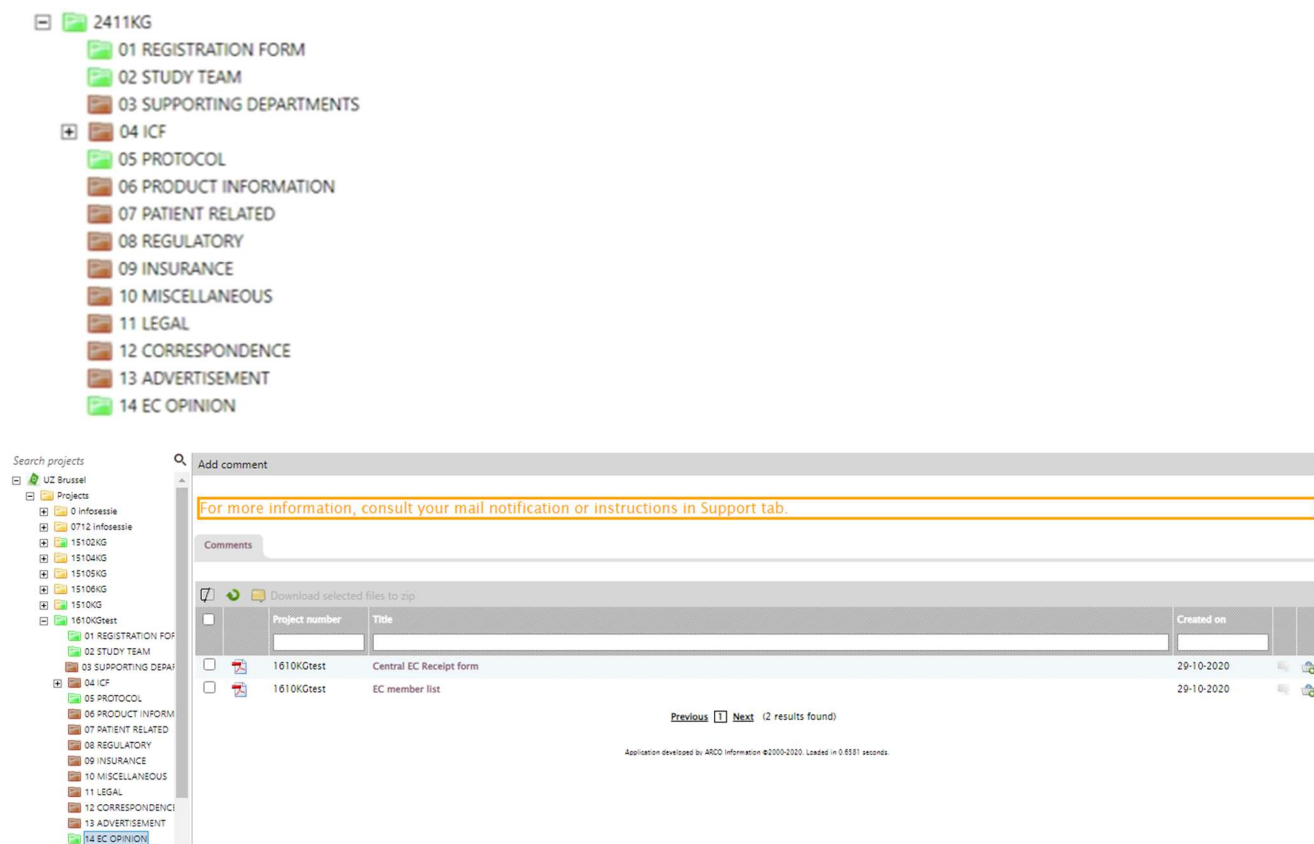
Project title:

test

Follow this [Dyco Flow](#) link to access the project.

Kind regards,
Medical Ethics Committee

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



The screenshot displays the Dyco Flow web application. On the left, a sidebar shows a folder structure for project '1610KGtest'. The folders are numbered 01 to 14, with folder 14 'EC OPINION' highlighted in light green. The main content area shows a table of documents uploaded to folder 14. A yellow box highlights a message: 'For more information, consult your mail notification or instructions in Support tab.'

	Project number	Title	Created on
<input type="checkbox"/>	1610KGtest	Central EC Receipt form	29-10-2020
<input type="checkbox"/>	1610KGtest	EC member list	29-10-2020

Navigation links: [Previous](#) [Next](#) (2 results found)

Application developed by ARGO Information ©2000-2020. Loaded in 0.6581 seconds.

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

Add comment

Comments




Download selected files to zip

	Project number	Title	Created on
<input type="checkbox"/>	test1911	Authorization EC Preliminary advice with remarks	19-11-2020
<input type="checkbox"/>	test1911	Central EC Receipt form	19-11-2020
<input type="checkbox"/>	test1911	EC member list	19-11-2020

[Previous](#) [Next](#) (3 results found)

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.

Search projects

Send to EC for review Add comment

For more information, consult your mail notification or instructions in Support tab.

General	Project codes	Dates	Study users (3)	Department (1)	Project status	Comments (0)
Project number	301120_SO					
Project short name						
Title project Dutch	301120					
Title project English	301120					
Type of trial						
EudraCT number						
BUN						
Multicentric/Monocentric	Multicentric					
Local Ethics Committee						
Central Ethics Committee	UZB – VUB BRUSSEL					
Is our Ethics Committee the Central EC?	Yes					
Number committed participants:						
Cancel reason						

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”.

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.

Add comment

For more information, consult your mail notification or instructions in Support tab.

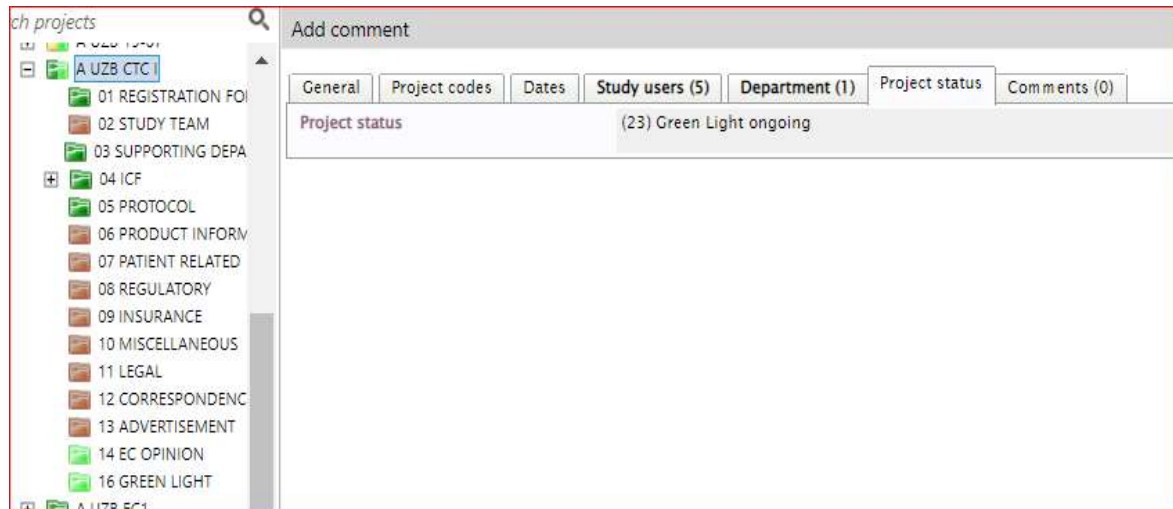
Comments

  Download selected files to zip

<input type="checkbox"/>	Project number	Title	Created on	
<input type="checkbox"/>	test2910	Authorization EC Preliminary advice with remarks	17-11-2020	
<input type="checkbox"/>	test2910	Authorization EC Single opinion positive advice	17-11-2020	
<input type="checkbox"/>	test2910	Central EC Receipt form	29-10-2020	
<input type="checkbox"/>	test2910	EC member list	17-11-2020	

[Previous](#) [Next](#) (4 results found)

→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:

The 'Sign' window displays a form for completing the 'Green Light' task. The form includes the following fields and options:


- EC number:** EC-2019-031
- Original title:** TEST
- Approval dates and status:**
 - Approved by the (Leading) Ethics Committee (CME) on: 23-08-2019
 - Approved by the FAMHP (FAGG): ☒ Not applicable ☐ Yes
 - Registered on www.clinicaltrials.gov: ☐ Not applicable ☐ Other ☐ Yes
- Signatures and dates:**
 - Clinical trial agreement signed by all parties and by the CEO of UZ Brussel: ☒ Not applicable ☐ Yes
 - Initiation meeting taken place on: 26-08-2019
 - Financial disclosure form signed: ☒ Not applicable ☐ Yes
 - IMP is available at the site: ☒ Not applicable ☐ Yes
 - IVRS is in place: ☒ Not applicable ☐ Yes

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 .

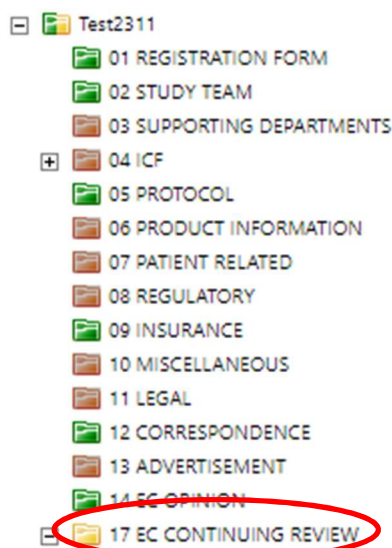


An email from Dyco Flow will be sent to confirm that the study can start at the study site.

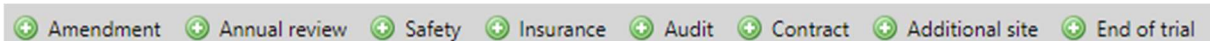


14 CONTINUING REVIEW

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.

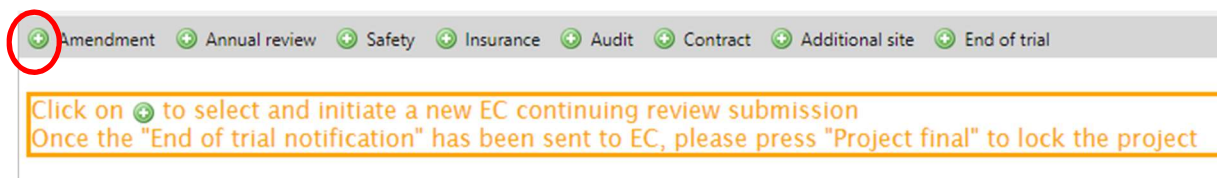


Different types of documents can be uploaded here:



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.

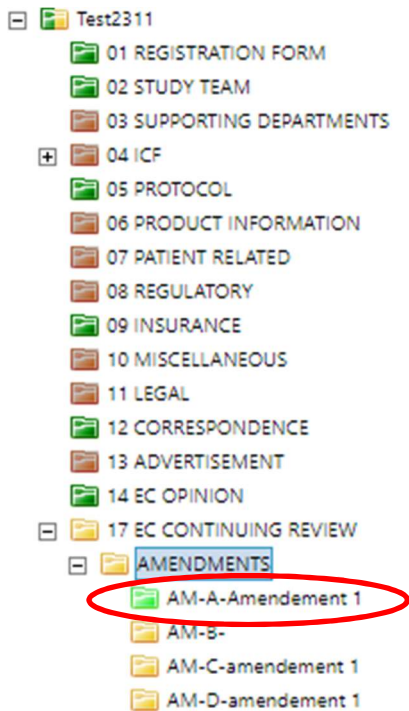


The following screen will appear:

Project number	Test2311		
EC continuing review type	AMENDMENTS	EC continuing review type code	AM
Sequence	D		
Name new subfolder	(*) <input type="text"/>		

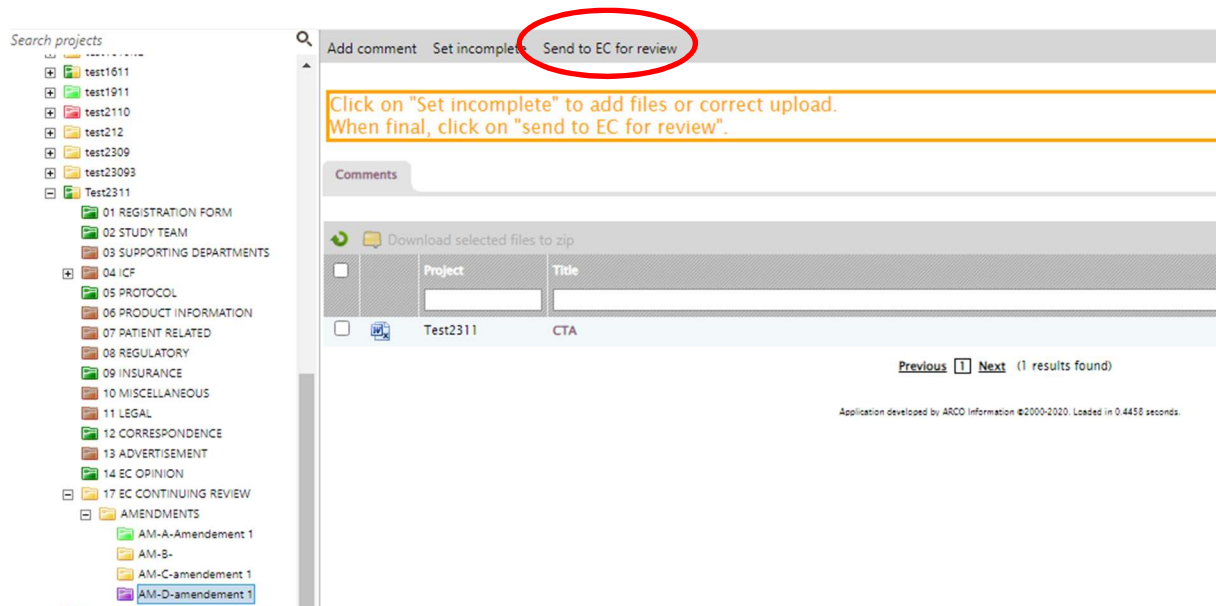
The system automatically creates a sequence number. The first amendment will be coded AM-A, the 2nd amendment will be called AM-B. Following this sequence the name of this new subfolder (e.g. the version of the Amendment) can be indicated. After adding the name, click on create.


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.

Dyco Flow-INFO :A final EC continuing review of Project Test 14122020 has been uploaded Inbox x



UZB Dyco Flow <no_reply_uzb_Dyco_Flow@digidyco.com>
aan UZB-PI, DycoFlowUZB

do 7 jan. 09:36 (5 dagen geleden) ☆ ↶ ⋮

Engels > Nederlands Bericht vertalen

Uitschakelen voor: Engels x

Dear UZB PI,


A final EC opinion related to **Continuing** review of Project **Test 14122020** has been uploaded.
The corresponding subfolder with the new documents is available.
This information requires no actions.

Project title:
Test 14122020

Follow this link [Dyco Flow](#) to access the project.

Kind regards,
Medical Ethics Committee



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 .

Search projects

- 2411KG
- 26082020SO
- 301120_SO
 - 01 REGISTRATION FOR
 - 02 STUDY TEAM
 - 03 SUPPORTING DEPA
- 04 ICF
- 05 PROTOCOL
- 06 PRODUCT INFORM
- 07 PATIENT RELATED
- 08 REGULATORY
- 09 INSURANCE
- 10 MISCELLANEOUS
- 11 LEGAL
- 12 CORRESPONDENCE
- 13 ADVERTISEMENT
- 16 GREEN LIGHT
- 17 EC CONTINUING R
- AMENDMENTS
 - AM-A-amenden
 - AM-C-protocol

Add comment

Comments

Download selected files to zip

	Project	Title
<input type="checkbox"/>	301120_SO	amendment Protocol V3 dd. 30 11 2020
<input type="checkbox"/>	301120_SO	Final template approval AM-A-amendment protocol

Previous 1 Next (2 results found)

Application developed by ARCO Information #2000-2020. Loaded in 0.4766 seconds.

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)

 Search projects

 Search documents

 **Search comments**

 Search project status

 Search project status

Search Projects


Project number

Project short name

Original title


PlannedInitiationDate

Exact



PlannedEndDate

Exact




ECIdentifier

Department

Sponsor name

Project status



Find

Search documents

All

Name

Project number

Find

Search comments

All

Comments

Project number

Find

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.

Dyco Flow	
My Projects Tasks Reports Support	
DycoFlow > E-Learning	
Title	Category
Contact Information Dyco Flow	Support
Insurance exceptions	Support
Study Team - Roles Responsibilities and Task Delegation	Support
GDPR	GDPR
Disable pop ups blocking in browsers	Support
Dyco Flow UZB user manual and video instructions	Support
GDPR checklist klinisch onderzoek FEB2021 Protected	Support
Documents per folder - 22FEB2022	Support
Vereiste documenten per studie 22FEB2022	Support
Human Material Request Form - Dyco Flow	Support
Previous 1 Next (10 results found)	
Application developed by ARCO Information ©2000-2022. Loaded in 0.9834 seconds.	

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.

Dyco Flow

My Projects

Tasks

Reports

Support

My Work

Open Workflows

Archive

Search

Search (My Work)

Project	Title	Procedure	Step	Step start date
A E T26	Update STUDY-A E T26	STUDY-MAIN-Folder - Update for admins	Update	28-07-2019
A T E 25a	Update users STUDY-A T E 25a	STUDY-MAIN-Folder - UsersTable Update	Update Users	25-07-2019
A Tc 21-21-07	Update STUDY-A Tc 21-21-07	STUDY-MAIN-Folder - Update for admins	Update	22-07-2019
	NEW STUDY created by Catherine CTC on 2019-06-16 16:28:26	STUDY-MAIN-Folder - Insert	Input Fields	16-06-2019
AA sign HD	STUDY REGISTRATION	Registration form	Fill Parameters CTC	06-06-2019
	NEW STUDY created by Catherine CTC on 2019-06-06 09:11:07	STUDY-MAIN-Folder - Insert	Input Fields	06-06-2019



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)

- o Cover letter
 - o Declaration of conflict of interest (if applicable)
 - o Publications/articles
 - o Copy FCE (Federale Commissie voor Embryo onderzoek) dossier - research on embryo's (if available)
 - o Human Material request form (if applicable)
 - o DMC Charter
 - o General Practitioner Letter
- 11 Legal**
- o Clinical Trial Agreement (draft versions allowed)
 - o Other agreements if applicable (e.g., Data transfer agreement, material transfer agreement)
 - o Budget
- 12 Correspondence**
- o Previous communication with CS/CME
 - o Correspondence between parties (if significant for the project)
- 13 Advertisement**
- o Flyer/project poster (recruitment documents)

17 APPENDIX II: COLOURS FOLDERS

Main folders

