

# DYCO FLOW USER INSTRUCTIONS

Version April 2024



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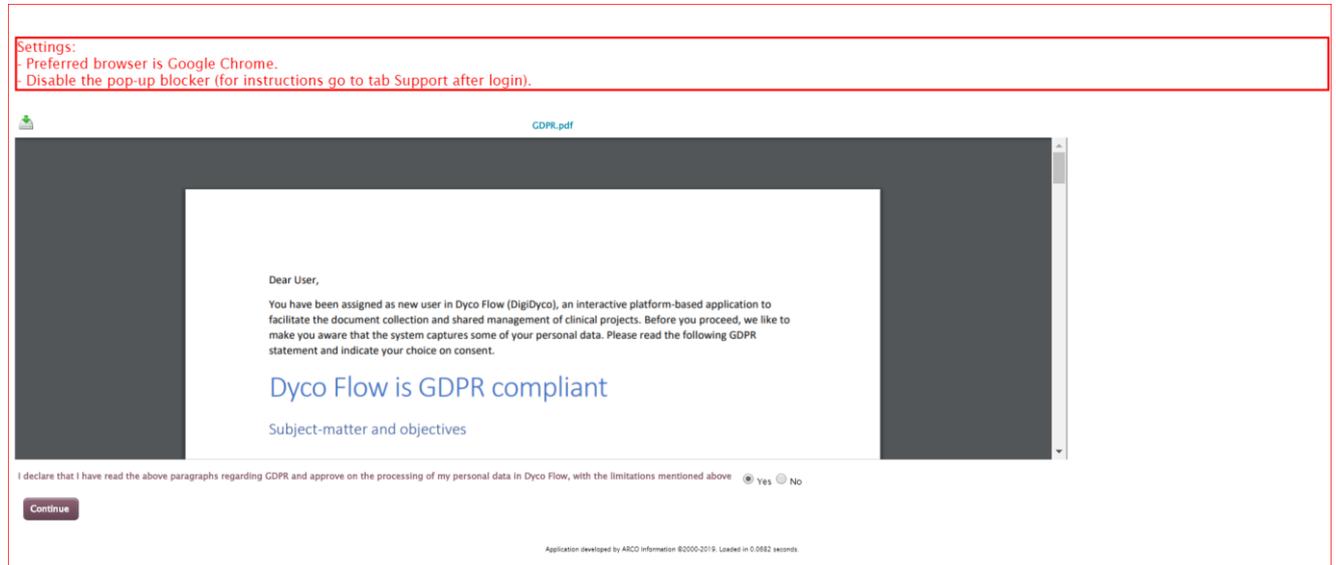
## 1 LOG IN DETAILS

Link received via email

Login = User name = your email

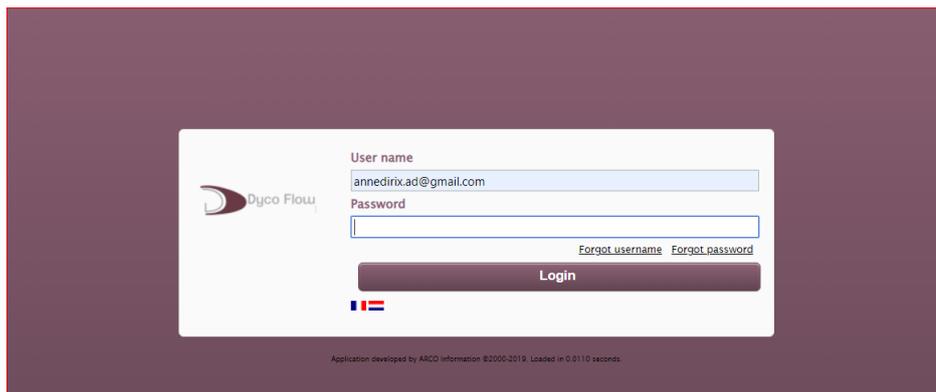
Password (PW): received by email, change upon first login

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:



User name  
annedirix.ad@gmail.com

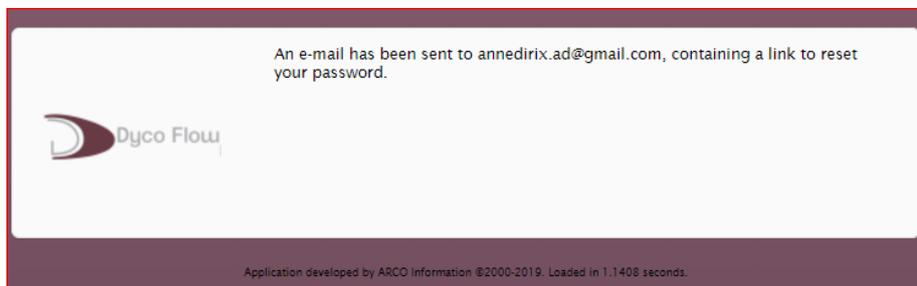
Code  
91THL

Refresh

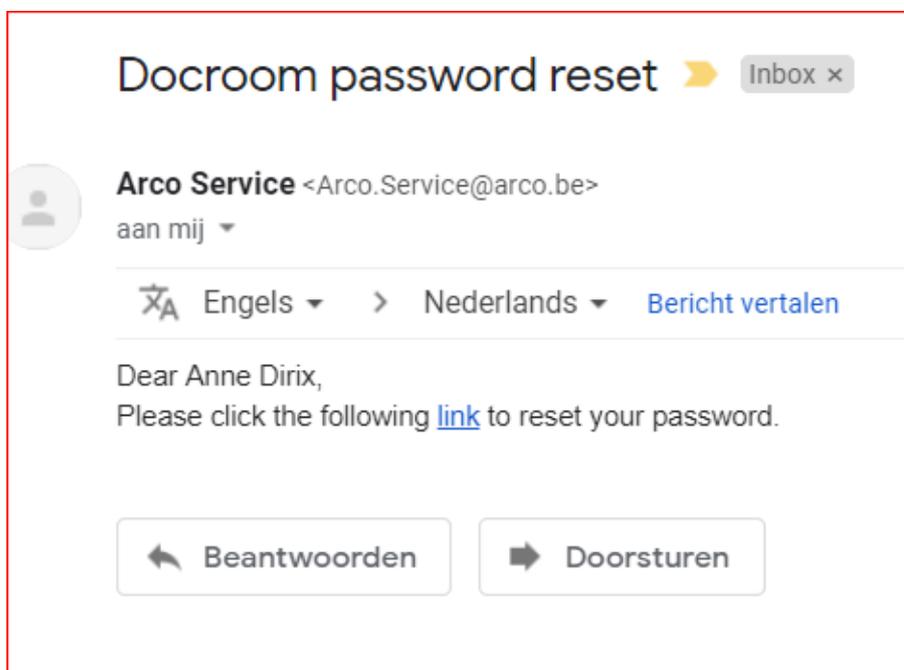
Request

Application developed by ARCO Information ©2000-2019. Loaded in 0.0444 seconds.

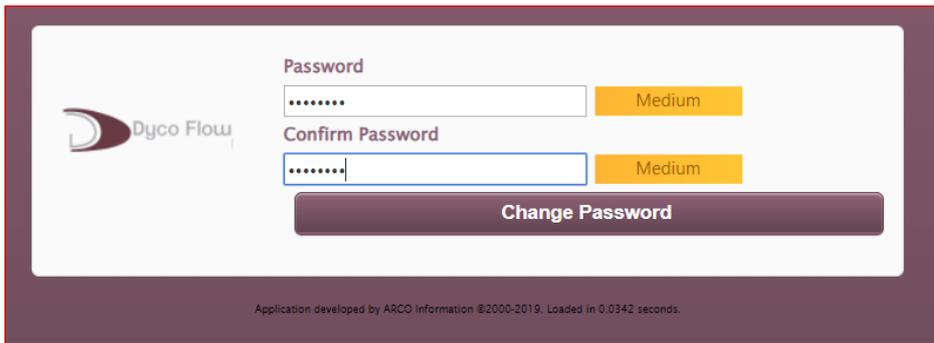
3. A warning is sent out:



4. A notification is sent out:



5. Reset the password:



### 3 RESET EXPIRED PASSWORD

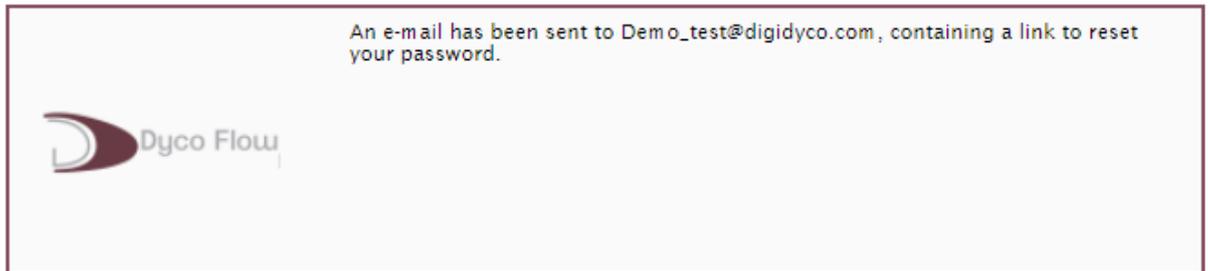
1. When user logs in with an expired password, he should click on 'Reset password forgotten/expired'



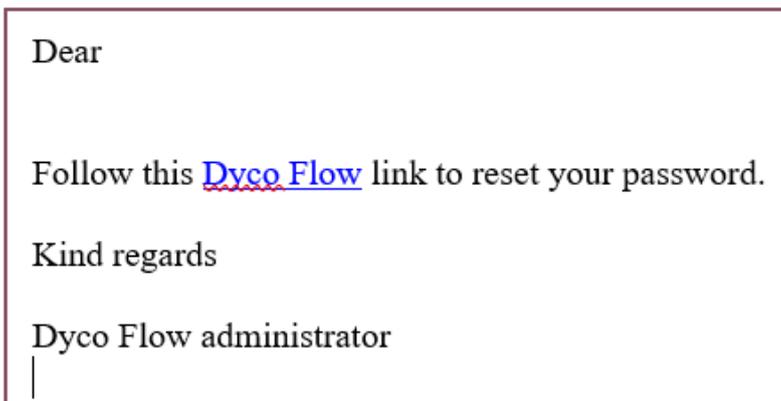
2. The user must complete the window below.



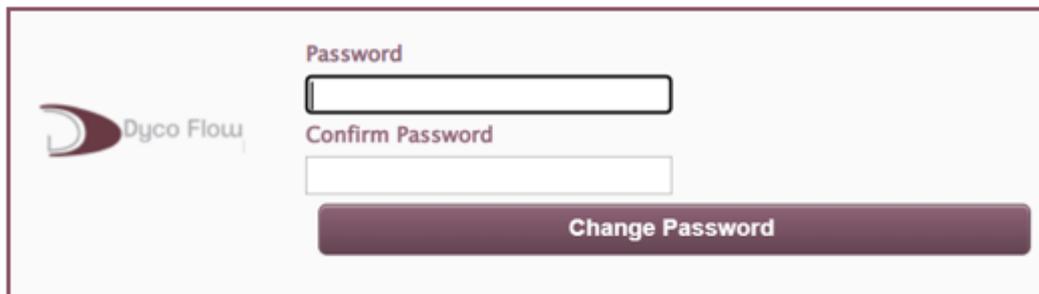
3. A message informing that an email with a link to rest the password, will be sent.



4. The user clicks on the 'Dyco Flow' link in the email.



5. A new pop-up window will allow the user to change his password.

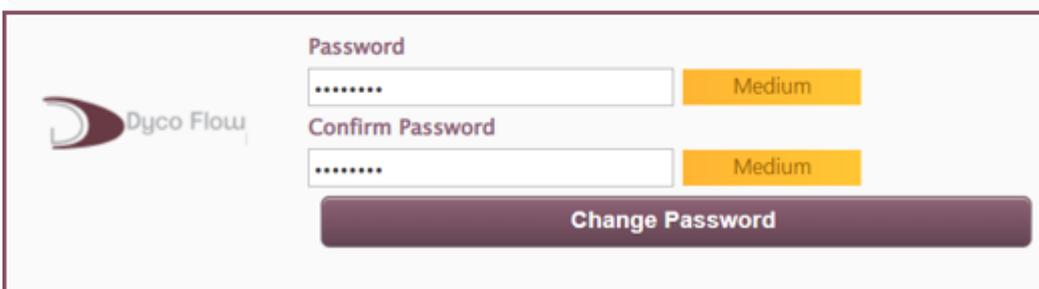


 Dyco Flow

Password

Confirm Password

**Change Password**



 Dyco Flow

Password  Medium

Confirm Password  Medium

**Change Password**

6. After changing the password, the user can login.

## 4 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, a webform has to be completed and submitted:

[https://vub.fra1.qualtrics.com/jfe/form/SV\\_cvxoo1kGKJjODNs](https://vub.fra1.qualtrics.com/jfe/form/SV_cvxoo1kGKJjODNs)

Information requested includes but is not limited to:

- 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>  
aan klara.godderis, DycoFlowUZB

di 12 jan. 08:28 (23 uur)

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,

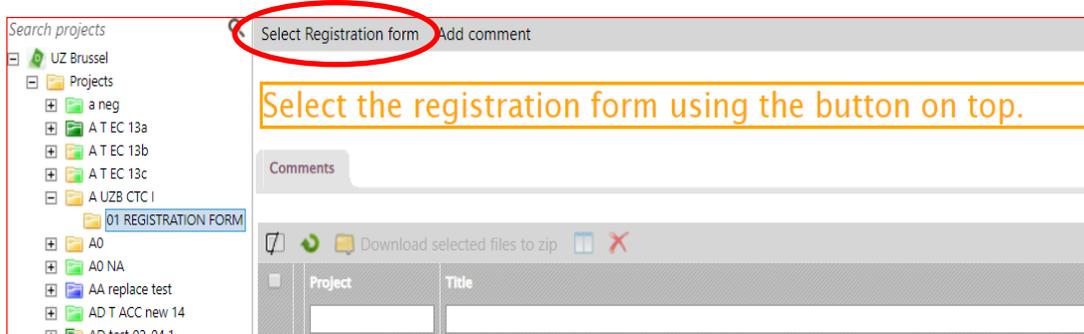
The Central Study office/Clinical Trial Center



→ 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”.



Complete the data and click on button "Open registration form"

Registration Form type (\*)

Select the Central Ethics Committee  (\*)

Select all Local Ethics Committees

Is our Ethics Committee the Central EC?

Application developed by ARCO Information ©2000-2020. Loaded in 0.8992 seconds.

**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:

0. Project info A	1. Project info B	2. Medical Ethics Committee	3. Participants	4. Recruitment and informed consent	5. Project progress
-------------------	-------------------	-----------------------------	-----------------	-------------------------------------	---------------------

Send for signature Save Save draft in Tasks Return to form selection

Fill in all fields and click Send for Signature

Registration Form type Interventional with medical product/medical device

Principal investigator (project responsible):

Principal investigator UZB PI

Head of the department UZB HD

Sub-investigator

Name	Profile	GCP certificate (valid till)
No Data Found.		

Contact for the study

Name	E-mail	Phone number
No Data Found.		

Project short name

Project number screenshots

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

0. Project info A | 1. Project info B | 2. Medical Ethics Committee | 3. Participants | 4. Recruitment and informed consent | 5. Project progress

Goal of the experiment (maximum 2000 characters)

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.

Name	Profile	GCP certificate (valid till)
 Danny Vinck	Physician	30-08-2020

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

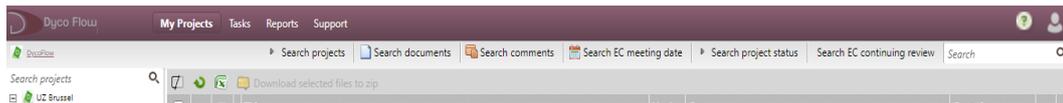
Name	E-mail	Phone number
 Klara	klara.godderis@uzl	007

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

Fill in all fields and click Send

Extra documents

Title
 Required document for the EC submission per study type



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

Name	Profile

Name	E-mail

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.

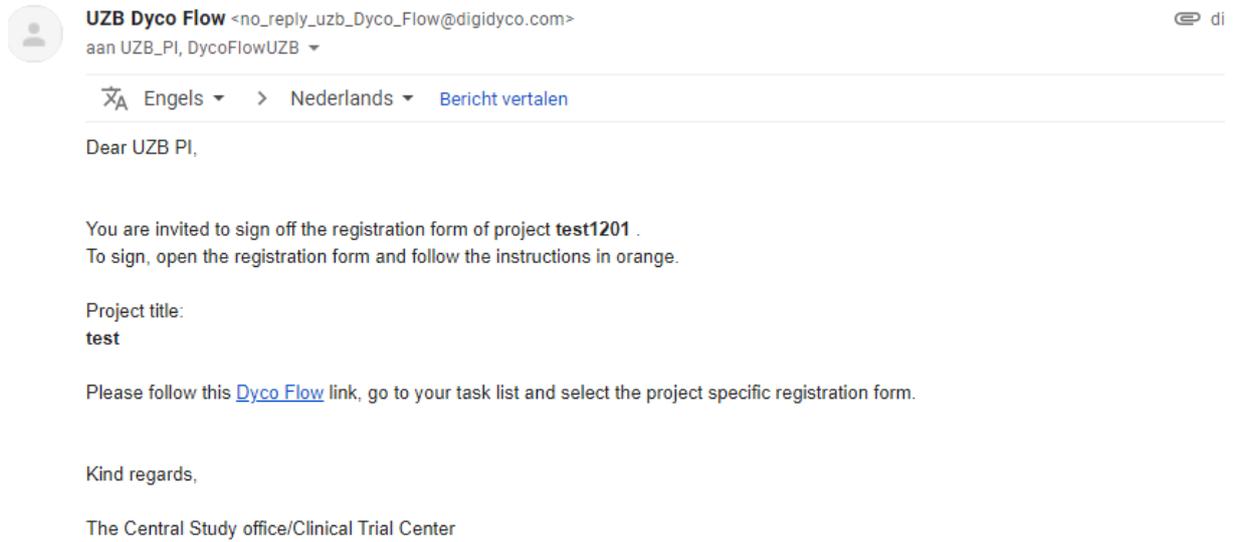
Name	Profile

Name	E-mail

## 6 SIGNING PROCESS PRINCIPAL INVESTIGATOR / HEAD OF DEPARTMENT

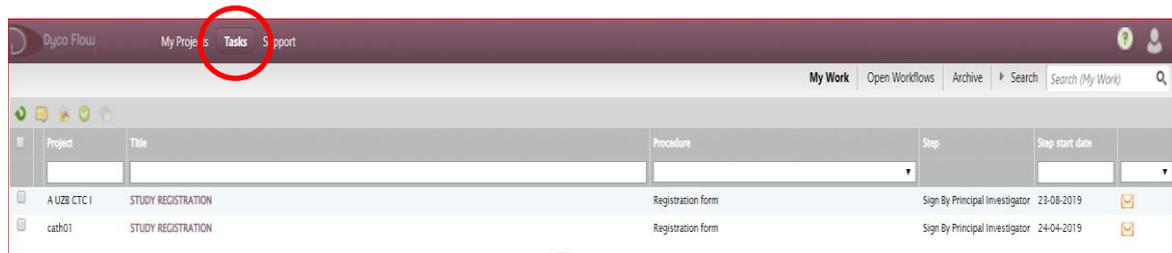
The PI and the HD receive an email from Dyco Flow to invite them to sign the registration form.

### 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.

Sign Refuse Save draft in Tasks

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.

Comments

Step Sign By Principal Investigator  
Project number screenshots

Application developed by ARCO Information #2000-2003. Loaded in 0.5143 seconds.

STUDY REGISTRATION.pdf

UZB  
UNIVERSITEIT ZIEKENHUIS BRUSSEL

ADVIESAANVRAAG AAN DE COMMISSIE MEDISCHE ETHIEK  
BETREFFENDE EEN PROJECT VOOR DOORNIEMING BIJ DE MENS

INTERVENTIONELE STUDIES met gebruik van  
een product of medical device

Hoofdonderzoeker (verantwoordelijke voor de studie):  
Naam : UZB PI  
Profiel : Arts  
GCP attest (geldig tot) 09/01/2021

Mede-onderzoekers:

Naam	Profiel	GCP attest (geldig tot)

Dienst en verantwoordelijke van de dienst:

Dienst	Verantwoordelijke van de dienst
Digidyco department 1	UZB HD

Externe Diensten:

Contactpersoon(en) voor de studie (bv. studiecoördinator, studieverpleegkundige of administratieve studiemedewerker):

Naam	Telefoonnummer	E-mailadres
Klara	007	klara.godderis@uzbrussel.be

javascript:GetContentWindow().ExecuteUserEvent(112199,false);

### 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

HOOFDONDERZOEKER  
Voor gezien en akkoord,

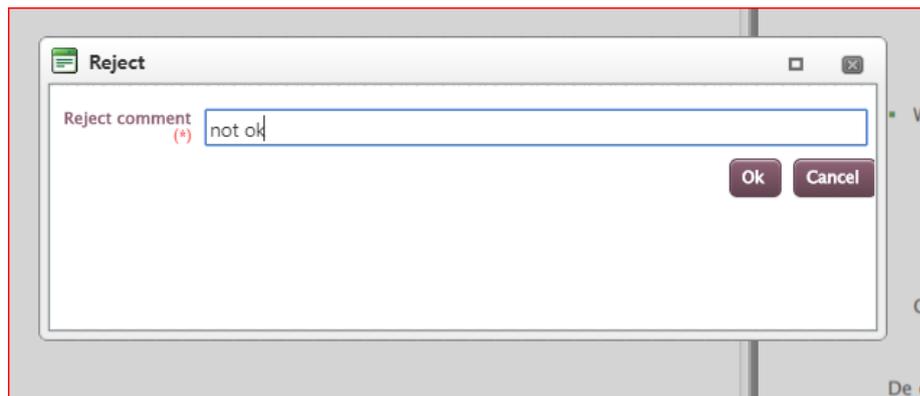
Titel, Naam, Voornaam	Handtekening	Datum

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

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**

<b>HOOFDONDERZOEKER</b> Voor gezien en akkoord,		
Titel, Naam, Voornaam	Handtekening	Datum
Electronically signed by Catherine PI on 23/08/2019 17:26:45 (reviewed and approved)		

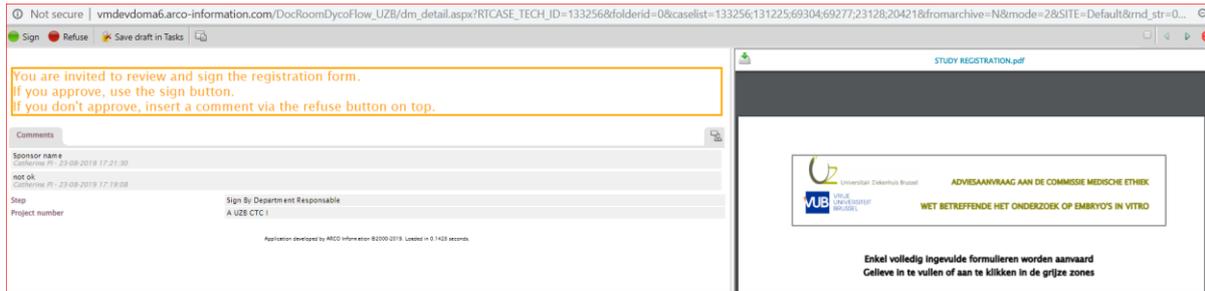
**DIENSTHOOFD(EN) of -VERANTWOORDELIJKE(N)**  
Voor gezien en akkoord,

Titel, Naam, Voornaam	Handtekening	Datum
-----------------------	--------------	-------

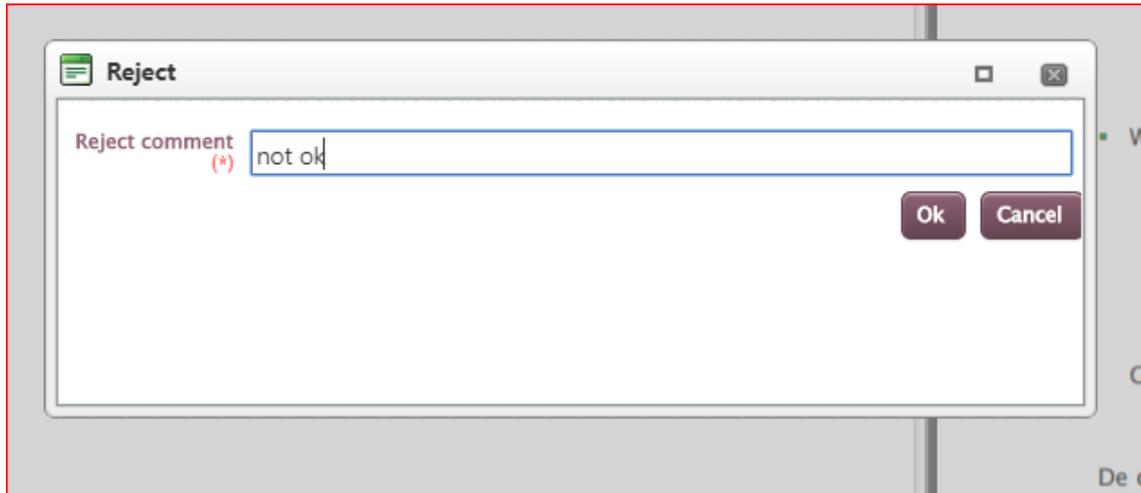
Electronically signed by HD UZB on 17/12/2021 11:35:53 (document signed for approval)



## To refuse the form



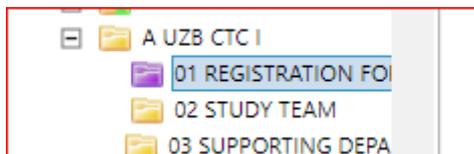
HD clicks on “Refuse” and fills in the reason for rejection (see part “To refuse the form” by PI):



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.

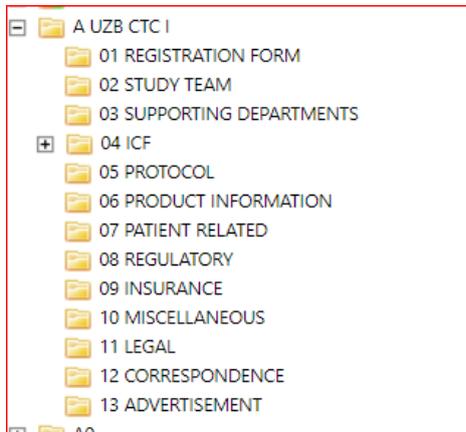
Once all signatures are in place, the folder 01 Registration form turns PURPLE .



**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).

## 7 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:**

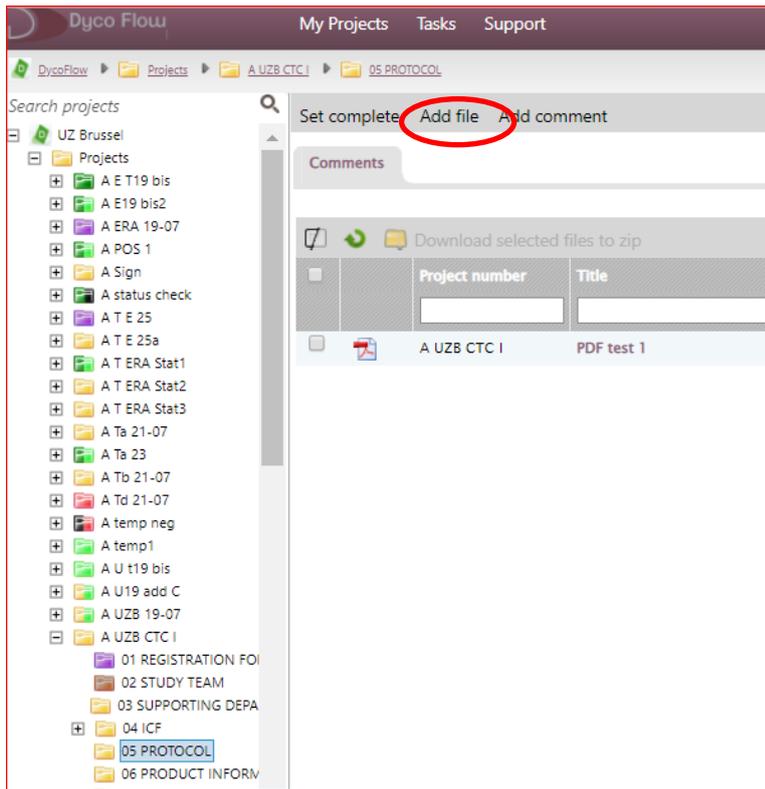
Click on a folder from 02-13 to upload documents.

Do not forget to consult the supporting documents

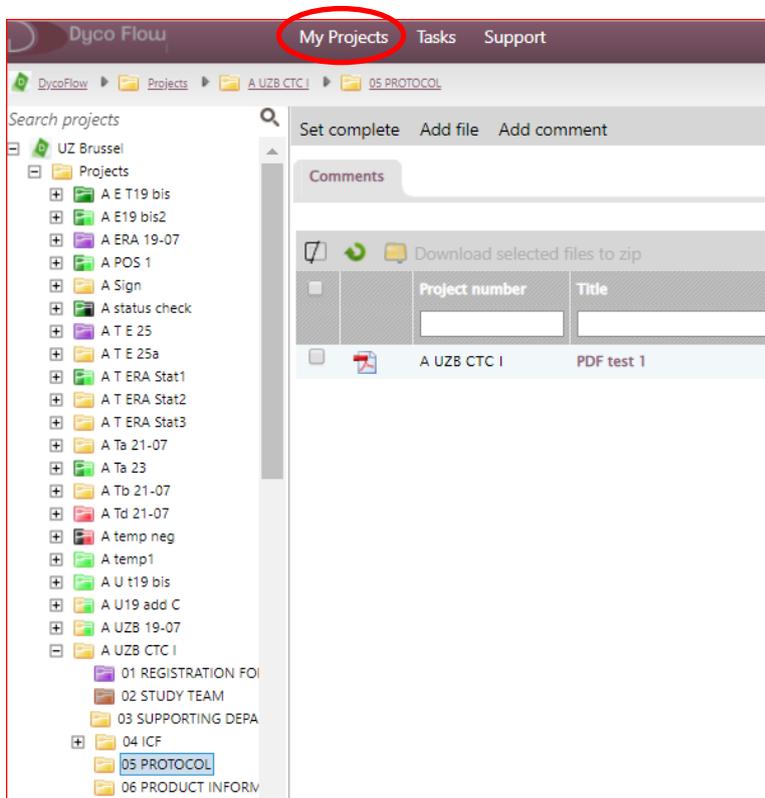
- "Required documents for the EC submission per study type"
- "Documents per folder"

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.**

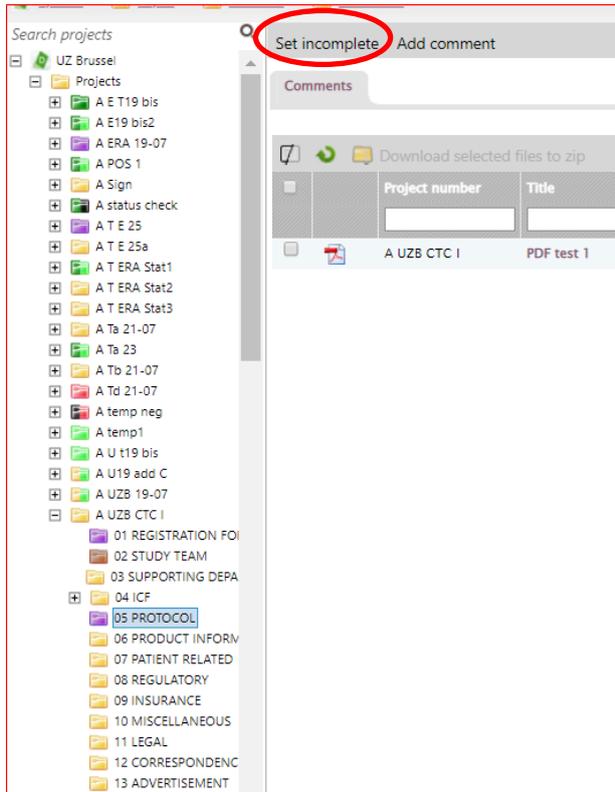


Once all the documents have been uploaded in their relevant folder, click on “Set complete”. The folder will turn PURPLE .

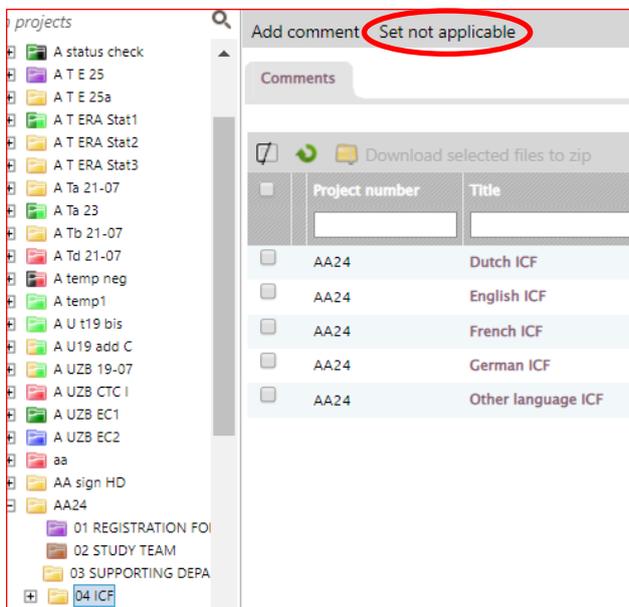


In case an extra document needs to be uploaded the Submitter can click on “Set incomplete” and add the extra file.

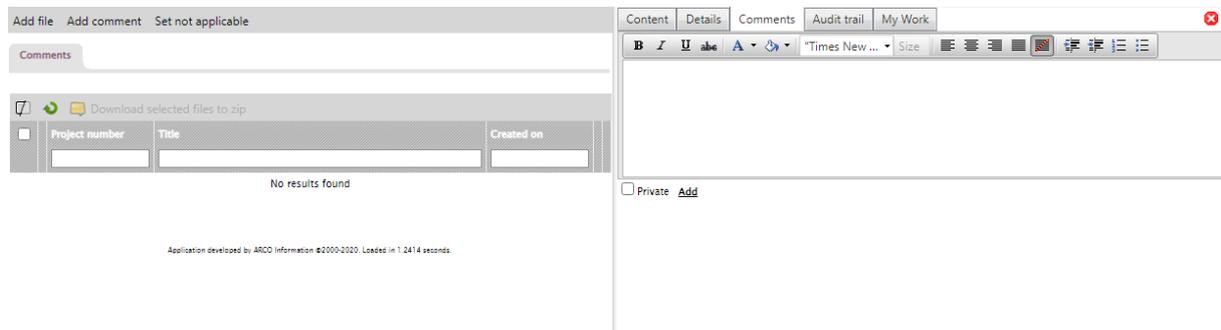
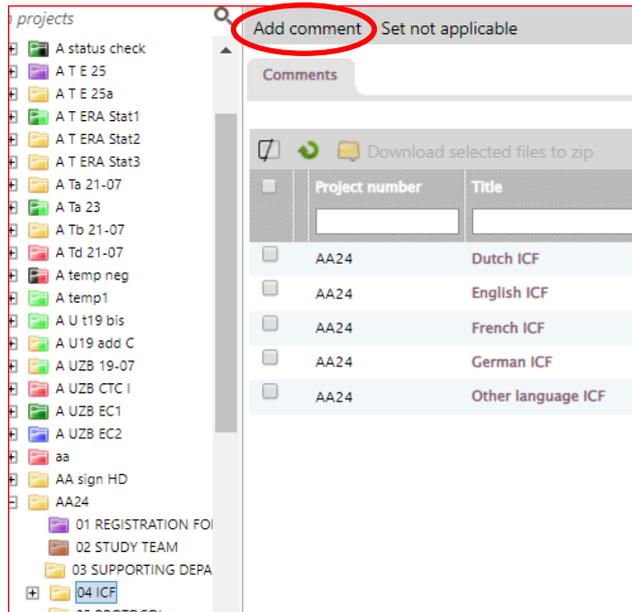
Do not forget to click again on “Set complete” afterwards (folder turns PURPLE ).



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.

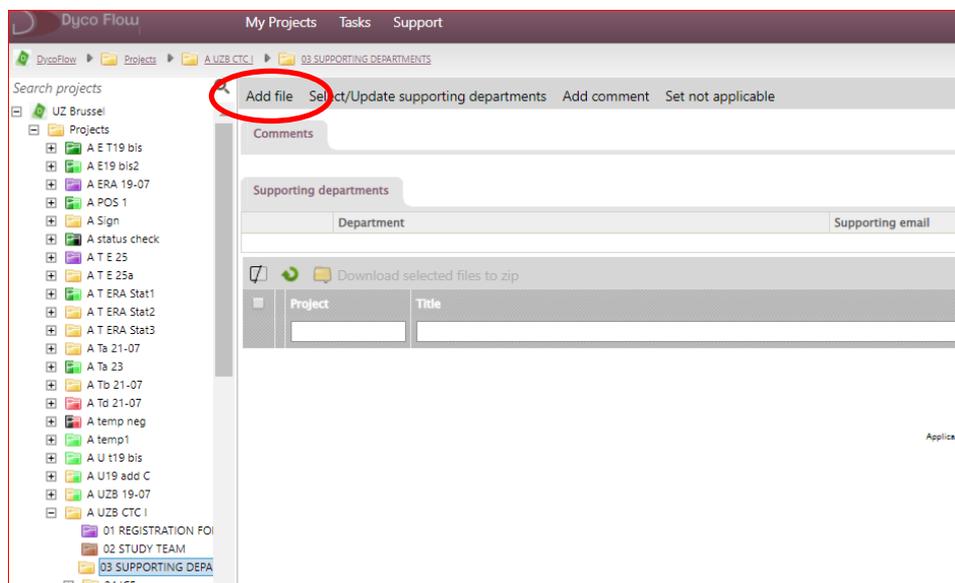


## 2. Special folders

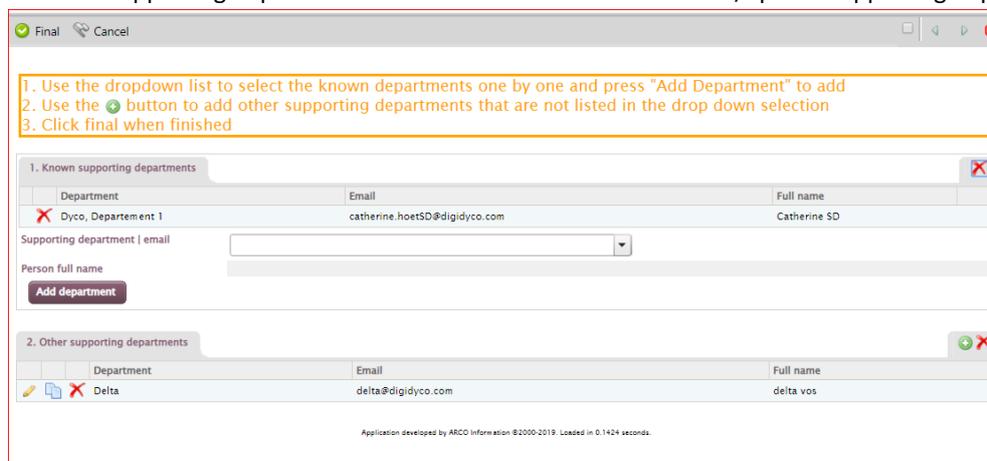
- Folder 03: Supporting departments.

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”.



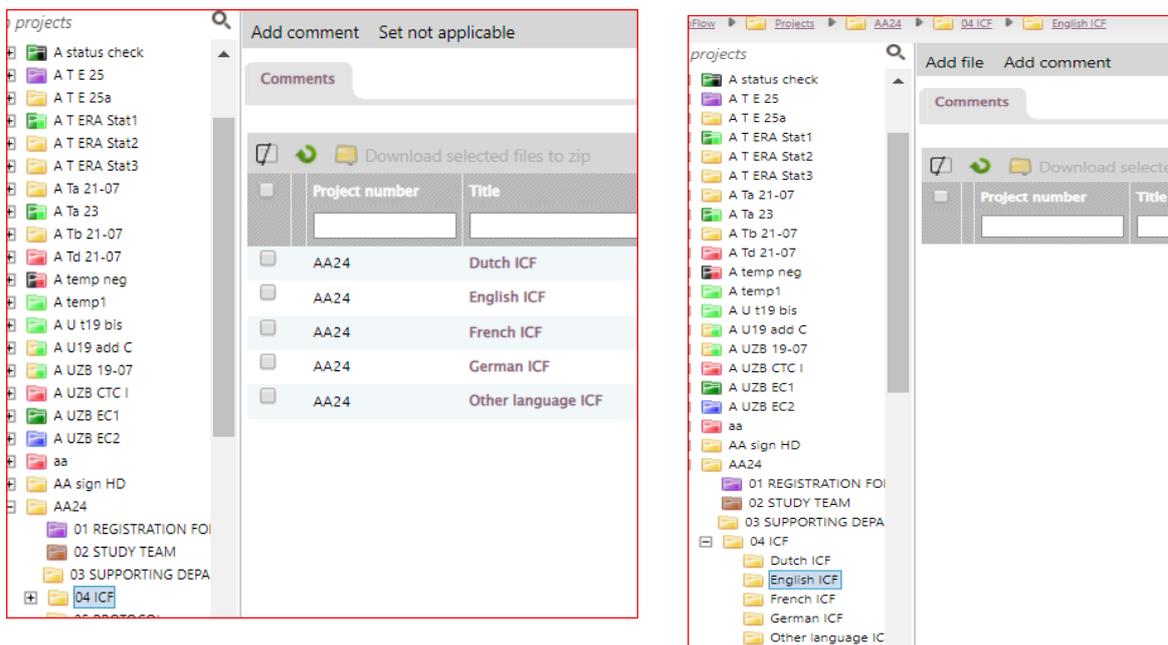
To add a supporting department the Submitter can click on “Select/update supporting departments”.



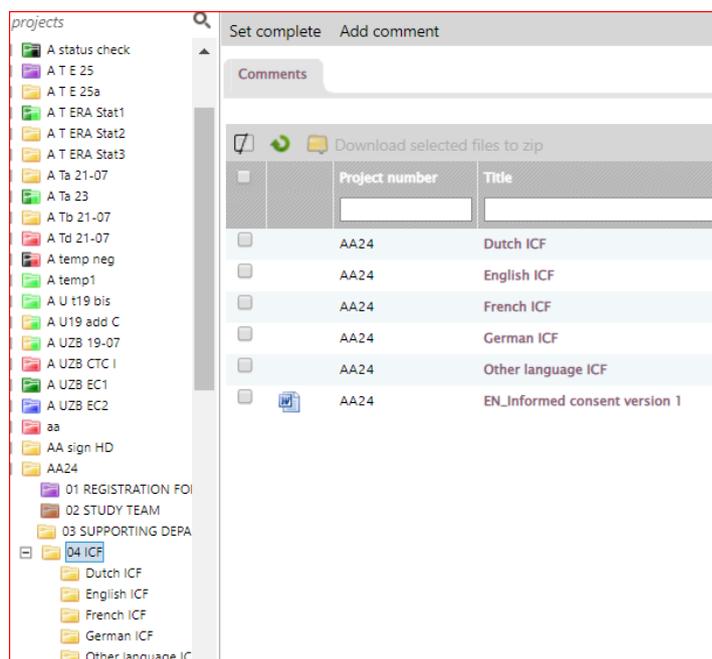
Here the Submitter can either select one of the supporting departments from the scroll list or can add an extra supporting department.

- Folder 04: ICF

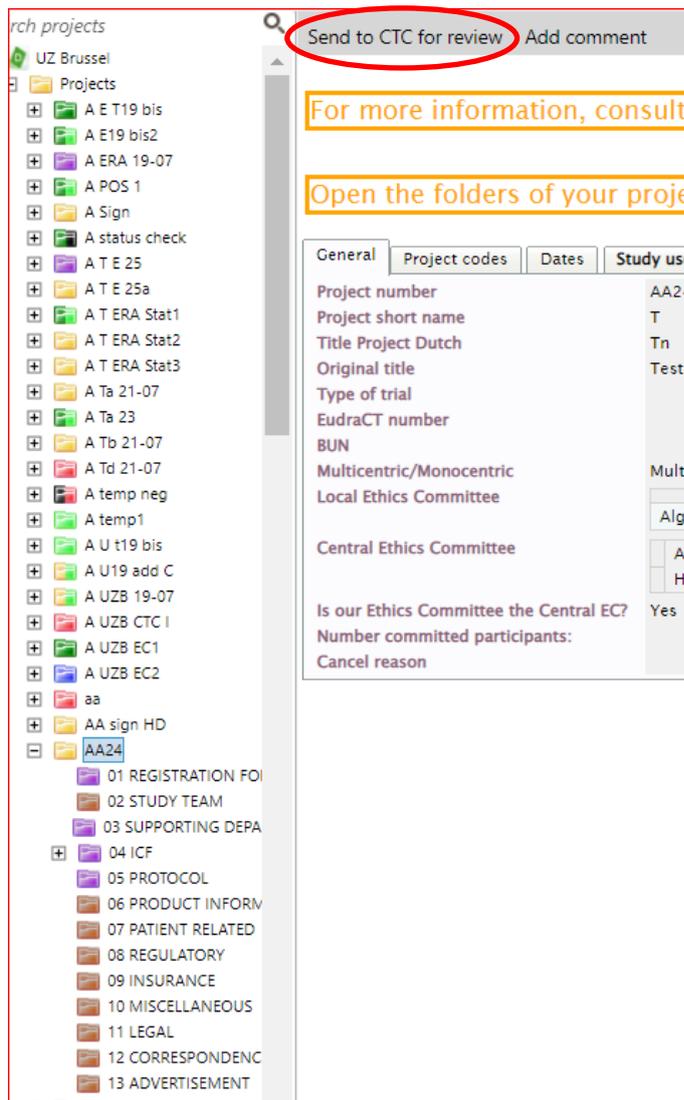
Before adding files, select one of the subfolders. Then click on “Add file” and upload the document.



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.

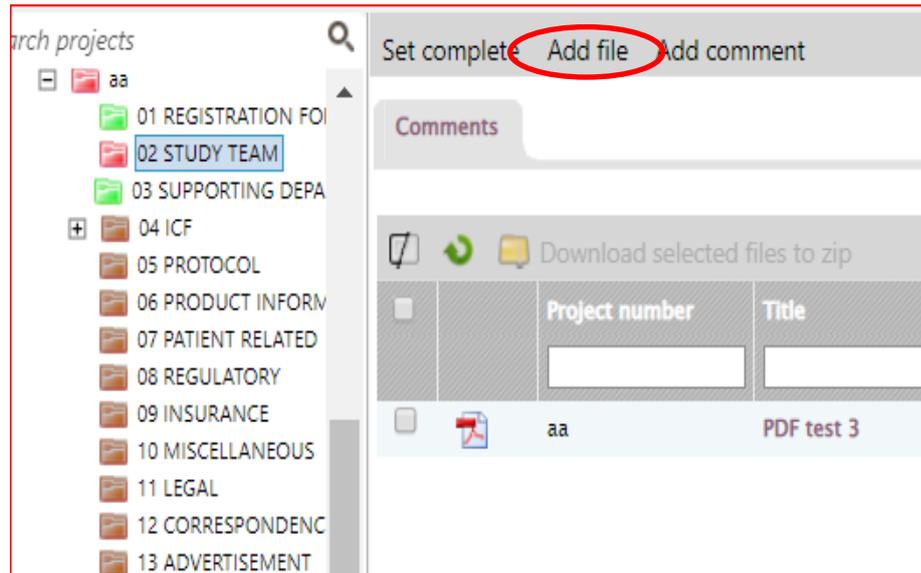
After review by the CTC the study will either be returned to the Submitter with some comments or items that need to be modified/uploaded. Or the study will be sent directly to the EC when it is validated as complete by the CTC.

## 8 PROJECT RETURNED TO SUBMITTER FOR ACTION

→Login User: Submitter

Click on the RED  folders.

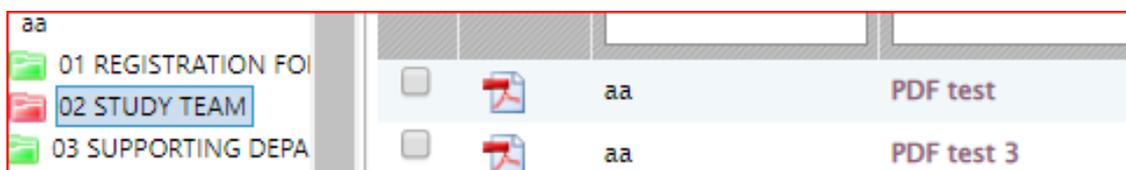
1. Read the comments on the top of the window, comply with the request.
  - a. **To respond to the comments:** click on “Add comment”.
  - b. **To upload a new document:**



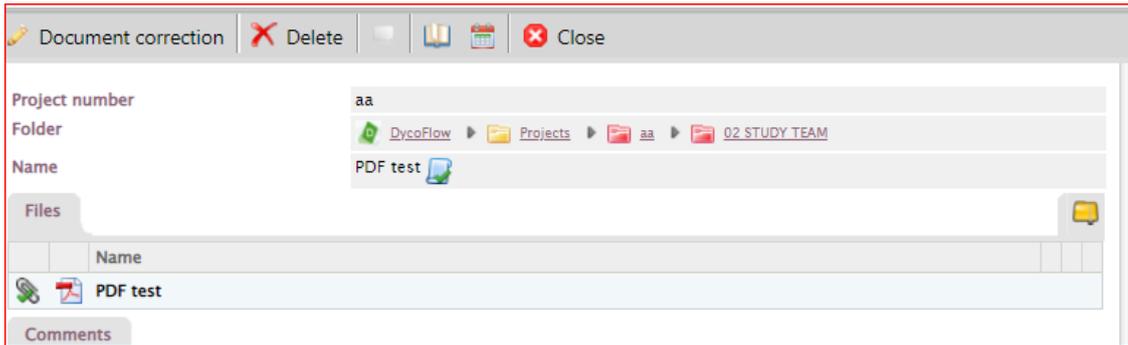
- Click on “Add file” in the folder menu (grey).
- Click on “Select” to select your document.
- Click on “Add”.
- Click on “Save & Close”.

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

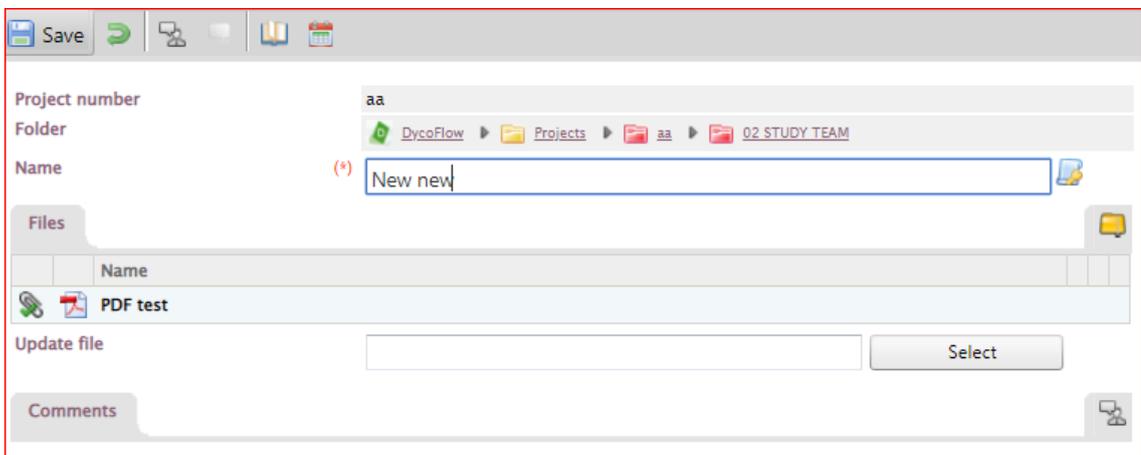
- Click on the original document.



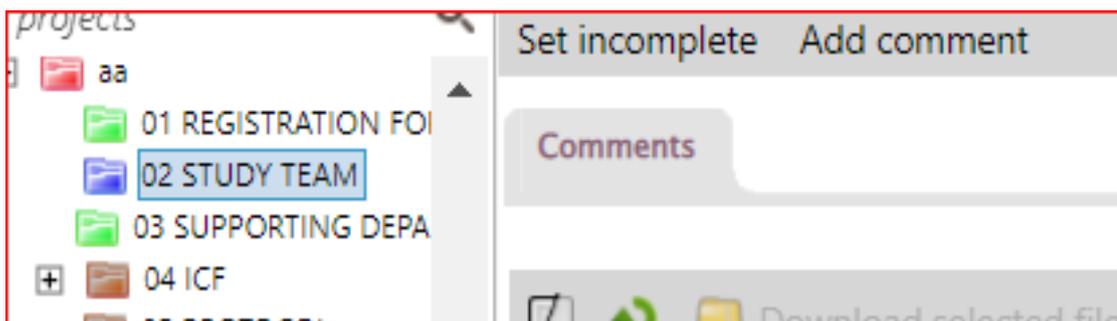
- Click on "Document correction".



- 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 .

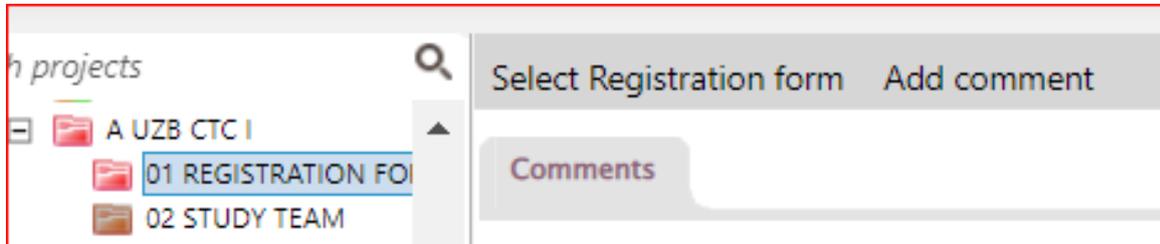


d. **To replace the registration form**

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.

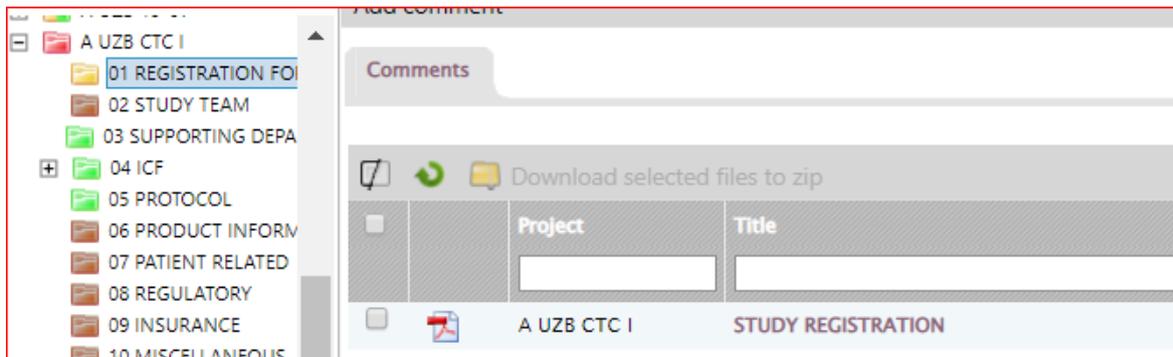
First the Submitter must remove the old registration form via “Remove registration form”.

- The Submitter clicks on “Select registration form”

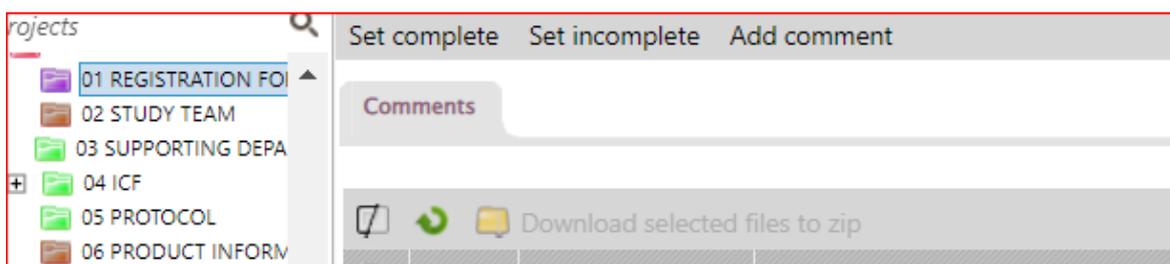


- The Submitter selects, opens, completes the new form and can then “Send for signature”

- Folder 01 Registration form turns YELLOW .

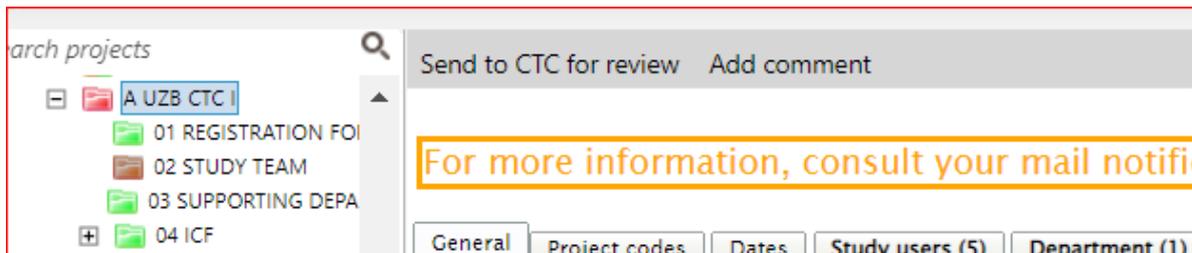


- After completion of the signing process, the folder 01 Registration form turns PURPLE .



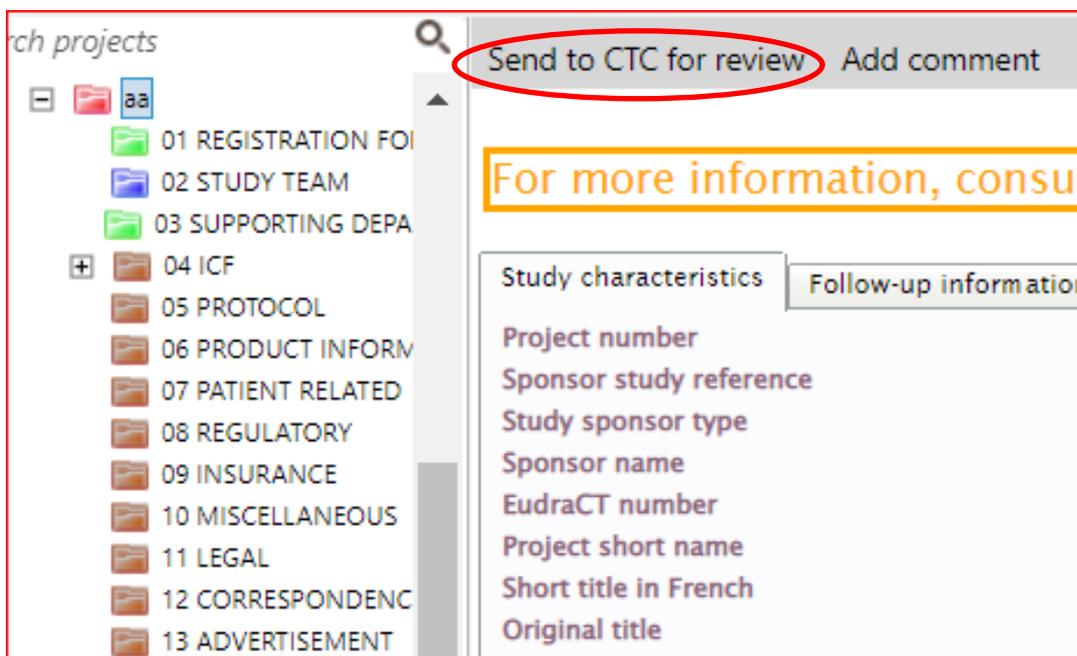
- The Submitter can select “Set complete” or “Set incomplete”.

- 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.

## 9 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.



**UZB Dyco Flow** <no\_reply\_uzb\_Dyco\_Flow@digidyco.com>  
aan klara.godderis, DycoFlowUZB ▾

 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



## 10 STUDY NOT VALIDATED BY EC

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”).

### DYCO FLOW-INPUT : Project test0812 not validated by EC Inbox x



**UZB Dyco Flow** <no\_reply\_uzb\_Dyco\_Flow@digidyco.com>  
aan klara.godderis, DycoFlowUZB ▾

Engels ▾ > Nederlands ▾ Bericht vertalen

Dear Klara Godderis,

Project **test0812** was verified and not validated by EC due to missing or incorrect submission document(s).

Project title:

**test**

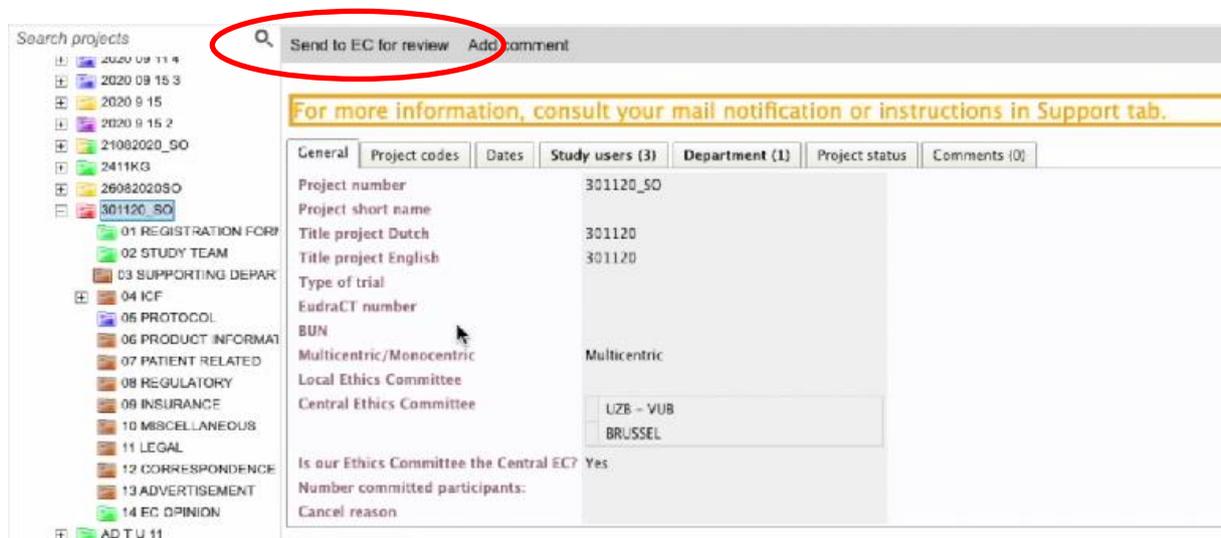
Please consult the **folder and document comment(s)**.

If a message was added to a document, the comment icon colour turned 'orange'.

Follow this [Dyco Flow](#) link and check the rejected documents in the red folders.

Kind regards,  
Medical Ethics Committee

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



The screenshot shows the Dyco Flow interface. On the left is a tree view of folders, with '301120\_SO' selected. The main area displays a form for project details. At the top of the form, there are two buttons: 'Send to EC for review' and 'Add comment'. The 'Send to EC for review' button is circled in red. Below the buttons is a yellow banner with the text: 'For more information, consult your mail notification or instructions in Support tab.' The form has several tabs: 'General', 'Project codes', 'Dates', 'Study users (3)', 'Department (1)', 'Project status', and 'Comments (0)'. The 'General' tab is active, showing fields for 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, and Cancel reason.



## 11 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

 **UZZ Dyco Flow** <no\_reply\_uzb\_Dyco\_Flow@digidyco.com>  
aan Klara.godderis, DycoFlowUZZ

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 .

2411KG

- 01 REGISTRATION FORM
- 02 STUDY TEAM
- 03 SUPPORTING DEPARTMENTS
- 04 ICF
- 05 PROTOCOL
- 06 PRODUCT INFORMATION
- 07 PATIENT RELATED
- 08 REGULATORY
- 09 INSURANCE
- 10 MISCELLANEOUS
- 11 LEGAL
- 12 CORRESPONDENCE
- 13 ADVERTISEMENT
- 14 EC OPINION

Search projects

UZZ Brussel

Projects

- 0 infosesie
- 0712 infosesie
- 15104KG
- 15104KG
- 15104KG
- 15104KG
- 15104KG
- 1610KGtest
- 01 REGISTRATION FOR
- 02 STUDY TEAM
- 03 SUPPORTING DEPAR
- 04 ICF
- 05 PROTOCOL
- 06 PRODUCT INFORM
- 07 PATIENT RELATED
- 08 REGULATORY
- 09 INSURANCE
- 10 MISCELLANEOUS
- 11 LEGAL
- 12 CORRESPONDENCE
- 13 ADVERTISEMENT
- 14 EC OPINION

Add comment

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

Comments

Download selected files to zip

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

Previous Next (2 results found)

Application developed by ARCO Information ©2000-2020. Loaded in 0.6531 seconds.

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



## 12 PRELIMINARY ADVICE



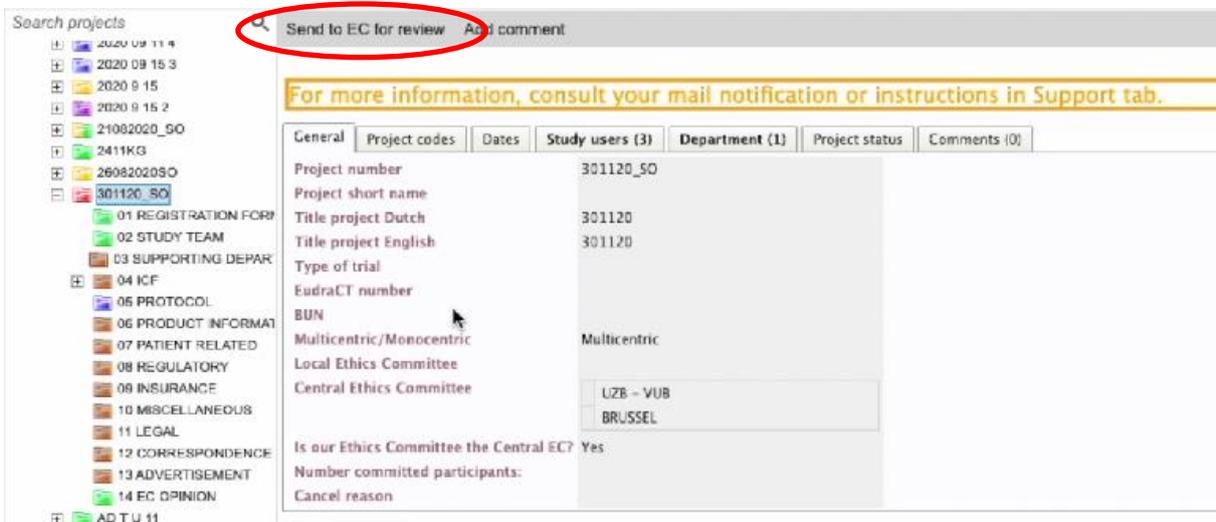
In the preliminary advice, the remarks from the Ethics Committee are described.

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.



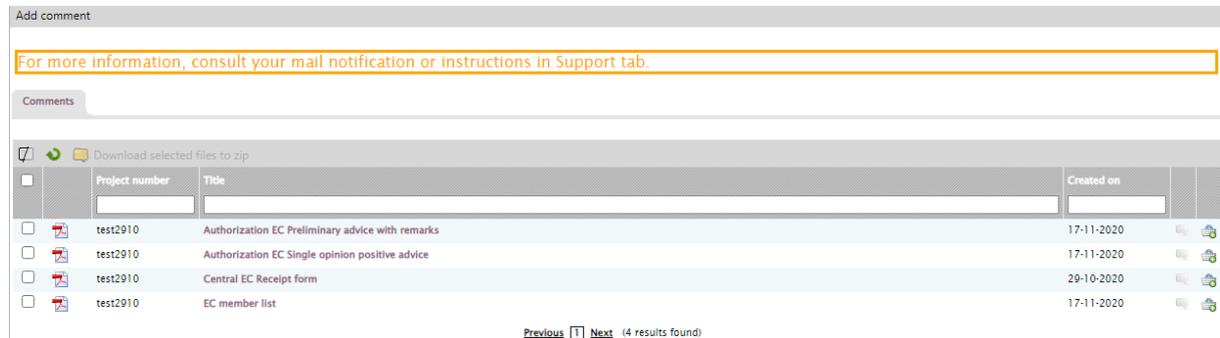
**Important: in case the study team/sponsor disagrees with (one of) the remarks of the EC, a reason needs to be provided via “Add comment”.**

## 13 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.



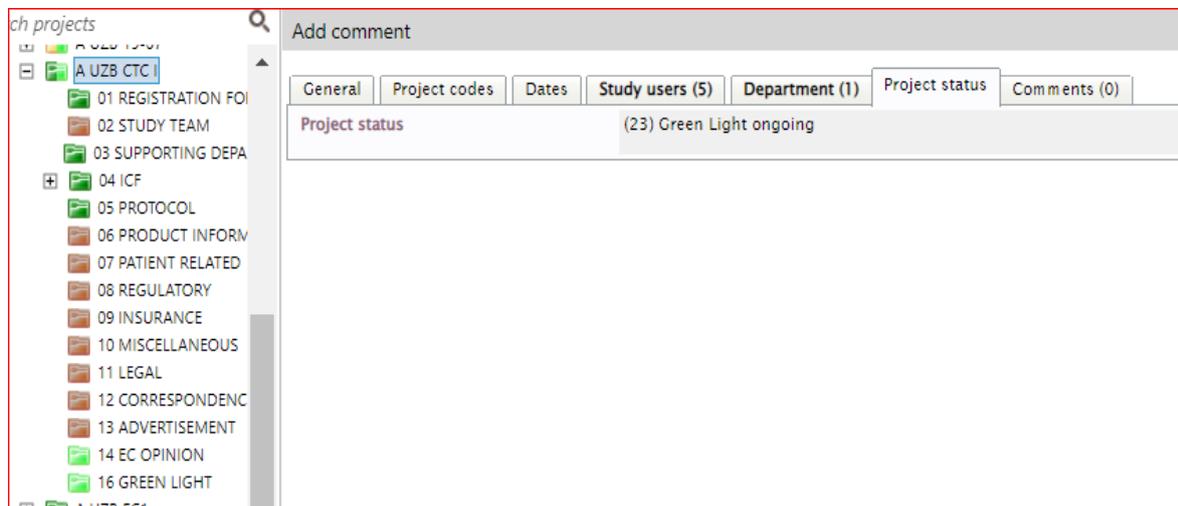
The screenshot shows a web application interface with a search bar at the top containing the text "For more information, consult your mail notification or instructions in Support tab." Below the search bar is a "Comments" section. The main part of the interface is a table with the following columns: "Project number", "Title", and "Created on". The table contains four rows of data:

Project number	Title	Created on
test2910	Authorization EC Preliminary advice with remarks	17-11-2020
test2910	Authorization EC Single opinion positive advice	17-11-2020
test2910	Central EC Receipt form	29-10-2020
test2910	EC member list	17-11-2020

At the bottom of the table, there are navigation links: "Previous" and "Next" with a count of "(4 results found)".

## 14 GREEN LIGHT

→ Login User: Principal Investigator



The screenshot shows a web application interface with a sidebar on the left containing a list of folders. The main part of the interface is a "Project status" overview. The sidebar lists folders from "01 REGISTRATION FO" to "16 GREEN LIGHT". The main part of the interface has a search bar at the top and a "Project status" section with the following tabs: "General", "Project codes", "Dates", "Study users (5)", "Department (1)", "Project status", and "Comments (0)". The "Project status" section shows "(23) Green Light ongoing".

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:

Sign Save draft in Tasks

EC number EC-2019-031

Original title TEST

this study has been approved by the (Leading) Ethics Committee (CME) on this study has been approved by the FAMHP (FAGG) (\*) 23-08-2019

this study has been registered on www.clinicaltrials.gov (\*)  Not applicable  Yes

the clinical trial agreement has been signed by all parties and by the CEO of UZ Brussel (\*)  Not applicable  Other  Yes

the initiation meeting has taken place on (\*) 26-08-2019

the financial disclosure form has been signed (\*)  Not applicable  Yes

IMP is available at the site (\*)  Not applicable  Yes

IVRS is in place (\*)  Not applicable  Yes

When signing the PI chooses 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.



**UZH Dyco Flow** <no\_reply\_uzb\_dyco\_flow@digidyco.com>  
aan klara.godderis, DycoFlowUZB

ma 11 jan. 14:35 (2 dagen geleden) ☆ ↶ ⋮

Engels > Nederlands Bericht vertalen

Uitschakelen voor: Engels x

Dear Klara Godderis,

We are pleased to announce that this project meets the requirements to start at UZ Brussel.  
Please find the SOP describing the responsibilities of the researcher and the research team in the SUPPORT tab of Dyco Flow.

At this stage the folders 01-14 are locked. For all further actions (submission amendments, renewal insurance, submission of reports, ...) documents and information should be uploaded in the continuing review subfolders.

Project **test0812**.  
Project title:  
**test**

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

Kind regards,

The Central Study office/Clinical Trial Center

## 15 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.

- ☐ 📁 Test2311
  - 📁 01 REGISTRATION FORM
  - 📁 02 STUDY TEAM
  - 📁 03 SUPPORTING DEPARTMENTS
  - ☐ 📁 04 ICF
  - 📁 05 PROTOCOL
  - 📁 06 PRODUCT INFORMATION
  - 📁 07 PATIENT RELATED
  - 📁 08 REGULATORY
  - 📁 09 INSURANCE
  - 📁 10 MISCELLANEOUS
  - 📁 11 LEGAL
  - 📁 12 CORRESPONDENCE
  - 📁 13 ADVERTISEMENT
  - 📁 14 EC OPINION
  - ☐ 📁 17 EC CONTINUING REVIEW

Different types of documents can be uploaded here:

+ Amendment + Annual review + Safety + Insurance + Audit + Contract + Additional site + End of trial

### 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.



Amendment Annual review Safety Insurance Audit Contract Additional site End of trial

Click on + to select and initiate a new EC continuing review submission  
Once the "End of trial notification" has been sent to EC, please press "Project final" to lock the project

The following screen will appear:

Create Cancel

Project number Test2311

EC continuing review type AMENDMENTS EC continuing review type code AM

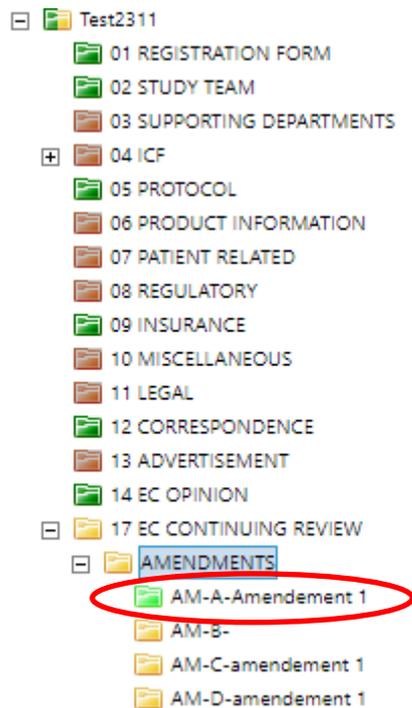
Sequence D

Name new subfolder (\*)

You are creating a new subfolder for your document upload

The system automatically creates a sequence number. The first amendment will be coded AM-A, the 2<sup>nd</sup> 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> do 7 jan. 09:36 (5 dagen geleden) ☆ ↶ ⋮  
aan UZB\_PI, DycoFlowUZB ▾

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"/>		
<input type="checkbox"/>	301120_SO	ammendement 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.

## 16 GENERAL TOOLS

### 1. SEARCH TOOLS:

The search tool provides the opportunity to search on different topics. If you have several project running in Dyco Flow 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

Project number

Project short name

Original title

PlannedInitiationDate

PlannedEndDate

ECIdentifier

Department

Sponsor name

Project status

### Search documents

All

Name

Project number

### Search comments

All

Comments

Project number

## 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**

My Work | Open Workflows | Archive | Search | Search (My Work)

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 Dyco Flow.

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 admin	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 admin	Update	22-07-2019	
AK sign HD	NEW STUDY created by Catherine CTC on 2019-06-16 16:28:26	STUDY-MAIN-Folder - insert	Input Fields	16-06-2019	
	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	

## 17 APPENDIX I: DOCUMENTS PER FOLDER

Protocols, ICFs, 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 Dyco Flow.

\* Mandatory for every type of protocol

\*\*Mandatory for every type of protocol, except for studies under CTR and MDR that have to be submitted as light dossiers.

- 01** Registration form (to be completed in Dyco Flow) (“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\*\*
  - o for case reports/case series: publication (e.g. abstract, poster, manuscript)
- 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
  - o For Light dossiers: approval/authorization 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
  - o Decision Medical Device Framework Board
- 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)

## 18 APPENDIX II: COLOURS FOLDERS

### Main folders

