Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?

For questions please contact support.montblanc@bayer.com.

Please note: All user names in Mont Blanc will consist of First Name.Last Name followed by the standard ending @Bayer.com (i.e., first.last@bayer.com). This username is not a valid email address. This username will give you access to the Bayer-developed system.

Contents

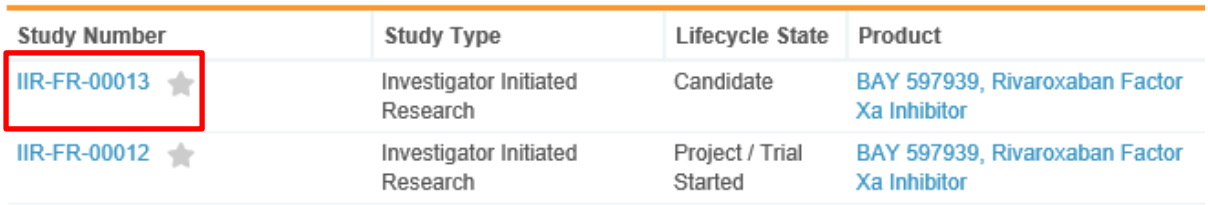
After successful login to Mont Blanc, the approved study can be viewed and to provide updates to the study, please go to the section "Study Info".

Mont Blanc – Investigator Initiated Research (IIR): How to update an approved IIR?

How to submit study updates

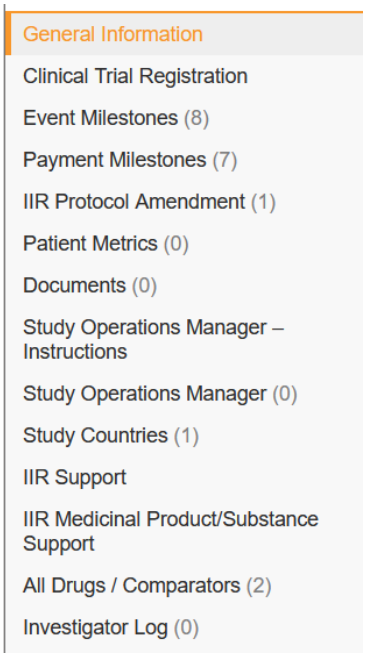
1. Please go to the section “Study Info”.

2. Click on the study number hyperlink, this brings you to the study.



Study Number	Study Type	Lifecycle State	Product
IIR-FR-00013	Investigator Initiated Research	Candidate	BAY 597939, Rivaroxaban Factor Xa Inhibitor
IIR-FR-00012	Investigator Initiated Research	Project / Trial Started	BAY 597939, Rivaroxaban Factor Xa Inhibitor

3. You will then find the following sections in Mont Blanc:



General Information:

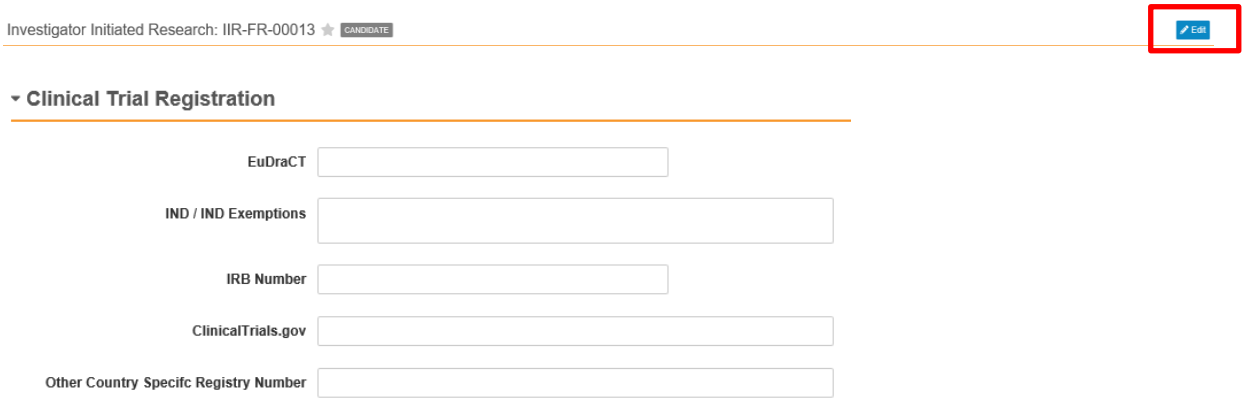
This section shows the information that was entered in the study concept.

Clinical Trial Registration:

Here you can enter Clinical Trial Registration numbers like: EuDraCT, IND/ IND Exemptions, IRB Number, ClinicalTrials.gov or other country registration number

To enter a number, click on the Pencil button 

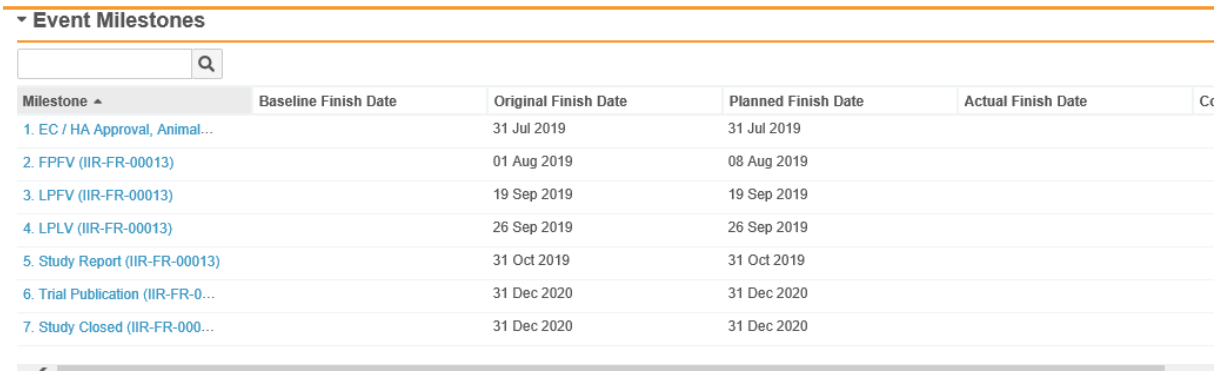
button in the upper right corner, then the information in this section can be entered. After you have entered the number(s), please click on “Save”.



Event Milestones:

To update planned or actual dates, please double click in the field that needs updating and select the new date from the calendar function.

Please note: the original finish date will not change after an updated new planned date or actual date has been entered.



Milestone	Baseline Finish Date	Original Finish Date	Planned Finish Date	Actual Finish Date	Cc
1. EC / HA Approval, Animal...		31 Jul 2019	31 Jul 2019		
2. FPFV (IIR-FR-00013)		01 Aug 2019	08 Aug 2019		
3. LPFV (IIR-FR-00013)		19 Sep 2019	19 Sep 2019		
4. LPLV (IIR-FR-00013)		26 Sep 2019	26 Sep 2019		
5. Study Report (IIR-FR-00013)		31 Oct 2019	31 Oct 2019		
6. Trial Publication (IIR-FR-0...		31 Dec 2020	31 Dec 2020		
7. Study Closed (IIR-FR-000...		31 Dec 2020	31 Dec 2020		

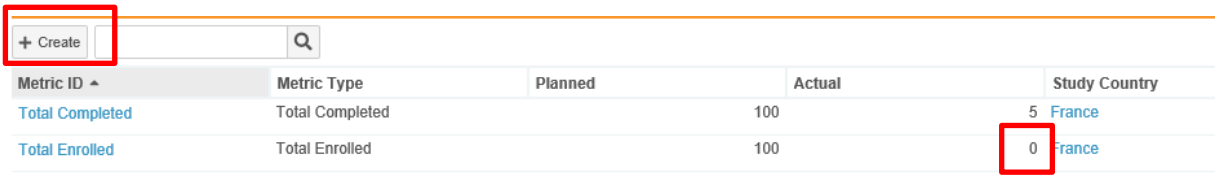
Payment Milestones

This section is for your information only.

Patient Metrics

When patients have enrolled, entered, or completed treatment, please update the patient numbers directly in the table, by making a double click in the field.

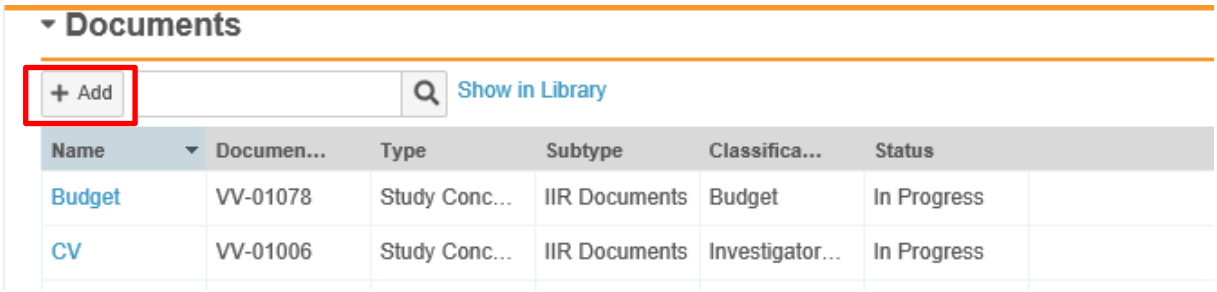
If you miss a specific metric type (e.g. total entered treatment), please click on the create button and create a new metric type.



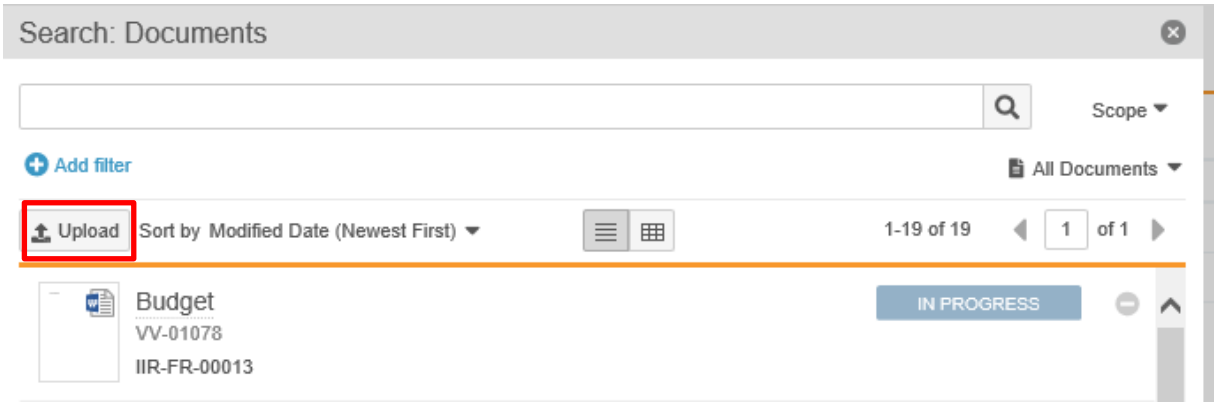
Documents

In this section, all documents uploaded will appear in Mont Blanc for this study.

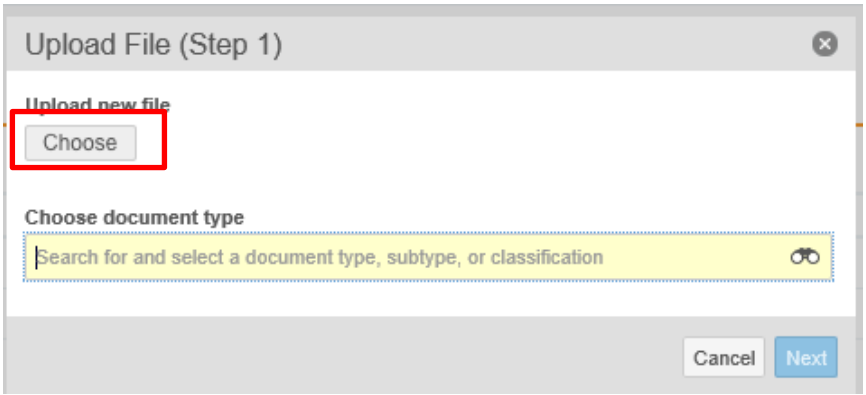
1. To upload another one, please click on +Add



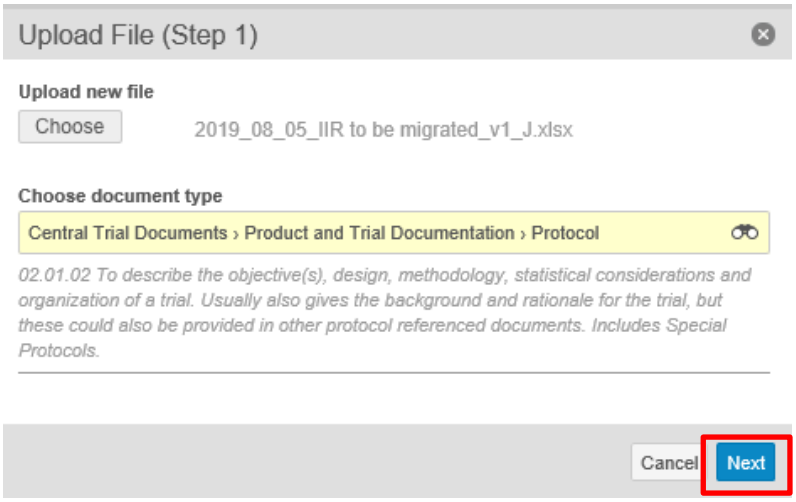
2. Click "Upload"



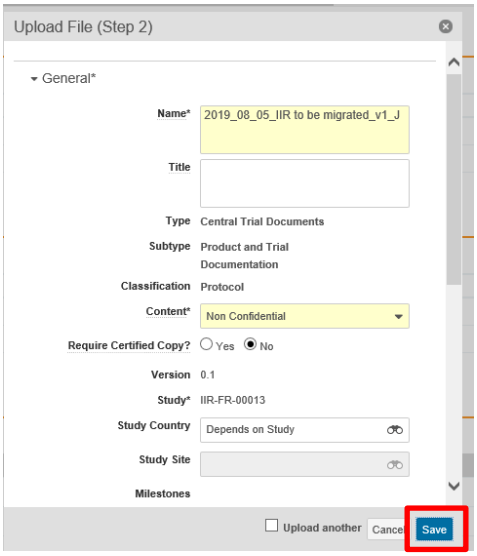
3. Click "Choose" and select a document from your local drive.



4. Choose a document type, by typing in a specific word like "protocol", then click Next.



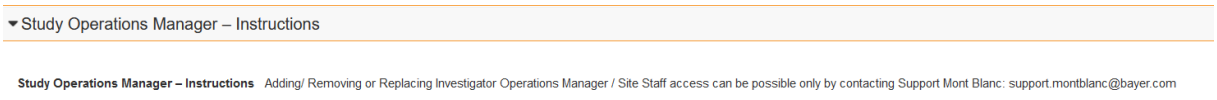
5. And click “Save”

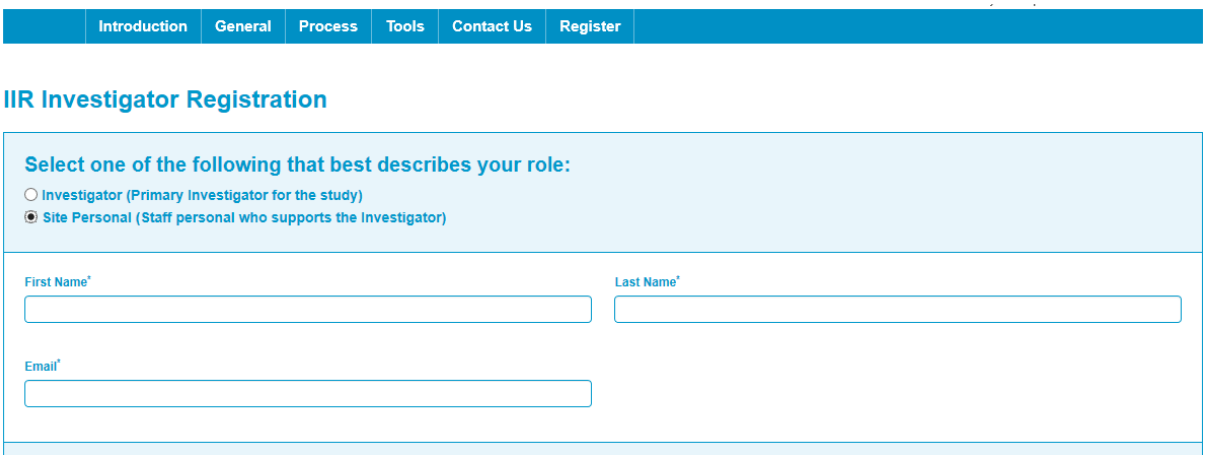


6. Then you can upload another document or click “Close”.

Study Operations Manager (Site Personnel):

In this section, other Site Personnel can be given access to the study. This user first needs to complete the registration template on this portal **http://iirportal.bayer.com**, then please contact support.montblanc@bayer.com and we can grant the access.

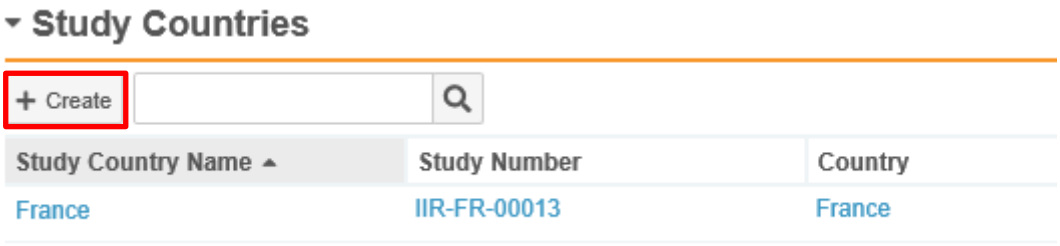




Study countries

All participating countries should be added in this section.

Please click on the "Create" button to list another country.



IIR Support

This section contains the information from the study concept but can be updated by the Bayer Responsible Person. The section is read only. If you would like to request a change, please contact the Bayer Responsible Person.

IIR Medicinal Product

This section contains the information from the study concept but can be updated by the Bayer Responsible Person. The section is read only. If you would like to request a change, please contact the Bayer Responsible Person.

Additional Study Drugs / Comparators

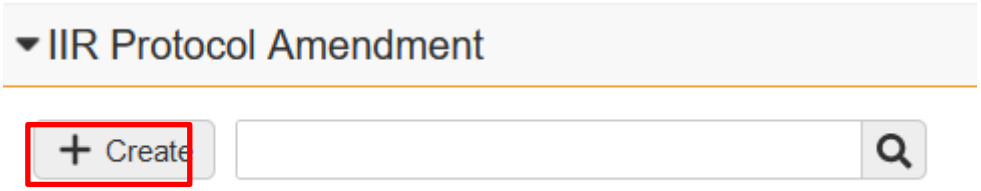
This section lists all additional study drugs / comparators that are used in the study as mentioned in the General information section. The section is read only. If you would like to request a change, please contact the Bayer Responsible Person.

Investigator Log

This section is the place where Bayer documents that an investigator has changed during the lifecycle of the study.

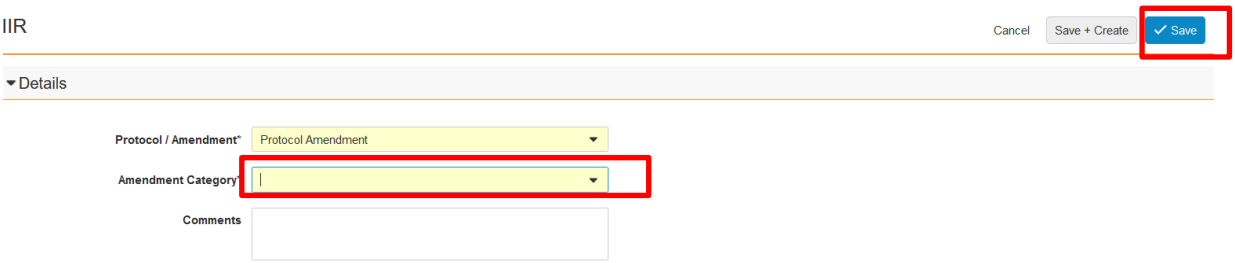
How to submit a protocol amendment

If you would like to submit an amendment to the protocol, please go to section "IIR Protocol Amendment" and click on the create button:

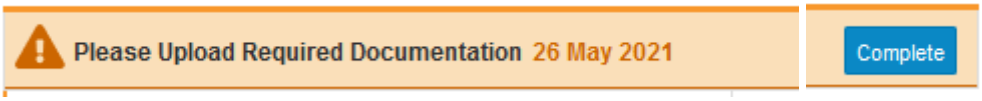


Then select the amendment category (Minor or Major) and click "Save"

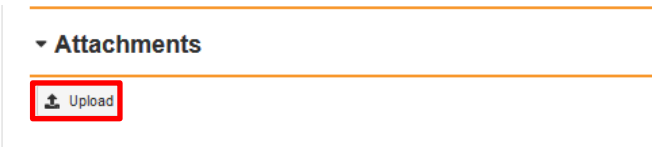
- Major amendments include change to inclusion/exclusion criteria, primary endpoint and in study design (including drug dosage/exposure and number of study subjects)
- Minor amendments include e.g. change of contact details



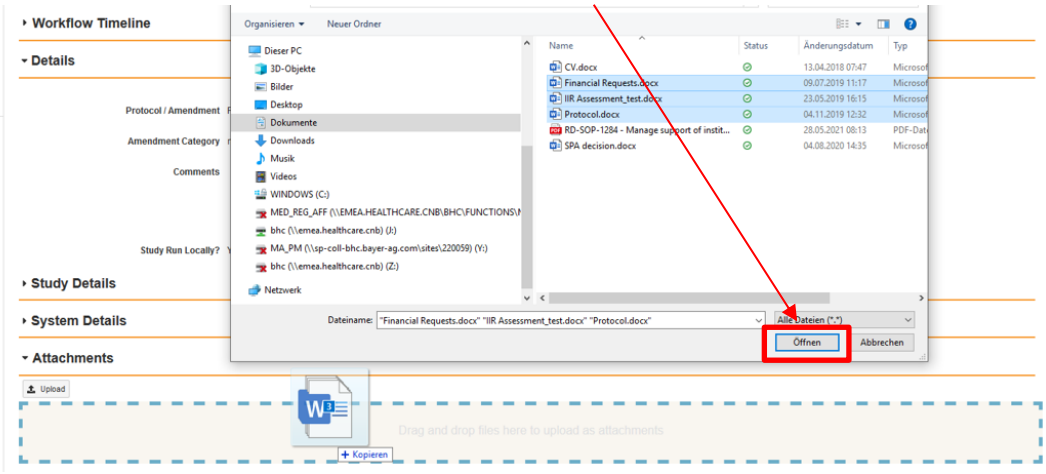
Then you will see another task bar, this is just a reminder not to forget to upload some documents. You can **complete** the task now or later, however, please upload the necessary documents under Attachments.



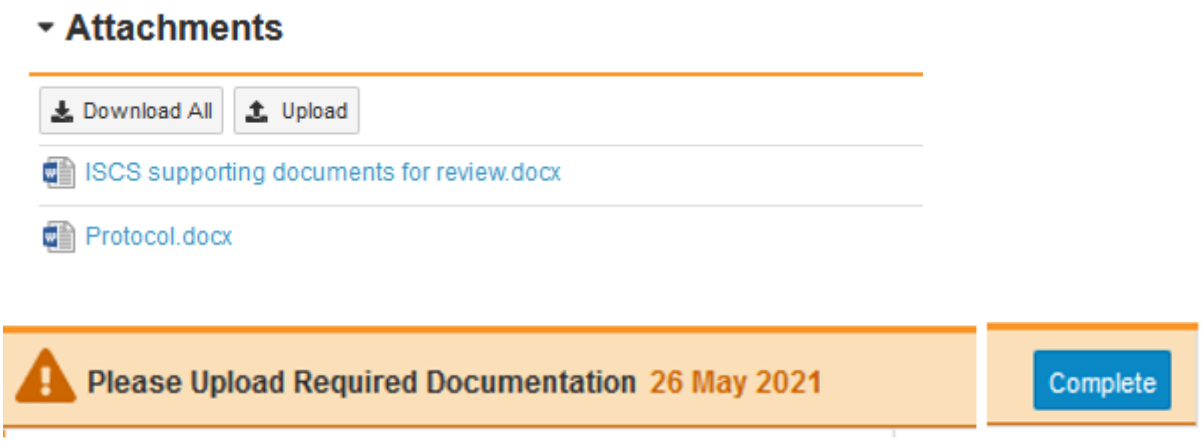
Go to Attachments, click "Upload"



Select documents from your local drive, you can upload more than one document and drag & drop it to “Attachments” section or alternatively click “open”



Once the documents are available at the latest then **complete** the task:



Now an email is sent to the IIR Responsible and will start the review cycle.

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