

Mont Blanc – Investigator Initiated Research (IIR): How to submit an IIR Study concept?



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

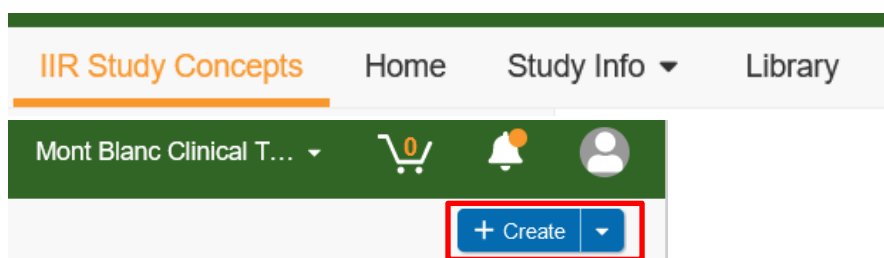
Please login to [Mont Blanc](#), and open the “IIR Study Concepts” tab

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 user name is not a valid email address. This user name will give you access to the Bayer-developed system.

Prior to submitting your concept please ensure you have the following available for upload

- IIR Assessment Form (for [clinical](#), [preclinical](#), [Covid-19](#))
- CV
- Budget (if applicable)

Please open the “IIR Study Concepts” tab. Click the “Create” button at the top **RIGHT**.



Submit a new study concept

Please fill in all required information, which can easily be identified by the yellow color of the fields.

Most of these entries should be made in the section “IIR Proposal”.

▼ IIR Proposal

Study Number

Nominated Investigator*	<input type="text"/>	Short Title*	<input type="text"/>
Nominated Organization*	<input type="text"/>	Protocol Title*	<input type="text"/>
Investigator's Degree		Therapeutic Area	
Product(s) Used in Study*	<input type="text"/>	Indication Group*	<input type="text"/>
Related Product*	<input type="text"/>	Indication*	Depends on Indication Group <input type="text"/>
Bayer prod./subs. used as Comparator* <input type="radio"/> Yes <input type="radio"/> No		Study Phase*	<input type="text"/>
Please enter Bayer prod./subs.:	<input type="text"/>	Blinding*	<input type="text"/>
Non-Bayer prod./subs. used as Comparator* <input type="radio"/> Yes <input type="radio"/> No		Control*	<input type="text"/>
Please enter Non-Bayer prod./subs.:	<input type="text"/>	Primary Country*	<input type="text"/>
Study Type*	<input type="text"/>	Planned Number of Countries*	<input type="text"/>
Prospective / Retrospective*	<input type="text"/>	Planned Number of Patients/Subjects*	<input type="text"/>
Preclinical Part Included? <input type="radio"/> Yes <input type="radio"/> No		Planned Number of Sites*	<input type="text"/>
Human Material Included? <input type="radio"/> Yes <input type="radio"/> No		Study Ownership IIR*	<input type="text"/>

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Please select the type of support you are requesting from Bayer.

▼ IIR Support

Support Requested from

Total Study Cost

Financial Amount Requested

Currency

- Analytical
- Financial
- Medicinal Product/Substance
- Equipment
- Other

You can select multiple entries from the list. (i.e Financial and Medicinal Product/Substance)

If Study Drug is requested (labeled: Medicinal Product / Substance in the list), please also complete the next section:

▼ IIR Medicinal Product/Substance Support

Medicinal Product/Substance request Yes No

Please enter Bayer prod./substance

Est. Amount / Unit (Bayer Med. Product)

Placebo Requested Yes No

Amount of Placebo (unit as Med. Product)

Comments

The next step is important!

Please click on the save Button in the upper right corner of the form:

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Cancel Save + Create **Save**

- Instructions
- IIR Proposal**
- IIR Support
- IIR Medicinal Product/Substance Support

Now the status of your concept submission can be viewed as “Initiated”:

IIR: IIR-FR-00016 ★ INITIATED

However, please do not click on the “Complete” button at this stage.

Task: Complete Information **Complete** !

Workflow Timeline

- The next step is to upload your CV and a completed IIR Assessment Form (for [clinical](#) or [preclinical](#) studies) and Budget information if applicable

You will find a new section in the submission for: “Submitted Documents”

Submitted Documents

+ Add

Click on the section title and then on the small gray “Add” button.

Then click “Create”

Search: Documents

Fields All Documents

Filters

Create Document Name (A-Z) 1-16 of 16

Then you have two options: “Upload” or “Document from Template”.

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- With “**Document from Template**” you will be able to work **on-line on the IIR Assessment Forms** (clinical or preclinical)
- By selecting “Upload” you can select a document from your local drive.

Both options are explained below:

A: Create a Document from Template

Please select “Document from template” and click “Continue”

The screenshot shows a dialog box titled "Create Document" with a close button (X) in the top right corner. Below the title, there is a label "Select Creation Method." followed by a dropdown menu. The dropdown menu is currently set to "Document from Template". At the bottom of the dialog box, there are two buttons: "Cancel" and "Continue". The "Continue" button is highlighted with a red rectangular box.

On the next screen you are asked to “choose a document type”. Please either select or type: “**Study Concept Form/ Assessment Form**”

The screenshot shows a web application interface. At the top, there is a navigation bar with links for "IIR Study Concepts", "Home", "Study Info", and "Library". Below the navigation bar, the main heading is "Create Document from Template (Step 1)". Underneath, there is a section titled "Choose document type" with a search input field containing the text "Select a document type, subtype, or classification". Below the search field, there is a list of document types under the heading "RECENT". The first item in the list is "Study Concept Documents > IIR/ISCS Documents > Study Concept Form/ Assessment Form", which is highlighted with a red rectangular box. Other items in the list include "Study Concept Documents > IIR/ISCS Documents > Budget" and "Study Concept Documents > IIR/ISCS Documents > Documentation of Sponsor Capabilities (incl. CV)".

Then open the go to “Choose template” and you will find three templates for “pre-clinical”, “clinical” and “COVID-19” studies, select the right template and click “next”

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Create Document from Template (Step 1)

Choose document type

Study Concept Documents > IIR/ISCS Documents > Study Concept Form/ Assessment Form

Choose template

Select a document template

- COVID_Clinical IIR_Assessment Form_v.3.0
- IIR assessment form clinical IIR
- IIR assessment form preclinical IIR

Cancel Next

On the next screen please enter a Name for the document and click “Save”

Cancel Save

General*

Name*

Title

Type Study Concept Documents

Subtype IIR/ISCS Documents

Classification Study Concept Form/
Assessment Form

Content Non Confidential

Version 0.1

Milestones

After you clicked “Save” you will automatically return to the study concept and see the document you have created under “Submitted Documents”, in the example the name of the document is “IIR XYZ”.

Submitted Documents

+ Add

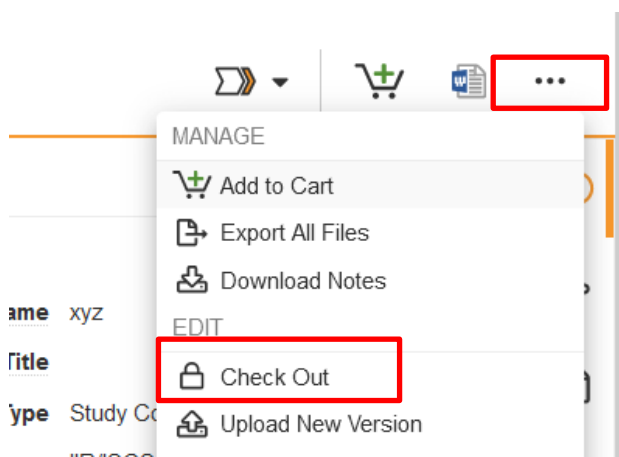
Name	Document Number
IIR XYZ	WV-01573

To complete the template, please click on the blue link under “Name” (IIR XYZ) this will open the document.

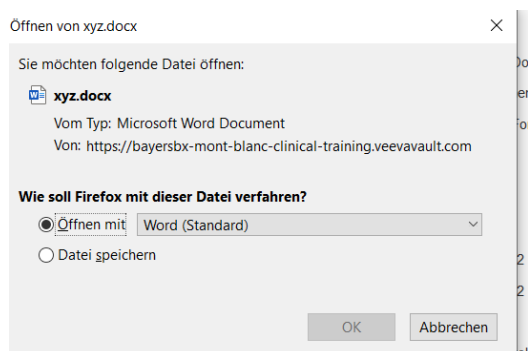
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Now go to the action menu at the right and select “Check out”

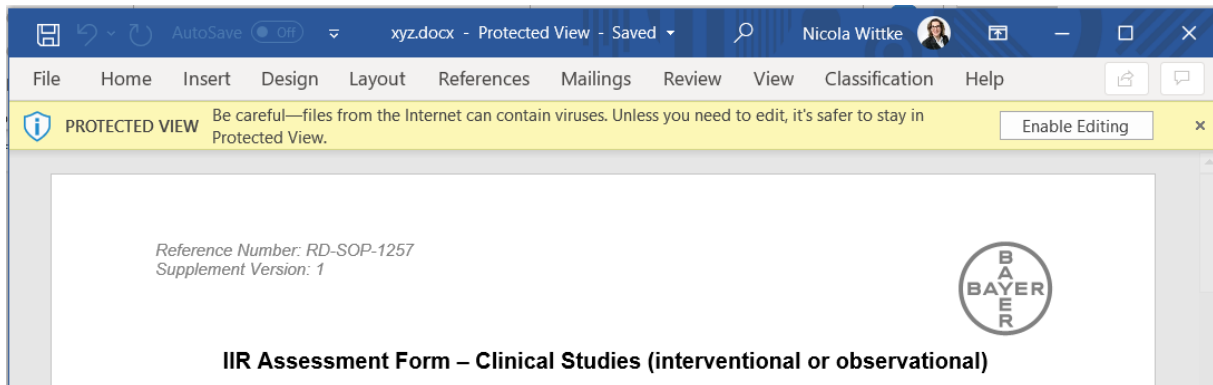


Then confirm that you will open the file:

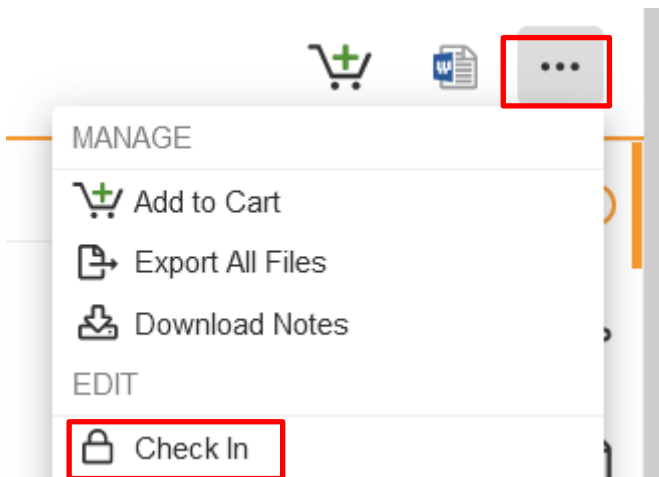


The document will open in Word, enable the editing, then make your updates and save the document on your local drive.

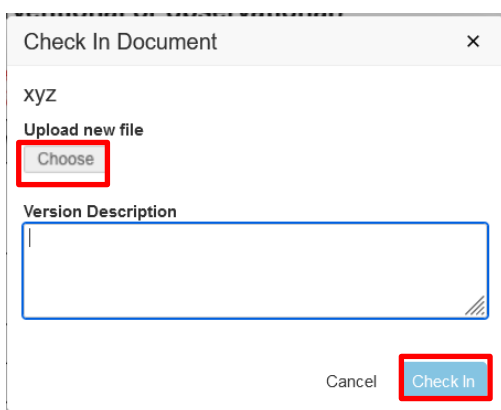
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Go back to Mont Blanc, go to the action menu select “Check in”.



Please click on “Choose” to be able to upload the document from you Local Drive and click “Check In”



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Navigation icons: Home, Shopping cart, Document, More

INFORMATION [edit icon] [info icon]

▼ General

Name xyz

Title

Type Study Concept Documents

Subtype IIR/ISCS Documents

Classification Study Concept Form/ Assessment Form
[Reclassify](#)

Content Non Confidential

Document Number VV-00030

Created By IIR Inv_Test on 02 Nov 2021 1:52 PM CET

Last Modified By IIR Inv_Test on 02 Nov 2021 1:52 PM CET

Version 0.1

Lifecycle Base Doc Lifecycle

Status In Progress

Milestones

Document Date

Study Type

Communication Log

Global ID 71657_451

Global Version ID 71657_451_78889

Document Link

Document Version Link

► Contracts & Budgets

▼ Study Concept Information

Comments

IIR/ISCS Study Concept Identifier [IIR-CA-00009](#)

When you click on the blue link behind the IIR / ISCS Study Concept Identifier you will return to the study.

Now you can upload further documents, e.g. from your local drive.

B: Create a Document from your Local Drive

Under Submitted documents, first click “add” then click “create”

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Search: Documents

Fields

► Filters

Document Name (A-Z)

Then select “upload” and click “continue”

Create Document

Select Creation Method.

Upload

Click “Choose” and select a document from your local drive

Upload Files (Step 1)

Drag and drop files to upload here

Files for upload cannot exceed 4 GB in size. Files over 4 GB and Audio/Video files over 4 GB will not be rendered. [Learn more.](#)

or choose files to upload

Choose document type and field values

Document Type

Select a document type, subtype, or classification

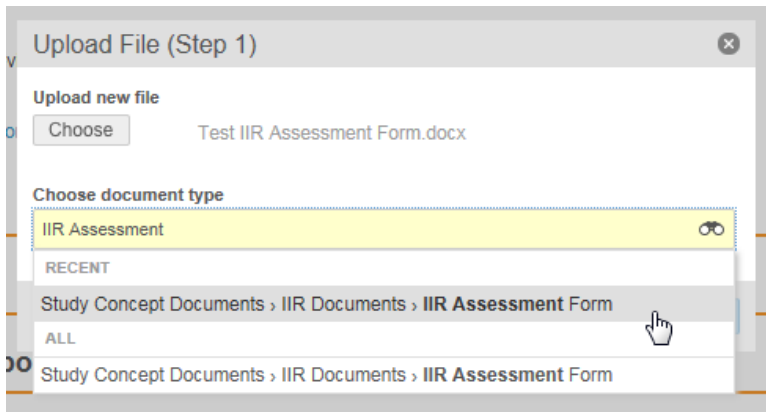
Name	Änderungsdatum	Typ	Größe
Test IIR Assessment Form.docx	09.05.2019 10:56	Microsoft Word D...	13 KB

Please choose a document type, then the following options will be available:

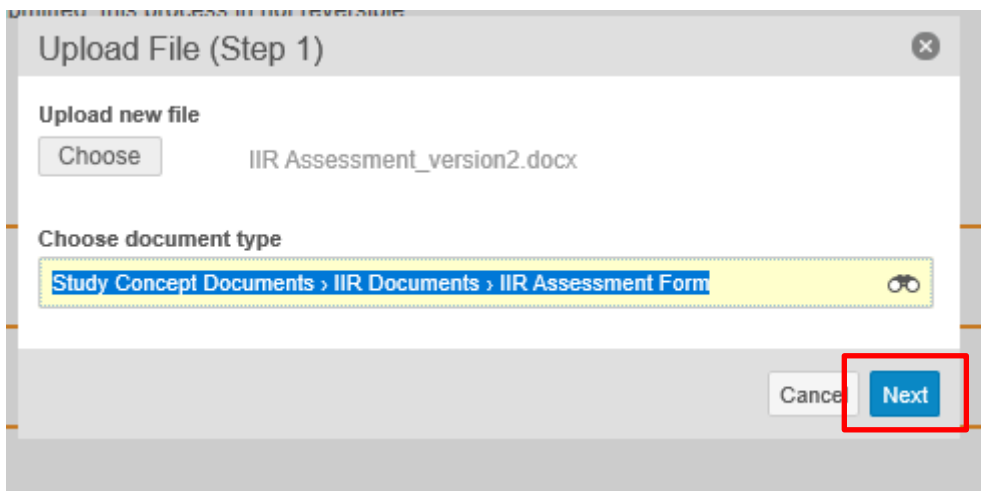
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- IIR Assessment Form
- Budget
- Investigator CV
- Study Publication
- Other miscellaneous documents



Then click “Next”



In the “Next” window you can leave the entries as they are and click “Save”.

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Upload File (Step 2)

General*

Name* IIR_Assessment_version2

Title

Type Study Concept Documents

Subtype IIR Documents

Classification IIR Assessment Form

Content* Non Confidential

Version 0.1

Milestones

Document Date

Study Type

Study Concept Information

Upload another

The document upload is complete. Repeat the same steps to upload your CV and a Study Budget if applicable, please

Click “Close” to complete this step for your concept submission.

Search: Documents

Upload Sort by Modified Date (Newest First) 1-10 of 10 1 of 1

Document Name	ID	Status
IIR Assessment_version2	VV-01104	IN PROGRESS
Budget	VV-01078	IN PROGRESS
Financial Requests	VV-01007	IN PROGRESS
1. CV	VV-00997	IN PROGRESS
Financial Requests	VV-00998	IN PROGRESS

Close

All uploaded documents will be visible in the “Submitted Documents” Section:

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Submitted Documents

Name	Subtype	Classification
Test Curriculum Vitae	IIR Documents	Investigator CV
Test IIR Assessment Form	IIR Documents	IIR Assessment Form

Please review and edit your submission by clicking the **“Complete”** button on the top of the **“Concept Submission”** form:



Please confirm your entries are correct in the pop-up window. If everything is correct, click

Click Complete to Submit for Review

Clicking Complete below will forward your Study Concept to the Bayer IIR committee for formal review. Please ensure you have uploaded the required documents before clicking Complete.

Study Type*
Interventional

Prospective / Retrospective*
Prospective

Short Title*
Interventional clinical Study on Xarel

Protocol Title*
Interventional clinical Study on Xarelto

Study Phase*
Phase I

Primary Country*
France

*Required to proceed

Cancel **Complete**

“Complete” again.

The concept status has been updated to **“Submitted”**. Bayer will review the submission and a representative will contact you.

IIR: IIR-FR-00016 ★ SUBMITTED

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An email will be sent to you as confirmation that Bayer has received the study proposal and will now review it.



Study Concept **IIR-FR-00016** has been submitted

Dear IIR Investigator2 We confirm that Bayer has received the submitted study proposal. The proposal will now be reviewed in the Bayer electronic approval system (Mont Blanc) and we will provide further feedback about the outcome.

Request Title: Interventional clinical Study on Xarelto Product: BAY 597939, Rivaroxaban Factor Xa Inhibitor

For any questions you may have regarding the IIR process in Mont Blanc, please write an e-mail to IIR-Support@bayer.com or contact the company system responsible for IIR at following address:

Bayer AG

Medical Affairs & Pharmacovigilance, Pharmaceuticals

Business Excellence

13342 Berlin Germany

Kind regards, Vorstand: Werner Baumann, Vorsitzender | Liam Condon, Hartmut Klusik, Kemal Malik, Wolfgang Nickl, Stefan Oelrich, Heiko Schipper

Vorsitzender des Aufsichtsrats: Werner Wenning

Sitz der Gesellschaft: Leverkusen | Amtsgericht Köln, HRB 48248

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