

Research Portal Ziekenhuis Oost-Limburg

Manual

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1. DOCUMENT HISTORY

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3. LIST OF ABBREVIATIONS

The following table presents the abbreviations and acronyms used in this manual.

CTA	Clinical Trial Agreement
CTR	Clinical Trial Regulation
CTU	Clinical Trial Unit
CV	Curriculum Vitae
CUP	Compassionate Use Program
DPO	Data Protection Officer
EC	Ethics Committee
GCP	Good Clinical Practice
IVDR	In Vitro Diagnostic Regulation
MDR	Medical Device Regulation
MNP	Medical Need Program
UR	Urgent Request
ZOL	Ziekenhuis Oost-Limburg

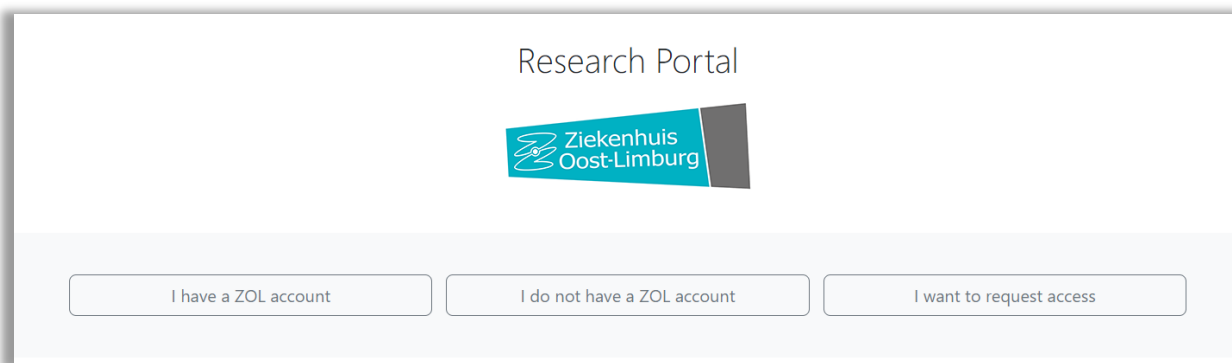
4. INTRODUCTION

The Research Portal is a joint realisation of Future Health (Clinical Trial Unit (CTU)) and the ethics committee (EC) of Ziekenhuis Oost-Limburg (ZOL). This manual describes the functioning of the online Research Portal and contains instructions to guide users through the approval procedures. The Research Portal is built exclusively in English and can be reached via the following link: <https://researchportal.zol.be/>.

In case of questions or problems, please contact the CTU through ctu@zol.be or +32 89 80 40 10.

5. ACCESS TO THE RESEARCH PORTAL

To initiate the approval process for a project in ZOL, researchers and sponsors need to submit the project via the Research Portal of ZOL. The Research Portal is accessible through the following link: <https://researchportal.zol.be/>. Access to the portal is safeguarded with multi-factor authentication. All access through a non-ZOL PC will require either an authenticator app or an SMS authentication. The link to the Research Portal will lead to the following webpage:



The procedure to obtain access differs depending on the user being internal or external

5.1 Employees ZOL (internal users)

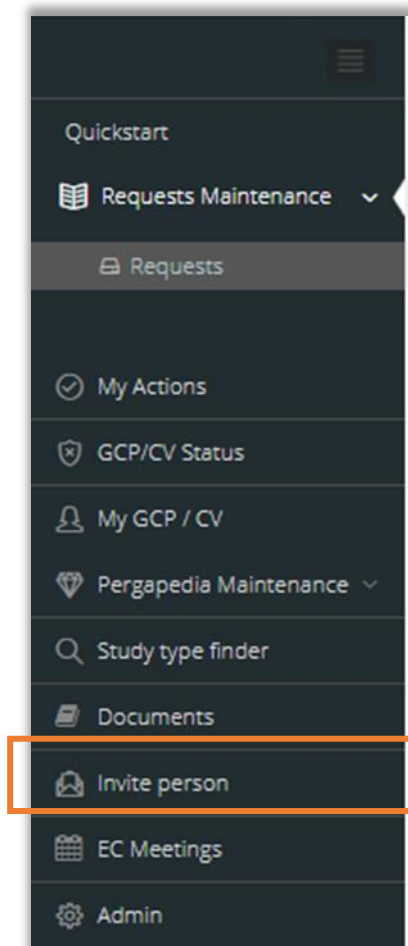
All persons with an active account of ZOL, i.e., all employees and independent physicians of ZOL, are granted automatic access to the Research Portal, after selecting the option 'I have a ZOL account'.

5.2 External users

External users, e.g., monitors/clinical research associates (CRAs), employees of a sponsor, a contract research organization (CRO), have two options to obtain access to the Research Portal.

5.2.1 Option 1: By invitation from a registered user

An external user can be invited to the Research Portal by a previously registered user. To invite an external user, the previously registered user should click on **'Invite person'** in the left-hand column of the Research Portal and fill in the external user's first name, last name, email, mobile phone and company. Please do not use a generic email address and ensure to provide the mobile phone number in the correct format.



The users account will be automatically created.

Access to a project can be granted by adding the user to a custom actor type in the 'Actors' tab of the respective project.

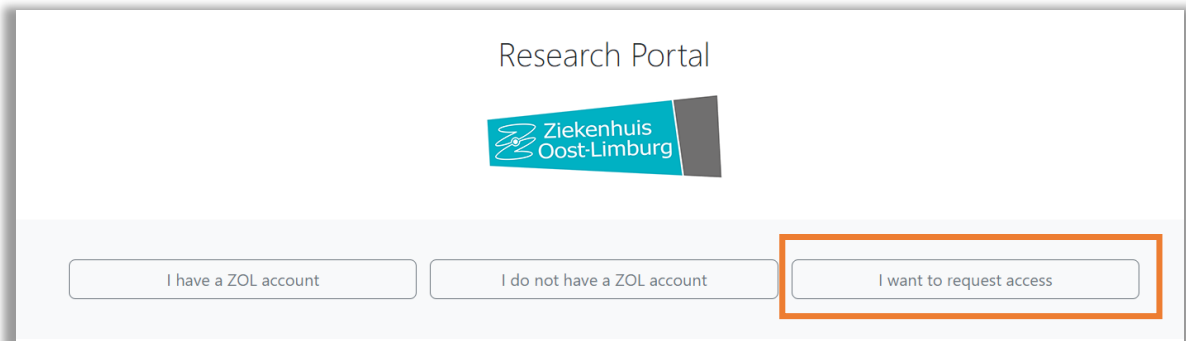
If this option is followed, the external user can log-in to the Research Portal by selecting the option 'I do not have a ZOL account'.



5.2.2 Option 2: By requesting access

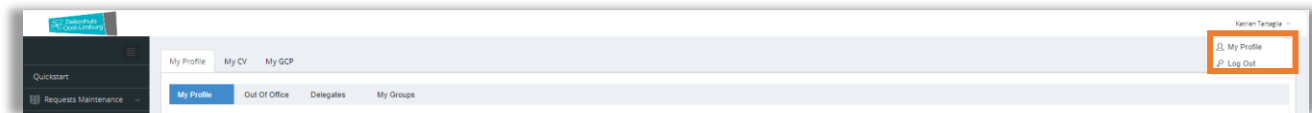
External users can request access to the Research Portal by clicking on the option 'I want to request access'. The user will need to provide his/her first name, last name, email, mobile phone, company and a reason for the access request (e.g., study title and local Principal Investigator of the study the user wants to create). Please do not use a generic email address and ensure to provide the mobile phone number in the correct format.

The CTU will review the entered information and grant access to the Research Portal. The external user receives a confirmation mail with login information and should now select the option 'I do not have a ZOL account'.



6. MY PROFILE

Users are asked to complete their profile information and keep it up to date at all times.



6.1 My Profile

In 'My profile' it is possible for users to register an out of office, to assign a delegate and to verify which groups they are allocated to.

Out of office: Register your out of office in the Research Portal and assign a delegate who will receive emails and/or actions that are generated by the portal during your absence. Registering your out of office is recommended in order to guarantee an efficient approval flow. The Research Portal provides the possibility to receive the emails and/or actions yourself as well for verification purposes upon your return.

Delegates: Select a user that can follow up on your emails and/or actions during an out of office or permanently. To be able to perform an action, the delegate should have access to the respective study. Therefore, the delegate should be added to a custom actor type in the 'Actors' tab of the respective study.

My Groups: Under 'My groups' you can find more information on which groups you are a member of. The advantage is that a group can be directly added to a study, granting access to the study for each group member. If you would like to create a group, please contact ctu@zol.be.

6.2 CV

In the section 'My CV' the user can upload his/her CV.

In order to proceed with the approval process of a project, a **valid signed and dated CV of the Principal Investigator** of the project is required. Please note that a CV is valid for a period of three years.

6.3 GCP

In the section 'My GCP' the user can upload a valid GCP certificate. All individuals involved in clinical research are required to obtain a valid GCP certificate.

In order to proceed with the approval process of a project, a **valid GCP of the Principal Investigator** of the project is required. Please note that a GCP certificate is valid for a period of three years.

7. DIFFERENT PROJECT TYPES

All clinical studies, projects, programs (*in this manual referred to as 'project' or 'request'*) conducted within ZOL or for which services are performed by ZOL, need to be submitted and approved through the Research Portal of ZOL before the start of the project/services.

For each of the following project types, a specific approval procedure is implemented in the Research Portal:

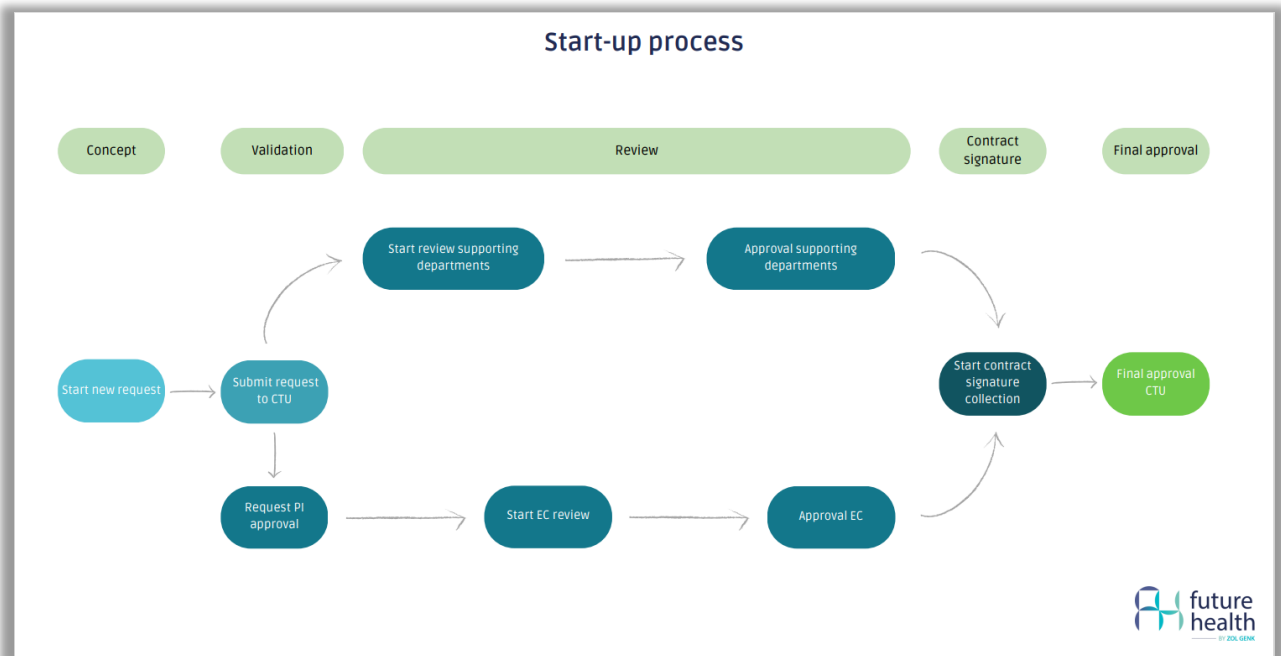
- **Prospective study** (Interventional and non-interventional studies)
- **Prospective study CTR/MDR/IVDR**: A study with an investigational product or a (in vitro diagnostic) medical device.
- **Retrospective study**
- **Fast tracks**: These projects include e.g. anonymous questionnaires, advertisement external study, governmental project, internal quality project, retrospective register, case report and ZOL as a service provider.
- **Biobank study**: The study investigates previously collected human bodily material (e.g., blood, tissue) stored within the biobank. No new data, nor samples are collected in this study type.
- **Medical Need Program (MNP) – Compassionate Use Program (CUP) – Urgent Request (UR)**

The 'study type finder' in the left-hand menu can assist to identify the correct project type template. After responding to a series of questions, the system will suggest the appropriate study type. By clicking on 'Review' and subsequently 'Submit', the user will be automatically redirected to a new request of the appropriate type.

ATTENTION: It is not possible to change the study type afterwards. In case of doubt, please contact ctu@zol.be.

8. GENERAL APPROVAL FLOW OF A PROJECT

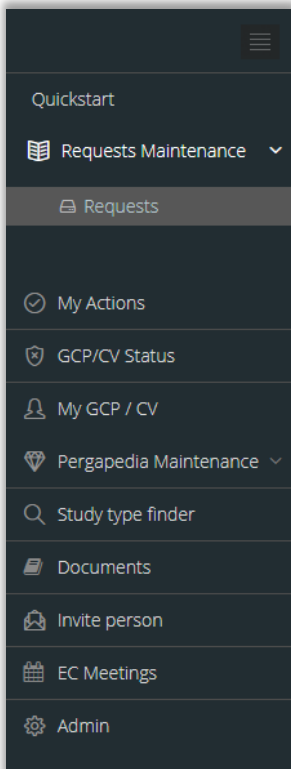
The figure below illustrates the general approval flow in the Research Portal. Depending on the project type, certain steps may or may not be applicable.



- **Concept:** Create a new project (*in this manual and in the application referred to as the 'request'*), complete all mandatory fields and upload all required documents.
- **Validation:** Once submitted to the CTU, the general admissibility of the request is checked. After being declared admissible, the request is sent to the supporting departments and PI for review.
- **Review:** After approval of the PI, the request is sent to the EC for advice. Review by the supporting departments continues during this phase.
- **Contract signature:** If all supporting departments and the EC have given their approval, the contract can be signed.
- **Final approval:** Once the contract is fully signed and provided to the CTU, final approval is granted by the CTU.

9. GENERAL LAYOUT OF THE RESEARCH PORTAL

On the left-hand side, the Research Portal contains a column with the main system options. Below, an overview of all possible options is provided. Please note that not all users have access to all options.



Quickstart: briefly explains how to submit a study application in 4 steps, and contains general info about the system, contact information of supporting departments, etc. On the Second page of this Quickstart you will find short instruction videos showing different steps on how to use the tool.

Requests maintenance: gives an overview of the projects (requests) you have access to.

My Actions: gives an overview of all the open actions assigned to you. In each study, study specific actions are also visible in the tab ‘My open actions’.

GCP/CV status: access is restricted to CTU and members of the Ethical Committee (EC). This system option gives access and an overview of the validity of the uploaded CVs and GCP certificates of the users.

My GCP/CV: gives you access to your profile, with the possibility to upload a GCP certificate and CV, and assign delegates for your notifications and tasks during an out of office period.

Pergapedia Maintenance: access is restricted to CTU and EC administrators. This system option gives access to the set-up of the system.

Study type finder: can be used to select and start the right project type template.

Documents: contains Biobank document templates that can be used during the submission process to start up Ubilim-submission. In the ‘Biobank’ tab of the study request, the template that can be used is referred to.

Invite person: all registered users in the portal can invite other persons to the portal by adding the required information in the form. Please do not forget to add the invited person to the project they need to have access to.

EC Meetings: access is restricted to CTU and EC administrators. This option provides an overview of all planned EC meetings and their agendas.

Admin: access is restricted to CTU and EC administrators.

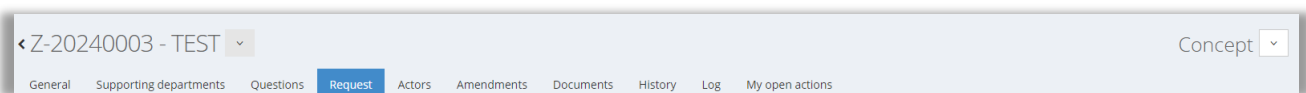
10. GENERAL LAYOUT OF A PROJECT (REQUEST)

Throughout a request, different types of fields are used:

- **Free text:** This field has no restrictions concerning the format of the text.
- **Typeahead single selection:** This field automatically generates a list of suggested answers in real-time when you type.
- **Radio buttons:** A single answer must be selected.
- **Check boxes:** Multiple answers can be selected.
- **Dropdown list:** An answer can be selected from a dropdown list.
- **Date:** A date can be entered in the following format DD/MM/YYYY or by selection from the calendar displayed in the field.

For clarity, some fields are accompanied with additional information (marked with ⓘ).

Every request consists of a main menu with different tabs. Some of the tabs have subtabs and not all tabs are applicable to all the different project types. You are allowed to work over the different tabs during the submission process. All changes are automatically saved.



10.1 General

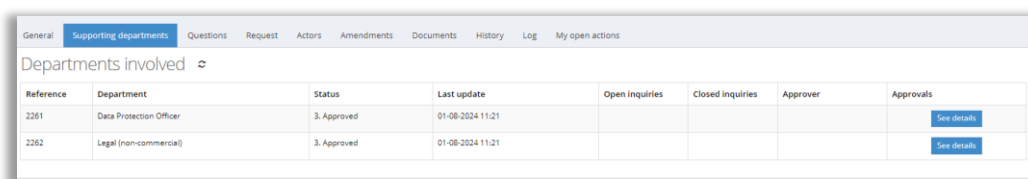
The tab 'General' gives an overview of the project request and allows you to submit the request. It is not possible to enter any information in this overview, as these fields are linked to data that will be filled in via the other tabs of the Research Portal.

As long as essential fields (marked with a ⚠) are not completed, it will not be possible to submit the application.

Please note that all fields and documents related to the submission for the CTU, supporting department and/or EC approval flow can no longer be changed once the request has been submitted. Therefore, your request must be complete and accurate before submission. The 'Documents' remain accessible after submission of the request.

10.2 Supporting departments

The tab 'Supporting departments' provides an overview regarding the (contract) negotiation status with the supporting departments (Biobank, Cardiology, Data Protection Officer (DPO), Data Science, Gastroenterology, Laboratory, Legal, Nuclear Medicine, Nursing department, Ophthalmology, Pathology, Pharmacy and Radiology).



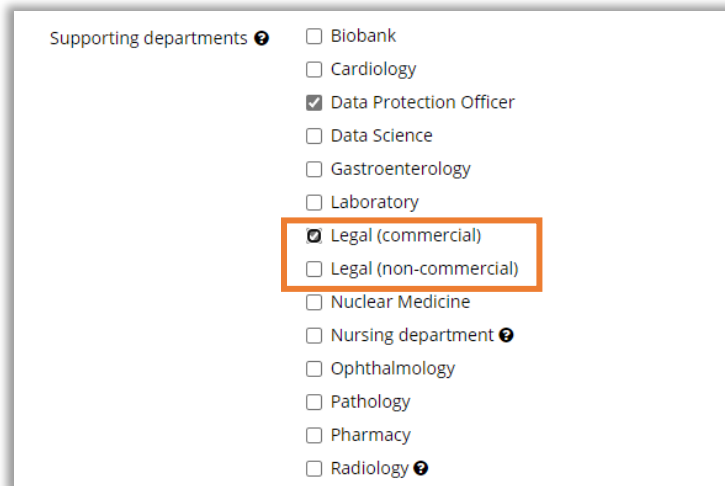
Reference	Department	Status	Last update	Open Inquiries	Closed Inquiries	Approver	Approvals
2261	Data Protection Officer	3. Approved	01-08-2024 11:21				See details
2262	Legal (non-commercial)	3. Approved	01-08-2024 11:21				See details

Attachment 1 of the manual provides an overview of the contact person for each of the supporting department.

The negotiations with the supporting departments will only start if the involved supporting departments are ticked in the tab ‘Study information’ and the study is validated by the CTU (after submission of the request by the user is performed).

ATTENTION: The review of a contract with a commercial sponsor or a contract with a non-commercial sponsor is performed by different legal reviewers. Accordingly, it is important to tick the correct legal supporting department.

The DPO is automatically ticked because each project will be reviewed by the DPO.



Supporting departments ⓘ

- Biobank
- Cardiology
- Data Protection Officer
- Data Science
- Gastroenterology
- Laboratory
- Legal (commercial)
- Legal (non-commercial)
- Nuclear Medicine
- Nursing department ⓘ
- Ophthalmology
- Pathology
- Pharmacy
- Radiology ⓘ

10.3 Questions

The tab ‘Questions’ registers all open and closed questions which were sent during the approval process of the project.

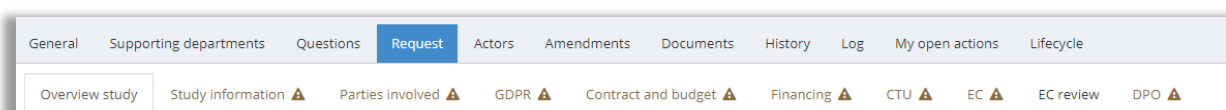
10.4 Request

In the tab 'Request', all details about the study request need to be filled in. Depending on the type of request, specific tabs will appear with conditional questions. If certain tabs are not displayed, those tabs do not apply to your request. Please note that some of the subtabs refer to other tabs of the main menu. For example, as indicated in the tab ‘Parties involved’, persons need to be added through the tab ‘Actors’.

In several tabs, documents will need to be uploaded using the provided blue buttons. When uploading documents using the blue buttons, the documents will automatically be placed in the correct category of the ‘Documents’ tab. It is advised to complete as much document details as possible (e.g version number, version date).

When all essential fields in the ‘Request’ tab are filled in, you will be able to submit the request in the ‘General’ tab.

Figure below gives an overview of the different subtabs in the ‘Request’ tab.



- **Overview study:** This tab provides an overview of the status of different phases during the approval process and during the study conduct. This tab is read-only: the fields are filled automatically. In case of questions, please contact ctu@zol.be.
- **Study information:** This tab collects information regarding the project (e.g. title, department, study type, sponsor), study conduct and insurance.
- **Research content:** This tab collects information about the study design, study interventions and patient specific information.
- **Parties involved:** In this tab, all involved parties are shown with the corresponding contact person (sponsor, local principal investigator, sub-investigator, study team members and students). The contact persons need to be filled in using the tab 'Actors'.
- **Study subjects and recruitment:** This tab collects information about the type and number of participants, the informed consent and the recruitment material.
- **GDPR:** This tab collects information regarding the personal data and medical data which will be processed (recorded/stored/forwarded) for the project. This tab will also collect information on how the data is processed during the project.
- **Contract and budget:** This tab collects information to facilitate the negotiation process with the supporting departments. In the tab 'Study information' the involved supporting departments will need to be ticked before their specific section will appear in the 'Contract and budget' tab.
- **Financing:** This tab will appear only if it concerns a non-commercial project (cfr. tab 'Study information', subtab 'General information', data field 'Study initiated by'). This tab will collect information regarding the funding of a project and master agreements of which the project is part.
- **CTU:** Access of this tab is restricted to the CTU administrators. This tab provides a checklist for the CTU administrators.
- **EC:** Access of this tab is restricted to the EC administrators. This tab provides a checklist for the EC administrators.
- **EC review:** This tab will collect information regarding the EC communication between Principal investigator (or delegate) and EC members.
- **DPO:** Access of this tab is restricted to the DPO administrators. This tab collects information regarding the risk assessment performed by the DPO. The conclusion of the risk assessment will be visible for all users in the tab 'GDPR' in the section 'J. Risk Assessment'.

10.5 Amendments

This tab provides the link to the submitted Amendments of a project. This can be contract amendments (financial, legal, ..) or EC amendments (non-substantial, substantial, ..).

10.6 Documents

In the 'Documents' tab, you can find an overview of all documents related to the request. Although it is possible to directly upload documents in this tab, it is strongly recommended to upload your documents using the 'Request' tab and the provided blue buttons when submitting an initial request. In this way, you are ascertained that all obligatory documents are uploaded and that the correct category is assigned automatically.

Alternatively, and in later stages of the request, documents can be uploaded directly in the 'Documents' tab. Enter the necessary information for each document using the blue pencil. It is advised to complete as much document details as possible (e.g. version number, version date). By assigning the document category, the document will also become visible in the corresponding question of the request itself.

ATTENTION: All documents must be uploaded separately. Zip files are not permitted, your request will be found inadmissible.

ATTENTION: If your research involves the biobank as a participating department, please use the obligatory biobank templates and upload these in the 'Contract and budget' tab of your request. The differences between the two biobank templates is the requirement of registration only versus registration and (temporary) storage of the samples.

10.7 History

Once your study request is submitted, the status of individual approval steps can be followed in the 'History' tab.

The 'view ticket' button is only accessible for the CTU and EC administrators and provides more information regarding the different approval steps performed by the responsible persons within the process.

10.8 Log

In the 'Log' tab, the Research Portal keeps track of a detailed audit trail with an overview of all additions/adaptations that occurred within a request.

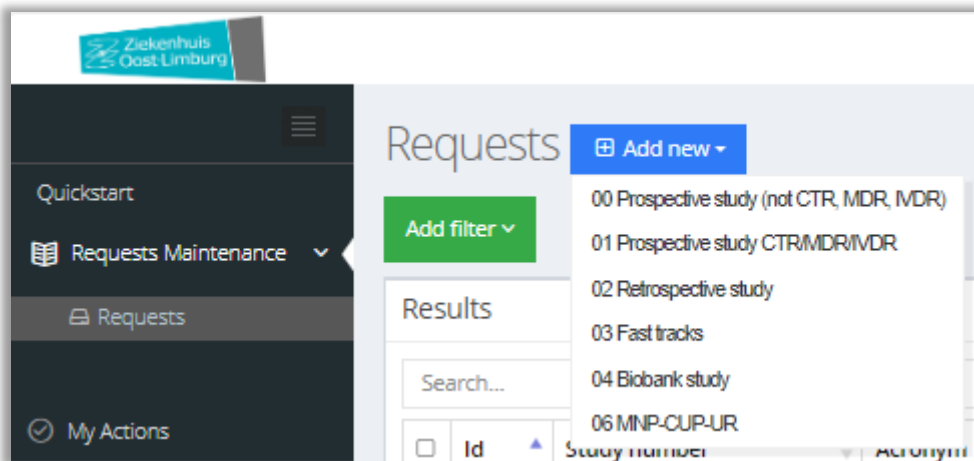
10.9 My open actions

A user's open actions related to a specific study can be found in the tab 'My open actions'. Users also receive notification emails throughout the process in which the actions required by the user are described and a link is included that directs to the specific action.

11. CREATE OR FIND A REQUEST

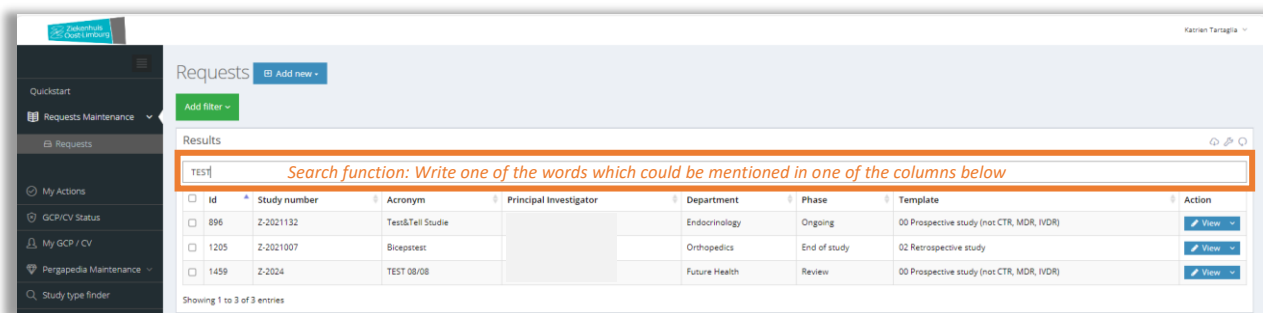
11.1 Creation of a new request

Both internal and external users can create and submit a new study request in the Research Portal. This can be done by navigating to the 'Requests Maintenance' section in the left-hand column of the portal and subsequently selecting 'Add new'. First, the type of request needs to be selected before a new request will open. The different types of requests are described in more detail in section 7. In case of doubt about which type to use, please check the study type finder. In case of questions, please contact ctu@zol.be.




11.2 Search an existing request

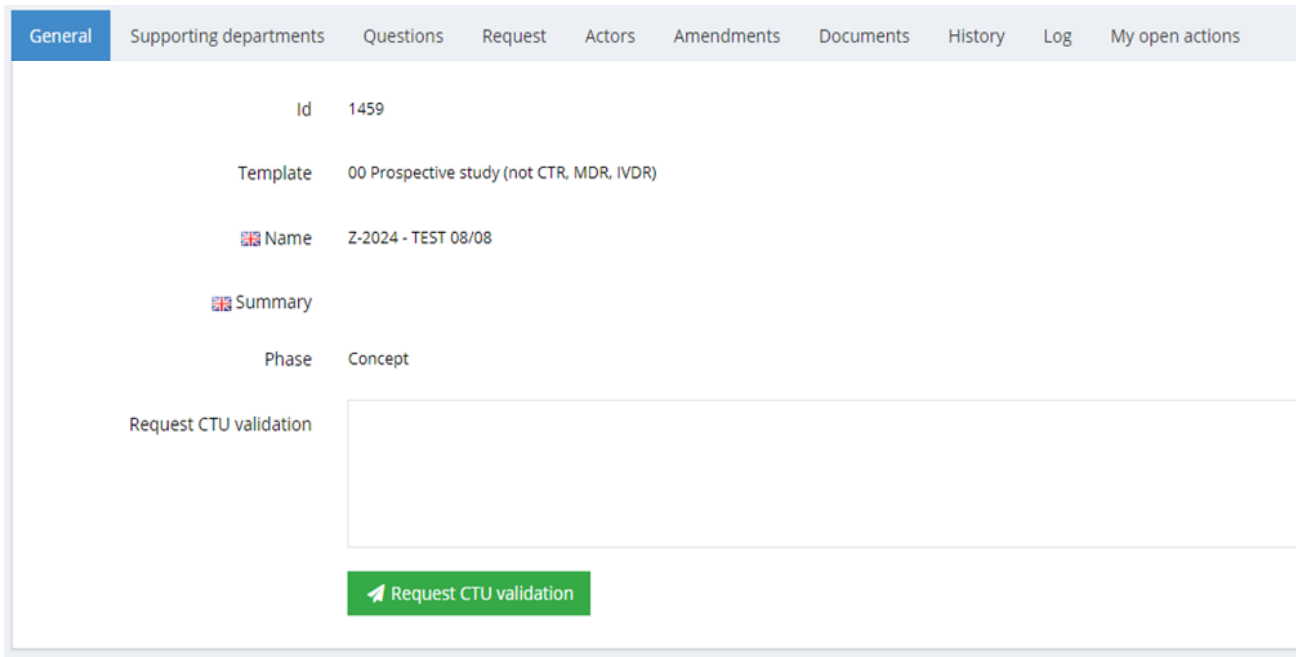
To find all the requests that you have access to, click on 'Requests' in the left-hand column of the Research Portal. A specific request can be found using the 'Search' function.



Alternatively, a filter can be set by selecting 'Add filter'. This allows to only view requests in a certain phase (Where phase is ...) or of a certain study type (Where template is ...).

12. SUBMISSION OF A REQUEST

All essential fields and tabs (marked with ) need to be completed before a study request can be submitted. By clicking on the green 'Request CTU validation' button within the 'General' tab, the request can be submitted and will proceed from the CONCEPT phase to the next phase, VALIDATION.



The screenshot shows the 'General' tab of the Research Portal interface. The top navigation bar includes tabs for 'General', 'Supporting departments', 'Questions', 'Request', 'Actors', 'Amendments', 'Documents', 'History', 'Log', and 'My open actions'. The main content area displays the following details:

- Id:** 1459
- Template:** 00 Prospective study (not CTR, MDR, IVDR)
- Name:** Z-2024 - TEST 08/08
- Summary:** (indicated by a red icon)
- Phase:** Concept

Below these details, there is a section for 'Request CTU validation' with a large empty text input field. At the bottom of this section is a green button with a white arrow icon and the text 'Request CTU validation'.

13. APPROVAL PROCESS OF A REQUEST

In section 8 a general overview is given regarding the approval process of a request. Each type of project may show minor deviations from the general schedule. In **attachment 2** of this manual a schematic view of the different processes can be found.

IMPORTANT: An approval process can only start when the request has been submitted by a user (section 12). A next step within an approval process (including change of phase) can only be achieved if an 'action' is confirmed by the responsible person.

13.1 Actions

The responsible person that needs to perform an action will receive an email notification and the action will appear in the 'My Actions' log in the Research Portal.

Starting from the email, the action can be performed by clicking on the referred link.

RESEARCH PORTAL ZIEKENHUIS OOST-LIMBURG

Dear,

Your validation of the following project is required. To finalize this action or raise questions, please [click here](#).

Comments from study team (if any):

Study Title: RETRO test 2.0
 Study number: FT-2024
 PI: Future Health
 Department: [Click here](#)
 Template:
 Link to the study:

Kind regards,
 Clinical Trial Unit
 Ziekenhuis Oost-Limburg
 Office M9.38, Synaps Park 1, 3600 Genk
ctu@zol.be
 089/80 40 10

This e-mail was automatically sent via the researchportal.zol.be application.

Decision
 I accept I decline

Comments

SUBMIT

+ Ask a question

Open Questions Closed Questions

No data yet

Go directly to the required action

Go to the request to inquire more information

Make a decision or ask a question

13.2 Questions

In case of uncertainties it is better to ask a question, then to decline the project. Questions can be posted via an 'Action' window (section 13.1). The button 'Ask a question' will open a pop-up window where a question can be uploaded.

Question ✕

Question

Details

Audience

Wendy De Roock
Charlotte Tuerlinckx

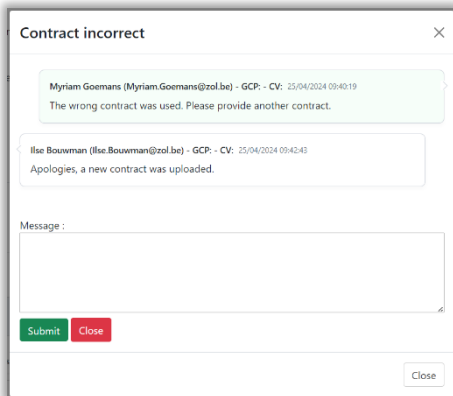
⇄

Ilse Bouwman

Submit

Enter the title of the question in the field 'Question' and the full question in the field 'Details'. In the below section 'Audience' you can select the recipient of the question. By clicking on submit, the question will be forwarded to the selected Audience.

Once a question is posted, an email notification is sent to the study team and the question is logged in the request in the tab 'Questions'. From now on, a back and forth communication between the study team, CTU, supporting department or EC is feasible until the question is closed.



Once the recipient has answered the question, the initiator of the question will receive an email notification. Until the concerns/question have been resolved, it is possible to continue with a back and forth communication between the study team, CTU, supporting departments and EC. Once all concerns have been resolved the question can be closed by the person who initiated the question. All questions will be closed automatically once a decision regarding the related action has been made. In the meantime, the study team will receive reminders every 3 days regarding the open question.

For each project, the legal department will provide feedback regarding the Clinical Trial Agreement, Data Transfer Agreement, etc by using this 'Questions' option. Each time a review of the Agreement is performed the adjusted Agreement will be uploaded in the 'Documents' tab. It is advisable to use a consistent file naming for a specific document. For example, a Clinical Trial Agreement could be filed as: CTA_draft, CTA_comments1, CTA_comments2, CTA_final_legal, CTA_final_signed. In addition, the CTA can be filed in section K1. Clinical Trial Agreement.

14. AMENDMENT

Once a project receives approval of the EC, all involved supporting departments approved the project and the signed contract is uploaded, the study can start in ZOL.

IMPORTANT: In order to recruit patients also the approval of the sponsor is required.

Once the project started and changes are required regarding the protocol, budget, contract, or PI an amendment should be submitted.

The option "non-substantial" or "substantial amendment" in the Research Portal should only be selected if the Ethics Committee of ZOL is the leading EC. If EC ZOL is acting as a local EC, these amendments do not need to be submitted in the Research Portal.

15. FOLLOW-UP A PROJECT AFTER APPROVAL

After approval of your project, the phase of the study should be updated continuously as the project proceeds. The changes in lifecycle phase should be registered in the tab 'Lifecycle' of the request.

The Research Portal defines 4 different lifecycle phases:

- **Ongoing:** The 'FINAL CTU APPROVAL' phase will change to 'ONGOING' once the start of recruitment has been reported in the Research Portal. In addition, the following project milestones will have to be reported as well:
 - First patient recruited in ZOL
 - End of the global recruitment period
- **End of study:** This phase will be activated once the study has been reported as 'study closed at ZOL' in the Research Portal.
- **On hold:** If a study is temporarily stopped, it can be registered by completing the 'study on hold date' in the Research Portal.
 - Once the study can restart, the restart date should be reported in order to change the phase of the study back to 'ongoing'
- **Early discontinuation:** If the study is early discontinued, it can be registered by completing the 'early discontinuation' date.

16. ATTACHMENT 1: CONTACT DETAILS OF SUPPORTING DEPARTMENTS

Supporting Department	Contact Person	Email	Telephone
Legal/DPO	Myriam Goemans	Myriam.Goemans@zol.be	+32 89 80 80 12
Pharmacy	Sarah de Sy	Clinicaltrials.pharmacy@zol.be	+32 89 32 14 23
Laboratory	Dr Joris Penders	Clinicaltrials.laboratory@zol.be	+32 89 32 46 67
Pathology	Annick Moors	Annick.moors@zol.be	+32 89 32 47 40
Nuclear Medicine	Valerie De Boel	Valerie.deboel@zol.be	+32 89 32 46 45
Radiology	Ellen Gielen	Ellen.Gielen@zol.be	+32 89 32 46 12
Cardiology	Evi Theunissen	Evi.Theunissen@zol.be	+32 89 80 72 51
Gastro-enterology	Diana Clemente	Studie.mdl@zol.be	+32 89 80 40 49
Ophthalmology	Dr Mieke Wirix	Studies.oftalmologie@zol.be	+32 89 32 61 55
Data Science	Noëlla Pierlet	Noella.Pierlet@zol.be	+32 89 80 20 55

17. ATTACHMENT 2: SCHEMATIC VIEW OF THE APPROVAL PROCESS OF THE DIFFERENT PROJECT TYPES

