Submission of a clinical research project
How to request the creation of a new project in Dyco Flow

## Introduction

The submission of a clinical research project (including TFE) involving Hôpital Erasme patients is processed using a digital platform called Dyco Flow. Dyco Flow is an interactive data and document capture software shared by all involved parties.

The submission via DycoFlow applies to anyone who is conducting a research project (including final year work or TFE) involving at least one human being, data or human body material (HBM) relating to a human being, who has been, is being, will be treated or examined at the Hôpital Erasme.

## Things to consider before you begin:

## Registry submissions are also made via Dyco Flow.

## Case reports do not go through Dyco Flow. They are submitted directly to the CE.

## Analyzes of residual human body material or existing patient data are retrospective studies.

## Retrospective studies can only be performed using residual human body material or data previously stored in biobanks or registered registries, respectively.

## Biobanks are intended to store human body material and records to capture patient data. For the creation of a biobank, please contact the SRB by email at Service.Rech-biomed.erasme@hubruxelles.be

## Information to follow before completing the table below:

* Please note that **the head of department and the PI must be a staff member of one of the 3 institutions of the HUB** and use an email address @hubruxelles.be.
* The hospital does not allow PG and consultants to be PI, they can be **co-investigator**.
* **The Head of department must be informed of your project** and must have had access to your protocol **before** you start the submission.
* Incorrect emails = blocked project (email addresses are used as login).
* Only submitters can enter data and upload documents. **The PI cannot modify his project in Dyco Flow unless he is also a submitter**.

Requesting access for: Clinical study - Registry - Compassionate use program - Medical need program

Please note that the scroll down option is available for the type of study and the list of departments

|  |  |
| --- | --- |
| **Sponsor type** | [Select] |
| **Department** | [Select] |
| **Project with :**[ ]  **an Investigational Medical Product (IMP) registered on the EU portal (CTIS)** [ ]  **a medical device following the Medical Device Regulation (MDR)** | (for more information contact the SRB) |
| **Original title** |  |
|  | **First name** | **Last name** | **Email address** | **Role in Dyco Flow** |
| **Yourself** |  |  |  | Submitter |
| **PI** |  |  |  | PI |
| **Other user 1** |  |  |  | [Select] |
| **Other user 2** |  |  |  | [Select] |
| **Other user 3** |  |  |  | [Select] |
| **Other user 4**  |  |  |  | [Select] |

**** Copy and paste the completed table in an email, write“**Dyco Flow-INPUT REQUIRED: create a new project”** in the OBJECT/SUBJET field of the email and sent it to [Service.Rech-biomed.erasme@hubruxelles.be](file:///C%3A%5CUsers%5Cnora_bahhodh%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CFACN4AES%5CService.Rech-biomed.erasme%40hubruxelles.be)

## First Connection to DYCO FLOW

After your project has been created, you receive an email from “Erasme Dyco Flow” to login onto your new project. **For new users only**: Dyco Flow has sent you, an email called “**New account login instructions**” containing all the instructions to create your Dyco Flow account.

**IMPORTANT**: *before you begin, make sure that* ***POP-UP WINDOWS*** *are activated in your browser (go to the internet to find the appropriate procedure, it is different for each browser).*

**** Open “**User guide 1: Getting started**”. Follow the instructions (see print screen below). When you are done move on to User guide 2 etc.

