EU-SolidAct: eCRF user guide

1) Website address:

https://ccde-ecrf.com/EnnovClinical/login
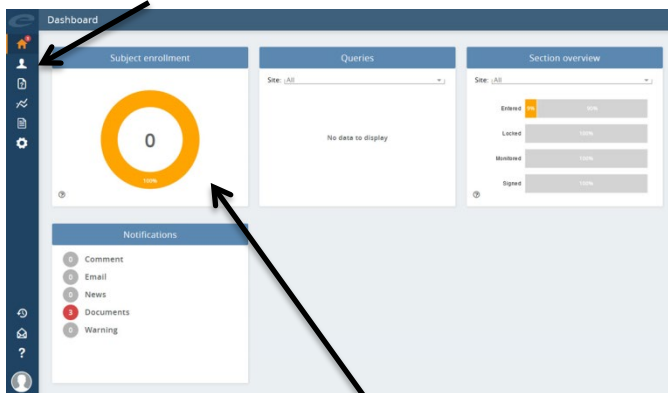
Specify the study name, your login and password

Choose the interface language

2) Dashboard: home page of the eCRF made up of several widgets.

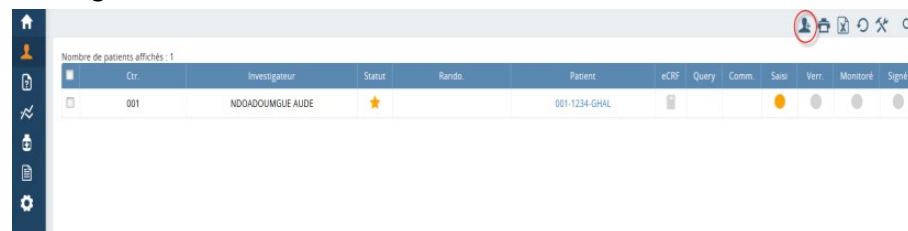**Patient overview. Allow to access to the CRF of each patient and to create new patient**

Subject enrollment widget: displays the number of patient in the site.

3) Creation of a new patient:

Patients are created by clicking the "patient overview" section. To add a patient to the study, click the "Create new patient" button:

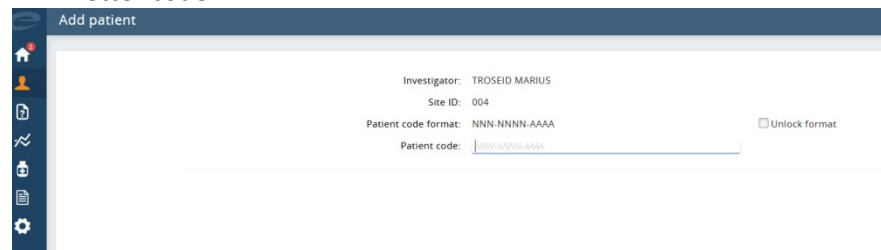Select the investigator associated to the site by double clicking on the Investigator's name

Enter patient ID code according to the list given at site initiation visit:
NNN: site number
NNN: patient number
AAA: letter code

4) Data entry

To access the eCRF of each patient and start data entry, investigators should go to the Patient overview and click on eCRF

Icons summarizing the pages status

Menus allowing to access functionalities (save data, lock pages, creation of comments, …) and tools

5) Randomization

A patient can be randomized if, at least, WHO Disease stage has been entered in "Eligibility to Part A and B" page and the following randomization page at Baseline:

Fill the information and click on "Randomize"

Kit number will appear