



# **USER GUIDE – CRF ONLINE**



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## **1. ACCES TO THE PLATFORM. STUDY, USER & PASSWORD**

The platform has been validated with the following Internet browsers:

- Internet Explorer v6 and later versions
- Mozilla Firefox v1.0 and later versions
- Netscape Navigator v5 and later versions

On the login page, the link Need help? can be seen. If it's clicked, a new page appears and I want to test browser compatibility can be selected. This will allow testing the browser and hardware configuration to check whether there are any compatibility problems with the use of the platform. The following items will be verified:

- Configuration of the browser anti-popups
- Browser type (Internet Explorer, Firefox, Netscape).
- Java script management based on the browser
- Java script activation in the browser
- Screen resolution

**Connection to the study:**

First of all, you have to introduce the following url: [www.e-bioclever.com](http://www.e-bioclever.com)



Down on the right you can choose the language for the application. By default, the language is English.

In order to enter to the study you must write the name of the study that they have indicated.

Each investigator will have a different user and password, and that will be delivered personally or by email. This password must be personal and non-transferrable. If you need other passwords for other investigators or collaborators of your center, you have to request it to the monitor.

**Password reset**

Hello I , please define a password and confirm it.

Password rules:

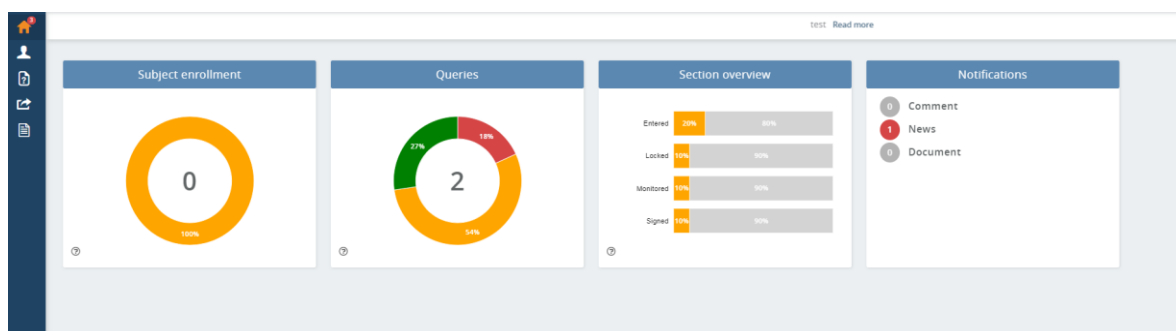
- Between 8 and 15 characters long

the first time that you connect to the study with the delivered password, you will be required to change your password, for security reasons.

Enter a password containing between 6 and 15 alphanumeric characters without any accent mark [a-z] [A-Z] [0-9], confirm your password by entering it again and click "OK".

## 2. HOME PAGE

The clinical study home page, accessible once the user is logged in, is presented as follows:



The homepage of the study will allow you Access to the following sections:

- 1- **Subject enrollment:** through the first widget that appears on the homepage, by clicking on the central number or by clicking on the left side menu, on the man icon, you will access to the patient list.
- 2- **Queries:** You can see the percentage of resolved queries, and pending queries. By clicking on the central number you will access to the queries list.
- 3- **Section overview:** From this widget, you can see the percentage of completeness of your included patient.
- 4- **Notifications:** Here you can see if you have any pending reading notification.

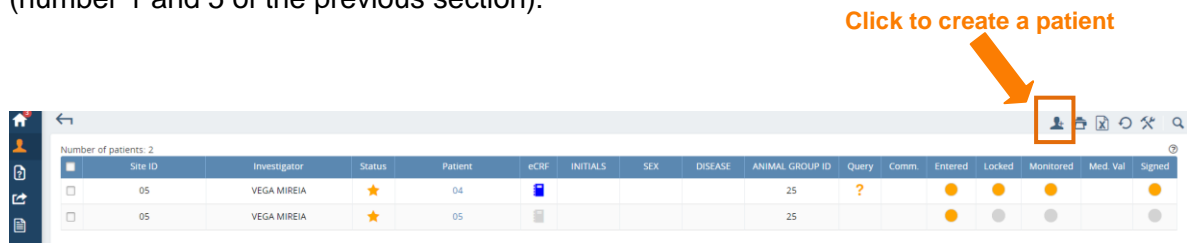
Through the left side menu, you can access to:

- 5- **Patients overview:** Access to the list of patients, where you can create new patients.
- 6- **Queries management:** When you click here, a new menú will be opened and then you can select:
  - **Pending queries:** queries that have to be resolved.
  - **Test overview:** you can run the queries in order to see if there are any error in the included data.
- 7- **Documents:** You can Access to all documentation of the study (which you will be allowed to download it). When you click it, a new menu will be opened, and you will be able to select:

- **News**: In this section you will see documents that the manager will upload there, as newsletters, information on amendments to the protocol, maintenance of the website, etc.
- **Study documents**: this section you will find study documents, such as protocol, informed consent, patient information sheet, CRF, adverse event forms, etc. Everything can be downloaded and printed.
- **Reports**: In this section, if the promoter allow it, you will be able to see files in Excel format with the data entered in the eCRF.
- **My documents**: Here you can find the printed pdf's of the eCRF.

### 3. CREATING A NEW PATIENT

To create a new patient, you must access through the home page to 'Patients overview' (number 1 and 5 of the previous section):



A new screen is displayed with the number that the program automatically assigns to the patient, the first two numbers being the code of the center and the three following numbers the consecutive numbers of the patient.

To confirm the creation of the new patient, you have to click on: *Next*, as you can see in the following image:

Investigator: INVESTIGADOR INVESTIGADOR

Site ID: 01

Patient code: 01008

Back

Next

On the next screen, you should click on "Create patient". Then, if everything is correct, a message confirming the creation of it will appear.

If the patient has been created successfully, the first page of the eCRF will be opened.

## 4. DATA ENTRY FOR A PATIENT

There are two different ways to access into the eCRF, in order to introduce the data of the patient.

The first one is as we have already seen, after the creation of the patient, you can directly access to the data entry screen.

The second way, it would be, in case you want to enter the data of a patient that was previously created, you could access the CRD from the menu "Patient overview" (see Fig. Home page section 1 and 5), where we can access to the list of all patients and the status of each one is shown:

	Site ID	Investigator	Status	Patient	eCRF	INITIALS	SEX	DISEASE	ANIMAL GROUP ID	Query	Comm.	Entered	Locked
<input type="checkbox"/>	05	VEGA MIREIA	★	04					25	?			

  
**Access to the CRF**

Once you have access to the data entry screen, then you could see the page divided in three different zones:



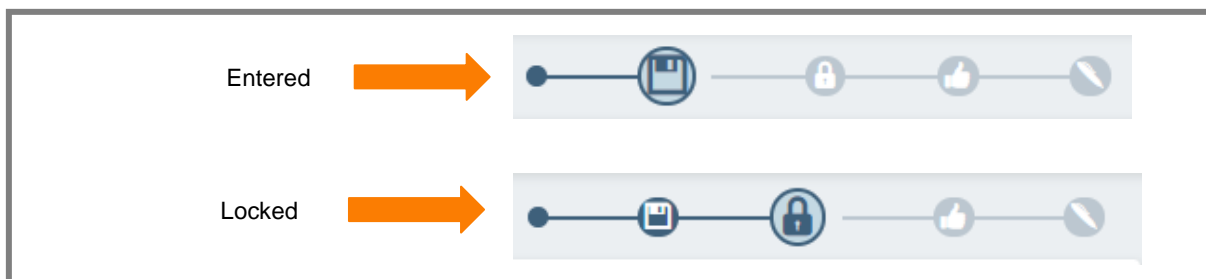
The screenshot shows the eCRF interface with three labeled zones:

- Page status:** Located at the top of the browser window, showing the URL and navigation icons.
- CRF Page:** The main content area displaying the patient's data entry form, including a date field and a table of inclusion criteria.
- Navegador:** A sidebar menu on the left containing a list of items such as "CRF 1", "SCREENING", "1- Criterios de selección", "2- demographic", "3- Vital Sign", "4- Medical History", "5- Medical History", and "MONTH 1".

**4.1** The part of the "CRF page" will change as we entered the data and when we move into another page.

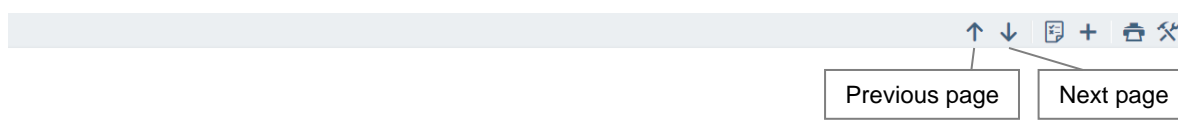


**4.2** The part of “*Page status*” shows the current status of the page of the CRF that we are looking for. With 4 different possible status:



**4.3** The “*CRF navigator*” allow you to move inside the CRF. You can be placed on any page of the CRF by clicking on it.

When the page is complete you can go to the next page using the arrows in the upper right part of the screen. Using it, you can also access to the previous page.



If you want to move into another page you can also do it by clicking on the page that you want to access in the “*CRF navigator*”.

Following, we are going to explain the **tools** button  with the functions that we can do in this menu:

- Cancel page entry (delete all the data of the page)
- See the formats of the fields included in the page.
- See the field history (you can see all the values included in this field since the start of the study)
- Pre - test overview (in order to detect errors on the data)
- Return to the patient list (CRF overview)
- Return to the section view (Section overview)
- Return to the pages view (Page overview)

Then, we will see the meaning of different buttons:

**'Entry comments'  :**

- Entry comments: For any problema doing the data entry, or general comments, you can write them using this button. If the button has an answer, you can consult it in the page of the CRF or going to the comment through the homepage.

**'Print'  :**

- Print the CRF to PDF. You can print any part of the CRF (entire CRF, section or current page). The file in pdf format will appear on the folder: My documents.

**'Notifications'  :**

- Notifications. You can access with this button, to the list of comments or queries that you have in the page where you are.

**'Lock'  :**

- Lock. When you finish the data entry, then, you must click on the padlock icon, in order to lock the page.

During the data entry you can see different validations. We will see it in the next section.

## 5. DATA VALIDATION

The data validation is done automatically during the data entry.

There are three different validation ways and warning:

**Format validation:** If the values are not entered with the required format an error message will appear, warning you that the introduced that are not correct.

Note 1: If you don't know part of a date you can enter UK. For example if you don't know the day: UK/04/2018, or if you don't know the month: UK/UK/2018, and if you don't know in general the date, you can enter: UK/UK/UK.

Note 2: Decimals must be separated with a dot '.' (Ex.: 1.25).

**Range validation:** If the values that you have entered are not within the allowed ranges, then, a message will appear indicating the permitted range.

**Pre-test validation:** Once the data introduction is finished, and you move into another page, then, the consistency of the entered data will be validated.

A loading symbol will appear while the platform are validating the data:

The screenshot shows a form titled 'CRITERIOS DE SELECCIÓN' with two sections: 'CRITERIOS DE INCLUSIÓN' and 'CRITERIOS DE EXCLUSIÓN'. Each section contains two rows of criteria with 'No' and 'Yes' radio buttons. A loading spinner is visible between the two sections.

CRITERIOS DE SELECCIÓN		
<b>CRITERIOS DE INCLUSIÓN</b>		
1.	Paciente > 6 años.	<input type="radio"/> No <input type="radio"/> Yes
2.	Otorgar el consentimiento para participar en el estudio tras haber leído y comprendido la información facilitada en el documento de consentimiento informado. En el caso de los menores de edad, serán sus padres o tutores legales quienes deberán otorgar dicho consentimiento	<input type="radio"/> No <input type="radio"/> Yes
<b>CRITERIOS DE EXCLUSIÓN</b>		
1.	Paciente que este participando en un ensayo clínico.	<input type="radio"/> No <input type="radio"/> Yes
2.	Presentar cualquier condición que, a juicio del investigador, pueda alterar las variables clínicas o analíticas incluidas en el estudio.	<input type="radio"/> No <input type="radio"/> Yes

Once the consistency of the data have been validated, if there are any inconsistency, you will automatically remain in the same page and you will see warning icons showing where are the inconsistent data.

The screenshot shows the same form as above, but with yellow warning triangles next to the 'No' radio buttons for criteria 1 and 2 in both sections, indicating inconsistencies.

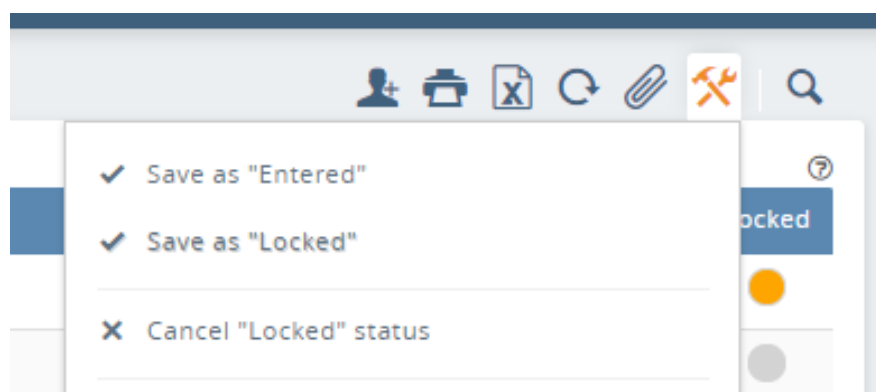
CRITERIOS DE INCLUSIÓN		
1.	Paciente > 6 años.	<input type="radio"/> No <input type="radio"/> Yes
2.	Otorgar el consentimiento para participar en el estudio tras haber leído y comprendido la información facilitada en el documento de consentimiento informado. En el caso de los menores de edad, serán sus padres o tutores legales quienes deberán otorgar dicho consentimiento	<input type="radio"/> No <input type="radio"/> Yes
<b>CRITERIOS DE EXCLUSIÓN</b>		
1.	Paciente que este participando en un ensayo clínico.	<input type="radio"/> No <input type="radio"/> Yes
2.	Presentar cualquier condición que, a juicio del investigador, pueda alterar las variables clínicas o analíticas incluidas en el estudio.	<input type="radio"/> No <input type="radio"/> Yes

In case you have inconsistent data, you can choose, if you want to solve it know and correct the errors, or if you want to move into the next page you can do it and the validation symbol won't appear again. But then, please, know that all the errors that you don't correct, later, this errors will appear as a query on the homepage.

## 6. LOCKING A PATIENT

In order to review and validate the data, after the introduction the values the page must be locked. Only in this way the data manager will know that this page is finished and ready to review.

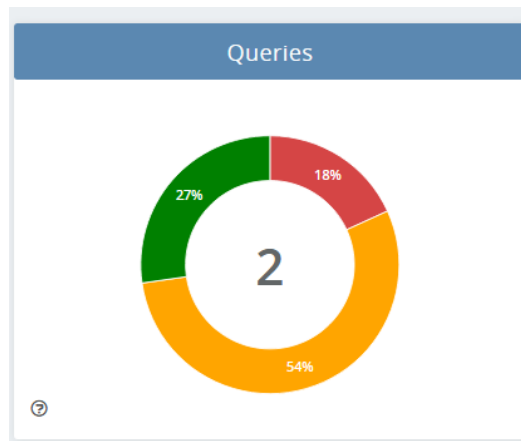
The patient can be locked from the page that has just been filled as we have seen in the previous section, or from the patient overview page. First you have to select all the patients that you want to lock, and then you have to go to the tools icon and there you will see the different options, there you have to click, save as locked.



A confirmation message will appear before do the final lock.

## 7. QUERIES MANAGEMENT

The number of queries that are pending, appear directly on the homepage, inside the graphic:



You have to click on the number that appear in the center of the graphic in order to enter to the queries section.

In the graphic, you can see: in red the pending queries, in green the verified queries by the data manager, and, in yellow the answered queries that are waiting for the data manager review.

You can also access to the queries from the patient overview. Where you can see a question mark:

Site ID	Investigator	Status	Patient	eCRF	INITIALS	SEX	DISEASE	ANIMAL GROUP ID	Query	Comm	Entered	Locked
05	VEGA MIREIA	★	04	■				25	?	●	●	

By clicking the question mark, you will go directly to the queries section. In this section you can see the complete list of the queries. At the top we have fields that you can use if you want to filter it. Each query can be answered by clicking the *reply* button.

<input type="checkbox"/>	Reply	VEGA M.	05	04	Awaiting reply	08/11/2018 15:26	MIREIA BONET	-	-	-	MONTH 1	p6 - Vital Sign	Date
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All the queries that appear in the list must be solved.

Patient: 04  
Page: CRF n°1 - MONTH 1 - p6  
Created on: 08/11/2018 15:26  
Created by: MIREIA BONET (BONET)  
User type: DM

Query status: Awaiting reply  
Sent on: 08/11/2018 15:26  
Sent by: MIREIA BONET (BONET)  
Replied on: -  
Replied by: -

Query:  
test

**1- To correct the data ("Current value"), enter the accurate data in the "New value" column. The "Reply" column will automatically switch to "To be corrected".**

CRF Section	Page	Field	Current value	Reply	New value
MONTH 1	p6 - Vital Sign	Date	<EMPTY>	<input type="radio"/> No change <input checked="" type="radio"/> To be corrected	DD/MM/YYYY

**2- Reason for change or confirmation (this is a comment field only, do not use it to enter/correct data):**

Confirm
Cancel

The intention of the query is always to answer a question. For this, we can see the list of fields involved in the question, and the value of each of them.

Then, we can confirm or correct each field. You can also write the reason for the change.

When the query is corrected, only has to be sent through the button: **Confirm** or **Correct**.

## 8. SUMMARY

Here you will find a summary of the steps that you have to follow from the beginning until the end of the patient:

1. Creation of the patient
2. Introduction the data of the patient.
3. When all the data have been entered, then block the patient.
4. External validation.
5. Query resolution.