

<b>OnlineCRF LLC</b>		
Guide For Investigators		

# OnlineCRF System User Guide (Investigator)

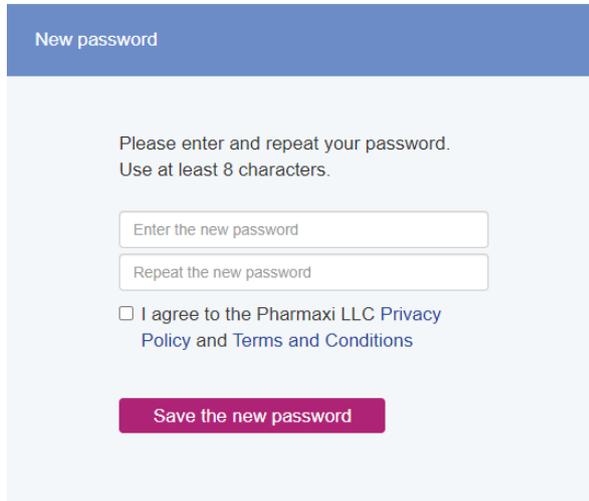
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# 1. Login

## 1.1. Creating a password

As soon as the CRA creates your account your e-mail will receive a notification (Fig. 1). It contains a link to the account password creation page (Fig. 1).



**Fig. 1. Password creation page**

Creating a password requires:

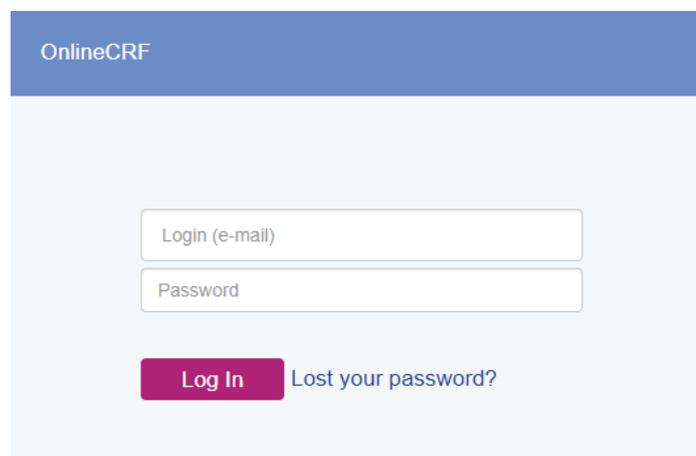
1. Fill in both fields of the form with the same password
2. Tick the agreement with the Privacy Policy and the Terms and Conditions
3. Click “Save the new password”

The password must be at least 8 characters long (in any language and using any characters).

In addition, the letter of account creation contains a link to the users’ authorization page, which remains active throughout working with the system.

## 1.2. Log in to account

After creating the password, the user authorization page is displayed (Fig. 2).



**Fig. 2. User authorization page**

To log in to OnlineCRF you need:

1. Enter the e-mail in the “e-mail” field (to which the message about creating an account was sent)
2. Enter the password created for the account in the “Password” field (see 1.1)
3. Click the “Log In” button

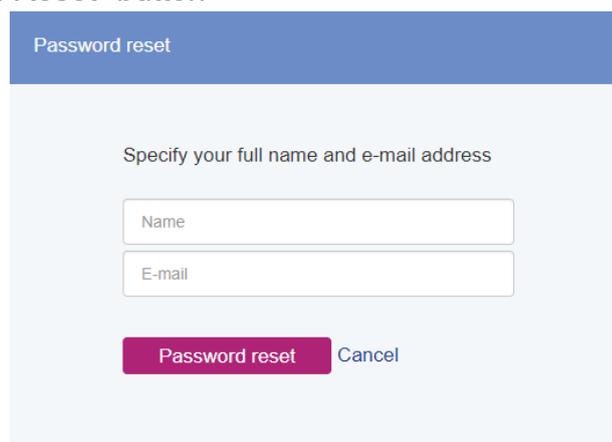
The system determines the role of the user based on their e-mail and passwords and opens the corresponding home page.

**Pay attention!** To comply with GCP, it's important that users don't share accounts or allow others temporary access to their accounts.

### 1.3. Password reset

In case of losing the password, it is necessary to create a request for password reset. To do so, follow these steps on the user authorization page (Fig. 2)

1. Click “Lost your password”
2. Enter your full name in the Password Reset form (Fig. 3)
3. Enter the e-mail the account is assigned to in the Password Reset form (Fig. 3)
4. Click the “Password Reset” button



**Fig. 3. Password reset request form**

After that, the e-mail address will receive a message with a link to the password reset page (Fig.4).

Password reset

Please enter and repeat your password.  
Use at least 8 characters.

Enter the new password

Repeat the new password

Save the new password

**Fig. 4.** Password reset page

**Pay attention!** If you make several password reset requests one after another, the last sent link will be valid.

Password reset requires:

1. Fill in both fields of the form with the same password
2. Click “Save the new password” button

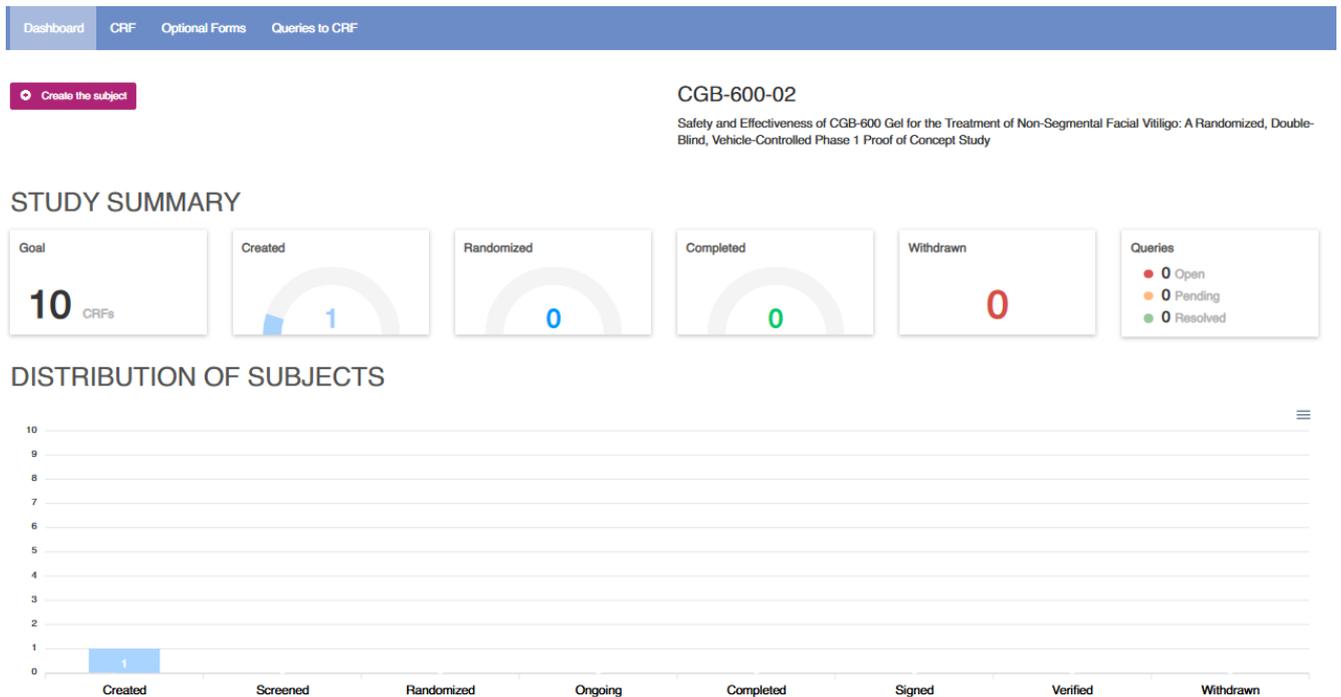
The password must be at least 8 characters long (in any language and using any characters).

#### **1.4. Session time**

After a period of 30 minutes of inactivity, the system logs out the user automatically. To continue working in the system, repeat the authorization process.

## 2. Dashboard

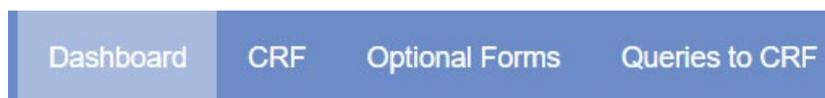
After logging in, the home page “Dashboard” opens (Fig. 5).



**Fig. 5. Homepage**

“Dashboard” page contains the following information blocks:

### A) System navigation Menu



**Fig. 6. “System navigation” block**

The system navigation menu (Fig. 6) is displayed at the top of the page and does not change its position when switching tabs.

**Pay attention!** After finishing using the system, you must log out. This is especially important if the personal computer is not being used.

### B) Logout button



**Fig. 7. “Logout” button**

The “Logout” button (Fig. 7) is displayed at the top of the page and does not change its position when switching tabs.

Logging out requires:

Click the “Logout” button in the System navigation menu at the top of the page

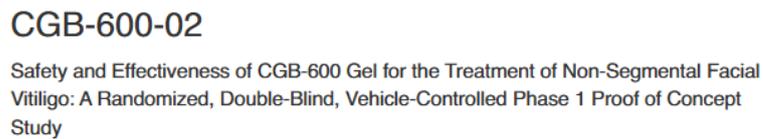
**C) “Create the subject” block**



**Fig. 8.** “Create the subject” block

This is “Create the subject” button (Fig. 8). It creates subjects’ eCRF (the process is described later in this manual).

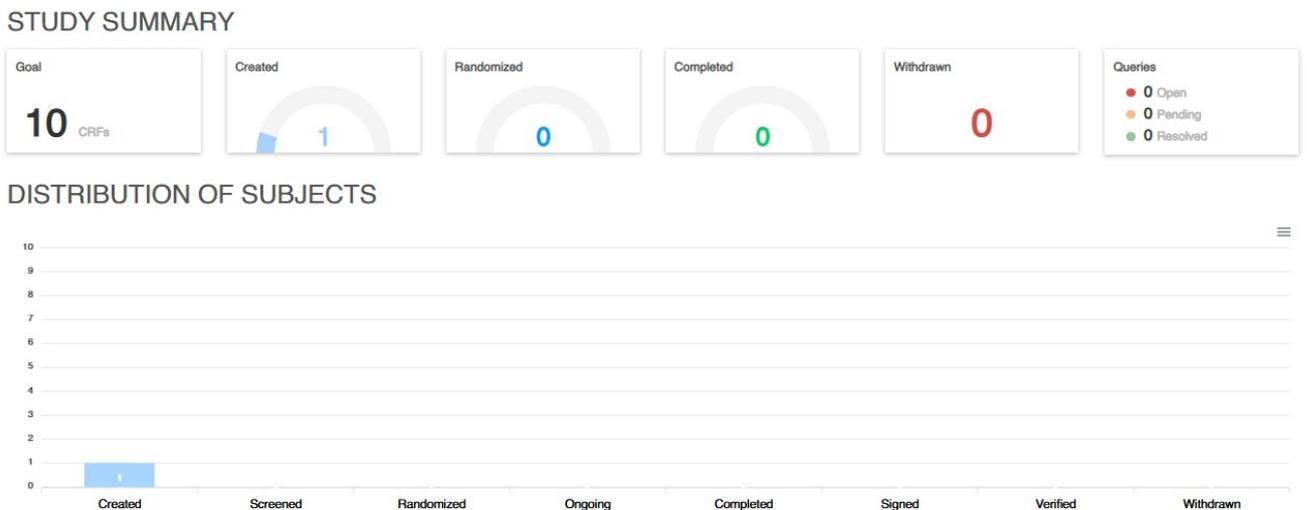
**D) General project information**



**Fig. 9.** “General project information” block

This section (Fig. 9) contains general information about the study: code and name of the project.

**E) “Project status” block**



**Fig. 10.** “Project status” block

This section (Fig. 10) contains information on the key indicators of the project: patient limit for Study Site (SS) (“Goal”); the number of subjects’ CRFs created in the SS (“Created”); the

number of CRFs of subjects who were screened (“Screened”); the number of CRFs subjects who were randomized (“Randomized”); the number of CRFs subjects in the process of data collection (“Ongoing”); the number of completed CRFs (“Completed”); the number of signed CRFs (“Signed”); the number of verified CRFs (“Verified”); the number of CRFs of withdrawn patients (“Withdrawn”).

## F) “User Support” block



**Fig. 11.** “User Support” block

This section (Fig. 11) at the bottom of the home page displays user support contacts: e-mail and phone numbers that can be used in case of questions related to the Clinical Study Protocol, documentation, and system operation.

The User support section is displayed at the bottom of the page and does not change its position when switching tabs.

## G) Privacy Policy and Terms and Conditions links

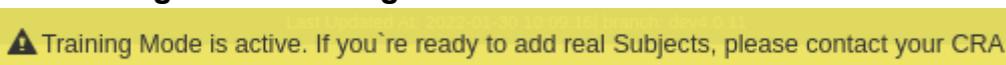


**Fig. 12.** Privacy Policy and Terms and Conditions links

Here (Fig. 12) the user can re-visit the rules of using the system. When you click the “Privacy Policy” or “Terms and Conditions” button, a pop-up window containing the text of the document appears.

The User support section is displayed at the bottom of the page and does not change its position when switching tabs.

## H) Study Site training mode warning



**Fig. 13.** SS training mode warning

This warning (Fig. 13) serves as a reminder that the SS is in the training mode currently.

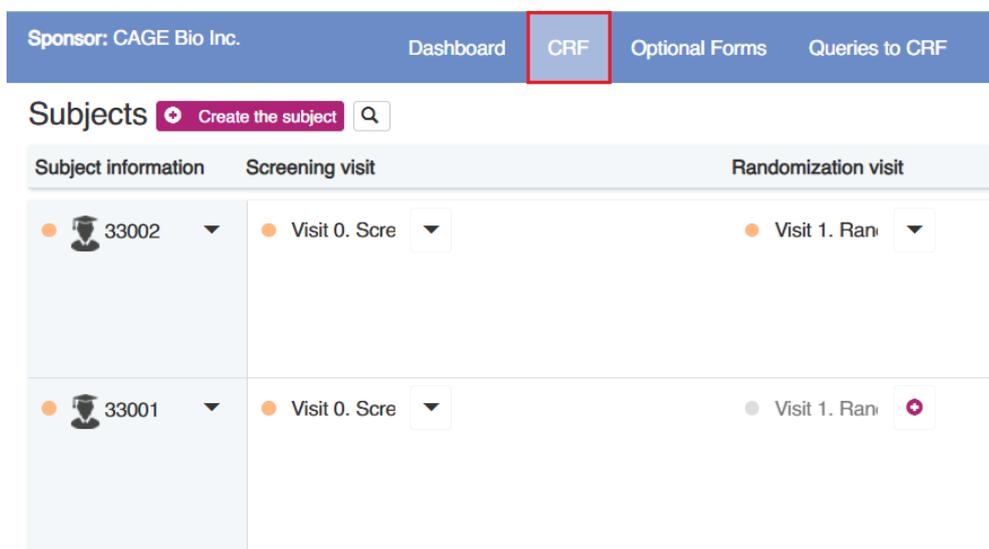
The training mode is designed to familiarize users with the system functions and tools available. The functions and tools available during the training mode and operating mode are the same.

**Pay attention!** At the end of the training mode, all data entered by users (eCRFs, optional forms, queries) will be deleted, their recovery is impossible. Therefore, no real subject data is entered during the training mode. If you are ready to create real subjects’ CRFs, please let your Monitor know.

**Pay attention!** Creating real subjects CRFs is only possible when the training mode is over. The warning disappears when the training mode is over.

### 3. Work with subjects' tab

“CRF” tab (Fig. 14) contains system functions designed to work with electronic CRFs of subjects.



**Fig. 14.** “CRF” tab

“CRF” tab (Fig. 14) displays a list of CRFs of subjects created in users' SS. In addition, you can find all the functions for working with CRFs here.

**Pay attention!** The CRF list is empty if no subject's CRF was created.

#### 3.1.1. Creating subjects' CRF

Creating subjects' CRF requires:

1. Go to the “CRF” tab
2. Click the “**Create the subject**” button (Fig. 15)

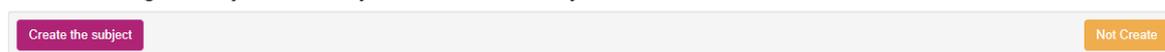


**Fig. 15.** “Create the subject” button

3. On the “Subject creating” page click “Create the subject” button (Fig.16)

#### Subject creating

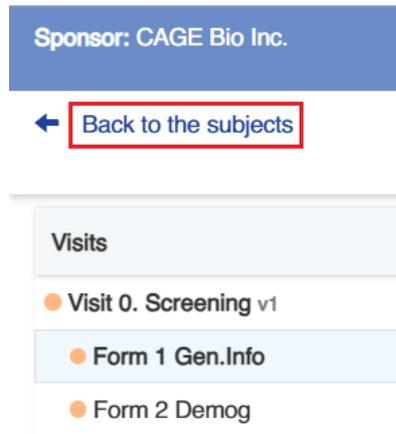
Before creating the subject, check if you have all necessary documents.



**Fig. 16.** “Subject creating” page

**Pay attention!** As the subject is created, it automatically receives a unique number which consists of two parts: the number of the SS and the serial number of the subject in the system.

- If you click the “Back to the subjects” button (Fig. 17) the new subject along with the CRF will be displayed in the list of patients



**Fig. 17. "Back to the subjects" button**

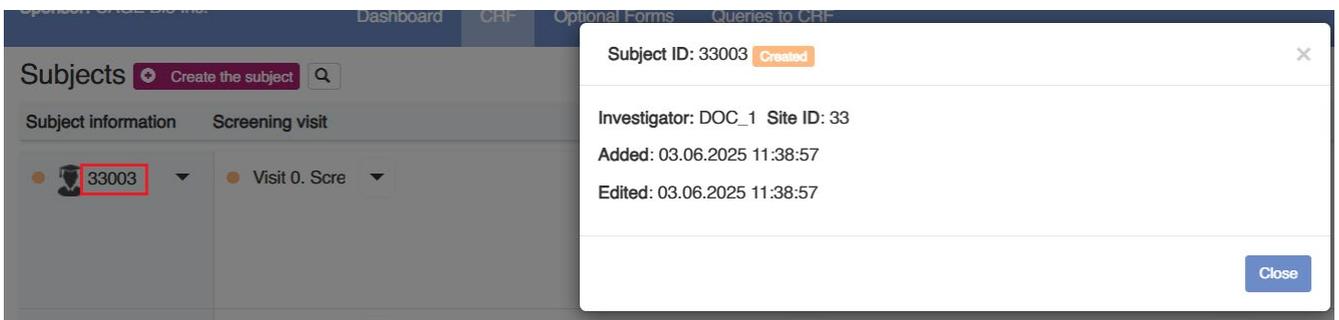
### 3.1.2. Subjects CRFs list

The subjects list (Fig. 18) contains CRF of all subjects created in the users' SS:

Subject information	Screening visit	Randomization visit	Data collection visit	Closeout visit
33003	Visit 0. Scre	Visit 1. Ran	Visit 1. Basr Visit 2. (Day) Visit 3. (Day) Show visits 4-12	Close-out V
33002	Visit 0. Scre	Visit 1. Ran	Visit 1. Basr Visit 2. (Day) Visit 3. (Day) Show visits 4-12	Close-out V
33001	Visit 0. Scre	Visit 1. Ran	Visit 1. Basr Visit 2. (Day) Visit 3. (Day) Show visits 4-12	Close-out V

**Fig. 18. The subjects list**

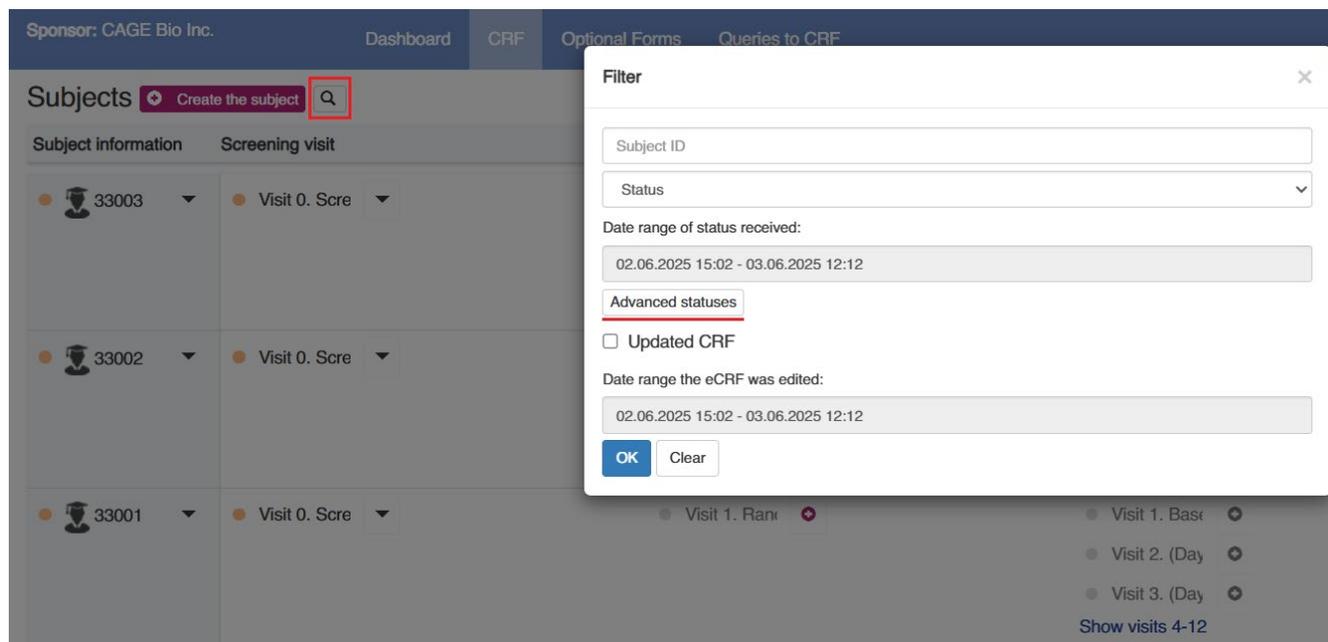
**Pay attention!** To obtain extended information (Fig. 19) about the subject click on the subjects' screening number.



**Fig. 19. Extended subject information**

### 3.1.3. Subject CRF search filters

The OnlineCRF system allows you to search for the subjects' CRFs by the selected parameter (Fig. 20).



**Fig. 20. CRF search filters**

CRFs can be filtered by the following parameters: subject ID, CRF status and time of last CRF edit.

Searching for CRFs requires:

1. Specify the parameter in the corresponding filter field
2. Click "OK"
3. To clear the search box or reset filters, click the "Clear" button

The OnlineCRF system also has an extended status filter, which is used to search by subject status (Fig. 20.1).

To use the extended filter, set the switch next to the subject status to the appropriate position: "No", "Inc", "Excl" and click the "Apply" button.

Example:

To identify a subject withdrawn at the screening stage, set the "Withdrawn" switch to "Inc" and the "Screening started" switch to "Inc" as well.

Filter			X
No	Inc	Excl	
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Withdrawn
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Created
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Screening started
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Screened
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Randomization started
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Randomized
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Data collection started
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Data collection finished
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Closing of the CRF has been started
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Completed
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Verified
<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Signed

Apply Back

**Fig. 20.1. Extended status filter**

**Pay attention!** To reset the extended filter parameters, click the “Clear” button in the CRF search filter window (Fig.20).

### 3.1.4. Subjects’ eCRF

After the new subject is created the user goes to the eCRF page. The eCRF (Fig. 20.2) in the OnlineCRF system contains such sections: visits, forms and navigation menu.

Sponsor: CAGE Bio Inc. Dashboard CRF Optional Forms Queries to CRF DOC\_1 Logout

← Back to the subjects CRF 33004 > Visit 0. Screening > Form 1 Gen.Info Last updated: 03.06.2025 13:39 Save Withdraw Fill out the form: OFMH OFCM

Next form →

Visit 0. Screening visit date: 03.06.2025 Delete visit

GENERAL INFORMATION

Visit date: \*  /  /  dd.mm.yyyy

Did the subject sign the Informed consent form?\*

Yes

No

Fields marked with \* must be filled out

Save Last updated: 03.06.2025 13:39

Visits

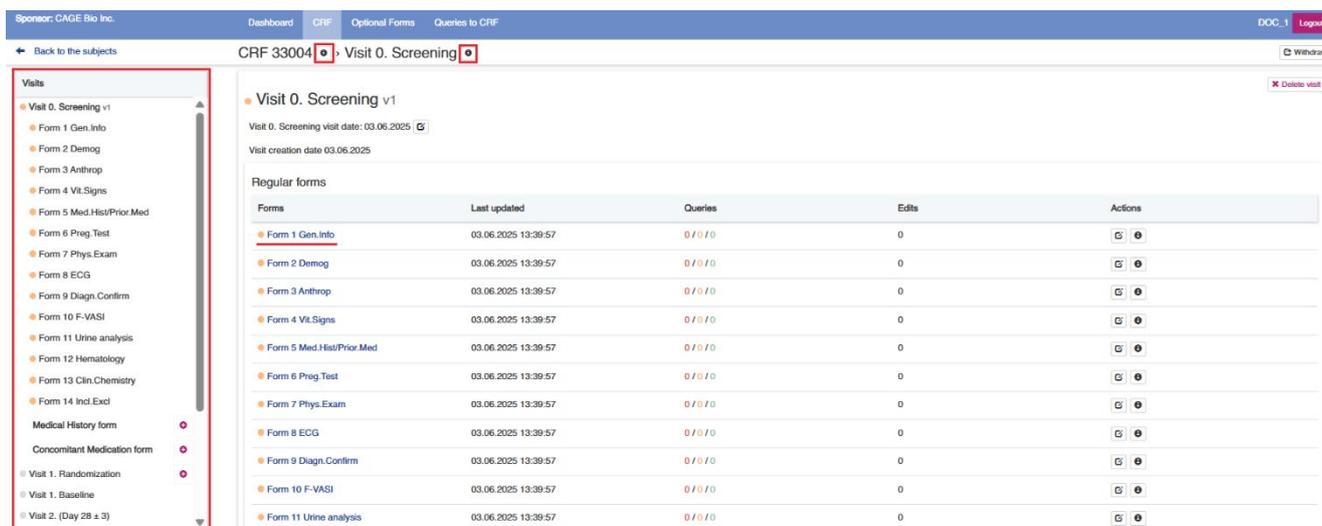
- Visit 0. Screening v1
- Form 1 Gen.Info
- Form 2 Demog
- Form 3 Anthrop
- Form 4 Vit.Signs
- Form 5 Med.Hist/Prior.Med
- Form 6 Preg.Test
- Form 7 Phys.Exam
- Form 8 ECG
- Form 9 Diagn.Confirm
- Form 10 F-VASI
- Form 11 Urine analysis
- Form 12 Hematology
- Form 13 Clin.Chemistry
- Form 14 Incl.Excl

**Fig. 20.2. Subject’s eCRF**

There are several types of visits: a screening visit, a data collection visit, and a CRF close-out visit.

Each of them has a visit passport (Fig. 20.3). It contains detailed information about the subject, the visit, the form, as well as links to the form of the selected visit.

To proceed to visit the passport, you need to click on the name of the visit in the eCRF navigation menu.

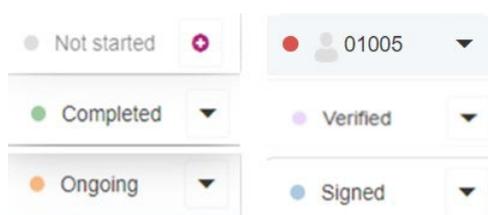


**Fig. 20.3.** Visit passport in the eCRF

### 3.1.5. Subject status, visit status, form status

To make tracking activity in the eCRF convenient, all subjects, visits, and forms have statuses. Depending on the stage of visit, form or subject, the system provides color identification of progress.

- Gray color – no data entered;
- Yellow color - subject, visit or form is in the process of filling;
- Green color - subject, visit, form has been filled;
- Purple color - subject, visit, form is verified;
- Blue color - subject, visit, form has been signed;
- Red color - subject, visit, form has been withdrawn;

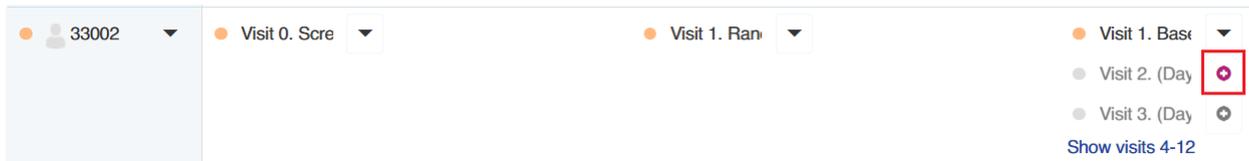


**Fig. 20.4.** Color identification of progress

### 3.1.6. Creating a visit in eCRF

Creating a regular visit requires:

1. Click the “Plus” button next to the selected visit (Fig. 21)



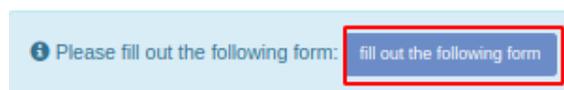
**Fig. 21. Creating a visit in eCRF**

2. Fill in the displayed form with valid data
3. Click the “Save” button at the top or bottom of the form (Fig. 22)

 A screenshot of the eCRF form for 'Visit 0. Screening'. At the top, there is a breadcrumb trail: 'CRF 33002 > Visit 0. Screening > Form 2 Demog'. To the right of the breadcrumb is a 'Last updated: 03.06.2025 11:32' timestamp and a 'Save' button highlighted with a red box. Below the breadcrumb is a text field containing 'Visit 0. Screening visit date: 03.06.2025' with a calendar icon. The main section is titled 'DEMOGRAPHIC DATA' and contains several fields: 'Age:\*' (text input), 'Year of birth:\*' (dropdown), 'Sex:\*' (radio buttons for Male and Female), 'Race:\*' (radio buttons for Caucasian, Black or African American, Asian, Not Reported, Unknown, Other), and 'Ethnicity:\*' (radio buttons for Not Hispanic or Latino, Hispanic or Latino, Unknown). At the bottom, there is a note 'Fields marked with \* must be filled out' and another 'Save' button highlighted with a red box, along with the same timestamp.

**Fig. 22. Saving the visit form**

4. Proceed to the next form of the visit by clicking the “Fill out the following form” or the tab with the name of the form (Fig.23)

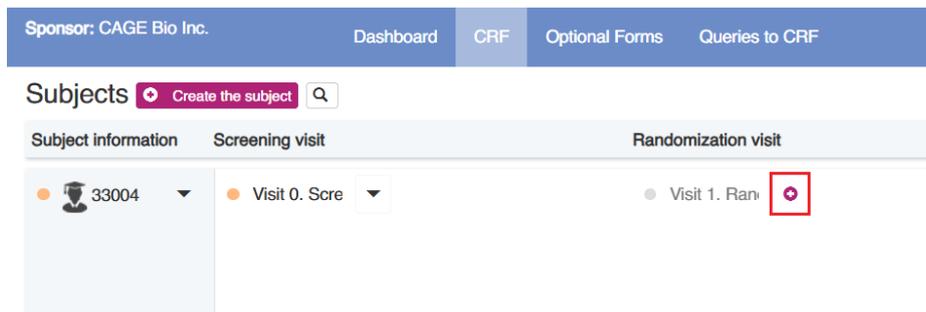


**Fig. 23. Creating the next visit form**

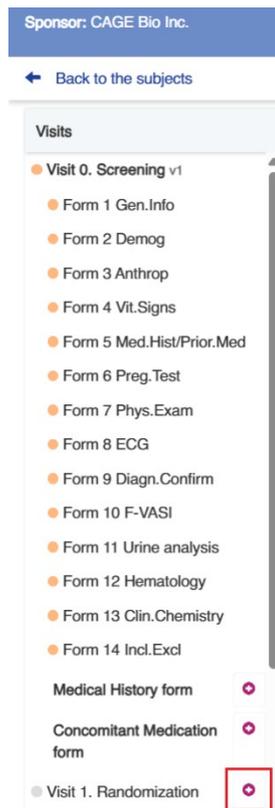
### 3.1.6.1. Randomization Visit

Randomization of the subject involves the following steps:

1. Go to the subject’s CRF list (Fig. 23.1) or visit form in eCRF (Fig. 23.2).
2. Click “Create” button on the Randomization Visit (Fig. 23.1/Fig. 23.2).

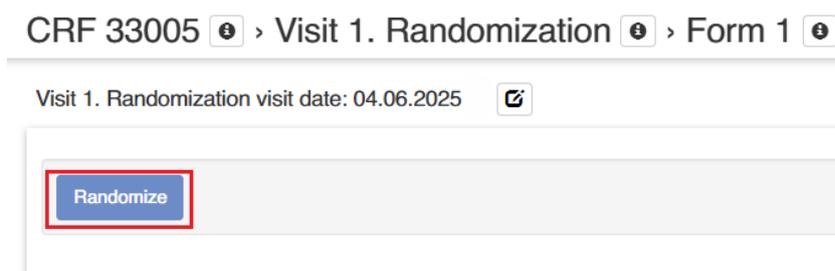


**Fig. 23.1.** “Create” button (CRF list)



**Fig. 23.2.** “Create” button (Visit form)

3. Enter the date and then click the “Randomize” button in the form (Fig. 23.3).



**Fig. 23.3.** “Randomization” button

### 3.1.7. General instructions for data entry

This section provides a list of fields and general instructions for data entry

#### 1. “Day Month Year Time” field (Fig. 24)



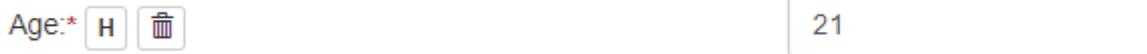
**Fig. 24.** Field for date and time entry

Field for date entry is presented in the format: “DD/MM/YYYY”, “MM/YYYY”, “YYYY”.

Field for time entry is presented in the format: «hour:min».

To fill “Date and time” field you may use the drop-down menu.

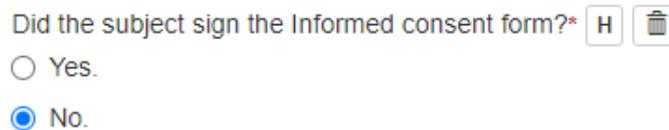
#### 2. Numeric field (Fig. 25)



**Fig. 25.** Numeric field

The numeric field is used to enter numbers (can only accept a combination of numbers).

#### 3. Switch (Fig.26)



**Fig. 26.** Switch field

The switch allows you to select only one option.

To select a certain option, click on the switch  next to it. If you make a mistake, click on the switch  next to another item.

#### 4. Checkbox (Fig.27)



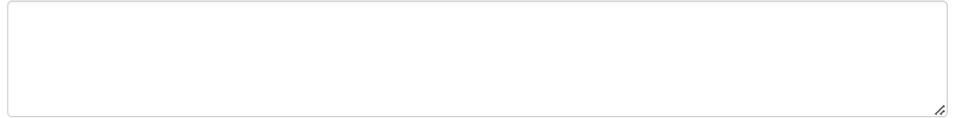
**Fig. 27.** Checkbox

The checkbox allows you to choose multiple answers among given options.

To select a certain option, click on the box next to it. If you made a mistake, click the checkbox next to the selected item.

#### 5. Text field (Fig. 28)

Surgery:\*



**Fig. 28. Text field**

This field allows you to enter text data. The field accepts any combination of letters, numbers and symbols.

**Pay attention!** The visit form may contain repeating groups of fields (Fig. 28.1) with “plus” and “cross” buttons. The “plus” button adds a repeating group of fields. The “cross” button removes the repeating group.



**Fig. 28.1. Repeating groups of fields**

### 3.1.8. Data validation

To reduce the number of errors during data entry, the system automatically checks the compliance of the data entered to the specified range of values. In case of detecting suspicious data, the system displays an error message next to the field. There are two types of errors: blocking and non-blocking.

Blocking error (Fig. 29) displays the message until the value is changed to a valid one. Non-blocking error (Fig. 29.1) displays a message that can be closed.



**Fig. 29 Blocking error**



**Fig. 29.1 Non-blocking error**

The OnlineCRF system can confirm the value that caused the non-blocking error. If the user is sure about the data entered it is necessary to click the “Confirm the value” button (Fig. 30).



**Fig. 30 “Confirm the value” button**

### 3.1.9. Optional forms

When filling in the CRF, the user may need to fill out the optional (additional) form (Fig. 31).

Have any adverse events/reactions been noticed?\*

Yes

Please, fill in the AE/AR form.

No

**Fig. 31.** Notification to fill in an optional form

Creating an optional form requires:

1. At the top of the current form find the button with the name of an optional form required and click it (Fig. 32)

Fill out the form:

**Fig. 32.** Creating an optional form

2. Confirm the creation of the form by clicking “OK” in the pop-up window
3. Fill in the form with valid data and click “Save”

**3.1.10. Editing CRF data**

Editing CRF data requires:

1. Find the visit form (Fig. 33)

Visits

- Visit 0. Screening v1
  - Form 1 Gen.Info
  - Form 2 Demog
  - Form 3 Anthrop
  - Form 4 Vit.Signs
  - Form 5 Med.Hist/Prior.Med
  - Form 6 Preg.Test
  - Form 7 Phys.Exam
  - Form 8 ECG
  - Form 9 Diagn.Confirm
  - Form 10 F-VASl
  - Form 11 Urine analysis
  - Form 12 Hematology
  - Form 13 Clin.Chemistry
  - Form 14 Incl.Excl

Visit 0. Screening visit date: 02.01.2025

---

ANTHROPOMETRIC DATA

Height:* <input type="button" value="H"/> <input type="button" value="🗑️"/>	175	cm
Body weight:* <input type="button" value="H"/> <input type="button" value="🗑️"/>	65	kg

Fields marked with \* must be filled out

Last updated: 03.06.2025 16:14

**Fig. 33.** Subject visit form

2. Select the field that needs editing
3. Click the “Edit” button  next to the field (Fig. 34)



**Fig. 34. “Edit” button**

4. Edit the value of the field and specify the reason for editing (Fig.35)
5. Click the “Save” button



**Fig. 35. Editing CRF data**

After the field has been edited, the “Edit history” button appears next to it. When you click , the following info is displayed: old value, new value, action performed, name of the Investigator (who made the changes), date and time of editing, field status.

Height: ×

Value	Action	User	When	Field status
190	Edited	DOC_1	03.06.2025 16:17:38	Correct 
175	Saved	DOC_1	03.06.2025 16:14:20	Correct
175	Entered	DOC_1	03.06.2025 16:14:10	Correct

Close

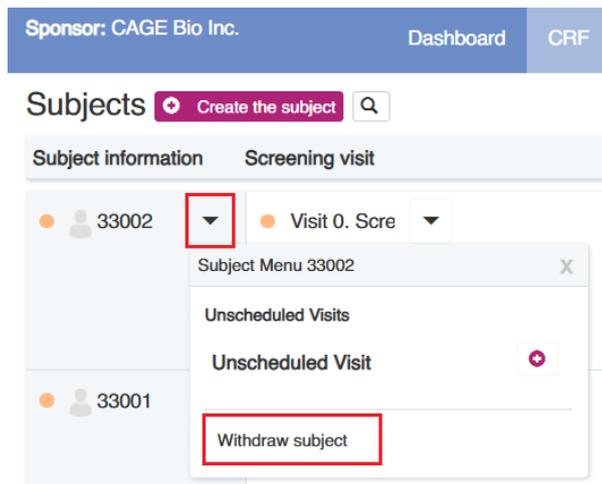
**Fig. 35.1. “Edit history” button**

### 3.1.11. Subject withdrawal

There are two ways of subject withdrawal: from the “Subject Menu” in the list of subjects and from the visit form in eCRF.

Subject withdrawal requires:

1. Go to the CRF tab
2. Click on the subjects’ menu (Fig. 36)



**Fig. 36. Subject`s menu**

3. Click on the “Withdraw subject” button
4. Confirm the subject withdrawal by clicking the “OK” button in the pop-up window
5. Fill the subject withdrawal form (Fig. 37) and click “Save”

PREMATURE TERMINATION OF THE SUBJECT'S PARTICIPATION IN THE INVESTIGATION

Please, specify the date of the subject's termination of participation in  investigation.\*

Please, specify the reason of the subject's termination of participation in  investigation:

Inclusion criteria were not met.\*

No.

Yes.

Withdrawal criteria were met.\*

No.

Yes.

I confirm that the subject prematurely terminated the participation in the investigation.\*

Yes.

No.

I confirm that all data entered are complete and correspond to the primary documentation.\*

Yes.

No.

**Fig. 37. Subject withdrawal form**

Withdrawing the subject from the visit form requires:

1. Open the subjects' eCRF
2. Go to the visit form or visit passport
3. At the top of the page, click the “Withdraw” button (Fig. 38)

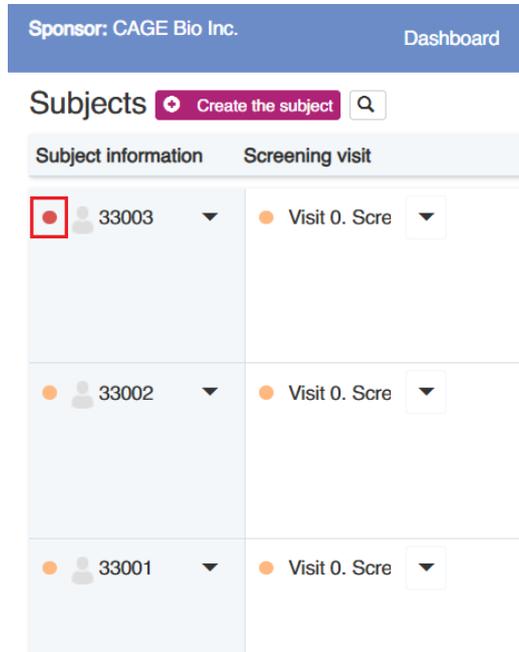


**Fig. 38. “Withdraw” button**

4. Confirm the subject's withdrawal by clicking the “OK” button in the pop-up window

5. Fill the subject withdrawal form (Fig. 37) and click “Withdraw”

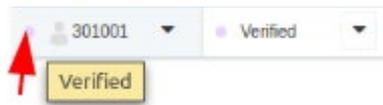
After withdrawal, the subject's CRF status changes to “Withdrawn” (Fig. 39). The form and visit status remain unchanged. When such a CRF is being verified the CRF status remains “Withdrawn” while visit status changes.



**Fig. 39.** Withdrawn subjects' CRF

### 3.1.12. Working with a subjects verified CRF

During monitoring, the Monitor can verify both individual forms and the CRF as a whole. Such forms / CRFs acquire the status of “Verified” (Fig. 40). Further editing of their data is not possible.



**Fig. 40.** Verified CRF

**Pay attention!** To edit the data in such CRF click “Verification reset request” (Fig. 41). It will be sent to your Monitor.



**Fig. 41.** “Verification reset request” button

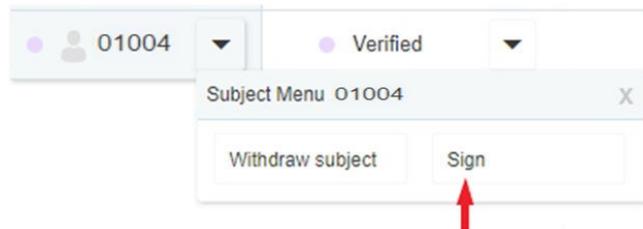
### 3.1.13. Signing the subject's CRF with an electronic signature

After the Monitor checks and verifies all visits of the subjects' CRF, the Investigator with the PI status can sign this CRF.

**Pay attention!** The digital signature confirms the authenticity of the data entered in the CRF.

Signing CRF requires:

1. Go to the subjects' CRF list
2. Click the "Sign" button in the "Subject Menu" of the verified CRF (Fig. 42)



**Fig. 42.** "Sign" button

3. Confirm the signature (fill in "Digital signature": e-mail (login) and account password, confirm the accuracy of the data entered) (Fig. 43)
4. Click the "Sign" button (Fig. 43)

A screenshot of a 'Digital signature' form. It has a title 'Digital signature' in blue. Below the title are two input fields: the first is labeled 'Login (e-mail)' and the second is a password field with asterisks. Below these fields is a checkbox with the text 'I confirm the authenticity of the entered data'. At the bottom right, there are two buttons: 'Sign' (highlighted in blue) and 'Cancel'.

**Fig. 43.** Confirm the signature

As a result, the CRF will change its` status to "Signed" (Fig. 44). Editing data in such a CRF is impossible.



**Fig. 44.** "Signed" status

**Pay attention!** You can only sign CRF with no "Open" or "In progress" queries.

**Pay attention!** All the forms and Visits are created and completed by the person with the role of the doctor.

### 3.2. Working with Optional Forms ("Optional Forms" tab)

The tab "Optional forms" (Fig. 45) displays a list of optional forms created in the users' SS. In addition, it provides system functions designed to work with optional forms.

Sponsor: CAGE Bio Inc.    Dashboard   CRF   **Optional Forms**   Queries to CRF    DOC\_1   Logout

Optional forms 2 of 2

**Filter**

Optional form code

Subject ID

Site ID

Choose form type

Choose form

Status

OK   Clear

Form	Site	Subject ID	Created by	Created at	Actual date	Queries	Actions
<span style="color: green;">●</span> Concomitant Medication form for visit Visit 0. <span style="color: orange;">●</span> Screening	33	33002	doc1	03.06.2025	03.06.2025	0 / 0 / 0	🗑️
<span style="color: orange;">●</span> Unblinding form for visit Visit 1. <span style="color: blue;">●</span> Baseline	33	33001	doc1	03.06.2025	02.01.2025	0 / 0 / 0	🗑️

2 of 2

Subjects per page   30   15

**Fig. 45. Optional forms list**

**Pay attention!** The list is empty if no subject's CRF was created.

### 3.2.1. Optional forms list view

The list of Optional forms (Fig. 45) contains:

- The **Form** column displays the shortened name of the form, the status of the form, and the visit when the form was created.
- The **Site** column contains the SS name.
- The **Subject ID** contains the subjects' screening number.
- The **Created by** column contains the creators' name.
- The **Created at** column contains the date the form was created.
- The **Actual date** column contains the date the user entered when creating the form.
- The **Queries** column contains information about the number of queries and their status<sup>1</sup>.
- The **Actions** column contains features that you can use to work with the optional form.

### 3.2.2. Optional form search filters

The OnlineCRF system allows you to search for optional forms by the selected parameter (Fig. 46).

**Filter**

Optional form code

Subject ID

Site ID

Choose form type

Choose form

Status

OK   Clear

<sup>1</sup> **The red number** indicates the number of queries corresponding to the status "Open". **The orange number** indicates the number of queries corresponding to the status "In progress". **The green number** indicates the number of queries corresponding to the status "Closed".

When you click on the number of queries, a list of requests with the selected status, created in the current visit, is displayed.

**Fig. 46. Optional form search filters**

Forms can be filtered by: Optional Form code, subject ID, Site ID, type of optional form, form name, form status.

Searching for an optional form requires:

1. Specify the option to search in the corresponding filter field
2. Click “OK”
3. To clear the search box or reset filters, click the “Clear” button

### 3.2.3. Optional form editing

Editing Optional forms requires:

1. Click the “Edit” button next to the selected form in the list of Optional forms (Fig. 45)
2. Edit the selected field

## 4. “Working with Queries” tab

The “CRF Queries” tab (Fig. 47) displays all queries created to the data entered by the user (Investigator) along with system functions.

All queries are divided into two groups: Subject CRF queries (“CRF” tab), Optional forms queries (“Optional forms” tab). The functions available for both types of queries are the same.

From	To	Subject ID	Query date	Edited	Status	Actions
CRA Johnson	Dr. House	301005	10-03-2022 16:35	No	● Opened	↻
CRA Johnson	Dr. House	301002	10-03-2022 16:34	No	● Opened	↻

**Fig. 47. Queries list**

**Pay attention!** The list is empty if no subject’s CRF was created.

**Pay attention!** The system sends an electronic notification when the Monitor creates a query for the data you enter. It provides a link to the “Query History” page of the query created.

After creating a query, the “Number of queries”  button appears next to the field (to which the query was created) (Fig. 48). The inner number indicates the number of queries created for this field. The color of the button indicates the status of the request(s), as follows: **red** – “Open”, **orange** – “In progress”, **green** – “Closed”.

Did the subject sign the Informed consent form?\*

Yes.

No.

**Fig. 48. “Number of queries” button**

When you click the “Number of requests” button a filtered list of requests to this field appears. It only contains queries with the status you selected.

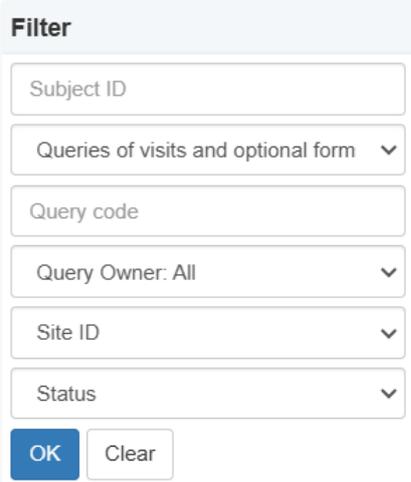
## 4.1. List of queries

The list of queries (Fig. 47) contains:

- The “**From**” column displays the author's name.
- The “**To**” column displays the name of the Investigator who entered the subjects' data.
- The “**Subject ID**” column displays the subject`s screening number.
- The “**Query Date**” column displays the date and time the query was created.
- The “**Edited**” column specifies whether the field was edited after the query appeared.
- The “**Status**” column contains information about the query status.
- The “**Actions**” column contains the “History”  button for detailed information about the query.

## 4.2. Queries search filters

The OnlineCRF system allows you to search for queries by certain parameter (Fig. 49).



**Fig. 49.** Query search filters

Queries can be filtered by such parameters: patient screening number, queries of visit or optional form, query code, query owner, site ID, and query status.

Searching for a query requires:

1. Specify the search parameter in the corresponding filter field
2. Click “OK”
3. To clear the search box or reset filters, click the “Clear” button

## 4.3. View query history

Viewing query history requires:

1. Click the “History”  button for a certain query in the list of queries
2. As a result, the page “Query history” is displayed (Fig. 50)

Query history: Opened Edited: No

Event: Visit 0 (Day 1) Screening Subject ID: 01003 Randomized  
 Form: Form 5. Demog. Investigator: doc1\_bl

Chapter: Age: Start value: 42  
 Question: Age: End value: 42

From	Date	Message
CRA	21.02.2024	Please, check the value, according to the source data, the subject is 30 years old

Add message

Add message

**Fig. 50. Query history**

The query history contains all the information about the query: the query status; whether the data has been edited after the query was created; the value of the field when the query was created; the value of the field when the query history is viewed; the visit when the query was created and the form where the query was created; a link to the field the query was created for; subjects' screening number and the CRF status; name of the Investigator who entered the data; name of the query author; query creation date; the whole history of notifications. Moreover, query history displays all the functions available (adding a message).

#### 4.4. Responding to the query

Responding to the query requires:

1. Go to Query history (see 4.3)
2. Write a reply message in the text box and click "Add message" (Fig. 51)

Query history: Opened Edited: No

Event: Visit 0 (Day 1) Screening Subject ID: 01003 Randomized  
 Form: Form 5. Demog. Investigator: doc1\_bl

Chapter: Age: Start value: 42  
 Question: Age: End value: 42

From	Date	Message
CRA	21.02.2024	Please, check the value, according to the source data, the subject is 30 years old

Add message

text message

Add message

**Fig. 51. Responding to the query**

All added messages are saved on the Query history page.

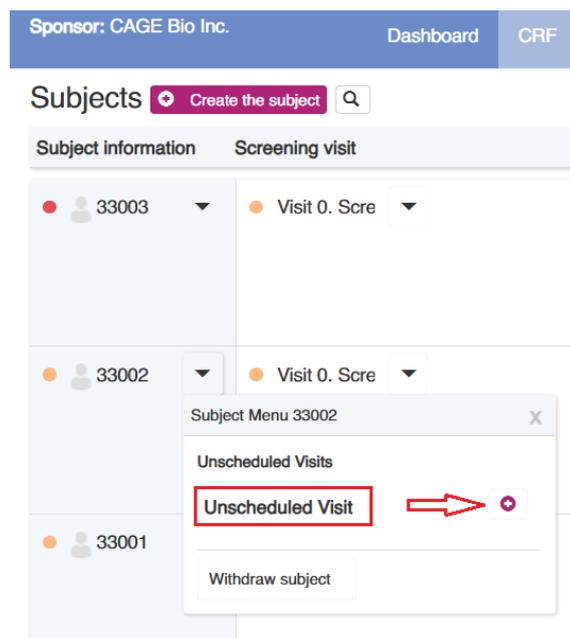
**Pay attention!** You can't add a message to a closed query.

## 4.5. Unscheduled Visit

During the course of the investigation, an additional onsite visit (unscheduled) may be deemed necessary. There are two ways to create an unscheduled visit: from the CRF tab in the list of subjects and from the visit form in eCRF.

Creating an Unscheduled Visit from the CRF tab requires the following:

1. Go to the CRF tab
2. In the Subject Menu click the “Plus” button near the name of an unscheduled visit (Fig. 52)

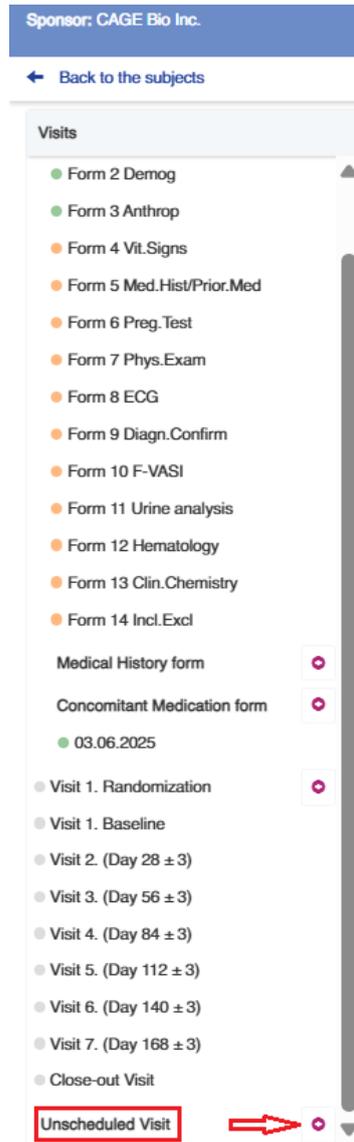


**Fig. 52.** *Unscheduled Visit creation (CRF tab)*

3. Fill in the forms of the Visit with valid data

Creating an Unscheduled Visit from the visit form in eCRF requires the following:

1. Open the subjects' eCRF
2. Go to the visits list
3. Confirm the creation of the visit by clicking the “Plus” button near the name of an additional visit required (Fig. 53)



**Fig. 53.** *Unscheduled Visit creation (subjects' eCRF)*

4. Fill in the forms of the Visit with valid data