

eCRF user's guide for clinical sites

EU-SOLIDACT

Introduction (1/2)

- CSOnline is a Clinsight solution for online clinical trial management
- It allows investigators to enter the data of their patients directly in the electronic case report form
- All forms should be filled in according to the source document by the investigator or their representatives (representatives should have signed the “list of investigator’s co-worker and their roles in the trial”)
- The principal investigator in each center is responsible for data entry in the eCRF in his/her center

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Introduction (2/2)

How to request access to the database?

- A form requesting access to the e-CRF should be sent to the Inserm U1136:
solidact.inserm@iplesp.upmc.fr
- The Project Data Manager will send the login and passwords to all the users after receiving the request forms

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Protocol Name:	<input type="text"/>	<input type="checkbox"/>	
Protocol Short Name:	<input type="text"/>	<input type="checkbox"/>	
Protocol version:	<input type="text"/>	<input type="checkbox"/>	
¶			
Site name:	<input type="text"/>	<input type="checkbox"/>	
Site number:	<input type="text"/>	<input type="checkbox"/>	
Town:	<input type="text"/>	<input type="checkbox"/>	
Country:	<input type="text"/>	<input type="checkbox"/>	
¶			
eCRF - Site user Name* (first name and LAST NAME):	Email (each person will receive a personal login and password for the eCRF to their email address below):	Role* <input type="checkbox"/>	
<input type="text"/>	<input type="text"/>	Site PI: <input type="checkbox"/>	
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	
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<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	
* Site Principal Investigator (PI, investigator (physician), nurse, etc.)			
¶			
Site users access information requested by:	Role	Date	Signature
<input type="text"/>	Project Manager (PM)	<input type="text"/>	<input type="text"/>
<input type="text"/>			
¶			
Site users access information request form granted by:	Role	Date	Signature
<input type="text"/>	Lead Data Manager (LDM)	<input type="text"/>	<input type="text"/>
<input type="text"/>			
¶			

Connection (1/2)

- COnline has been validated with the following internet browsers:
 - Internet Explorer
 - Mozilla Firefox
 - Netscape Navigator
- Website address: <https://www.ccde-ecrf.com/EnnovClinical/login>

eNNOV >Clinical

EUSOLIDACT

Login

Password

Log in

Need help?

← Enter study name

← Enter your login

← Enter your password

English ▾

Choose the interface language

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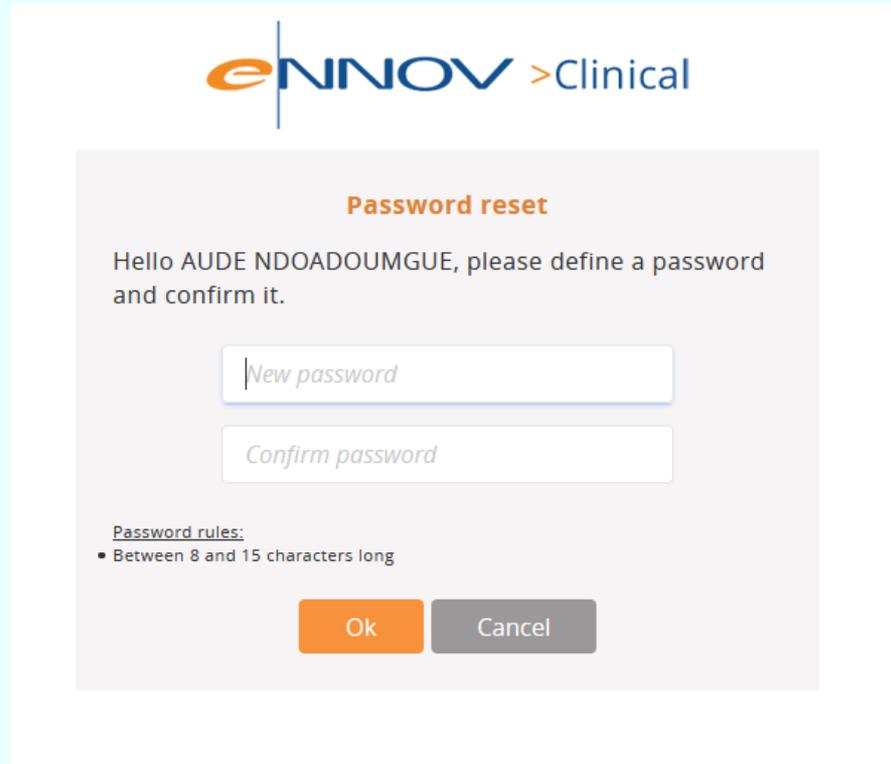
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Connection (2/2)

- If you are connected to the study for the first time with the login and password provided by the study manager, you are required to change your password for security reasons:



The screenshot shows a web interface for 'eNNOV >Clinical'. At the top, the logo 'eNNOV >Clinical' is displayed. Below it, a dialog box titled 'Password reset' is shown. The dialog contains the text: 'Hello AUDE NDOADOUMGUE, please define a password and confirm it.' There are two input fields: the first is labeled 'New password' and the second is labeled 'Confirm password'. Below the input fields, there is a section for 'Password rules:' with a bullet point: 'Between 8 and 15 characters long'. At the bottom of the dialog, there are two buttons: 'Ok' (orange) and 'Cancel' (grey).

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

Now you are the only one to know this new password and connect to the study safely.

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Home Page (1/4)

The clinical study home page (Dashboard), accessible once the eCRF user is logged, is presented as follows. It is made up of several widgets providing information on the study

The dashboard is titled "Dashboard" and features the EUSOLIDACT logo in the top right corner. A vertical navigation menu on the left contains icons for home, user profile, help, charts, notifications, and documents, with callouts 1 through 6. The main content area includes three widgets: "Subject enrollment" (a donut chart showing 0/100%), "Queries" (displaying "No data to display"), and "Section overview" (a progress bar chart with categories: Entered 7%, Locked 100%, Monitored 100%, Signed 100%). Below these is a "Notifications" widget showing counts for Comment (0), Email (0), News (0), and Documents (3). At the bottom left, a user profile card for "Aude NDOADO..." is visible, with callouts 7 through 9. Callout 10 points to the profile card, 11 to the "Subject enrollment" widget, 12 to the "Queries" widget, 13 to the "Section overview" widget, and 14 to the EUSOLIDACT logo.

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↑
- Information on the
connected user
- To log off

Home Page (2/4)

- 1: Dashboard : This is the home page of CSOnline. It is made up of several widgets providing information on the study.
- 2: Patients overview: It displays the progress of the patients and allows you to access the CRF of each patient.
- 3: Query management: It gives you access to the list of queries
- 4: Inclusion curve: It displays the total number of patients included into the study based on the expected number. This curve is visible only if it has been configured by the data manager.
- 5: Therapeutic units: it displays the list of therapeutic units
- 6: Documents:
 - News: displays the list of news related to the study
 - Study documents: displays the documents related to the study (protocol, blank CRF...)
 - Reports: displays the different reports generated for CSOnline
 - My documents: stores the CRFs and other documents generated in PDF format

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Home Page (3/4)

7: History: History of the navigation through the e-CRF.

8: Internal email box (webmail): To write and read emails.

9: Contact and technical support: Customized page of the structure in charge of the clinical study containing the contact information. In case of technical issues with the CSOnline application, select the technical support menu

10: "Notifications" widget: It displays the number of pending entry comments, emails, news, documents, deviation forms, notes or warning messages.

11: "Subject enrollment" widget : The figure in the middle of the ring displays the number of patients in the study. The colored parts of the ring allow you to view the distribution based on the statuses of the defined patients

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Home Page (4/4)

12: "Queries" widget: The figure in the middle of the ring displays the number of pending queries.

13: "Section overview" widget: The diagrams inform you of the progress of the sections based on the different statuses.

Remarks regarding these 3 widgets: The question mark positioned at the bottom left part of the ring allows you to display or hide the diagram legend. Click the colored parts of the rings (or bars for the section overview) to have direct access to the desired category (e.g.: ongoing included patients, pending queries...). A search zone is available to filter the site (the search availability depends on the logged-in profile). It is also possible to click the widget titles to reach the general menus (e.g.: Patients overview, list of queries and section overview).

14: Document creation: It displays the documents which were generated in PDF after a printing task. The bell informs you when there are pending generated documents.

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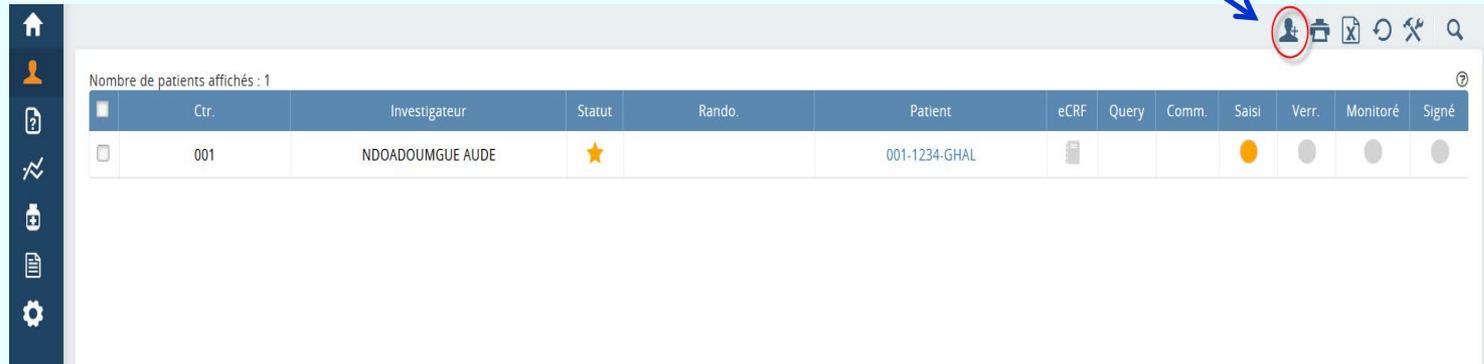
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Creating a patient

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



Nombre de patients affichés : 1

	Ctr.	Investigateur	Statut	Rando.	Patient	eCRF	Query	Comm.	Saisi	Verr.	Monitoré	Signé
<input type="checkbox"/>	001	NDOADOUMGUE AUDE	★		001-1234-GHAL							

Investigator: AUDE NDOADOUMGUE
Site ID: 001
Patient code format: NNN-NNN
Patient code:

Patient ID code
NNN = center n°
NNN = patient n°

To cancel the creation of the patient, click the "Back" button at the bottom left.
To continue the creation of the patient, click "Next" after filling out the required fields.
If one of the compulsory fields is left blank, an error message is displayed: "Patient code is blank", "Initials not entered"...

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Data entry (1/8)

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

Site ID	Investigator	Status	Rando.	Patient	eCRF	Site Name	Query	Comm.	Entered	Locked	Monitored	Signed
001	NDOADOU MGUE AUDE	★		001-001-ALNK					●	●	●	●

Menus allowing to access functionalities (save data, lock pages, creation of comments, ...) and different tools (printing a PDF, ...)

Back to home page

Icons summarizing the pages status

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★ Patient 001-001-ALNK Patient code: EUSOLIDACT | Draft

← ● 🔒 📄 📄 🔒

001-001-ALNK

- Eligibility to SolidAct PART A or B
- Consent and Study Selection
 - 1 - Consent**
 - 2 - Clinical status / WHO Disease Stage at Screening
- PART A - Moderate Disease
- PART B - Severe Disease
- Additional Forms

EU-SolidAct SCREENING ASSESSMENT (DAY-1)

Participant ID code: **001-001-ALNK**

Center number:	001	Site name:	St Antoine
Country:	FRANCE		

CONSENT

Date of initial consent:

Type of consent:

Legally authorized representative. If Yes,

Agreement for further use of personal data?

Agreement for storage and use of biological samples in EU-SolidAct?

Agreement for use of biological samples for further research?

Following the legally authorized representative or independent doctor's consent/emergency inclusion procedure, was a continuation consent obtained from the participant?

If No, specify the reason:

Other reasons. Specify:

If No, was a continuation consent obtained from a legally authorized representative?

↑ ↓ 📄 📄 📄 📄

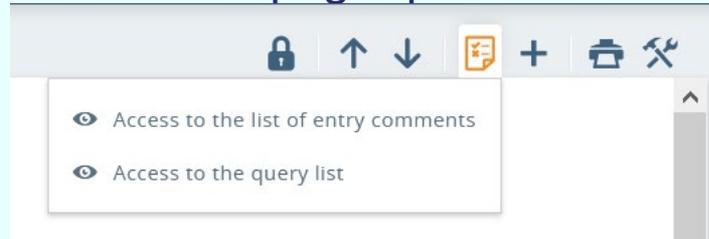
1 2 3 4 5

CRF displayed in the form of a tree structure (current page in bold orange)

Data entry (2/8)

1: These arrows are used to navigate through the pages in the CRF

2: Gives access to page queries and comments



Comments

When entry comments are not replied, a red notification appears containing the number of pending comments on the page. The field concerned has become yellow

When the entry comment is replied, the field becomes green, the red notification disappears and a green checkmark notifies that all the comments of the page are validated.

Queries

When queries are not replied, a red notification appears containing the number of pending queries on the page. A red question mark also appears beside the field concerned.

When the query is replied, it becomes green, the red notification disappears and a green checkmark notifies that all the queries of the page are solved

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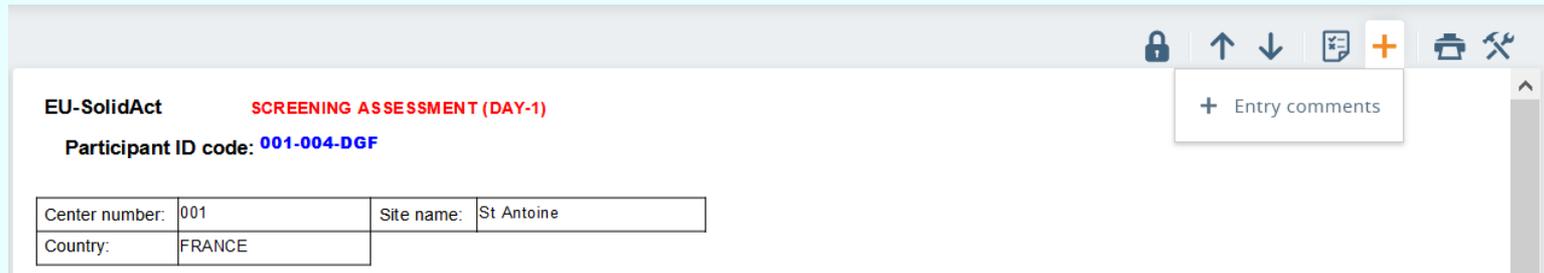
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Data entry (3/8)

3: If the investigator or their representatives do not understand a query or he/she cannot enter a value in a field, etc,... he/she can create a comment by placing the cursor in the concerned field and clicking the “+”.

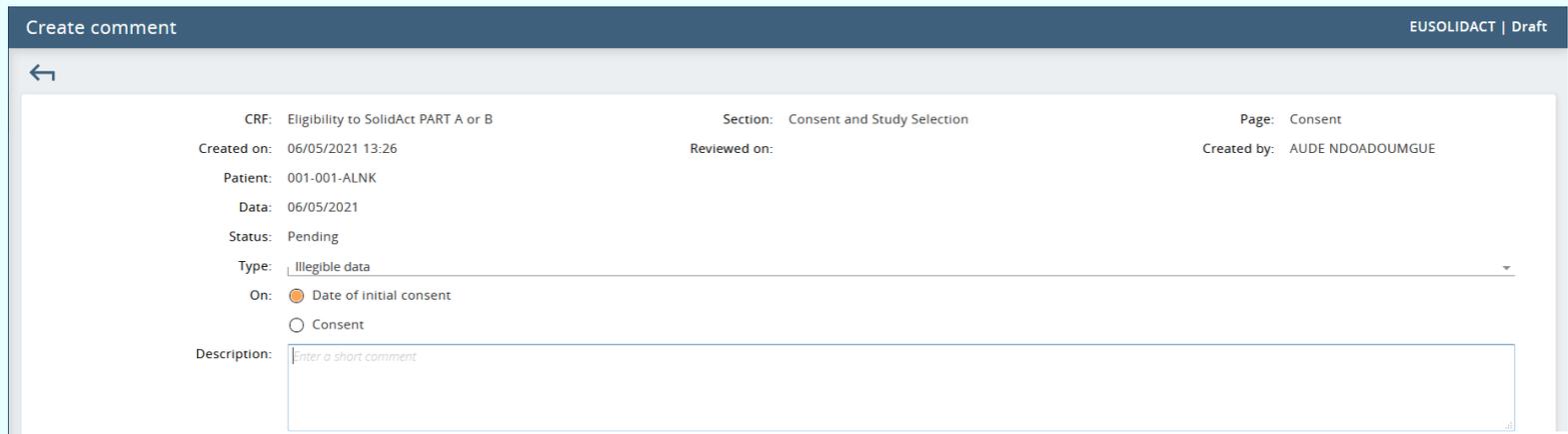


The screenshot shows the top part of the EU-SolidAct interface. At the top right, there is a toolbar with icons for lock, up/down arrows, a document icon, a plus sign, a printer icon, and a wrench icon. Below the toolbar, the text "EU-SolidAct" is followed by "SCREENING ASSESSMENT (DAY-1)" in red. Below that, "Participant ID code: 001-004-DGF" is displayed. A table contains the following data:

Center number:	001	Site name:	St Antoine
Country:	FRANCE		

To the right of the table, a dropdown menu is open, showing a plus sign icon and the text "Entry comments".

The investigator or their representatives will fill in the description box and click “Ok” to save the comment



The screenshot shows the "Create comment" form in the EUSOLIDACT system. The form is titled "Create comment" and has "EUSOLIDACT | Draft" in the top right corner. The form contains the following information:

CRF: Eligibility to SolidAct PART A or B Section: Consent and Study Selection Page: Consent
Created on: 06/05/2021 13:26 Reviewed on: Created by: AUDE NDOADOUYGUE
Patient: 001-001-ALNK
Data: 06/05/2021
Status: Pending
Type: Illegible data
On: Date of initial consent
 Consent
Description:

Ok

Cancel

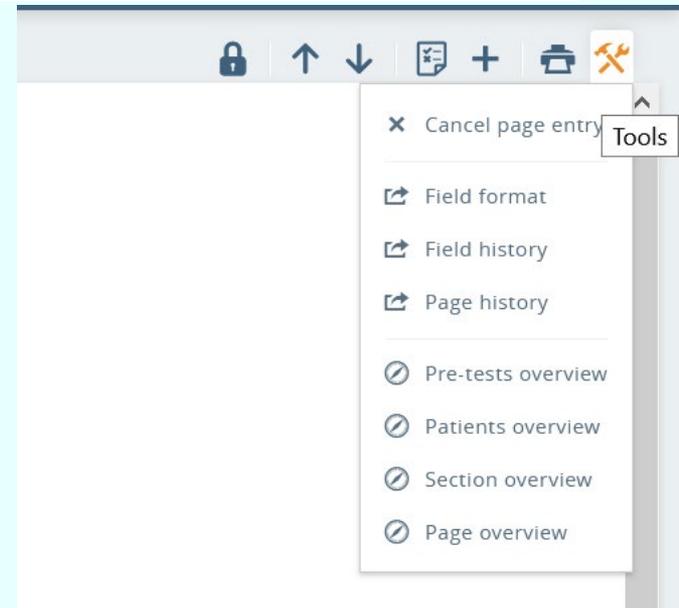
Data entry (4/8)

4: This button allows the CRF to be printed in PDF from the data of the patient. The generated file will be accessible in the "Personal directory"

5:

The "Tools" menu is symbolized by the  icon and is used to perform the following actions.

- Cancel all actions: enter data, lock, monitor, validate and sign
- Display the field formats (Features of the fields to be entered)
- Display the field history of the selected field
- Display the page history (Audit trail of the page tracking statuses)
- Follow up the pre-tests
- Return to the Patients Overview
- Return to the Section Overview
- Return to the Page Overview



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Data entry (5/8)

The EUSOLIDACT e-CRF consists of 4 parts:

- Eligibility to Part A or Part B: this section will determine to which part of the study the participant is eligible and depends on the WHO Disease stage at screening
- Part A- Mild/Moderate disease: from screening visit to D91 visit. If a participant included in Part A changes from Moderate to Severe Disease, the participant can be included in Part B. “Early stop” pages should be filled in Part A including WHO Disease stage to unlock Part B eCRF.
- Part B- Severe/Critical disease: from screening Visit to D91 visit.
- Additional forms: Adverse Events; Disease Related Events; SAE; Pregnancy

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Data entry (6/8)

The following code should be used in the CRF for missing values

NA: Not Applicable

NK: Not Known

ND: Not Done

EU-SolidAct **Baseline (Day 1)**

Participant ID code: **001-004-DGF**

SAFETY BIOCHEMISTRY

If more than 24H since screening, repeat blood sample for safety before first dose of medication

Date: 15/05/2021

Not done

Parameters	Value	Unit	Out of normal range?	If Yes, is it clinically important? If Yes, an AE/SAE page should be filled	Tick if the date is different from above	Not done
Hemoglobin	6	g/dL	YES	YES	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
WBC		-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
Lymphocytes		-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
Neutrophils		-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
Platelets		-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
Creatinine	NK	-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
Glucose	NA	-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>
Total bilirubin	ND	-	-	-	<input type="checkbox"/> DD/MM/YYYY	<input type="checkbox"/>

Do not forget to fill the AE/SAE page(s) if the biochemistry results are clinically important

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Data entry (7/8)

Each icon represents a page status, the statuses are symbolised by two colours:

- Light grey: pending
- Dark blue: completed

Examples of page statuses:

- Page not entered, not locked, not monitored and not signed



- Page entered, not locked, not monitored and not signed



- Page entered, locked, not monitored and not signed



- Page entered, locked, monitored and not signed



- Page entered, locked and to re-monitor



- Page entered, locked, monitored and signed



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Data entry (8/8)

Once the pages of the CRF are entered, they must be locked in order to attest that the data entry phase is completed. When the pages are all locked, the job of the monitor can start. There are 2 options:

- Locking the pages one by one, as and when they are entered in the CRF;
- Locking several pages at the same time from the different overviews.

To lock a page, click the "Lock" button (1) located in the CRF menu. Then the page switches to the "Locked" status. The "Unlock" function is accessible via the "Tools" menu and "Cancel "Locked" status" (there is no keyboard shortcut as is the case for the lock function). 1

★ Patient 001-001-ALNK

Search: Patient code

EUSOLIDACT | Draft

001-001-ALNK

Eligibility to SolidAct PART A or B

Consent and Study Selection

1 - Consent

EU-SolidAct SCREENING ASSESSMENT (DAY-1)

Participant ID code: 001-001-ALNK

Center number:	001	Site name:	St Antoine
Country:	FRANCE		

CONSENT

Locking a page means that the data can no longer be modified directly from the CRF. Nevertheless, if you want to correct data, you must previously unlock the page, change the data and relock the page in order for the ARC to start monitoring.

If the page has already been monitored by the CRA, you will not be allowed to cancel the lock status of the page. The only solution is to ask the CRA to unlock the page or create a query on the data to be changed.

Likewise, if the page is already signed or validated, you will not be allowed to cancel the lock status of the page as long as the "signed" and "validated" statuses of the page are not cancelled.

Randomization (1/2)

Randomization of participants to a treatment arm is done at the baseline visit

Specify if the participant was previously included in Part A of the study or not and click on the Randomize button

★ Patient 001-123-ERF - (St Antoine)

9 - Demographics Data

10 - Co-Morbidities and Risk Factors

11 - SARS-Cov-2 Vaccination

12 - WHO COVID-19 Disease Progression Scale

13 - Vital Signs

14 - Safety Biochemistry

15 - Biobanking and Add on studies

16 - Randomization for Part B

17 - Trial treatment, SoC Details, Concomitant medication...

D3

D5

EU-SolidAct **Baseline (Day 1)**

Participant ID code: **001-123-ERF**

RANDOMIZATION FOR PART B

SolidAct Part B / Severe disease

- Center: 001
- Previous entry in Part A: NO YES
- High flow oxygen or NIV (severe disease) vs mechanical ventilation/ECMO (critical disease) at baseline (score 6 to 9)

Randomize

Date of randomization:

Randomization result:

Treatment kit number:

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Randomization (2/2)

The date of randomization and treatment kit number is displayed once the randomization is done

Randomization results are hidden for double-blind studies

EU-SolidAct **Baseline (Day 1)**

Participant ID code: **001-123-ERF**

RANDOMIZATION FOR PART B

SolidAct Part B - Severe disease

- Center: 001
- Previous entry in Part A: NO YES
- High flow oxygen or NIV (severe disease) vs mechanical ventilation/ECMO (critical disease) at baseline (score 6 to 9)

Randomize

Date of randomization: 14/05/2021

Randomization result:

Treatment kit number: 11955

Should the need for an emergency randomization arise, the fields on the following pages must be filled to enable randomization:

- Consent page
 - Clinical status / WHO Disease Stage at screening
 - Study treatment arm available at the centre (Page 1)
 - Inclusion and exclusion criteria (Pages 2-4)
 - WHO COVID-19 Disease progression scale at baseline (Page 12)
- } Consent and study selection

Patients overview (1/4)

Click on the “Patient overview” in the Home page.

Patients’ overview table displays the CRF progress state for each patient.

Each one of the 4 levels of the overview tables is based on the same appearance:

- A menu bar including all the features of the page based on the level of the overview table (Creation of patient / Printing / Update / Display of the legend and/or filters / Tracking tool).
- A table containing the list of patients, CRFs, sections or pages.

Each column can be sorted out by clicking its heading and an icon symbolizes the sort order (ascending or descending).

Patients overview

EV SOLIDACT | Draft

Number of patients: 5

	1	2	3	4	5									
	Site ID	Investigator	Status	Rando.	Patient	eCRF	Site Name	Query	Comm.	Entered	Locked	Monitored	Signed	
<input type="checkbox"/>	001	NDOADOUNGUE AUDE	★	👤	001-004-DGF	📄	St Antoine			●	●	●	●	
<input type="checkbox"/>	001	NDOADOUNGUE AUDE	★	👤	001-005-FSR	📄	St Antoine			●	●	●	●	
<input type="checkbox"/>	001	NDOADOUNGUE AUDE	★	👤	001-006-VCG	📄	St Antoine			●	●	●	●	
<input type="checkbox"/>	001	NDOADOUNGUE AUDE	★		001-109-ALN	📄	St Antoine			●	●	●	●	
<input type="checkbox"/>	001	NDOADOUNGUE AUDE	★	👤	001-234-SDF	📄	St Antoine			●	●	●	●	

8

6

7

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Patients overview (2/4)

1: The patient's status (ongoing, selected...)

2: Randomization status: A displayed Randomize icon indicates that the participant has been randomized to a treatment arm

3: The patient code: by clicking the blue link, you have access to the sections overview table for the patient

4: Click the icon in the eCRF column to have access to the first page of the patient's CRF

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The CRF icon can have different colour codes based on the actions remaining to be done on the CRF of the patient.



White: No data entered in the CRF yet, data entry must start



Grey: Data has been entered; data entry should continue



Red: Pages are entered but they have not been locked



Green: Pages have to be monitored by the CRA



Blue: Queries awaiting replies



Purple: The CRF has to be signed



Black: All pages are signed

The color of the CRF icon depends on the logged-in user's profile:

- Data entry profile (Investigator, keyboard operator, clinical trial technician): The data entry or locking operations will be privileged over the monitoring.
- CRA or manager-type profile: The monitoring will be privileged over the data entry or locking operations.

Patients overview (3/4)

5: Displays the investigator's site

6: These columns indicate the presence of queries, entry comments... and specify the statuses linked to the data entry, lock, monitoring, medical validation and signature

7: Click the "?" to display or hide the legend related to the icon of the eCRF column.

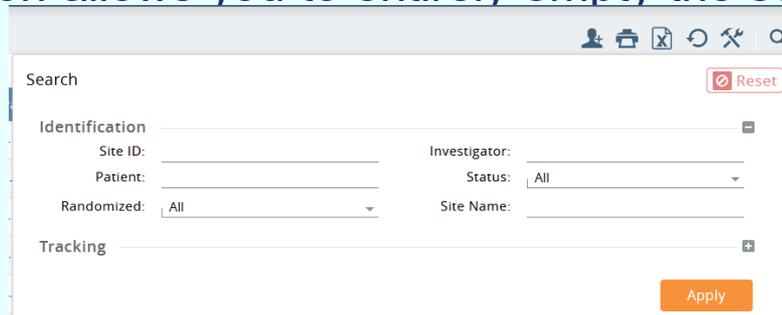
8:

The  icon is used to print the CRF of selected participants

The  icon exports the patients overview in an Excel format

The  refreshes the patients overview page

The  icon is used to run searches within the overview tables. The "Reset" button allows you to entirely empty the search zone



Search Reset

Identification Investigator:

Site ID: Investigator:

Patient: Status:

Randomized: Site Name:

Tracking +

Apply

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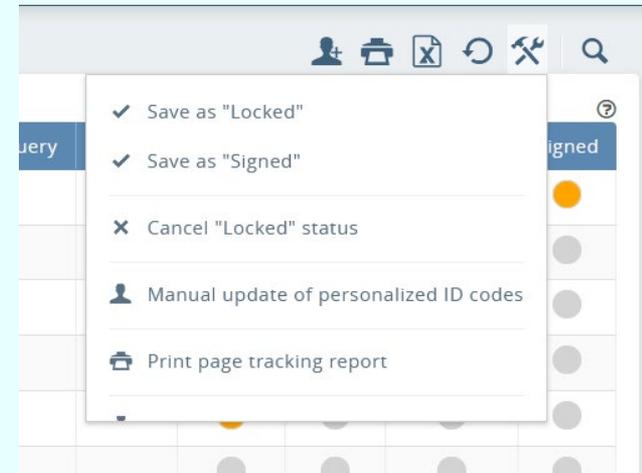
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Patients overview (4/4)

The  icon gives access to patient related functionalities such as:

- Save as “Entered”
- Save as “Locked”
- Save as “Signed”
- Patient code modification
- Patient Deletion
- Treatment unblinding



The data entry, lock, monitoring and investigator’s signature statuses are symbolized by colored dots:

-  Step not done ("Not done" status)
-  **In progress:** at least one page of the CRF is entered ("Partial" status)
-  **Step completed** ("Complete" status)



A screenshot of a patient overview table. The table has columns for 'Query', 'Comm.', 'Entered', 'Locked', 'Monitored', and 'Signed'. The 'Query' column shows a green question mark for two rows. The 'Entered', 'Locked', and 'Monitored' columns show orange dots for both rows. The 'Signed' column shows a grey dot for both rows.

Query	Comm.	Entered	Locked	Monitored	Signed
?		●	●	●	●
?		●	●	●	●

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SAE notification (1/2)

-SAE pages are found in the Additional forms section of the eCRF

-The two SAE pages need to be completed and the “I declare” box at the bottom of the second SAE page will have to be ticked for the initial SAE declaration to be made. An e-mail alert will then be sent to the Pharmacovigilance ANRS

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The screenshot displays the eCRF interface for SAE notification. On the left, a sidebar titled 'Additional Forms' lists various form categories: Concomitant Medications, Adverse Events, Disease-Related Event, SAE 1, 16 - Serious adverse event initial notification form 1, 17 - Serious adverse event initial notification form 2 (highlighted in orange), and Pregnancy. The main form area is divided into sections: 7. Concomitant medication (table), 8. Other causal relationship (fields for study procedure, COVID-19 progression, etc.), and 9. Investigator (fields for date, name, phone, and signature). A red box highlights the 'I declare the SAE' checkbox, which is checked. A blue arrow points to this checkbox from the right side of the image.

Name and/or DCI	Route of administration	Daily dose	Start date	End date	Indication	Causal relationship with SAE/AESI
			DD/MM/YYYY	DD/MM/YYYY		-
			DD/MM/YYYY	DD/MM/YYYY		-
			DD/MM/YYYY	DD/MM/YYYY		-

7. Concomitant medication (list relevant concomitant medication, at the time of SAE onset)

8. Other causal relationship

Study procedure (exams, strategy...): - specify: _____

Progression of COVID-19 disease: -

Other medical condition/illness: - specify: _____

Other: - specify: _____

9. Investigator

Date of reporting: DD/MM/YYYY

Investigator name (mandatory): _____

Phone number where the investigator can be reached: _____

Signature: _____

I declare the SAE (An automatic email will be sent to PV team)

I declare modifications on the SAE initial notification form (2nd page)

If you need to modify/correct a SAE page after the SAE has already been declared to PV team, please indicate that you have modified the page. An automatic alert email will be sent to PV team

[Return to the previous page](#)

SAE notification (2/2)

If the SAE pages need to be modified/corrected after the initial declaration, you will have to correct the field and choose “Modification 1” in the "I declare modifications on the SAE initial notification form" field at the end of each page so that a new email alert is sent to the Pharmacovigilance team. Modification 2 will be chosen if it is the second time a modification is made on the page and so on. Once an Initial form is filled, Complementary SAE forms will opened.

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The screenshot displays the SAE notification form interface. On the left is a sidebar menu with the following items:

- 001-123-ERF
- Eligibility to SolidAct PART A or B
- PART B - Severe Disease
- Additional Forms
- Concomitant Medications
- Adverse Events
- Disease-Related Event
- SAE 1
- 16 - Serious adverse event initial notification form 1
- 17 - Serious adverse event initial notification form 2
- Pregnancy

The main form area contains the following sections:

- 7. Concomitant medication** (list relevant concomitant medication, at the time of SAE onset)

Name and/or DCI	Route of administration	Daily dose	Start date	End date	Indication	Causal relationship with SAE/AESI
			DD/MM/YYYY	DD/MM/YYYY	Ongoing : <input type="checkbox"/>	-
			DD/MM/YYYY	DD/MM/YYYY	Ongoing : <input type="checkbox"/>	-
			DD/MM/YYYY	DD/MM/YYYY	Ongoing : <input type="checkbox"/>	-

- 8. Other causal relationship**

Study procedure (exams, strategy...)	-	specify:	
Progression of COVID-19 disease	-		
Other medical condition/illness	-	specify:	
Other	-	specify:	

- 9. Investigator**

Date of reporting: DD/MM/YYYY

I declare the SAE (An automatic email will be sent to PV team)

Investigator name (mandatory):

Phone number where the investigator can be reached:

Signature:

I declare modifications on the SAE initial notification form (2nd page)

If you need to modify/correct a SAE page after the SAE has already been declared to PV team, please indicate that you have modified the page. An automatic alert email will be sent to PV team.

Modification 1

Modification 2

Modification 3

Modification 4

Modification 5

Modification 6

DRE notification

When reporting Adverse Events in the corresponding form, a link allows to access the list of « Disease Related Events » (DRE).

DRE should not be reported as AE but in the DRE page, **unless a causality relationship with IMP is considered: in that case, a SAE form should be reported if serious.**

EU-SolidAct **Disease Related Events**

Participant ID code: **001-034**

>>> Disease Related Event (DRE) should not be reported as AE/SAE unless there is a link with the trial treatment and event is serious. In this case fill a SAE form.

Nature of the event	Severity	Start date	End date (recovering)	Presence before inclusion in the trial	Causal relationship to study treatment	Seriousness
-	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
-	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Hyper/Hypoglycaemia	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Anaemia	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Acute renal failure	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Pancreatitis	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Cardiac disorders ¹	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Myocarditis / pericarditis	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
ARDS ²	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Pneumothorax	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Pleural effusion	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Stroke / Cerebrovascular accident	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
Coma / Confusion	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-
-	-	DD/MM/YYYY	DD/MM/YYYY	-	-	-

1: cardiac arrhythmia (cardiac flutter, cardiac fibrillation), cardiac ischemia, cardiac arrest, congestive heart failure
2: Severe Acute Respiratory Distress Syndrome

If DRE is "Possibly related" and meet the definition of an SAE, please complete an SAE form [Go to SAE](#)

When the first page is filled, another page will open automatically. [Return to the previous page](#)

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Signatures (1/2)

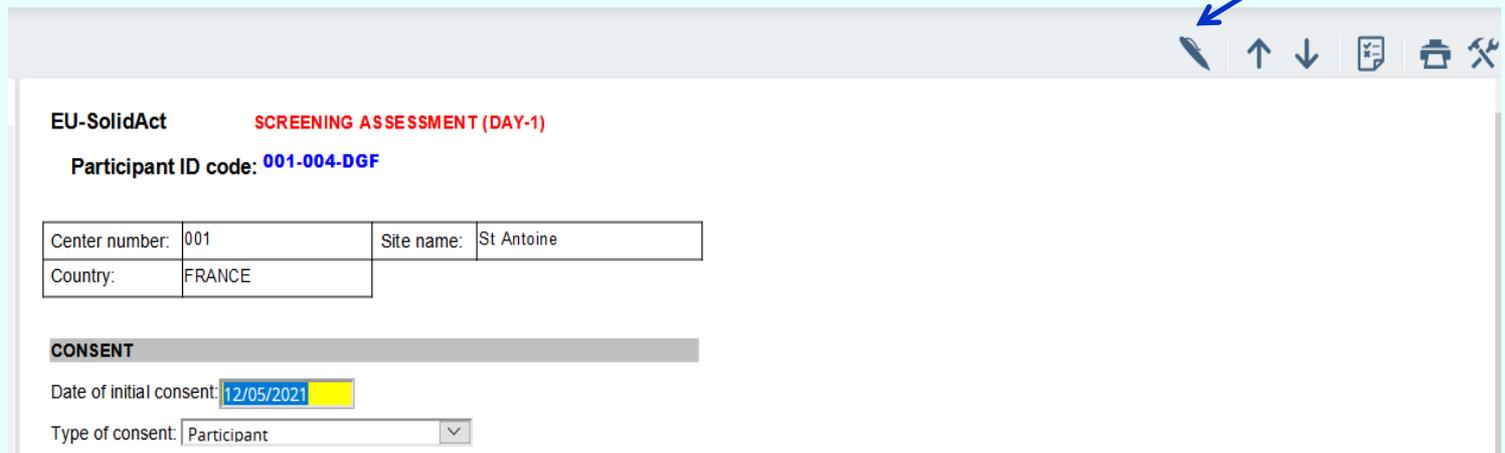
When the pages are entered, locked and monitored by the CRA, the investigator has to sign them which means that s/he is professionally responsible in regards to all the data entered for the patient.

There are two options:

- Sign each page one by one as soon as they are monitored;
- Sign several pages at the same time.

Warning: It is not possible to sign a page that has not previously been entered and locked.

The first option consists in signing the page from the CRF once the CRA has monitored the page. To do so, use the signature button in the CRF menu. The page signature status is symbolized by a colored pen icon located in the upper part of the screen. Grey color: the page is not signed. Blue color: the page is signed.



The screenshot shows a web interface for a Clinical Research Form (CRF). At the top right, there is a toolbar with several icons: a pen (signature), up and down arrows, a document with a checkmark, a printer, and a wrench. A blue arrow points to the pen icon. Below the toolbar, the form content is displayed. It includes the text "EU-SolidAct" and "SCREENING ASSESSMENT (DAY-1)" in red. Below that, "Participant ID code: 001-004-DGF" is shown in blue. A table contains the following data:

Center number:	001	Site name:	St Antoine
Country:	FRANCE		

Below the table, there is a section titled "CONSENT" in bold. Under "Date of initial consent:", the date "12/05/2021" is entered in a yellow box. Under "Type of consent:", a dropdown menu is set to "Participant".

The second option consists in signing several pages in just a single operation by using the action buttons of the different overviews at the patient, section and page level.

Signatures (2/2)

Your password is required for any operations linked to the page signature.

The screenshot shows a web application interface with a patient record on the left and an 'Electronic signature' dialog box in the center. The patient record includes the following items:

- 001-004-DGF
- Eligibility to SolidAct PART A or B
- Consent and Study Selection
- 1 - Consent
- 2 - Clinical status / WHO Disease Stage at Screening
- PART B - Severe Disease

The 'Electronic signature' dialog box contains the following information:

- Study: U9430058D
- Patient: 001-004-DGF
- Page(s): CRF 1(1)
- Date: 14/05/2021
- Login: AUDE NDOADOUMGUE
- Reason: Review
- Print CRF in PDF format:
- Password: [masked]

Buttons: Sign, Cancel

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Monitored and signed data must not be modified. Data modification is not possible when the page is signed since it has to be locked to be signed. Only non-locked pages can be modified.

However, if you want to modify data, first you must unlock the page. Proceed as follows:

- First cancel the signed status of the page;
- Contact the CRA to delete the monitoring of the page, if need be;
- And unlock the page.

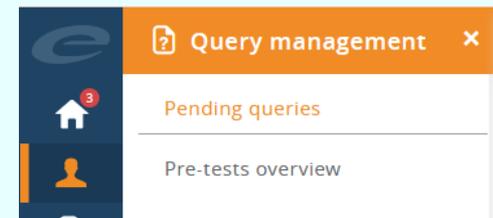
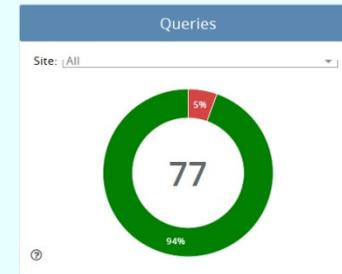
Once the page is unlocked, the data can be modified.

Queries (1/2)

When pages are entered and signed, data is verified by the CRA or the data manager. If inconsistencies are detected, they create manual or automatic queries to which the investigator will have to reply.

Queries can be accessed from:

- The study dashboard by clicking the "Queries" widget title, the list of pending queries is displayed.
- Click the "Query management" menu of CSOnline to have access to the list of "Awaiting reply" queries (modify the search to display the other queries).



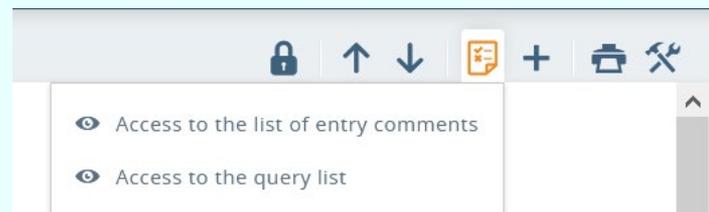
In each overview table (Patients, Section or Page overview), question marks symbolizing the presence of pending queries appear in the "Query" column. The question mark color symbolizes the query status at the patient/section/page level based on the overview table concerned.

-  Orange: at least one pending query
-  Green: all queries are processed

Click the question mark to display the queries related to the patient.

	eCRF	Query	Comm.	Entered	Locked	Monitored	Signed
							
							
							
							
							
							
							
							

- Through the CRF by clicking on the notification icon



Queries (2/2)

Click the "Reply" link to display the query detail:

List of queries

←

Total number: 4

		Investigator	Site ID	Patient v 1	Query status	Created on ^ 2	Created by	Section	Page
<input type="checkbox"/>	Reply	MARTINEZ V.	FR060	FR-060-023-FUCL	Awaiting reply	20/11/2020 09:24	AUORE DURAND	M12	p53 - Résultat de laboratoire 2/2

Query reply

Patient: FR-060-023-FUCL
Page: CRF 2 - p53

Created on: 20/11/2020 09:24
Created by: AUORE DURAND (DURANDAUR)
User type: DM

Query status: Awaiting reply

Sent on: 23/11/2020 15:36
Sent by: AUORE DURAND (DURANDAUR)

Replied on: -
Replied by: -

3) Indicate the reason for change

1) Check the "To be corrected" button

2) Enter the appropriate value here or directly in the CRF

Query:
La donnée est manquante. Veuillez compléter la donnée, SVP.

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
Patient témoin non VIH M12	p53 - Résultat de laboratoire 2/2	Vitamine B1 Résultat	<VIDE>	<input checked="" type="radio"/> No change <input type="radio"/> To be corrected	
Patient témoin non VIH M12	p53 - Résultat de laboratoire 2/2	Vitamine B1 Non fait	<VIDE>	<input checked="" type="radio"/> No change <input type="radio"/> To be corrected	

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

4) Confirm query reply

Confirm Cancel

If a correction/modification is done directly in a eCRF page (other than queries), please remember to save the modification.

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Unblinding (1/2)

Unblinding should be done only if required for the participant's safety. If possible, contact the sponsor and/or the pharmacovigilance team before proceeding to unblinding.

The unblinding of a randomized patient is done as follows:

- Select the patient to be unblinded and click on the "Tools" icon in the patient overview page

Patients overview

Number of patients: 6

	Site ID	Investigator	Status	Rando.	Patient	eCRF	Site Name	Query
<input type="checkbox"/>	001	NDOADOUMGUE AUDE	★	🔒	001-004-DGF	📄	St Antoine	
<input type="checkbox"/>	001	NDOADOUMGUE AUDE	★	🔒	001-005-FSR	📄	St Antoine	
<input type="checkbox"/>	001	NDOADOUMGUE AUDE	★	🔒	001-006-VCG	📄	St Antoine	
<input type="checkbox"/>	001	NDOADOUMGUE AUDE	★		001-109-ALN	📄	St Antoine	
<input type="checkbox"/>	001	NDOADOUMGUE AUDE	★	🔒	001-123-ERF	📄	St Antoine	
<input checked="" type="checkbox"/>	001	NDOADOUMGUE AUDE	★	🔒	001-234-SDF	📄	St Antoine	

- ✓ Save as "Locked"
- ✓ Save as "Signed"
- ✗ Cancel "Locked" status
- 👤 Manual update of personalized ID codes
- 🖨️ Print page tracking report
- 🔒 Treatment unblinding

- Select Treatment unblinding and choose the randomization to be unblinded

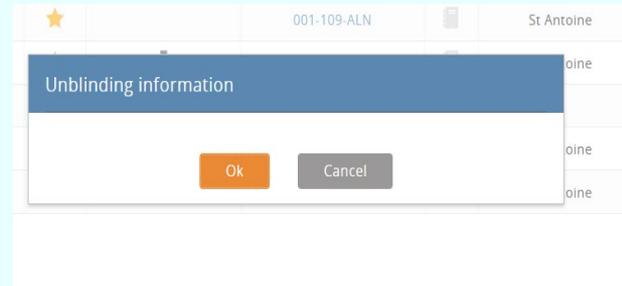
Unblinding information

Randomization

Ok Cancel

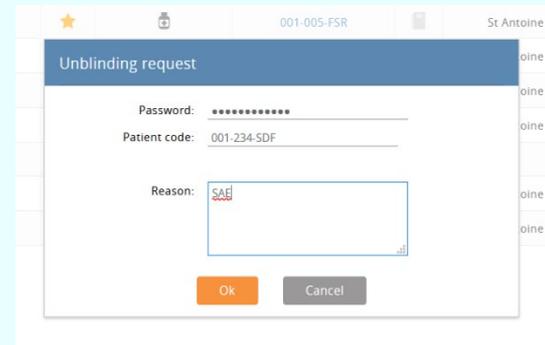
Unblinding (2/2)

Click on “Ok”



A dialog box titled "Unblinding information" with a blue header bar. It contains two buttons: "Ok" (orange) and "Cancel" (grey).

Enter your user password, the patient ID and the reason for Unblinding



A dialog box titled "Unblinding request" with a blue header bar. It contains three input fields: "Password:" (masked with dots), "Patient code:" (001-234-SDF), and "Reason:" (SAE). It also has "Ok" (orange) and "Cancel" (grey) buttons.

Only the site's principal investigator has access to unblinding with his/her personal login/password

Unblinding results are displayed after you click on “Ok”



A dialog box titled "Treatment unblinding" with a blue header bar. It displays the following information:

- Treatment unblinding: 14/05/2021 16:30:03
- User: AUDE NDOADOUMGUE
- Patient code: 001-004-DGF
- Reason: SAE

Allocation date	Section	Therapeutic units	Treatment
12/05/2021 21:37:03	Baseline (Day 1)	10566	Baricitinib

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