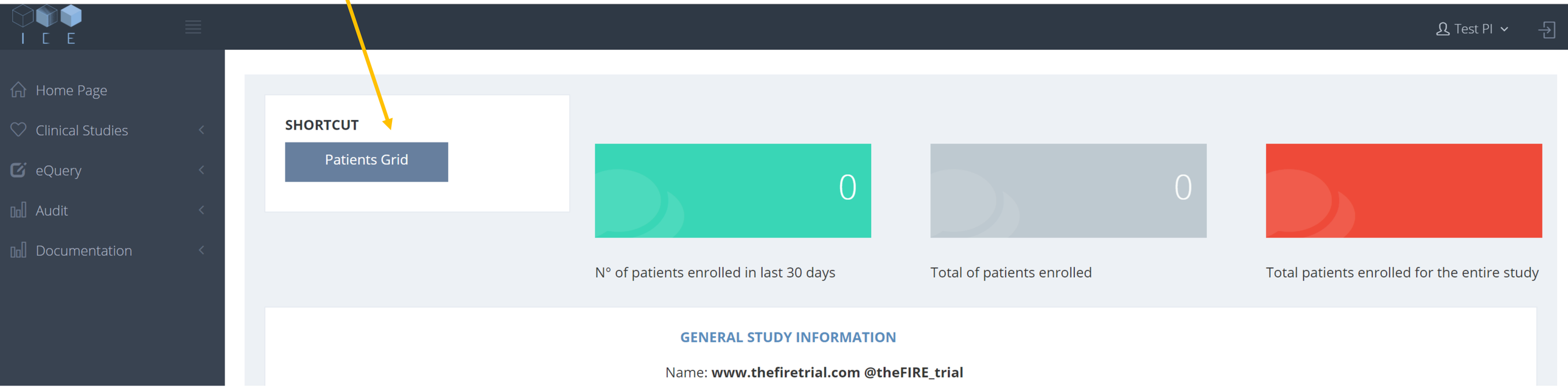
Functional versus Culprit-only Revascularization in Elderly Patients with Myocardial Infarction and Multivessel Disease: the FIRE Trial

Electronic Case Report Form
-Guidelines-

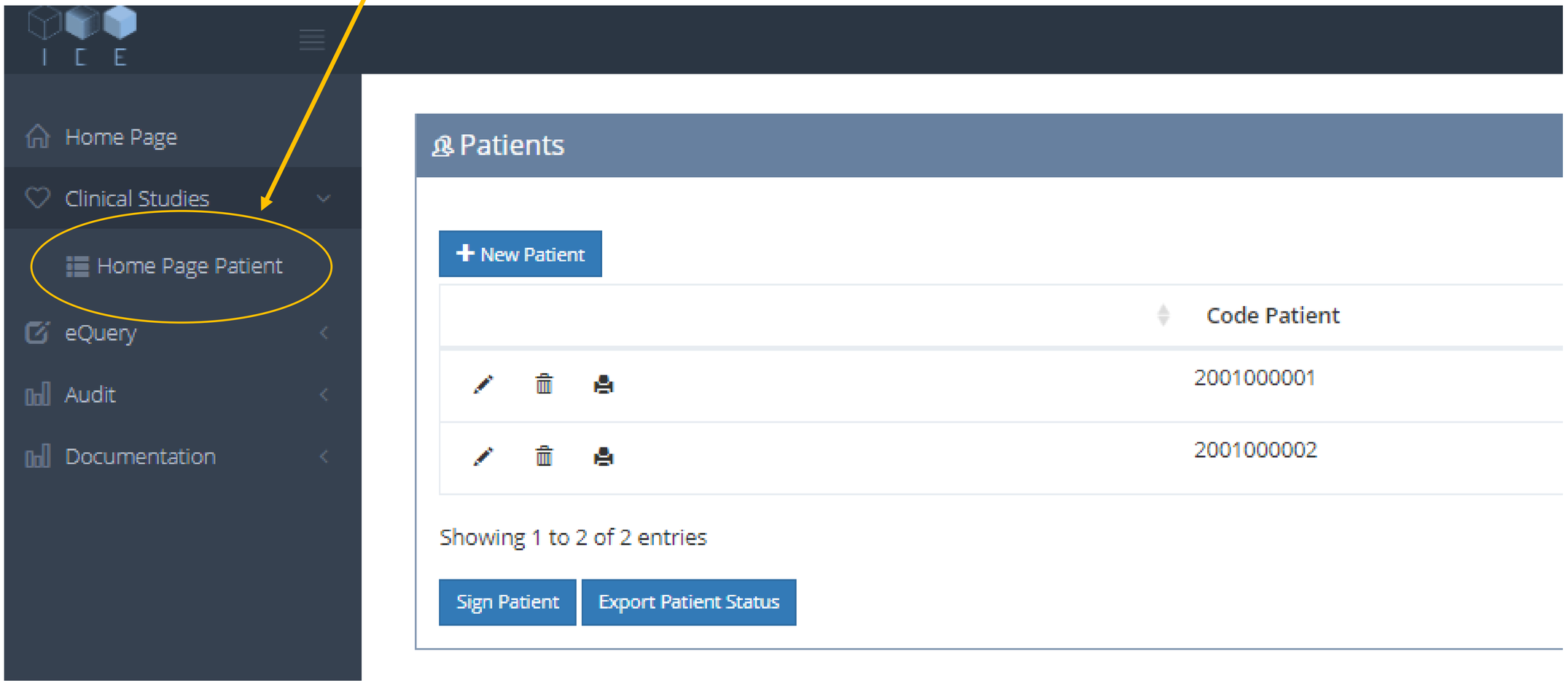
GENERAL INFORMATION

This is the HomePage of our eCRF !!!

To access the list of patients and to randomize a new patient, please click «Patients grid»



During the activities, you can quickly achieve the list of randomized patients with this shortcut



In this page you will find the list of randomized patients !!!

To select a patient, please click the symbol with the pencil

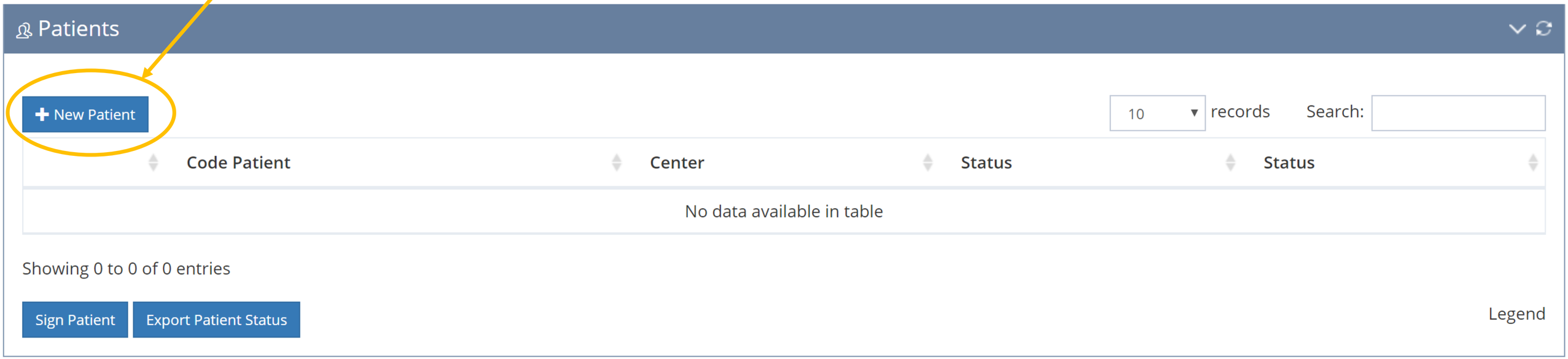
You will be immediately directed in the eCRF of the patient

Here, you can find the automatically generated ID for the patient

Please, this code must be linked, in a separate file with the name and surname of the patient

This is crucial for the follow-up

To randomize a new patient, please click «New Patient»

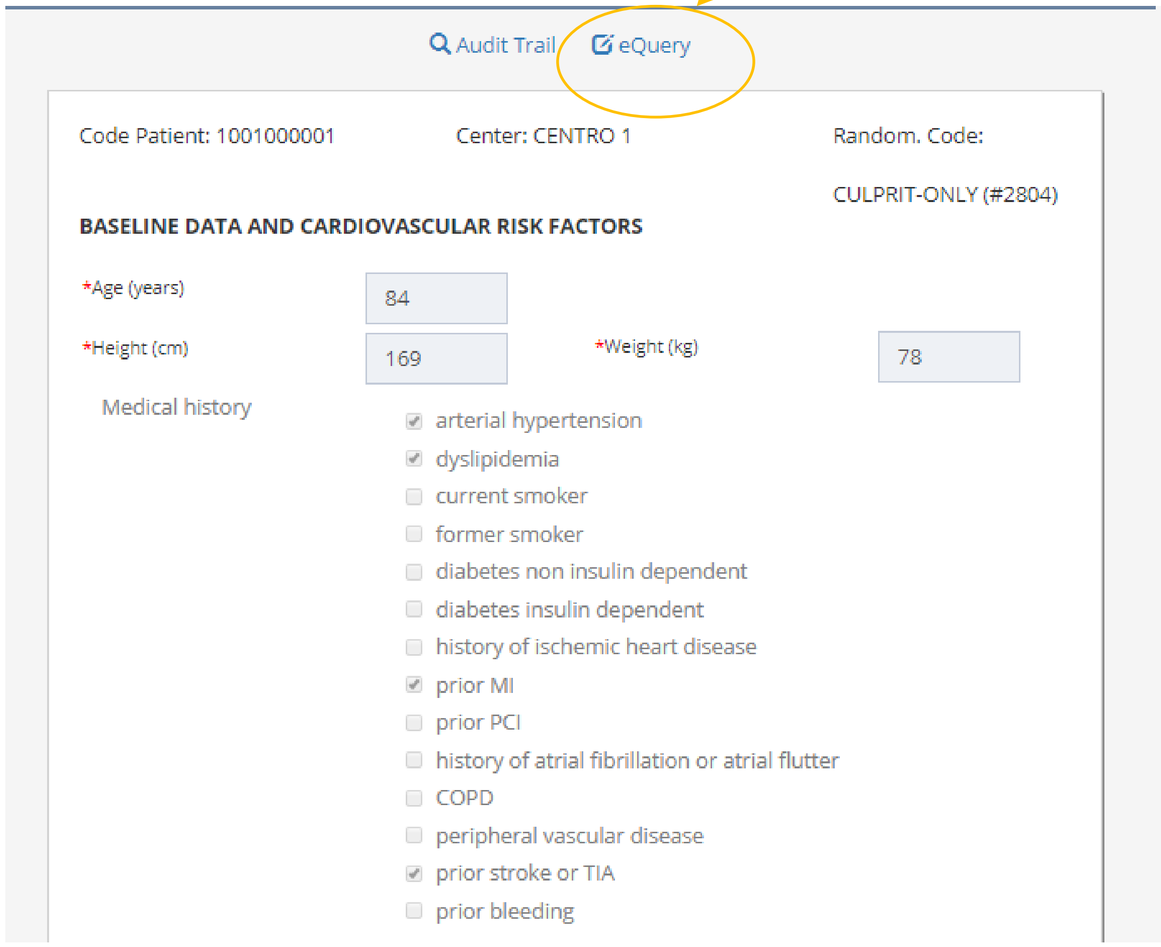


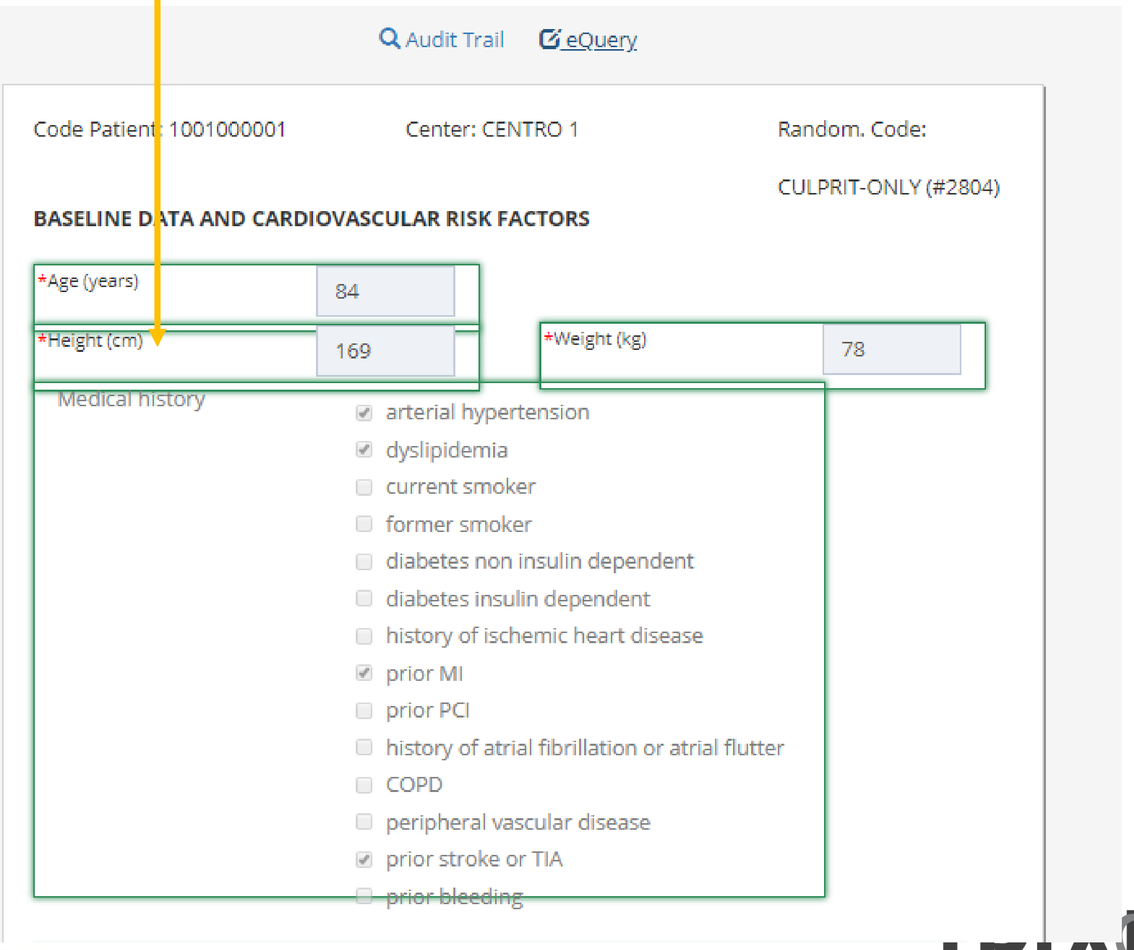
To change data in eCRF

Click eQuery

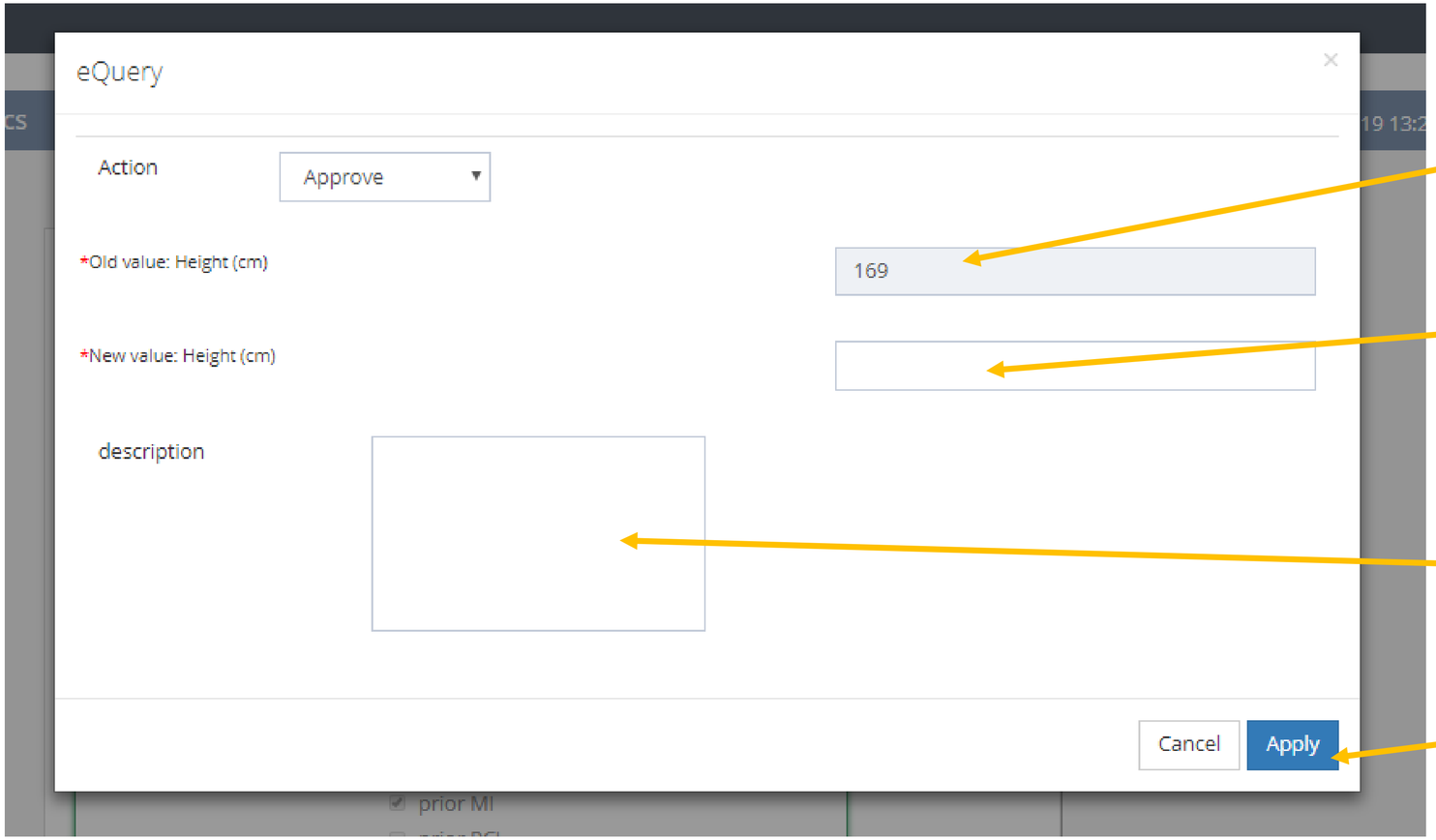
Click the item that needs the correction

Please note that you have to click on the question (e.g. height) and not on the the answer (e.g. 169)





To change data in eCRF



Here, you find the wrong value

Below the field where you have to add the correct value

Here, you must detail the reason for change

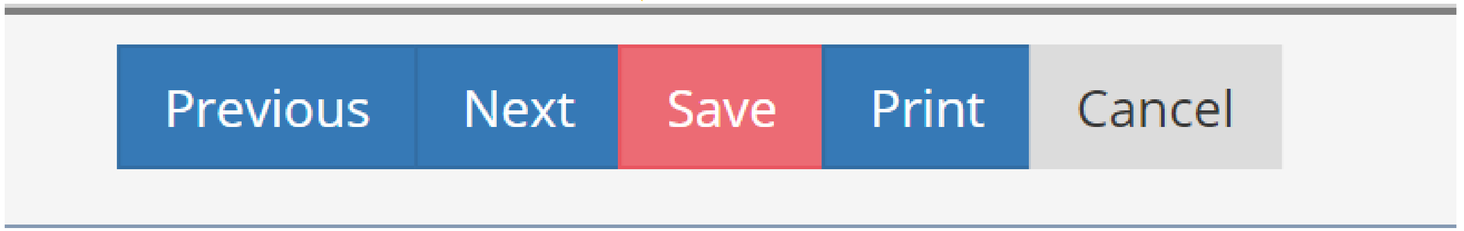
Finally, click on «apply»

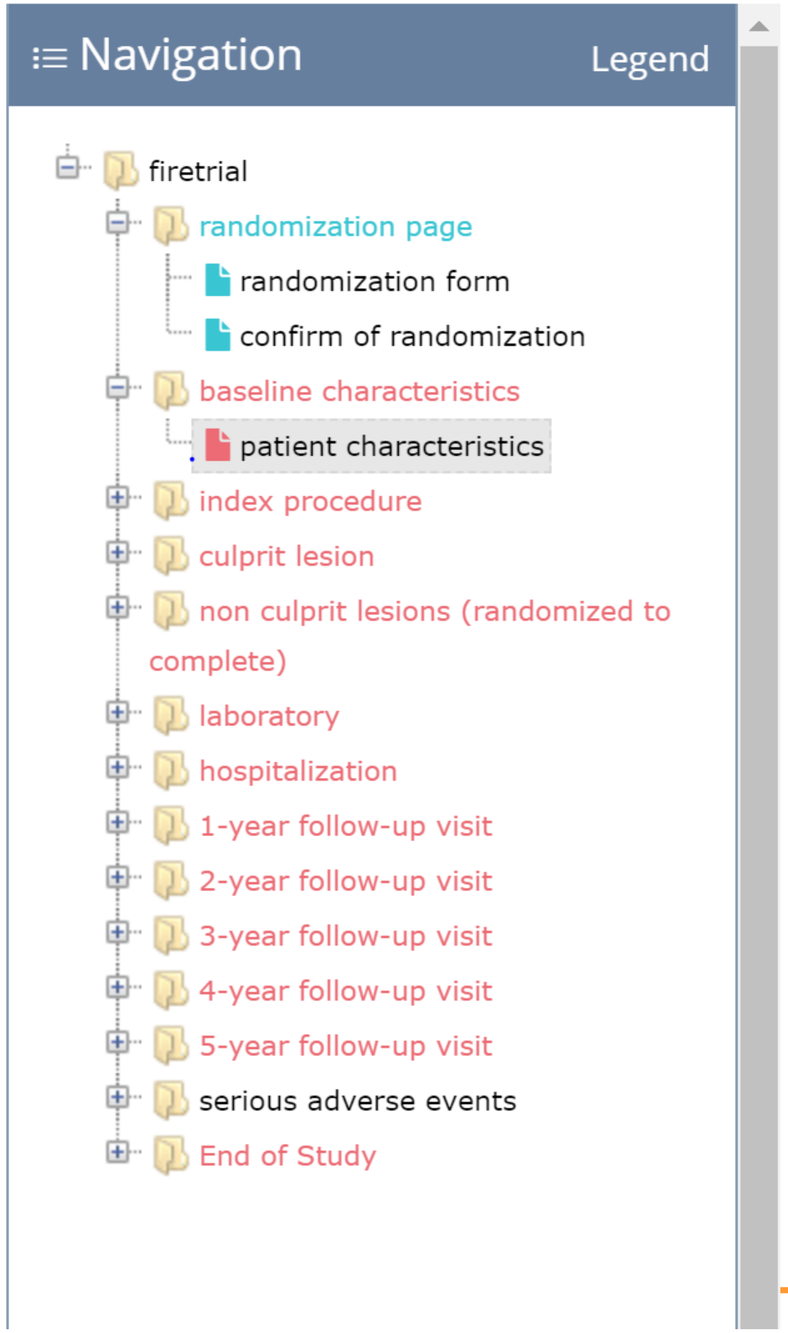
GENERAL CONSIDERATION

At the end of each page, you will find the menu below

Before to leave the page, you must click «SAVE»

To go to the next page, please click «NEXT»





GENERAL CONSIDERATION

On the right, you find the navigation menu of the eCRF

Some pages are equal in all patients (e.g. randomization form, laboratory, discharge, follow-up, etc…)

On the contrary, other pages are different because of the randomization arm (e.g. index procedure, staged procedure, non culprit lesions, etc…)

Use this menu to move inside the eCRF

PAGES OF THE eCRF

Inclusion criteria

*Age ≥75 years	no	yes
*Patient hospitalized for STEMI or NSTEMI	no	yes
*Multi-vessel disease at CAA	no	yes
*Successfull treatment of culprit lesion	no	yes

Exclusion criteria

*Absence of clear culprit lesion	no	yes
*Planned surgical revascularization	no	yes
*Non-cardiovascular co-morbidity reducing life expectancy to < 1 year	no	yes
*Any factor precluding 1-year follow-up	no	yes
*Prior CABG	no	yes
*Non culprit in the LM	no	yes

Randomization

*Hospital admission date	16-07-2019	
*Randomization date	16-07-2019	
*ST-segment elevation MI	no	yes
*Male sex	no	yes

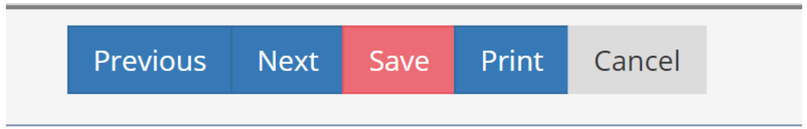
In order to randomize the patient, please save this form and then click on the randomization button that will appear under this label.

If the criteria are respected, the randomization arm will appear on the top right corner of the form

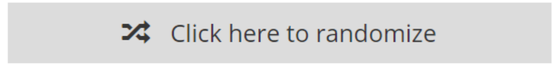
In the randomization page, you have to fill the inclusion criteria (mandatory YES) and the exclusion criteria (mandatory NO).

The dates of hospital admission and randomization are required together with two stratification variables (ST-segment elevation and sex)

Then, please click «SAVE»



The randomization button will appear

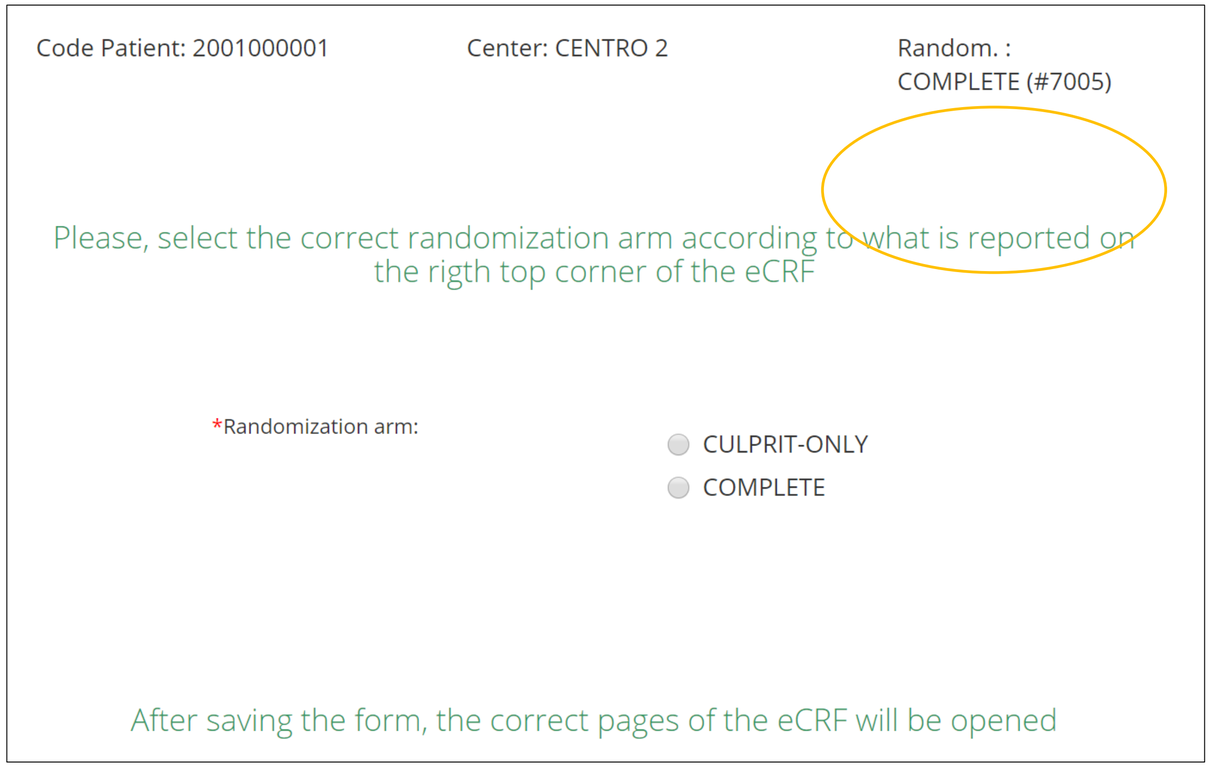


Please, click to randomize

The randomization arm will appear at the top right

And then push «NEXT» to continue.

FIRE TRIAL



This page requires that you confirm the randomization arm.

Please, click the correct arm.

Note that you can fill this page also in a different moment.

At the time of the randomization only the first page is mandatory.

Code Patient: 2001000001 Center: CENTRO 2 Random. Code:

COMPLETE (#7005)

BASELINE DATA AND CARDIOVASCULAR RISK FACTORS

*Age (years)

*Height (cm) *Weight (kg)

Medical history

- arterial hypertension
- dyslipidemia
- current smoker
- former smoker
- diabetes non insulin dependent
- diabetes insulin dependent
- history of ischemic heart disease
- prior MI
- prior PCI
- history of atrial fibrillation or atrial flutter
- COPD
- peripheral vascular disease
- prior stroke or TIA
- prior bleeding

*Physical activity at home: none light moderate intensive

CLINICAL PRESENTATION AND ASSESSMENT

*Systolic blood pressure (mmHg)

*Heart rate (bpm)

*Killip class I II III IV

*Cardiac arrest at presentation yes no

*ST segment deviation (both elevation and depression) yes no

White Blood Cell (first value) (u/µl)

Creatinine (first value) (mg/dl)

Haemoglobin (first value) (g/dl)

This page is focused on general data.

We have to calculate the following scores:

- **PRECISE DAPT**
- **SYNTAX II**
- **GRACE risk score**
- **PARIS**

The computation is automatic !!! You have only to fill the variables.

This value is crucial to calculate the occurrence of contrast induced acute kidney injury (in the next pages we ask the peak value of creatinine after the procedure).

FIRE TRIAL

Code Patient: 2001000002 Center: CENTRO 2 Random. Code:

GENERAL DATA CULPRIT-ONLY (#7006)

*Date of index procedure

*Access site ○ radial ○ femoral ○ other

Procedure duration (minutes)

Dose of contrast medium (ml)

Type (brand) of contrast

Dose Area Product (mGy * cm2)

*Did any complication occur? ○ yes ○ no

*If yes, please clarify

Did you use any of the following devices?

- ☐ temporary pace-maker implantation
- ☐ IABP
- ☐ other left ventricular assistance
- ☐ orotracheal intubation
- ☐ IVUS
- ☐ OCT
- ☐ Rotablator

*How many non-culprit lesions were identifiable? ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

*Randomization was performed

- ○ at the index procedure
- ○ after the end of the index procedure but within 48 hours

This is the INDEX PROCEDURE PAGE for patients randomized to ONLY CULPRIT REVASCULARIZATION

These variables are optional, but they might be important for substudies. Try to fill as much as you can !!!

This field is important!!! The eCRF will generate a number of NON CULPRIT LESION PAGE equal to the number that you sign HERE.

Note that you can randomize a patient up to 48 hours after the end of the index procedure.

This is convenient for STEMI patients, but if feasible, try to randomize NSTEMI patients during the index procedure.

FIRE TRIAL

Code Patient: 2001000001 Center: CENTRO 2 Random. Code:

GENERAL DATA COMPLETE (#7005)

*Date of index procedure 17-07-2019

*Access site ◉ radial ○ femoral ○ other

Procedure duration (minutes) 60

Dose of contrast medium (ml) 250

Type (brand) of contrast omnipaque

Dose Area Product (mGy*cm2) 2500

Did any complication occur? ○ yes ◉ no

*If yes, please clarify

Did you use any of the following devices?

☐ temporary pace-maker implantation ☐ IABP ☐ other left ventricular assistance
☐ orotracheal intubation ☑ IVUS ☐ OCT ☐ Rotablator

*How many non-culprit lesions were identifiable? ○ 1 ◉ 2 ○ 3 ○ 4 ○ 5

*When did you perform the randomization?
◉ at the index procedure
○ after the end of the index procedure but within 48 hours

*When did you perform the functional assessment?
○ at index procedure
◉ at staged procedure

*Did the functional assessment identify at least one positive non-culprit lesion? ◉ yes ○ no

*When did you perform the revascularization of the non-culprit lesions?
○ at index procedure
◉ at staged procedure

This is the INDEX PROCEDURE PAGE for patients randomized to COMPLETE REVASCULARIZATION

These variables are optional, but they might be important for substudies. Try to fill as much as you can !!!

This field is important!!! The eCRF will generate a number of NON CULPRIT LESION PAGE equal to the number that you sign HERE.

These variables describe how was performed randomization, the time of functional assessment and of revascularization.

FIRE TRIAL

Code Patient: 2001000001 Center: CENTRO 2 Random. Code:

COMPLETE (#7005)

GENERAL DATA OF THE STAGED PROCEDURE

*Date of the staged procedure

*Access site ○ radial ○ femoral ○ other

Procedure duration (minutes)

Dose of contrast medium (ml)

Type of contrast

Dose Area Product (mGy * cm2)

*Did any complication occur? ○ yes ○ no

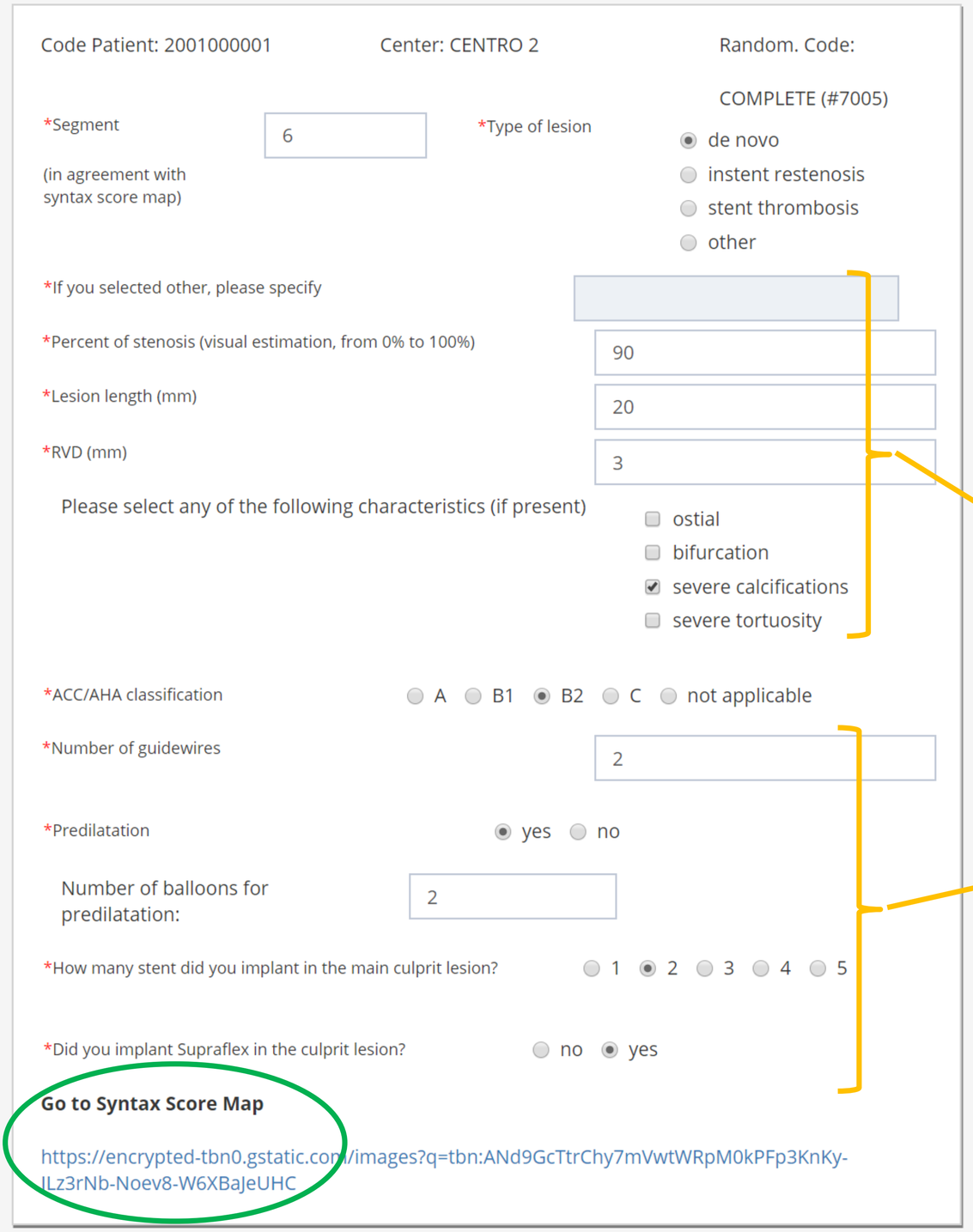
*If yes, please clarify

Did you use any of the following devices?

- ☐ temporary pace-maker implantation
- ☐ IABP
- ☐ other left ventricular assistance
- ☐ orotracheal intubation
- ☐ IVUS
- ☐ OCT
- ☐ Rotablator

This page will appear only for patients randomized to COMPLETE REVASCULARIZATION and only if you sign that the functional evaluation or the revascularization or both have been performed in a staged procedure.

FIRE TRIAL



Code Patient: 2001000001 Center: CENTRO 2 Random. Code:

COMPLETE (#7005)

*Segment 6

(in agreement with syntax score map)

*Type of lesion
- de novo
- instent restenosis
- stent thrombosis
- other

*If you selected other, please specify

*Percent of stenosis (visual estimation, from 0% to 100%) 90

*Lesion length (mm) 20

*RVD (mm) 3

Please select any of the following characteristics (if present)
- ostial
- bifurcation
- severe calcifications
- severe tortuosity

*ACC/AHA classification A B1 B2 C not applicable

*Number of guidewires 2

*Predilatation yes no

Number of balloons for predilatation: 2

*How many stent did you implant in the main culprit lesion? 1 2 3 4 5

*Did you implant Supraflex in the culprit lesion? no yes

Go to Syntax Score Map

https://encrypted-tbn0.gstatic.com/images?q=tbn:ANd9GcTtrChy7mVwtWRpM0kPFp3KnKy-lLz3rNb-Noev8-W6XBaJeUHC

This is the CULPRIT LESION PAGE

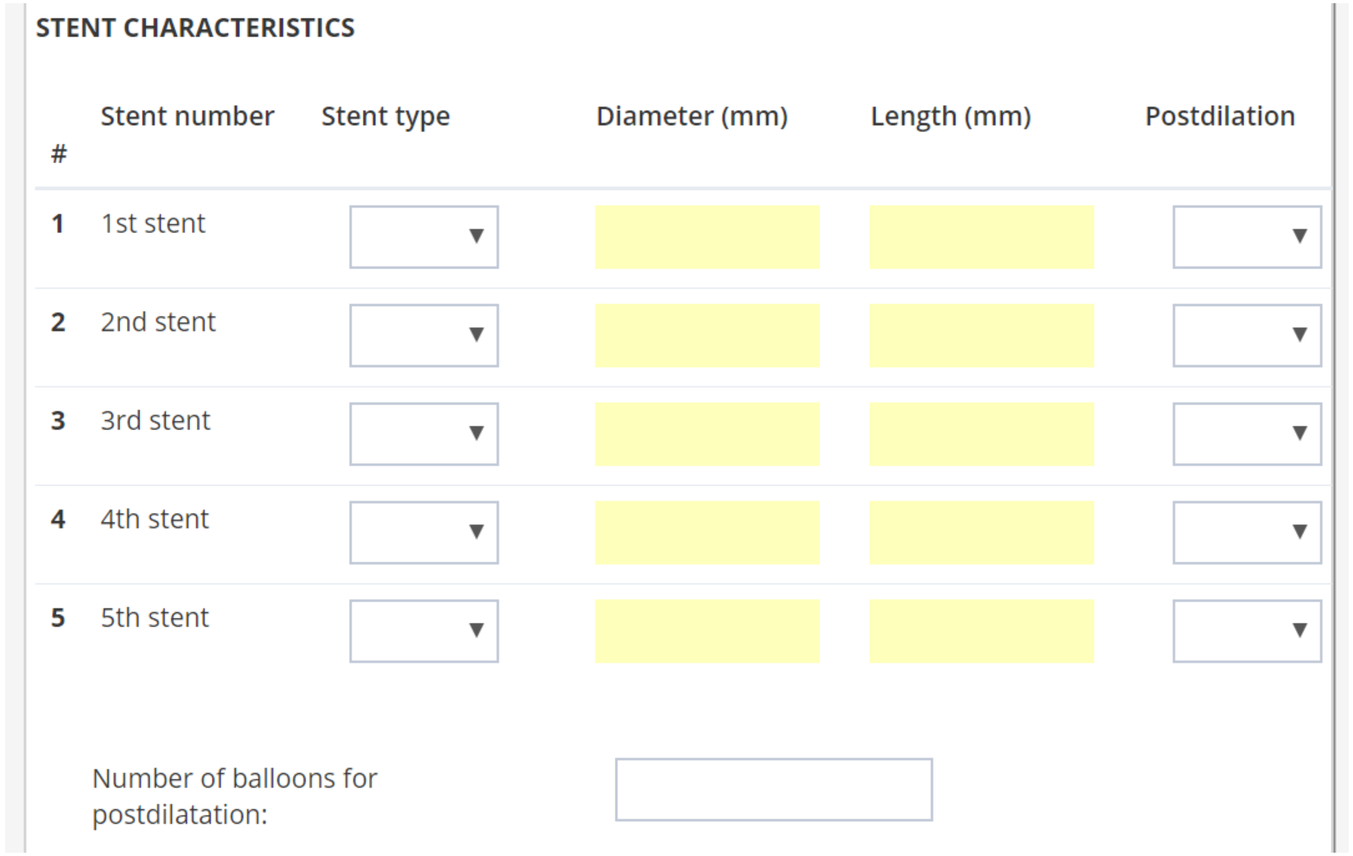
If you do not remember the number of the segment, you can check the Syntax Score Map at the link reported at the end of the page.

These values are based on the visual estimation of the operator. The corelab will perform the QCA in a separate CRF.

Here, we ask some details about the procedure. These information are important for substudies.

FIRE TRIAL

STENT CHARACTERISTICS PAGE


STENT CHARACTERISTICS

#	Stent number	Stent type	Diameter (mm)	Length (mm)	Postdilation
1	1st stent				
2	2nd stent				
3	3rd stent				
4	4th stent				
5	5th stent				

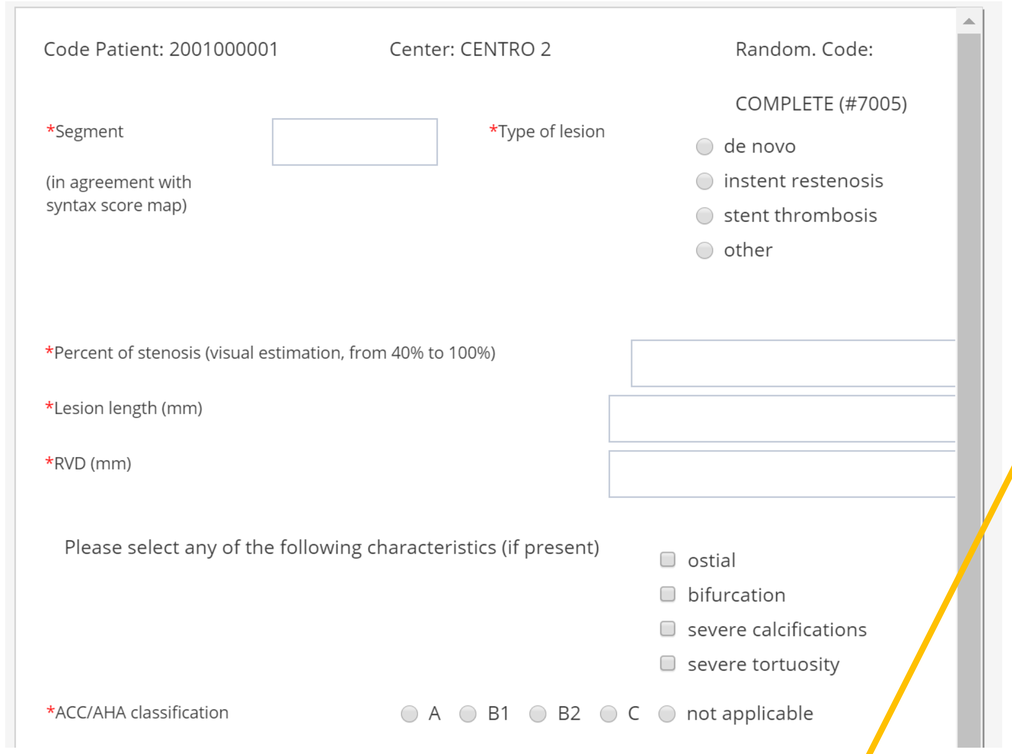
Number of balloons for postdilatation:

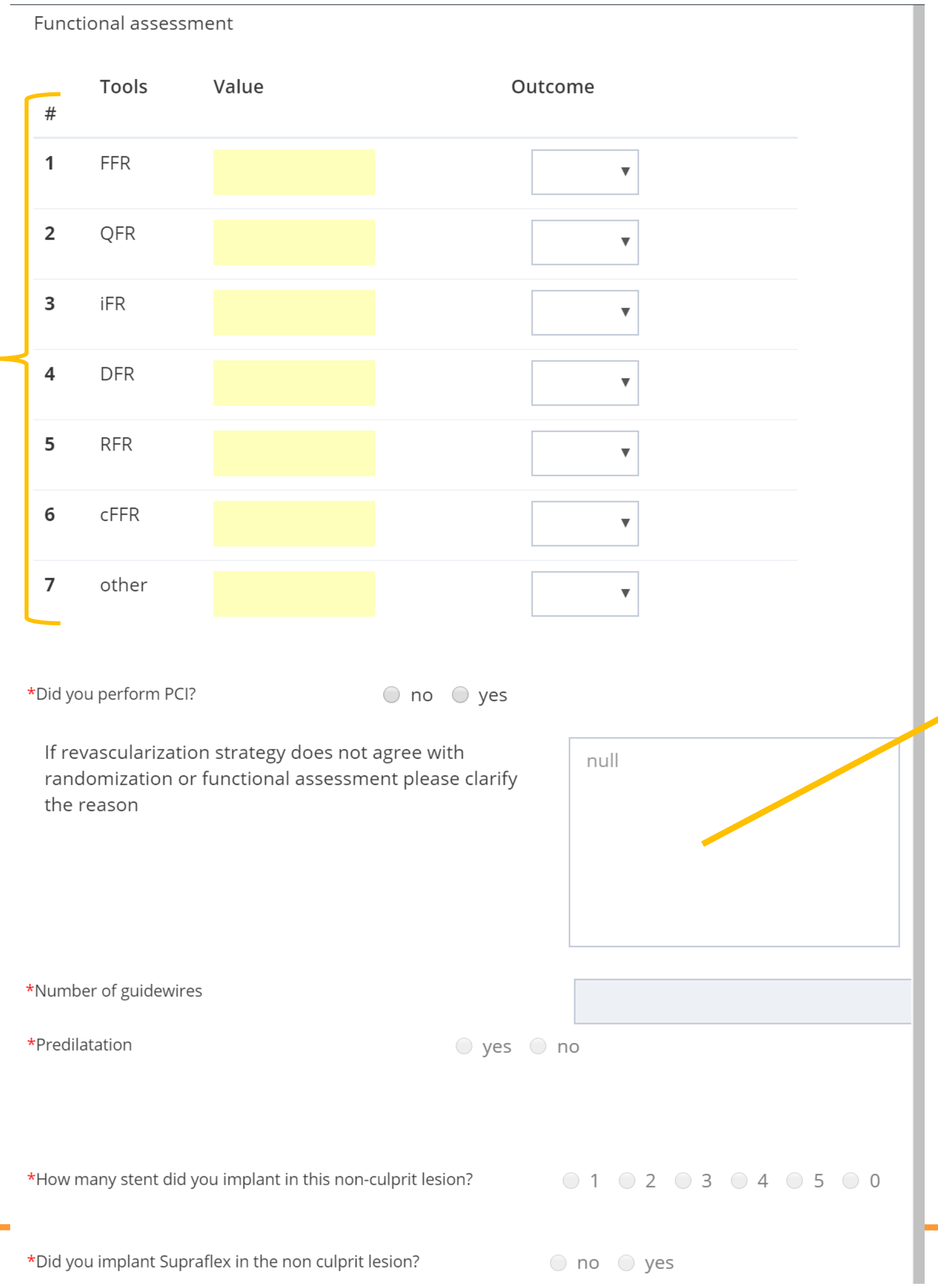
This page appers when you report that one lesion (both culprit and non culprit) has been treated with at least one stent.

Please, remember that our protocol strongly suggest the use of sirolimus eluting biodegradale polymer stent (Supraflex Cruz) in all lesions.

If you implant in the same lesion more than 5 stents, please report only the first five.

This is the NON CULPRIT LESION PAGE for patients randomized to COMPLETE REVASCULARIZATION





Per protocol, you can use the tool for functional evaluation that you prefer. In addition, you are totally free to collect data with more than one tool.

THIS IS HIGHLY SUPPORTED !!!

If you collect angiographic projections, the corelab will calculate QFR values.

If you do not respect the randomization (e.g. treatment of non culprit lesion without functional evaluation) or functional result (e.g. treatment of non culprit lesion with negative functional result), you must clarify the reason.

FIRE TRIAL

This is the NON CULPRIT LESION PAGE for patients randomized to ONLY CULPRIT REVASCULARIZATION

Code Patient: 2001000002 Center: CENTRO 2 Random. Code:

CULPRIT-ONLY (#7006)

*Segment

(in agreement with syntax score map)

*Type of lesion

- de novo
- instent restenosis
- stent thrombosis
- other

*Percent of stenosis (visual estimation, from 40% to 100%)

*Lesion length (mm)

*RVD (mm)

Please select any of the following characteristics (if present)

- ostial
- bifurcation
- severe calcifications
- severe tortuosity

*ACC/AHA classification A B1 B2 C not applicable

*Did you perform PCI? no yes

It is quite similar to the previous one.

Being the only culprit revascularization arm, the functional assessment MUST NOT BE PERFORMED.

If you treat this lesion, it is a protocol deviation. You must clarify the reason.

FIRE TRIAL

Code Patient: 2001000002 Center: CENTRO 2

*Creatinine (highest value) (mg/dl)

*Select the troponin type: I T

*Troponin I (peak) (ng/dl)

*Troponin T (peak) (ng/dl)

White blood cell (peak) (u/µL)

Neutrophil (first value) (u/µL)

Lymphocyte (first value) (u/µL)

Haemoglobin (lowest value) (g/dl)

Platelet (first value) (u/µL)

CK-MB (peak) (ng/dl)

Uric acid (mg/dl)

Cholesterol LDL (mg/dl)

Glycemia (value at discharge)

Protein (g/dl)

Albumin (g/dl)

This is the LABORATORY DATA PAGE

We ask only two mandatory values:

- **Creatinine at peak: for contrast induced acute kidney injury**
- **Troponin at peak: for estimation of MI size**

However, if you fill also other fields many substudies and analyses can be carried out, increasing the possibility to share with all investigators publications and papers!!

FIRE TRIAL

*Date of discharge

*How many nights in intensive care unit?

*How many nights in cardiology ward?

Please select the correct items:

- [ ] Discharged at home
- [ ] Transferred to other non-cardiology department
- [ ] Transferred to spoke hospital
- [ ] Transferred to cardiac rehabilitation unit
- [ ] Other

*Did you observe any major adverse events? no yes

*Left Ventricular Ejection Fraction (%)

*Was the SAQ completed? no yes

*Was the EQ-5D completed? no yes

*Was the SPPB performed? no yes

*Was the CFS performed? no yes

This page is the last one of the eCRF about INDEX HOSPITALIZATION

Per protocol, all procedures must be completed within the index hospitalization.

To perform the evaluation of frailty, quality of life and improvement overtime, we kindly ask to perform these 4 scales.

NOT MANDATORY, but highly appreciated!

The eCRF will automatically generate the page of the scale if you click «YES»

You will find them in the navigation menu !!!

FIRE TRIAL

Medication in use

- [ ] aspirin
- [ ] clopidogrel
- [ ] prasugrel
- [ ] ticagrelor
- [ ] vitamin k antagonist
- [ ] novel oral anticoagulant
- [ ] ACE-inhibitor or ARB
- [ ] beta-blocker
- [ ] calcium channel blocker
- [ ] diuretic
- [ ] statin
- [ ] ranolazine
- [ ] ivabradine
- [ ] nitrates
- [ ] oral antidiabetics
- [ ] insulin
- [ ] other

*DAPT length suggested (months)

*Triple therapy suggested? ○ no ○ yes

*if yes, please specify the length (months)

MEDICAL THERAPY at discharge

Please note that the protocol, in agreement with current evidences and consensus document, suggests a relatively short DAPT regimen!

We enroll older MI patients aged ≥75 years.
Age ≥75 years is one of the criteria for HBR (minor) according to recent consensus document.

If the patient show additional HBR criteria, please try to suggest one-month DAPT regimen.
It will be helpful to assess the safety of Supraflex Cruz with very short DAPT regimen.

FIRE TRIAL

FOLLOW-UP PAGE

This is the page for all follow-up visits (from 1 to 5 years)

*date of follow-up

*CCS: No angina I II III IV NA

*NYHA: No dyspnea I II III IV NA

*did the patient have any type of non-invasive ischemia testing? no yes

*Was the SAQ completed? no yes

*Was the EQ-5D completed? no yes

*Was the SPPB performed? no yes

*Was the CFS performed? no yes

*Cholesterol LDL was at target? no yes

*Blood pressure was well controlled? no yes

*Physical activity at home: none light moderate intensive

*Did you observe any major adverse event? no yes

Page without adverse event !!!

*date of follow-up

*CCS: No angina I II III IV NA

*NYHA: No dyspnea I II III IV NA

*did the patient have any type of non-invasive ischemia testing? no yes

*Was the SAQ completed? no yes

*Was the EQ-5D completed? no yes

*Was the SPPB performed? no yes

*Was the CFS performed? no yes

*Cholesterol LDL was at target? no yes

*Blood pressure was well controlled? no yes

*Physical activity at home: none light moderate intensive

*Did you observe any major adverse event? no yes

PLEASE IMMEDIATELY FILL THE ADVERSE EVENTS FORM FOR EACH SINGLE ADVERSE EVENT THAT YOU OBSERVED!

PLEASE COLLECT ANY INFORMATION AND SEND IT FOR CEC ADJUDICATION!

Page with adverse event !!!

Please, remember to collect source docs for CEC adjudication of the adverse event.

FIRE TRIAL

*Is the patient still on aspirin? no yes

*Date of stop

*Reason of stop

*Is the patient still on P2Y12-receptor inhibitor? no yes

*Specify the P2Y12-receptor inhibitor

*Date of stop

*Reason of stop

Other medication in use

- vitamin k antagonist
- novel oral anticoagulant
- ACE-inhibitor or ARB
- beta-blocker
- calcium channel blocker
- diuretic
- statin
- ranolazine
- ivabradine
- nitrates
- oral antidiabetics
- insulin
- other

MEDICAL THERAPY at follow-up

Please collect detailed information about DAPT regimen.

One of the most important substudy will be about stent performance in this high bleeding and high ischemic risks population.

FIRE TRIAL

SERIOUS ADVERSE EVENT PAGE

*Did you observe any major adverse events? ○ no ○ yes

*Date

Please select type of major events

- ☐ death
- ☐ new myocardial infarction
- ☐ revascularization
- ☐ stent thrombosis
- ☐ stroke
- ☐ heart failure
- ☐ non fatal cardiac arrest
- ☐ new onset atrial fibrillation
- ☐ new coronary angiography
- ☐ bleeding complication
- ☐ rehospitalization for cardiac cause
- ☐ rehospitalization for non-cardiac cause
- ☐ other

If you choose other, please specify

FOR ANY OF THE ABOVE-MENTIONED ADVERSE EVENT, PLEASE COLLECT ANY INFORMATION AND SEND IT FOR CEC ADJUDICATION!

You must fill this page if one adverse event occurs during the follow-up.

We ask to collect source documentation about adverse event for CEC adjudication.

Send all source documentation to:

thefirestudy@gmail.com

FIRE TRIAL

If you are filling this page, the patient completed the study.

Please clarify:

*Date of last contact:

*The patient:

- Completed the 5-year follow-up
- Died
- Withdraw the consent
- Lost to follow-up
- Other

*If Died, date of death:

*If Other, please specify:

Please specify

This is the page that you must fill if the patient completed the study !!!