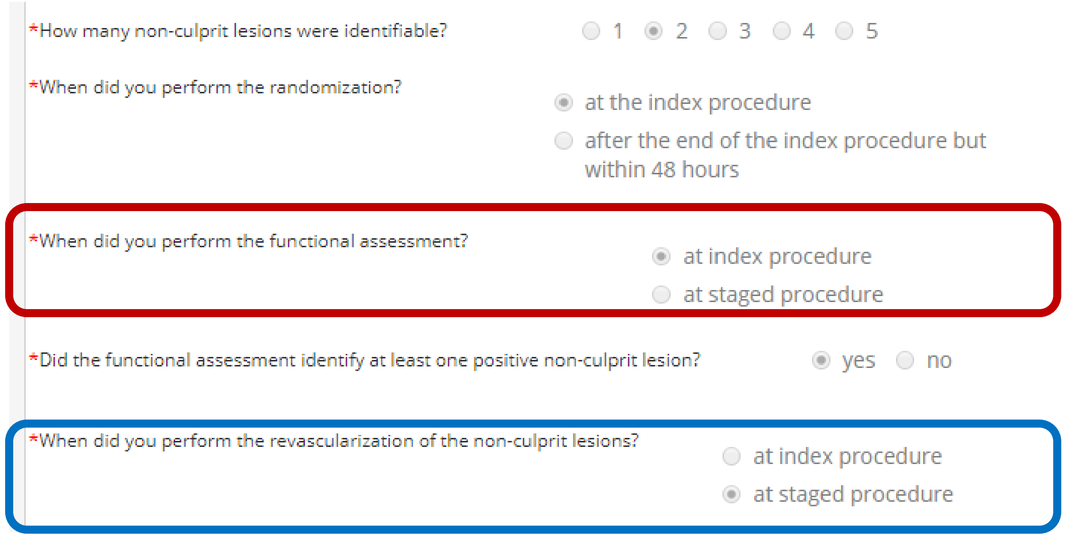
Tutorial: How to fill the eCRF if a SAE (between index and staged procedure) precludes to perform the staged procedure

Although uncommon, it can happen that one patient of the complete arm develops a serious adverse events after the randomization and before the staged procedure:

Case 1:

after functional assessment

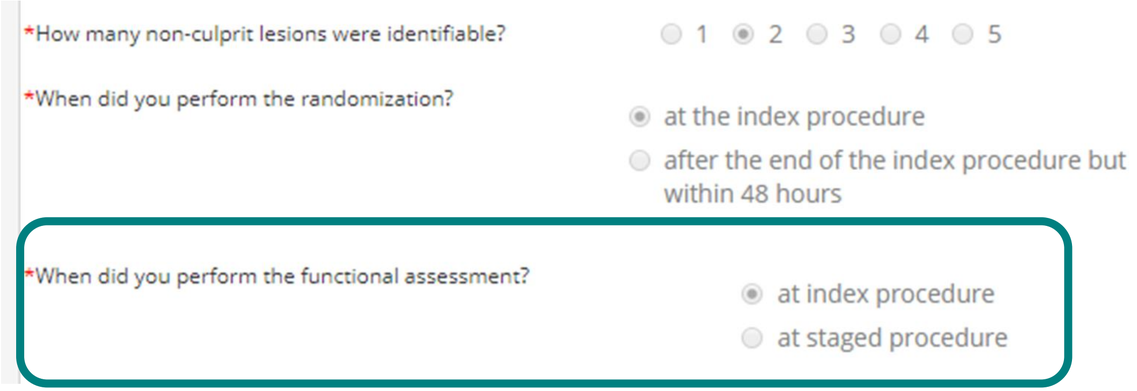
before staged procedure for PCI

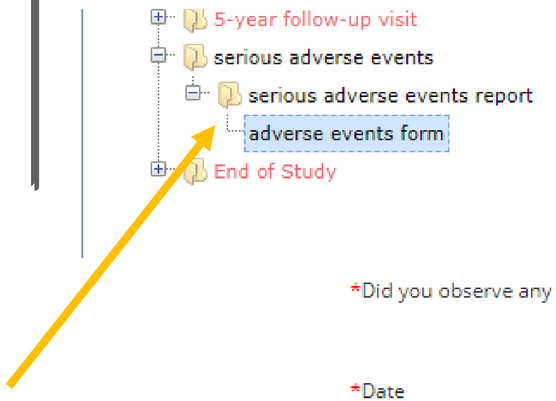


Case 2:

before staged procedure

for both functional assessment and PCI





*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!

It is crucial to report this SAE in the serious adverse events form!!

Any adverse event after the randomization must be reported and it will be adjudicated by CEC

FIRE TRIAL

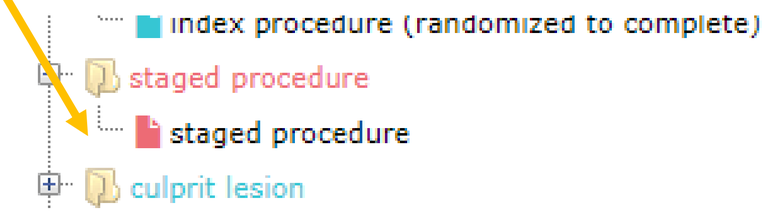
In few cases, the SAE after the index procedure can modify the clinical management of the patient and he/she will not receive the staged procedure, although he/she has been randomized to COMPLETE

(i.e. death, serious bleeding complication, etc…)

In this case, we ask you:

- **To leave blank the staged procedure page**
- **To report in the SAE page that the staged procedure has not been performed specifying the reason**

Please, leave blank the staged procedure page



COMPLETE (#3)

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

Report in the SAE page that the staged procedure has not been performed specifying the reason

- 5-year follow-up visit
- serious adverse events
  - serious adverse events report
    - adverse events form
- End of Study

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

*Date 19-08-2019

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: staged procedure not performed for the occurrence of serious bleeding event requiring surgery and red blood cell transfusion

FOR ANY OF THE ABOVE-MENTION[illegible]
SEND IT FOR CEC ADJUDICATION!