EuPreCHO: European study on perioperative management and outcome following Preoperative Transthoracic Echocardiography in noncardiac surgery patients.

FAQ:

It is important to fill out the CRF1 first and then CRF2 since the consistency check rules are based on data entered CRF1. If some of the data are pending, please wait to compltee the eCRF until you have all data available for entry.

If data is missing, please do not enter '0' and use the flag system to add a note 'data missing'

- During TTE- Recruitment period can we recruit non-TTE patients?

  No. After screening the first 50 recruited patients MUST be with TTE. After this, you may start recruiting non-TTE patients.

- When creating a subject in OpenClinica what the Start Date should be?

  Please enter the date that of your first data entry.

- Can the patient be included on the day of the surgery?

  Yes. As long as informed consent has been obtained before surgery, patients can be included in the study on the day of their surgery

- How to proceed if the procedure is cancelled?

  IIf surgery is cancelled, please complete the CRF2 and DO NOT REMOVE the patient from the study.

  ➔ There are no monitoring visits. Documents should be stored as per protocol (signed informed consent forms (ICF) or other identifiable data should be stored separately from source documents)

Preop/Periop and intraoperative data CRF1

Q15.1- if a patient has more than one treatment, which one has to be selected?
- Please select the highest level of antiglycaemic treatment - if the patient is managed on diet and insulin, please select insulin; if patient is treated with both oral antiglycaemic agents (e.g. metformin, GLP-1i) and insulin, please select only iinsulin
Q16.1 -What if Hb is measured in different units across sites?

Haemoglobin Preop Unit, a link has now been added for conversion of mmol/L to g/dL.

Q17 -Q18- Are troponin and BNP measurements mandatory for both cohorts?

Troponin and BNP values are for both cohort (Patients with TTE, and patients without TTE). Troponin measurement is mandatory for this study and BNP is not mandatory.

Q 17.1 is focused on the measured of Troponin

Q 17.2- Every centre has a value for the 99th percentile upper limit of normal (ULN) specified for their local assay, please make sure to add that specific number.
Definition: The 99th percentile ULN is the value which 99% of measurements in a healthy population fall below. This is a statistical value, and is usually given by the manufacturer of the assay. Check with your laboratory for the assay you use in your hospital. (Some assays also include separate values for males and females. In this case, please report the 'common' value for the 99th percentile ULN).
Q 18.1 is focused on the measured of B-type Natriuretic Peptide
Q 18.2- Every centre has one value of 99th Percentile of local assay, please make sure to add that specific number.
Q 23 - please select 'Yes, if history of Coronary Artery Disease includes one of the provided answers in Q23.1 (previous myocardial infarction, previous coronary intervention, previous coronary artery bypass). If none of the answers apply, please select 'No'
Q 26.1 what if answer is not provided?
Please provide your response in the flag
Q 27.1,what if answer is not provided?
Please provide your response in the flag
Q.28 What to select if the answer is (atrial fibrillation - atrial flutter, Heart blocks, History of cardiac arrest)?
please select 'Yes', if History of cardiac arrhythmia or heart blocks includes one of the provided answers in Q28.1 (atrial fibrillation - atrial flutter, Heart blocks, History of cardiac arrest), if none of the answer, please select 'No'.

For non-TTE subjects, there has been un update for Questions 51 to 62.
If TTE data older than 6 months exist, please answer **Q51b 'For non TTE subjects, is data available older than 6 months?'** with 'Yes' and fill out the data. The questions are **not** mandatory, but we ask for your assistance to make the database as informative as possible please

Q57. Definition of significant left ventricular diastolic dysfunction with signs of elevated filling pressures

Documentation as per local clinical practice, of interest a per protocol are: Moderate-severe left ventricular systolic dysfunction, Significant (Grade II or more) LV diastolic

dysfunction with evidence of increased LV filling pressures, Significant right ventricular dysfunction, Severe left-sided valvulopathies. This should be at least assessed for qualifying for focused TTE

Please note that the study protocol uses the definition of significant LV diastolic dysfunction according to the 2016 ASE/EACVI guidelines. In summer 2025, new guidelines were published by the ASE to define LV diastolic dysfunction and increased filling pressures (for details see below). If your center has implemented the updated 2025 ASE guidelines, please report according to that new definition. In essence, we ask you to report left ventricular diastolic dysfunction according to the definition of the guidelines used in your institution. This is implied/covered by the sentence in the protocol "....**OR corresponding diagnosis in the TTE report**."

2016 JASE/EACVI guidelines
- E/A ratio >2 OR
- E/A ratio <0.8 AND E>50cm/sec AND at least ≥ 2 additional criteria (Average E/e' ratio >14, peak TR velocity >2,8 m/sec, LA volume index >34 mL/m2) OR
- E/A ratio >0.8 to <2 AND at least ≥ 2 additional criteria (Average E/e' ratio >14, peak TR velocity >2,8 m/sec, LA volume index >34 mL/m2)) [

2025 ASE guidelines (Nagueh SF, et al. J Am Soc Echocardiogr. 2025 Jul;38(7):537-569)

1. Reduced é velocity: septal <6 or lateral <7 or average <6,5 cm/sec AND
2. Increased E/é: septal >15 or lateral >14 or average >14 AND
3. Increased TR velocity >2.8m/s or PASP >35 mmHg

Ifonly TR or E/é criteria is positive, or any 2 of these 3 variables are positive then the following should be sought to confirm the diagnosis of significantly increased LAP (i.e. >Grade 2)

4. Pulmonary vein S/D<0.67 OR
5. LARS >18%
6. LAVI >34ml/m2
7. IVRT <70ms

Q.60 - If the Echo report does not specify severe MR, please select 'No'

Q. 67- Changes in medications:

If no medication was given from the beginning, and no new medication was introduced, please select the answer 'NO' (if the patients did not have any chronic medication and no new medication was introduced, please answer 'no')

Q68-Extended PACU : PACU duration is based on the routine that is required for the type of the surgery and routine in your centre, and as long as there is no extension due to some difficulties, the answer should be **'**NO'.

Please refer to ***Part II: Study specific instructions;*** *Perioperative management Page 14;*

EuPreCHO Postoperative Data CRF2

Q91- WHODAS:

What if the patient is still in hospital at day 30? Ask them to answer as if they were expected to perform the activities described, e.g. household, walking 1 km
What if you were able to reach for follow up but that are too ill to answer the questionnaire (e.g. sedated and intubated)? A fourth option has been added, 'Patient unable to complete the questionnaire due to severe health impairment'.

Q93 + Q94 + Q95- These mandatory questions should be completed even for inpatients
DAOH- Q104: If patients are not reachable for follow, in the updates Openclinica version, you have the possibility to select ,'patient could not be reached '.