



## FAQ

June 2023

### Recruitment number

- ➔ **The chief investigator of the study has approved that the maximum number of the recruitment subjects by centre can be 220 subjects (instead of 200 subjects)**

### Authorship policy

We would like to clarify the authorship policy. Because of new demands by peer reviewing journals, only steering committee members will review the manuscript and be named under the eventual manuscript title.

All collaborators, who have kindly enrolled patients according to the numbers requested, will of course be named on the list which will appear in PubMed when the work is eventually published.

All participants will receive a certificate for their participation in the study after the main publication.

The number of investigators allowed from each centre will be determined by the number of patients enrolled by that centre. The table below shows the number of investigators that will be collaborators. Collaborators will be listed in small font size at the end of the manuscript but will receive credit on PubMed as full co-authors just the same. For more information, please refer to the “Publication and Dissemination Policy” section of the protocol.

Number of patients completed	Number of investigators at that centre
45	1
85	2
120	3
150	4

### OpenClinica

*Sign Subject.* 

Only the investigator of each centre can sign the subject after completion  of the subject in the system.

Signing the subjects can be done only one by one. As we are still busy with data cleaning, if an investigator signs the subjects, we need to unsign the subjects if needed and the investigator has to resign the subject. Therefore, we invite the investigator to not sign the subjects until we complete the data cleaning for the study.

*Subject ID.*

Format xxx-xxx-xxx 3-digit code for country, 3 digit code for the hospital and 3 digit for individual patient number

e.g. Belgium (032), centre (001), First subject in (001): 032-001-001

Centre number: MP032-001

**Birthdate** has been removed and only year of birthday is in CRF.



## Secondary ID.

Please do not enter the secondary ID. The secondary ID should remain empty.

### Study Subject Record

Study Subject ID	OC
Secondary ID	
OID	S
Status	sig
Study Name	M

## Unknow/Missing Data.

How do we act when values are unknown but the possibility has not been considered in the eCRF? **You can leave the field blank and add an annotation flag „data not available“ or „unknown“. For any additional information that is not in the crf, you can use the flag.**

## Surgery cancelled?

The subject should be removed from the eCRF

## Q10.

What dose of insulin should be given in question 10.1 if patients inject "according to scheme"? Or should one refer to a specific day? **According to usual routine. What total dose of insulin would this patient take daily normally**

## Q12.

Refer to the "daily" or rather to the "usually performed, even if not daily" procedure? **Yes, Ideally DM patients monitor themselves daily but this may not always be the case. What we are seeking to find here is their usual METHOD of monitoring or whether it is happening at all (blood, urine or none at all)**

## Q13-17.

Refer to the time of consent or the time of the operation?

**Either one! Question aims to get information on recent control of DM. Ideally 3 months before surgery, but if a patient is consented some weeks before that, it's their 3 month recall prior to the date of the question being asked.**

## Q23.

The SORT model, Which score should be considered: risk prediction or SORT-clinical judgement risk prediction? **clinical judgement risk prediction**

23. SORT Score\* |\_\_|\_\_|\_\_| (0-100%)

To calculate SORT score use <http://www.sortsurgery.com> (see appendix 12)

## Q33.



### *Intraop anaesthesia technique.*

#### 33. Intraop anaesthesia technique\*

- GA volatile    GA TIVA propofol only    GA TIVA propofol remifentanyl    Regional spinal or epidural only  
 Regional peripheral nerve block only    Regional combined with GA    Regional + Sedation

If the hospital use sufentanil. How should it be document balanced anaesthesia (GA TIVA propofol) with sufentanil and alfentanil under item 33? **add these opioids to the flag section.**

#### Q16.

Which value should be given? **Highest glucose value**

Q24. Which value should be given? **Highest creatinine value in 3 months**

Q25. Which value should be given? **Highest glucose on day of surgery**

Q27. How to specify when patients take long-acting insulin the night before?

**Record the long acting insulin dose, regardless whether it was taken night before or morning of...**

Q28. The patient that did the usual long acting insulin on the day before surgery because of an urgency. How to proceed? **Yes, for insulin given day before surgery and Not for any insulin given day of the surgery itself**

Q30. Please up to maximum of 500 U of insulin

Q31. What should be indicated in question when switching from one procedure to another? **If the surgery changes from minimally invasive to open, please cite the most invasive procedure, i.e. it becomes OPEN**

Q32. How do you define "staff" and "trainee"? **In some healthcare systems, there are non physician-consultant anesthetists who are also not trainees, e.g. nurse anesthetists, "staff grade" / associate specialists colleagues in the UK.**

-How do they define "PACU"? if the "recovery room" where patients are followed up for 2-4 hours postoperatively and a separate "PACU" if patients need planned or unplanned overnight follow-up. Sometimes patients go directly to the ICU postoperatively. How should we then document the "PACU" period? Or in other words, how do you define "INTRAOPERATIVE DATA" and "PACU DATA AND POSTOPERATIVE DAY 1"? **For the purpose of MOPED study, "PACU" encompasses both your "recovery" room and your PACU. Intraop data ends when patients leaves the OR and is transferred either to ITU or PACU.**

**PACU time is time from entering ITU/PACU until end of operative day, i.e. "Day Zero" Day 1 postop is the first day after the day of surgery.**

**Q39 and Q40: the Q39, if the answer NO, is selected, for the Q40, the answer 'Other' should be selected'**



**Q45.** patients undergoing major surgery often go directly to HDU/ICU, bypassing the PACU. I record this information given upon arrival at the HDC/UCI?

**Record the patient data from HDU or ICU if that's where they were sent after surgery**

**Q56.** All the insulin done since discharge from UCPA until discharge home? For the patient that was doing short acting insulin in the ward but because of high levels introduce an intermediate acting insulin. How to specify?

**Yes , up to a maximum of 500 U of insulin. You may add the different types of insulin together.**

**Example: If a patient took 20 units of intermediate-long acting insulin in the morning and 10 units of act rapid after each of two meals, then the total insulin consumption that day was 40 U (20 + 10 + 10). If this happened each day for 5 days until discharge, then total post PACU insulin would be 200 U (40 each day x5 days).**

**Q68.** What if there is no deviation?

If there are no deviations from normal, then the CCI is zero. Please enter zero for Q68 and therefore zero for CCI Q.70. You can enter as an annotation by the flag system.

**Q70.** For no deviation what to enter?

zero for CCI. You can enter as an annotation by the flag system.

**Question 68-69 and 70 are not mandatory to be filled in. They should be filled in only when there is a complication**