

Case report form (CRF)

Template with example items for the running example

Foundations of Clinical Research · Example study: cumulative fluid balance and 28-day mortality in septic shock

Good CRF design (guidance: delete before use)

- Collect only what you need to answer the objectives: every item must map to a variable in the data dictionary and to the analysis plan.
- Identify participants by study ID only, never by names or medical record numbers. The ID is in the header of every page.
- One item per question. State the unit beside every number. Use coded tick boxes (☐ 1 Yes ☐ 0 No) rather than free text.
- Always give a way to say “not done” (ND) or “unknown” (UNK), so a blank always means “forgotten”.
- Dates as DD/MM/YYYY and times as 24-hour hh:mm. Record raw values; let the database do calculations.
- Pilot the CRF on 3–5 patients and revise it before the study starts. Version and date every page.

Completion instructions

- Use a black ballpoint pen. Write clearly in capitals, one digit per box; right-align numbers ([] [] 7 [] [] 2).
- ND = test or measurement not done. UNK = done but result unknown or not found in the records.
- To correct: draw one line through the error, write the correct value beside it, add your initials and the date. Never use correction fluid or overwrite.
- Source documents: ICU chart, fluid balance chart, laboratory system, medical notes.

Form 1. Eligibility and enrolment

All inclusion answers must be 1 (Yes) and the exclusion answer 0 (No) to enrol.

#	Item	Answer	Not done / unknown
1.1	Age ≥ 18 years	☐ 1 Yes ☐ 0 No	
1.2	Septic shock (Sepsis-3): vasopressor needed for MAP ≥ 65 mmHg AND lactate > 2 mmol/L despite fluids	☐ 1 Yes ☐ 0 No	
1.3	Any exclusion criterion present? (list in protocol)	☐ 1 Yes: not eligible ☐ 0 No	
1.4	Date of enrolment	[] [] / [] [] / [] [] [] []	
1.5	Consent obtained from	☐ 1 Patient ☐ 2 Legal representative ☐ 3 Deferred consent ☐ 4 Waiver approved	

Form 2. Demographics and baseline (ICU admission)

#	Item	Answer	Not done / unknown
2.1	Age at ICU admission	[] [] [] [] years	
2.2	Sex	☐ 1 Male ☐ 2 Female	☐ ND ☐ UNK
2.3	Body weight	[] [] [] [] . [] [] kg	☐ ND ☐ UNK

Study: [ACRONYM] Site no. [] [] Participant ID [] []-[] []-[] [] []

No names on this form

#	Item	Answer	Not done / unknown
2.4	Weight was	☐ 1 Measured ☐ 2 Estimated	
2.5	ICU admission date and time	[] [] / [] [] / [] [] [] [] [] [] : [] []	
2.6	Source of infection (tick one)	☐ 1 Lung ☐ 2 Abdomen ☐ 3 Urinary ☐ 4 Skin/soft tissue ☐ 5 Other	☐ ND ☐ UNK
2.7	Chronic kidney disease	☐ 1 Yes ☐ 0 No	☐ ND ☐ UNK
2.8	Chronic heart failure	☐ 1 Yes ☐ 0 No	☐ ND ☐ UNK
2.9	Diabetes mellitus	☐ 1 Yes ☐ 0 No	☐ ND ☐ UNK

Form 3. Severity in the first 24 hours (SOFA and lactate)

Record the WORST value in the first 24 h after ICU admission. Choose ONE unit per laboratory test for the whole study and print it on the CRF (delete the other).

System	Variable (worst value)	Value	Unit	SOFA points	ND / UNK
Respiration	PaO ₂ /FiO ₂ ratio; on ventilator?	[] [] [] ☐ vent	mmHg	[] (0–4)	☐ ND ☐ UNK
Coagulation	Platelets	[] [] [] []	×10 ³ /μL	[] (0–4)	☐ ND ☐ UNK
Liver	Bilirubin	[] [] [] []	[μmol/L or mg/dL]	[] (0–4)	☐ ND ☐ UNK
Cardiovascular	MAP and highest vasopressor dose	[] [] [] []	[mmHg; μg/kg/min]	[] (0–4)	☐ ND ☐ UNK
Central nervous system	Glasgow Coma Scale (before sedation)	[] [] []	3–15	[] (0–4)	☐ ND ☐ UNK
Renal	Creatinine; urine output	[] [] [] [] [] [] [] []	[μmol/L or mg/dL]; ml/day	[] (0–4)	☐ ND ☐ UNK
Total	SOFA total score		points	[] [] (0–24)	☐ ND ☐ UNK
Lactate	Lactate at ICU admission	[] [] [] . []	mmol/L	(not scored)	☐ ND ☐ UNK

Study: [ACRONYM] **Site no.** [][] **Participant ID** [][]-[][][][]

No names on this form

Form 4. Daily fluid input and output (Days 1–5)

Day 1 = from ICU admission to the first midnight; Days 2–5 = midnight to midnight. Copy values from the fluid balance chart in ml. Shaded rows are calculated by the database, so leave them blank on paper.

Item	Unit	Day 1	Day 2	Day 3	Day 4	Day 5
Date	DD/MM	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___
Resuscitation fluid boluses (crystalloid)	ml					
Colloids / albumin	ml					
Maintenance IV fluids	ml					
Drug dilution and line flushes	ml					
Blood products	ml					
Enteral and oral intake	ml					
A. Total input	ml					
Urine output	ml					
Other losses (drains, gastric, RRT net removal)	ml					
B. Total output	ml					
<i>Daily balance (A – B)</i>	ml					
<i>Cumulative balance</i>	ml					
<i>Cumulative balance ÷ weight (2.3)</i>	ml/kg					
Fluid chart complete for 24 h?		☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N	☐ Y ☐ N

Study: [ACRONYM] Site no. [][] Participant ID [][]-[][][][]

No names on this form

Form 5. Outcome at Day 28

#	Item	Answer	Not done / unknown
5.1	Vital status at day 28 after enrolment	☐ 0 Alive ☐ 1 Dead	☐ UNK (lost)
5.2	If dead: date of death	[][] / [][] / [][][][]	☐ UNK
5.3	Date of ICU discharge	[][] / [][] / [][][][]	☐ still in ICU
5.4	Renal replacement therapy started during ICU stay	☐ 1 Yes ☐ 0 No	☐ UNK
5.5	Source of day-28 information	☐ 1 Medical record ☐ 2 Phone call ☐ 3 Other	

Sign-off

	Initials	Date (DD/MM/YYYY)
CRF completed by		[][] / [][] / [][][][]
CRF checked against source by		[][] / [][] / [][][][]
Entered into database by		[][] / [][] / [][][][]

Data dictionary

One row per variable in the database, in the same order as the CRF. Variable names: lower case, no spaces, ≤ 12 characters, never reused. Use the same codes everywhere (1 = yes, 0 = no) and the same missing-value codes: -88 = not done, -99 = unknown. Valid ranges become the range checks in your database.

Variable name	Label (question)	Type	Units / codes	Valid range / check	Missing codes	CRF item
study_id	Participant study ID	Text	SS-NNN (site, then number)	Unique; required	none	All
enrol_dt	Date of enrolment	Date	DD/MM/YYYY	Within study period	required	1.4
consent	Consent obtained from	Categorical (nominal)	1 = patient, 2 = representative, 3 = deferred, 4 = waiver	1–4	–99	1.5
age	Age at ICU admission	Integer	years	18–110	–99	2.1
sex	Sex	Binary	1 = male, 2 = female	1, 2	–88 / –99	2.2
weight	Body weight	Continuous	kg, 1 decimal	30–250	–88 / –99	2.3
icu_adm_dt	ICU admission date	Date	DD/MM/YYYY	≤ enrol_dt	required	2.5
sepsis_src	Source of infection	Categorical (nominal)	1 = lung, 2 = abdomen, 3 = urinary, 4 = skin, 5 = other	1–5	–88 / –99	2.6
sofa_tot	SOFA total score, first 24 h	Integer (ordinal)	points	0–24; = sum of 6 components	–88 / –99	3
lactate0	Lactate at ICU admission	Continuous	mmol/L, 1 decimal	0.1–30	–88 / –99	3
fin_d1 ... fin_d5	Total fluid input, day n	Continuous	ml	0–20 000	–99	4
fout_d1 ... fout_d5	Total fluid output, day n	Continuous	ml	0–20 000	–99	4
cfb_d5	Cumulative fluid balance to day 5	Continuous (derived)	ml	= $\sum (\text{fin_dn} - \text{fout_dn})$	derived	4
cfb_kg_d5	Cumulative fluid balance per kg, day 5	Continuous (derived)	ml/kg	= cfb_d5 / weight; check if outside –150 to +300	derived	4
vital_d28	Vital status at day 28	Binary	0 = alive, 1 = dead	0, 1	–99	5.1
death_dt	Date of death	Date	DD/MM/YYYY	≥ enrol_dt and ≤ enrol_dt + 28; only if vital_d28 = 1	–99	5.2
[name]	[label]	[type]	[units / codes]	[range / check]	[code]	[item]