

Draft Manuscript: Assignment Brief (Individual Product 2)

Foundations of Clinical Research · Level 1: From Clinical Question to Publication

Organisation: Neudata ([#ClearDataClearImpact](#))

Assessment type: Individual assignment. Results read together in Sessions 5 and 6, writing modelled live in Sessions 7 and 8 and done by you as homework, peer reviewed in the 2 weeks after Session 8.

Who: every participant writes their own manuscript. You choose **one** of the five FLUID-ICU questions (Q1 to Q5). There are no groups.

What we give you: the results. For each question there is a results pack with all the tables, figures and numbers you need. You do not analyse any data: you write the paper.

Output: a STROBE-guided original article of about **2,000 words**, a review of one classmate's draft, and a response-to-reviewers letter

Marked with: [Manuscript_Rubric.pdf](#) (formative); peer review follows [Peer_Review_Instructions.pdf](#)

1. Purpose

In the proposal you plan a study that has not been done. In this assignment you do the other half of the research journey: you take the results of a study that **has** been done and turn them into a paper that a journal could review. You will practise everything from Sessions 5 to 8: reading Table 1 and regression outputs, writing Methods and Results, calibrated language in the Discussion, the abstract and title, a reporting checklist, peer review and responding to reviewers.

Nobody needs to run any software. The instructor runs the analyses live in R in Sessions 5 and 6, and for each question there is a **results pack** with all the numbers, tables and figures you need. Participants who completed the free Neudata course *Clinical Data Analysis in R* may reproduce the analyses with the scripts in [Course/Data/](#), but this is optional.

Important: simulated data. FLUID-ICU is a **simulated training dataset**. Your manuscript is a training exercise. Say so in the Methods and on the title page ("This manuscript uses simulated data created for training; it reports no real patients"), and never submit it to a journal or present it as real research.

2. The course dataset: FLUID-ICU

A simulated multicentre prospective cohort of about **600 adults with sepsis** admitted to 4 ICUs. It contains demographics, comorbidities (diabetes, chronic kidney disease, heart failure, hypertension), infection source, severity (SOFA, APACHE II), lactate, mean arterial pressure, vasopressors, mechanical ventilation, daily fluid in and out on days 1 to 3, weight, cumulative fluid balance at day 3 (ml/kg) and positive balance (yes/no), acute kidney injury (KDIGO), renal replacement therapy, ventilator-free days, ICU length of stay and 28-day mortality with time to death or censoring.

What you will find in [Course/Data/](#) (in the online course folder): the raw and clean data, the data dictionary, the **cleaning log**, the statistical analysis plan (written before the analysis), the R scripts, and one results pack per question.

3. The five questions: choose one

The five questions are introduced in Session 5. In class the instructor works through them with the whole class: Q1 in full, and Q2 to Q5 as shorter worked examples. **By the end of Session 6, choose one question for your manuscript** and tell the course lead (by email or the form shared in the chat). Any question may be chosen by any number of participants. Q1 is the one done in full in class, so it is the easiest start; Q2 to Q5 are a little more of a challenge.

Q	Research question	Exposure	Outcome	Main analysis in the results pack
Q1	Is a positive fluid balance by day 3 associated with higher 28-day mortality? (the primary question)	Positive cumulative fluid balance by day 3 (yes/no)	28-day mortality	Crude and adjusted logistic regression (OR); Kaplan-Meier curves and Cox model (HR)
Q2	Is cumulative fluid balance associated with acute kidney injury?	Cumulative fluid balance at day 3 (ml/kg)	AKI (KDIGO)	Crude and adjusted logistic regression
Q3	Is cumulative fluid balance associated with fewer ventilator-free days?	Cumulative fluid balance at day 3 (ml/kg)	Ventilator-free days to day 28	Linear regression and a non-parametric comparison
Q4	Is initial lactate associated with 28-day mortality, and does the answer change with how missing lactate is handled?	Initial lactate (mmol/l)	28-day mortality	Logistic regression; complete-case analysis vs multiple imputation
Q5	Among survivors, is fluid balance associated with a longer ICU stay?	Cumulative fluid balance at day 3 (ml/kg)	ICU length of stay in survivors	Median (IQR); linear regression on the log scale or non-parametric tests

Your results pack is [Course/Data/results_packs/QN/results_pack_QN.md](#), where N is your question number (e.g. [results_packs/Q4/results_pack_Q4.md](#)). Each results pack contains Table 1, figures, regression tables and plain-language notes. **Use only the numbers in your results pack.** If something you need is missing, ask the instructor rather than estimating it.

4. What you write, and when

Use the Word template [Course/Templates/Manuscript_Template_IMRaD.docx](#) and follow the **STROBE** checklist for cohort studies.

Step	When	What you do	Output
1. Understand the data	Session 5 (5.2, 5.4)	With the class: read the data dictionary, the cleaning log, and Table 1 and the figures of the Q1 results pack	Notes: who is in the cohort, how variables are defined, what was cleaned
2. Interpret the results and choose your question	Session 6 (6.2, 6.4), then homework	With the class: read the comparisons, the regression and Kaplan-Meier/Cox outputs, crude vs adjusted estimates and the missing-data sensitivity analysis. After the session: choose your question and read its results pack	A "key numbers" list for your question: the main effect with 95% CI, plus 3 to 5 supporting results
3. Methods + Results	Session 7 (manuscript workshop 1: the instructor drafts Q1 live with the class), then homework	Draft the Methods (design, setting, participants, variables, data sources, bias, statistical methods incl. missing data) and the Results (participants first, then descriptive, main and other analyses) for your question	First draft of about 600 words (final length: Methods about 550, Results about 450; see the table below) + Table 1 + one further table or figure
4. Introduction, Discussion, Abstract, Title	Session 8 (manuscript workshop 2: modelled live on Q1), then homework	Write the Introduction (funnel), the Discussion (six moves, calibrated language), the structured abstract and the title	Complete draft
5. Final tidy and submission	By 23:59 on the day of Session 8	Fill the STROBE checklist with page numbers, check the numbers, add the AI-use statement, submit	Draft manuscript
6. Peer review	Within 1 week after Session 8	Review the one classmate's draft the instructor sends you (Peer_Review_Instructions.pdf)	Review report
7. Response and revision	Within 2 weeks after Session 8	Respond point by point to the review you received and revise your draft	Response letter + revised manuscript

Length and format

Part	Target	Notes
Title page	No target	Title, your name as author, a CRediT statement, word count, the simulated-data statement, an acknowledgement of the course
Structured abstract	250 words or fewer	Background, Methods, Results (main effect with 95% CI), Conclusions
Introduction	about 350 words	Three paragraphs: what is known, then what is not known, then the aim
Methods	about 550 words	STROBE items 4 to 12; include the statistical-analysis paragraph and how missing data were handled
Results	about 450 words	Participants first; numbers with denominators and 95% CIs; no interpretation
Discussion	about 650 words	In this order: main finding, comparison with literature (incl. Paper 2, Hyun 2023, in Course/Papers/), possible explanations, strengths and limitations, implications, conclusion
Main text total	about 2,000 words	Introduction to Discussion (plus or minus 10%); abstract, tables and references not counted
Tables and figures	Table 1 + up to 2 more	Each must stand alone (title, units, n, abbreviations explained)
References	10 to 20	Vancouver style, managed in Zotero or another reference manager
STROBE checklist	Completed	With the page number for each item, or "not applicable"

5. Authorship and acknowledgement

You are the single author of your manuscript. Use it to practise the authorship ideas from Session 7 (ICMJE criteria and CRediT roles):

- **CRediT statement:** list your own roles and those of the people who produced the data and analysis, e.g. "Conceptualisation, writing (original draft), writing (review and editing): [your name]. Data curation, formal analysis: course instructors."
- **Acknowledgements:** the course instructors created the dataset and ran the analysis. They are acknowledged, not listed as authors, e.g. "The simulated FLUID-ICU dataset and its analysis were provided by the Neudata course *Foundations of Clinical Research, Level 1*. We thank [name of the classmate who reviewed the draft] for their peer review."

You may discuss the results with classmates, but the text must be your own.

6. Rules

- **Numbers:** report only numbers from your results pack (or from your own reproduction with the course scripts, if you used them, and say so). Never round in ways that change the meaning. Give 95% CIs with every main estimate.
- **Language:** FLUID-ICU is observational. Write "associated with", not "caused" or "led to". No "trend towards significance".

- **Missing data:** say how much was missing and how it was handled, as shown in your results pack.
- **Originality:** write in your own words and cite every source. Quote sparingly and with quotation marks. Two participants who chose the same question will have the same numbers, but their text must be their own.
- **AI-use statement (required):** at the end of the manuscript, add one of these:
- "AI use: none."
- "AI use: [tool name] was used to [improve the English / translate drafts / suggest wording]. The author checked every sentence and reference and takes full responsibility for the content."

AI tools must **not** be used to produce results, invent or find references you have not read, or write the interpretation for you. AI tools cannot be authors. When you review a classmate's manuscript, **do not paste it into an AI tool**. It is confidential.

7. Submission and file names

Send everything to the course lead by email (or upload it to the online course folder):

File	Due
Surname_Manuscript_QN_draft.docx (draft + completed STROBE checklist as an appendix)	23:59 on the day of Session 8
Surname_Review_of_[author's surname].docx (review report)	1 week after Session 8
Surname_Manuscript_QN_revised.docx (with tracked changes) and Surname_Response_to_Reviewers.docx (using Course/Templates/Response_to_Reviewers_Template.docx)	2 weeks after Session 8

Within 2 days of Session 8 the course lead sends each participant **one** classmate's draft to review, by email or through the course folder. Each participant reviews one draft and receives one review. Where possible the instructor pairs drafts on a different question from your own, so that you read a second question in depth.

8. Feedback

- Feedback on the manuscript comes from the classmate who reviews your draft ([Peer_Review_Instructions.pdf](#)) and from the instructors.
- Instructors mark the revised manuscript and the response letter with [Manuscript_Rubric.pdf](#) and return written comments within about 3 weeks. If you do not send a revision, the draft is marked instead.
- **The marks are formative.**