Data collection instrument for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

DOCUMENT: SAR-2023-020-IJ-v01

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CRF: case report form

2 CONTEXT

2.1 Objectives

To develop and describe a case report form for the study of efficacy of a novel medical device for aiding in ultrasound-guided intravenous cannulation procedures.

3 CASE REPORT FORM

3.1 Data to be collected

Upon study start the raw data will be collected in a raw table, that will be processed before analysis. Each row represents all information collected from each study participant, and each participant included will require a unique study ID. This dataset will include the dates of the data collection. Table 1 shows the structure of the raw dataset.

Table 1 *Raw dataset structure.*

id	date	birth	sex	experience	first	duration1	censored1	duration2	censored2	easy
1										
2										
3										
…										
N										

Date of birth will be recorded and valid dates will be enforced by the instrument. Sex will be collected as a binary variable. Level of experience will be recorded as a continuous variable, measured in years.

First trial will be recorded as a binary variable. Time until successful cannulation will be measured once for each trial, and the duration of each trial will be recorded as time, validated by the data collection instrument as hours, minutes and seconds.

3.2 Data instrument

3.2.1 Participant characteristics

Figure 1 shows how the CRF will collect the participant characteristics. Sex will be collected as a binary variable, with labels for female and male. The date of birth will be collected, with validation specifying that only valid dates will be allowed. Experience will be collected as continuous, and validation will require that only non-negative numbers will be accepted.

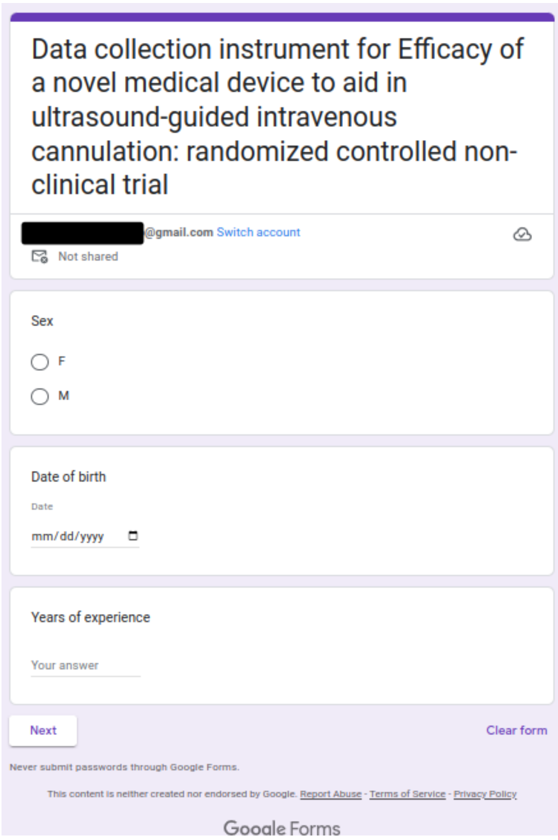
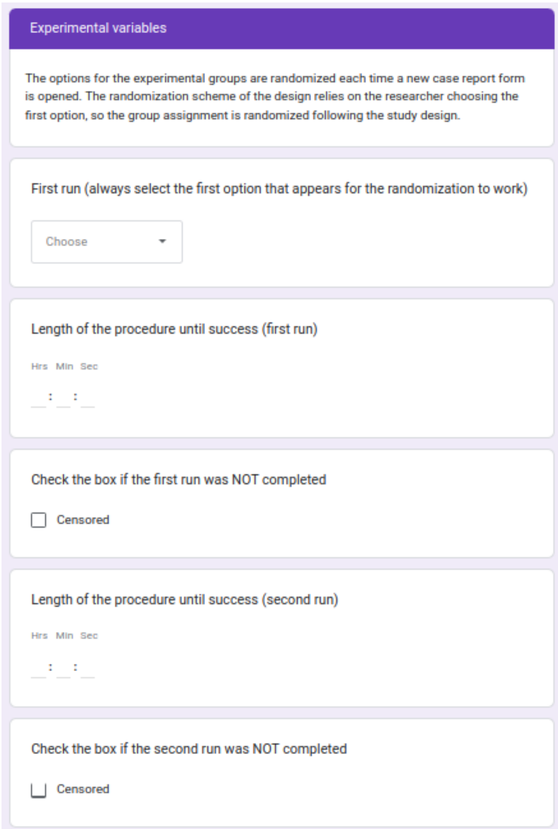


Figure 1 *Data instrument: demographic characteristics.*

3.2.2 Experimental data

Figure 2 shows how experimental data will be collected. The first run is collected as a binary and represents the group to which the measurement was assigned to, labelled test of control (see **SAP-2023-019-IJ-v01** for a comprehensive description of the exposure).

There are two fields for length of the procedure, both requiring a valid time that can be measured with a chronometer. As the instrument requires an hour for the recording a valid time measurement, the hour field can be recorded as zero. It is recommended that a chronometer is chosen that will measure time with at least minutes and seconds, instead of only seconds. The data instrument does not allow for higher precision than seconds.



Experimental variables

The options for the experimental groups are randomized each time a new case report form is opened. The randomization scheme of the design relies on the researcher choosing the first option, so the group assignment is randomized following the study design.

First run (always select the first option that appears for the randomization to work)

Choose

Length of the procedure until success (first run)

Hrs Min Sec

__ : __ : __

Check the box if the first run was NOT completed

☐ Censored

Length of the procedure until success (second run)

Hrs Min Sec

__ : __ : __

Check the box if the second run was NOT completed

☐ Censored

Figure 2 *Data instrument: experimental measurements.*

The first run is the assigned exposure in the group field (“First run”). The second run will be measured after the first run is performed, and recorded in the instrument.

The randomization scheme is implemented in the CRF by showing the groups in a random order. For the randomization to be successfully fulfilled, the experimenter must choose the first option for all forms being recorded (see section 4).

There is an additional question on how much easier the participant thought using the device was when compared to the unaided procedure (Figure 3). This variable is measured in a Likert scale with 5 points (from strongly disagree to strongly agree), that will allow for a qualitative exploration of user perspective.

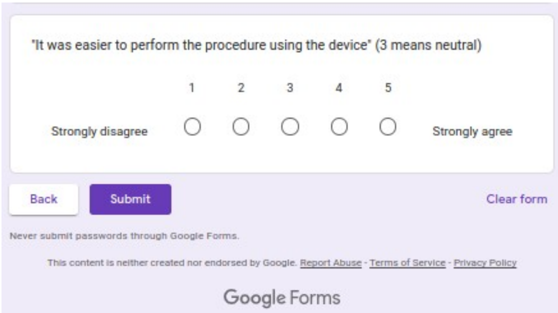


Figure 3 *Data instrument: qualitative feedback.*

4 OBSERVATIONS AND LIMITATIONS

This instrument adheres to the specifications of the analytical plan of the study (**SAP-2023-019-IJ-v01**) by collecting all data required for analysis. It ensures data type validation for each variable to be collected.

The randomization scheme specified in the analytical plan is implemented in a selectable field in the CRF. This is a limitation since it relies on the experimenter to follow the group assignment defined in the study design, rather than enforcing it. To mitigate this risk, an explicit instruction is included in the group field, as a reminder that the experimenter must choose the assigned exposure instead of choosing it arbitrarily.

5 REFERENCES

- **SAP-2023-019-IJ-v01** – Analytical Plan for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

6 APPENDIX

6.1 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2023-020-IJ/

6.2 Associated analyses

This document is part of a larger project and is supported by other analyses, linked below.

Analytical Plan for Efficacy of a novel medical device to aid in ultrasound-guided intravenous cannulation: randomized controlled non-clinical trial

https://philsf-biostat.github.io/SAR-2023-019-IJ/

The analysis will be done and the study results described in a future report. A link to the report page will be included in the link above, in the consultant's Portfolio.