

Quantitative research preparation - Data entry methods

Set-up & Conduct- Methods & Data
Collection

VERSION

5.0

Aim

To choose an efficient method and corresponding computer program for data entry (including online data collection). In choosing, one should take into consideration the types of data, research population, risk of data entry errors, research processes, privacy, (GCP) regulations, NFU guidelines and the necessary time investment for both the creation of the entry screen as well as the data entry. This guideline only applies to quantitative research and not qualitative research.

Requirements

- Choose the most efficient method and corresponding computer program (or custom made solution) given the study design, data collection methods, data types, quality, usability and regulations.
- Make use of the standard programs offered by the Data Management department (VUmc)/RDM (AMC).
- The advice is, if possible, to make maximum use of online data collection tools. This saves data entry time and generally improves the quality of the data, for example by a proper routing and required variables in a digital questionnaire.
- For WMO required research, it is mandatory to use a certified Clinical (Trial) Data Management System for the eCRFs / Electronic Data Capture (EDC), and apply the appropriate settings.

Documentation

- Describe the chosen data entry method(s) and the associated program(s) or custom-made solution(s).
- Describe the motivation for any deviation from the standard software offered by the Data Management department if applicable.
- Notice: In the case of WMO required research and when Case Report Forms are being used, you are required to make use of a certified Clinical Data Management System. The following information must be recorded in the data management plan:
 - Information about the validation of the system in accordance with ICH E6 / GCP (R2) guidelines and if applicable with FDA guidelines 21 CFR Part 11.
 - Information about security aspects, including database and server
 - Information about Backup and Recovery procedures
 - Information about the Audit trail
 - Information about the validation of the electronic signature
 - Information about the logging procedure

Information about the hosting provider. Additionally, ensure that the clinical database meets all NFU guidelines (ch. 9.2.2)

- Only collect data specified in the protocol
- Ensure privacy and security safeguards:
 - do not collect directly identifiable data,
 - minimize indirectly identifiable data (also ensure the subject ID does not hold initials or other personal data that could help identify the patient),
 - ensure no data can be collected /entered until the Informed Consent Form is signed
 - restrict view and edit rights per site to the relevant roles of staff members,
 - ensure a sign off by the local PI is possible per patient,etc.

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- Ensure the study database is both tested by the team and by an independent person
- Contact (Research) Data Management to be informed of additional requirements

Responsibilities

- Executing researcher: To consider different data entry methods and choose the most suited method together with the project leader.
- Project leaders: To advise the investigator to choose highly efficient and reliable methods and computer programs for data entry and designing data entry screens.
- Research assistant: N.a.

How To

In most instances, research data will need to be entered before the data can be analyzed. There are various methods of data import, with associated computer programs, available for this task.

Programmes to conduct Clinical Trials and built Electronic Case Report Forms under the strict conditions of Good Clinical Practice

1. Castor EDC, a web-based Clinical Data Management System
2. *OpenClinica, a web-based Clinical Data Management System. As of 2020, OpenClinica is no longer supported by the AMC CRU as OpenClinica studies are no longer accepted on the TraIT platform.*

Programmes for creating internet questionnaires:

1. The built-in survey module of Castor;
2. LimeSurvey (for AMC researchers, nWMO);
3. Survalyzer (for VUmc researchers, nWMO);
4. [Qualtrics \(UvA\)](#);
5. Easion
6. KLIK PROM portal (www.hetklikt.nu, info@hetklikt.nu)

Programmes for creating forms for manual data entry of questionnaires or registration forms on paper

1. Castor
2. Blaise
3. SPSS data edito. Not recommended as SPSS does not enable an audit trail of edits to your dataset. Not allowed for WMO required research.

Programmes for creating forms for conducting computer-assisted face-to-face and telephone interviews

1. Blaise
- Please note that not all programs can be used free of charge.

Please also note that it is not permitted to store any contact information such as names of research participants and other privacy sensitive data in these programs. Contact your Data Privacy Officer and (Research) Data Management in case you want to use your Electronic Data Capture system for sending out surveys to participants as well, as you may need /want to include a participant's e-mailaddress to send out your survey.

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Sometimes it is not possible to make use of the offered standard software and a custom-made software solution is required. For more information and outsourcing a custom-made software solution you can contact the (Research) Data Management department (VUmc: datamanagement@vumc.nl, or AMC/combined locations: rdm@amsterdamumc.nl).

We advise to use the program Castor for web-based questionnaires. Please contact Research Data Management department for advise and workshops.

Manual input is usually selected if questionnaires contain a significant number of open questions, if the data needs to be processed during input, or if relationships with other databases need to be established during input, for instance, a link to a database containing all of the medicines. Each input screen being created needs to be in line with the specifications in the codebook. Specify the quality control checks in a Data Validation and Derivation Plan (RDM Template): digital and manual controls used for validation and built-in dependent variables (e.g. only asking if someone is pregnant if the question regarding male/female is answered with female). Variables that do not need to be entered, because they are based on scores from previously entered variables, should be programmed for automatic calculation

Please contact the Data Management department (Vumc) or Research Data Management (AMC) for more information and advice about the best choice for entering your data.

Audit questions

2. Has the most efficient method been selected, given the research population and nature of the data?
3. Has a validated programme been used for the data input?
 - a. If not, why not?
4. Have the data been stored in the underlying database in line with the specifications in the code book?

LINKS

Link
https://rsp.uva.nl/uitvoeren/informatie-verzamelen/online-vragenlijsten/online-vragenlijsten.html?cb

DOCUMENT HISTORY

Version	Status	Date	Name
5.0	Revision	12NOV2020	Amber Boots, Elize Vlainic
4.0	Updated based on current standards and processes	02DEC2016	EMGO
3.0	Revision format	12MAY2015	EMGO
2.1	English translation	01JAN2010	EMGO
2.0	Updated based on current standards and processes	27MAY2009	EMGO
1.1	Update	19OCT2006	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	