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# Information and guidance for Primary Care Research Staff on research data queries

The purpose of this guide to summarise what research data is, how it is collected and potential problems that can arise with incorrect or missing data.

## 1. What is research data?

The foundation of all research is good quality data which can lead to new medicines, therapies, or treatment pathways. The data collected during a study helps to answer the research question and only data specified in the protocol should be collected.

## 2. Where is research data collected from?

Data can be collected directly from a participant during a trial visit e.g. blood pressure reading or adverse event reporting. It can also be taken from the participants' clinical record or laboratory reports e.g. medical history.

## 3. How is the research data recorded?

All research related activity should be documented in the participants' clinical record and is referred to as source documentation. This data can then be entered on to a data capture tool known as a case report form (CRF) these can be paper or electronic (eCRF). The sponsor should provide guidance regarding completion of the CRFs.

## 4. Who is responsible for data collection?

The Principal Investigator (PI) should ensure the accuracy, completeness, legibility, and timeliness of the data reported on the CRFs. The PI can delegate data collection/entry tasks

to members of the research team. Only those delegated should record and/or correct data in the CRFs.

### 5. When should data be entered on the CRF?

Ideally CRFs should be completed at the study visit or as soon as possible following the visit. Data cannot be entered onto a CRF if it is not in the clinical record or for some documents e.g. signed informed consent forms, in a research file. However, direct CRF entries are sometimes considered source data where the CRF is the site of the original recording e.g. there is no other written or electronic record of data.

### 6. What are the potential problems with research data?

Issues can arise with data if there is an error or discrepancy discovered when a validation check, done manually (source data validation or SDV) or by a computer program is performed. This generates what is known as a data query. A data query can be due to -

- a discrepancy between the source document and the CRF data.
- an unclear entry in the CRF.
- missing data.
- inconsistent data.
- data outside the expected range.

### 7. Who performs SDV?

The sponsor will designate a person/representative to perform onsite or virtual visits to conduct the SDV process, these are often known as ‘monitoring’ visits. The ‘monitor’ will check whether there are any deviations from the protocol and if all source data was transferred into the CRF correctly.

### 8. 8. How can a data query be resolved?

The CRF completion guideline and/or eCRF training should provide information about how to resolve data queries. Queries can also be resolved during a ‘monitoring’ visit.

### 9. Where can I find more information about data?

The trial protocol will have section dedicated to Data Management which you should refer to. There is also some Data Quality training on NIHR Learn -

https://learn.nihr.ac.uk/course/view.php?id=477#section-0 - (accessed 05/06/2023)