

Introduction

1 Welcome



Monitor

Review, query, SDV, Lock and Export data



- Welcome to Monitor Training!

Thanks to this training you become a better monitor by being able to make use of all the features Viedoc can offer.

You will find that monitoring in Viedoc is fun because you are able to do more stuff than you might be used to. Monitoring in Viedoc is also easy as the system helps you to easily find and perform the tasks you are responsible for.

If you are new to the system we recommend that you first go through the Site User Training program before continuing here.

2 What are my responsibilities as a monitor in Viedoc?

- What you can do as a monitor can differ between projects. Please therefore make sure you understand what is applicable for your study.

The most commonly performed activities for the monitor are described below:

- Manage queries (raise, approve / reject)
- Manage pre-queries (release / reject)
- Perform Clinical Review
- Perform SDV
- Lock data
- Export and preview data in tables and graphs
- Follow and compare data quality and site performance between sites

Term	Definition
Query	A query can be raised by the CRA and/or DM depending on the study. A query is always visible to the site staff immediately after being saved.
Pre-query	A pre-query is a query that needs to be approved before it is released (visible) to the site. The normal workflow is that the DM raises a pre-query, the CRA approves or rejects it. If approved, it becomes visible to the site for resolution. Pre-queries are however not used in all studies.
Clinical Review	Can be compared to the process performed on paper when each CRF page is initialized by the monitor. Similar for an eCRF each form can be reviewed for accuracy and completeness without the CRA having access to source data. Clinical Review is therefore something that is done before or between site visits.
SDV	Source Data Verification. Requires that the CRA has access to source notes/hospital records and is normally therefore performed during the site visit.
Lock data	After confirming data is accurate it is locked. This is an activity that can be managed by the CRA and/or DM. A locked form cannot be edited by the site so locking should only be performed when no more changes are expected to the form and all queries are solved.

3 Additional responsibility

- If you have been appointed the Site Manager role you can also invite and manage users at the sites you are responsible for. This is described in more detail in a separate chapter.

In any case, it is very important that you understand how the system works not only from the monitors perspective but also from the sites perspective so you are also able to assist the site staff when necessary.

In case you need support yourself, the responsible Study Manager is there to help you.

4 Support and Access

- Every study has at least one appointed study and site manager responsible for managing all users that need to have access to the system.

Please remember that access is given by invitation only so if you need access to the system, please contact the responsible Study Manager for further assistance.

