DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

DZHK-SOP-P-01

Clinical Data Review

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Date	11.02.2019	11.02.2019	11.02.2019	11.02.2019
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1 TABLE OF CONTENTS

1.1 Introduction

This SOP describes the tools that the data capture system secuTrial®, currently used for DZHK studies, provides to support quality assurance processes regarding clinical study data. It is important to comply with the periods and quality processes recommended herein as these drive data quality and patient fee reimbursements. The timelines depicted in this SOP are in favour of a projectable and promptly funds flow. Beyond individual studies, these processes are also relevant for integrating study data into the procedures described by the DZHK Use and Access Policy.

1.2 List of Abbreviations

Abbreviation	Meaning
DEC	Data entry complete
DZHK	Deutsches Zentrum für Herz-Kreislauf-Forschung e. V. (German Centre for Cardiovascular Research)
eCRF	Electronic case report form
SOP	Standard Operating Procedure

1.3 Objective

The SOP describes the steps for performing quality assurance of clinical data in secuTrial®. It primarily specifies which secuTrial® functions must be used at which step of the documentation process to correctly document the data entry process by status. Descriptions of how quality assurance must be performed are not within the scope of this SOP. In particular, this SOP does not provide guidelines on how clinical monitoring must be conducted for individual studies.

The timelines depicted in this SOP are in favour of a projectable and promptly funds flow and are to be followed.

1.4 Target audience

This SOP applies to DZHK studies that are using the secuTrial® system of the Data Handling unit in Göttingen as a primary capture system for their clinical data. Within the scope of this SOP, the term “study” also includes in a broader sense registers and cohorts.

This SOP is particularly directed at DZHK study managements, as they are responsible for the data quality of their studies and organize local processes within one study via study centre contracts.

1.5 Application and tasks

The quality assurance process in secuTrial® is supposed to promote completeness and correctness of the clinical data captured. Most of all, the correct usage of the secuTrial® functions as foreseen for this process allows for retrieving or querying the status of

individual data sets within the system at any time. This is a requirement for the accounting process as well as for data provision by the DZHK Transfer Office.

1.6 TERMS AND DEFINITIONS

This SOP describes the use of the following secuTrial® functions and components:

- Study Nurse: A person assigned the secuTrial® role of Study Nurse. Role assignment is based on the corresponding user application.
- Clinical Investigator: A person assigned the secuTrial® role of Clinical Investigator. Role assignment is based on the corresponding user application. Usually, at least the local chief investigators are allocated this role. Multiple persons per site may be assigned the role of Clinical Investigator.
- Formular (Form): Within the scope of this SOP, the term “form” always describes an electronic capture form implemented in secuTrial®. Forms related in terms of content are usually comprised into one form family.
- Item: A single question or a single data point in a form
- Visite (Visit): A visit in secuTrial® represents a patient contact at a specified point in time. A previously defined collection of forms is documented for an individual visit, and, if applicable, depending on existing study arms.
- Visitenplan (Visit schedule): The patient-specific visit schedule is the collection of all visits (including those already performed and visits scheduled for the future) of a patient. The distinct structure of the visit schedule depends on the applicable study protocol and on study arm assignment.
- Data Entry Complete: A function used to mark data entry as completed within a form. This function is executed via the button ““Save + close entry”.
- Open / Answer / Resolve query): Functions used to ask / answer / resolve queries for individual items within a form.
- Set Review A Status: A function used to assign the Review A Status to a form / visit. This will lock all forms concerned for further entries or changes. This will not affect the query feature. Review A Status may only be revoke by persons with special permission.
- Set Review B Status: A function used to assign the Review B Status to a form / visit. This will lock all forms concerned for further data entries. This will not affect the query feature. Review B Status cannot be revoked, not even by the Data Handling.

2 REQUIREMENTS

2.1 DEVICES / HARDWARE

PC with internet access to allow for use of secuTrial®, and secuTrial® user access. The main study centre will send a request for access to the Data Handling unit during initiation (see Study Preparation / Conduct).

2.2 PERSONNEL

Initial documentation of clinical data in secuTrial® will usually be performed by a person with the role of Study Nurse or Clinical Investigator. The person performing this task must have been trained in using the software. Training is offered regularly by the Data Handling.

The responsible person of an enrolling study centre (role: Clinical Investigator) will clear the clinical data for quality assurance and study-specific monitoring after completion of data entry by setting Review A Status. Multiple persons per site may be assigned the role of Clinical Investigator.

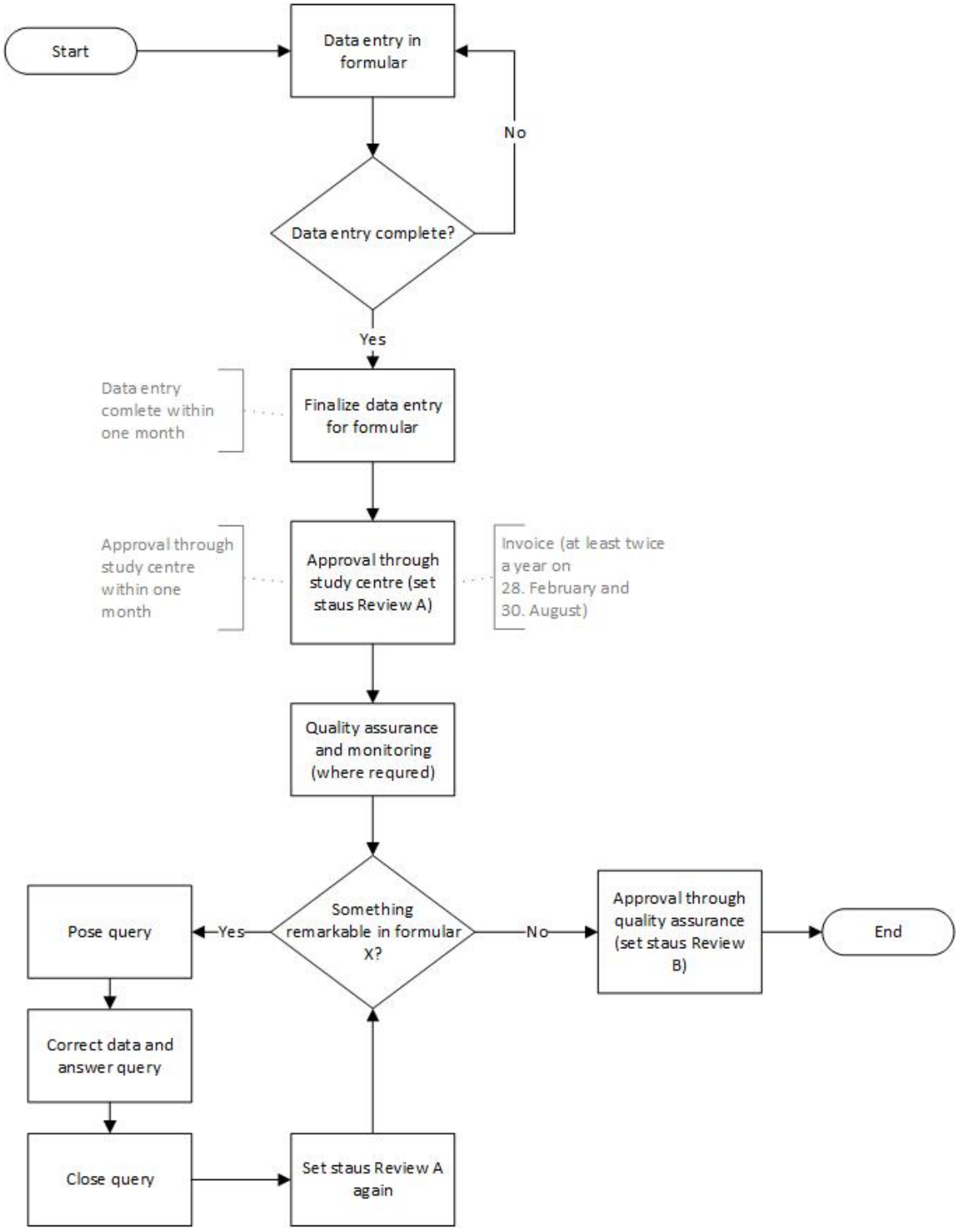
Clinical data review is a two-step process. First, the clinical data are reviewed by the sponsor's study-specific quality assurance or their designees, such as clinical monitors. In addition to that, the DZHK Data Handling can perform cross-study quality assurance procedures. The quality assurance personnel will open "queries".

The persons who initially performed documentation will answer these queries, i.e. the roles of Study Nurse and Clinical Investigator at the enrolling study centre. Queries will be closed by study-specific quality assurance or the Data Handling unit after they have been completely resolved.

The responsible persons at the main study centre will set Review B Status after the processing of all queries for a form or visit is completed.

3 Implementation / Workflow / Work Steps

3.1 Procedure Flowchart



3.2 CONDUCT

The following quality assurance procedure must be performed for each visit and the forms entailed in this visit. Only persons with the required role in secuTrial® (e.g. Clinical Investigator) will have the permissions required to perform the individual steps (e.g. setting Review A Status). Roles are assigned study-specifically and according to the user application.

Data Entry:

The clinical data collected during the patient visit will be entered into the corresponding form in secuTrial®. Data entry may be done during one or more sessions, however, the form must be saved at the end of a session at the latest. A promptly data entry has been proven to be a quality criterion for clinical trials. After a form has been completely filled in, documentation must be finished by the documenting person (roles Study Nurse or Clinical Investigator) using the function ”save + close entry”. The form then obtains a data entry complete (DEC) status. This process should usually be completed within one month following the patient visit. For patient visits that take place until end of December, data acquisition takes place until 15th January of the following year and for patient visits that take place until end of June data acquisition takes place until 15th July the same year

After data entry has been completed, the responsible person at the study centre (Clinical Investigator) will be informed of the status change of the form by an automatic notification (by email). The Clinical Investigator is obligated to review the entries.

Release by the study centre (“Review A Status”):

Following the review of the entries, the responsible Clinical Investigator at the enrolling study centre will clear the form for quality assurance by setting Review A Status. This step should be completed within one month following data entry completion at the latest or within 2 months following completion of all patient visit assessments at the latest. Patient visits that are completed by the end of December Review A is to be performed until 31st January of the following year and patients visits that are completed by the end of June Review A is to be performed until 30th July of the same year.

After Review A Status has been set for all forms of one visit, the study centre places an invoice for this visit at the main study centre. To keep the administrative burden minimal invoices should be bundled and placed several times a year. Invoices are to be placed at least two times a year by each enrolling study centre (or rather by the responsible department of the respective institution). For patient visits that are completed by the end of December, the 28th of February of the following year shall be the latest date to receive the respective invoice of the enrolling centre, and for patients visits that are completed by the end of June, the 31st of August of the same year shall be the latest date to receive the respective invoice of the enrolling centre. These time lines are mandatory. They enable the main study centres (their institutions, respectively) on the other hand, at certain deadlines, to call for funds for the invoiced patient fees in the DZHK funding management department.

After Review A Status has been set, study-specific quality assurance or the assigned clinical monitor will be informed of the clearance for quality assurance by means of an automatic notification (by email).

Performing quality assurance:

All harmonised items (marked by ** in eCRF) can be subject to a DZHK quality assurance, which is performed identically across studies. Individual quality assurance measures shall in addition be performed specified for each study, including clinical monitoring. These will be done by the main study centre or third parties, such as an external CRO, at the visits or on the Review A Status-released forms. If any issues are noted during these processes, queries will be sent, which in turn must be answered in a timely manner at the data-capturing study centre by the Study Nurse or Clinical Investigator. When processing queries, incorrect values must be corrected in the respective item directly.

If data are modified in the course of answering queries, the respective form automatically loses its Review A status. Thus, after all queries have been resolved, the Clinical Investigator must release the forms concerned for quality assurance once more (by setting Review A Status).

If the answers are satisfying, quality assurance will close the queries. Otherwise, new queries will be sent. The secuTrial® message feature may be used for communication between quality assurance and the study centre.

DZHK quality assurance will be performed within two months following release of all forms of a visit. Study-internal quality assurance and – if applicable – clinical monitoring are to be completed within six months following release of a visit.

Clearance by quality assurance ("Review B Status"):

After completion of all quality assurance measures, Review B Status will be set by the main study centre or respective third parties. This explicitly also applies to forms that are not checked by the clinical monitoring (e.g. in case of use of a risk based monitoring). In this case the responsibility for the assurance of data quality equally lies with the main study centre or respective third parties. Technical requirement for setting Review B Status is that no queries remain open.

Latest with Closing of the data base (Data Lock) all forms of all visits need to have Review B. After Review B Status has been set, the local investigator at the enrolling study centre capturing the data will be informed of the changed status by means of an automatic notification (by email).

3.3 PROCEDURE IN CASE OF DEVIATIONS

Premature completion of data entry (DEC) may be undone by the user. Annulment of DEC status is only possible as long as no queries exist in the respective form. If a form containing queries needs to be reopened (annulment of DEC status), all queries need to be cancel prior.

Premature clearance of forms or visits for quality assurance (Review A Status) may be undone by authorised users. Annulment of blocking of a form for further editing is only possible as long as no queries are present in the respective form.

A blocking of a form for further editing by premature setting of Review B status **cannot** be revoked. Any other changes to the form concerned are to be performed using the secuTrial® query feature.

3.4 LITERATURE AND REFERENCES

1. secuTrial® User Manual version 1.0
2. Study Preparation / Conduct Guidance

3.5 CHANGE

Change compared to the previous version

Section	Description of the change to the previous version
3	Change of timeline to payment of patient fees

3.6 PERSONS INVOLVED

Name	Role	Involvement
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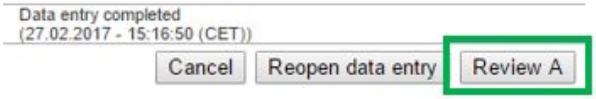
Frank Edelmann	Main coordinating investigator EX-VAD-DZHK11, Speaker WGCR	Review
Matthias Nauck	Speaker Clinical Research Platform	Approval

3.7 ANNEX

The following illustrations show the secuTrial® interface elements relevant to this SOP.

Data entry complete

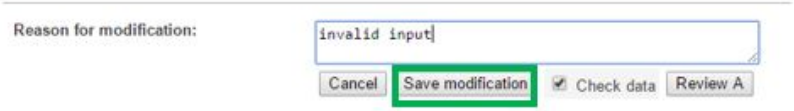
Release by the study centre ("Review A Status")



Performing quality assurance

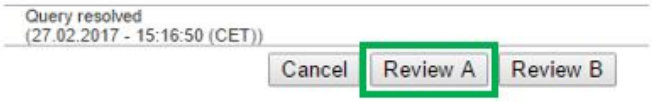
open query

answered query



resolved query

Release by the study centre ("Review A Status")



Completion of quality assurance ("Review B Status")