OnlineCRF
SMART & EFFICIENT

Computerized Systems used in Clinical Trials Requirements

Compliance checklist.

OnlineCRF is compliant with the following requirements:

Primary requirements

- ✓ Data is exported in such a way, that all information regarding each individual subject of the study is related to that subject.
- ✓ Computerized systems are designed in the following way:
  - All requirements assigned by the protocol to Computerized systems are satisfied.
  - The process of data creation, modification, maintenance, archiving, retrieval, or transmission are structured so that preclude errors.
- ✓ There are security measures in order to prevent unauthorized access to system data.

Electronic Signatures

- ✓ The name of the individual who enters data is displayed on the data entry screen throughout the data entry session.
- ✓ For long periods of inactivity an automatic log off is provided.

Audit Trails

- ✓ Time-stamped audit trails created by the system contains the date and time of the records and user's actions (create, modify, or delete electronic records). A record is created when it is saved in the system.
- ✓ Audit trails are retained for a period as long as that is required for the subject's electronic records and must be available for review and copying.
- ✓ Personnel who create, modify or delete electronic records are not able to modify the audit trails.
- ✓ Audit trails are readable both at the study site and at any other location where associated electronic study records are maintained.

- ✓ Audit trails are created incrementally, in chronological order, and in a manner that does not allow new audit trail information.

Date/Time Stamps

- ✓ Controls are in place to ensure that the system's date and time are correct.
- ✓ Dates and times are local to the activity that is documented and include the year, month, day, hour and minute.

System features

- ✓ Systems used for direct entry of data include features that will facilitate the collection of quality data.
  - Prompts, flags, or other help features within the system are used to alert the user about data that are out of acceptable range. Features that automatically enter data into a field when that field is bypassed are not used.
  - eCRFs are designed to allow users to make annotations. With annotations data comes out with better quality by allowing ad hoc information to be captured. The record clearly indicates who recorded the annotations and when (date and time).
- ✓ Systems used for direct data entry are designed to include features that facilitate the inspection and review of data. Data tags (different color, different font, flags) are used to indicate which data have been changed or deleted.
- ✓ Retrieval of Data:
  The system provides the ability to retrieve and review the data recorded by the older versions of the system.
- ✓ Reconstruction of Study:
  A study can be reconstructed. This applies to the data, how the data is obtained or managed.

Security

- ✓ Physical Security:
  In addition to internal safeguards built into the system, external safeguards are in place to ensure that access to the system and to the data is restricted to unauthorized personnel.

- ✓ Logical Security:
  - Access to the system data is restricted and monitored via the system, which requires log-on, security procedures, and audit trail. The data can not be altered, browsed, queried, or reported via external software applications that are not allowed by the system protection.
  - There is a general record that indicates the names of authorized person, their titles and a description of their access privileges for any point in time.
  - There are special controls to prevent, detect, and mitigate effects of computer viruses on study data and software.

System dependability

- ✓ Systems documentation provide an overall description of system and the interconnection between hardware, software, and physical environment.
- ✓ System functional testing is performed and all software limitations, problems, and defects are studied.
- ✓ Documentation, required for system validation demonstration:
  - Written design specification that describes what the system is intended to do and how it is intended to do it.
  - A written test plan based on the design specification, including both structural and functional analysis.
  - Testing results and evaluation of how these results demonstrate the predetermined design specification has been met.
- ✓ To provide change control. All changes to the system are documented.

System controls

- ✓ Software Version Control:
  There are measures to ensure that versions of system used to generate, collect, maintain and transmit data is the versions that are stated in the system's documentation.
- ✓ Backup and Recovery of Electronic Records:
  - Backup and recovery procedures are clearly outlined in the SOPs and are sufficient to avoid data loss. Records are backed up regularly in a way that would prevent a catastrophic loss and ensure the quality and integrity of the data.

- Backup records are stored at a secure location specified in the project documentation.
- Backup and recovery logs are maintained to facilitate an assessment of the nature and scope of data loss resulting from a system failure.

Training of personnel

✓ Qualifications:
- Each person who enters or processes data has the education, experience or combination thereof necessary to perform the assigned functions.
- Individuals responsible for monitoring the trial have education and experience in the use of the system necessary to adequately monitor the trial.

✓ Training:
- Training is provided to individuals in the specific operations that they are performing.
- Training is conducted by qualified individuals on a continuing basis, as needed, to ensure familiarity with the computerized system and with any changes of the system during the course of the study.

✓ Documentation:
Employee education, training, and experience should be documented.

Records inspection

✓ System is able to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review and copying.