Towards a better Clinical Research
From the GCP to the Computer System Validation "FDA cfr 21part 11" till the GDPR and LPD compliance check. The implementation of a Quality System

Luca Clivio, Area ICT, Knowledge Engineering in Life Science Informatics
Tatiana Terrot, CTU-EOC, Operation Manager

Introduction

When starting a clinical trial the sponsor must ensure and document that the electronic data processing is **complete, accurate, reliable, integer** throughout the whole study.

To ensure this, the sponsor must have computerized system(s) and standards based on the recognized international guidelines such us:

- ICH GCP [2])
- FDA cfr 21 part 11
- ECRIN for academics
- GDPR/LPD

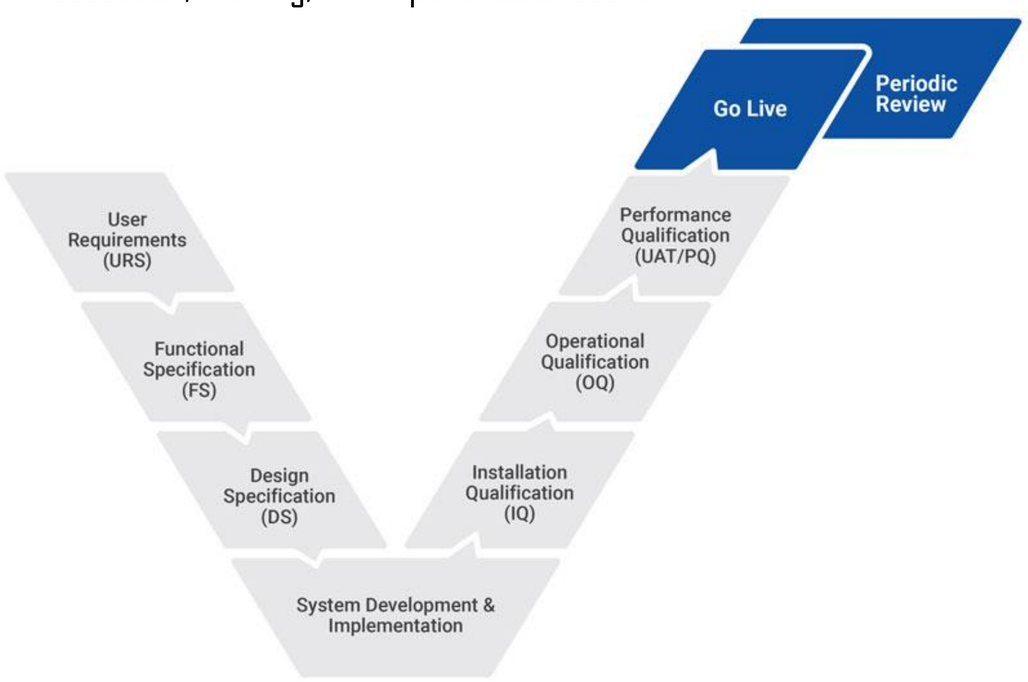
Principles set forth in these guidelines are embodied in the validation process covering the:

- computer system (software)
- processes for data handling, storage and processing (including statistical analysis)
- consistent intended performance

Methods

Sponsor when handling data must ensure through written procedures and appropriate computerized system the adequacy of:

- IT infrastructure (software local functionality and testing)
- system security to prevents unauthorized access (hackers) and system safety to cope with unexpected hardware or software failures (bad luck)
- software maintenance (and business continuity plan)
- data backup and contingency planning
- control of user and assigned roles
- data integrity when making changes to the software, such as upgrades or migration/process/transfer of data
- change control for the software CTMS (Clinical Trial Management System) that may contain an eCRF (electronic Case Report Form)
- Due to GDPR/LPD every single clinical data should be provided of a "identity tag" to assess who, when and the reason why it should be accessed and modified or hidden/deleted.
- education, training, and experience of users



Computer System Validation

Not only a set of documents, but a way of working. Both data management and informatics are involved.

Every software built for managing clinical data should be validated against a set of steps that have the main role of assuring that the data introduced in the system is safe and correctly treated in order to obtain a set of indicators known as CIA (confidentiality, integrity, authenticity), the reason why a common set of tools like the Office suites (spreadsheets, general use databases) cannot be used in this contexts without huge customizations that can make them unusable as they are.

No alternatives to eCRF today, even paper CRF don't really exist cause they are born as electronic documents, they are simply printed, manually fulfilled, manually rewritten (hence double source of input mistakes) in an electronic database for analysis. They are really printed CRF, with no control on data entry.

Results

the proper application of international guidelines involves the **process of validating the computer system** through procedures and must consistently cover the configuration, installation and use of the system , then ensure:

- **completeness:** dataset has all the relevant and necessary information for a given purpose. A complete dataset should not have any missing, duplicated, or irrelevant values that could affect the analysis
- **accuracy:** trained users, data checks, and queries management
- **reliability :** reproducibility of the data, record retention
- **Integrity:** no distortion or lost of data when changes to the software, migration/processing/transfer of data are made,

Conclusion

Data management in clinical trials is not limited to the purchase or use of software but is a working method based on the security of data flow through appropriate software and Standard Operating Procedures in order to ensure the fulfillment of Confidentiality, Integrity, Authenticity indicators throughout the "lifecycle" of the processed data.

Funding
Internal funding