ICH GCP E6(R2) Section	Critical-to-Quality Questions
5.5.3.h	How do you ensure data integrity including data describing context, content and structure when making changes to the computerized systems, software upgrades or data migration?
5.18.3	Have you implemented a system for risk prioritization and monitoring?
	Is your monitoring approach based on the study risk assessment?
	How do you document the rationale for chosen monitoring techniques?
	Do you analyze accumulating data with statistical analysis methods?
	Do you use results of the data analysis for targeted on-site monitoring?
5.18.6.e	How do you document centralized monitoring activities?
5.18.7	Are your monitoring plans tailored to the specific human subject protection and data integrity risks of the trial?
	Do your monitoring plans describe: - monitoring strategy - monitoring responsibilities - monitoring methods and - rationale for their use?
	Is the required additional training for non-routine clinical practice appropriately planned?
5.20.1	Is a CAPA SOP with root cause analysis available?

ICH GCP E6(R2) Section	Critical-to-Quality Questions
8.1	Is a record of storing locations available for essential documents and source documents?
	Do(es) the storage system(s) provide document identification, version history, search and retrieval functions?
	Does the investigator have continuous access and control of CRF data?
	Is an SOP in place that demands all document copies filed in the TMF to be certified copies?

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ICH GCP E6(R2) Readiness Questionnaire

ICH GCP E6(R2) Section	Critical-to-Quality Questions
1.63	Does any SOP define the process of preparing a certified copy?
	Are certified copies being verified through a dated signature?
	Are certified copies being verified through a validated process?
	How does the SOP ensure that the certified copy has "the same information, including data that describe the context, content, and structure, as the original"?
1.64	Does any SOP define the process of preparing a monitoring plan?
	Does the SOP request that the monitoring plan "describes the strategy, methods, responsibilities, and requirements for monitoring the trial"?

ICH GCP E6(R2) Section	Critical-to-Quality Questions
1.65	Does any SOP define the validation of computerized systems from design until decommissioning?
	Does the SOP request "a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results" as basis for the validation?
2.10	Does any SOP request clinical trial information to "be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification", "irrespective of the type of media used"?
2.13	Does the quality management system/SOP focus on aspects of the trial that are essential to ensure human subject protection and reliability of trial results?
4.2.5	Does any SOP request to inform the investigator that he/she "is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site"?
4.2.6	Does any SOP request to inform the investigator that "if the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated"?
4.9.0	Does any SOP request to verify that source documentation and trial records of investigator/institution are "attributable, legible, contemporaneous, original, accurate, and complete", with traceable changes, not obscuring original entries, explanations for changes, and audit trail?

ICH GCP E6(R2) Section	Critical-to-Quality Questions
5.0	How do you ensure that the methods used to assure and control quality are proportionate to the risks inherent in the trial and the importance of the information collected (apart from "trial activities focused on ensuring human subject protection and reliability of trial results")?
	Are protocols, tools (e.g., software deployed for data capture and remote monitoring, document, medication and lab sample trackers, communication tools, etc.) and procedures efficiently designed for data collection and processing?
5.0.1	Does any SOP guide you on how to identify and document those processes and data that are critical to ensure human subject protection and the reliability of trial results already in the planning stage?
5.0.2	Do you identify risks that threaten these critical trial processes and data as per the applicable SOPs?
5.0.3	Do you evaluate the identified risks to determine their likelihood, impact and detectability as per the applicable SOPs?
5.0.4	Do you plan responses to identified risks as per the applicable SOPs?
	Do you establish predefined quality tolerance limits to control risks as per the applicable SOPs?
5.0.5	Do you document these activities?
	Do you inform stakeholders, e.g., regulatory authorities, investigators, about these activities as per the applicable SOPs?

ICH GCP E6(R2) Section	Critical-to-Quality Questions
5.0.6	Do you periodically conduct risk review meetings with involved stakeholders as per the applicable SOPs?
5.0.7	Do you have an SOP on writing Clinical Study Reports including a description of the risk-based quality management system?
	Do you have an SOP on risk reporting concerning the continuous documentation of important deviations from quality tolerance limits and remedial actions taken (to be included in the clinical study report)?
5.2.2	Do you have an SOP defining your approach to oversight of any trial-related duties and functions?
5.5.3.a	Is your validation of electronic trial data handling systems or remote electronic trial data systems based on a risk assessment?
5.5.3.b	Do you have SOPs for such systems covering: - system setup - installation - use - validation - functionality testing - data collection and handling - system maintenance - system security measures - change control - data backup - recovery - contingency planning and - decommissioning - transition to a new system (if applicable)?
	Do SOPs manage the responsibilities of sponsor, investigator and other parties when using these systems?
	Is there training material available or training provided for the use of such systems?