DArcyComplianceConsulting
We Build Compliance Cultures

Inspection Readiness Checklist

Sample Questions: How Do You Perform?

Are you Inspection Ready?

From a Clinical Perspective, there are certain requirements that need to be in place for conducting clinical trials. When the Agencies conduct an Inspection of your site, these requirements not only need to be in place but must have supporting evidence.

Do you have this in place?

DArcy Compliance Consulting has developed our own checklist of clinical processes to consider.

These are some of the questions we ask when conducting an Inspection Readiness assessment.

It's not an exhaustive list but intended to give you an idea of what you need!

How Do You Perform?

01 General Planning & Regulatory Requirements

Score

- What currently exists to guide clinical personnel to initiate, conduct, monitor and complete clinical programs in human subjects according to Regulations, ICH E6(R2) guidelines?
- What internal clinical processes are described in policies, procedures, guidelines, job aids, etc.?
- Is there a Clinical Development Plan or central repository of program objectives, proposed studies, sites used, PIs, etc.?
- Is a process for risk identification, management, mitigation in place? A Clinical Quality Risk Management Plan (CQRMP)?
- Are there internal procedures for IND/CTA maintenance and reporting? Is there evidence that these are followed?

02 Vendors

Score

- How are vendors selected? How is oversight of trial-related duties and functions done on work contracted to a CRO?
- How is oversight of trial-related duties and functions conducted when these are sub-contracted to another party by the CRO?

03 Clinical Trial Design/Protocol/IB

Score

- Describe the process for drafting, finalizing and approving a protocol
- Are critical processes and data in place to ensure a) human subject protection and b) reliability of trial results?
- Describe the process for developing and updating an IB

04 Investigators/Sites

Score

- Are defined selection criteria in writing?
- What is the process for collecting, filing, and maintaining financial disclosure information? How are conflicts of interest assessed?
- How is compensation determined? Is there a documented process for study payments?
- Is there a process for creating, reviewing and approving clinical study agreements?
- How is training (GCP, protocol) performed and documented?
- How is protocol conformance monitored? What is the process for evaluating and recording protocol deviations/violations?

05 Informed Consents

Score

- What is the process for creating, reviewing, and ensuring that ICs contain the necessary elements and are translated into the appropriate language?
- What process exists to ensure ICs are completed and signed properly?

06 Subject Recruitment

Score

- In general, how are subjects identified for trials?
- How is compensation to subjects determined?

07 Monitoring of clinical trial sites – Do you have a systematic, prioritized, risk-based approach to monitoring?

Score

- Recruitment & enrollment
- Informed Consent
- Qualifications of the PI/Sub-Investigator
- Debarment/licensure screening
- Safety/AE reporting- are procedures followed for collecting, reviewing, and reporting safety data?
- Clinical supply chain of custody/storage
- IRB approvals of protocol, informed consent, recruitment materials
- Data collection & verification

08 IRB – how do you ensure the GCP compliance of the IRB's used in reviewing their clinical trials:

Score

- Qualifications of members
- Adequacy of review
- Conflicts of interest

09 TMF

Score

- How is the TMF currently structured, managed and maintained?

10 AE/SAE

Score

- How do you monitor and evaluate AE/SAE in their clinical trials?
- Is there a procedure for SAE reconciliation?
- Are Data Monitoring Committees (DMC) in place?

11 Data Management ▸ Score

- What is your approach to validation of electronic trial data handling and/or remote electronic trial data systems? Is risk assessment performed?
- Are SOPs in place? What do the SOPs cover?
- Where is data management conducted?

12 Clinical Trial Registration and Results ▸ Score

- What is in place to ensure requirements are met for registering clinical trials and reporting clinical trial results?
- Is there a documented process for preparation of a CSR? Is it followed?

13 Clinical Supplies ▸ Score

- In manufacturing is there evidence of batch record review?
- How is chain of custody, accountability, storage, returns covered?
- Training of site personnel?

14 Specimens ▸ Score

- Is there documentation to show adherence to internal procedures for collection and handling of specimens?
- Are sample management procedures (handling, storage) in place?

For help on Inspection Readiness, speak to the experts at DArcy Compliance Consulting, we can help you determine your 'Readiness' for an Agency Inspection.

Note: These are example questions and do not represent a complete Inspection Readiness Audit

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