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CORE COMPETENCY FRAMEWORK FOR

Clinical Study Monitoring™

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Executive Summary

The Association of Clinical Research Professionals (ACRP) is pleased to provide the clinical research enterprise with a set of core competencies required for clinical study monitoring. This is the first-ever set of monitoring competencies harmonized with the Core Competency Framework for Clinical Research Professionals developed by the Joint Task Force (JTF) for Clinical Trial Competence. The clinical study monitoring competency framework was developed by a Task Force of industry representatives using the JTF framework as the foundational reference. The Task Force also reviewed and incorporated elements from proprietary member competency documents and publicly available competency frameworks. A Steering Committee, comprised of 10 senior and executive level individuals from several sponsors and CROs, provided the critical oversight and strategic insights needed to ensure we were building competencies that they believe will be the foundation by which monitors are hired, trained, and assessed. This Executive Summary is intended to provide some additional information and context for the competency framework and its use in practice.

The Core Competency Framework for Clinical Study Monitoring identifies the core competencies required of individuals involved in clinical study monitoring. Monitoring, as an activity, is undergoing significant change, and new roles intended to support monitoring activities are emerging. The Framework is intended to define the competencies of all individuals involved in the function of clinical study monitoring. Given the relatively new promotion and adoption of risk-based monitoring principles and practices, ACRP will monitor the industry landscape to assess how the industry is implementing these principles within their organizations, and will update the CSM framework as needed to ensure it is accurately representing practice.

The competency framework does not address how clinical study monitors develop the competencies described within the framework, nor does the framework address organization specific hiring practices, prerequisites, competencies or training and development requirements which should be unique to those groups. It is ACRP's hope that by developing competencies or training and development requirements which should be unique to those groups. It is ACRP's hope that by developing the monitoring competency framework, organizations will further adopt these competencies as requirements of clinical monitors within their organizations and build from this model any company specific requirements for the role, including, for example, creating role profiles and developing training programs.

What is Driving Change

Industry is seeking new and different ways to conduct clinical studies as complexity increases, costs continue to rise, and success rates decline. At the same time, industry is challenged by a critical shortage of monitors and seems poised to respond by moving toward hiring practices that favor competence over experience requirements. These factors combined have created a need to standardize expectations and performance standards related to monitoring activities.

Where You Can Expect Change

Expect increased utilization of technology to streamline and accelerate study conduct. Professionals involved with or impacted by monitoring activities should anticipate greater focus on data considered most critical to studies and increase utilization of electronic data, case report form software, "The Internet of Things," mobile tech, and risk mitigation tools. The future of monitoring will also require significant change in relationships between research partners, particularly the relationships between staff at study sites and sponsors/contract research organizations.

How You Can Use the Framework

Regardless of your role in clinical research, the ACRP Core Competency Framework for Clinical Study Monitoring can be used to help you understand:

- What is changing in your role as a clinical trial monitor
- What is changing in your role as a clinical trial monitor
- What is expected of you in relation to monitoring-related activities
- Where to focus your professional development activities
- The competencies for which hiring managers are looking
- What to look for when recruiting staff
- And much more

ACRP thanks the following organizations for contributing to the Core Competency Framework for Clinical Study Monitoring

AstraZeneca
Advanced Clinical
Biogen, Inc.
Cancer Research UK
Celgene
Clinical Works
Consortium of Academic Programs in Clinical Research
Covance
Duke Clinical Research Institute
ExecuPharm
ICON
INC Research
InVentiv
Metrics Champion Consortium
PRA Health Sciences
University of North Carolina at Wilmington

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Scientific Concepts and Research Design	Basic features of the disease or condition under study	Explains the disease process or condition and expected course as well as the treatment options and standard of care. Identifies signs and symptoms of disease. Identifies documentation of diagnosis in subject record. Uses accurate medical terminology.	Explains the disease process or condition and expected course. Identifies signs and symptoms of disease. Identifies documentation of diagnosis in subject record. Uses accurate medical terminology. Describes the indication and the associated therapeutic area as well as the treatment options and standard of care. Identifies the relevant study procedures.	Explains the disease process or condition and expected course. Identifies signs and symptoms of disease. Identifies documentation of diagnosis in subject record. Uses accurate medical terminology. Describes the indication and the associated therapeutic area as well as the treatment options and standard of care. Identifies the relevant study procedures. Summarizes the class of drugs or device and why the product is being developed. Discusses and recognizes alternative treatments.	Explains the disease process or condition and expected course. Identifies signs and symptoms of disease. Identifies documentation of diagnosis in subject record. Uses accurate medical terminology. Describes the indication and the associated therapeutic area as well as the treatment options and standard of care. Identifies the relevant study procedures. Summarizes the class of drugs or device and why the product is being developed. Discusses and recognizes alternative treatments. Evaluates risks and benefits of product intervention on the disease or condition.	Explains the disease process or condition and expected course. Identifies signs and symptoms of disease. Identifies documentation of diagnosis in subject record. Uses accurate medical terminology. Describes the indication and the associated therapeutic area as well as the treatment options and standard of care. Identifies the relevant study procedures. Summarizes the class of drugs or device and why the product is being developed. Discusses and recognizes alternative treatments. Evaluates risks and benefits of product intervention on the disease or condition. Instructs and guides team through problem solving and mobilizes team to intended goals and solutions.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Scientific Concepts and Research Design	Product Development Lifecycle and Significance of Design Features in Clinical trial protocols	Defines the different phases of product development. Identifies key protocol sections, critical processes and data, and potential areas for risk. Explains research methodology and purpose of assigned protocol, including primary and secondary endpoints. Describes the rationale for complying with clinical study procedures and their impact in protecting the rights and well being of the patients.	Defines the different phases of product development. Identifies key protocol sections, and with assistance, identifies critical processes and data, and evaluates potential areas for risk. Explains research methodology and purpose of assigned protocol, including primary and secondary endpoints. Escalates protocol design questions to project team members.	Defines the different phases of product development. Identifies key protocol sections, and with minimal assistance, identifies critical processes and data, evaluates potential areas for risk. Explains research methodology and purpose of assigned protocol, including primary and secondary endpoints. Escalates protocol design questions to project team members. Identifies risks associated with clinical trial design.	Defines the different phases of product development. Identifies key protocol sections, and identifies critical processes and data, and evaluates potential areas for risk. Explains research methodology and purpose of assigned protocol, including primary and secondary endpoints. Escalates protocol design questions to project team members. Identifies risks associated with clinical trial design. Answers questions regarding protocol design. Serves as resource and mentor on protocol design to team members.	Defines the different phases of product development. Identifies key protocol sections and trains/coaches project team on critical processes and data, and potential areas of risk. Explains research methodology and purpose of assigned protocol, including primary and secondary endpoints. Escalates protocol design questions to project team members. Identifies risks associated with clinical trial design. Answers questions regarding protocol material. Serves as resource and mentor on protocol design to team members. Assesses applicability of issues and solutions across study.

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Ethical and Participant Safety Considerations	Subject Confidentiality and Data Rights and Privacy	Identifies confidential information and complies with global and local laws and guidelines. Is aware of potential scenarios where privacy and confidentiality may be compromised and takes action to mitigate risk.	Identifies confidential information and complies with global and local laws and guidelines. With guidance, has some awareness of potential scenarios where privacy and confidentiality may be compromised and takes action to mitigate risk. Identifies and escalates privacy and confidentiality violations, and implements corrective actions.	Identifies confidential information and complies with global and local laws and guidelines. Is aware of potential scenarios where privacy and confidentiality may be compromised and, with minimal guidance, takes action to mitigate risk.Identifies and escalates privacy and confidentiality violations. Performs root cause analysis and implements preventive and corrective actions.	Identifies confidential information and complies with global and local laws and guidelines. Is aware of potential scenarios where privacy and confidentiality may be compromised and takes action to mitigate risk. Identifies and escalates privacy and confidentiality violations. Performs root cause analysis and implements preventive and corrective actions. Serves as a resource and mentor to team members.	Identifies confidential information and complies with global and local laws and guidelines. Is aware of potential scenarios where privacy and confidentiality may be compromised and coaches or trains project team on actions to mitigate risk. Identifies and escalates privacy and confidentiality violations. Performs root cause analysis and implements preventive and corrective actions. Serves as a resource and mentor to team members.

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Ethical and Participant Safety Considerations	Informed Consent Process	Evaluate the process of obtaining ethical informed consent prior to subject participation and verify informed consent documentation per relevant guidelines and regulations. Is aware of potential scenarios where informed consent may be compromised (e.g. vulnerable population inclusion, revised version(s) of informed consent form) and takes action to mitigate risk. Collaborate with site staff to evaluate withdrawal of consent and verify proper documentation of same.	Evaluates the process of obtaining ethical informed consent prior to subject participation and verify informed consent documentation per relevant guidelines and regulations. With guidance, has awareness of potential scenarios where informed consent may be compromised and takes action to mitigate risk. Collaborate with site staff to evaluate withdrawal of consent and verify proper documentation of same. Identifies and escalates informed consent violations and implements corrective actions. Documents and escalates non-compliance issues.	Evaluates the process of obtaining ethical informed consent prior to subject participation and verify informed consent documentation per relevant guidelines and regulations. Is aware of potential scenarios where informed consent may be compromised and takes action, with minimal guidance, to mitigate risk. Collaborate with site staff to evaluate withdrawal of consent and verify proper documentation of same. Identifies and escalates informed consent violations. Documents and escalates non-compliance issues. Performs root cause analysis and implements preventive and corrective actions.	Evaluates the process of obtaining ethical informed consent prior to subject participation and verify informed consent documentation per relevant guidelines and regulations. Is aware of potential scenarios where informed consent may be compromised and takes action to mitigate risk. Collaborate with site staff to evaluate withdrawal of consent and verify proper documentation of same.Identifies and escalates informed consent violations. Documents and escalates non-compliance issues. Performs root cause analysis and implements preventive and corrective actions. Serves as a resource and mentor to team members.	Evaluates the process of obtaining ethical informed consent prior to subject participation and verify informed consent documentation per relevant guidelines and regulations. Is aware of potential scenarios where informed consent may be compromised and coaches/trains project team on action(s) to mitigate risk. Collaborate with site staff to evaluate withdrawal of consent and verify proper documentation of same.Identifies and escalates informed consent violations. Documents and escalates non-compliance issues. Performs root cause analysis and implements preventive and corrective actions. Serves as a resource and mentor to team members. Engages in risk management with internal and external stakeholders.

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DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Medicines Development and Regulation	Training Compliance	Completes and documents organizational and project-related training within defined timelines and in compliance with ICH GCP training, local and ISO regulations and requirements.	Completes and documents organizational and project-related training within defined timelines and in compliance with ICH GCP training, local and ISO regulations and requirements.	Completes and documents organizational and project related training within defined timelines and in compliance with ICH GCP training, local and ISO regulations and requirements. Seeks additional training options internally and externally.	Completes and documents organizational and project related training within defined timelines and in compliance with ICH GCP training, local and ISO regulations and requirements. Seeks additional training options internally and externally. Mentors and provides project-related training.	Completes and documents organizational and project related training within defined timelines and in compliance with ICH GCP training, local and ISO regulations and requirements. Seeks additional training options internally and externally. Mentors and provides project-related training. Identifies the training applicable to the study. Provides additional project-related training, as needed. Verifies study team's compliance with project-related training.

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Clinical Trial Operations (GCPs)	Subject recruitment and retention at the investigator site	Engages PI and site staff in discussions about ethical recruitment and retention efforts, evaluates recruitment and retention strategy and verifies ethics committee approval of subject-facing materials. Is aware of potential recruitment and retention challenges at the study and site level, and takes action to mitigate risk.	Engages PI and site staff in discussions about ethical recruitment and retention efforts, evaluates recruitment and retention strategy and verifies ethics committee approval of subject-facing materials. With support, gains awareness of potential recruitment and retention challenges at the study and site level, and takes action to mitigate risk. Identifies and escalates issues, and implements corrective action to recruitment.	Engages PI and site staff in discussions about ethical recruitment and retention efforts, evaluates recruitment and retention strategy and verifies ethics committee approval of subject-facing materials. Is aware of potential recruitment and retention challenges at the study and site level, and, with minimal support, takes action to mitigate risk. Identifies and escalates issues, and implements corrective action to recruitment. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions.	Engages PI and site staff in discussions about ethical recruitment and retention efforts, evaluates recruitment and retention strategy and verifies ethics committee approval of subject-facing materials. Is aware of potential recruitment and retention challenges at the study and site level, and takes action to mitigate risk. Identifies and escalates issues, and implements corrective action to recruitment. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions. Serves as a resource and mentor to team members.	Engages PI and site staff in discussions about ethical recruitment and retention efforts, evaluates recruitment and retention strategy and verifies ethics committee approval of subject-facing materials. Is aware of potential recruitment and retention challenges at the study and site level, and coaches/ trains project team on action(s) to mitigate risk. Identifies and escalates issues, and implements corrective action to recruitment. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions. Serves as a resource and mentor to team members. Oversees and analyzes the effectiveness of the patient recruitment plan. Instructs and guides team through problem solving and mobilizes team to intended goals and solutions. Assesses applicability of issues and solutions across study. Engages in risk management with internal and external stakeholders.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	Identification, reporting and resolution of suspected misconduct	Identifies the signs of misconduct. Evaluate the severity of issues to assist in determining if misconduct has occurred. Report suspected misconduct in compliance with regulations and company policies. Facilitates corrective action of issues.	Identifies signs of suspected misconduct and collect supporting information. Communicate suspicions and facts collected to stakeholders. Seeks guidance on how to facilitate corrective and preventive action plan. Tactfully discusses concerns with the principal investigator (PI) and implement action plan with support from stakeholders.	Identifies signs of suspected misconduct and collect supporting information. Communicates suspicions and facts collected to stakeholders. Seeks guidance on how to facilitate corrective and preventive action plan. Tactfully discusses concerns with the PI and implements action plan with limited support from stakeholders.	Identifies signs of suspected misconduct and collect supporting information. Communicates suspicions and facts collected to stakeholders. Seeks guidance on how to facilitate corrective and preventive action plan. Tactfully discusses concerns with the PI and implements action plan with limited support from stakeholders. Provides support to junior CRAs in collecting information and discussing concerns with site staff.	Identifies signs of suspected misconduct and guides the CRA in the collection of supporting information. Communicate suspicions and facts collected to additional stakeholders. Coaches CRA in tactfully discussing concerns with the suspected source of the misconduct and guides the CRA in implementing an action plan. Provides sustained support to quality groups and other stakeholders during the investigation and reporting of misconduct. When and if necessary, participates in discussions with the PI.

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Clinical Trial Operations (GCPs)	Compliance (including any amendments) to ensure protection of the rights and well being of patients, the integrity of the study and the data	Assesses site capabilities and develops plans to support the site to achieve compliance via training, ongoing communication and procurement of relevant study tools. Identifies deviations from the protocol, SOPs, applicable regulatory requirements and other governing study documents/plans. Report non-compliance according to company policies and project plans.	With support, assesses site capabilities and develops plans to support the site to achieve compliance via training, ongoing communication and procurement of relevant study tools. Identifies deviations from the protocol, SOPs, and the applicable regulatory requirements. Escalates issues, documents non-compliance in system of record, and confirms ethics committee reporting as required. Protection of study blind, if applicable. Retrains site personnel as needed. Follows up in a timely manner to verify compliance. Implements corrective action(s) with support.	Assesses site capabilities and develops plans to support the site to achieve protocol compliance via training, ongoing communication and procurement of relevant study tools. Identifies deviations from the protocol, SOPs, and the applicable regulatory requirements. Escalates issues, documents non-compliance in system of record, and confirms ethics committee reporting as required. Protection of study blind, if applicable. Retrains site personnel as needed. Follows up in a timely manner to verify compliance. Implement corrective action(s) with minimal support.	Assesses site capabilities and develops plans to support the site to achieve protocol compliance via training, ongoing communication and procurement of relevant study tools. Identifies deviations from the protocol, SOPs, and the applicable regulatory requirements. Escalates issues, documents non-compliance in system of record, and confirms ethics committee reporting as required. Retrains site personnel as needed. Protection of study blind, if applicable. Follows up in a timely manner to verify compliance. Implements corrective action(s). Conducts trend analysis and escalates as needed. Mentors junior CRAs in dealing with non-compliant sites.	Assesses site capabilities and develops plans to support the site to achieve protocol compliance via training, ongoing communication and procurement of relevant study tools. Escalates issues, verifies/completes documentation of non-compliance in system of record, and confirms ethics committee reporting as required. Mentors junior CRAs in retraining site personnel as needed. Follows up in a timely manner to verify compliance. Conducts trend analysis, identifies root cause and risk to study, escalates as needed. Retrains project team as needed.

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Clinical Trial Operations (GCPs)	ICH GCP	Demonstrates a working knowledge of GCP guidelines. Predicts possible GCP noncompliance based on the trial and site complexities and manages these risks as part of a risk management plan. Identifies and reports ICH GCP non-compliance discovered during monitoring activities. Takes appropriate action designed to prevent recurence of detected deviations.	Successfully completes initial and ongoing ICH GCP training. Performs study responsibilites in accordance with ICH GCP. Predicts, with assistance, possible GCP noncompliance based on the trial and site complexities and manages these risks as part of a risk management plan. Monitors investigative sites to verify the trial is conducted and documented in accordance with ICH GCP. Escalates non-compliance and works with site personnel to correct areas of non-compliance and prevent recurrence, with support from stakeholders.	Successfully completes ongoing ICH GCP training. Performs study responsibilities in accordance with ICH GCP. Predicts, with minimal assistance, possible GCP noncompliance based on the trial and site complexities and manages these risks as part of a risk management plan. Monitors investigative sites to verify the trial is conducted and documented in accordance with ICH GCP. Escalates non-compliance and works with site personnel to correct areas of non-compliance and prevent recurrence, with limited support from stakeholders.	Successfully completes ongoing ICH GCP training. Performs study responsibilities in accordance with ICH GCP. Predicts possible GCP noncompliance based on the trial and site complexities and manages these risks as part of a risk management plan. Monitors investigative sites to verify the trial is conducted and documented in accordance with ICH GCP. Escalates non-compliance and advises site on creation or revision of site procedures to gain compliance and prevent recurrence. Conducts trend analysis and escalates recommendations for auditing. Participates in preparing audit responses.	Successfully completes ongoing ICH GCP training. Performs study responsibilities in accordance with ICH GCP. Predicts, with assistance, possible GCP noncompliance based on the trial and site complexities and documents these risks as part of a risk management plan. Oversees monitoring of investigative sites to verify the trial is conducted and documented in accordance with ICH GCP. Escalates non-compliance and mentors junior CRAs on how to advise site on creation or revision of site procedures to gain compliance and prevent recurrence. Conducts trend analysis and escalates recommendations for auditing. Participates in preparing audit responses.

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Clinical Trial Operations (GCPs)	Adequacy of approvals or notifications to Ethics Committees/IRBs and/or Regulatory Authorities	Tracks site approval and expiry dates to anticipate filing and submission timelines. Performs review of competent authority and IRB/IEC documents and submissions. Verify that the appropriate approvals and correspondence with regulatory bodies and ethics committees are documented and filed.	Tracks site approval and expiry dates to anticipate filing and submission timelines. Verify that the investigator provides all the required reports, notifications, applications and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial. Able to access and review project repository for competent authority and IRB/IEC documents. Reviews current documents from the repository against site files to assess for any gaps in approval or submissions. Reports deficiencies in approvals or documentation in accordance with the project plan(s).	Tracks site approval and expiry dates to anticipate filing and submission timelines. Verifies that the investigator provides all the required reports, notifications, applications and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial. Assists with the preparation of Ethics Committee (EC) or Clinical Trial Authority (CTA) documents and respond to EC and/or competent authority queries based on company division of responsibility. Accesses and reviews project repository for competent authority and IRB/IEC documents. Reviews current documents from the repository against site files to assess for any gaps in approval or submissions. Creates a timeline of study activities, IRB/IEC approval dates, and documents approved by the IRB/IEC. Reports deficiencies in approvals or documentation in accordance with the project plan(s).	Tracks site approval and expiry dates to anticipate filing and submission timelines. Verifies that the investigator provides all the required reports, notifications, applications and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial. Assists with the preparation of EC or CTA documents and respond to EC and/or competent authority queries based on company division of responsibility. May also be responsibile for maitenance of changing country requirements for EC & competent authority directives, regulations and guidelines. Accesses and reviews project repository for competent authority and IRB/IEC documents. Reviews current documents from the repository against site files to assess for any gaps in approval or submissions. Creates a timeline of study activities, IRB/IEC approval dates, and documents approved by the IRB/IEC. Reports deficiencies in approvals or documentation in accordance with the project plan(s).	Oversee the work of CRAs and/or startup personnel to verify that all investigators provides the required reports, notifications, applications and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial. Based on company division of responsibility, verifies the preparation of EC or CTA documents are being done according to local process, and that responses to EC and/or competent authority queries are completed within timelines. May also be responsibile for maintenance of changing country requirements for EC & competent authority directives, regulations and guidelines. Establishes a project repository for competent authority and IRB/IEC documents. Verifies that CRAs review current documents from the repository against site files to assess for any gaps in approval or submissions. Creates a timeline of study activities, IRB/IEC approval dates, and documents approved by the IRB/IEC. Reports deficiencies in approvals or documentation in accordance with the project plan(s).

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	Identify differing safety events and understand the reporting requirements of each	Differentiates the types of safety events that occur during clinical trials. Identifies, in advance of study initiation, anticipated safety events that may occur. During study, identifies safety events and verifies safety events are reporting in accordance with the protocol on the CRF. Determines whether all safety events are reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).	Review the study protocol definition for adverse events, serious adverse events, and other safety events, their reporting timeframes, and reporting processes. Identifies, with assistance, anticipated safety events that may occur. Reviews source records and medical charts for untoward medical events. Confirms that events have been appropriately reported. Discusses issues or questions with the PI and/or medical monitor to verify that medical determinations are made in a timely manner.	Review the study protocol definition for adverse events, serious adverse events, and other safety events, their reporting timeframes, and reporting processes. Identifies, with minimal guidance, anticipated safety events that may occur. Reviews source records and medical charts for untoward medical events. Confirms that events have been appropriately reported. Discusses issues or questions with the PI and/or medical monitor to verify that medical determinations are made in a timely manner. Identifies project-specific issues or trends with safety reporting and brings these issues to the attention of the project lead	Identifies anticipated safety events that may occur. Reviews source records and medical charts for untoward medical events. Confirms that events have been appropriately reported. Discusses issues or questions with the PI and/or medical monitor to verify that medical determinations are made in a timely manner. Identifies project-specific issues or trends with safety reporting and brings these issues to the attention of the project lead and recommends solutions to address the issues or trends.	Verifies CRA team is clear on the protocol definitions and requirements for safety identification and reporting. Creates monitoring tools as needed to assist CRAs in meeting these requirements. Identifies anticipated safety events that may occur and coaches/trains project team on these events. Liases with investigator, medical monitors, and project leadership to resolve areas of uncertainty or concern in a timely manner.

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Clinical Trial Operations (GCPs)	The purpose of essential documents and the requirements for maintenance and archival	Knowledge of essential documents; Reviews site regulatory file for completeness; Develops follow-up plan with site staff; Reconcile site files with trial master file; Verifies investigator is aware of archiving responsibilities and has plans to comply with requirements.	Has an understanding of the required essential documents according to ICH GCP Section 8. Reviews site documents and verifies they are accurate, complete, current, and include required updates. Collects documents prior to expiration or as corrections/updates are necessary. Determines if additional documents are required when omitted or based on changes to site staff, facilities or processes. Verifies consistency between site files and the trial master file. Determines site's policy for archiving and evaluates against regulatory requirements. Documents archiving location(s) and timelines.	Has an understanding of the required essential documents according to ICH GCP Section 8. Reviews site documents and verifies they are accurate, complete, current, and include required updates. Collects documents prior to expiration or as corrections/updates are necessary. Determines if additional documents are required when omitted or based on changes to site staff, facilities or processes. Verifies consistency between site files and the trial master file. Determines site's policy for archiving and evaluates against regulatory requirements. Documents archiving location(s) and timelines. Identifies trends across study sites and brings these issues to the attention of the project lead	Has an understanding of the required essential documents according to ICH GCP Section 8. Reviews site documents and verifies they are accurate, complete, current, and include required updates. Collects documents prior to expiration or as corrections/updates are necessary. Determines if additional documents are required when omitted or based on changes to site staff, facilities or processes. Verifies consistency between site files and the trial master file. Determines site's policy for archiving and evaluates against regulatory requirements. Documents archiving location(s) and timelines. Identifies trends across study sites and brings these issues to the attention of the project lead and provides recommended solutions to resolve issues.	Creates a regulatory review checklist containing all applicable documents and versions for the study. Oversee the work of CRAs to verify that all site files are reviewed against the checklist/ICH-GCP required essential documents to verify all study documents have been reviewed, approved, and correctly filed when applicable. Communicates country specific requirements for essential documents and verifies site and CRA compliance. Conducts and/or reviews file audits and resolves trends to prevent deviations, errors or omissions with essential document maintenance.

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Clinical Trial Operations (GCPs)	Audit and inspection processes	Preparation, participation, documentation and follow-up of audits and/or inspections. Support resolution of Corrective And Preventive Actions (CAPA) resulting from site audits or inspections.	Reviews and follows company provided instruction for the role that will be performed in the audit and/or inspection. Provides assistance as requested within the scope of the role. Assist in the development of appropriate risk mitigation plan, demonstrating corrective and preventive action with follow up and within identified timelines with support. Communicate with site personnel, QA and project leadership.	Reviews and follows company provided instruction for the role that will be performed in the audit and/or inspection. Provides assistance as requested within the scope of the role. Assist in the development of appropriate risk mitigation plan, demonstrating corrective and preventive action with follow up and within identified timelines with limited support. Communicate with site personnel, QA and project leadership.	Reviews and follows company provided instruction for the role that will be performed in the audit and/or inspection. Provides assistance as requested within the scope of the role. Mentor junior CRAs in the development of appropriate risk mitigation plan, demonstrating corrective and preventive action with follow up and within identified timelines. Communicate with site personnel, QA and project leadership.	Reviews and follows company provided instruction for the role that will be performed in the audit and/or inspection. Provides assistance as requested within the scope of the role. Verify the completeness and accuracy of risk mitigation plan, demonstrating corrective and preventive action with follow up and within identified timelines. Communicate with site personnel, QA and project leadership. Following implementation, verifies the effectiveness of the agreed actions. Communicates lessons learned if and when applicable to the project team.

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Clinical Trial Operations (GCPs)	Understands the roles and responsibilities and relationships between the CRA and Investigators, sponsor and EC/IRBs per ICH-GCP	Verifies that the investigator has adequate qualifications and resources and these remain adequate throughout the trial period, and that the staff and facilities, including laboratories and equipment, are adequate to safely and properly conduct the trial and these remain adequate throughout the trial period. Develops risk mitigation plans, in the event of a change in adequacy of investigator qualifications or resources.	Performs interview with site staff and PI, examines equipment, patient population as it pertains to the protocol and facility and makes a determination about acceptability for the trial. Reviews site policies and practices for adherence to the protocol and ICH-GCP prior to and throughout the study. Conducts ongoing review of site staff, facilities and study documentation to verify staff and facilities remain adequate to perform the trial. When inadequacy is identified, communicate the deficiency to stakeholders and implement corrective action with support.	Performs interview with site staff and PI, examines equipment, patient population as it pertains to the protocol and facility and makes a determination about acceptability for the trial. Reviews site policies and practices for adherence to protocol and ICH-GCP prior to and throughout the study. Conducts ongoing review of site staff, facilities and study documentation to verify staff and facilities remain adequate to perform the trial. When inadequacy is identified, communicate the deficiency to stakeholders and implement corrective action with minimal support.	Performs interview with site staff and PI, examines equipment, patient population as it pertains to the protocol and facility and makes a determination about acceptability for the trial. Reviews site policies and practices for adherence to protocol and ICH-GCP prior to and throughout the study. Conducts ongoing review of site staff, facilities and study documentation to verify staff and facilities remain adequate to perform the trial. Reviews site staff credentials and regulatory audit documents if deficiencies were noted. When inadequacy is identified, communicate the deficiency to stakeholders and implement corrective action. Mentors junior CRAs on assessing investigator site adequacy and achieving compliance.	Verifies the CRA team understands the trial requirements for site and investigator adequacy. Performs interview with site staff and PI, examines equipment, patient population as it pertains to the protocol and facility and makes a determination about acceptability for the trial. Reviews site policies and practices for adherence to protocol and ICH-GCP prior to and throughout the study. Oversees initial and ongoing review of site staff, facilities and study documentation to verify staff and facilities remain adequate to perform the trial. Reviews site staff credentials and regulatory audit documents if deficiencies were noted. Mentors others on site suitability. When inadequacy is identified, communicate the deficiency to stakeholders and implement corrective action. Review recommendations from CRAs and participate in the site selection process.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	The requirements for accurate and complete site source documents. Verification that data reported in the CRF is consistent with source documentation.	Performs source data review (SDR) and source data verification (SDV) of critical data, as per the monitoring plan, to verify the site is collecting accurate and verifiable data.	Performs source data review (SDR) and source data verification (SDV) of critical data, as per the monitoring plan, to verify the site is collecting attributable, legible, contemporaneous, original and accurate (ALCOA) data. Evaluates site procedures to confirm CRA direct access to all source data. Follows approved procedures when direct access to source data is not available (i.e. certified copies with electronic medical records). Uses critical thinking to review subject charts and supplemental source documentation to determine the accuracy and completeness of data generated for the study. Documents status of review for each subject visit. Writes queries to address inconsistencies with protocol and GCP requirements. Initiates follow-up actions to assist site in achieving compliance. Able to identify non-compliance and implement corrective actions with support.	Performs source data review (SDR) and source data verification (SDV) of critical data, as per the monitoring plan, to verify the site is collecting attributable, legible, contemporaneous, original and accurate (ALCOA) data. Evaluates site procedures to confirm CRA direct access to all source data. Follows approved procedures when direct access to source data is not available (i.e. certified copies with electronic medical records). Uses critical thinking to review subject charts and supplemental source documentation to determine the accuracy and completeness of data generated for the study. Documents status of review for each subject visit. Writes queries to address inconsistencies with protocol and GCP requirements. Initiates follow-up actions to assist site in achieving compliance. Able to identify non-compliance and implement corrective actions with limited support.	Performs source data review (SDR) and source data verification (SDV) of critical data, as per the monitoring plan, to verify the site is collecting attributable, legible, contemporaneous, original and accurate (ALCOA) data. Evaluates site procedures to confirm CRA direct access to all source data. Follows approved procedures when direct access to source data is not available (i.e. certified copies with electronic medical records). Uses critical thinking to review subject charts and supplemental source documentation to determine the accuracy and completeness of data generated for the study. Documents status of review for each subject visit. Writes queries to address inconsistencies with protocol and GCP requirements. Initiates follow-up actions to assist site in achieving compliance. Able to identify non-compliance and implement corrective actions. Mentor junior CRAs on the requirements for source documents.	Confirms source data review (SDR) and source data verification (SDV) of critical data, as per the monitoring plan, to verify the site is collecting attributable, legible, contemporaneous, original and accurate (ALCOA) data. Evaluates site procedures to confirm CRA direct access to all source data. Follows approved procedures when direct access to source data is not available (i.e. certified copies with electronic medical records). Uses critical thinking to review subject charts and supplemental source documentation to determine the accuracy and completeness of data generated for the study. Documents status of review for each subject visit. Writes queries to address inconsistencies with protocol and GCP requirements. Initiates follow-up actions to assist site in achieving compliance. Able to identify non-compliance and implement corrective actions. Mentor junior CRAs on the requirements for source documents. Serves as the point of escalation when issues arise with source documents at sites including access requirements, direct access to source data and systems, site staff compliance and closure of issues. Verifies CRAs are reviewing and reporting on all necessary documentation per protocol requirements. Documents the expectations for source documents that CRAs are to review in the monitoring plan. Initiates follow-up actions to assist site in achieving compliance. Able to identify non-compliance and implement corrective actions. Mentor junior CRAs on the requirements for source documents. Evaluates source document verification and review process at the project and individual site level to assess risk mitigation.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	Plans and conducts all types of monitoring visits.	Plans, conducts and completes follow-up activities for on-site and/or remote qualification, initiation, interim, central and close-out visits according to written procedures.	Adheres to monitoring plan, standard operating procedures, and any other written procedures in reference to conducting all types of monitoring visits. Receives guidance and mentoring to manage complex issues.	Adheres to monitoring plan, standard operating procedures, and any other written procedures in reference to conducting all types of monitoring visits independently. Manages complex issues with limited support. When not possible to meet deliverables, informs appropriate team/manager.	Adheres to monitoring plan, standard operating procedures, and any other written procedures in reference to conducting all types of monitoring visits independently. Capable of managing complex issues. When not possible to meet deliverables, informs appropriate team/manager. Mentors junior CRAs in planning and conducting monitoring visits.	Adheres to monitoring plan, standard operating procedures, and any other written procedures in reference to overseeing that all types of monitoring visits are being performed. When not possible to meet deliverables, informs appropriate team/manager and develops contingency plans as necessary. Mentors junior CRAs in planning and conducting monitoring visits. Mentors junior CRAs in managing complex issues and takes the lead on resolving complex issues. Assists team in creating monitoring plan. Procures adequate resources to ensure rate of source data review is adequate to protect patient safety and promote data integrity.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	Time Management and Prioritization of Work	Evaluates assignments and effectively prioritizes and manages work activities according to study plans.	Evaluates assignments, effectively prioritizes and manages work activities according to study plans. Communicates visit activities to stakeholders so that an assessment of activity level can be monitored and forecasted. Shares concerns and requests additional resources to internal team to achieve on-time deliverables.	Evaluates assignments, effectively prioritizes and manages work activities according to study plans. Communicates visit activities to stakeholders so that an assessment of activity level can be monitored and forecasted. Shares concerns and requests additional resources to internal team to achieve on-time deliverables. Volunteers to help in downtime. Seeks guidance for alternate site assignments.	Evaluates assignments, effectively prioritizes and manages work activities according to study plans. Communicates visit activities to stakeholders so that an assessment of activity level can be monitored and forecasted. Shares concerns and requests additional resources to internal team to achieve on-time deliverables. Volunteers to help in downtime. Proactively suggests cost effective site assignment changes.	Evaluates assignments, effectively prioritizes and manages work activities according to study plans and needs. Communicates activities to stakeholders so that an assessment of activity level can be monitored and forecasted. Shares concerns and requests additional resources to internal team to achieve on-time deliverables. Effectively assigns sites to CRAs to manage budget, geographical, and experiential needs.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	Verifies that bio-samples have been appropriately handled, stored, labelled, and shipped.	Verifies site staff knowledge and ability to properly collect, handle, store, and ship lab samples. Reviews onsite facilities, records, samples, sample storage, temperature monitoring and equipment calibration records for compliance. Confirms adequate supplies, training and delegation. Develops risk mitigation plans, as needed, to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, handle, store, and ship lab samples. Reviews onsite facilities, records, samples, sample storage, temperature monitoring and equipment calibration records for compliance. Confirms adequate supplies, training and delegation. Develops risk mitigation plans as needed, with support, to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, handle, store, and ship lab samples. Reviews onsite facilities, records, samples, sample storage, temperature monitoring and equipment calibration records for compliance. Confirms adequate supplies, training and delegation. Develops risk mitigation plans as needed, with minimal support, to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, handle, store, and ship lab samples. Reviews onsite facilities, records, samples, sample storage, temperature monitoring and equipment calibration records for compliance. Confirms adequate supplies, training and delegation. Develops risk mitigation plans, as needed, to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, handle, store, and ship lab samples. Reviews onsite facilities, records, samples, sample storage, temperature monitoring and equipment calibration records for compliance. Confirms adequate supplies, training and delegation. Reviews risk mitigation plans, as needed, to address areas of identified risk. Provides retraining to project teams to disseminate to sites regarding proper procedures.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	Verifies that third party vendor data is appropriately collected, transferred, and stored.	Verifies site staff knowledge and ability to properly collect, transfer and store study data for third party study vendors. Identifies potential areas of risk and develops risk mitigation plans, as needed, to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, transfer and store study data for third party study vendors. Identifies potential areas of risk and develops risk mitigation plans, as needed, with support to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, transfer and store study data for third party study vendors. Identifies potential areas of risk and develops risk mitigation plans, as needed, with minimal support to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, transfer and store study data for third party study vendors. Identifies potential areas of risk and develops risk mitigation plans, as needed, to address areas of identified risk.	Verifies site staff knowledge and ability to properly collect, transfer and store study data for third party study vendors. Assists in the development of processes and tools to verify proper processing of study vendor data. Identifies potential areas of risk and coaches/trains project team(s) on the development of risk mitigation plans, as needed, to address areas of identified risk.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	IP Accountability	Verifies IP accountability. Reviews IP records and reconciles with subject records. Reviews IB reference material.	Verifies randomization process by ensuring dispensing procedures are compliant with IB and instructions for use. Verifies adequate IP supplies, and reviews storage, including temperature logs, when needed, Confirms IP is kept in a secure location and adheres to the requirements for storage. Reviews IP records and reconciles with all subject records and system of record, performs compliance calculations. Identifies, escalates and seeks guidance on corrective action for IP issues.	Verifies randomization process by ensuring dispensing procedures are compliant with IB and instructions for use. Verifies adequate IP supplies, and reviews storage, including temperature logs, when needed, Confirms IP is kept in a secure location and adheres to the requirements for storage. Reviews IP records and reconciles with all subject records and system of record, performs compliance calculations. Identifies, escalates and implements site corrective action for IP issues with limited support.	Verifies randomization process by ensuring dispensing procedures are compliant with IB and instructions for use. Verifies adequate IP supplies, and reviews storage, including temperature logs, when needed, Confirms IP is kept in a secure location and adheres to the requirements for storage. Reviews IP records and reconciles with all subject records and system of record, performs compliance calculations. Identifies, escalates and implements site corrective action for IP issues and identifies and escalates trends related IP issues. Mentors junior CRAs on IP accountability processes and verification.	Confirms CRA team knows and verifies randomization processes and IP instructions for use. Oversees CRAs to verify adequate IP supplies, storage, records and reconciliation with all subject records and system of record. Serves as the point of escalation for site issues regarding IP. Identifies, escalates and implements corrective action for IP issues and identifies and escalates trends related to IP. Develops action plan to correct IP issues.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	IP Chain of custo	Reviews and verifies documentation of receipt, labeling, storage, dispensing records, return or final disposition of IP.	Verifies on site supplies against shipping records and/or system of record. Reconcile site supply with dispensing records. Review documentation of return or final disposition. Identify expiring IP using product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues with support.	Verifies on site supplies against shipping records and/or system of record. Reconcile site supply with dispensing records. Review documentation of return or final disposition. Identify expiring IP using product labeling and verify IP replacement. Identifies, escalates, and implements site corrective action for IP issues with limited support.	Verifies on site supplies against shipping records and/or system of record. Reconcile site supply with dispensing records. Review documentation of return or final disposition. Identify expiring IP using product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues. Identifies emerging trends for IP issues and escalates. Mentors junior CRAs on requirements for documented chain of custody of IP.	Verifies CRA team verifies on site supplies against shipping records and/or system of record; reconciles site supply with dispensing records; reviews documentation of return or final disposition; identifies expiring IP using product labeling; and verifies IP replacement. Identifies, escalates, and implements corrective action for IP issues. Identifies emerging trends for IP issues and escalates. Develops action plan to correct IP issues.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical Trial Operations (GCPs)	IP Blinding and R	Verifies integrity of blind and randomization process.	Verifies integrity of blind, adherence to stratification and randomization process. Identifies reporting procedures for accidental unblinding, including subject's ability to continue in the study, and implements corrective action, if needed, with support. Can verbalize the emergency unblinding procedure in the protocol.	Verifies integrity of blind, adherence to stratification and randomization process. Identifies reporting procedures for accidental unblinding, including subject's ability to continue in the study, and implements corrective action, if needed, with limited support . Can verbalize the emergency unblinding procedure in the protocol.	Verifies integrity of blind, adherence to stratification and randomization process. Identifies reporting procedures for accidental unblinding, including subject's ability to continue in the study, and implements corrective action, if needed. Can verbalize the emergency unblinding procedure in the protocol. Mentors junior CRAs in blinding, unblinding and randomization procedures.	Confirms CRA team verifies integrity of blind, adherence to stratification and randomization processes. Identifies reporting procedures for accidental unblinding, including subject's ability to continue in the study, and implements corrective action, if needed. Can verbalize the emergency unblinding procedure in the protocol. Mentors junior CRAs in blinding, unblinding and randomization procedures.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Study and Site Management	Assessment of PI Qualification and Resources	Assesses study protocol activities to verify trial records are accurate, complete and current. Confirms the PI or delegated staff member has performed and documented all activities. Throughout the trial, evaluates investigator and site staff for qualification and training, provides study-specific training and inspects facilities to confirm adequacy. Evaluates compliance with the protocol and GCP and investigator engagement and revises the risk mitigation plans as necessary based on performance. Verifies documentation of investigator oversight and delegation. Evaluates the PI's availability to meet to discuss study progress, understanding of the study protocol, status of all subjects, applicable regulations, and ICH-GCP and overall level of involvement in implementing compliance. Identifies and escalates issues and implements corrective action.	Assesses study protocol activities to verify trial records are accurate, complete and current. Confirms the PI or delegated staff member has performed and documented all activities. Throughout the trial, evaluates investigator and site staff for qualification and training, provides study-specific training and inspects facilities to confirm adequacy. Evaluates compliance with the protocol and GCP and investigator engagement and revises, with guidance, risk mitigation plans as necessary based on performance. Verifies documentation of investigator oversight and delegation. Evaluates the PI's availability to meet to discuss study progress, understanding of the study protocol, status of all subjects, applicable regulations, and ICH-GCP and overall level of involvement in implementing compliance. Identifies and escalates issues and implements corrective action.	Assesses study protocol activities to verify trial records are accurate, complete and current. Confirms the PI or delegated staff member has performed and documented all activities. Throughout the trial, evaluates investigator and site staff for qualification and training, provides study-specific training and inspects facilities to confirm adequacy. Evaluates compliance with the protocol and GCP and investigator engagement and revises, with minimal guidance, risk mitigation plans as necessary based on performance. Verifies documentation of investigator oversight and delegation. Evaluates the PI's availability to meet to discuss study progress, understanding of the study protocol, status of all subjects, applicable regulations, and ICH-GCP and overall level of involvement in implementing compliance. Identifies and escalates issues and implements corrective action. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions.	Assesses study protocol activities to verify trial records are accurate, complete and current. Confirms the PI or delegated staff member has performed and documented all activities. Throughout the trial, evaluates investigator and site staff for qualification and training, provides study-specific training and inspects facilities to confirm adequacy. Evaluates compliance with the protocol and GCP and investigator engagement and revises the risk mitigation plans as necessary based on performance. Verifies documentation of investigator oversight and delegation. Evaluates the PI's availability to meet to discuss study progress, understanding of the study protocol, status of all subjects, applicable regulations, and ICH-GCP and overall level of involvement in implementing compliance. Identifies and escalates issues and implements corrective action. Performs root cause analysis, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions. Serves as a resource and mentor to team members.	Assesses study protocol activities to verify trial records are accurate, complete and current. Confirms the PI or delegated staff member has performed and documented all activities. Throughout the trial, evaluates investigator and site staff for qualification and training, provides study-specific training and inspects facilities to confirm adequacy. Evaluates compliance with the protocol and GCP and investigator engagement and revises the risk mitigation plans as necessary based on performance. Verifies documentation of investigator oversight and delegation. Evaluates the PI's availability to meet to discuss study progress, understanding of the study protocol, status of all subjects, applicable regulations, and ICH-GCP and overall level of involvement in implementing compliance. Identifies and escalates issues and implements corrective action. Performs root cause analysis, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions. Serves as a resource and mentor to team members. Instructs and guides team through problem solving and mobilizes team to intended goals and solutions. Assesses applicability of issues and solutions across study. Engages in risk management with internal and external stakeholders.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Data Management and Informatics	Critical Data & Processes	Performs data review utilizing system of record to identify and mitigate potential issues and risks. Has an awareness of the interrelatedness of study systems and analyzes data trends to direct future monitoring actions. Communicates with centralized monitoring team members. References risk assessment documentation to anticipate and mitigate potential issues.	Performs data review utilizing system of record to identify and mitigate potential issues and risks. With support, begins to develop an awareness of the interrelatedness of study systems and analyzes data trends to direct future monitoring actions. Communicates with centralized monitoring team members. References risk assessment documentation to anticipate and mitigate potential issues. Identifies and escalates issues and implements corrective action preventive plan.	Performs data review utilizing system of record to identify and mitigate potential issues and risks. Analyzes data trends and site performance metrics. Communicates with centralized monitoring team members. References risk assessment documentation to anticipate and mitigate potential issues.Identifies and escalates issues and implements corrective action preventive plan. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions.	Performs data review utilizing system of record to identify and mitigate potential issues and risks. Has an awareness of the interrelatedness of study systems and analyzes data trends to direct future monitoring actions. Communicates with centralized monitoring team members. References risk assessment documentation to anticipate and mitigate potential issues.Identifies and escalates issues and implements corrective action preventive plan. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions. Serves as mentor and resource to team members.	Performs data review utilizing system of record to identify and mitigate potential issues and risks. Knows the interrelatedness of study systems and analyzes data trends to direct future monitoring actions. Executes communication plan with centralized monitoring team members and/or onsite monitoring team members. References risk assessment documentation to anticipate and mitigate potential issues.Identifies and escalates issues and implements corrective action preventive plan. Performs root cause analysis and utilizes available resources to implement corrective and preventive actions. Serves as mentor and resource to team members. Analyzes data trends across sites and project and recommends, develops, implements and assesses applicability of risk-mitigation plans. Engages in risk management with internal and external stakeholders.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Data Management and Informatics	Query Issuance and Resolution	Writes clear, concise and directed queries that comply with ICH-GCP. Works with site staff to facilitate effective query resolution processes and timeline compliance.	Writes clear, concise and directed queries that comply with ICH-GCP. Works with site staff to facilitate effective query resolution processes and timeline compliance. Maintains effective communication with site staff to resolve queries and escalate issues.	Writes clear, concise and directed queries that comply with ICH-GCP. Works with site staff to facilitate effective query resolution processes and timeline compliance. Maintains effective communication with site staff to resolve queries and escalate issues. Provides detailed query reports/status to site staff.	Writes clear, concise and directed queries that comply with ICH-GCP. Works with site staff to facilitate effective query resolution processes and timeline compliance. Maintains effective communication with site staff to resolve queries and escalate issues. Provides detailed query reports/status to site staff. Understands, escalates and resolves issues regarding study progress and data delivery per timelines. Performs root cause analysis of data quality, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions.	Writes clear, concise and directed queries that comply with ICH-GCP. Works with site staff to facilitate effective query resolution processes and timeline compliance. Maintains effective communication with site staff to resolve queries and escalate issues. Provides detailed query reports/status to site staff. Understands, escalates and resolves issues regarding study progress and data delivery per timelines. Performs root cause analysis of data quality, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions. Creates and provides detailed query metrics to project stakeholders. Evaluates query trends and solutions to mitigate risk.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Data Management and Informatics	Clinical Trial Systems of Record	Demonstrates competency with clinical trial systems of record and reports on site and project metrics accurately and on time.	Demonstrates competency with clinical trial systems of record and reports on site and project metrics accurately and on time. Produces and uses site and project reports to expedite processes and task completion.	Demonstrates competency with clinical trial systems of record and reports on site and project metrics accurately and on time. Produces and uses site and project reports to expedite processes and task completion. Serves as resource and mentor to team members to answer questions about system best practices.	Demonstrates competency with clinical trial systems of record and reports on site and project metrics accurately and on time. Produces and uses site and project reports to expedite processes and task completion. Serves as resource and mentor to team members to answer questions about system best practices.	Demonstrates competency with clinical trial systems of record and reports on site and project metrics accurately and on time. Produces and uses site and project reports to expedite processes and task completion. Serves as resource and mentor to team members to answer questions about system best practices. Consults with system administrators through project lifecycle to manage system access of clinical team and sites. Mitigates data capture and reporting risks.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Data Management and Informatics	Compliance with Electronic Record Requirements and Regulations	Completes and documents regulatory compliance assessment	Confirms that site systems used for study conduct are assessed for study use and compliant with ICH GCP. Verifies system access is well controlled. Identifies and escalates issues and implements corrective action.	Confirms that site systems used for study conduct are assessed for study use and compliant with ICH GCP. Verifies system access is well controlled. Identifies and escalates issues and implements corrective action. Performs root cause analysis, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions.	Confirms that site systems used for study conduct are assessed for study use and compliant with ICH GCP. Verifies system access is well controlled. Identifies and escalates issues and implements corrective action. Performs root cause analysis, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions.	Confirms that site systems used for study conduct are assessed for study use and compliant with ICH GCP. Verifies system access is well controlled. Identifies and escalates issues and implements corrective action. Performs root cause analysis, evaluates process gaps and uses available resources to develop and implement corrective and preventive actions. Assesses applicability of solutions across study.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Leadership and Professionalism	Personal Work Product Accountability	Submits quality deliverables on time, and participates in and contributes to team activities. When not able to meet timelines, informs appropriate manager and team members in advance of deadline so that remediation activities can be identified and implemented.	Submits quality deliverables on time, and participates in and contributes to team activities. Assimilates to shifting requests and priorities. When not able to meet timelines, informs appropriate manager and team members in advance of deadline so that remediation activities can be identified and implemented.	Submits quality deliverables on time, and participates in and contributes to team activities. Assimilates to shifting requests and priorities. When not able to meet timelines, informs appropriate manager and team members in advance of deadline so that remediation activities can be identified and implemented.	Submits quality deliverables on time, and participates in and contributes to team activities. Assimilates to shifting requests and priorities. When not able to meet timelines, informs appropriate manager and team members in advance of deadline so that remediation activities can be identified and implemented. Identifies and initiates improvement measures to confirm internal processes are efficient.	Submits quality deliverables on time, and participates in and contributes to team activities. Assimilates to shifting requests and priorities. When not able to meet timelines, informs appropriate manager and team members in advance of deadline so that remediation activities can be identified and implemented. Identifies and initiates improvement measures to confirm internal processes are efficient. Accountable for project and team performance. Provides team oversight to confirm project expectations and deadlines are met. Develops solutions to improve performance.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Leadership and Professionalism	Cultural Awareness and Sensitivity	Demonstrates respect for cultural diversity and conventions. Anticipates areas of cultural sensitivity and develops proactive means to address them.	Promotes respect for cultural diversity and conventions with all individuals. With support, identifies areas of cultural sensitivity and develops proactive means to address them. Demonstrates ability to successfully establish and maintain culturally sensitive working relationships.	Promotes respect for cultural diversity and conventions with all individuals. With minimal support, anticipates areas of cultural sensitivity and develops proactive means to address them. Demonstrates ability to successfully establish and maintain culturally sensitive working relationships.	Promotes respect for cultural diversity and conventions with all individuals. Anticipates areas of cultural sensitivity and develops proactive means to address them. Demonstrates ability to successfully establish and maintain culturally sensitive working relationships. Acts as role model demonstrating respect for the variety of thought while encouraging alignment with the strategic direction.	Promotes respect for cultural diversity and conventions with all individuals. Anticipates areas of cultural sensitivity and coaches/trains project team on proactive means to address them. Demonstrates ability to successfully establish and maintain culturally sensitive working relationships. Models respect for variety of thought while encouraging alignment with the strategic direction. Confirms team members comply with professional standards.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Leadership and Professionalism	Professional Behavior	Demonstrates and projects professional demeanor and communications consistent with organizational policies and practices	Demonstrates and projects professional demeanor and communications consistent with organizational policies and practices. Behaves in ways that demonstrate and foster personal initiative, critical thinking and trustworthiness. Remains accountable to and positively engaged with others. Demonstrates commitment to customer service.	Demonstrates and projects professional demeanor and communications consistent with organizational policies and practices. Behaves in ways that demonstrate and foster personal initiative, critical thinking and trustworthiness. Remains accountable to and positively engaged with others. Demonstrates commitment to customer service.	Demonstrates and projects professional demeanor and communications consistent with organizational policies and practices. Behaves in ways that demonstrate and foster personal initiative, critical thinking and trustworthiness. Remains accountable to and positively engaged with others. Demonstrates commitment to customer service.	Demonstrates and projects professional demeanor and communications consistent with organizational policies and practices. Behaves in ways that demonstrate and foster personal initiative, critical thinking and trustworthiness. Remains accountable to and positively engaged with others. Demonstrates commitment to customer service. Confirms team members comply with professional standards.

DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Communication and Teamwork	Relationship and Communication with Clinical Study Team Members and Investigative Site Staff	Communicates to effectively resolve compliance issues. Provides clear and technically accurate information and instructions, both orally and in writing. Maintains timely communication. Engages in effective discussions. Demonstrates attentive and active listening. Abides by communication plan and pathway.	Communicates to effectively resolve compliance issues. Provides clear and technically accurate information and instructions, both orally and in writing. Maintains timely communication. Engages in effective discussions. Demonstrates attentive and active listening. Abides by communication plan and pathway.	Communicates to effectively resolve compliance issues. Provides clear and technically accurate information and instructions, both orally and in writing. Maintains timely communication. Engages in effective discussions. Demonstrates attentive and active listening. Abides by communication plan and pathway.	Communicates to effectively resolve compliance issues. Provides clear and technically accurate information and instructions, both orally and in writing. Maintains timely communication. Engages in effective discussions. Demonstrates attentive and active listening. Abides by communication plan and pathway.	Communicates to effectively resolve compliance issues. Provides clear and technically accurate information and instructions, both orally and in writing. Maintains timely communication. Engages in effective discussions. Demonstrates attentive and active listening. Abides by communication plan and pathway. Confirms team members comply with professional communication standards.

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