





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 Clinica

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	Basic features	Explains the disease process	Explains the disease process or	Explains the disease process or	Explains the disease process or	Explains the disease process or
Concepts	of the disease	or condition and expected	condition and expected course.	condition and expected course.	condition and expected course.	condition and expected course.
and	or condition	course as well as the	Identifies signs and symptoms of	Identifies signs and symptoms of	Identifies signs and symptoms of	Identifies signs and symptoms of
Research	under study	treatment options and	disease. Identifies documentation of	disease. Identifies documentation of	disease. Identifies documentation of	disease. Identifies documentation of
Design		standard of care. Identifies	diagnosis in subject record. Uses	diagnosis in subject record. Uses	diagnosis in subject record. Uses	diagnosis in subject record. Uses
		signs and symptoms of	accurate medical terminology.	accurate medical terminology.	accurate medical terminology.	accurate medical terminology.
		disease. Identifies	Describes the indication and the	Describes the indication and the	Describes the indication and the	Describes the indication and the
		documentation of diagnosis	associated therapeutic area as well as	associated therapeutic area as well as	associated therapeutic area as well as	associated therapeutic area as well as
		in subject record. Uses	the treatment options and standard of	the treatment options and standard of	the treatment options and standard of	the treatment options and standard of
		accurate medical	care. Identifies the relevant study	care. Identifies the relevant study	care. Identifies the relevant study	care. Identifies the relevant study
		terminology.	procedures.	procedures.	procedures. Summarizes the class of	procedures. Summarizes the class of
					drugs or device and why the product is	drugs or device and why the product is
				Summarizes the class of drugs or	being developed. Discusses and	being developed. Discusses and
				device and why the product is being	recognizes alternative treatments.	recognizes alternative treatments.
				developed. Discusses and recognizes		Evaluates risks and benefits of product
				alternative treatments.	Evaluates risks and benefits of product	intervention on the disease or
					intervention on the disease or	condition.
					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	Product	Defines the different phases	Defines the different phases of product	Defines the different phases of product	Defines the different phases of product	Defines the different phases of product
Concepts	Development	of product development.	development. Identifies key protocol	development. Identifies key protocol	development. Identifies key protocol	development. Identifies key protocol
and	Lifecycle and	Identifies key protocol	sections, and with assistance, identifies	sections, and with minimal assistance,	sections, and identifies critical	sections and trains/coaches project
Research	Significance of	sections, critical processes	critical processes and data, and	identifies critical processes and data,	processes and data, and evaluates	team on critical processes and data,
Design	Design Features	and data, and potential	evaluates potential areas for risk.	evaluates potential areas for risk.	potential areas for risk. Explains	and potential areas of risk. Explains
	in Clinical trial	areas for risk. Explains	Explains research methodology and	Explains research methodology and	research methodology and purpose of	research methodology and purpose of
	protocols	research methodology and	purpose of assigned protocol, including	purpose of assigned protocol, including	assigned protocol, including primary	assigned protocol, including primary
		purpose of assigned	primary and secondary endpoints.	primary and secondary endpoints.	and secondary endpoints. Escalates	and secondary endpoints. Escalates
		protocol, including primary		Escalates protocol design questions to	protocol design questions to project	protocol design questions to project
		and secondary endpoints.	project team members.	project team members.	team members.	team members. Identifies risks
		Describes the rationale for			Identifies risks associated with clinical	associated with clinical trial design.
		complying with clinical study		Identifies risks associated with clinical	trial design.	Answers questions regarding protocol
		procedures and their impact		trial design.		material. Serves as resource and
		in protecting the rights and				mentor on protocol design to team
		well being of the patients.			design.	members.
						Assesses applicability of issues and
					protocol design to team members.	solutions across study.



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Ethical and	Subject	Identifies confidential	Identifies confidential information and			
Participant	Confidentiality	information and complies	complies with global and local laws and			
Safety	and Data Rights	with global and local laws	guidelines. With guidance, has some	guidelines. Is aware of potential	guidelines. Is aware of potential	guidelines. Is aware of potential
Considerati	and Privacy	and guidelines. Is aware of	·	scenarios where privacy and	scenarios where privacy and	scenarios where privacy and
ons		potential scenarios where		confidentiality may be compromised	confidentiality may be compromised	confidentiality may be compromised
		privacy and confidentiality	be compromised and takes action to	and, with minimal guidance, takes	and takes action to mitigate risk.	and coaches or trains project team on
		may be compromised and	mitigate risk. Identifies and escalates	action to mitigate risk.ldentifies and	Identifies and escalates privacy and	actions to mitigate risk. Identifies and
		takes action to mitigate risk.	privacy and confidentiality violations,	escalates privacy and confidentiality	confidentiality violations. Performs	escalates privacy and confidentiality
			and implements corrective actions.	violations.	root cause analysis and implements	violations. Performs root cause analysis
				Desferons and some state of	preventive and corrective actions.	and implements preventive and
				Performs root cause analysis and	Campaga and magazine	corrective actions. Serves as a resource
				implements preventive and corrective	Serves as a resource and mentor to	and mentor to team members.
				actions.	team members.	



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



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Medicines	Training	Completes and documents	Completes and documents	Completes and documents	Completes and documents	Completes and documents
Developme	Compliance	organizational and project-	organizational and project-related	organizational and project related	organizational and project related	organizational and project related
nt and		related training within	training within defined timelines and in	training within defined timelines and	training within defined timelines and in	training within defined timelines and in
Regulation		defined timelines and in	compliance with ICH GCP training, local	in compliance with ICH GCP training,	compliance with ICH GCP training, local	compliance with ICH GCP training, local
		compliance with ICH GCP	and ISO regulations and requirements.	local and ISO regulations and	and ISO regulations and requirements.	and ISO regulations and requirements.
		training, local and ISO		requirements.		Seeks additional training options
		regulations and				internally and externally. Mentors and
		requirements.		Seeks additional training options		provides project-related training.
				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.
						project related training.



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Subject	Engages PI and site staff in	Engages PI and site staff in discussions	Engages PI and site staff in discussions	Engages PI and site staff in discussions	Engages PI and site staff in discussions
Trial	recruitment and	discussions about ethical	about ethical recruitment and	about ethical recruitment and	about ethical recruitment and	about ethical recruitment and
Operations	retention at the	recruitment and retention	retention efforts, evaluates	retention efforts, evaluates	retention efforts, evaluates	retention efforts, evaluates
(GCPs)	investigator site	efforts, evaluates	recruitment and retention strategy and	recruitment and retention strategy	recruitment and retention strategy and	recruitment and retention strategy and
		recruitment and retention	verifies ethics committee approval of	and verifies ethics committee approval	verifies ethics committee approval of	verifies ethics committee approval of
		strategy and verifies ethics	subject-facing materials. With support,	of subject-facing materials. Is aware of	subject-facing materials. Is aware of	subject-facing materials. Is aware of
		committee approval of	gains awareness of potential	potential recruitment and retention	potential recruitment and retention	potential recruitment and retention
		subject-facing materials.	recruitment and retention challenges	challenges at the study and site level,	challenges at the study and site level,	challenges at the study and site level,
			at the study and site level, and takes	and, with minimal support, takes	and takes action to mitigate risk.	and coaches/ trains project team on
		Is aware of potential	action to mitigate risk. Identifies and	action to mitigate risk. Identifies and	Identifies and escalates issues, and	action(s) to mitigate risk. Identifies and
		recruitment and retention	escalates issues, and implements	escalates issues, and implements	implements corrective action to	escalates issues, and implements
		challenges at the study and	corrective action to recruitment.	corrective action to recruitment.	recruitment. Performs root cause	corrective action to recruitment.
		site level, and takes action			analysis and utilizes available resources	Performs root cause analysis and
		to mitigate risk.		Performs root cause analysis and	to implement corrective and	utilizes available resources to
				utilizes available resources to	preventive actions.	implement corrective and preventive
				implement corrective and preventive		actions. Serves as a resource and
				actions.	Serves as a resource and mentor to team members.	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	Identification,	Identifies the signs of	Identifies signs of suspected	Identifies signs of suspected	Identifies signs of suspected	Identifies signs of suspected
Trial	reporting and	misconduct.	misconduct and collect supporting	misconduct and collect supporting	misconduct and collect supporting	misconduct and guides the CRA in the
Operations	resolution of	Evaluate the severity of	information. Communicate suspicions	information. Communicates suspicions	information. Communicates suspicions	collection of supporting information.
(GCPs)	suspected	issues to assist in	and facts collected to stakeholders.	and facts collected to stakeholders.	and facts collected to stakeholders.	Communicate suspicions and facts
	misconduct	determining if misconduct	Seeks guidance on how to facilitate	Seeks guidance on how to facilitate	Seeks guidance on how to facilitate	collected to additional stakeholders.
		has occurred.	corrective and preventive action plan.	corrective and preventive action plan.	corrective and preventive action plan.	Coaches CRA in tactfully discussing
		Report suspected	Tactfully discusses concerns with the	Tactfully discusses concerns with the PI	Tactfully discusses concerns with the PI	·
		misconduct in compliance	principal investigator (PI) and	and implements action plan with	and implements action plan with	the misconduct and guides the CRA in
		with regulations and	implement action plan with support	limited support from stakeholders.		implementing an action plan. Provides
		company policies.	from stakeholders.			sustained support to quality groups
		Facilitates corrective action				and other stakeholders during the
		of issues.				investigation and reporting of
						misconduct. When and if necessary,
						participates in discussions with the PI.



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



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	ICH GCP	Demonstrates a working	Successfully completes initial and	Successfully completes ongoing ICH	Successfully completes ongoing ICH	Successfully completes ongoing ICH
Trial		knowledge of GCP	ongoing ICH GCP training. Performs	GCP training.	GCP training.	GCP training.
Operations		guidelines.	study responsibilites in accordance	Performs study responsibilities in	Performs study responsibilities in	Performs study responsibilities in
(GCPs)			with ICH GCP. Predicts, with assistance,	accordance with ICH GCP. Predicts,	accordance with ICH GCP. Predicts	accordance with ICH GCP. Predicts,
		Predicts possible GCP	possible GCP noncompliance based on	with minimal assistance, possible GCP	possible GCP noncompliance based on	with assistance, possible GCP
		noncompliance based on the	the trial and site complexities and	noncompliance based on the trial and	the trial and site complexities and	noncompliance based on the trial and
		trial and site complexities	manages these risks as part of a risk	site complexities and manages these	manages these risks as part of a risk	site complexities and documents these
		and manages these risks as	management plan. Monitors	risks as part of a risk management	management plan. Monitors	risks as part of a risk management
		part of a risk management	investigative sites to verify the trial is	plan. Monitors investigative sites to	investigative sites to verify the trial is	plan. Oversees monitoring of
		plan.	conducted and documented in	verify the trial is conducted and	conducted and documented in	investigative sites to verify the trial is
			accordance with ICH GCP. Escalates	documented in accordance with ICH	accordance with ICH GCP. Escalates	conducted and documented in
		Identifies and reports ICH	I -	GCP. Escalates non-compliance and	non-compliance and advises site on	accordance with ICH GCP. Escalates
		GCP non-compliance	personnel to correct areas of non-	works with site personnel to correct	creation or revision of site procedures	non-compliance and mentors junior
		discovered during		areas of non-compliance and prevent	to gain compliance and prevent	CRAs on how to advise site on creation
		monitoring activities. Takes	with support from stakeholders.	recurrence, with limited support from	recurrence.	or revision of site procedures to gain
		appropriate action designed		stakeholders.		compliance and prevent recurrence.
		to prevent recurence of			•	Conducts trend analysis and escalates
		detected deviations.			recommendations for auditing.	recommendations for auditing.
						Participates in preparing audit
					Participates in preparing audit	responses.
					responses.	
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DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Adequacy of	Tracks site approval and	Tracks site approval and expiry dates	Tracks site approval and expiry dates	Tracks site approval and expiry dates	Oversee the work of CRAs and/or
Trial	approvals or	expiry dates to anticipate	to anticipate filing and submission	to anticipate filing and submission	to anticipate filing and submission	startup personnel to verify that all
Operations	notifications to	filing and submission	timelines. Verify that the investigator	timelines. Verifies that the investigator	timelines. Verifies that the investigator	investigators provides the required
(GCPs)	Ethics	timelines.	provides all the required reports,	provides all the required reports,	provides all the required reports,	reports, notifications, applications and
	Committees/IRB		notifications, applications and	notifications, applications and	notifications, applications and	submissions, and that these documents
	s and/or	Performs review of	submissions, and that these documents	submissions, and that these documents	submissions, and that these documents	
	Regulatory	competent authority and	are accurate, complete, timely, legible,	are accurate, complete, timely, legible,		dated, and identify the trial. Based on
	Authorities	· ·	dated, and identify the trial. Able to	dated, and identify the trial. Assists	dated, and identify the trial. Assists	company division of responsibility,
		•	access and review project repository	with the preparation of Ethics	with the preparation of EC or CTA	verifies the preparation of EC or CTA
		1	for competent authority and IRB/IEC	Committee (EC) or Clinical Trial		documents are being done according
		•	documents. Reviews current	Authority (CTA) documents and		to local process, and that responses to
			documents from the repository against		company division of responsibility.	EC and/or competent authority queries
			site files to assess for any gaps in	authority queries based on company	May also be responsibile for	are completed within timelines. May
		and filed.	approval or submissions. Reports	division of responsibility. Accesses and	maitenance of changing country	also be responsibile for maintenance of
			deficiencies in approvals or	reviews project repository for	requirements for EC & competent	changing country requirements for EC
			documentation in accordance with the	, , , , , , , , , , , , , , , , , , , ,	authority directives, regulations and	& competent authority directives,
			project plan(s).	documents. Reviews current	guidelines. Accesses and reviews	regulations and guidelines. Establishes
					project repository for competent	a project repository for competent
				site files to assess for any gaps in	authority and IRB/IEC documents.	authority and IRB/IEC documents.
				approval or submissions. Creates a	Reviews current documents from the	Verifies that CRAs review current
				timeline of study activities, IRB/IEC		documents from the repository against
				approval dates, and documents	for any gaps in approval or	site files to assess for any gaps in
				approved by the IRB/IEC. Reports deficiencies in approvals or	submissions. Creates a timeline of study activities, IRB/IEC approval dates,	approval or submissions. Creates a
				documentation in accordance with the	and documents approved by the	approval dates, and documents
				project plan(s).	· · · · · · · · · · · · · · · · · · ·	approved by the IRB/IEC. Reports
					approvals or documentation in	deficiencies in approvals or
					accordance with the project plan(s).	documentation in accordance with the
					accordance with the project plants.	project plan(s).
						project plants).



Trial differing safety operations (GCPs) events and understand the reporting requirements of each occur. During study, identifies safety events and verifies safety events and verifies safety events are reporting in accordance with last events have been appropriately reported. Trial differing safety differing safety events that occur during clinical trials. Identifies, in advance of study initiation, anticipated safety 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 processes. Identifies, with assistance, anticipated safety events and verifies safety events and verifies safety events are reporting in accordance with been appropriately reported. Safety events that occur during clinical trials. Identifies, in advance of study initiation, anticipated safety events, their reporting timeframes, and reporting processes. Identifies, with assistance, anticipated safety events are records and medical charts for guidance, anticipated safety events that may occur. Reviews source records and medical charts for guidance, anticipated safety events that may occur. Reviews source records and medical charts for untoward medical charts for untoward medical events. Confirms that events have been appropriately manner. Identifies project-specific	
differing safety events and understand the reporting requirements of each occur. During study, identifies safety events and verifies safety events and verifies safety events and verifies safety events are reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s). Trial differing safety events and differing safety events and understand the reporting understand the reporting understand the reporting in accordance of study initiation, anticipated safety events that may occur. Reviews source records and medical charts for untoward medical events. Confirms that events have been appropriately events that may occur. Reviews source records and medical charts for untoward medical events. Confirms that events have been appropriately events 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, in advance of study initiation, anticipated safety events, and other safety events, their reporting timeframes, and reporting processes. Identifies, with animinal 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. Trial durifies, in advance of study initiation, anticipated safety events at the reporting and brings these issues to the attention of the 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. Trial durifies, in advance of study initiation, 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	RA team is clear on the
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these issues to the attention of the	



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



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Audit and	Preparation, participation,	Reviews and follows company provided	Reviews and follows company provided	Reviews and follows company provided	Reviews and follows company provided
Trial	inspection	documentation and follow-	instruction for the role that will be	instruction for the role that will be	instruction for the role that will be	instruction for the role that will be
Operations	processes	up of audits and/or	performed in the audit and/or	performed in the audit and/or	performed in the audit and/or	performed in the audit and/or
(GCPs)		inspections. Support	inspection. Provides assistance as	inspection. Provides assistance as	inspection. Provides assistance as	inspection. Provides assistance as
		resolution of Corrective And	requested within the scope of the role.	requested within the scope of the role.	requested within the scope of the role.	requested within the scope of the role.
		Preventive Actions (CAPA)	Assist in the development of	Assist in the development of	1	Verify the completeness and accuracy
		resulting from site audits or	appropriate risk mitigation plan,	appropriate risk mitigation plan,		of risk mitigation plan, demonstrating
		inspections.		demonstrating corrective and	mitigation plan, demonstrating	corrective and preventive action with
			1,	preventive action with follow up and	corrective and preventive action with	follow up and within identified
				within identified timelines with limited	follow up and within identified	timelines. Communicate with site
			support. Communicate with site	support. Communicate with site	timelines. Communicate with site	personnel, QA and project leadership.
			personnel, QA and project leadership.	personnel, QA and project leadership.	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.
						when applicable to the project team.



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Understands	Verifies that the investigator	Performs interview with site staff and	Performs interview with site staff and	Performs interview with site staff and	Verifies the CRA team understands the
Trial	the roles and	has adequate qualifications	PI, examines equipment, patient	PI, examines equipment, patient	PI, examines equipment, patient	trial requirements for site and
Operations	responsibilities	and resources and these	population as it pertains to the	population as it pertains to the	population as it pertains to the	investigator adequacy. Performs
(GCPs)	and	remain adequate	protocol and facility and makes a	protocol and facility and makes a	protocol and facility and makes a	interview with site staff and PI,
	relationships	throughout the trial period,	determination about acceptability for	determination about acceptability for	determination about acceptability for	examines equipment, patient
	between the	and that the staff and	the trial. Reviews site policies and	the trial. Reviews site policies and	the trial. Reviews site policies and	population as it pertains to the
	CRA and	facilities, including	practices for adherence to the protocol	practices for adherence to protocol	practices for adherence to protocol	protocol and facility and makes a
	Investigators,	laboratories and equipment,		and ICH-GCP prior to and throughout		determination about acceptability for
	sponsor and	are adequate to safely and	the study. Conducts ongoing review of	, ,	,	the trial. Reviews site policies and
		properly conduct the trial	site staff, facilities and study	site staff, facilities and study	site staff, facilities and study	practices for adherence to protocol
	GCP	and these remain adequate	documentation to verify staff and	documentation to verify staff and	· ·	and ICH-GCP prior to and throughout
		throughout the trial period.		facilities remain adequate to perform		the study. Oversees initial and ongoing
		Develops risk mitigation		the trial. When inadequacy is		review of site staff, facilities and study
		· · · · · · · · · · · · · · · · · · ·	identified, communicate the deficiency		,	documentation to verify staff and
			·	to stakeholders and implement	deficiencies were noted. When	facilities remain adequate to perform
			corrective action with support.	corrective action with minimal	inadequacy is identified, communicate	
		resources.		support.	•	and regulatory audit documents if
					implement corrective action.	deficiencies were noted. Mentors
						others on site suitability. When
					Mentors junior CRAs on assessing	inadequacy is identified, communicate
					investigator site adequacy and	the deficiency to stakeholders and
					achieving compliance.	implement corrective action.
						Davisson and a dations from CDA
						Review recommendations from CRAs
						and participate in the site selection
						process.
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DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	The		Performs source data review (SDR) and			Confirms source data review (SDR) and source
Trial	requirements		` '	· ,	source data verification (SDV) of critical	data verification (SDV) of critical data, as per the
	for accurate and		data, as per the monitoring plan, to	data, as per the monitoring plan, to	data, as per the monitoring plan, to	monitoring plan, to verify the site is collecting
(GCPs)	complete site	data, as per the monitoring			verify the site is collecting attributable,	attributable, legible, contemporaneous, original and accurate (ALCOA) data. Evaluates site
(source	plan, to verify the site is	legible, contemporaneous, original and	legible, contemporaneous, original and	legible, contemporaneous, original and	procedures to confirm CRA direct access to all
	documents.	l' '	accurate (ALCOA) data. Evaluates site	accurate (ALCOA) data. Evaluates site	accurate (ALCOA) data. Evaluates site	source data. Follows approved procedures when
	Verification that		procedures to confirm CRA direct	procedures to confirm CRA direct	procedures to confirm CRA direct	direct access to source data is not available (i.e.
	data reported in	Termagic data.	access to all source data. Follows	access to all source data. Follows	access to all source data. Follows	certified copies with electronic medical records). Uses critical thinking to review subject charts and
	the CRF is		approved procedures when direct	approved procedures when direct	approved procedures when direct	supplemental source documentation to
	consistent with		access to source data is not available	access to source data is not available	access to source data is not available	determine the accuracy and completeness of
	source		(i.e. certified copies with electronic	(i.e. certified copies with electronic	(i.e. certified copies with electronic	data generated for the study. Documents status
	documentation.			· ·	medical records). Uses critical thinking	of review for each subject visit. Writes queries to
	aocamentation.		to review subject charts and	to review subject charts and	to review subject charts and	address inconsistencies with protocol and GCP requirements. Initiates follow-up actions to
				,	supplemental source documentation to	
			determine the accuracy and	determine the accuracy and	determine the accuracy and	identify non-compliance and implement
			•	completeness of data generated for	completeness of data generated for	corrective actions. Mentor junior CRAs on the
			the study. Documents status of review	'	the study. Documents status of review	requirements for source documents.
			•	for each subject visit. Writes queries	for each subject visit. Writes queries	Serves as the point of escalation when issues
			to address inconsistencies with	to address inconsistencies with	to address inconsistencies with	arise with source documents at sites including
			protocol and GCP requirements.	protocol and GCP requirements.	protocol and GCP requirements.	access requirements, direct access to source data
				Initiates follow-up actions to assist site	Initiates follow-up actions to assist site	and systems, site staff compliance and closure of issues.
			in achieving compliance. Able to	in achieving compliance. Able to	in achieving compliance. Able to	issues.
			identify non-compliance and	identify non-compliance and	identify non-compliance and	Verifies CRAs are reviewing and reporting on all
			implement corrective actions with	implement corrective actions with	implement corrective actions.	necessary documentation per protocol
			' ·	limited support.	Implement corrective actions.	requirements.
			support.	innited support.	Mentor junior CRAs on the	Documents the expectations for source
					_	documents that CRAs are to review in the
					requirements for source documents.	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.
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DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Plans and	Plans, conducts and	Adheres to monitoring plan, standard			
Trial	conducts all	completes follow-up	operating procedures, and any other			
Operations	types of	activities for on-site and/or	written procedures in reference to			
(GCPs)	monitoring	remote qualification,	conducting all types of monitoring	conducting all types of monitoring	conducting all types of monitoring	overseeing that all types of monitoring
	visits.	initiation, interim, central	visits. Receives guidance and	visits independently.	visits independently.	visits are being performed. When not
		and close-out visits	mentoring to manage complex issues.			possible to meet deliverables, informs
		according to written		Manages complex issues with limited	Capable of managing complex issues.	appropriate team/manager and
		procedures.		support. When not possible to meet	When not possible to meet	develops contingency plans as
				deliverables, informs appropriate	deliverables, informs appropriate	necessary. Mentors junior CRAs in
				team/manager.	team/manager.	planning and conducting monitoring
						visits.
					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.
						data integrity.
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DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Time	Evaluates assignments and	Evaluates assignments, effectively	Evaluates assignments, effectively	Evaluates assignments, effectively	Evaluates assignments, effectively
Trial	Management	effectively prioritizes and	prioritizes and manages work activities	prioritizes and manages work activities	prioritizes and manages work activities	prioritizes and manages work activities
Operations	and	manages work activities	according to study plans.	according to study plans.	according to study plans.	according to study plans and needs.
(GCPs)	Prioritization of	according to study plans.	Communicates visit activities to	Communicates visit activities to	Communicates visit activities to	Communicates activities to
	Work		stakeholders so that an assessment of	stakeholders so that an assessment of	stakeholders so that an assessment of	stakeholders so that an assessment of
			activity level can be monitored and	activity level can be monitored and		activity level can be monitored and
				forecasted. Shares concerns and		forecasted. Shares concerns and
			requests additional resources to	requests additional resources to	requests additional resources to	requests additional resources to
			internal team to achieve on-time	internal team to achieve on-time	internal team to achieve on-time	internal team to achieve on-time
			deliverables.	deliverables.	deliverables. Volunteers to help in downtime.	deliverables.
				Volunteers to help in downtime. Seeks	downtime.	Effectively assigns sites to CRAs to
				guidance for alternate site		manage budget, geographical, and
				assignments.	assignment changes.	experiential needs.



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



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Clinical	Verifies that	Verifies site staff knowledge				Verifies site staff knowledge and ability
Trial	third party	and ability to properly		to properly collect, transfer and store	to properly collect, transfer and store	to properly collect, transfer and store
Operations	vendor data is	collect, transfer and store	study data for third party study	study data for third party study	study data for third party study	study data for third party study
(GCPs)	appropriately	study data for third party	vendors. Identifies potential areas of	vendors. Identifies potential areas of	vendors. Identifies potential areas of	vendors. Assists in the development of
	collected,	study vendors. Identifies	risk and develops risk mitigation plans,	risk and develops risk mitigation plans,	risk and develops risk mitigation plans,	processes and tools to verify proper
	transferred, and stored.	potential areas of risk and develops risk mitigation plans, as needed, to address areas of identified risk.		as needed, with minimal support to address areas of identified risk.	as needed, to address areas of identified risk.	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	IP	Verifies IP accountability.	Verifies randomization process by	Verifies randomization process by	Verifies randomization process by	Confirms CRA team knows and verifies
Trial	Accountability	Reviews IP records and	ensuring dispensing procedures are	ensuring dispensing procedures are	ensuring dispensing procedures are	randomization processes and IP
Operations		reconciles with subject	compliant with IB and instructions for	compliant with IB and instructions for	compliant with IB and instructions for	instructions for use. Oversees CRAs to
(GCPs)		records. Reviews IB	use. Verifies adequate IP supplies, and	use. Verifies adequate IP supplies, and	use. Verifies adequate IP supplies, and	verify adequate IP supplies, storage,
		reference material.			reviews storage, including temperature	
			logs, when needed, Confirms IP is kept	,	logs, when needed, Confirms IP is kept	
			in a secure location and adheres to the		in a secure location and adheres to the	·
				requirements for storage. Reviews IP		site issues regarding IP. Identifies,
			1	records and reconciles with all subject	,	escalates and implements corrective
			records and system of record, performs compliance calculations. Identifies,	compliance calculations. Identifies,	compliance calculations. Identifies,	escalates trends related to IP.
			1	escalates and implements site	escalates and implements site	escalates trends related to IF.
			corrective action for IP issues.	corrective action for IP issues with	•	Develops action plan to correct IP
				limited support.	identifies and escalates trends related	issues.
					IP issues.	
					Mentors junior CRAs on IP	
					accountability processes and	
					verification.	



Circlea of custod Reviews and verifies or site supplies against shipping records and/or system of labeling, storage, dispensing crocks. Record	DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
labeling, storage, dispensing records, return or final disposition of IP. labeling, storage, dispensing records, return or final disposition of IP. labeling, storage, 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. labeling, storage, dispensing records. Review documentation of return or final disposition of IP. labeling, storage, 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. labeling, storage, 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 limited support. labeling, storage, 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. labeling and verify IP 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. labeling are 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. labeling are 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 issu	Clinical	IP Chain of custo	Reviews and verifies	Verifies on site supplies against			Verifies CRA team verifies on site
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. 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. 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. 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. Develops action plan to correct IP issues. Mentors junior CRAs on requirements	Trial		documentation of receipt,	shipping records and/or system of	shipping records and/or system of	shipping records and/or system of	supplies against shipping records
disposition of IP. 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. 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 limited support. 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. 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. Develops action plan to correct IP issues. Mentors junior CRAs on requirements	Operations		labeling, storage, dispensing	record. Reconcile site supply with	record. Reconcile site supply with	record. Reconcile site supply with	and/or system of record; reconciles
disposition. Identify expiring IP using product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues with support. disposition. Identify expiring IP using product labeling and verify IP replacement. Identifies, escalates, and implements site corrective action for IP issues with limited support. disposition. Identify expiring IP using product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues with limited support. 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. Develops action plan to correct IP issues. Mentors junior CRAs on requirements	(GCPs)		records, return or final	dispensing records. Review	dispensing records. Review	dispensing records. Review	site supply with dispensing records;
product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues with support. product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues with limited support. product labeling and verify IP replacement. Identifies, escalates, and implements corrective action for IP issues. Identifies emerging trends for IP issues and escalates. Identifies emerging trends for IP issues and escalates. Develops action plan to correct IP issues. Mentors junior CRAs on requirements			disposition of IP.	documentation of return or final	documentation of return or final		
replacement. Identifies, escalates, and implements corrective action for IP issues with support. replacement. Identifies, escalates, and implements corrective action for IP issues with limited support. 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. Mentors junior CRAs on requirements.				, , , ,	, , , ,	, , , ,	, , , , , ,
implements corrective action for IP issues with support. implements site corrective action for IP issues. implements corrective action for IP issues. implements corrective action for IP issues. Identifies emerging trends for IP issues and escalates. Develops action plan to correct IP issues. Mentors junior CRAs on requirements					· · · · · · · · · · · · · · · · · · ·		
issues with support. issues with limited support. issues. Identifies emerging trends for IP issues and escalates. Develops action plan to correct IP issues. Mentors junior CRAs on requirements				1 .	•	1 .	·
Identifies emerging trends for IP issues and escalates. Develops action plan to correct IP issues. Mentors junior CRAs on requirements				l ·	•	•	l ·
Identifies emerging trends for IP issues and escalates. Develops action plan to correct IP issues. Mentors junior CRAs on requirements				issues with support.	issues with limited support.	issues.	
and escalates. Develops action plan to correct IP issues. Mentors junior CRAs on requirements							issues and escalates.
issues. Mentors junior CRAs on requirements							
Mentors junior CRAs on requirements						and escalates.	· · · · · · · · · · · · · · · · · · ·
							issues.
						for documented chain of custody of IP.	



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



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Study and	Assessment of	Assesses study protocol	Assesses study protocol activities to	Assesses study protocol activities to	Assesses study protocol activities to	Assesses study protocol activities to verify
Site	PI Qualification	activities to verify trial	verify trial records are accurate,	verify trial records are accurate,	verify trial records are accurate,	trial records are accurate, complete and
Manageme	and Resources	records are accurate,	complete and current. Confirms the PI	complete and current. Confirms the PI	complete and current. Confirms the PI	current. Confirms the PI or delegated staff
nt		complete and current.	or delegated staff member has	or delegated staff member has	Tor delegated starr member has	member has performed and documented
		Confirms the PI or delegated	performed and documented all	performed and documented all	performed and documented all	all activities. Throughout the trial,
		staff member has performed	activities. Throughout the trial,	activities. Throughout the trial,	activities. Throughout the trial,	evaluates investigator and site staff for
		and documented all	evaluates investigator and site staff for	evaluates investigator and site staff for	evaluates investigator and site staff for	qualification and training, provides study-
		activities. Throughout the	qualification and training, provides	qualification and training, provides	qualification and training, provides	specific training and inspects facilities to confirm adequacy. Evaluates compliance
		trial, evaluates investigator	study-specific training and inspects	study-specific training and inspects	Ictudy enocific training and increases	with the protocol and GCP and
		and site staff for	facilities to confirm adequacy.	facilities to confirm adequacy.	facilities to confirm adequacy.	investigator engagement and revises the
		qualification and training,	Evaluates compliance with the protocol		Evaluates compliance with the protocol	risk mitigation plans as necessary based
		provides study-specific	and GCP and investigator engagement	and GCP and investigator engagement	and GCP and investigator engagement	on performance. Verifies documentation
		training and inspects	and revises, with guidance, risk	and revises, with minimal guidance,	and revises the risk mitigation plans as	of investigator oversight and delegation.
		facilities to confirm	mitigation plans as necessary based on	risk mitigation plans as necessary	necessary based on performance.	Evaluates the PI's availability to meet to
		adequacy. Evaluates	performance. Verifies documentation	based on performance. Verifies		discuss study progress, understanding of
		compliance with the	of investigator oversight and	documentation of investigator	oversight and delegation. Evaluates the	the study protocol, status of all subjects,
		protocol and GCP and	delegation. Evaluates the PI's	oversight and delegation. Evaluates the	•	applicable regulations, and ICH-GCP and
				PI's availability to meet to discuss study		overall level of involvement in implementing compliance. Identifies and
			, , , , , , , , , , , , , , , , , , , ,	progress, understanding of the study	protocol, status of all subjects,	escalates issues and implements
		mitigation plans as	protocol, status of all subjects,	protocol, status of all subjects,	applicable regulations, and ICH-GCP	corrective action. Performs root cause
		necessary based on	applicable regulations, and ICH-GCP	applicable regulations, and ICH-GCP	and overall level of involvement in	analysis, evaluates process gaps and uses
		performance. Verifies	and overall level of involvement in	and overall level of involvement in	implementing compliance. Identifies	available resources to develop and
		documentation of	implementing compliance. Identifies	implementing compliance. Identifies	and escalates issues and implements	implement corrective and preventive
		investigator oversight and	and escalates issues and implements	and escalates issues and implements	corrective action. Performs root cause	actions. Serves as a resource and mentor
		delegation. Evaluates the	corrective action.	corrective action.	analysis, evaluates process gaps and	to team members.
		PI's availability to meet to			uses available resources to develop	
		discuss study progress,		Performs root cause analysis and	and implement corrective and	Instructs and guides team through
		understanding of the study		utilizes available resources to	preventive actions.	problem solving and mobilizes team to
		protocol, status of all		implement corrective and preventive	6	intended goals and solutions.
		subjects, applicable		actions.	Serves as a resource and mentor to	Assesses applicability of issues and
		regulations, and ICH-GCP			team members.	solutions across study.
		and overall level of				
		involvement in				Engages in risk management with internal
		implementing compliance.				and external stakeholders.
		Identifies and escalates				
		issues and implements corrective action.				
		CONTECUIVE ACTION.				
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DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
	Critical Data &	Performs data review		Performs data review utilizing system		Performs data review utilizing system
Manageme	Processes	utilizing system of record to	of record to identify and mitigate	of record to identify and mitigate	of record to identify and mitigate	of record to identify and mitigate
nt and		identify and mitigate	potential issues and risks. With	potential issues and risks. Analyzes	potential issues and risks. Has an	potential issues and risks. Knows the
Informatics		potential issues and risks.	support, begins to develop an	data trends and site performance	awareness of the interrelatedness of	interrelatedness of study systems and
		Has an awareness of the	awareness of the interrelatedness of	metrics. Communicates with	study systems and analyzes data trends	analyzes data trends to direct future
		interrelatedness of study	study systems and analyzes data trends	centralized monitoring team members.	to direct future monitoring actions.	monitoring actions. Executes
		systems and analyzes data	to direct future monitoring actions.	References risk assessment	Communicates with centralized	communication plan with centralized
		trends to direct future	Communicates with centralized	documentation to anticipate and	monitoring team members. References	monitoring team members and/or
		monitoring actions.	monitoring team members. References	mitigate potential issues. Identifies and	risk assessment documentation to	onsite monitoring team members.
		Communicates with	risk assessment documentation to	escalates issues and implements	anticipate and mitigate potential	References risk assessment
		centralized monitoring team	anticipate and mitigate potential	corrective action preventive plan.	issues.Identifies and escalates issues	documentation to anticipate and
		members. References risk	issues. Identifies and escalates issues		and implements corrective action	mitigate potential issues.Identifies and
		assessment documentation	and implements corrective action	Performs root cause analysis and	1.	escalates issues and implements
		to anticipate and mitigate	preventive plan.	utilizes available resources to	analysis and utilizes available resources	corrective action preventive plan.
		potential issues.		implement corrective and preventive	to implement corrective and	Performs root cause analysis and
				actions.	preventive actions.	utilizes available resources to
						implement corrective and preventive
					Serves as mentor and resource to team	actions. Serves as mentor and resource
					members.	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.
		1	<u>l</u>	<u>l</u>		



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Data	Query Issuance	Writes clear, concise and	Writes clear, concise and directed			
Manageme	and Resolution	directed queries that comply	queries that comply with ICH-GCP.			
nt and		with ICH-GCP.	Works with site staff to facilitate			
Informatics		Works with site staff to	effective query resolution processes			
		facilitate effective query	and timeline compliance. Maintains			
		resolution processes and	effective communication with site staff			
		timeline compliance.	to resolve queries and escalate issues.			
					Provides detailed query reports/status	Provides detailed query reports/status
				Provides detailed query reports/status	to site staff.	to site staff. Understands, escalates
				to site staff.		and resolves issues regarding study
					Understands, escalates and resolves	progress and data delivery per
					issues regarding study progress and	timelines. Performs root cause analysis
					* *	of data quality, evaluates process gaps
						and uses available resources to
					Performs root cause analysis of data	develop and implement corrective and
					quality, evaluates process gaps and	preventive actions.
					uses available resources to develop	
					and implement corrective and	Creates and provides detailed query
					preventive actions.	metrics to project stakeholders.
						Englished and advantage
						Evaluates query trends and solutions to
						mitigate risk.
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1						
1						



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Data	Clinical Trial	Demonstrates competency			Demonstrates competency with clinical	
Manageme	Systems of	with clinical trial systems of	trial systems of record and reports on	trial systems of record and reports on	trial systems of record and reports on	trial systems of record and reports on
nt and	Record	record and reports on site	site and project metrics accurately and	site and project metrics accurately and	site and project metrics accurately and	site and project metrics accurately and
Informatics		and project metrics		on time. Produces and uses site and	on time. Produces and uses site and	on time. Produces and uses site and
		accurately and on time.	project reports to expedite processes	project reports to expedite processes	project reports to expedite processes	project reports to expedite processes
			and task completion.	and task completion.	and task completion. Serves as	and task completion. Serves as
						resource and mentor to team members
				Serves as resource and mentor to team	' '	
				members to answer questions about system best practices.	practices.	practices.
				system sest 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	Compliance	Completes and documents	Confirms that site systems used for	Confirms that site systems used for	Confirms that site systems used for	Confirms that site systems used for
Manageme	with Electronic	regulatory compliance	study conduct are assessed for study	study conduct are assessed for study	study conduct are assessed for study	study conduct are assessed for study
nt and	Record	assessment	use and compliant with ICH GCP.	use and compliant with ICH GCP.	use and compliant with ICH GCP.	use and compliant with ICH GCP.
Informatics	Requirements		Verifies system access is well	Verifies system access is well	Verifies system access is well	Verifies system access is well
	and Regulations		controlled. Identifies and escalates	controlled. Identifies and escalates	controlled. Identifies and escalates	controlled. Identifies and escalates
			issues and implements corrective	issues and implements corrective	issues and implements corrective	issues and implements corrective
			action.	action.	action. Performs root cause analysis,	action. Performs root cause analysis,
					evaluates process gaps and uses	evaluates process gaps and uses
				Performs root cause analysis, evaluates	1	available resources to develop and
				process gaps and uses available	implement corrective and preventive	implement corrective and preventive
				resources to develop and implement	actions.	actions.
				corrective and preventive actions.		
						Assesses applicability of solutions
						across study.



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



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



DOMAIN	COMPETENCY	EXPECTATION	ENTRY-LEVEL MONITOR	INTERMEDIATE MONITOR	SENIOR MONITOR	CLINICAL LEAD
Leadership	Professional	Demonstrates and projects		Demonstrates and projects	Demonstrates and projects	Demonstrates and projects
and	Behavior	professional demeanor and	professional demeanor and	professional demeanor and	professional demeanor and	professional demeanor and
Profession		communications consistent	communications consistent with	communications consistent with	communications consistent with	communications consistent with
alism		with organizational policies	organizational policies and practices.			
		and practices	Behaves in ways that demonstrate and	Behaves in ways that demonstrate and	Behaves in ways that demonstrate and	•
			1	foster personal initiative, critical	foster personal initiative, critical	foster personal initiative, critical
				thinking and trustworthiness. Remains	9	thinking and trustworthiness. Remains
			accountable to and positively engaged	accountable to and positively engaged		accountable to and positively engaged
			with others. Demonstrates	with others. Demonstrates		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
Communic	Relationship		Communicates to effectively resolve	Communicates to effectively resolve		Communicates to effectively resolve
ation and	and	resolve compliance issues.	compliance issues. Provides clear and			
Teamwork	Communication	Provides clear and	technically accurate information and	technically accurate information and	technically accurate information and	technically accurate information and
	with Clinical	technically accurate	instructions, both orally and in writing.			
	Study Team	information and	•	Maintains timely communication.	•	Maintains timely communication.
		instructions, both orally and	Engages in effective discussions.			
	Investigative	in writing. Maintains timely		Demonstrates attentive and active		Demonstrates attentive and active
	Site Staff	communication. Engages in	listening. Abides by communication			
		effective discussions.	plan and pathway.	plan and pathway.	plan and pathway.	plan and pathway.
		Demonstrates attentive and				
		active listening. Abides by				Confirms team members comply with
		communication plan and				professional communication standards.
		pathway.				

