Medical Services in Clinical Studies
Snapshot

MEDICAL SERVICES	DESCRIPTION of the SERVICE
Medical Management	
Oversight Medical, Safety and Scientific aspects of Phase I – IV Projects	Assume overall responsibility of medical, safety and scientific aspects of a clinical research project as from the design stage till final completion of the project. Contributing to the global study management and the asssurance scientific integrity via providing medical and safety expertise
Development of Study Concepts and Design of Clinical Trials	Development of research concepts and study design for either indivdual clinical trials of various phases and objectives or a complete development program
Medical Expertise for DSMB, IRC and Steering Committee	Contributing to the global study management and the assurance scientific integrity via providing medical and safety expertise as external expert or as part of steering committee, Independent Data Review Committee or Data Safety Monitoring Boards
Medical Monitoring	
24/7 Medical Monitoring	Monitoring the medical and scientific conduct of the study across the clock (during both business nad non-business hours) to ensure patient safety, ethical study conduct and scientific integrity of the study data via strict compliance with approved study protocol and applicable laws and regulations.
Medical and Scientific Support to Study Sites and Project Teams	Provide expert opinion and continuous support to various stakeholders in the study including study teams and investigation sites with regard to medical and scientific aspects of a study to ensure patient safety, ethical study conduct and scientific integrity of the study data via strict compliance with approved study protocol and applicable laws and regulations
Response to Queries and Interaction with Investigators, IRBs, ECs and Authorities	
Regular Review of Study Data	
Medical Input and Documents Review	
CTP, ICF, CRF, CSR and IBD	
Scientific Publications and Marketing and Promotional Materials	
Medical Review of Clinical and Safety Data	
AEs, Concomitant Medications and Lab Results	
Medical Review of Data Listings, Validation and Coding	
Review of TFLs	
Medical Review of SAEs	
Medical Review of Event Narratives	

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STUDY PHASE	ACTIVITY	SPECIFIC TASKS
Development Phase	Study Design	Studying the safety and development profile of IMP
		Development of synopsis in collaboration with involved stakeholders
		Meetings, interaction and consultation with KOLs
		Study team meetings and discussions on synopsis
	Development of key documents	Synopsis review and finalization
		Protocol development meetings
		Protocol draft review, comments and re-reviews
		IB Update (if required)
		ICF review and finalization
	Business Partners	"Meetings for selecting vendors and study partners"
		Review of proposols
		Attending bid defenses (if required)
		Review and finalization of contracts
Set-up Phase	Regulatory support	Drafting responses to CA/EC queries
	Study Documents Development	Medical Management Plan (MMP): Draft, comments review, finalization
		Safety Management Plan (SMP) review, SAE/AESI/ Pregnancy report template review
		PD Guidance document: Draft, comments and finalization
		PD report, Log development
		Review of annotated CRF, CRF completion guidelines and participate in UAT
		Data Management Plan (DMP) review and comments
		Data validatioln plan (DVP) review and comments
		Medical Review Plan (MRP) draft, comments and finalization
		Eligibility Checklist draft, comments and finalization
		Patient Profiles template draft, comments and finalization
		Medical listings template draft, comments and finalization
		Narratives template and categories draft, comments and finalization

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STUDY PHASE	ACTIVITY	SPECIFIC TASKS
		SAP review and comments
	Study Team Training	Investigator Meetings
		Site visits (as required)
		CRA trainings (as required)
Study Conduct Phase	Guidance Management	Answering Site and Team questions
		Q&A Logs review
	Eligibility Review	Eligibility checklist & Log Review
	PD Management	PD reports review and sign off
		PD Logs review
	Periodic Data Review	Periodic Patient Profiles and Medical Listings review, Medical Query Tracker review and update
		Periodic study team meetings
	Safety Review	Periodic Safety Report development
		SAE Review
		CIOMS/SAE Narrative Review
		DSUR Review (as required)
Close-out Phase	Data Review & Cleaning	Aggregate and patient profile reviews, Queries tracker review
	Narratives Review	Narratives review (DMC/CSR)
		Queries Tracker review
		Narratives Finalization
	TLFs Review	Mock TLFs Review
		Comments Review/Meeting
		Final TLFs Review
	Clinical Study Report	Draft CSR Review
		Comments Review/Meetings
		Final CSR Review

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