Policies

All Policies

- 100 Quality Management System Policy
- 101 Good Documentation Practices Policy
- 102 Audit Policy
- 103 Training Policy
- 104 Corrective and Preventive Action Policy
- 105 Quality System Requirements for Vendors Manufacturing Investigational Product Policy
- 201 Qualified Medical Expertise Policy
- 202 Protocol Development Policy
- 203 Clinical Trial Records Policy
- 204 Investigator's Responsibility Policy
- 205 Clinical Site Monitoring Policy
- 206 Clinical Site Activation Policy
- 207 Continuity of Operations Policy
- 208 Multicenter Clinical Trial Policy
- 301 Serious Adverse Events Reporting Policy
- 302 Implementing Sponsor-Initiated Temporary Clinical Holds Policy
- 303 Interim Analysis Reporting Policy
- 305 Sponsor Determination of Expectedness Policy
- 306 Independent Data and Safety Oversight Policy
- 401 Conflict of Interest Policy
- 402 Regulatory Compliance & File Management Policy
- 403 Oversight by Institutional Review Board Policy
- 404 Manufacturer Expanded Access Policy
- 405 Posting to ClinicalTrials.gov Policy
- 406 Selection of IND or IDE Regulatory Filing Policy
- 407 Communications with the FDA Policy
- 408 Determining When to Prepare an Investigator's Brochure Policy
- 409 Single Patient Expanded Access Policy
- 410 Final Clinical Study Reports for Studies under CCR-held INDs or IDEs Policy
- 411 Emergency Exceptional Release of Product Policy
- 412 Responding to FDA Clinical Holds Policy
- 502 Investigational Product Stability Studies Policy
- 503 Oversight of Investigational Product Shipments Policy

Policy Updates

Quarter	Date	Change	Policy
2024 Q1	03/27/24	Revision	207 Continuity of Operations Policy
	03/27/24	Revision	202 Protocol Development Policy
	03/21/24	Revision	204 Investigator's Responsibility Policy
	03/21/24	Revision	201 Qualified Medical Expertise Policy
	03/12/24	Revision	306 Independent Data and Safety Oversight Policy
	03/06/24	Revision	301 Serious Adverse Events Reporting Policy
	02/13/24	Revision	206 Clinical Site Activation Policy
	01/31/24	Revision	402 Regulatory Compliance & File Management Policy
	01/31/24	Revision	403 Oversight by Institutional Review Board Policy
	01/31/24	Revision	404 Manufacturer Expanded Access Policy
	01/31/24	Revision	407 Communications with the FDA Policy
	01/31/24	Revision	408 Determining When to Prepare an Investigator's Brochure Policy
	01/24/24	Revision	203 Clinical Trial Records Policy
	01/24/24	Revision	401 Conflict of Interest Policy
	01/10/24	Revision	410 Final Clinical Study Reports for Studies under CCR-held INDs or IDEs Policy
	01/05/24	Revision	104 Corrective and Preventive Action Policy
	01/05/24	Revision	103 Training Policy
	01/05/24	Revision	102 Audit Policy
	01/05/24	Revision	101 Good Documentation Practices Policy
2023 Q4	11/08/23	New Policy	503 Oversight of Investigational Product Shipments Policy

	11/08/23	New Policy	502 Investigational Product Stability Studies Policy
2023 Q3	09/18/23	Revision	303 Interim Analysis Reporting Policy
	09/08/23	New Policy	412 Responding to FDA Clinical Holds Policy
	09/06/23	New Policy	302 Implementing Sponsor-Initiated Temporary Clinical Holds Policy
	08/01/23	Revision	405 Posting to ClinicalTrials.gov Policy
	07/26/23	Revision	100 Quality Management System Policy
	07/25/23	New Policy	305 Sponsor Determination of Expectedness Policy
2023 Q2	05/04/23	Revision	105 Quality System Requirements for Vendors Manufacturing Investigational Product Policy
2023 Q1	03/31/23	Revision	203 Clinical Trial Records Policy
	03/16/23	Revision	406 Selection of IND or IDE Regulatory Filing Policy
	01/30/23	Revision	206 Clinical Site Activation Policy
2022 Q4	12/30/22	Revision	203 Clinical Trial Records Policy
	12/19/22	Revision	306 Independent Data and Safety Oversight Policy
	11/17/22	Revision	409 Single Patient Expanded Access Policy
	11/16/22	Revision	301 Serious Adverse Events Reporting Policy
	11/14/22	Revision	208 Multicenter Clinical Trial Policy
	11/04/22	Revision	205 Clinical Site Monitoring Policy