Loft Company

Report: GCP
Loft Company GCP + Core Questions + Audit + Advanced + Sponsor Specific

v1.0.2026-11-14

Created: 2026-11-13 23:03
Closed: 2026-11-13 23:18
Answered: 99%

Compliance Score:

98%

(493/500)

Almost all requirements met; very low risk.
A very little uncertainty due to small fraction of measuring points not addressed.

Top Risks:

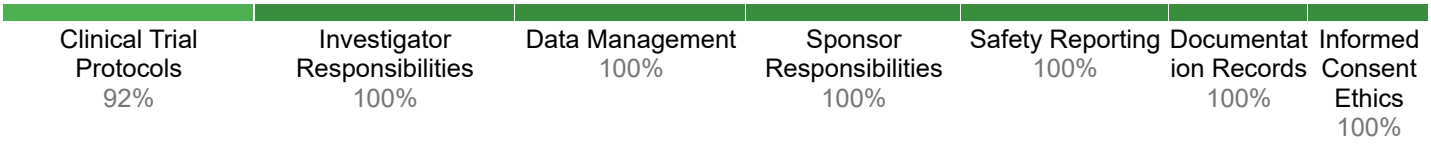
Clinical Trial Protocols – 30% Compliant
1. Are protocol amendments documented, justified, and reviewed during audits? Unanswered
Criticality: Medium

Clinical Trial Protocols – 30% Compliant
2. Are clinical trial protocols reviewed and approved by an independent ethics committee before study initiation? Partially
Criticality: High

Compliance By Section:

Clinical Trial Protocols	92%	Informed Consent Ethics	100%	Investigator Responsibilities	100%
Sponsor Responsibilities	100%	Data Management	100%	Safety Reporting	100%
Documentation Records	100%				

Sections, Weighted



Compliance by Criticality

Criticality	Measurement Points	Yes	Partially	No	Missing	Compliance %
High	50	49	1	0	0	99 %
Medium	50	49	0	0	1	98 %
Total	**100**	**98**	**1**	**0**	**1**	**98 %**

Criticalities, Weighted

Clinical Trial Protocols

Clinical Trial Protocols ensure that studies are scientifically sound, ethically designed, and conducted according to approved protocols and regulatory standards.

Are clinical trial protocols reviewed and approved by an independent ethics committee before study initiation?	**Partially**

Criticality: High

Are protocol amendments documented, justified, and reviewed during audits?	**Unanswered**

Criticality: Medium

Are deviations from the approved protocol documented and addressed appropriately?	**Yes**

Criticality: High

<< The rest of this section is left out in this sample/preview >>

Recommendations:

Clinical Trial Protocols

Clinical Trial Protocols ensure that studies are scientifically sound, ethically designed, and conducted according to approved protocols and regulatory standards.

1. Review and approve clinical trial protocols by an independent ethics committee before study initiation.

Criticality: High

2. Document, justify, and review protocol amendments during audits.

Criticality: Medium

Compliance Score: 98% (493/500)
Almost all requirements met; very low risk.