

RACI / Responsibility Matrix

Clinical Trial Pathology Responsibility Matrix

Activity	SMY Pathology Consulting, LLC	Precipio (CLIA/CAP Lab)	Sponsor / CRO
Study pathology strategy	R	I	A
Protocol pathology input	R	I	A
Specimen accessioning	I	R	A
Specimen processing	I	R	A
Technical testing (flow, FISH, molecular)	I	R	A
Hematopathology interpretation	R	C	A
Result review & clinical correlation	R	C	A
Query resolution	R	C	A
CLIA/CAP compliance	R(CLIA)	R	A
Audit support (pathology)	R	C	A

Key:

- **R** = Responsible
- **A** = Accountable
- **C** = Consulted
- **I** = Informed

☞ This alone signals *audit maturity*.

Vendor Questionnaire “Cheat-Sheet” Answers

Q: Are you a CLIA-certified laboratory?

Yes, SMY Pathology Consulting, LLC is CLIA accredited and provides hematopathology consultation and clinical trial pathology oversight. Specimen processing and technical laboratory testing are performed in collaboration with a CLIA- and CAP-accredited reference laboratory partner (Precipio).

Q: Who performs specimen accessioning and testing?

Specimen accessioning, processing, and technical testing are performed by a CLIA- and CAP-accredited laboratory partner (Precipio). SMY Pathology Consulting provides interpretive hematopathology review and pathology oversight.

Q: How is regulatory compliance ensured?

Regulatory compliance is maintained through collaboration with a CLIA- and CAP-accredited laboratory partner for technical testing, combined with pathology interpretation and oversight by a board-certified hematopathologist.

Q: Describe your role in clinical trials.

SMY Pathology Consulting provides hematopathology consultation, interpretive review, protocol alignment, and pathology oversight supporting CRO-managed clinical trials in hematologic malignancies and precision medicine.

Q: Do you subcontract laboratory work?

Technical laboratory testing is performed by a CLIA- and CAP-accredited reference laboratory partner (Precipio). This collaborative model ensures regulatory compliance, data integrity, and high-quality pathology support.

SITE QUALIFICATION / AUDIT QUESTIONS

Q: Describe your quality system.

SMY Pathology Consulting operates under defined quality principles aligned with CLIA and CAP standards. Technical laboratory testing is performed by a CLIA- and CAP-accredited partner laboratory, while pathology interpretation and oversight are provided by a board-certified hematopathologist.

Q: How are deviations handled?

Any pathology-related deviations are documented, assessed for impact, and communicated to the sponsor or CRO as appropriate, with corrective actions implemented in collaboration with the laboratory partner when applicable.

Q: How do you ensure data integrity?

Data integrity is ensured through regulated laboratory testing, documented interpretation, clear role delineation, and adherence to protocol-defined pathology requirements.

Q: Are you audit-ready?

Yes. SMY Pathology Consulting supports sponsor and CRO audits related to pathology interpretation, reporting, and oversight, in coordination with the CLIA- and CAP-accredited laboratory partner for technical testing components.