Sapience Global Consulting – Sponsor-Focused FAQ Brochure

Independent Oversight Assurance That Strengthens Your Governance, Protects Your Patients, and De-Risks Your Submission.

1. What does Sapience Global Consulting do for sponsors?

Sapience strengthens a sponsor's entire clinical oversight ecosystem by ensuring that the teams who administer IDMCs, DSMBs, CECs, EACs, and IACs—whether internal sponsor staff, CRO partners, or specialized third-party vendors—operate these committees correctly, consistently, and in complete alignment with global regulatory expectations.

Sapience does not run committees; instead, Sapience ensures your committees are run properly.
Sponsors rely on Sapience to:

- Train internal teams, CROs, and adjudication vendors on how to administer IDMC/IAC operations properly
- Audit oversight workflows to identify operational, regulatory, or safety governance gaps
- QC all committee documentation, including charters, minutes, event packets, adjudication decisions, and communication pathways
- Prepare physician members and chairs to fulfill their regulatory obligations confidently
- Review and correct committee materials so they stand up to FDA, EMA, MHRA, PMDA, and Health Canada inspection
- Validate the quality and integrity of oversight deliverables across the study lifecycle

Our work removes the risks caused by inconsistent committee administration, strengthens oversight discipline, and helps sponsors avoid delays, observations, and safety escalation failures.

2. How does Sapience reduce regulatory, safety, and operational risk for sponsors?

Sapience ensures the operational teams that manage IDMC/IAC processes do so in full compliance with:

- FDA DMC Guidance (2006 + 2024 draft)
- EMA DMC Guideline and Q&A
- EU CTR/CTIS rules
- MHRA and PMDA expectations
- ISO 9001, 14155, ISO 13485, ICH E6(R3)
- DIA, RAPS, SQA, and GCP/GxP audit principles

We reduce sponsor risk by:

- Identifying safety signal handling weaknesses before they appear in inspections
- Ensuring consistent interpretation of endpoints by auditing adjudication workflows
- Detecting incomplete or incorrect IDMC minutes, which are a common source of inspection findings
- Remediating documentation issues long before regulatory submission
- Evaluating blinding, data flow, and communication pathways to ensure independence is maintained
- Ensuring consistency in event package construction, reducing reviewer burden and error rates
- Confirming escalation procedures and safety reporting workflows meet global expectations

Sapience builds regulatory defensibility into the sponsor's entire oversight framework.

3. What sponsor pain points does Sapience solve that other vendors often overlook?

Sponsors repeatedly report that Sapience resolves the problems that hinder trial progress, increase regulatory exposure, and create last-minute remediation burdens.

Sapience fixes:

- Improperly formatted or incomplete IDMC/IAC charters created by inexperienced vendors
- Inconsistencies between charter language and operational practice are a major red flag during audits
- Event packages that lack required source evidence, delaying adjudication

- Minutes that fail inspections because they omit critical details or misrepresent discussions
- Administrators who lack regulatory training create compliance gaps
- CRO oversight teams who misinterpret escalation timelines or communication pathways
- Documentation that lacks traceability, hindering submission readiness
- Vendor processes that fail FDA/EMA scrutiny, requiring sponsor remediation

Sapience prevents quality issues from snowballing into costly regulatory setbacks.

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4. How does Sapience help sponsors meet global regulatory expectations?

Sapience's frameworks, templates, and review methods are built directly from global regulatory guidance.

We help sponsors meet expectations by providing:

- Charter audits and rewrites aligned to FDA/EMA/MHRA/PMDA/CTR requirements
- Documentation QC to ensure meeting minutes, decisions, and event adjudications meet inspection standards
- Regulatory-consistent workflows for safety signal handling, unblinding, escalation, and communication
- Structured decision logs that maintain independence and traceability
- COI evaluation frameworks for all IDMC/IAC members
- AI/digital endpoint oversight assurance aligned with Good Machine Learning Practice (GMLP)

Our alignment reduces the burden on QA/RA teams, prevents observations, and creates inspection-ready governance.

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5. What committees does Sapience support through assurance, training, and auditing?

Sapience provides oversight assurance—not administration—for:

- Data Monitoring Committees (IDMC/DSMB)
- Clinical Events Committees (CEC)
- Endpoint Adjudication Committees (IAC/EAC)
- Safety Review Boards
- Genetic/IBC oversight committees
- Digital and AI-assisted endpoint committees
- Device and combination product oversight boards

No matter who administers your committee, Sapience ensures it is done correctly.

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6. How quickly can Sapience evaluate and support committee readiness?

Sapience is often called in after a trial has already begun or before the first patient in to evaluate risks.

We can:

- Assess committee readiness within days
- Perform rapid charter audits and gap analyses
- Deliver immediate QC of meeting materials and workflows
- Provide emergency coaching or remediation before regulatory inspections

Sponsors use Sapience for both proactive oversight planning and urgent repair work.

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7. How does Sapience maintain independence while aligning with sponsor goals?

Because Sapience does not run committees, our independence is absolute.

We protect sponsors through:

- Neutral evaluation of committee workflows
- Clear separation from operational decision-making
- Auditable assessment pathways
- Strict confidentiality and firewalls
- Blinded/unblinded process audits that ensure regulatory compliance

Our involvement strengthens—not compromises—committee independence.

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8. How does Sapience's global expert training benefit sponsors?

One of the top questions we've fielded over the years is "*Do you train the member physicians for their IDMC or IAC committee roles*?" Sapience's training:

- Provides training to new or existing IDMC/IAC members and chairpersons
- Member documented training for the Sponsor eTMF
- Support sponsors with subspecialty insight on committee composition
- Review cross-regional oversight for multinational programs
- Support the Sponsor with an independent perspective during audits or remediation
- Provide add-on training based on rare disease and complex endpoint interpretation

This global vantage point helps sponsors avoid common adjudication or safety governance pitfalls.

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9. How does Sapience improve adjudication quality and turnaround times—without administering committees?

Sapience accelerates sponsor timelines by improving the quality of the inputs, documentation, and workflows that slow committees down.

We help by:

- Auditing event package construction to eliminate missing data
- Training administrators to standardize workflows and communications
- Reviewing adjudication criteria for clarity and regulatory alignment
- Ensuring charter language supports efficient reviewer operations
- Eliminating documentation errors that create rework
- Ensuring CRO/vendor teams follow consistent decision pathways

A well-run committee—supported by Sapience's assurance—moves faster, produces fewer errors, and withstands greater regulatory scrutiny.

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10. How does Sapience lighten the workload for sponsor teams?

Sapience takes on the oversight work that overwhelms clinical operations teams but shouldn't fall on them.

We assist by:

- Review the event or data package deliverables from the vendors to the committees
- Consulting for the drafting or refining of oversight governance documents
- Training Sponsor/CRO/vendor staff
- Overseeing the quality of charter-based processes
- Ensuring quality meeting minutes, recommendations, and decision logs
- Conducting escalation pathway audits
- Reviewing safety narratives, communication plans, and deliverables

Sponsors reclaim focus while Sapience ensures their internal staff or administration vendors meet expectations.

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11. How does Sapience ensure sponsors are always inspection-ready?

Sapience prepares sponsors for regulatory inspections by ensuring their oversight documentation meets global standards.

Sponsors receive:

- Inspection-ready documentation packets
- Traceable oversight decision pathways
- Quality minutes, charters, and governance files

- Mock inspections and interview preparation
- Corrective-action guidance for oversight vendors
- Assurance for AI/digital endpoint documentation, which regulators increasingly challenge

Many sponsors say Sapience is the difference between a smooth inspection and a painful one.

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12. What therapeutic areas and study designs does Sapience support?

Because Sapience audits *processes*, not only *therapeutic specialties*, we support oversight assurance across all programs, including:

- Oncology & hematology
- Neurology & neurodegenerative conditions
- Cardiology
- Cell & gene therapy
- Infectious disease
- Rare & ultra-rare disease
- Device & combination product trials
- Digital therapeutic and AI-assisted endpoints
- Adaptive, decentralized, and global Phase I–IV trials

Wherever regulatory requirements apply, Sapience ensures you're ready for submission.

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13. How does Sapience support sponsors using AI-assisted or digital endpoints?

Sapience applies the principles of:

- FDA/Health Canada/MHRA Good Machine Learning Practice
- Evolving EMA guidelines
- PMDA expectations for algorithmic transparency
- ICH E6(R3) requirements for validation and data governance

We help sponsors:

- Validate data-driven and AI-driven adoption for endpoint processes
- Ensure algorithm outputs used for adjudication are reliable
- Prevent data drift, bias, and reproducibility issues
- Prepare documentation for inspector scrutiny
- Audit the vendor's implementation and reporting workflows

Digital endpoint oversight is a growing area of sponsor vulnerability, especially as AI plays a bigger role in study designs—Sapience closes that gap.

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14. What does the typical sponsor journey look like with Sapience?

Sapience provides a structured, high-touch journey:

1. Oversight risk assessment of protocols, charters, workflows, and vendor models
2. Training for sponsor, CRO, vendor, or a combination, and physician teams
3. Audit and QC of committee setup, documentation, and governance
4. Real-time support during steady-state operations
5. Remediation and escalation support as needed
6. Inspection readiness and closeout assurance

Sponsors consistently describe the Sapience experience as "clarifying," "professional," and "transformative."

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15. How does a sponsor begin working with Sapience?

Sponsors typically contact Sapience:

- When it is determined that an IDMC or IAC is required, to ensure committees are set up correctly
- Mid-study, when oversight issues begin to appear
- Before inspection, to prepare documentation and teams
- After inspection to remediate findings
- Before the disbanding of the IDMC or IAC

Sapience provides a tailored proposal that includes:

- Scope of training or audits
- Documentation QC plan
- Timelines and deliverables
- Charter or workflow revision pathways
- Regulatory expectations aligned to each region

Once engaged, Sapience rapidly deploys a structured oversight assurance framework that protects both the sponsor *and* the trial.

Contact

info@sapiencegc.com | (800) 513-1442 | www.sapiencegc.com