A Site's Guide to Managing Study Delays, Holds, and Cancellations

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Executive Summary

Study delays, holds, and cancellations are usually beyond a site's control. While sponsors and CROs face clear impacts, these disruptions also harm research sites financially, operationally, and reputationally. Sites invest heavily in study preparation (staffing, infrastructure, planning) and suffer when studies stall.

Unfortunately, delays, holds, and cancellations surged in 2025 compared to 2024. This issue was a top concern at the 2025 SCRS Global Site Solutions Summit.

While no single factor perfectly predicts these disruptions, sites can watch for warning signs and use risk-based strategies to protect their business, communities, and patient populations. This guide shares strategies from large, sophisticated research site networks for the benefit of the site industry.

Background

Sponsors don't make decisions to delay, hold, or cancel studies lightly. These decisions stem from regulatory considerations, operational changes, financing uncertainty, geopolitical concerns, and other factors. But these decisions also harm site operations.

Study disruptions have increased over the past few years, making sustainability a major threat to sites. At the 2025 SCRS Global Site Solutions Summit, this was one of the most discussed issues. Devana Solutions analyzed over 53,000 unique clinical trials and found that 12% experienced delays, holds, or cancellations. Over a 3-year period, these disruptions increased 40% to 60% compared to previous periods. Barry Lake, President & Co-Founder of Devana, reports: "delays, holds, and cancellations are up 105% in 2025 year-to-date over 2024."

Like sponsors, sites invest considerable time and resources to prepare for and maintain studies, even with no enrollment activity. Sites make staffing decisions, purchasing decisions, business plans, and opportunity cost tradeoffs in good faith for their sponsor and CRO customers. Study disruptions can be just as harmful (or more) to sites as to sponsors. Even if a study is only delayed, sites often aren't compensated for rework, retraining, and refreshing costs.

Beyond financial harm, sites face reputational damage with referral sources and communities they've worked hard to build relationships with due to this unpredictability. Sites also suffer alongside the most important stakeholders: proposed, interested, and prescreened participants who lose momentum to participate. If this happens repeatedly, participants lose faith in the site and the clinical trials industry overall. Sites often hear participants say: "why should I believe you this time?" Building trust with referral sources, communities, and participants is costly. Rebuilding trust costs even more.

Fortunately, many strategies exist that sites can use alone or with cooperation from sponsors and CROs to reduce this negative impact. The site community remains generous and non-competitive in sharing their expertise, successes, and lessons learned for the greater good.

Predicting Study Delays, Holds, and Cancellations

Other than perhaps a bankruptcy announcement, no single indicator perfectly predicts that a study will be delayed, held, or cancelled. We know of no meta-analysis ranking which variables predict better than others. Nevertheless, these common (but not exhaustive) indicators suggest a study may be at higher risk:

Vetting Sponsor Financing and Operations

One major risk source is the sponsor's financial health and ability to fund the trial through its lifecycle (with reserves for possible protocol amendments). While this may seem daunting, CROs routinely perform financial stress tests on sponsors, especially smaller ones, before taking on contracts. A CRO's involvement may reduce anxiety about the sponsor's financial ability to complete the study, though it doesn't guarantee sustainability (for example, the sponsor might use study cash for an acquisition).

A CRO offering poor payment terms (quarterly instead of monthly payments, holdbacks instead of full compensation) or firmly resisting removal of "paid-when-paid" clauses may indicate the CRO feels more risk of sponsor default. Sites can ask CROs if they've done financial vetting of the sponsor, though the CRO may not share details.

However, should a site feel strongly about vetting the sponsor (or CRO) on their own, there are several resources:

For publicly owned/traded companies:

For publicly owned/traded sponsors/CROs, sites have an advantage because (1) they must report financials to their government entity for public posting and (2) many websites and financial institutions track news on these companies. The site can use paid or free stock trackers (Yahoo! Finance, SeekingAlpha, etc.) to seek information or set up a portfolio of all publicly traded sponsors and CROs relevant to their work to check financial status and news regularly.

Be aware that the larger and more complex the sponsor, the less meaningful this information may be as a predictor of individual study financing (the finances of a sponsor with one or two products are more tied to those products than a sponsor with multi-billion-dollar diversified assets). Nevertheless, sponsor financial health may be critical in risk assessment.

For financial information: Key indicators appear in public financial statements (for the U.S. SEC, the 10-Q and 10-K statements) or quarterly investor calls. This information is publicly available on SEC.gov's EDGAR or through portfolio tracking sites. Of note, the timing requirement of such public disclosures varies by country, thus depending on the country, the information may be too outdated to be useful.

- Income Statement: Declining revenue or operating profits (EBITDA) or repeated losses. Note: This may not apply to companies with only pre-commercial products.
- Balance Sheet: Low or diminishing cash on hand; high or rising "Current Ratio" (watch ratios lower than 1.5); high or rising "Debt-to-Equity" ratio (over 2.0 is high).
- Statement of Cash Flows: Negative cash flow indicates "paper profits" aren't converting to real cash to pay bills.

For news: Sites use sources like Endpoints and Fierce Biotech. Risk indicators include poorer than expected financial performance, acquisitions or mergers, pipeline reprioritization announcements, workforce changes (layoffs), key leadership resignations and less than optimal study results. For publicly traded companies, certain significant events must be promptly disclosed to the public in government filings (e.g. in the U.S., acquisitions, material asset sales and key leadership departures must be reported to the SEC on Form 8-k within four business days of the event).

For privately held companies:

Unlike publicly owned companies, privately held companies don't have to disclose financial statements or key updates to the public. Companies like Pitchbook and Crunchbase offer information on millions of private companies, though this information isn't always complete and gets out of date quickly. Note that sites may consider these services cost prohibitive when only looking up one or two companies a year as there is no guarantee that the companies of interest will be in that database and the site may be disappointed in the information as being no more meaningful than the results of a basic internet search.

Generally, assume a more diversified privately-owned sponsor (with profits from products already on market) or one with sufficient cash in the bank is lower risk than a startup that must raise funds while sponsoring studies, especially if they're struggling to raise funds.

For financial information: A site can ask the sponsor for their most recent (hopefully audited) financial statements as part of its feasibility requirements. They may refuse or only provide limited information from investor pitch decks. Remind them that information provided falls under the non-disclosure obligations already agreed to for the study's confidential information. Otherwise, private equity intelligence companies or general internet searches may be the only option.

For news: Many companies offer email newsletters for press releases that can be subscribed to. Be aware that press releases only provide news the company wants the public to hear. Internet searches can be useful, but sites may prefer real-time information pushed to them. Many companies offer free or paid monitoring and alert services that browse the internet, social media and news outlets for keywords like the sponsoring company's name. These services are never perfect but may help find news about the sponsoring company.

Other Risk Factors

Other risk indicators are less objective than financial health but are often noticed by experienced sites. None are definitive predictors, but are worth considering:

Mostly Observed During Pre-Feasibility:

- **Class of Product:** Be aware of industry trends for certain product classes at high risk. For example, vaccines currently have an unusually high cancellation rate.
- **Clinical Hold Risk:** If the product is high risk, there's arguably higher risk of the study being put on clinical hold due to safety concerns. Such opinions can be informed by the contents of the Investigator's Brochure or product labeling, previous research on products in the same class as the product in the study and other news sources.
- **History of Delays, Holds, or Cancellations:** If the sponsor has a history of delays, holds, or cancelled studies, they're arguably at higher risk of doing so again.
- **Foreign Sponsors/CROs:** Geopolitical changes may cause problems repatriating funds to pay the site. One risk assessment variable is to learn if the sponsor or CRO has an office in the site's local country and if so, if the contract is with that entity (over a foreign entity) and are the funds present in that local office versus in the other country(ies).
- **Non-Awarded Studies:** This occurs when the site enters into dialogue with a CRO for a study that the CRO has not yet been awarded. In fact, the site may receive solicitation from more than one CRO for the same study as the sponsor is putting its management out to bid. When CROs are just fishing for the ability to run a study or otherwise only getting indications of interest for them to put in a bid, arguably this is of higher risk of delays or cancellations than an awarded study. It is generally prudent to ask if the study the CRO is gathering information for is already awarded or under bid.

Mostly Observed During Feasibility:

- **Overly Aggressive CTA Terms or Low Initial Budget Offer:** Sponsors or CROs markedly more protective than the norm may indicate higher risk.
- **Unprepared or Inexperienced Sponsor/CRO Team:** Teams that are overly disorganized or below average in knowledge about trial conduct may indicate they are not be fully prepared to manage the study through its lifecycle.
- **Disproportionate Third-Party Dependencies:** While solution providers bring expertise and speed to study startup and conduct, critical dependencies can create risk when they (i) have their own operational issues or (ii) require complex integration with other systems. For example, sponsors/CROs may not have selected a provider yet or must switch providers mid-study. Risk increases when third-party dependencies have no redundancy or backup plan, such as an electronic system with no ability to shift to paper if needed.
- **Unestablished Third-Party Site Dependencies:** Many protocols require third-party services the site cannot provide in-house, such as specialized technology or healthcare services (MRIs, device implantations). Early pre-arrangements and ongoing monitoring to assure continued availability of these services are critical to avoid the site being the cause of the disruption.

Mostly Observed During The Study:

- **Lack of Response to Issues:** Slow responses to critical issues may indicate the sponsor or CRO is reprioritizing resources away from the study.
- **Late Payments:** Not paying according to schedule may indicate needing to become more protective of their cash or cash flow for purposes other than the study.
- **Outcomes of Related Studies/Products:** If similar products aren't achieving desired safety and efficacy outcomes, it may be the product class rather than individual products. Monitor medical journals and results posting resources (clinicaltrials.gov) for both the study product and similar products in the same class to assess study viability.

For studies deemed at higher risk of delays, holds or cancellations, sites should be more aware in monitoring any of these and/or other indicators they deem important and be prepared to act promptly and appropriately.

Normal Considerations for Study Cancellations

In many cases, study cancellations are announced after the clinical trial agreement (CTA) has been fully executed. Assuming industry normal contracting practices, the site would be owed budget amounts related to activities for startup, closeout, and other non-refundable costs affiliated with orderly study termination.

- **Non-Refundable Start-Up Fees:** The Non-Refundable Start-Up Fee (see SCRS Guide To Common Invoiceables) may bundle multiple items or be split into separate line items. For example, a Mock Subject Quality Assurance Run-Through Fee ("Patient Negative One") may be bundled or billed separately. If the study is cancelled before the service was provided, the service wouldn't be performed for closeout. Always include "Non-Refundable" to protect against sponsors/CROs claiming refunds despite incurred costs. The CTA should also specify the fee is due "upon execution of the CTA" (usually within thirty days), not contingent on subsequent events like the Site Initiation Visit or enrollment of the first participant.
- **Protocol Close-Out Fees:** Like the Non-Refundable Start-Up Fee, this may be bundled or unbundled into separate line items. For example, if Investigational Product Return/Destruction Fee is unbundled and necessary after cancellation, it would still be reimbursed once performed. Record Storage Fee may or may not be incurred depending on whether the site is required by regulation to keep site files (cancelled after enrollment) or not (cancelled before enrollment).
- **Other Non-Cancelable Costs:** Other miscellaneous non-cancelable costs may be in the budget's invoiceable list or referenced in contract language. For example, if Coverage Analysis is unbundled and charged separately, this would be reimbursed if incurred in good faith. CTA language (usually in the termination section) typically covers "any non-cancelable obligations properly incurred for the Study by the Institution either prior to receipt of notice of termination or necessary for the orderly closeout of the Study."
- **Cancelled Protocol Fee:** Sites often face resistance including this in the CTA budget as sponsors/CROs view cancellation as unlikely. However, if costs in the categories above constitute all costs, there's no reason to

add this fee as it would be double-billing. If all costs aren't included, bundling remaining projected costs into this fee could be justified.

Occasionally a study is cancelled prior to CTA execution. In these situations, it's not uncommon for the sponsor and site to enter into a one-time agreement covering costs the site incurred in good faith.

Other CTA Guidance

- **Risks Surrounding Requests for Exclusivity:** Sponsors or CROs may attempt to impose "exclusivity" language in CTAs such as "the Investigator and Institution agree not to engage with other clinical studies that directly compete with the Study." Even when narrowly defined (e.g., "during the patient enrollment period"), such language imposes challenges. It's especially dangerous when studies unpredictably become delayed or held for extended periods. The site may be precluded from doing business for months or years while the study remains delayed or held. Such language should be avoided or severely limited. If sites entertain any exclusivity provision, remember that exclusivity typically warrants premium pricing and extra perks not offered to those without exclusivity restrictions.
- **Site's Termination Option For Prolonged Inactivity:** CTAs should include the option for sites to terminate the agreement in the event of prolonged delays or holds. While not currently in most initial agreements, if requested, sponsors/CROs have accepted language like: "Institution may terminate this agreement with thirty (30) days-notice in the event Sponsor holds, delays, or otherwise restricts Institution's ability to conduct the Protocol for any period lasting more than sixty (60) days after Institution's execution of this Agreement." Sponsors/CROs may initially resist, claiming they've undertaken considerable setup expense. However, studies do get delayed or held despite contrary incentives, and consequently harms sites as well, especially if exclusivity was agreed to. Nothing prevents the site and sponsor/CRO from reentering the CTA when the study restarts. The CTA and budget would likely need renegotiation anyway due to protocol changes, and prior successful negotiation should streamline startup timelines. Sites should thoroughly consider this decision and maintain goodwill intent to reactivate with the sponsor or CRO.
- **Monthly Site Retainer Fee:** If the site remains on standby for prompt startup after a delay or hold, an emerging strategy is a monthly retainer fee (similar to the SCRS Guide's Periodic Protocol Maintenance Fee) to accommodate direct and indirect costs of keeping the study ready. This accomplishes two things: First, it addresses costs to retain necessary staff, technology fees, and infrastructure. Otherwise, future startup may be impossible or significantly elongated if the site must re-recruit/re-train staff or re-setup technology. Second, it incentivizes sponsor transparency about whether the study will be cancelled or prolonged extensively. This strategy may supplement or replace other strategies for addressing extended delays or holds. While sites prefer to conduct studies rather than sit idle, this monthly retainer fee during the delays or holds may be necessary to ensure the best quality and expeditious service after the delay or hold is lifted.

Financial Forecasting

Financial forecasting is necessary to run any sustainable business. A site's financial forecasting is critical for determining near-future need for investment, lines of credit, staffing, physical plant, and nearly everything else it takes to run a site.

Sites must determine what risk variables they believe are most important and aggregate that thinking into their forecast. For example, if the site believes there's an 85% chance the study will be delayed, held, or cancelled, then projected revenue should be discounted accordingly. If at a later time they believe there's only a 25% chance, then they can adjust projected revenue accordingly.

Pipeline revenue projections (studies prior to CTA execution) have a higher chance of delays, holds, and cancellations than post-CTA. Forecasting should be updated both cyclically (usually monthly), when critical information is learned (such as publication of a previous study that failed) or as critical milestones approach (such as notification that an interim data analysis is scheduled or if the sponsor/CRO is “throttling” enrollment meaning instead of allowing the site to enroll its full target of 30 participants, they cap it at an initial 10 and reassess after every subsequent 10 enrolled).

Other Mitigation Strategies

- **Flex Staffing:** Whenever possible, build in the capability to reassign staff affected by study disruptions to other duties within the site organization or temporarily to another local site. Staffing companies may offer temp staff or consulting services on how to best flex staff. This is just as critical for PIs as it is for other staff.
- **Strategic Staging of Start-Up Activities:** For studies at high risk, be more strategic in staging activities. For example, don't begin creating recruitment materials until after the CTA is signed and the non-refundable startup fee is paid. Postpone infrastructure setup or training that isn't needed until later in the study lifecycle. This risk-based staging is key for costly or unreimbursed activities.
- **Mitigating Reputational Harm:** Never make promises to prospective participants or their referral sources regarding start time or study availability. Communicate appropriately and up front that these decisions ultimately belong to sponsors and may change at their discretion.
- **Study Portfolio Diversification:** Sites should diversify their study portfolio across multiple sponsors, therapeutic areas, etc. to hedge against risk if any one variable fails.
- **Risk-Based Pricing:** Some sites may charge a premium for studies at high risk of delays, holds, or cancellations.
- **Short-Term Operating Reserves:** Maintain cash or financially liquid reserves to float through estimated timeframes of study disruptions. More cash reserves (e.g. 6 months or more) means a better ability to weather revenue shortfalls until studies reopen, a pivot to other existing studies, or the securing of new studies.
- **New Business Development:** Don’t wait for a study to be delayed, held or cancelled to seek out new studies. Always be actively developing relationships for new studies.

Conclusion and Acknowledgements

Study delays, holds, and cancellations have detrimental impacts on many stakeholders, including and especially sites. With both generally accepted and emerging strategies, much of this impact can be avoided or mitigated. It's hoped that those not familiar with the strategies here will benefit from them. However, it's encouraged that discussion doesn't stop here and that sites can also share prior and emerging successes and lessons learned with each other in meetings and online forums. Finally, it's also encouraged that sites, sponsors, and CROs all band together wherever they can not only to enact these and other ideas but also come up with other creative solutions to help solve this common problem affecting our interdependency.

This guide is a credit to the generosity of individuals and organizations who remain committed to the success of the site industry as a whole. On behalf of SCRS and the site community, I would like to acknowledge and thank, in alphabetical order, Jennifer Byrne, Clare Grace, Dan Kearney, Barry Lake, and Carlos Orantes for their generous and enthusiastic contributions to this guide as well as the many others that inspired its creation through conversations in conferences and online forums.

Looking forward,

David Vulcano, LCSW, MBA, CIP, RAC, FACRP
Honorary President, SCRS