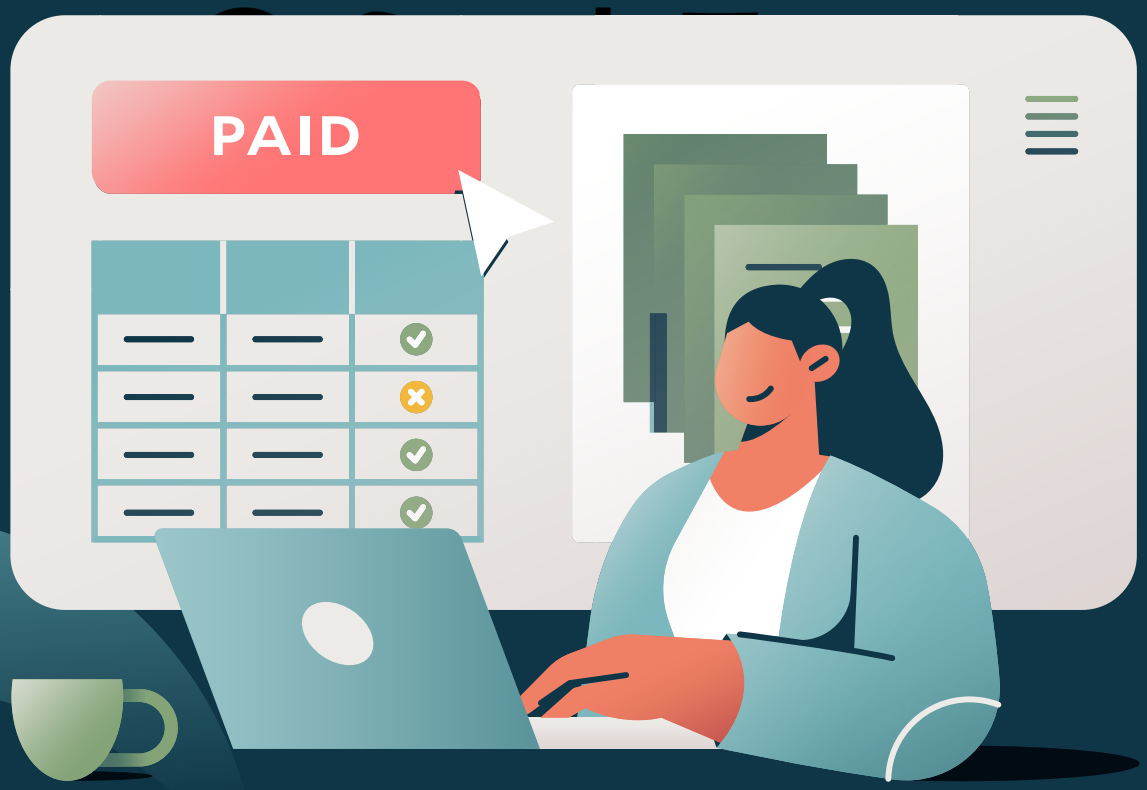
OneStudyTeam

# How to Increase Productivity and Profitability with eSource and Site Financials Technology



# Productivity and Profitability for Clinical Research Sites: *Challenges and Solutions*

### CHALLENGES:

So much can get in the way of productivity and profitability for clinical trial sites. Manual source template creation that delays study startup. Manual visit window calculations that take up valuable time. Patient identification via spreadsheets and limited searchability. Handwritten data-entry errors or missed lab assessments that lead to corrections and extra followup work. Manual visit window calculations that take extra time. Tedious budgeting and financial management with no simple way to track billable activities or the statuses of invoices and payments. **When your team doesn't have the right tools to improve workflows, efficiency goes down and trial timelines and goals get missed.** Billable activities or payments get overlooked and tight budgets get tighter. Staff satisfaction can suffer, and so can patient care and satisfaction.

### SOLUTIONS:

Luckily, all of these barriers to productivity and profitability are preventable. It's just a matter of choosing the technology tools that are right for your team. The **StudyTeam® for Sites** platform for managing patient recruitment and enrollment was designed with all of these challenges in mind. At its core, StudyTeam is an easy-to-use platform that equips sites with the tools to build out patient databases across trials, to seamlessly receive patient referrals where they manage pre-screening and enrollment, and to automatically update sponsors about enrollment progress while sharing critical insights that enable sponsors to identify actionable barriers to that progress.

## StudyTeam for Sites features 4 suites:

**RECRUITMENT SUITE:** With these tools, it's easy to build a detailed, digital patient database to track enrollment statuses and to quickly identify patients across trials.

**VISIT MANAGEMENT SUITE:** Here, you can efficiently schedule patients within automated visit window tolerances per protocol while tracking the completion status of each visit with digital checklists.

**ESOURCE SUITE:** With eSource templates created for your team, you can conduct comprehensive visits while capturing source data accurately, thanks to data-error alerts and visit progress bars.

**SITE FINANCIALS SUITE:** With your trial protocol and costs per billable activities built into StudyTeam, you can automate routine financial tasks, generate invoices, and build out accurate budgets.

When you implement StudyTeam, you're already on track to accelerate recruitment and enrollment. Now it's time to boost productivity and profitability. Keep reading to learn more about how to achieve that with the eSource and Site Financials suites built into the platform.

# 4 Ways StudyTeam's eSource Solution Streamlines Site Workflows

The FDA's 2013 guidance for electronic source data capture promotes the use of eSource in clinical trials to streamline investigations while improving the reliability, quality, integrity, and traceability of data. eSource platforms enable sites to capture all or some data for patient visits electronically, including medication logs.

How are sites choosing which eSource vendors to work with? **It's important to consider: Am I gaining an eSource platform that adds accuracy and ease to my clinical trial workflows?** Here are four ways StudyTeam for Sites' eSource solution streamlines site workflows in clinical trials.

## 1. Electronic data capture in StudyTeam can improve data quality.

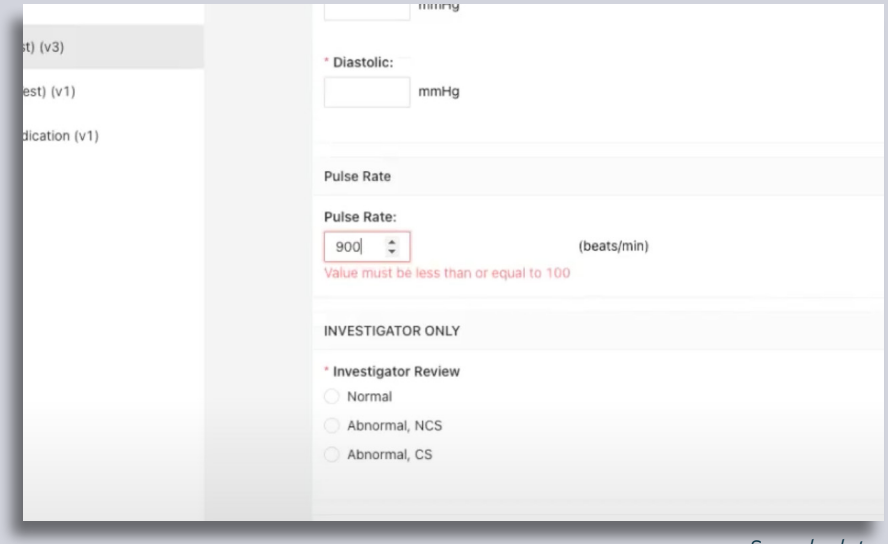
Precise data entry ensures that trial findings accurately reflect the effect of a study on patients, so researchers and regulators alike can make informed decisions when bringing therapies to market. Precise data entry also prevents sites from doing extra work — you don't have to follow up on missed lab assessments or data-entry errors.

To improve data quality, sites who use StudyTeam's eSource solution are equipped with templates for electronic data capture that are designed to accurately align with each specific protocol and case report form.

To ensure accuracy, StudyTeam's eSource functionality also includes validation. With eSource, you're able to set ranges in certain fields to help prevent keystroke errors. For example, you can set an appropriate range for pulse rate, so that field is flagged if an improbable pulse rate is entered, to reduce errors.

Another example is if a legitimate reading, like blood pressure, falls outside of an acceptable range per the protocol, you can be alerted and take appropriate action. This could qualify as an adverse event that needs to be documented, or it could require dropping the patient from the trial because they no longer meet the I/E criteria.

## Validation

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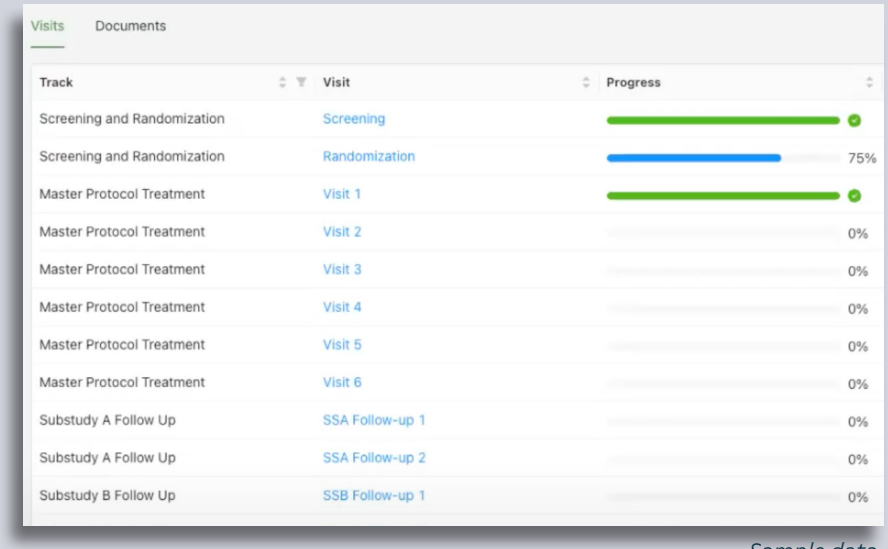
## Progress bar

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## 2. With eSource in StudyTeam, sites save time and effort.

When you use StudyTeam to manage recruitment, enrollment, and ongoing patient visits, you can receive custom eSource forms designed for you, based on your trial's protocol and your site's custom needs. Receiving source templates that are already designed and configured saves you meaningful time.

You can then easily enter information into the digital forms with a few clicks and keystrokes while you manage patients. Because digital data entry improves both accuracy and legibility, you don't have to spend time and effort correcting mistakes. You also prevent a slowdown in source management later on. To ensure you're securely entering data, detailed standard operating procedures have been developed to ensure StudyTeam's eSource capabilities are validated and in compliance with applicable regulations such as the FDA's 21 CFR Part 11.

For sites who also prefer to use paper forms for certain processes, StudyTeam helps generate paper source templates with custom QR codes. When those paper forms are filled out and ready for upload, you can quickly upload multiple documents at once into a digital patient binder, with automatic categorization.

## 3. Sites who use eSource in StudyTeam increase data completeness.

When you work with paper, it's possible to inadvertently overlook a section of a form that needs to be filled out, especially when you're overloaded with patients and complex protocols. With eSource in StudyTeam, you get additional guidance to ensure that study procedures are performed correctly. You actually see a visual representation of progress with each form: Progress bars indicate whether documentation for a screening visit, for example, is fully complete. StudyTeam users can see blue bars indicating incomplete documentation with an associated percentage of how close the tasks are to being completed; you can see green bars with a check mark

indicating a visit that is 100% complete with all source documentation uploaded and ready to go.

When you click into an incomplete visit, you can see which documents are completed in the patient binder, and which need additional information. If you are working with a paper document, you might never notice missing fields until you go to enter the information into your EDC, or until you get a query from your CRA. In addition to seeing completion levels, you can access a full audit trail to see who was in the system and who signed off on the work.

## 4. StudyTeam's eSource capabilities include expert technical support.

When you use the eSource solution in StudyTeam, you closely collaborate with a dedicated team of support professionals. Our end goal is not only to provide you with software, but a solution with dedicated support to help you achieve your clinical trial objectives.

**Our support professionals:**

- Onboard and train new StudyTeam for Sites users;
- Manage the customization of eSource templates per trial;
- Process product feedback and enhancement requests;
- Provide ongoing support to StudyTeam for Sites users;
- Provide support with Standard Operating Procedures (SOPs).

"StudyTeam has been exceptionally responsive, providing invaluable support to our site's research staff," said Violet Heard, clinical research coordinator at Sound Medical Research in Port Orchard, Washington. "Moreover, the team at OneStudyTeam has consistently demonstrated a friendly and professional approach, always eager to seek and incorporate feedback. We genuinely appreciate the level of support StudyTeam delivers."

## What does the transition to eSource look like?

For sites that already use StudyTeam and its built-in Visit Schedule feature, it's easy to implement our eSource solution. This doesn't require an instant switch to digital-only source documentation; rather, eSource in StudyTeam allows you to bridge that process. If you choose to, you can slowly transition over time to digital source documentation without unnecessarily disrupting your workflow.

When eSource is used in conjunction with StudyTeam for Sites, research sites are empowered to streamline their clinical enrollment processes with higher accuracy, improved efficiency, and a reduced risk of protocol deviations and audit findings. That means fewer resources need to be allocated to data collection corrections, or unexpected patient follow-ups to complete missed visit tasks and address protocol deviations. Because eSource improves workflow productivity in these ways, it naturally optimizes operational costs as well.

CASE STUDY

# Site reduces visit times and monitoring corrections by 50%

## About Seacoast Kidney & Hypertension Specialists

Seacoast Kidney & Hypertension Specialists, led by Dr. Sucharit Joshi, is a renowned research practice located in New Hampshire that specializes in kidney and hypertension trials. Ashlee Morris, the lead clinical research coordinator, plays a pivotal role in managing trials from inception to close-out. With more than a decade of experience, Seacoast Kidney has garnered recognition from CRAs and sponsors for their exceptional performance and high patient recruitment rates.

### CHALLENGE

Extended patient visit times and lack of patient confidence stemmed from site staff's cumbersome use of paper source documents. Additionally, the complexity of these documents increased the time it took to get new staff trained, while leading to monitoring corrections.

### SOLUTION

By switching from paper source to eSource, Seacoast Kidney eliminated time spent flipping through source documents to ensure protocols were being followed. Instead, they leaned on built-in templates and alerts to help with protocol adherence and to allow more time for focused, one-on-one patient interaction.

## Industry Challenges

When asked what contributed to them leaving the study, a third of participants said too much time required.

The average clinical research assistant stays at their job for 1-2 years. Many have limited or no experience in the research field.

The average time to handle monitoring queries is 15 minutes. If a site has 10 queries per monitoring visit, that's 2.5 hours spent away from patient care.

## Results with StudyTeam

**50%**

**REDUCTION IN PATIENT VISIT TIMES**

**50%**

**REDUCTION IN STAFF TRAINING TIME**

**50%**

**REDUCTION IN MONITORING CORRECTIONS**

## SOLUTION: Improving patient visits, staff training, and data accuracy by digitizing source data input

Rather than continuing to spend days creating source templates, Morris implemented StudyTeam's eSource solution for her research team. She did have one concern: Would it be easy to implement?

"A member from OneStudyTeam helped in the beginning with a standard operating procedure to ensure we had everything from a compliance standpoint and that we were able to answer questions if monitors came or in the case of a sponsor audit," Morris said.

OneStudyTeam's implementation process includes personalized assistance such as eSource form creation, one-on-one platform training, configuration of preset ranges for patient data to help prevent errors, and other system customizations based on protocol and site needs.

"We've hired people who have been research-naive and it was helpful to have StudyTeam with those built-in protocol parameters that could guide and flag things to avoid errors," Morris said.

## IMPACT: Streamlining operations and improving patient care

After implementing eSource, Morris noticed a 50% reduction in patient visit length.

"We actually had patients comment about how much faster the visits seemed once we switched to eSource because we're not flipping through papers," Morris said.

She also noticed how seamless the visits were. Instead of directing her attention at a paper file, she could spend more time focusing on patients during the visits.

Additionally, Morris reported an improvement in data accuracy and staff training time. Because eSource offers built-in protocol parameters, new staff was quicker to train. Her team saw a 50% reduction in both training time and monitoring corrections.

"We were spending 45 minutes on visits," Morris said. "I did a visit today with eSource and was done with the data collection within 20 minutes. And it also helps me spend more face-to-face time with the patient."

By implementing StudyTeam's eSource solution, Seacoast Kidney not only streamlined operations but also improved patient care and data integrity. Patient experiences noticeably improved, with streamlined visits and reduced wait times.

**"OneStudyTeam is so involved, so it never seemed like we were going to be stuck without support. The building of that relationship before we really jumped all the way in with eSource was very helpful and has been instrumental in the success of this for our site."**

Ashlee Morris
**Lead Clinical Researcher**
Seacoast Kidney & Hypertension Specialists

# 4 Reasons Sites Need to Automate Processes Around Clinical Trial Billing

When you look at clinical trial site financials at a high level, gaps in invoice creation, gaps in billing, and gaps in payment reconciliation can all add up. That combination of gaps can mean your site team is leaving hard-earned money on the table. It could even mean what was initially a profitable study is actually costing you money. That limited income could prevent you from taking on other profitable studies, too.

Setting up automated processes around tracking, billing, and budgeting can improve both efficiency and accuracy. Here are four specific benefits sites have to gain from automating clinical trial billing with software.

## 1. To easily and automatically track billable activities

Accurate activity tracking can be difficult — it requires frequent and clear communication between staff to ensure that they are not just accurately capturing that work, but that it's getting translated into appropriate documentation to get paid by the sponsor.

While communication is still important in checking off the right study activity tasks, clinical trial billing software can automatically document those tasks along with the associated costs of each activity.

## 2. To build accurate invoices for efficient reimbursement

Reimbursement processes can already be slow for trials. Depending on the contract between a site and a sponsor, reimbursement cadences can be as prolonged as every three months. Invoicing errors, specifically tasks that are billed incorrectly, can further delay payments from sponsors. To ensure your site team is getting paid in an efficient manner to support operations, it's important to be proactive in submitting timely and accurate invoices. Automated tracking of invoiceable activities leads to accurate invoicing, to keep timelines moving efficiently.

## 3. To improve cost estimation and resource allocation

As part of a site team, you need an easy and accurate way to document costs so you know what your actual margins are, or if your study is profitable. Automations that assign specific dollar amounts to specific trial tasks can ensure accuracy, and that you aren't estimating or charging less for study activities than you need to be. This can also ensure there aren't any billable study activities going uncharged. With these set charges in place, it's easier to get a full picture of your site's cash flow for future budgeting as well as for determining needs for additional resources.

## 4. To free up time for patient care and protocol adherence

Manual accounting processes can create an overwhelming workload for research staff, especially if they're not trained in that skillset. This extra effort can detract from patient care while slowing down overall trial workflows. While automated systems may require some time for the initial setup and occasional updates, the bulk of your team's workload will be allocated to patient care.

With automated clinical trial billing, you can have more clarity around your site's true operating costs, you can effectively allocate financial resources to ensure your trials stay within budget, you can ensure fewer hidden costs slip through the cracks, and you can be certain that less money is left on the table. Bonus: Your site team can have more productive discussions with sponsors about costs.


### Use clinical trial billing software like Site Financials in StudyTeam for Sites to ensure your tracking, billing, and budgeting is the most efficient and accurate it can be.

Site teams who use StudyTeam can easily automate processes around clinical trial site billing using the built-in Site Financials suite. Site Financials assigns a budget to all trial activities like patient visits, procedures, and other study activities, and then automatically tracks when those activities have been completed in real time. Using Site Financials, you will quickly generate budgets and accounts receivable to increase efficiency, accuracy, and profitability while improving clinical trial workflows.

Keep reading for a more in-depth look at the benefits of Site Financials in StudyTeam.

# 3 Clinical Trial Billing Challenges Research Sites Solve with StudyTeam

According to a 2023 survey by the Society for Clinical Research Sites, 55% of sites faced decreased profits compared to the previous year, while almost 80% of sites reported less than six months of capital in the bank. Sites are faced with ample administrative challenges that lead to big losses in revenue such as:

- identifying and managing patients across multiple trials (while scheduling them in the correct visit windows);
- updating sponsors on pre-screening and enrollment progress;
- accurately capturing and storing source documentation.

**The result: Clinical trial site burden is often high.** On top of that, budget management and sponsor invoicing adds a whole extra set of complexities, which carry huge costs.

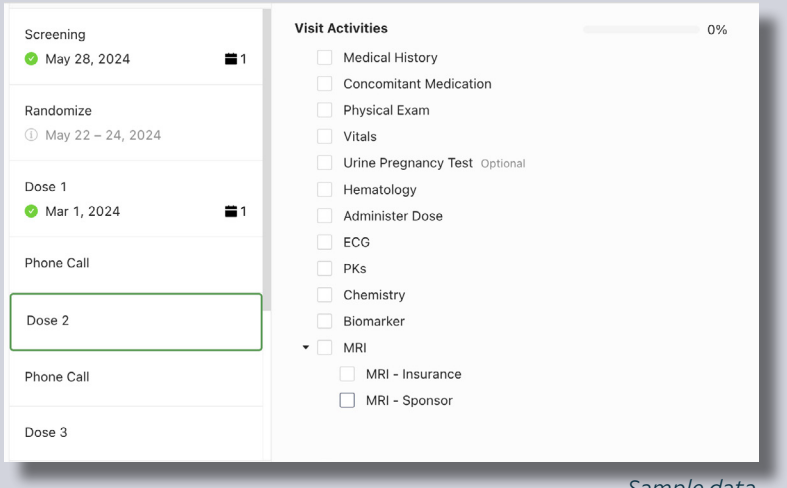
So what's leading to these financial concerns, and how can you address them? Take a look at three top clinical trial billing challenges sites are working with, and see how StudyTeam's Site Financials suite helps sites like yours simplify those processes.

## CHALLENGE 1: Complicated coverage analysis

When juggling multiple trials and waves of patients with different health conditions, it can be tricky and time-consuming to determine which costs are billable to insurance and which are covered by the sponsor. This can lead to sites not invoicing for certain activities and, ultimately, losing revenue.

When site teams log in to Site Financials, StudyTeam's clinical trial billing software, they don't even have to think about billable costs – the billability of each visit activity is already baked into their pre-screening and screening checklists, with associated costs attached.

For instance, when a patient enrolled in a trial arrives for a dose visit, you can log into StudyTeam to mark the completion of activities related to that visit. StudyTeam streamlines this process by automatically adding the associated billing costs once the activities are checked off. It's like having a personal accountant integrated with your site staff.

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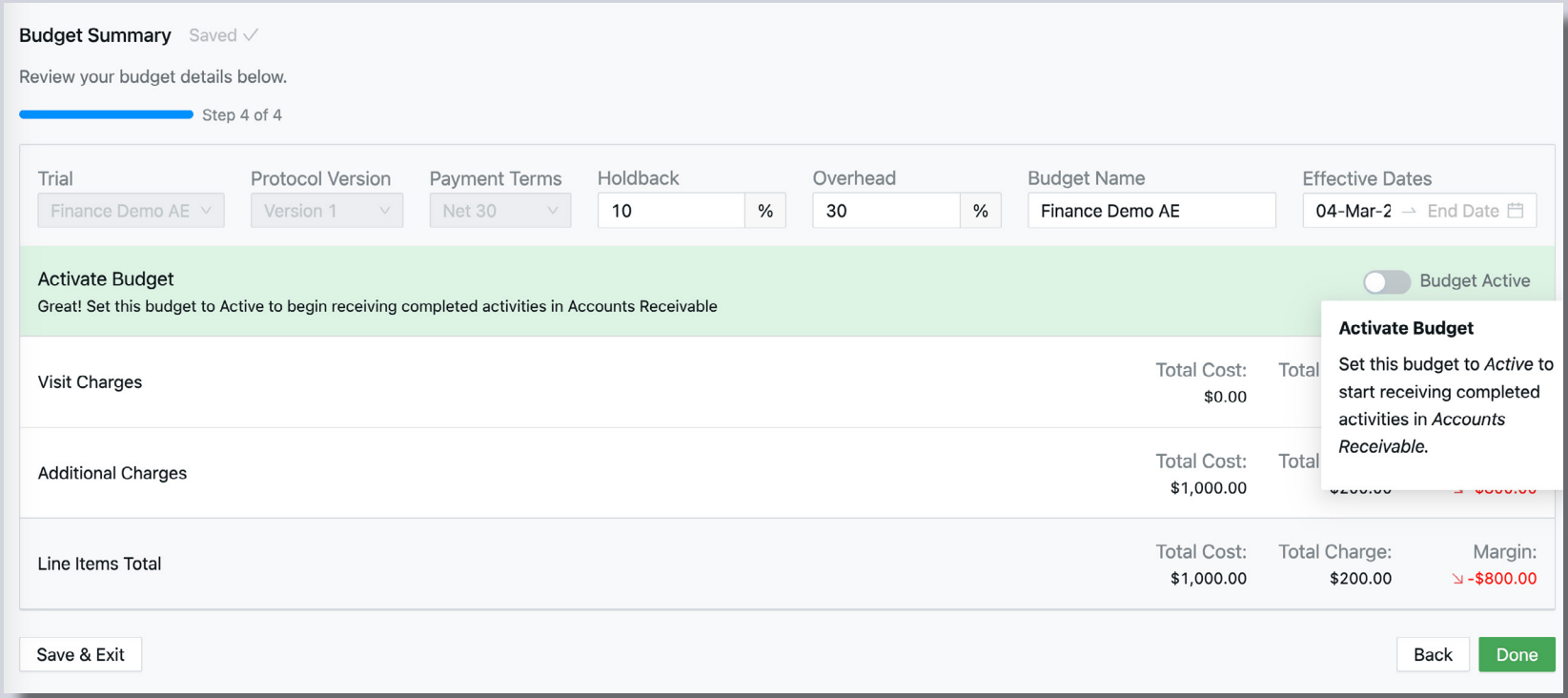
OneStudyTeam experts assist in setting up this system for your entire team. Now, everyone at your site can log into StudyTeam, record activity completions for each patient visit, and automatically track the associated costs for invoicing.

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## CHALLENGE 2: Tedious budgeting

Sites are tasked with developing detailed budgets that account for all trial-related expenses, including patient visits, holdbacks before certain trial milestones are hit, and overhead costs. Not only is this time-consuming, but it requires accurate calculations.

To reduce budgeting time and ensure accurate expense tracking, StudyTeam's Site Financials suite factors holdbacks and overhead percentages into each budget. When you first start to build out a budget in StudyTeam, you can add the known percentages for holdbacks and overhead. Then, as you add costs for visit charges into the system, holdback and overhead will automatically be calculated for those items.

When building out your budget for a specific trial, you can also factor in additional charges such as protocol start-up fees, protocol execution fees, and protocol close-out fees.

Once you review the budget summary – complete with visit charges, additional charges, and line items total, your site can start receiving completed activities in accounts receivable.

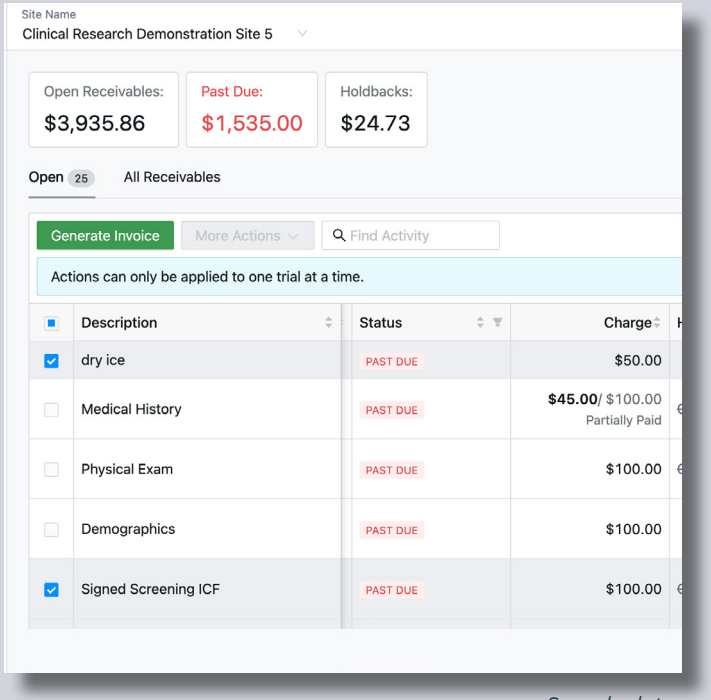
## CHALLENGE 3: Time-consuming tracking of sponsor invoices and payments

Invoicing your sponsor is an ongoing process during a trial – you need to keep track of milestones achieved, as well as costs incurred, and periodically generate invoices accordingly. Because of complicated coverage analysis, most sites miss various invoiceable activities. With Site Financials, it's easier for you to track items that need to be invoiced and to generate invoices. It's also easier to track invoices that are pending payment, as well as payments received.

For example, when a screening visit is completed, all of the checked-off visit activity items (with associated dollar amounts) flow into StudyTeam's Site Financials suite. Here, you can view all of the activity charges, the applied overhead per activity, and the applied holdbacks per activity, as well as the total holdbacks for the visit. Then you can automatically track the money you expect in open receivables compared to the ongoing holdbacks that will be billed at the end of the trial, or when a certain milestone is hit. Check off the invoiceable items and click the convenient "Generate Invoice" button with payment terms and due date included. Download the PDF version and email it directly to your sponsor contact.

Once you finish, you'll see the dollar amount associated with "Open Receivables" automatically change to factor in your most recent invoice.

Payment reconciliation is the next step. If you receive an ACH transfer or check, you can create a new payment in Site Financials with the right trial and sponsor payer assigned. Once you record each payment, you can see whether those payments have covered all invoices or whether payments are still needed.

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## With clinical trial billing software in StudyTeam for Sites, you can add critical automations to tracking, billing, and budgeting.

When you use StudyTeam for Sites to manage patient recruitment, enrollment, billing, and budgeting for your clinical trials, you can reduce your team's administrative burdens. That means freeing up more time for patient care while ensuring your site gets paid in full by your sponsor for all relevant trial activities and costs. Eliminate complicated coverage analysis for your team, reduce tedious budgeting tasks, and save time tracking sponsor invoices and payments. When you're ready, StudyTeam's Site Financials suite can be set up and available for use in just two weeks.

Within the StudyTeam for Sites platform, you can improve data accuracy, sponsor invoicing, budgeting, and overall trial performance. Why? Because you can manage all of these elements in one easy-to-use platform that scales to fit your site's needs. When these solutions enable you to boost productivity, they also help you increase profitability.

**Learn more about everything StudyTeam can do for your specific site and trial needs.**

## Click to get a demo of eSource

## Click to get a demo of Site Financials


OneStudyTeam