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Partnering to Advance Human Health

Automated Accountability and Reconciliation: A cost analysis of the savings over paper-based systems





The process of manually accounting for Investigational Product (IP) during the course of a clinical trial has been variously described as a "necessary evil" and "onerous." And, perhaps worst of all, the task of reconciling discrepancies in supply records that have accumulated over the course of a trial can often can add significant delays to the study closeout phase.

One would assume that by adopting chain-of-custody software which is integrated with the trial's Interactive Response Technology (IRT) system, companies can dramatically improve the process and their experience with it. The assumption is that automation cuts costs and shortens timelines. But by how much? Is the investment really worth it?

To attempt to quantify the value of software that provides visibility to supplies from release to destruction, Almac Clinical Technologies sponsored a survey of trial personnel involved in the accountability and reconciliation process.

The research was designed to determine the time spent on reconciling supplies, resolving discrepancies at sites and completing close-out activities for those using manual systems vs. those using an automated system (including those using hybrid a combination of the two). The dollar value associated with those activities performed by Clinical Research Associates (CRAs) was then calculated under each situation. In presenting the results of that analysis, this paper estimates the average cost saving to be achieved by implementing chain-of-custody software.



About the survey

Research methodology

Almac Clinical Technologies contracted with a third-party research firm to field a web-based survey in the second quarter of 2018. Study coordinators, clinical operations staff, clinical research associates (CRAs) / study monitors all identified by Almac and a select group of its customers were invited to complete the survey. A total of 93 people responded, 98 percent of whom were directly involved in managing and/or tracking drug accountability. Half were also responsible for overseeing the return of supplies to the depot and just over half (54 percent) were responsible for seeing that supplies are destroyed. Note: those respondents who used a hybrid process with some aspects automated and some aspects manual were asked to give two responses, one for each approach.

Analytical assumptions

The following assumptions were made:

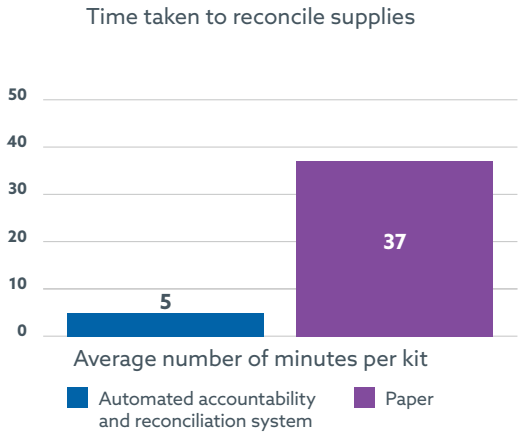
- The average CRA (or closest equivalent) annual salary is US $100,000 based on data derived from Willis Tower Watson. This equates to an hourly rate of approximately $48.00.
- CRAs work an 8-hour day.
- The CRA and study coordinator tasks were interchangeable when the system was used for most of the time, so it was decided to use their data interchangeably when it comes to cost calculations, for the purposes of this analysis it was assumed an average salary that equals the CRA salary.
- The average trial lasts two years (derived from a sample of Almac's database).
- The average number of sites participating in a Phase 3 clinical trial is 54, according to analysis from Global Data.
- The average number of kits per site is 388, again based on a sampling of 458 studies in the Almac database (the minimum was 203, the maximum 886).

Reconciling supplies

Respondents were asked how long it takes to perform accountability and reconciliation steps for each kit. The results, shown in Figure A, reveal that automating the steps cuts the time involved from 37 minutes to 5 minutes per kit.

To calculate a dollar value for that efficiency, multiplied the number of minutes saved per kit by the average number of kits and sites and by the average hourly rate for CRAs. This calculation is shown in Table 1 and *amounts to an estimated average cost saving of $536,371!*

Figure A



The functions of a chain-of-custody tool

- Provides on-demand visibility to supplies throughout the supply chain – from IP release through product destruction.
- Records the location, custody owners and condition of supplies as they move through the physical supply chain.
- Guides users through the process of managing and documenting returned kits.
- Facilitates self-managing error identification and correction.
- Supports root-cause analysis of issues relating to any IP event.

Table 1: The value of time saved in reconciling supplies

Time Reduction per Kit in Minutes	x	Average Kits at Site	x	Average Number of Sites	=	Average Number of Hours Saved	x	Average CRA Hourly Rate	=	Total Savings
32	x	388	x	54	=	11,174	x	$48	=	$536,371

Automating the steps cuts the time involved from 37 minutes to 5 minutes per kit for a total reduction of 87%

Resolving supply discrepancies

Time spent on resolving discrepancies at sites

Survey participants were asked how much time they devote to resolving discrepancies related to supplies at sites. Their responses shown in Figure B, indicate that automation cuts the time required to resolve discrepancies at sites from 37 minutes to 16 minutes.

Time spent on resolving discrepancies due to transcription errors

Participants were asked to indicate the percentage of data that contains discrepancies due to transcription errors.

Not surprisingly, those who rely on chain-of-custody software report having fewer discrepancies than do those who use manual systems. (See Figure C.) When the process is automated, the average percentage of data discrepancies due to transcription errors is 5% vs. 15% for those who rely on paper records.

According to the data, using an automated system reduces both the number of record discrepancies along with the time required to reconcile data on each kit.

Figure B

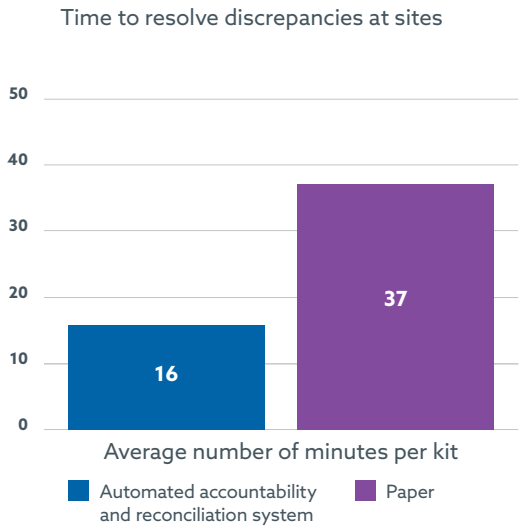
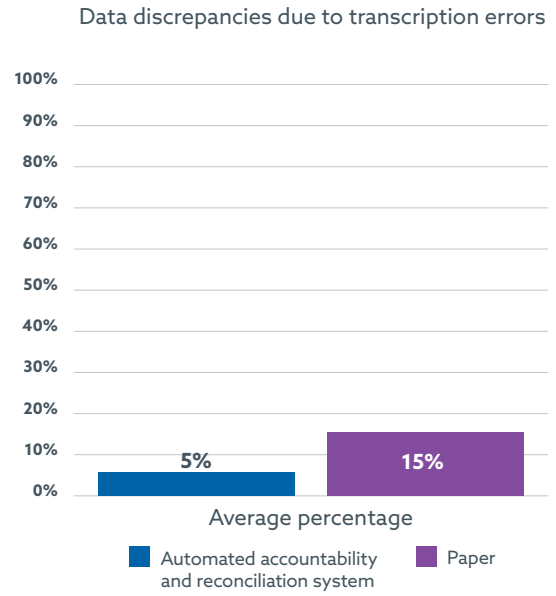


Figure C



An automated system reduces both the number of record discrepancies along with the time required to reconcile data on each kit

Completing close-out activities

When asked to report how much time was spent CRAs spend in completing close-out activities per kit, survey respondents revealed that on average, they spend 61 minutes when working with a paper based system vs. 40 minutes when working with an automated accountability and reconciliation system. (See Figure D.)

To calculate the value of this in CRA wages, multiplied the minutes of saved (21 per kit) by the average number of kits per site, the average number of sites per study and by the hourly rate for CRAs. As illustrated in Table 2, *this equates to a saving of $351,994!*

Figure D

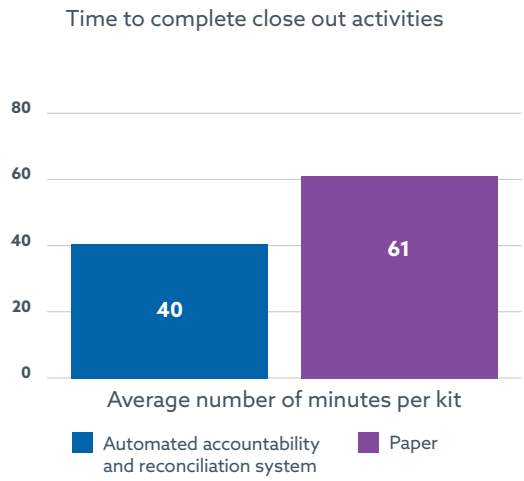


Table 2: The value of completing close-out activities

Time Reduction per Kit in Minutes	x	Average Kits at Site	x	Average Number of Sites	=	Average Number of Hours Saved	x	Average CRA Hourly Rate	=	Total Savings
21	x	388	x	54	=	7,333	x	$48	=	$351,994

Conducting site visits

Frequency of site visits

According to respondents, the frequency of visits to sites varies, but 46% of respondents perform monthly visits to sites in a given trial, regardless of whether they use an automated or a paper-based system for accountability and reconciliation. (See Figure E.) Note: the "Other" category in the graph captured a range of answers including "twice a week" to "it depends on the number of patients" to "I am always on site." Can safely assume that a monthly visit schedule is a conservative assumption for our calculations of site visit duration and cost.

Time spent at sites

The survey asked participants to indicate how much time is spent at sites completing accountability and reconciliation activities. Having an automated system reduces this time from 19 hours to 12. (See Figure F.)

Assuming an average trial length of two years, can calculate the savings to be had from reducing the number of hours spent at site for each visit by 7. By multiplying the number of hours saved per visit by the number of visits across the length of the trial, by the average number of sites and by a CRA's daily rate, *we arrive at a per-trial saving of $435,456!* (See Table 3.)

Figure E

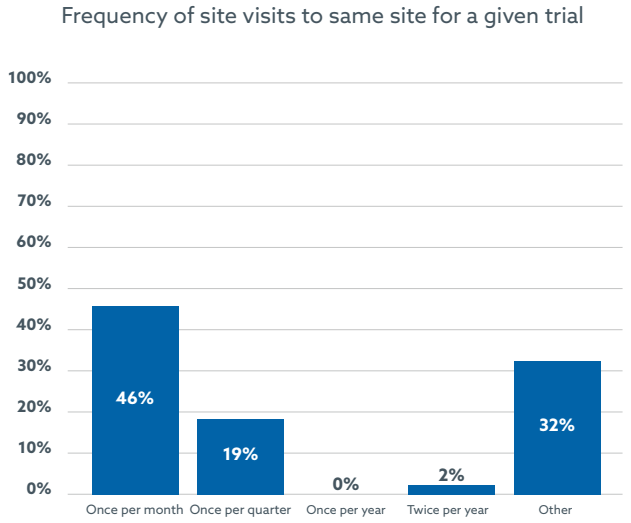


Figure F

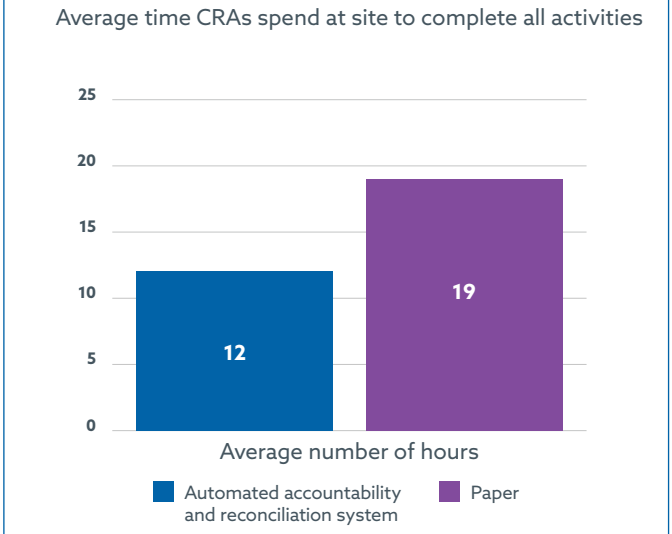


Table 3: Value of time savings in on-site monitoring visits

Hours saved per site visit	x	Number of visits across entire trial	x	Number of Sites	x	Average CRA Hourly Rate	=	Total Savings
7	x	24	x	54	x	$48	=	$435,456

The grand total

The survey measured the hard savings that can be realised by automating the accountability and reconciliation process within the trial's IRT system. The results reveal that on average, automation:

Reduces time by 87%

Reduces CRAs time per kit when reconciling supplies by 32 minutes for an average saving of $536,371.

Time spent cut in 1/2

Reduces time spent on resolving discrepancies at sites by more than a half.

Reduced errors

Reduces the frequency of transcription errors.

Trims time by 35%

Trims time spent on close-out activities by 21 minutes per kit for an average saving of $351,994 per trial.

Substantial cost savings

Reduces the time spent at sites completing accountability and reconciliation activities for an average saving of $435,456 per study.



These hard savings are in addition to other benefits of automated accountability and reconciliation systems, which include:



Support compliance with Good Clinical Practices (GCP) and Good Manufacturing Practices (GMP). Such systems serve as an extra step in ensuring that the protocol is followed and all supplies are accounted for.

Make monitoring easy. With a consolidated view of clinical and supply information, CRAs can plan their work up front and immediately identify issues that need to be addressed.

Produce correct and complete records. Intuitive workflows and validation steps prevent users from omitting steps or committing incorrect data.

Increase patient safety. Real-time validation checks at the time of dispensing and on the eligibility and condition of drug supplies reduce the opportunity for patients to be given the wrong treatment or one that has expired or experienced a temperature excursion.

Speed study close out. The system catches most discrepancies before they're recorded and those that do occur can be addressed at once. So, discrepancies don't accumulate and don't add to the study timeline.

The survey established that, all totalled, the use of an automated accountability and reconciliation system can save a company a minimum of **$1,323,821** per trial in tangible costs! Given that the cost of the necessary software module is a small fraction of the potential saving, an investment in it delivers a very healthy average return.

Recognizing that the industry needed an automated solution, just over a year ago Almac Clinical Technologies introduced Accountability & Reconciliation Tracking (ART™) functionality within its IRT platform, IXRS® 3. This native, extended tool is currently helping sponsors and CROs realize valuable savings of both time and money that come from easy setup streamlined site ops, error reduction and discrepancy resolution.

For more information about the report and the benefits of ART™ for your next clinical trial, please contact Almac Clinical Technologies at clinicaltechnologies@almacgroup.com.

An automated accountability and reconciliation system can save a company a minimum of $1,323,821 per trial in tangible costs

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