Automating Invoicing in EDC/CTMS: Study Build and Design Considerations

PEER REVIEWED

Automating invoicing is a significant benefit when using electronic data capture (EDC) systems and clinical trial management systems (CTMS). Understanding the extent and limitations of invoicing is an important consideration when selecting an EDC or CTMS. In multi-site studies, invoicing can become a tedious and time-consuming task when tracking is done using spreadsheets. Even when using a CTMS where invoicing is separate from the study's EDC, correlating the invoices to patient visits creates additional work compared to having the same function within the EDC. Payment items are sometimes missed, payments can be miscalculated, and sometimes payments can be made prematurely without certainty the task the payment is associated with has actually occurred. Leveraging an integrated solution makes this process more streamlined and efficient. This article includes recommendations for integrating this functionality into a study, things to consider, and questions to ask.

Using an EDC or CTMS with integrated invoicing allows the flexibility to adopt a more detailed and complex master fee schedule while reducing the work for the monitor. Traditionally, invoicing has been a complicated and arduous task. Monitors had to be very detailed about keeping track of and verifying that different events had occurred during the study in order to authorise the payment of the fees. This limited the complexity of the master fee schedule. If it became too complex, it became difficult to manage. Consequently, most of the fee schedules included a site initiation fee, a subject screening fee, a fee for a screen failure and a fee for a subject that completed the study.

When using an EDC and CTMS integrated solution, managing invoicing becomes an easy and natural process. The complexity is in setting up the master fee schedule and the EDC/CTMS during the study build. The main work becomes deciding what to pay fees for and what event(s) and conditions will trigger the payment of that fee. The EDC/CTMS can then automatically post that fee to an invoice, similar to how initiating a site was an event that triggered a payment in the past when the monitor initiated the site. Monitors also previously reviewed patient and study records in order to ensure whether a patient completed the study or was a screen failure, in order to determine payment. The event trigger for initiating the site was the monitor actually completing that task. The event trigger for a screen failure or patient who completed the study was the monitor's verification that in fact there was a screen failure or a study completion. When invoicing within the EDC/CTMS, it is only necessary to determine what the appropriate event triggers are. The EDC/CTMS team should be able to program the system to ensure those events trigger the posting of a fee to the invoice.

In fact, once the logic is set up that generates the invoices based on the event triggers, the monitor's work is to check and approve the invoices that are generated automatically as the sites complete their defined tasks. This saves the monitor a lot of time, which allows him/her to focus on other important monitoring tasks. The initial challenge is to determine the master fee schedule of items to be invoiced and what the triggers are for the item to be posted to the invoice.

As discussed above, typically sites receive a fee once they have been initiated or completed their initial training on the EDC/CTMS. Most EDCs can designate either a field being filled in or a form being in a certain state (e.g., In-Review (signed off by the site), Reviewed (by the monitor) or Final) in order to trigger the fee to appear on the invoice. In this case, selecting a field, such as the site initiation date, being filled in as the trigger is an excellent choice. It will be important for the monitor to know that this is the trigger so that the monitor does not fill this information out until the site is ready to go live and be initiated.

Likewise, some studies provide payment for certain labs as they are completed. While it is possible to use a field to trigger the lab payment, it is a much better choice to use the status of the form, e.g., is it in-work, or has it already been reviewed/finalised? This is because if the trigger for the invoice is the field for "X lab drawn", there is no guarantee or incentive for the site to review the labs once they are received. Instead, it is a better choice to generate the invoice line item once the form has been reviewed. When a form has been reviewed, that means the monitor has confirmed that the errors and queries have been resolved. It also means the monitor has confirmed the task has been completed, so it is natural for the fee for that lab to now appear on the invoice.

With the use of an EDC/CTMS invoicing solution, different amounts can easily be paid for different labs. The lab fee should only trigger if the lab was completed and the form has been reviewed. In this case, both the field for "X lab drawn" and the status of the form can be used to determine whether or not the fee should appear on the invoice. When the monitor reviews forms with this type of scenario, the monitor should confirm there are lab results corresponding to each type of lab marked as completed. Alternately, if the system is highly customisable, the trigger can be the field for "X lab drawn", one of the most common field names for lab results, and the form status as reviewed. For example, in a given study the payment of $20 is made for a blood test, $25 for a urine culture, and $50 for a DNA panel. In order for the payment to post, the following event triggers have to occur: for the blood test, a check box indicating the test was requested plus

the receipt of results for the field red blood cell count, and the form having been reviewed would cause the fee to post. In order for the urine fee to post, the check box for urine culture requested would be checked and a field such as urine clarity would have to be filled in as well as the form being reviewed by the monitor. The DNA panel would work the same way, requiring a check box for the test, a completed DNA result field, and the form as reviewed by the monitor.

Screening fees can be triggered from the inclusion/exclusion form. If the form has a field that determines inclusion or exclusion, such as a "qualified for study" or even "treatment group assignment", either one of those fields can be used together with the form having been reviewed by the monitor to post the screening fee to the invoice. In some systems, the fee can even vary depending on whether the animal is a screen failure or will be included in the study.

If the screen failure receives a reduced fee, it can be triggered off either the inclusion/exclusion form field, indicating the screen failure or the termination form if the screen failure is captured on it, plus the corresponding form being reviewed by the monitor. The best practice, though, would be to have the screen failure result on the inclusion/exclusion form set the status of screen failure on the termination form. Then the field and status of the termination form would trigger the fee posting to the invoice. The reason this is the best way to do it is it ensures the case data is complete.

Fees for surgery or services provided can also be triggered from a specified field that indicates the provision of the service or surgery and the form having been reviewed. This ensures that the site has entered all the pertinent information related to the surgery or service and the monitor has reviewed it.

Some studies prefer to ensure the forms are finalised before the fee can post to the invoice. In studies where the monitor has the ability to review and finalise the form, it makes sense for the monitor to go ahead and finalise the form. This does several things: it locks the form from further editing, visually lets the monitor know they are completely done with that form, and triggers the fee to post to the invoice.

Notice that, in order for the forms to be marked as reviewed, they have to be evaluated by the monitor or designee. When the monitor reviews the forms, s/he is confirming the information contained on the form is consistent and no flags are raised. Once s/he signs off on the form as reviewed, the fee that was submitted by the site's act of submitting the form for review is accepted and is posted to the invoice. This leverages the monitor's work of reviewing the form to automatically generate the invoice. For this reason, it is not necessary for the monitor to confirm that all events related to the fees on the invoice have actually occurred. In the process of monitoring the study in general, the confirmation of these events has already occurred.

Using an integrated EDC/CTMS for invoicing should allow more flexibility and a more robust set of fees than what have historically been possible. The main challenge will be to determine the triggers for the payment and ensure they will capture the fee at the correct time. As seen in the examples above, ensuring the monitor has reviewed the forms prior to posting the fees to the invoice is a good practice.

During user acceptance testing (UAT), it is important to test various scenarios to ensure the fees post correctly and fees that have previously been included in an invoice are not duplicated in future invoices. A duplicate posting could occur when a form is reviewed and later reverted into work and subsequently submitted for review again. The EDC needs to know that the fee has posted previously and should not be posted again. Ensure UAT includes testing several scenarios where a duplicate post could appear. The EDC provider should be able to suggest some scenarios to test.

The invoice should also allow the investigator to sign off on it in order to request payment. Once it has been submitted, a new invoice should be generated for future fees to appear. The investigator should be able to submit the invoice as frequently as determined by the study administration. The most common frequency is monthly. Additionally, since some studies require rescue treatments or also allow for payment for study-related treatment not included in the master fee schedule, the invoice should allow the investigator to post additional fees and the monitor should be able to allow or disallow these fees.


14-Mar-2016 01-Dec-2011

Phone: 404-474-4747

Purchase Order:

Due upon receipt

Bill To
Sponsor Company
Accounts Payable
Sponsor Address
Austin, TX 78704
Email: sponsor@company.com

Contact: Route to A. J. Smith

Visits

#	Patient	Visit Date	Visit Event	Visit Amount
1	ATL-027	04-Jan-2012	Screening (enrolled)	$525
2	5035	04-Jan-2012	Screening (enrolled)	$525
3	ATL-007	03-Dec-2014	Screening (enrolled)	$525
4	ATL-017	07-Feb-2015	Visit 1 (enrolled)	$525
5	ATL-038	30-Nov-2011	Screening (enrolled)	$525
6	ATL-038	07-Dec-2011	Visit 1 (enrolled)	$525
7	ATL-038	14-Dec-2011	Visit 2 (enrolled)	$525
8	ATL-009	30-Nov-2014	Screening (enrolled)	$525
9	ATL-009	04-Jan-2014	Visit 1 (enrolled)	$525
10	ATL-009	18-Jan-2014	Visit 2 (enrolled)	$525
11	ATL-024	01-Dec-2014	Screening (enrolled)	$525
12	ATL-020	22-Dec-2014	Screening (enrolled)	$525
13	ATL-031	22-Dec-2014	Screening (enrolled)	$525
14	ATL-014	21-Apr-2015	Screening (enrolled)	$525
15	ATL-014	29-Dec-2014	Visit 1 (enrolled)	$525
16	ATL-021	27-Apr-2015	Screening (enrolled)	$525
17	ATL-016	27-Apr-2015	Screening (enrolled)	$525
18	ATL-022	27-Apr-2015	Screening (enrolled)	$525
			Total Visit Payments	$ 9450

Data Entry

#	Data Entry Hours	Data Entry Date	Data Entry Description/Comments	Data Entry Amount
1	20	10-Mar-2016	Owner observations	$ 400
2				$
			Total Data Entry Payments	$ 400

Other Charges

#	Patient #	Date of Other Study Service	Description of Service	Other Study Amount
1	ATL-014	14-Mar-2016	Additional testing	$ 150
2				$
			Total Other Study Payments	$ 150

Total For This Invoice: $ 10000

Payment Information

Warning: Field 'signed off' should be filled in.

Click here to sign off on the invoice.

Payment received:

Figure 1 shows an example of an invoice in progress. Notice the items that have posted automatically are in the top section under the title "Visits." This invoice also includes a section for data entry because this study required data entry of patient/owner forms. It also includes a section for other miscellaneous charges. The monitor will only have to verify this last section of the invoice prior to payment. Once the investigator signs off, the invoice subtotals and total will be determined. The date of the invoice will also appear at the top of the invoice. Once the payment has been received by the site, they can further confirm its receipt by checking the box at the bottom of this form. The monitor will then know the site has received the payment.

With the automation of invoicing, it is now possible to make payments for different tests, labs, procedures, surgeries, etc. without increasing the monitor's burden of managing invoices and payment. Since the system will automatically post the fees to the invoice and the monitor has already reviewed the majority of the forms where the proof of event completion are found, the monitor can simply acknowledge and verify any custom fees that are on the invoice with confidence that the standard fees have posted appropriately, as this was tested during UAT.

Another consideration when evaluating EDC and CTMS solutions is whether these systems were created together with all the modules being built specifically to work together, or whether the solution is a compilation of stand-alone products that have programming that ties them together. Systems that are built to work together have the advantage of common language and programming strategy, which makes them more responsive and easier to customise than those which were created separately and then joined. If selecting the latter, ensure comfort with their functionality and customisability.

Using an integrated EDC and CTMS solution for invoicing, dosing calculations, inventory management and reordering will help any study run smoother. Carefully considering the master fee schedule and the triggers that will be used to post the fees to the invoice will ensure the fees provided the intended outcome of complete and accurate data. Together, these functions ease some of the tedious study management burden of monitors by automating these tasks. This allows monitors to focus on other more important things that can impact the study outcome.

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Dr Loyo is an eClinical Trials Specialist at Prelude Dynamics. She specialises in developing user-friendly interfaces for clinical electronic data capture (EDC), coaches clients through the EDC development process and how to leverage the trail management system functionality for efficient trial operation, delivers training, and consults on best practices in monitoring with EDC, the development of mid-study reporting tools, and final data export. Dr Loyo has been engaged in health-related research, education and marketing for 17 years. Her career highlights include working on the System Dynamics Model for CVD Prevention with the CDC, which won article of the year in Health Promotion Practice, and writing the Strategic Plan for Prevention of Obesity in Texas: 2005-2010.

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Dr Browner's primary expertise is implementing solutions to systems engineering, operations research, and computer science and mathematical problems. She has a Ph.D. in mathematics and over 20 years of experience in high-level design and analysis, software development, and design of models, simulators, and optimisation algorithms using operations research methods. In Dr Browner's early career, she created automated systems for the US Government and NATO, culminating in the position of Consulting Scientist at Lockheed Martin. Following her DOD work, Dr Browner entered the clinical applications domain as Chief Systems Engineer for a startup company developing practice management software. Dr Browner became a cofounder and CTO of Prelude Dynamics, designing and developing software tools to automate data collection, processing, and trial management for clinical trials.

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