



Sponsor Invoicing and Receipt Tracking

OnCore Coordinators enter the cost of each invoiceable subject milestone, as well as any protocol-related costs (such as IRB review fees) and pass thru items (MRIs, CT scans, etc.,) that can be billed to the sponsor.

Any of the budgeted milestone costs, protocol-related costs, or pass thru items can be added to a sponsor invoice in OnCore. Invoices can be emailed, printed and mailed to the study sponsor, or the financials team might simply use the invoices to reconcile the study-related costs incurred with sponsor payments received.





Entering Subject Data and Tracking Visits

Costs entered in the Financials Console > Milestones tab can't be added to an invoice until they occur and are recorded in OnCore. Invoices can be adjusted for missed visits, missed procedures, unscheduled visits, or additional procedures that are needed; anything that does not happen exactly according to the schedule of events in the clinical calendar is recorded as a visit variation.

Invoiceable items and visit variations can be generated when:

- Subject visits are checked in (marked as Occurred)
- Subject visits are marked as Missed
- Additional procedures are performed during a subject visit
- Additional (unscheduled) subject visits occur
- Subject statuses are achieved (for example, a subject reaches a status of On Study)
- Subject events are recorded (SAEs or screen failures)
- IRB reviews are documented for a protocol
- Pass thru procedures are performed during a subject visit (MRI, CT scan, etc.)





Typically, subject visits and milestones can be invoiced to the sponsor as soon as they are checked in (marked as *Occurred*) by the study team. Study team members (clinical research associates, research nurses, and so on) use the CRA Console and Subject Console to document subject information and track subject visits.

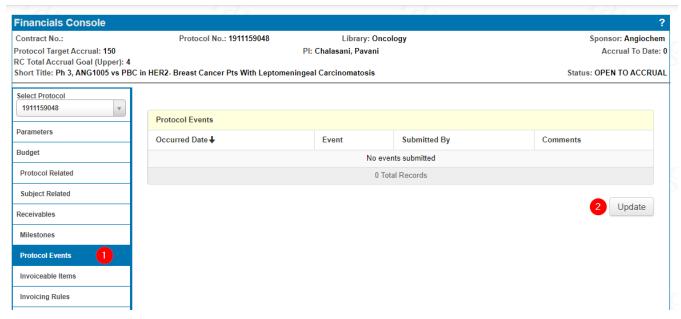
Creating Sponsor Invoices

All subject events (visits, subject statuses, SAEs, and/or screen failures) selected on the Milestones tab of the Financials Console appear in the Invoiceable Items tab and can be added to a sponsor invoice. Protocol-related events (IRB review fees, pharmacy fees) and pass thru events (expensive items such as MRIs or CT scans) can also be added to sponsor invoices.

Once an invoice is generated, the total amount can be adjusted by adding visit variations (any procedures or visits that were unplanned or missed) and either adding or crediting back charges appropriately.

Manually trigger protocol events for invoicing

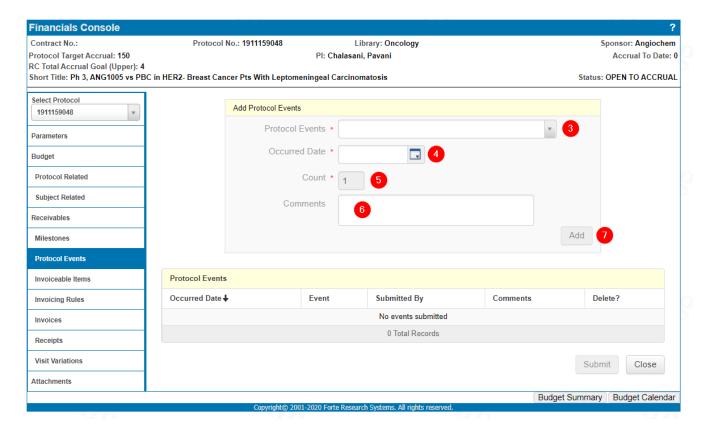
Some events automatically become invoiceable when specific data is tracked in OnCore – for example, protocol-related events might be triggered by an IRB review that is entered, or a study team member who documents an event in the CRA Console. Other protocol-related events need to be manually triggered after each occurrence, before they can be added to an invoice.







- 1. Navigate to Financials > Financials Console > Protocol Events.
- Click Update.



- 3. Select the **Protocol Event** from the drop-down list in the Protocol Events field.
- 4. Enter a date in the Occurred Date field.
- Enter a number in the Count field.
- **6.** Type a comment in the **Comments** field.
- Click Add.

This protocol event can now be added to an invoice.

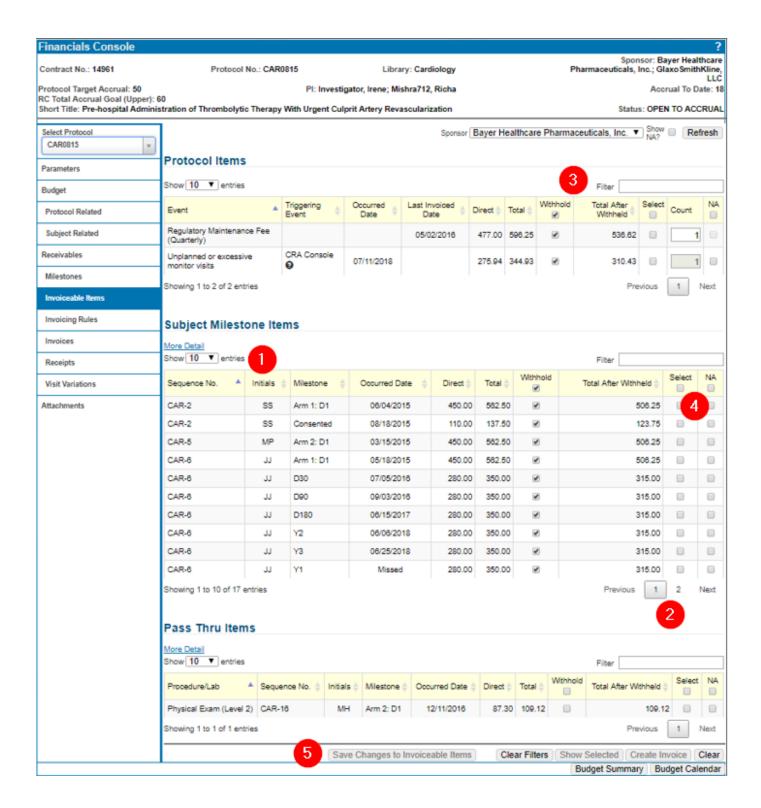
8. Repeat steps 1-6 to manually trigger other events.





Add protocol-related events to an invoice

9. Navigate to Financials > Financials Console > Invoiceable Items.







When the page opens, all three tables (**Protocol Items**, **Subject Milestone Items**, and **Pass Thru Items**) load independently.

1. **Show** [] **Entries** at the top of each table, limits the number of items shown on one page in the table. (The total number of entries on all pages is shown listed at the bottom left of each table.)

The **More Detail** link adds the Version, Status, and Status Date columns to the Subject Items table and the Version column to the Pass Thru Items table. To remove these columns, click Less Detail.

- 2. The page numbers (and **Previous** or **Next**) buttons at the bottom right of each table allow you to view additional pages of items in each table.
- 3. The **Filter** field allows you to enter free text to limit the items displayed in a table. Clicking the column headers allows you to sort the items in ascending or descending order.
- 4. Checkboxes allow you to select items on multiple pages within a table. Click the checkbox in the header of a column to select all items in that column, including those that aren't currently visible.
- 5. These buttons are at the bottom of the Invoiceable Items page.
- Save Changes to Invoiceable Items: This button saves any changes that have been made in a table, including the Withheld or NA columns. Changes will also be saved to pages that aren't currently visible.
- Clear Filters: This button clears all free text entered in the Filter fields in any of the three tables.
- Show Selected/Show All: Clicking the Show Selected button displays only those items that have the Select checkbox selected. Clicking Show All displays all items.
- **Create Invoice**: Clicking this button adds all selected items and creates an invoice. Note that all records on multiple pages will be added to the invoice regardless of whether the selected items are currently visible on the page.
- Clear: Clicking this button deselects all selected items.

You can also access the following budget tools from these buttons:

- Budget Summary: The budget summary provides a view of the estimated budget for the protocol.
- Budget Calendar: The Budget Calendar provides a view of budget-related events mapped to the protocol calendar.

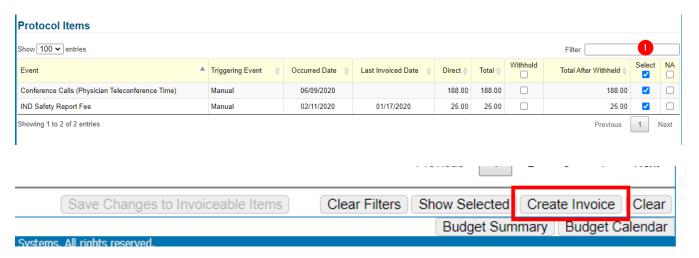




1. In the **Protocol Items** section, select the items to add to an invoice:

NOTE: Remember some Protocol Items are not a *variable* protocol-related event. This means that it can only be invoiced once during this entire study.

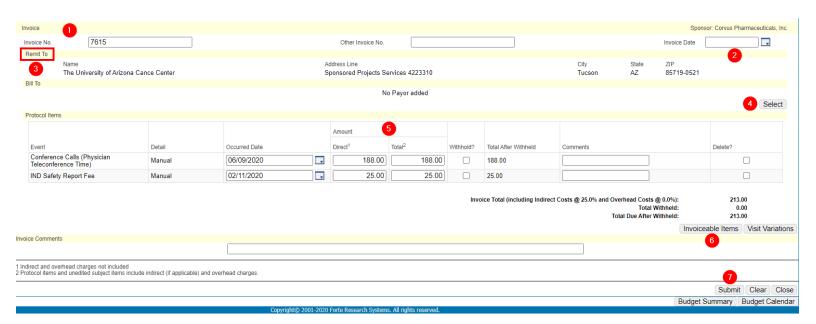
If you only want to add protocol items to this invoice, click **Create Invoice**. Otherwise, you can continue to select items to include on this invoice.







When the **Create Invoice** button is clicked, an invoice is created with all selected items. The invoice remains editable (additional items can be added, visit variations can be added, and so forth) until an Invoice Date is entered. **Do not enter an Invoice Date until the invoice is complete**. Invoices with an Invoice date cannot be edited; they can only be voided or amended.



- 1. OnCore will autogenerate an Invoice No. This can be customized for each invoice.
- 2. This is where you will enter the date of the invoice. See notes above regarding entering in a date.
- 3. **Remit To** address from the Parameters tab appears on the invoice automatically.
- Click Select to select the Bill To (Payor) information. Select the checkbox for the Payor and then click Submit.
- 5. Amounts in the **Direct** and **Total** columns can be edited, if needed.
- 6. If you want to add more Invoiceable Items to an invoice, click the **Invoiceable Items** button and select the items to add to the invoice.
- 7. Click Submit.





Add Subject-Related Milestones to an invoice

- 1. In the **Subject Milestone Items** section, select the checkboxes for all occurred visits (visits with an Occurred Date). These can be added to an invoice containing Protocol-Related Items or you can create a new invoice for these.
- 2. If Milestone payments are automatically paid by the sponsor, you will not need to invoice for them, so you will not add these to an invoice to send to the sponsor.
- 3. You will create a pseudo invoice to pull all of the Milestone visits for a subject into. The Invoice No. will be the Subject's Sequence No. Every time a visit is checked in that has a Milestone amount associated with it, the Milestone will show up in the Subject Milestone Items. Go to Invoices, click on the Invoice No. for that subject, click Update, click

Invoiceable Items, select the Subject Milestone Items to add to the invoice. Do NOT enter in an Invoice Date. Keep adding to this invoice as the subject completes Milestone visits.

Add pass thru procedures to an invoice

- 4. In the **Pass Thru Items** section, select the pass thru items checkbox(es).
- 5. Click Create Invoice.
- 6. You can also add the **Pass Thru Items** to an already existing invoice as long as an Invoice Date has not been entered.

Good to know

The costs of Subject Milestone Items are not editable on an invoice.

The costs of Protocol Items, Pass Thru Items, and Visit Variations can be manually adjusted on the invoice, if necessary.





Review/Manage Visit Variations

1. Navigate to the **Financials Console > Visit Variations** tab.

Review the list of missed and additional procedures and visits.

The **Unplanned?**, **Additional?**, **SOC**, **Missed**, and **NA** columns indicate *why* each of these items generated a Visit Variation.

You can see the comments added by clinical team members to explain each of these missed/added items.

2. Click **Update** in the lower left-hand corner.



3. Check the N/A for Invoice? checkbox if the variation shouldn't be invoiced.

Examples - A Missed visit does not need to be added to a sponsor invoice. We can't bill the sponsor for the visit since it didn't happen.

Other missed/additional procedures *should* be added to an invoice if we can invoice for the sponsor for them. The additional procedures will increase the invoice total; the missed procedures will be a credit back to the sponsor and will decrease the invoice total.

4. Click Verified? checkbox to mark a visit variation as verified, or no longer needing review. To mark all visit variations as verified, click the Mark All as Verified button at the bottom of the table. This will indicate to other members of the post-award financials team that all these variations have already been reviewed by someone. This will prevent a second team member from reviewing the same items again in the future.

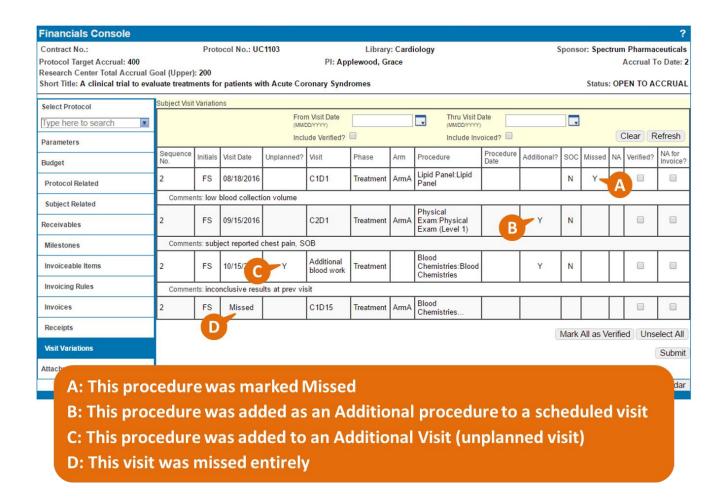
If a procedure is marked as N/A by the CRC, it did not occur and should not be included on an invoice. In Visit Variations, it will have a Y underneath the NA column.

5. Comments - In this column you can enter text (up to 100 characters) for each visit variation. Note that these comments are separate from those entered on the Subject Visit Update page and listed in the Visit Comments field under each variation. Click **Submit**.





- **6.** To see all Visit Variations that have been Verified, check the **Include Verified?** checkbox.
- Click Refresh.
- 8. To see all Visit Variations that have already been invoiced, check the **Include Invoiced?**Checkbox and click **Refresh**.
- 9. Visit Variations can also be filtered by **From Visit Date** and **Thru Visit Date**. Enter the dates and click **Refresh**.
- 10. To clear filters, click Clear.







Add Visit Variations to an invoice

- 1. Return to the **Financials Console > Invoices** tab.
- 2. Click the **Invoice No.** link to open an in-progress invoice.
- 3. If in view-only mode, click **Update**.
- 4. Click the **Visit Variations** button.
- Use the Select? checkboxes to include additional and missed procedures or visits on this invoice.
- 6. Click Submit.

Finalize an invoice

To finalize an invoice, you need to enter an Invoice Date.

1. Enter date in the Invoice Date field and click Submit.

The Update button no longer appears on this invoice. The only available options are Void and Amend.





Amending or voiding an invoice

Voiding an invoice will release its invoiceable items and visit variations so they can be added to another invoice in the future.

Amending an invoice will quickly void the current invoice and create a new, identical invoice that does not have an Invoice Date entered. This new invoice is editable.

View invoice withholdings

If a withholding percentage is entered for a sponsor in the Parameters tab of the Financials Console, a certain amount of each invoice will remain unpaid until study closure.

- 1. Navigate to Financials Console > Invoices.
- 2. Click the **Invoice Withholdings** horizontal tab.

All invoices are listed, with the total amounts due and the amount due after withholding. At the end of the study, make sure that the checks received from the sponsor cover the billed amounts and the withholding amounts on each invoice.





View and print an invoice

To generate an electronic invoice from OnCore:

- 1. If the invoice is currently in update mode, click **Close**.
- 2. In the Choose template section, in the lower right-hand corner, click the drop-down arrow and select Sponsor Invoice-UAHS logo. The PDF format is already selected. If you would like to export the invoice in a different format, then click the drop-down arrow and select the desired format.
- 3. Click Run Report.

A PDF document is generated in a new browser tab.





Tracking Receipts

When payments are received from a sponsor, they are tracked in the Financials Console > Receipts tab and applied to one or more finalized invoices to determine if the sponsor has paid the full amount due at study closure.

Enter a new receipt

- 1. Navigate to Financials Console > Receipts.
- Enter the check details:
 - Sponsor: leave as default
 - Check No.: enter check number from sponsor
 - Amount: enter amount on check
 - Date Received: enter date the check was received
 - Date Deposited: enter date the check was deposited (optional)
 - Date Reconciled: enter date this was reconciled (optional)

3. Click Add.

The receipt appears in the Payments Received table.





Apply a receipt to an invoice

- 1. Next to the sponsor receipt, click **Details**, and then click **Select**.
- Use the Select? checkboxes to apply this receipt to one or more invoices.
 Only finalized invoices (those with an Invoice Date) appear in this list.
- Click Submit.
- 4. Enter the **Payment** amount that should be applied to your invoice.

NOTE: The total amounts applied to each invoice cannot exceed the check amount.

5. Click Submit, and then click Close.

Navigate to **Financials Console > Invoices** to view the amount paid for each invoice, as well as the outstanding balances for each.

