

Clinical Research Invoicing System for Participants (CRISP)

GUIDE TO CREATING A CRISP INVOICE

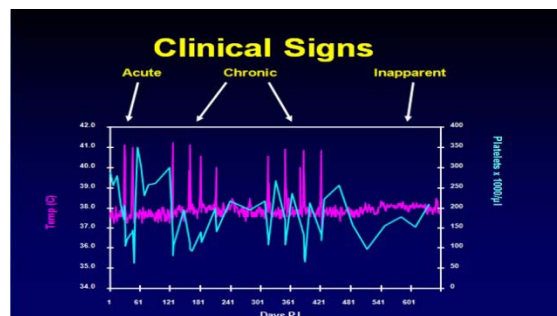


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General Information

What is CRISP?

Clinical **R**esearch **I**nvoicing **S**ystem for **P**articipants (CRISP) is a system that supports the tracking of patient events and is currently the invoicing process for industry sponsored clinical trials only.

Why CRISP?

CRISP is an auditable system that tracks clinical trial events and is used by both the department Financial Specialist and Study Coordinators along with Accounts Receivables (A/R) personnel. Invoices are to be processed through CRISP prior to A/R receiving the payment. This is for both invoiceable items and patient costs processed through Case Report Forms (CRFs).

Studies Required to be Entered into CRISP

- Any industry-funded clinical trials that have activity or end dates on or after 1/1/2013.
- Trials that end on or before 12/31/2012 will not have to be entered into CRISP; however, they can be entered at the department's discretion.

Once a PDRF for an industry-sponsored clinical trial is approved, the SPO will show up on the CRISP dashboard. Individuals who will initially have access to the record are the Financial Administrator and Clinical Trial Coordinator listed on the PDRF, as well as Accounts Receivables personnel.

The Financial Specialist has the ability to add other users or deactivate users who have left the department.

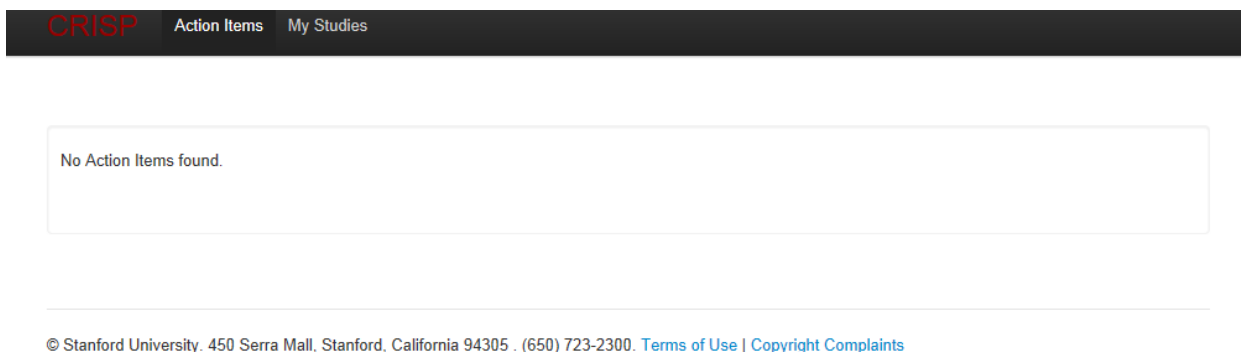
Getting Started

1. Access CRISP by navigating to <https://crisp.stanford.edu> on your internet browser.
2. Enter your SUNet ID and Password then click [Login].



The image shows the Stanford University WebLogin interface. At the top is the Stanford University logo. Below it, the text "WebLogin" is displayed with a link "(What is this?)". There are two input fields: "SUNet ID:" and "Password:". A "Login" button is positioned below the password field. A link for "Advanced settings" is located below the input fields. Below the form, there is a section for "Important Security Information" and a "Caution" note. At the bottom, there is a copyright notice: "© Stanford University. All Rights Reserved."

3. You should now be at the Main CRISP Menu (Initial Landing Page).



The image shows the CRISP Main Menu. At the top, there is a navigation bar with the "CRISP" logo and two menu items: "Action Items" and "My Studies". Below the navigation bar, there is a large white box with the text "No Action Items found." At the bottom of the page, there is a copyright notice: "© Stanford University. 450 Serra Mall, Stanford, California 94305 . (650) 723-2300. [Terms of Use](#) | [Copyright Complaints](#)"

Action Items - the Action Items page provides a list of items that require your attention.

My Studies - the My Studies page provides a list of all studies linked to your authority.

Accessing Your Studies

1. Click on My Studies to see a list of all of your studies. Refresh by clicking the [Show All](#) button. Note: You will automatically have access if your name was on the PDRF as the Financial Specialist or Study Coordinator.
2. You can also Search for a specific study using one of the following prompts:
 - Short Name – nickname associated with the study
 - SPO – SPO # generated in SeRa
 - PI – principal investigator
 - PTA – full PTA or Oracle 5-alpha award number
 - Sponsor – Sponsor name
3. You can sort by any blue hyper link column.

Search for

Trial #	Short Name	Subjects	Invoices	SPO #	PI	Setup Complete?	PTA	Sponsor
470	NRC Study	Subjects (9)	Invoices (9)	50114	Gurtner, Geoffrey C.	No	VACNX	Cook Biotech, Inc.
69	V212-001	Subjects (13)	Invoices (7)	49962	Brown, Janice (Wes)	Yes	1143825-100-VACMZ	Merck, Sharp and Dohme Research Labs
101	PROSPECT	Subjects (1)	Invoices (7)	51266	Zamanian, Roham T.	Yes	VACOO	Actelion Pharmaceuticals US, Inc.
329	GSK Lamictal	Subjects (0)	Invoices (7)	42641	Chang, Kiki D.	Yes	1122080-100-VABEX	GlaxoSmithKline
384	-	Subjects (0)	Invoices (7)	45156	Medeiros, Bruno Carneiro de	No	VACCS	Millennium Pharmaceuticals, Inc.
418	Hemagioma	Subjects (5)	Invoices (7)	46892	Benjamin, Latanya T.	No	VACGF	Institut de Recherche Pierre Fabre
123	Alemtuzumab - Extension protocol	Subjects (4)	Invoices (6)	52412	Dunn, Jeffrey E.	Yes	1149717-100-VACQD	Genzyme

4. Access a specific study by clicking the Trial # link.

Trial Setup - Trial Info

This is a summary screen that provides basic information for the study. It is pre-populated from the SeRA system.

Short Name: Training | SPO #: 40579 | PI: Fitzgerald, Peter J. | Sponsor: Xtent, Inc.

Trial Info

Principal Investigator Fitzgerald, Peter J.
SPO # 40579
Project Name Custom IV
Sponsor Xtent, Inc.
Short Name
PTA #
Billing Start Date
Billing Frequency
Budget End Date
Setup Complete?
Comments

Save Changes

1. You may update the following fields:
 - Short Name: Study short name or nickname
 - PTA #: PTA number or Oracle 5-alpha award number
 - Billing Start Date: default award start date
 - Billing Frequency: default billing frequency
 - Budget End Date: default award end date
 - Setup Complete?: default is “No.” The Financial Specialist can change to “Yes” after the Fee Schedule and Visit Procedures are completed. Once the Setup Complete is marked “Yes,” the Study Coordinator can enter visits.
 - Comments: free form field for notes such as Sponsor withhold amount/percentage.
2. Click on the **Save Changes** button when completed.

Trial Setup - Fee Schedule

The Fee Schedule creates a drop down menu for all invoiceable items (invoices to Sponsor sent by A/R) and CRF related items. Note: the Study Coordinator does not see this screen.

Short Name: Training | SPO #: 40579 | PI: Fitzgerald, Peter J. | Sponsor: Xtent, Inc.

Fee Schedule

<input type="checkbox"/> Name	Start Date	End Date	Fee	Fee Type
<input type="checkbox"/> Start-up Costs	30-OCT-2012		8,000.00	Study Start-up F
<input type="checkbox"/> Screening - Visit 1	30-OCT-2012		1,000.00	Per Subject Cos
<input type="checkbox"/> Visit 2	30-OCT-2012		1,200.00	Additional Subje
<input type="checkbox"/> Safety Report	30-OCT-2012		90.00	Other Study Rel

1 - 4

- To add a fee, click on the **Add Fee** button and enter the following information:
 - Name: name of fee
 - Start Date: defaults to today's date but can be changed to the award start date or other date
 - End Date: may be left blank unless the fee amount changes and a new fee needs to be added
 - Fee: fee amount from award document in whole dollars. No dollar sign (\$), period (.) or comma (,). The field will be automatically formatted.
 - Fee Type: one of the following fee types:
 - Per Subject Costs - per patient
 - Additional Subject Costs - invoiceable patient costs
 - Other Study Related - IRB or one-time fees
 - Study Start-up Fees - one-time start up fees
- To delete an erroneous fee, select the checkbox next to the fee and click on the **Delete Checked** button.
- Click on the **Save Changes** button when completed.

Additional Information:

- The fee information comes from the Sponsor award document (Schedule A) and approved budget
- **Start-up Fees** - the department must initiate the invoice for these
- **IRB Annual Renewal** - departments can attach a copy of the IRB approval letter on the invoice screen
- **Screen Failures** - this is usually an invoiceable item
- **SAE Reporting** - this is usually an invoiceable item
- Not all procedures need to be listed on the Fee Schedule if they are included as part of the visit (i.e. If three procedures are always done during Visit 1, the three procedures would be listed as "Visit 1" rather than three separate procedures).
- **Reminder – an invoice cannot be created for an item if it is not on the Fee Schedule. There is a pull down menu on the invoice that comes from the Fee Schedule.**

Trial Setup - Visit Procedures

The Visit Procedures records the type of procedure performed at each visit. There are a series of screens that will open based on your selections. This function is handled by the Financial Specialist. This part must be done first or else the Study Coordinator cannot do his/her part. Study Coordinators do not see these screens unless they are given Financial Specialist access.

Short Name: Training | SPO #: 40579 | PI: Fitzgerald, Peter J. | Sponsor: Xtent, Inc.

Visit Procedures

Visit #	Nickname	Procedure
Visit 1	Screening	Screening - Visit 1
Visit 2	Visit 2	

1 - 2

Add Visit

1. To add a visit, click on the **Add Visit** button. The visits always start from Visit 1.
2. Add a nickname and click on the **Save** button. (i.e. Baseline for Visit 1 or just Visit 1. It can be any visit name such as Visit 5 if this is not a new study).

Short Name: Training | SPO #: 40579 | PI: Fitzgerald, Peter J. | Sponsor: Xtent, Inc.

Visit

Visit 3

Nickname

Save Close

- To add a procedure, click on the **Add Procedure** button. Select a procedure from the pull down menu and enter the appropriate dates. This must be setup together with the visit.

Short Name: Training | SPO #: 40579 | PI: Fitzgerald, Peter J. | Sponsor: Xtent, Inc.

Visit

Visit 1

Nickname

Procedures

<input type="checkbox"/> Procedure	Start Date	End Date
<input type="checkbox"/> Screening - Visit 1	30-OCT-2012	

1 - 1

- Click on the **Save Changes** button when completed.

Additional Information:

- The procedure must be on the Fee Schedule or else it will not be listed on the pull down menu. If the item is not listed, go back to the Fee Schedule and add the procedure.
- The procedure name can be the same as the Visit Nickname.
- Visit Name cannot be created for a subject if it is not on the Visit Procedures (Nickname). There is a pull down menu on the Visit Name that comes from the Visit Procedure Nickname under Trial Setup.
- A Visit Procedure will be left blank if the procedure is not on the Trial Fee Schedule or listed as a Procedure under Trial Setup-Visit Procedures. This will leave a zero dollar amount on the invoice.

Trial Setup-Trial Users

The Trial Users provides a list of individuals who have access to this study. This screen is only seen by the Financial Specialist and A/R. The Financial Specialist can add or deactivate key users.

Short Name: Training | SPO #: 40579 | PI: Fitzgerald, Peter J. | Sponsor: Xtent, Inc.

Trial Users

Role	SUNet ID	Active?
Principal Investigator	pfitz	No
Financial Specialist	agujar	Yes
Accounts Receivables	ltat	Yes
Accounts Receivables	pumbias	No
Accounts Receivables	ljones1	Yes
Accounts Receivables	cyn1	No
Accounts Receivables	jmarsh	No
Accounts Receivables	dkurz	No
Financial Specialist	lerwin	Yes
Accounts Receivables	lerwin	Yes
Study Coordinator	lerwin	Yes
Study Coordinator	ltat	Yes

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Add User Save Changes

1. To add a user, click on the **Add User** button.
2. Select one of the following roles:
 - Accounts Receivables – role assigned to A/R Management. Supervisors, Billers & Receipts Staff – **does not see the Patients and Visits**
 - Co-Investigator – role assigned to co-PI
 - Financial Specialist – role assigned to Department Finance personnel – **does not see the Patients and Visits**
 - Principal Investigator – role assigned to PI
 - Study Coordinator – role assigned to Coordinator working on the study – **does not see the Trial Setup /Fee Schedule or Trial Setup/Visit Procedure.**

3. Enter the SUNet ID of the user.
4. Select “Yes” to make the user active or “No” to deactivate the user.
5. Click on the **Save Changes** button when completed.
 - **Note: individuals can be assigned multiple roles. It is advised that the Financial Specialist have both the Financial Specialist and Study Coordinator roles to understand the full picture of what is being entered into CRISP.**

Patients & Visits

The Patients & Visits provides a list of subjects involved in the study. This is the function handled by the Study Coordinator. The Study Coordinator cannot add Patients & Visits until the Financial Specialist has added the Fee Schedule and Visit Procedures.

Subject	Start Date	End Date	Visits	Disposition
LME-1234	30-OCT-2012	-	Visits (1)	Screen
LT-5678	30-OCT-2012	-	Visits (2)	Enrolled

1 - 2

Add Subject

1. To add a subject, click on the **Add Subject** button.
2. Enter the following fields:

The screenshot shows the 'Subject' form with the following fields: Subject Identifier (empty), Subject Start Date (31-OCT-2012), Subject End Date (empty), and Disposition (dropdown menu). The dropdown menu is open, showing options: Screen, - Select -, Screen, Enrolled, Screen Failure, Completed, Lost to Follow Up, Withdrawn, and Death. The 'Screen' option is highlighted. There are 'Save' and 'Close' buttons in the top right corner. At the bottom, there is a copyright notice: © Stanford University 450 Serra Mall, Stanford, California 94305 (650) 723-2300 Terms of Use | Copyright Complaints

- Subject Identifier - usually initials and some digits to identify the subject
- Subject Start Date - defaults to today's date but add actual start date
- Disposition – select appropriate item

3. Click on the **Save** button when completed.

- To add a visit for a particular subject, click on the Visits (#) link for that subject.
- Click on **Add Visit** button to add a Visit and enter the following fields:

Visit for LME-1234

Subject LME-1234 Save Close

Visit Type Scheduled

Visit Name 2 - Visit 2

Visit Date 30-OCT-2012

Comments

- Visit Type - defaults to Scheduled
- Visit Name - pull down menu from the Trial Setup-Visit Procedures
- Visit Date - defaults to today's date but enter actual visit date

- Click on the **Save** button when completed.
- You have just setup your first Subject and Visit. You can continue setting up Subjects and add their visits as they are seen. Once you are ready to send the CRF for those subjects seen, create a CRISP invoice and send it to A/R. Subject costs will automatically appear on the invoice, once generated.

Visits for LME-1234

Visit	Visit Type	Comments	Visit Date ▲	Procedures
Visit 1 - Screening	Scheduled		30-OCT-2012	Screening - Visit 1
1 - 1				

Add Visit

Invoice Requests

The invoice can be created by either the Study Coordinator or the Financial Specialist.

Request ID	Status	Invoice #	Invoice Date	Invoice Amount	Amount Paid	Request Date
5223	Pending	-	-	-	-	30-OCT-2012

1 - 1

Create Invoice Request

1. To create an invoice request, click on the **Create Invoice Request** button.
2. CRF Sent? Defaults to “No.” Change to “Yes” if a CRF was sent. A/R will not send an invoice to the Sponsor. This invoice request will be for record purposes only. If CRF was sent and outstanding patients haven’t been billed, they will automatically pop up on the invoice.

Invoice Request

Invoice Request ID

Invoice Request Date 31-OCT-2012

CRF Sent?

Save Close

3. Click on the **Save** button when completed.

4. An invoice template will be created. Depending on the type of expense, add or edit the fee type.

Invoice Request

Invoice Request ID 5269 Save Changes Close Delete

Invoice Request Date 31-OCT-2012

CRF Sent? No

Per Subject Costs

None Edit

Other Study Related Fees

None Add Other Fee

Study Startup Fees

None Add Startup Fee

Attachments

None Attach Document

5. To edit the Per Subject Costs, click on the **Edit** button. Enter any comments and mark the item billable “Yes” or “No” and click on **Save** when completed.

Subject Visit Billable Costs

Procedure <input type="button" value="v"/>	Comments	Billable?
Screening - Visit 1	<input type="text"/>	Yes <input type="button" value="v"/>

1 - 1

Save Cancel

6. To add Other Study Related Fees or Study Startup Fees, click on the **Add Other Fee** or **Add Startup Fee** button. Select the procedure from the pull down menu. Note: the procedure must be on the Fee Schedule. Enter the date, comments, and click on the **Save** button when completed.

Study Fee

Procedure: Safety Report

Fee Date: 31-OCT-2012

Comments

Save Cancel

7. To add an attachment or any supporting documents, click on the **Attach Document** button. Select [Browse] to search for the document. Click on the **Save** button when completed.

Add Attachment

Document Type: Other

Select File: Browse...

Comment

Save Cancel

8. Assign or route the invoice to the appropriate individual:
- With Study Coordinator authority, the box will show **Send to FS** (financial specialist)
 - With Financial Specialist authority, the box will show **Send to A/R** (A/R biller)
9. Select the appropriate Assignee from the pull down menu of names.

Assignee: Umblas, Pacita Ferrer

Comment

Assign Cancel

- Assign the invoice to your department Financial Specialist or A/R biller
 - Enter any comments to send to the Assignee
10. Click on the **Assign** button when completed. It is now in the Action Item menu for the FS or A/R biller.