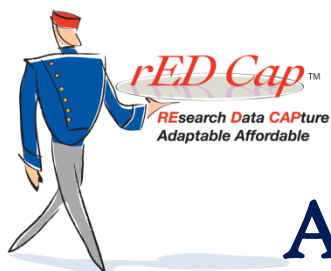




Web-based electronic data capture software
for data management of multi-center
research studies, developed by

BSI 
BioStat International, Inc.

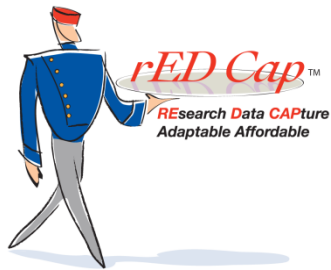


About BioStat International...

- A proven Contract Research Organization (CRO)
- Provides a full range of product development services to device and pharmaceutical companies
- Serves major clients such as device giant Roche Diagnostics and women's health leader Hologic

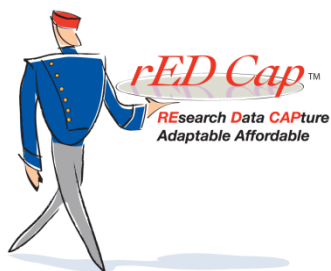


BSI's headquarters in Tampa



BSI's culture...

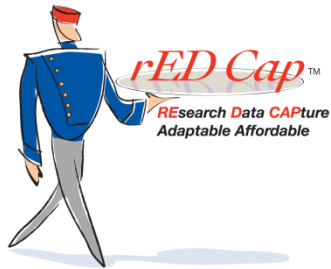
- Respect and support to our clients
- Embracing change and innovation
- Taking clients' priorities as our own
- Aiming for affordability and environmental responsibility
- Knowing that every circumstance creates its own opportunity



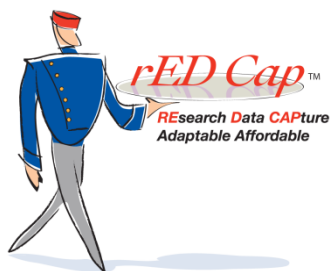
Our niche...

“Most clinical trial software is geared towards well-funded industry research. BSI recognized a void in the market for a well-managed and affordable web-based data management solution. **We developed software to fill that niche.**”

-- Maureen Lyden, M.S.
President and CEO
BioStat International, Inc.



We wanted a name for our new software
that reflected our company's culture.



We were inspired by
the story of Red Cap 42.

Hence, our name.

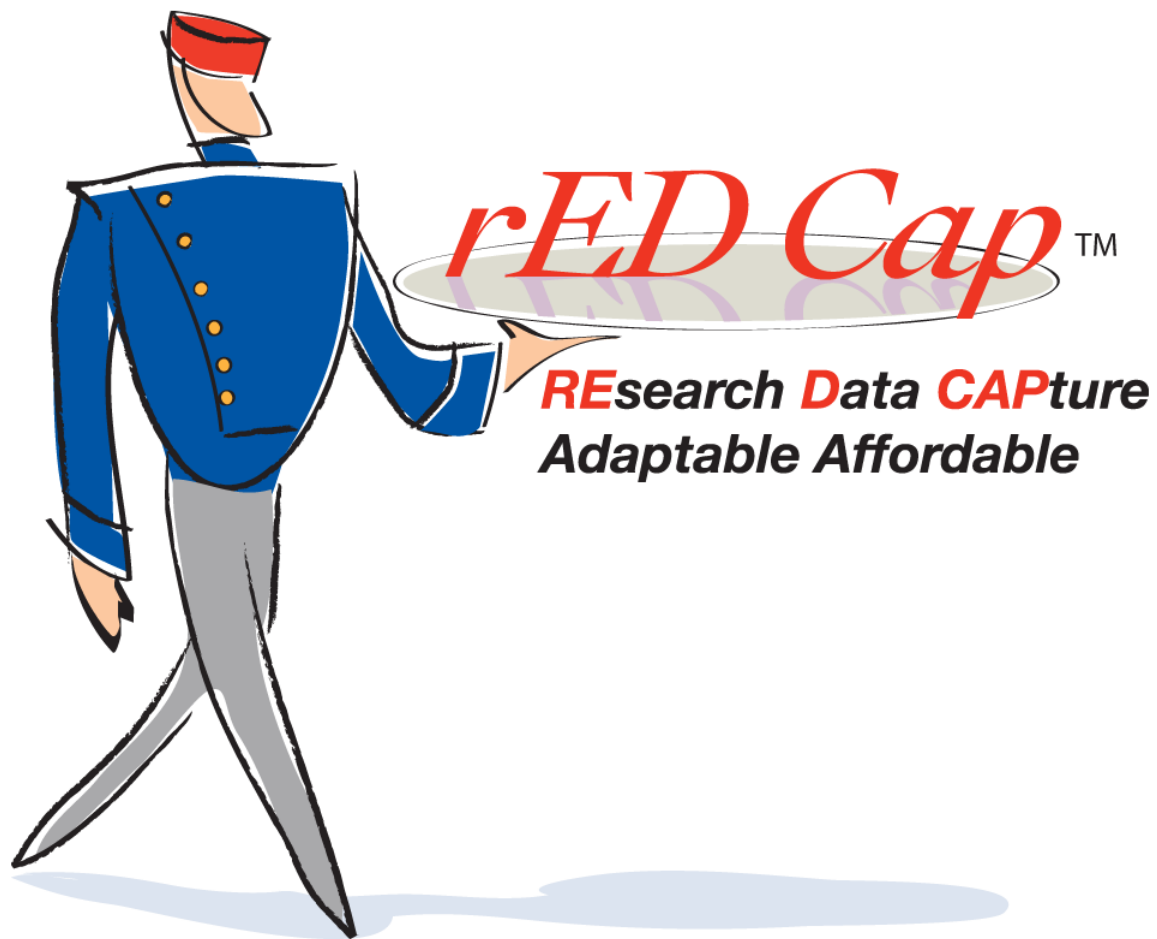


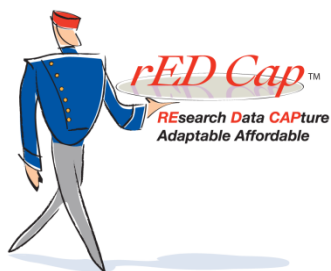
- “Red Cap 42” was a baggage handler at Grand Central Station during World War II.
- He shared a philosophy of service in the way he lived and treated others.
- We believe his philosophy was very much like our own.

*Look up.....*seek wisdom.

*Look in.....*grow as a person.

*Look out.....*help others.

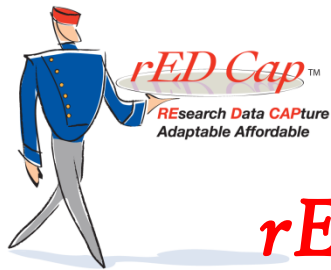




Why will you like *rED Cap*?

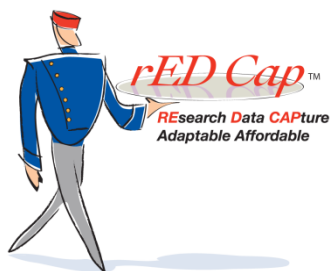
You'll work with an experienced CRO to design your eCRF, manage your hosting, and provide statistical expertise to your data management.

You'll get up to speed quickly with *rED Cap*. This system is easy and intuitive to use, with flexibility, adaptability and sophisticated data checking capability.



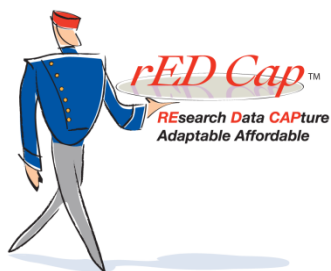
rED Cap is not just for regulated clinical trials...it's also ideal for

- Observational studies
- Pre-clinical
- R&D
- Post-Marketing/Marketing
- Registries



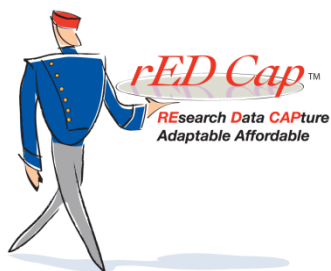
rED Cap is easy to use...

- Works with iPad, laptops, & supported desktop browsers (Explorer, Firefox, Google, Safari 5)
- Fully supports web page display & data segregation
- Includes ODM v1.3 base full-cycle clinical data warehouse



rED Cap offers professional design and training...

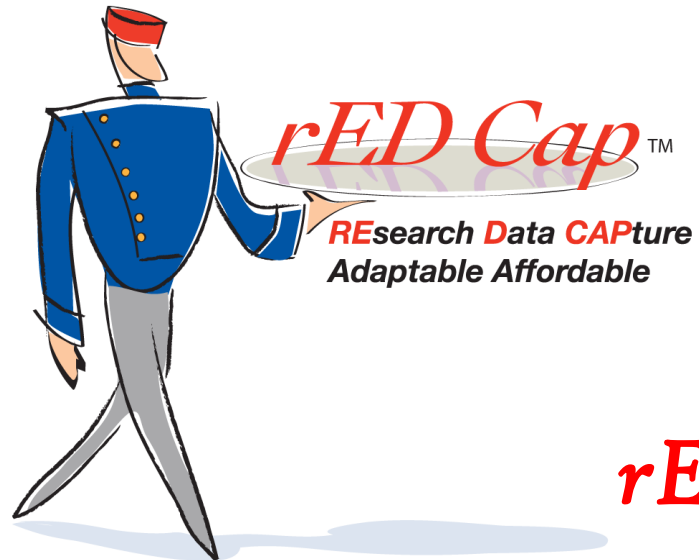
- eCRF design by experienced database & SAS® programmers
- Ongoing data review by data analysts & statisticians trained in protocol endpoints
- Customized training designed by experienced data managers & clinical monitors



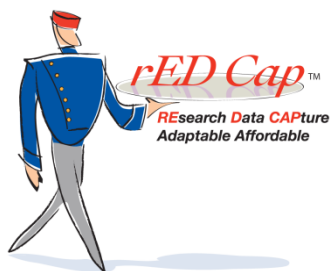
rED Cap has cost-effective pricing...

- **Based upon hours/tasks at competitive rates**
 - Study Administrator: eCRF and report development, user maintenance and technical support
 - Data Manager/Analyst – review data collection for statistical endpoint consistency and accuracy
 - System Administrator – manage hosting, configuration, synchronization and database security/integrity
- **No license or hosting fees**

AND NOW...



rED Cap at a glance



Get Help instantly!

AE Treatment **Tip** -- select --

AE Treatment Other

AE Outcome

AE Resolution Date

No AE Comment

AE Comments

Yes No

Yes No

Not Done

This field is required.

Subject Station

Query Station

Report Station

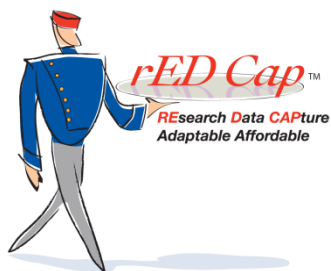
Document Station

Training Station

Information Booth

- Blank eCRFs
- rED Cap User Guide

- Use mouse-over tips presented by *rED Cap*.
- See alert messages as you type.
- If you have questions, just go to the Information Booth. It's always visible!



Use the Contact Help Desk

Username:

Password:

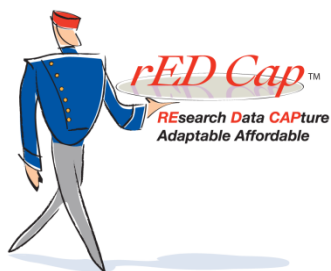
[Forgot your password?](#)

SECURE LOGIN

Need help? Please [Contact Help Desk](#) for support.

Subject Station
Query Station
Report Station
Document Station
Training Station
Information Booth
My Profile
Contact Help Desk

- Enjoy an on-line Help Desk with technical support that does not require logging in to the *rED Cap* study.
- Get an immediate ticket number assignment.
- Get a response within 24 hours.



Use the Contact Help Desk

Contact Help Desk

Please take some time to fill in this form. The more information you give us, the better we can serve you. Mandatory fields are marked with "*". When you're done, click the Submit button at the bottom of the page. Thank you.

Category*:	Please select a category ▾
Issue*:	<input type="text"/> 0 out of 5000 characters
First Name*:	<input type="text" value="Maureen"/>
Last Name*:	<input type="text" value="Lyden"/>
Phone*:	<input type="text" value="813-979-1619"/> ext. <input type="text"/> (format 999-999-9999)
Email*:	<input type="text" value="mlyden@biostatinc.com"/> format abc@xyz.com
<input type="button" value="Submit"/> <input type="button" value="Submit & Solve"/> <input type="button" value="Clear Form"/>	

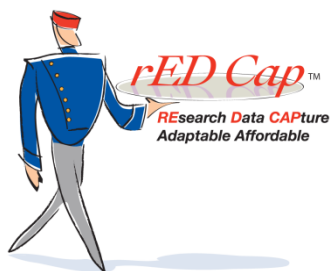
- Complete tech support form.
- Click submit.
- A ticket number is assigned.
- A confirmation email receipt is sent.



Get customized training and support

Subject Station
Query Station
Report Station
Document Station
Training Station
Information Booth
My Profile
Contact Help Desk
Logout

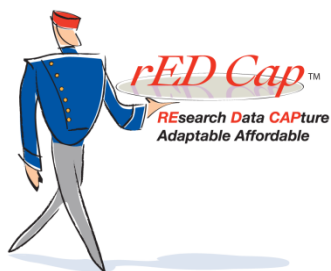
- Get separate URL, user ID and password.
- Select Training Station.
- Choose a Platform.
- Complete Review.
- Print certificate.



Customized Information Booth

Subject Station
Query Station
Report Station
Document Station
Training Station
Information Booth <ul style="list-style-type: none">• Blank eCRFs• eCRF Guidelines• FAQ's• rED Cap User Guide
My Profile
Contact Help Desk
Logout
i Signal Flags +
i Field Data Status +
i Field Action Icons +

- Blank eCRF
- *rED Cap* User Guide
- Examples of other possible entries:
 - FAQs,
 - eCRf Guidelines
 - Study specific Information



Standardized study reports

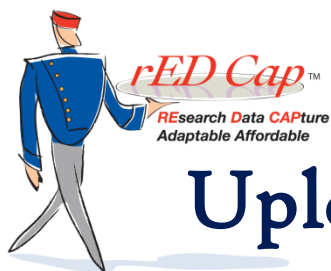


Disposition Reports	
Report Name	Description
Subject Disposition Summary by Site	Subject Disposition Report Summary by Site
Monitoring Reports	
Report Name	Description
Outstanding SDV Report	Outstanding SDV Report by Subject and Site
Query Reports	
Report Name	Description
Query Summary Report	Query Summary Report



At the Report Station:

- Standard reports:
 - Subject disposition
 - Query summary
 - Outstanding SDV
- Customized reports upon request
- Flexible report format (HTML, Excel)
- Print or save to PC

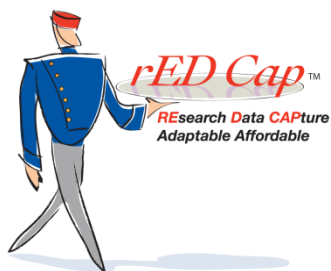


Upload relevant files from a study visit

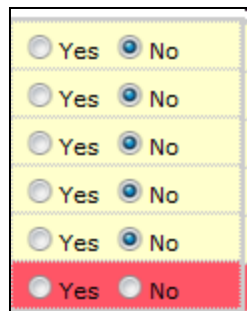
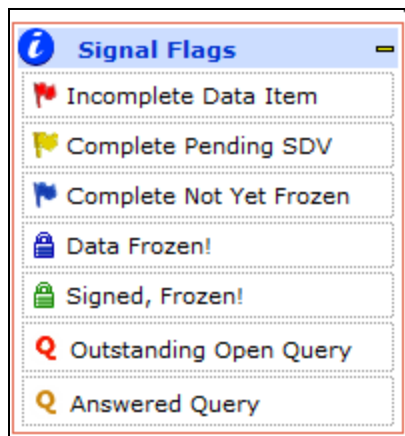
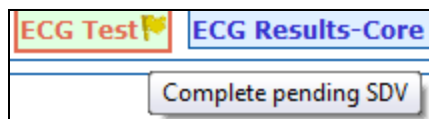
Start Time	12:15	HH:MM (24 Hr)
Stop Time	12:20	HH:MM (24 Hr)
Evidence of MI?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Investigator Comment	normal	
Upload ECG Tracing File	VIEW	EKG Tracing.gif



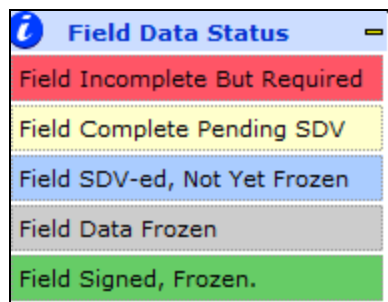
- Laboratory data
- Diagnostic data
- Photographs/Images
- Device outputs, e.g. glucose meters, etc.



Enjoy user-friendly operation



- See color or mouse-over for text.
- Select Signal Flags to view flags, padlocks and Q's.
- Select Field Data Status to view Incomplete, Complete, Pending SDV, Frozen and Signed-Off.





Share documents by study and site

Upload to Study-wide (Everybody)

Documents for Study-wide (Everybody)

Title (Uploaded By)

+ rED Cap Features and Benefits (Sponsor)

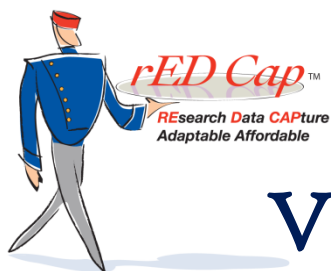
Upload to Site 001 - Dr. Watson (SITE)

Documents for Site 001 - Dr. Watson (SITE)

Title (Uploaded By)

+ Special File for Dr. Watson (Sponsor)



- Current protocol
- Instructions for use
- Guidelines
- Training materials
- Specific study forms/logs
- Source document templates

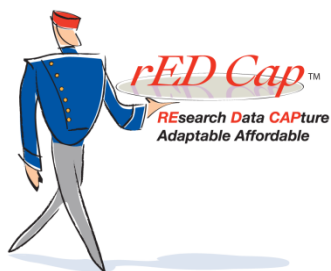


View or download documents

Subject Station
Query Station
Report Station
Document Station
Training Station
Information Booth
My Profile
Contact Help Desk
Logout

- Select Document Station.
- Click on '+' to expand.
- Click on icon to download or save to your PC.

Documents for Site 001 - Dr. Watson (SITE)
Title (Uploaded By)
— Special File for Dr. Watson (Sponsor)
File Name
X   Photo2.JPG



Upload documents to share

Site: 001 - Dr. Watson ▾

Upload to Site 001 - Dr. Watson (SITE)

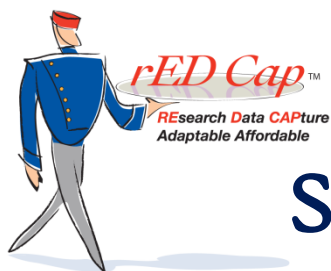
Required fields are marked with an asterisk: *

*Title:

Description:

Files: Select a file to attach:

- Select Document Station
- Click on “Upload”
- Browse and attach file
- Add a description
- Click here to save
- Add additional files to existing uploads



Share documents within sponsor team at the Monitor Station

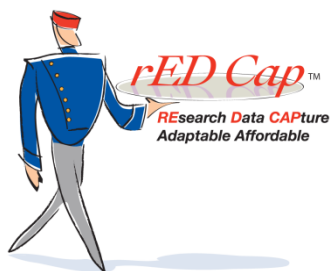
Site: -- Select Site --

Upload to Study-wide (Everybody)

Documents for Study-wide (Everybody)

Title (Uploaded By)	Date Time	
Monitor Reports (Maureen Lyden)	2012-08-13 08:57:56	
File Name	File Type	File Size
FM-11.07SSV_PSV_SIVReport2OCT09.pdf	application/pdf	129.46 KB
FM-12.05InterimVisitReport2OCT09.pdf	text/x-plain-to-save	70.87 KB
FM-13.04CloseOutVisitReport2OCT09.pdf	text/x-plain-to-save	56.54 KB
Travel Expenses (Maureen Lyden)	2013-03-08 18:56:51	
File Name	File Type	File Size
Employee Travel Checklist 2008.doc	application/msword	28 KB

- Monitoring Report templates
- Complete reports
- Expense reports
- Monitoring forms and tools



Queries are easy!



Site No. 001 - Dr. Watson Open Queries Answered Queries Closed Queries

print

ID/Action	Subject ID	Visit	Item Name	Query Text	Query Time	View
17.	001-001	Index Procedure	Procedure Date	Treatment date prior to informed consent date, please verify	2011-10-14 10:01:51	
18.	001-001	Baseline	DOB	please check date again	2011-10-14 10:17:38	

Procedure Date: 10/07/2011

Please provide your answer for this query in Response/Reason for Change field.

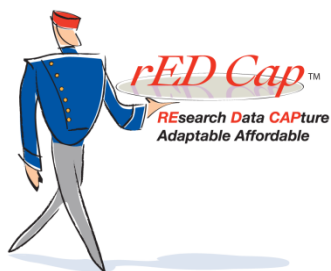
Query Text: Treatment date prior to informed consent date, please verify

Value Change? Change No Change Not Done

Procedure Date: 10/07/2011 mm/dd/yyyy

Response/Reason for Change:

- Select Query Station.
- Filter by Site, Open, Answered or Closed Queries.
- Sort and print listing.
- Use one click to answer Query directly into the eCRF.



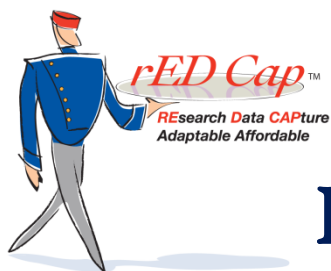
Even eCRF layout is flexible...

Last Visit	30 Days
Exit Date	10/12/2011 <input type="text"/> mm/dd/yyyy
Did the Subject Complete the Study Through Day 30?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Reason for Exit Prior to Day 30	Subject Withdrew Consent
D/C Reason Description	[disabled]
Date of Death	[disabled] <input type="text"/> mm/dd/yyyy

Heparin	<input type="radio"/> Yes <input type="radio"/> No	Units Given:	<input type="text"/>	units
NTG	<input type="radio"/> Yes <input type="radio"/> No	Micrograms Given	<input type="text"/>	ug
Dextran-40	<input type="radio"/> Yes <input type="radio"/> No	CC Given	<input type="text"/>	cc
<input type="button" value="Submit"/> <input type="button" value="Save for Later"/>				

Collection Date	<input type="text"/> <input type="text"/>				
Parameter	Not Done	Result	Unit	Normal Range (Normal, Low, High)	Clinically Significant? (Yes/No)
Hemoglobin (Hgb)	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> N <input type="radio"/> L <input type="radio"/> H	<input type="radio"/> Yes <input type="radio"/> No
RBC	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> N <input type="radio"/> L <input type="radio"/> H	<input type="radio"/> Yes <input type="radio"/> No
WBC	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> N <input type="radio"/> L <input type="radio"/> H	<input type="radio"/> Yes <input type="radio"/> No

- Listing
- Multiple columns per row
- Tabular



Need a paper CRF for the file?

Toolbox: Missed Visit Tool Not Done Tool CRF Tool

Subject ID	Last Visit	Date IC Signed	DOB	Procedure Date	Action
001-001 Exited	Index Procedure	10/10/2011	01/05/1990	10/07/2011	

- Select subject station
- Check the CRF Tool Box
- Click on the 'folder' icon
- View subject's completed CRFs
- Click on print

CRFs for Subject #001-001 Site: Dr. Watson

Protocol Name: Protocol # CTP002-1

Metadata Version Information:

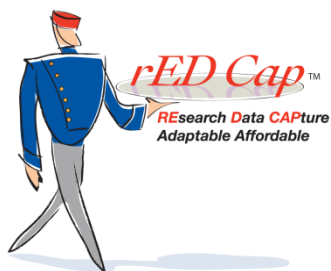
Metadata Version OID: m.mdv1
 Metadata Version Name: Meta Data Version 1
 Metadata Version Description: Meta Data Version 1
 Profile Snapshot Date and Time: 2011-10-18 18:35:09

Subject #001-001 Site: Dr. Watson Baseline

Baseline :: Eligibility :: Inclusion Criteria

All Answers Must Be "YES" To Be Included In Study

The subject is at least 18 years of age or older?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Subject has 1 or 2 lesions with > 60% stenosis in a 3-4 mm native coronary artery?	<input checked="" type="radio"/> Yes <input type="radio"/> No
The subject is scheduled for a coronary stent procedure?	<input checked="" type="radio"/> Yes <input type="radio"/> No
The subject agrees to abstain from enrollment in any other clinical trial for the duration of the study?	<input checked="" type="radio"/> Yes <input type="radio"/> No
The subject and/or guardian are able to read and understand instructions and give informed consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No
The subject is able and willing to follow the protocol requirements?	<input checked="" type="radio"/> Yes <input type="radio"/> No



How do I navigate *rED Cap*?

rED Cap Demo Study (Active): Subject Station

Site No. 001 - Dr. Watson

Site No. 001 - Dr. Watson [Add a new Subject](#)

print Search Subject ID: New

Subject ID	Last Visit	Full Name	DOB	Procedure Date	Action
001-001	30 Days	John A. Doe	06/20/1960	01/03/2013	edit

1 2 [Next] [Last] [Show All]

ID: 001-001 Date IC Signed: 10/10/2011 DOB: 01/05/1990 Procedure Date: 10/07/2011

Baseline [Index Procedure](#) [Post-Procedure](#) [30 Days](#) [Unscheduled](#) [Common Forms](#) [Exit](#)

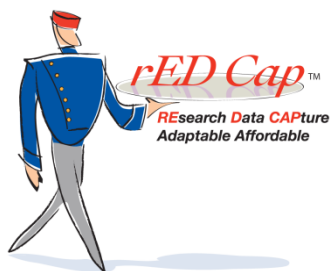
[Eligibility](#) [Medical History](#) [PE and Vital Signs](#) [ECG](#) [Angiography](#) [Labs](#)

[PhysExam](#) [Other PhysExam](#) [Vital Signs](#)

Toolbox: Actions

Pulse Rate	68	BPM
Respiratory Rate	12	BPM
Temperature	98	Unit <input type="radio"/> C° <input checked="" type="radio"/> F°
Systolic BP	124	mmHg
Diastolic BP	72	mmHg

- Stations, flags, status and icons on the left
- Study # and site/PI in header
- Filter by Status, use search for subject, and page easily.
- Click on Subject # to view visits
- Each visit tab contains all the eCRFs for that visit



Ready to add a subject?

Site No. 001 - Dr. Watson Toolbox: Missed Visit Tool Not Done Tool OK

[Add a new Subject](#)

print

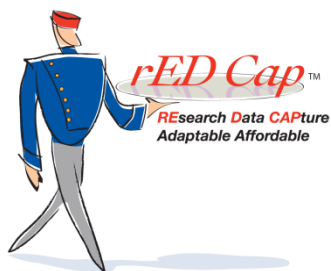
Subject ID	Last Visit	Date IC Signed	DOB	Procedure Date
001-001 Exited	30 Days	10/10/2011	01/05/1990	10/07/2011

*Site Name Site No. 001 - Dr. Watson

*Subject No.

[Submit](#)

- Select Subject Station
Note: This listing is customizable
- Click on Add a new Subject.
- Enter and Submit.
- *rED Cap* will not allow you to enter the same I.D. twice!
- Next....



...Subject Station

print

Subject ID	Last Visit	Date IC Signed	DOB	Procedure Date
001-001 Exited	30 Days	10/10/2011	01/05/1990	10/07/2011
001-002				

ID: 001-002 Date IC Signed: DOB: Procedure Date:

Baseline Index Procedure Post-Procedure 30 Days Unscheduled Common Forms Exit

ID: 001-002 Date IC Signed: DOB: Procedure Date:

Baseline Index Procedure Post-Procedure 30 Days Unscheduled Common Forms Exit

Eligibility Medical History PE and Vital Signs ECG Angiography Labs

Visit Date Inclusion Criteria Exclusion Criteria

Visit Date mmm/dd/yyyy

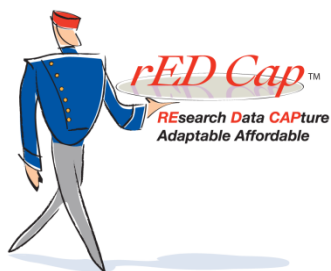
Not Done

This field is mandatory!

Days from Procedure Tip

Submit Save for Later

- Click on your subject.
- All the Required Visit tabs will appear.
- Enter in any visit order desired.
- Follow *rED Cap's* prompts, tips and messages.



Enter an AE

ID: 001-002 Date IC Signed: DOB: Procedure Date:

Baseline Index Procedure Post-Procedure 30 Days **Unscheduled** Common Forms

Concomitant Medications Adverse Events Comments

Concomitant Medications **Adverse Events** Comments

Adverse Events

Add: Adverse Events Print

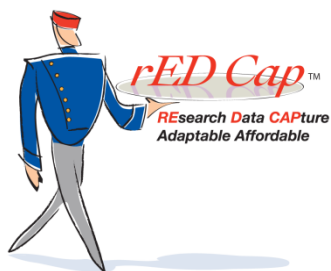
ID	Adverse Event Description	AE Onset Date	Action
1	Headache	06/08/2011	Select

Adverse Events

Add: Adverse Events Print

ID	Adverse Event Description	AE Onset Date	Action
1	Headache	06/08/2011	Select
2	Nausea	06/09/2011	Select

- The Common Form tab contains forms/logs that may/may not be needed.
- Multiple forms may be entered for each subject.
- Select “Adverse Events.”
- Enter data, submit and click Add: Adverse Event to add more.



Message to the Site

- Select a site
- Click the Message Tool
- Automatically creates an e-mail with lists of incomplete fields and outstanding queries.
- Edit to add more information.
- Sent to coordinator roles at site.
- Blinded copy sent to monitor's e-mail.

rED Cap Demo Study (Active): Subject Station

Site No. 001 - Dr. Watson

Site: 001 - Dr. Watson

Message to Site No. 001

print Search Subject ID [] [New] [] [] [] [] [] [] []

Subject ID	Last Visit	DOB	Procedure Date
001-001	30 Days	06/20/1960	01/03/2013

Message to Site Coordinator [Site No. 001 - Dr. Watson]

Please update the email message as needed.

From: Sally Jones<mlyden@biostatinc.com>

To: Marge Thatcher<mlyden@biostatinc.com>

Subject: Message from study: rED Cap Demo Study

Message:

Hi,

You have the following incomplete data fields:

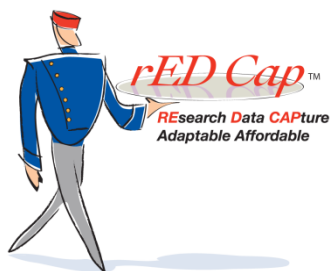
- Subject 001-003: 2 incomplete fields
- Subject 001-103: 2 incomplete fields
- Subject 001-203: 2 incomplete fields

You have the following outstanding queries:

- Subject 001-001: 3 open queries
- Subject 001-003: 1 open queries
- Subject 001-101: 3 open queries
- Subject 001-103: 1 open queries
- Subject 001-201: 3 open queries
- Subject 001-203: 1 open queries

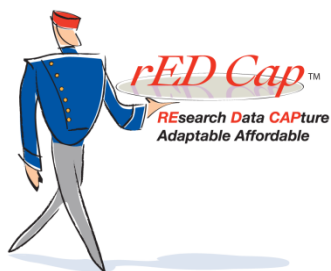
Please take a moment to login and take care of these issues. Thank you.
<https://dev.redcapbsi.com/studyaga/>

This message is sent through rED Cap study: rED Cap Demo Study



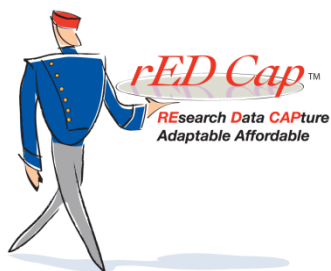
Other Features in *rED Cap*

- CFR 21 Part 11 compliance with audit trails and e-signature
- Double-data entry system for paper CRF or hybrid studies
- Excel data exports allowed by permission
- Sophisticated third-party access/viewing and entry system
- Ability to design powerful validation checks, create calculations, and disable entry fields and forms according to protocol requirements



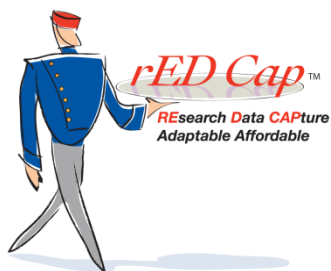
Special Tools in *rED Cap*

- Ongoing import of external data into special eCRF for viewing and reporting.
- Manage product inventory with custom designed forms and reports. Inventory data can interface with eCRF.
- Data transfer tool to bring in mapped EMR or other electronic data into the eCRF for ongoing data management and cleaning.
- Special blinded PHI forms with restricted access and export capability.



Get a quote for a project in *rED Cap* Do you know your data collection requirements?

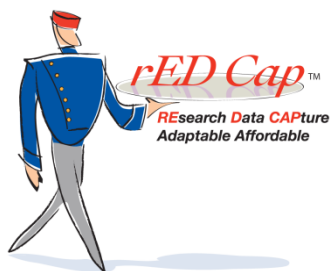
Provide your protocol/CRF template to BSI, along with site and user requirements. BSI will provide you with a quote for eCRF design and CRO support.



OR,

are you planning a project but don't know
exactly what you really need?

Just contact us at BSI. Our biostatisticians and
clinical managers will assist you in
protocol development and data collection.



Contact BSI today

Go to www.biostatinc.com and complete a Request for Information form.

Or call us!! 813-979-1619