

# Electronic Data Capture

- bidding adieu to paper CRFs!



Module 10 Topic 3

# What is EDC?

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Electronic Data Capture (EDC) is a technique for collecting clinical trial data in such a way that they are delivered in an electronic form instead of on paper.



## Electronic Data includes:

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- Lab data
- Patient data directly captured by instrumentation
- ePRO
- eSource
- Information first recorded on paper then entered into computer at investigator's site



# Advantage EDC – Dr. Jekyll

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- Fast data entry rapid data cleaning, no paper
- Large reduction in queries (50-70%)
- Clear, Rapid, Quality status reports on the performance of each site
- More effective site management/site visit scheduling





## Advantage EDC – Dr. Jekyll (contd)

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- Rapid, simultaneous data visibility to Monitors, PM, DM, Statisticians and Sponsors
- More efficient trial conduct – remote monitoring
- Project Management: Up-to-date information of site status and monitoring activities
- Faster (usually more expensive) clinical trials!
- DM less labor intensive/lower cost



## And Mr. Hyde!

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- Technology oriented, not understood clearly
- Software compliance to regulatory requirement
- Cost of implementation
- Cost of training
- Trial and error
- Relying on infrastructure
- Start-up slower
- Back end Data Integration questionable
- External data loading.. Is it fully integrated?
- What about paper CRF? Some no longer required?



# Best Practices for EDC

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- Keep multiple user requirements in mind
- Avoid last minute system modifications
- Systems – user friendly and flexible
- Systems – not restrict answers
- Adequate data validation tools and query management tools – build into EDC software
- Audit trails must be maintained



## Best Practices for EDC (contd)

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- Enable easy data transfer and integration with other databases
- Integrate laboratory and other non-CRF data into the EDC database
- User Acceptance Tests – performed and documented
- Change control procedures – all ‘user configurable procedures



## Best Practices for EDC (contd)

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- Automated report generation on metrics and project status
- Availability of appropriate technical support
- Established SOPs for EDC, data validation and archiving
- Integrate metrics on process and cost/benefit into the EDC process – to enable effective comparison of EDC vs non-EDC processes



# Challenges of EDC

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- Clinical challenges
- Site challenges
- Technology challenges
- Data Management challenges





# Clinical Challenges

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- CRA competence
- Can monitors tackle systems issues?
- Will monitors accept the change & challenge to their job?
- Do they have any interest in EDC?



# Clinical Challenges (contd)

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- Connectivity issues... staying connected?
- Training of monitors new job profile?
- Technical knowledge...



# Site challenges

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- Attitudinal issues - technology/change?
- Site infrastructure
- Internet connectivity - What about the band-width?
- Staffing issues
- Understanding of software/hardware
- Training requirements



# Technology challenges

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- Is the technology secure?
- How about data integrity?
- Assessment of software vendors? (off-the shelf vs in built)
- How about help desk, 24/7.. Additional resource?
- What about firewall, anti-virus, backup, disaster management?
- Is there a quick disaster recovery? At what cost?



# Data Management Challenges

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- Primary focus – technology / data management?
- Are we ready for changed scenario?
- Conformance to 21CRF11
- Acceptance of technology
- Challenge on creating front end, than focus on data entry?
- Data Management staff...



# Data Management Challenges

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- Data Management staff...





# What is Life Without a Challenge?

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# What is Life Without a Challenge?

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**A complete bore!**



# Study Start – Up Guide

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- EDC requires database go live by First Patient In (FPI) – timelines???
- Study Start-Up Guide: on-line system that provides all the tools, procedures and documents needed to support study start-up activities –the one-stop-shopping point for all your start-up information needs
- Compilation and analysis of existing study start-up materials
- Discover all the different ways people are interpreting SOPs and accomplishing their work
- Identify best practices



# Key Definitions

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- Archival e-CRF: a PDF file that consists of the completed e-CRF along with the associated e-CRF audit trail.
- May be an electronically signed record
- PDF recommendation may change over time
- Presentation of e-CRF in manner that resembles data entry form is critical to our position to retire EDC system when archival e-CRFs are accepted by investigator



# Roles and Responsibilities

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- Sponsor
- EDC System Owner
- Contract Research Association (CRO)
- Investigator



# System Preparation, Testing, Installation

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- Start up Time
- Data Entry Screen Design and Edits
- Customization of the EDC Tool
- Testing
- HW & Telecom Acquisition & Install





# Screen Design and Edits

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- Consistent with Technical Approach
- Experience of Investigator Staff
- Navigational Tools
- Re-usability of Standard Data Entry Screens
- Data migration to sponsor's database and requirements of the protocol
- Edit checks at point of data creation provide cleaner data than on paper CRFs



# Customizing & Testing the EDC Tool

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- Setting up new studies – do not change the underlying EDC software
- Standard DE screens, navigation aids, and edit checks need to be validated and catalogued prior to first use
- Any non-standard screens, aids, or edits must be fully tested prior to use
- For each study, testing of proper study setup, including data transfer, must be performed
- SOPs for completeness, accuracy, reliability, and consistent intended performance apply



# Hardware and Telecommunications

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Acquisition & Installation of:

- Hardware
- Software
- Phone Lines
- Internet Connections



# Preparing the Investigator

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- Review of Investigator Responsibilities
- Onsite SOPs and Policies
- Documentation Requirements
- Electronic Signatures
- EDC System Training



# Investigator SOPs and Policies

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- Business Continuity - backup & disaster/recovery procedures & support availability
- Method for access & maintenance of site SOPs & required system documentation (training records, access logs, operating manuals, contingency logs)
- Policy on electronic records & signatures as it applies to investigator staff
- Account & password issue and maintenance
- Archival e-CRF maintenance & storage policy



# Preparing Sponsor Staff

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- EDC System Training
- Investigator Responsibilities Training
- Method of Source Data Verification
- Monitor elapsed time between patient visits and data entry





# Service Level Agreement

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- Method used to communicate problems regarding the study and the EDC system
- Scope of responsibilities (i.e. types of questions handled by system support staff vs. CRAs or others)
- Time support staff are available
- Expected response time
- Problem escalation process
- Problem tracking and resolution communication process
- Disaster recovery



# Study Conduct

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- Investigator Data Entry
- Safety Monitoring
- Query Processing
- Allowable Sponsor Changes to EDC Sys
- Investigator Signature for Patient Data
- Mid-study Changes to EDC System
- Investigative Site Visits by Sponsor
- Investigative Site Visits by Regulatory Agency



# Investigator Data Entry

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- Data-knowledgeable staff entering data, so no double-data entry necessary
- SDV check against paper or electronic medical charts
- If entered directly into EDC system (eSource)
- Investigator e-signature recommended (must be Part 11 compliant)



# Safety Monitoring

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- Electronic identification & notification of SAEs to sponsor
- Must have additional process for SAEs to be communicated from investigator to sponsor to ensure timely reporting
- Sponsor must define the point in time when the clock starts regarding the need for sponsor review and reporting of SAEs



# Query Processing

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EDC system must handle:

- Auto-queries
- Manual Queries
- Tracking of query status (Open, Answered, Closed)
- Methods to view queries according to clinical site, patient, and e-CRF.



# Allowable Sponsor Data Changes

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- Investigators can always change data prior to lock
- Sponsors need to follow ICH E6 guidance on making changes to data (same for electronic CRF as for paper CRF):
- Sponsor must provide site with outline document of types of obvious changes sponsor is allowed to make
- Sponsor changes must be backed by source





# Investigator Signature

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- Investigator must confirm observations recorded on electronic case report forms
- If e-signatures used, must comply with 21 CFR Part 11
- Signoff on e-CRFs can be per patient or all at end of study
- Paper signatures can be used; sponsor keeps original, investigator keeps copy –eCRF does not need to be printed





# Mid-study Changes to EDC System

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Changes due to:

- Protocol / study design change
- Issue with EDC study implementation
- Upgrade to EDC software or hardware
- Must follow Change Control SOP
- Documentation of Change must be filed at both investigator and sponsor sites



# Site Visits

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- Sponsor (CRA) visits
- SDV for non e-Source
- Use patient medical record to ensure existence of patients when eSource is used
- Review investigator compliance with EDC policies; provide coaching as needed
- During-study Regulatory Agency visit
  - Read-only access to system
  - Recommended sponsor staff available for system assistance



# Study Close Out

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- Preventing Changes to the EDC Data
- Creation of Archival e-CRFs
- Acceptance and Signature of Archival e-CRFs
- Post-closure Changes



# Record Retention & Submission

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- Reconstruction of Study
- Site Inspections by Regulatory Agency
- Record Retention by Investigator
- Record Retention by Sponsor
- e-Sub CRFs
- e-CRTs



# Regulatory Review & Study Reconstruction

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- Once Archival e-CRF is accepted by site,
- EDC software and hardware can be removed
- Archival e-CRF includes reader to access the files (i.e. PDF)
- Regulatory inspector should need little or no training to access data via Archival e-CRF



# Investigator Record Retention

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- In addition to standard trial record retention requirements:
- Archival e-CRFs
- EDC system (only until archival e-CRFs are received and accepted by the investigator)
- Study Documentation
- Documentation of post-closure changes supplied by sponsor





# Sponsor Record Retention

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- In addition to standard trial record retention requirements:
- System validation documentation
- Archival e-CRFs & confirmation of investigator receipt
- Sponsor SOPs relating to EDC system
- Investigator SOPs relating to the EDC system
- Study specific design & validation documentation
- System configuration documentation
- Change Control & Recovery documentation
- Documentation of periodic review & refreshment of archival e-CRFs





## e-Sub CRFs and e-CRTs

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- Use blank e-CRF for annotated CRF
- Annotated CRF only include only data on e-CRF
- “Define” file should document methods used to derive/collect non e-CRF data
- Annotated e-CRF includes representation of screens used to enter data & associated data entry codes



# System Design Considerations

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- User Identification
- Audit Trails
- Password Resets
- Operational Checks
- Minimum Security Measures
- Controls for Open Systems
- Controls for Electronic Signatures
- Data transmission/migration to Sponsor Database
- System Validation



# System Design Considerations (contd)

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- Disaster Recovery
- Back-up Procedures
- Synchronizing Multiple Electronic Data Sources
- Clearing Cache
- Storage of Case Report Data Off-site from the Investigator



# Issues, Recommended Changes

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- Guidance for Industry: Computerized Systems Used in Clinical Trials
- Issues in the following areas have been resolved in the Sept. '04 Draft:
  - Reconstruction of Study
  - Site Inspection by Regulatory Agency
  - User Identification
  - Definition of Record Creation



# Issues, Recommended Changes (contd)

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## **CSUCT, Sept. '04 Draft:**

- We recommend that passwords or other access keys be changed at established intervals.
- Change to allow other security schemes that do not require periodic changing of passwords. For instance, advanced security models are accepted by the Department of Justice and widely utilized by other regulated environments such as the banking industry.
- This change is consistent with direction of Secure Access for Everyone (SAFE) initiative



# Issues, Recommended Changes (contd)

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## **CSUCT, Sept. '04 Draft:**

- “We recommend that each protocol identify at which steps a computerized system will be used to create, modify, archive, retrieve, or transmit data.”
- ..This is difficult for systems not provided by sponsor, especially in multi-center studies
- ..Identify those steps at which system is provided or endorsed by sponsor, and indicate whether it is optional or required





## Issues, Recommended Changes (contd)

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- Guidance for Industry: Providing Regulatory Submissions in Electronic Format –NDAs (January 1999), Section K3 on aCRFs, assumes all data and information are transmitted via a form.
- The “aCRF” for EDC studies should only cover data that are included in the e-CRF. Data captured by other means need not be displayed on an aCRF, and the corresponding comment column of the “define” file should document the method used to collect/derive those data.





# Issues, Recommended Changes (contd)

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## **21 CFR Part 11:**

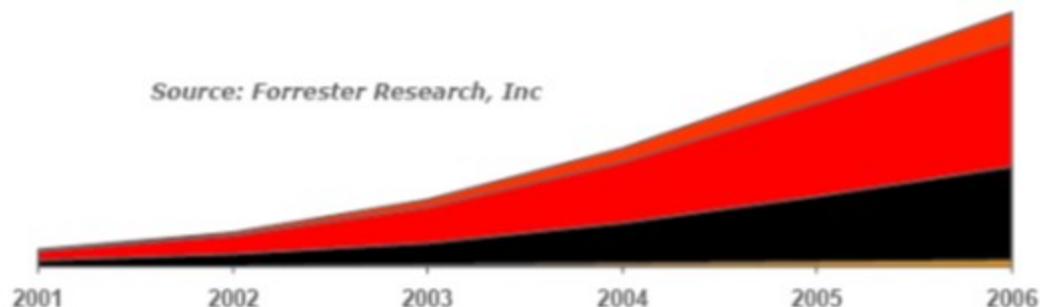
- More clarifications and examples of adequate controls for an open system would assure consistency.
- Clarification of what constitutes an adequate link between signatures and their associated records



# Paper to EDC Trials

- Phase I trials
- Phase II trials
- Phase III trials
- Phase IV trials

Source: Forrester Research, Inc

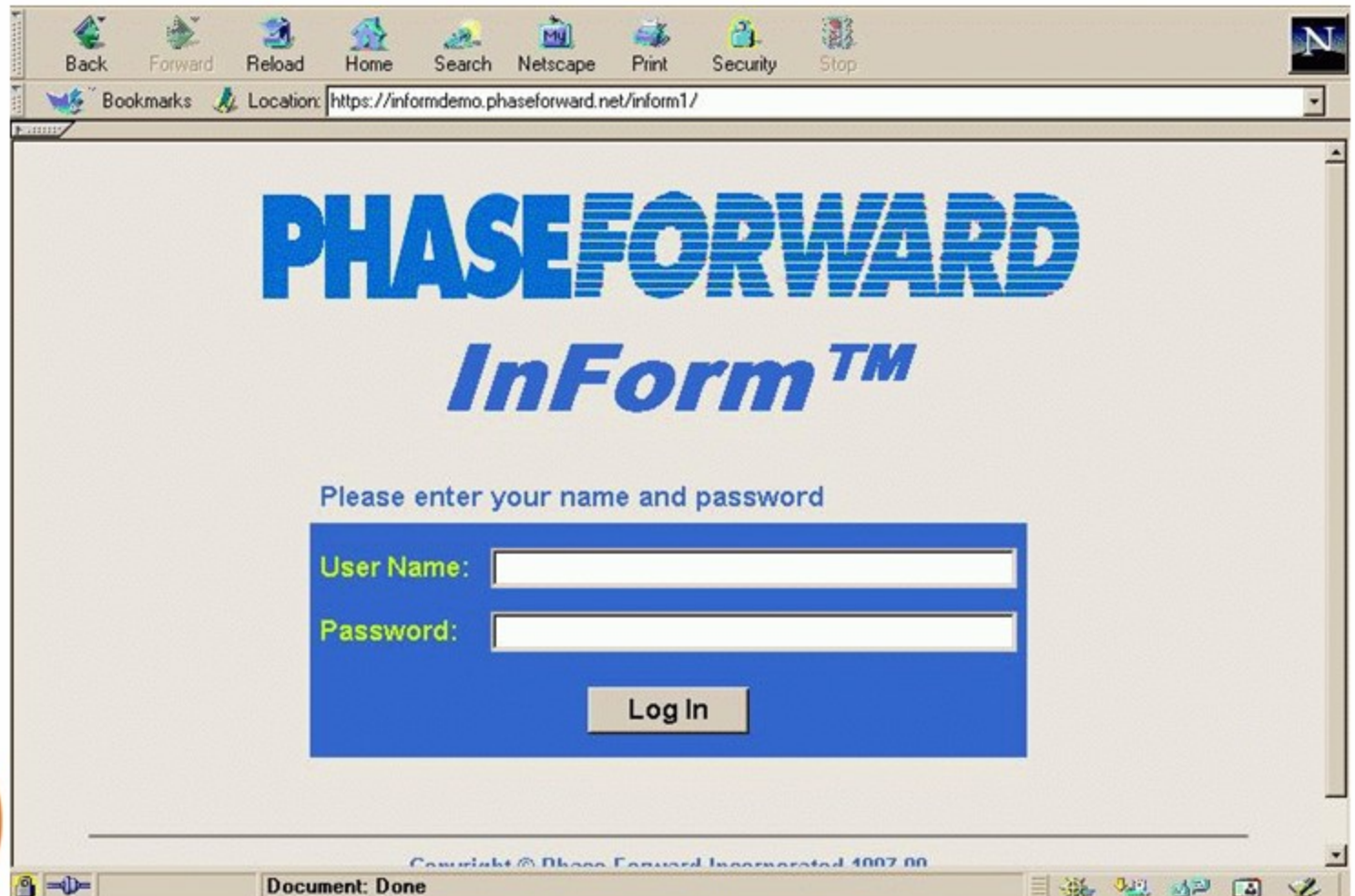


## Web enabled trial starts

Phase I trials	126	261	514	934	1,510
Phase II trials	651	1,320	2,508	4,313	6,532
Phase III trials	387	802	1,581	2,871	4,642
Phase IV trials	20	43	86	164	282
Totals	1,184	2,425	4,690	8,282	12,966
	4%	8%	14%	24%	35%



# Access/Login to InForm



The screenshot shows a Netscape browser window with the address bar displaying `https://informdemo.phaseforward.net/inform1/`. The main content area features the "PHASEFORWARD InForm™" logo. Below the logo, a prompt reads "Please enter your name and password". There are two input fields: "User Name:" and "Password:". A "Log In" button is positioned below the password field. The browser's status bar at the bottom indicates "Document: Done".

Back Forward Reload Home Search Netscape Print Security Stop

Bookmarks Location: `https://informdemo.phaseforward.net/inform1/`

# PHASEFORWARD

## *InForm™*

Please enter your name and password

User Name:

Password:

Log In

Copyright © Phase Forward Incorporated 1007 00

Document: Done



# Passwords

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- Using Passwords allows InForm to record every activity you perform and date stamps it
- InForm automatically logs you out after a period of inactivity from the system
- InForm will require you to re-login throughout the day
- Passwords will expire after a pre-determined period of time



**PART 11  
COMPLIANCE**

# User Support

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- There are four types of Help available
  - Hover help
  - Online product-specific help
  - Online study-specific documentation
  - eClinical Helpdesk





# Online & Hover Help

The screenshot displays a web application interface with a blue sidebar on the left and a main content area. The sidebar contains a 'CRC Quintiles' header, a 'HOME HELP LOGOUT' menu, and buttons for 'Enroll', 'Patients', 'Queries', 'Signatures', 'Documents', and 'Reports'. Below these is a link 'PF:GT :Base:VS'. The main content area has a top navigation bar with tabs: 'Base', 'Wk 1', 'Wk 2', 'Wk 4', 'Wk 5', 'Wk 8', and 'Unsch'. A 'CRF Help' tab is highlighted. Below the tabs is a 'Vital Signs' section with a list of items: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate, and 5. Pulse Rhythm. A 'CRF Help' window is open, showing a 'Contents' list with links to 'Screening Log', 'Eligibility (Run-In)', 'Signs and Symptoms', and 'Demographics'. A red arrow points from the 'CRF Help' tab to the 'Contents' list. The 'Item 3 Temperature' section is expanded, showing instructions: 'Report temperature in either Fahrenheit or Celsius. (The entry will be converted to the desired units for report purposes.)' and 'Report using decimal places, do not round to whole number.' The bottom of the window shows 'Page 5' and a 'Close' button. The browser's status bar at the bottom indicates 'Internet zone'.

CRF Help

InForm Help Frameset - Microsoft Internet Explorer provided by Q...

Protocol Guide CRF Help Visit Calculator Samp

Contents

- [Screening Log](#)
- [Eligibility \(Run-In\)](#)
- [Signs and Symptoms](#)
- [Demographics](#)

Item 3 Temperature

- Report temperature in either Fahrenheit or Celsius.  
(The entry will be converted to the desired units for report purposes.)
- Report using decimal places, do not round to whole number.

Page 5

Close

Internet zone

Print Preview Submit Return



# Online & Hover Help

The screenshot displays the InForm Help Frameset in a Microsoft Internet Explorer browser. The interface includes a top navigation bar with tabs for 'Protocol Guide', 'CRF Help', 'Visit Calculator', and 'Sample'. A left sidebar contains buttons for 'Patients', 'Queries', 'Signatures', 'Documents', and 'Reports'. A yellow box labeled 'System help' points to the 'Reports' button. Another yellow box labeled 'CRF Help' points to the 'CRF Help' tab. The main content area shows the 'Vital Signs' section with a list of items: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate, and 5. Pulse Rhythm. A 'Contents' sidebar on the left lists links: 'Screening Log', 'Eligibility (Run-In)', 'Signs and Symptoms', and 'Demographics'. A red arrow points from the 'CRF Help' box to the 'Item 3 Temperature' section. This section contains the following text: 'Report temperature in either Fahrenheit or Celsius. (The entry will be converted to the desired units for report purposes.)' and 'Report using decimal places, do not round to whole number.' Below this, there are radio buttons for 'Irregular (Specify):', 'Regularly Irregular', and 'Irregularly Irregular'. The bottom of the page features a 'Print Preview' button and 'Submit' and 'Return' buttons. The browser's address bar shows 'javascript:' and the status bar indicates 'Internet zone'.

System help

CRF Help

Protocol Guide

CRF Help

Visit Calculator

Sample

No: 111

Item 3 Temperature

- Report temperature in either Fahrenheit or Celsius.  
(The entry will be converted to the desired units for report purposes.)
- Report using decimal places, do not round to whole number.

Page 5

Internet zone

Print Preview

Submit

Return





# Online & Hover Help

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Base Wk 1 Wk 2 Wk 4 Wk 5 Wk 8 Unsch

InForm Help Frameset - Microsoft Internet Explorer provided by Q...

Protocol Guide CRF Help Visit Calculator Samp

System help

CRF Help

Contents

Screening Log

Eligibility (Run-In)

Signs and Symptoms

Demographics

Item 3 Temperature

- Report temperature in either Fahrenheit or Celsius.  
(The entry will be converted to the desired units for report purposes.)
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Page 5

Close

Internet zone

Irregular (Specify):

- ☐ Regularly Irregular
- ☐ Irregularly Irregular

Print Preview

Submit Return

PF:GT :Base:VS

Documents button



# Online & Hover Help

Base Wk 1 Wk 2 Wk 4 Wk 5 Wk 8 Unsch

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Page 5

Close

Internet zone

Irregular (Specify):

- ☐ Regularly Irregular
- ☐ Irregularly Irregular

Print Preview

Submit Return

PF:GT :Base:VS

Documents button

Help hyperlink



# Online & Hover Help

The screenshot shows a web application interface for data entry. On the left is a vertical navigation menu with buttons: Patients, Queries, Signatures, Documents, and Reports. The main content area is titled 'InForm Help Frameset' and contains a 'CRF Help' tab. A 'Vital Signs' table is visible with rows for Weight, Temperature, Blood Pressure, Pulse Rate, and Pulse Rhythm. A 'Contents' sidebar lists links like Screening Log, Eligibility (Run-In), Signs and Symptoms, and Demographics. A 'Item 3 Temperature' help window is open, showing instructions for reporting temperature. A 'Documents button' label points to the 'Documents' button in the left menu. A 'Help hyperlink' label points to the 'Pulse Rate' row in the Vital Signs table. A 'Hover Help' label points to a yellow tooltip that appears over the 'Pulse Rate' row, containing the text 'Click here to view information on completing CRFs'. Other labels include 'System help' pointing to the top of the left menu, 'CRF Help' pointing to the 'CRF Help' tab, and 'Documents button' pointing to the 'Documents' button.

Base Wk 1 Wk 2 Wk 4 Wk 5 Wk 8 Unsch

CRF Help

Protocol Guide CRF Help Visit Calculator Samp

Contents

Screening Log

Eligibility (Run-In)

Signs and Symptoms

Demographics

Page 5

Close

Internet zone

Irregular (Specify):

Regularly Irregular

Irregularly Irregular

Print Preview

Submit Return

No: 111

PF:GT :Base:VS

System help

CRF Help

Documents button

Help hyperlink

Hover Help





# Home Screen



CRC Quintiles

HOME HELP LOGOUT

Enroll

Patients

Queries

Signatures

Documents

Reports

## PHASEFORWARD

### Phase Forward Clinical Drug Trial

#### Study News

The following review of anti-hypertensives appeared in the New England Journal of Medicine. It discusses the mechanisms of action of Axelol. [Stovol, PA, Harner, M, et al. Mechanisms of Anti-Hypertensives in Mild-Moderate Essential Hypertension. New Eng J Med 176:345-349 \(1998\).](#)

#### Alerts

**Note** For recently enrolled patients at your site, an unusually large number of blood pressures recorded seem to have been measured in 5 mmHg steps. Please remind your study nurses that the protocol specifies blood pressures to be measured in 2 mmHg increments.

#### Enrollment

Total patient enrollment for all sites as of June 1st is 371. Study enrollment has exceeded our projections for three months in a row! Let's see if the team can make it four!

#### June's Top Enrolling Sites

The following sites achieved the highest enrollments during the month of June:

Site	Patients
Site 3	7
Site 4	5
Site 10	6
Site 14	7

#### Study Data Progress

##### CRBs to Complete

	Patients
CRBs with data to enter	01-002, 01-003, 01-008, 01-009, 01-010
CRBs with open queries	01-001, 01-002, 01-003, 01-006, 01-007, 01-008

Patient: 009090 (RFS) Visit: Baseline Go

# Browser & InForm

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- Accessing the study:
  - Project URL
  - Username
  - Password
  - Rights
- Browser Rules:
  - Never use the back button with InForm
  - Follow prompts to save information



# Access/Login to InForm

Back Forward Reload Home Search Netscape Print Security Stop

Bookmarks Location: <https://informdemo.phaseforward.net/inform1/>

**Project web address (URL)**

# PHASEFORWARD

## *InForm™*

Please enter your name and password

User Name:

Password:

Log In

Copyright © Phase Forward Incorporated 1997-00

Document: Done





# Passwords

---

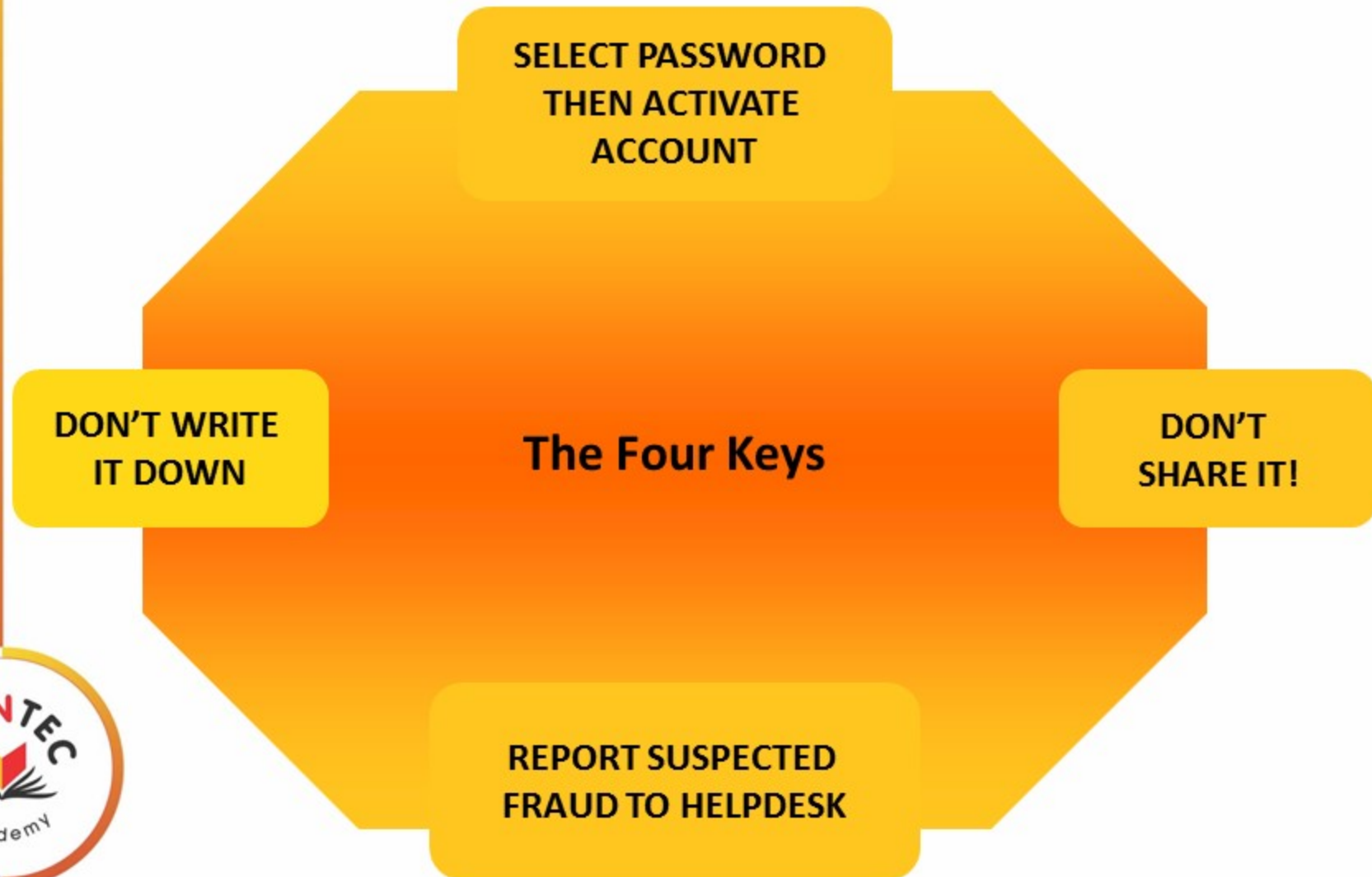
- Using Passwords allows InForm to record every activity you perform and date stamps it
- Automatic log off
- InForm will require you to re-login throughout the day
- Passwords will expire after a pre-determined period of time



**PART 11  
COMPLIANCE**

# Passwords (contd)

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# Changing a Password

InForm Log-In - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit Discuss

Address <http://cf004.webcrl.net/pl207/plts.dll>

 PHASEFORWARD™

**InForm™**

**Inactive user. Until you have been activated, you can only change your password. See trial administrator.**

Please enter your name and password

User Name:

Old Password:

New Password:

Confirm New Password:

By clicking the Submit button above, I am using my electronic signature to log in to the InForm system. Until I log out, the system will record all data entry and data modification actions under my electronic signature.

InForm is a data collection and trial management tool and is not to be used in the diagnosis or treatment of patients.

HEALTH-CARE PROFESSIONALS HAVE THE SOLE RESPONSIBILITY TO BE FULLY AWARE OF CURRENT PRACTICES AND STANDARDS, TO AVOID USE OF OUTDATED REGIMENS, AND TO EMPLOY GOOD CLINICAL JUDGEMENT IN SELECTING PATIENT TREATMENTS. Computer software in general and InForm in particular should NEVER substitute for up-to-date personal knowledge and good clinical judgement.

Done Internet

1. Type user name here

2. Type default/generic password here

3. Type new password here; it will appear like this: \*\*\*\*\*

4. Retype new password here; it will also display asterisks.




# Password Hint

InForm - Gil Lam (PM) - Microsoft Internet Explorer provided by Quintiles Transnational

File Edit View Favorites Tools Help

Address http://qlanswbc06.qlan.quintiles.com/PFST/pfts.dl?S=43ae21e88C=Navigator\_RenderTopFrameset

  
Gil Lam (PM)

HOME HELP LOGOUT

Patients  
Queries  
Documents  
Listings  
Admin  
Reports

### Password change

1. User Name:	glam
2. Password:	<input type="password"/>
3. New Password:	<input type="password"/>
4. New Password confirmation:	<input type="password"/>

### Email and forgot password data

5. E-mail:	<input type="text"/>
6. Hint Question:	<input type="text"/>
7. Answer:	<input type="text"/>

Submit Return

Done Internet

start Lauren Hause... eDC for CRAs... Details New F... Microsoft Pow... InForm - Gil L... J:\Common\Q... 4:37 PM

Users may enter a password hint to be emailed to them



# Help...

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- There are four types of Help available
  - Hover help
  - Online product-specific help
  - Online study-specific documentation
  - eClinical Helpdesk





# Online & Hover Help

The screenshot displays the InForm Help Frameset interface within a Microsoft Internet Explorer browser. The main application window has a blue sidebar on the left with navigation buttons: HOME, HELP, LOGOUT, Enroll, Patients, Queries, Signatures, Documents, and Reports. The top navigation bar includes tabs for Base, CRF Help (highlighted with a yellow box and a red arrow), Protocol Guide, Visit Calculator, and Sample. The main content area is divided into two panes. The left pane, titled 'Vital Signs', contains a list of vital signs: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate, and 5. Pulse Rhythm. The right pane, titled 'Item 3 Temperature', displays instructions for reporting temperature: 'Report temperature in either Fahrenheit or Celsius. (The entry will be converted to the desired units for report purposes.)' and 'Report using decimal places, do not round to whole number.' Below the instructions are three radio button options: 'Irregular (Specify)', 'Regularly Irregular', and 'Irregularly Irregular'. The bottom of the interface features a 'Print Preview' button and 'Submit' and 'Return' buttons. The browser's address bar shows 'InForm Help Frameset - Microsoft Internet Explorer provided by Q...'. The status bar at the bottom indicates 'Page 5' and 'Internet zone'.

Base CRF Help k 4 Wk 5 Wk 8 Unsch

DOV PI InForm Help Frameset - Microsoft Internet Explorer provided by Q...

LAB INC Protocol Guide CRF Help Visit Calculator Samp

CRC Quintiles

HOME HELP LOGOUT

Enroll

Patients

Queries

Signatures

Documents

Reports

PF:GT :Base:VS

Vital Signs

Vital Signs

1. Weight:

2. Temperature:

3. Blood Pressure:

4. Pulse Rate:

5. Pulse Rhythm:

Contents

[Screening Log](#)

[Eligibility \(Run-In\)](#)

[Signs and Symptoms](#)

[Demographics](#)

Item 3 Temperature

- Report temperature in either Fahrenheit or Celsius.  
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Page 5

Close

javascript

Internet zone

Irregular (Specify):

Regularly Irregular

Irregularly Irregular

Print Preview

Submit Return





# Online & Hover Help

The screenshot displays a web-based clinical trial data entry system. On the left, a vertical navigation menu includes buttons for 'HOME', 'HELP', and 'LOGOUT'. A yellow callout box labeled 'System help' points to the 'HELP' button. The main content area is titled 'Vital Signs' and contains a list of vital signs: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate, and 5. Pulse Rhythm. A yellow callout box labeled 'CRF Help' points to a 'CRF Help' button in the top navigation bar. This button has opened a help window titled 'InForm Help Frameset - Microsoft Internet Explorer provided by Q...'. The help window shows a 'Contents' list with links to 'Screening Log', 'Eligibility (Run-In)', 'Signs and Symptoms', and 'Demographics'. The main content of the help window is 'Item 3 Temperature', which includes instructions: 'Report temperature in either Fahrenheit or Celsius. (The entry will be converted to the desired units for report purposes.)' and 'Report using decimal places, do not round to whole number.' The help window also shows 'Page 5' and a 'Close' button. At the bottom of the main interface, there are buttons for 'Print Preview', 'Submit', and 'Return'. The bottom left corner features the 'KLINTEC Academy' logo.

System help

CRF Help

Protocol Guide CRF Help Visit Calculator Samp

Contents

Screening Log

Eligibility (Run-In)

Signs and Symptoms

Demographics

Item 3 Temperature

- Report temperature in either Fahrenheit or Celsius.  
(The entry will be converted to the desired units for report purposes.)
- Report using decimal places, do not round to whole number.

Page 5

Close

Irregular (Specify):

- Regularly Irregular
- Irregularly Irregular

Print Preview

Submit Return



# Online & Hover Help

The screenshot displays the InForm Frameset interface within a Microsoft Internet Explorer browser. The interface is divided into several sections:

- Left Sidebar:** Contains navigation buttons: HOME, HELP, LOGOUT, Enroll, Patients, Queries, Signatures, Documents, and Reports. A yellow box labeled "System help" points to the HELP button. A yellow box labeled "Documents button" points to the Documents button.
- Top Navigation:** Includes tabs for Base, CRF Help, Protocol Guide, Visit Calculator, and Samp. A yellow box labeled "CRF Help" points to the CRF Help tab.
- Main Content Area:** Displays the "Vital Signs" section with a list of items: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate, and 5. Pulse Rhythm. The "Item 3 Temperature" section is expanded, showing instructions: "Report temperature in either Fahrenheit or Celsius. (The entry will be converted to the desired units for report purposes.)" and "Report using decimal places, do not round to whole number." Below this, there are radio button options: "Irregular (Specify)", "Regularly Irregular", and "Irregularly Irregular".
- Bottom Bar:** Includes a "Preview" button and "Submit" and "Return" buttons.

The browser window title is "InForm Help Frameset - Microsoft Internet Explorer provided by Q...". The address bar shows "javascript:". The status bar indicates "Internet zone".



# Online & Hover Help

The screenshot displays the InForm Frameset interface within a Microsoft Internet Explorer browser. The interface includes a left-hand navigation menu with buttons for HOME, HELP, and LOGOUT. The main content area is divided into sections for Vital Signs and a list of items to be recorded. A pop-up window titled 'InForm Help Frameset' is open, showing the 'CRF Help' tab and the 'Item 3 Temperature' section. Annotations with yellow boxes and red arrows point to specific features:

- System help**: Points to the HELP button in the left navigation menu.
- CRF Help**: Points to the CRF Help tab in the pop-up window.
- Documents button**: Points to the Documents button in the left navigation menu.
- Help hyperlink**: Points to the '2. Temperature:' entry in the Vital Signs list.

The 'Item 3 Temperature' section in the pop-up window contains the following text:

**Item 3 Temperature**

- Report temperature in either Fahrenheit or Celsius.  
(The entry will be converted to the desired units for report purposes.)
- Report using decimal places, do not round to whole number.

The pop-up window also includes a 'Page 5' indicator and a 'Close' button. The bottom of the interface shows a 'Submit' button and a 'Return' button.

**KLINTEC Academy**



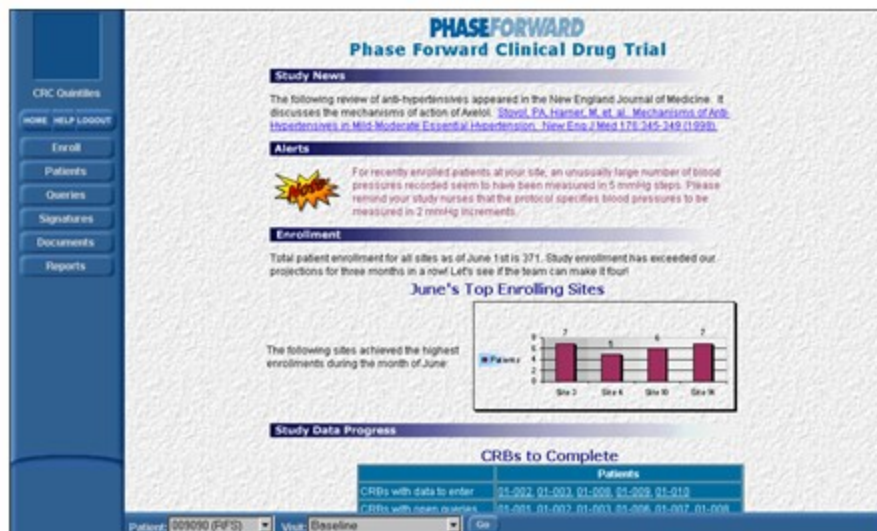
# Online & Hover Help

The screenshot displays the InForm Frameset interface within a Microsoft Internet Explorer browser. The interface is divided into several sections:

- Left Sidebar:** Contains navigation buttons: HOME, HELP, LOGOUT, Enroll, Patients, Queries, Signatures, Documents, and Reports. A yellow box labeled "System help" points to the HELP button. A yellow box labeled "Documents button" points to the Documents button.
- Top Navigation:** Includes tabs for Base, CRF Help, Protocol Guide, Visit Calculator, and Samp. A yellow box labeled "CRF Help" points to the CRF Help tab.
- Main Content Area:** Displays "Vital Signs" with a list of items: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate, and 5. Pulse Rhythm. A yellow box labeled "Help hyperlink" points to the "Temperature" item. Below this, a "Hover Help" window is open, showing details for "Item 3 Temperature":
  - Report temperature in either Fahrenheit or Celsius. (The entry will be converted to the desired units for report purposes.)
  - Report using decimal places, do not round to whole number.A yellow box labeled "Hover Help" points to this window.
- Bottom Section:** Includes a "Preview" button and "Submit" and "Return" buttons.

In the bottom left corner, there is a circular logo for "KLINTEC Academy" featuring a stylized book icon.

# Home Screen



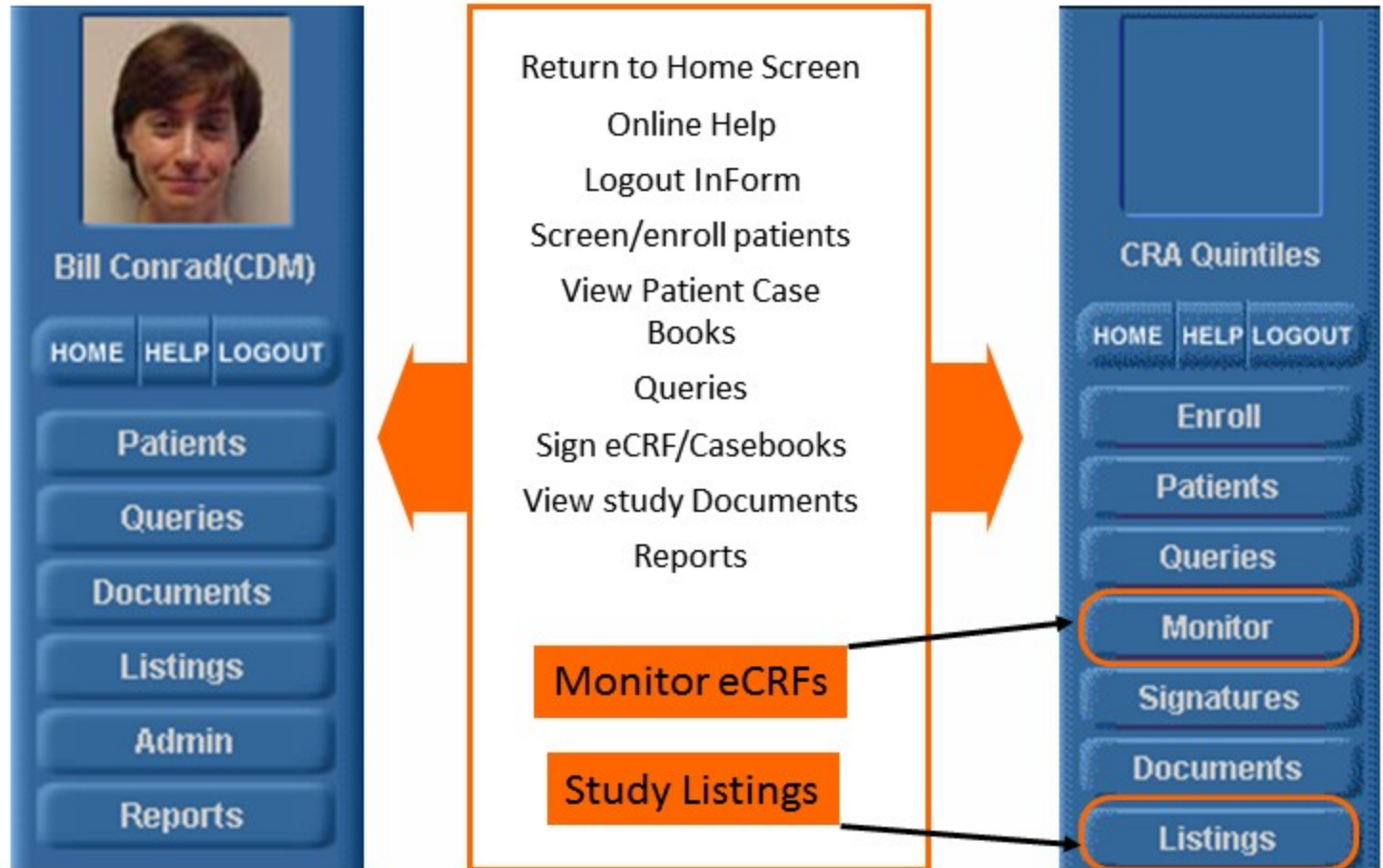
Navigation  
Pane

Content Pane

Content-Specific Pane



# The Navigation Pane





# User Rights




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- Permission to perform a specific activity
- Each InForm user has a set of rights
- Functionality within InForm depends on the rights assigned to user






# User Rights

## CRA

Demographics			
1.	<u>Gender:</u>	Male	
2.	<u>Date of Birth:</u>	1/4/55	
3.	<u>Race:</u>	Caucasian	

**CRA - *View* study data**  
**Coordinator - *Edit* study data**

## CRC

Demographics			
1.	<u>Gender:</u>	<input type="radio"/> Male <input checked="" type="radio"/> Female	
2.	<u>Date of Birth:</u>	Nov / 11 / 1959	
3.	<u>Race:</u>	<input checked="" type="radio"/> Caucasian <input type="radio"/> Other:	



# Navigation

The screenshot shows a web application interface for ECG/Chest X-Ray assessment. The interface includes a menu bar (File, Edit, View, Go, Favorites, Help), a toolbar (Back, Forward, Channels, Fullscreen, Mail, Print, Edit), and a sidebar (CRC Quintiles, HOME, HELP, LOGOUT). The main content area displays the assessment form for ECG/Chest X-Ray, with tabs for Base, Wk 1, Wk 2, Wk 4, Wk 5, Wk 8, and Unsch. The form includes sections for 12-Lead ECG and Chest X-Ray, with fields for Date of assessment, Interpretation, Type(s) of abnormality if present, and View. The interface also features a 'Print Preview' button and a 'Return' button at the bottom right.

**Do not use the Back button!**

**Yellow Up-arrow to Time/Event Schedule**

**Return to previous/main task**

12-Lead ECG

1. Date of assessment: [ ] / [ ] / [ ]
2. Interpretation:
  - ☐ Normal
  - ☐ Abnormal, not clinically significant
  - ☐ Abnormal, clinically significant
3. Type(s) of abnormality if present:
  - Sinus Tachycardia
  - Premature Ectopic Junctional Beats
  - Sinus Bradycardia
  - Premature Ectopic Atrial Beats

Chest X-Ray

4. Date of assessment: [ ] / [ ] / [ ]
5. View:
  - ☐ PA/Lateral
  - ☐ AP
  - ☐ Other: [ ]

Print Preview Submit Return



# Key Buttons

The screenshot shows the InForm web application interface within a Microsoft Internet Explorer browser window. The browser's address bar displays the URL: `http://cif004.webcf.net/pf207/plts.dll?S=51113011&C=Navigator_RenderTopFrameSet`. The application interface includes a top navigation bar with tabs for Base, Wk 1, Wk 2, Wk 4, Wk 5, Wk 8, and Unsch. Below this is a secondary set of tabs for DOV, PI, DEM, VS (selected), HH, EYE, PE, and ECG. A third set of tabs includes LAB, INC, and EXC. On the left side, there is a vertical menu with buttons for HOME, HELP, LOGOUT, and a list of reports: Enroll, Patients, Queries, Documents, Admin, and Reports. The main content area is titled 'Vital Signs' and contains a form with six numbered fields: 1. Weight, 2. Temperature, 3. Blood Pressure, 4. Pulse Rate (with a unit of bpm), 5. Pulse Rhythm (with radio button options for Regular, Irregular (Specify), Regularly Irregular, and Irregularly Irregular), and 6. Respiratory Rate (with a unit of breaths per minute). An orange callout box with the text 'Click "Logout" to securely exit the system' points to the LOGOUT button in the left menu. Another orange callout box with the text 'Click these links to return (up to the four most recently) to previously viewed pages.' points to a list of links in the bottom left corner: `F:SHD:Base:VS`, `F:SHD:Base:DEM`, `F:SHD:Base:PI`, and `F:SHD:Base:DOV`. A Microsoft Internet Explorer dialog box is also visible, asking 'Are you sure you want to exit InForm? Click OK to exit.' with OK and Cancel buttons.

Click "Logout" to securely exit the system

Click these links to return (up to the four most recently) to previously viewed pages.



# Types of Fields on eCRFs

PI **DEM** VS HH EYE PE ECG LAB

INC EXC

**Demographics** Patient: QM Patient No: 1000

**Demographics**

1. <u>Gender:</u>	<input checked="" type="radio"/> Male <input type="radio"/> Female
2. <u>Date of Birth:</u>	Mar / 1 / 1932
3. <u>Race:</u>	<input checked="" type="radio"/> Asian <input type="radio"/> Other
4. <u>Height:</u>	180 cm
5. <u>Wrist Circumference:</u>	3.0 in
<u>Frame:</u>	Small Frame

**Smoking History**

6. <u>Has the patient ever smoked?</u>	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Done
7. <u>If the patient has ever smoked, has the patient quit smoking?</u>	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Not Done
8. <u>If the patient currently smokes, the patient smokes:</u>	<input checked="" type="radio"/> Smokes: <input checked="" type="checkbox"/> Cigarettes <input checked="" type="checkbox"/> Pipe <input checked="" type="checkbox"/> Cigars <input type="radio"/> Not Done
9. <u>If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:</u>	<input type="radio"/> <input type="text"/> <input type="radio"/> Unknown <input checked="" type="radio"/> Not Done
10. <u>If the patient has ever smoked cigarettes, enter the number of years the patient smoked:</u>	<input checked="" type="radio"/> 2 <input type="radio"/> Unknown <input type="radio"/> Not Done

Print Preview Mark SV Ready Submit Return





# Types of Fields on eCRFs

PI **DEM** VS HH EYE PE ECG LAB  
INC EXC

**Demographics** Patient: QM Patient No: 1000

**Demographics**

1. <u>Gender:</u>	<input checked="" type="radio"/> Male <input type="radio"/> Female	Radio Buttons
2. <u>Date of Birth:</u>	Mar / 1 / 1932	
3. <u>Race:</u>	<input checked="" type="radio"/> Asian <input type="radio"/> Other	
4. <u>Height:</u>	180 cm	
5. <u>Wrist Circumference:</u>	3.0 in	
<u>Frame:</u>	Small Frame	

**Smoking History**

6. <u>Has the patient ever smoked?</u>	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Done	
7. <u>If the patient has ever smoked, has the patient quit smoking?</u>	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Not Done	
8. <u>If the patient currently smokes, the patient smokes:</u>	<input checked="" type="radio"/> Smokes: <input checked="" type="checkbox"/> Cigarettes <input checked="" type="checkbox"/> Pipe <input checked="" type="checkbox"/> Cigars <input type="radio"/> Not Done	
9. <u>If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:</u>	<input type="radio"/> <input type="text"/> <input type="radio"/> Unknown <input checked="" type="radio"/> Not Done	
10. <u>If the patient has ever smoked cigarettes, enter the number of years the patient smoked:</u>	<input checked="" type="radio"/> 2 <input type="radio"/> Unknown <input type="radio"/> Not Done	

Print Preview Mark SV Ready Submit Return



# Types of Fields on eCRFs

PI **DEM** VS HH EYE PE ECG LAB  
INC EXC

**Demographics** Patient: QM Patient No: 1000

**Demographics**

1. <u>Gender:</u>	<input checked="" type="radio"/> Male <input type="radio"/> Female	Radio Buttons
2. <u>Date of Birth:</u>	Mar / 1 / 1932	
3. <u>Race:</u>	<input checked="" type="radio"/> Asian <input type="radio"/> Other	List/Dropdown Boxes
4. <u>Height:</u>	180 cm	
5. <u>Wrist Circumference:</u>	3.0 in	
<u>Frame:</u>	Small Frame	

**Smoking History**

6. <u>Has the patient ever smoked?</u>	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Done
7. <u>If the patient has ever smoked, has the patient quit smoking?</u>	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Not Done
8. <u>If the patient currently smokes, the patient smokes:</u>	<input checked="" type="radio"/> Smokes: <input checked="" type="checkbox"/> Cigarettes <input checked="" type="checkbox"/> Pipe <input checked="" type="checkbox"/> Cigars <input type="radio"/> Not Done
9. <u>If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:</u>	<input type="checkbox"/> <input type="radio"/> Unknown <input checked="" type="radio"/> Not Done
10. <u>If the patient has ever smoked cigarettes, enter the number of years the patient smoked:</u>	<input checked="" type="radio"/> 2 <input type="radio"/> Unknown <input type="radio"/> Not Done

Print Preview Mark SV Ready Submit Return

# Types of Fields on eCRFs

PI **DEM** VS HH EYE PE ECG LAB  
INC EXC

Demographics

Patient: QM Patient No: 1000

**Demographics**

1. Gender: ☒ Male ☐ Female

2. Date of Birth: Mar / 1 / 1932

3. Race: ☒ Asian ☐ Other

4. Height: 180 cm

5. Wrist Circumference: 3.0 in

Frame: Small Frame

**Smoking History**

6. Has the patient ever smoked? ☐ Yes ☒ No ☐ Not Done

7. If the patient has ever smoked, has the patient quit smoking? ☐ Yes ☐ No ☒ Not Done

8. If the patient currently smokes, the patient smokes: ☒ Smokes: ☒ Cigarettes ☒ Pipe ☒ Cigars ☐ Not Done

9. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: ☐  ☐ Unknown ☒ Not Done

10. If the patient has ever smoked cigarettes, enter the number of years the patient smoked: ☒ 2 ☐ Unknown ☐ Not Done

Print Preview Mark SV Ready Submit Return

Radio Buttons

List/Dropdown Boxes

Text Boxes

# InForm Checks Your Entries


**DOV** **VITALS** **BLOOD**

**Vital Signs** Patient: FM Patient No: ENR-FRA-4

**Vital Signs**

1. Date/Time of Assessment (24 hour clock):	<input type="text"/> / <input type="text"/> / <input type="text"/> : <input type="text"/> : <input type="text"/>
2. Temperature:	<input type="text" value="enr"/> °F
3. Temperature Method:	<input type="radio"/> Oral <input type="radio"/> Axillary <input type="radio"/> Rectal <input type="radio"/> Aural
4. Pulse Rate:	<input type="text"/> bpm

**p00213.webcrf.net - [JavaScript Application]**

 Please enter a floating point value

**OK**

**Alpha entry where numeric was expected**

**Print Preview** **Submit** **Return**

**Document: Done**



# Making Corrections

- Prior to submitting the data

The screenshot shows a web-based data entry interface for 'Vital Signs'. At the top, a navigation bar includes a yellow arrow icon, a timeline with dates P1 D1 through P1 D6 (P1 D1 is highlighted), and tabs for DOV, VITALS, and BLOOD. The 'Vital Signs' section is active, displaying patient information: Patient: BBA, Patient No: ENR-FRA-8. The form contains four rows of data entry fields:

Vital Signs	
1. Date/Time of Assessment (24 hour clock):	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/>
2. Temperature:	<input type="text"/> °F
3. Temperature Method:	<input type="radio"/> Oral <input type="radio"/> Axillary <input type="radio"/> Rectal <input type="radio"/> Aural
4. Pulse Rate:	<input type="text"/> bpm

At the bottom of the form are buttons for 'Print Preview', 'Submit', and 'Return'. Annotations with red arrows point to specific elements:

- An orange box labeled 'Click Return to clear eCRF' points to the 'Return' button.
- An orange box labeled 'Use the Eraser Icon to clear each data value' points to the eraser icons on the right side of each data row.

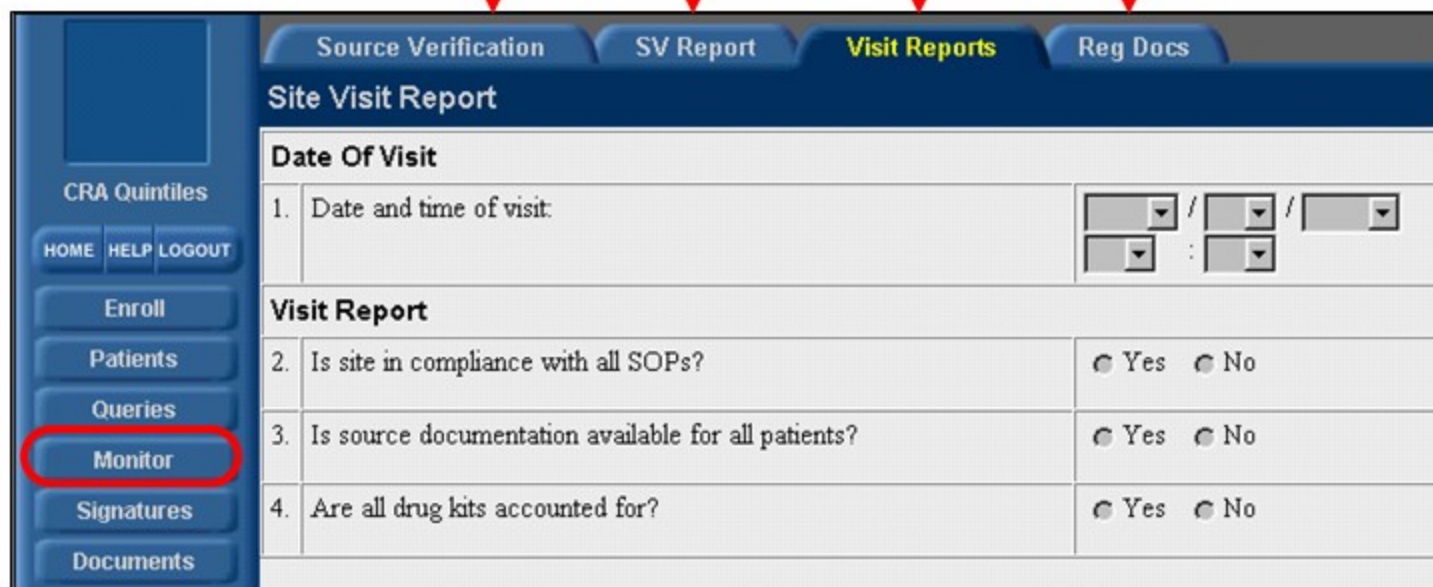




# Monitor Options

- Visit Report & Regulatory Docs checklist can be customized

Monitor Activities available



The screenshot shows the KLINTEC Academy web application interface. On the left is a sidebar with navigation buttons: CRA Quintiles, HOME, HELP, LOGOUT, Enroll, Patients, Queries, Monitor (highlighted with a red circle), Signatures, and Documents. The main content area has tabs for Source Verification, SV Report, Visit Reports (selected), and Reg Docs. Below the tabs is a 'Site Visit Report' form. The form includes a 'Date Of Visit' section with a date and time picker, and a 'Visit Report' section with four checklist items, each with 'Yes' and 'No' radio buttons.

Date Of Visit	
1. Date and time of visit:	<input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/>

Visit Report	
2. Is site in compliance with all SOPs?	<input type="radio"/> Yes <input type="radio"/> No
3. Is source documentation available for all patients?	<input type="radio"/> Yes <input type="radio"/> No
4. Are all drug kits accounted for?	<input type="radio"/> Yes <input type="radio"/> No





# Electronic Signatures

---

- Signing indicates that the individual confirms that the task they are responsible for is complete
- Documents are normally signed after all data/comments are **complete** and all queries **resolved**

Note: If data are changed after signature, signature is removed and PI must resign



# FDA Requirements

---

- Must use biometric means or two identification components
- Must use both components for first signing per session
- Can use one component for remainder of session

**User name  
&  
password**



# Freezing & Locking

---

**Prevents changes to the eCRF either temporarily or permanently**



# Freezing & Locking

---

## Freezing

- Prohibits data entry or data updates
- **Comments and query activities still permitted**
- Use unfreeze to enable data entry/update

## Lock

- **Locking prohibits entry, updates, comments or query activities**
- Data can be unlocked to make changes
- Can add additional patients



# Reports

---

- Report categories available
  - Patient
  - Case Records
  - Source Verification
  - Queries
  - Custom





# Example Report

Patient Case Records Query Source Verification Hot Spots Custom							
CRF Status - By Site							
Site	Patients Enrolled	CRFs Expected	CRFs Started	CRFs Started but Data Entry Not Completed		CRFs Started and All Data Entry Completed	
				With Open Queries (% CRFs started)	No Open Queries (% CRFs started)	With Open Queries (% CRFs started)	No Open Queries (% CRFs started)
PF	18	239	124 (52%)	2 (2%)	18 (15%)	5 (4%)	99 (80%)
TOTAL	18	239	124 (52%)	2 (2%)	18 (15%)	5 (4%)	99 (80%)

- Reports run interactively
- Report output is displayed on screen
- Report categories appear as tabs



# Listings

---

- Selected data items are sent to a spreadsheet
- These data items can be downloaded and saved to a local directory
  - Be sensitive to the distribution of this file (trial data)
- Once downloaded, data tables can be manipulated using Microsoft Excel
- Users may save their listings settings and run the same listing again later



# Listings (contd)

InForm - Gil Lam (PM) - Microsoft Internet Explorer provided by Quintiles Transnational

File Edit View Favorites Tools Help

Address http://qkanswbc06.qkan.quintiles.com/PFST/pfts.dl?S=43ae21e8&C=Navigator\_RenderTopFrameset Go Links

☒ Listings Export Tool Options: ☐ Global ☒ HTTPLinks ☐ Include Comments All Sites

**Visit Date and Time**

☐ 1. Date and Time of Visit

☐ All Visits ☐ Base ☐ Wk 1 ☐ Wk 2 ☐ Wk 4 ☐ Wk 8 ☐ Final ☐ Unsch ☐ Wk 16 ☐ Wk 32

**Patient Information**

\*\*\*WARNING: ANY CHANGES MADE TO THIS SUBJECT INFORMATION OF THIS SUBJECT - Changes that make these fields empty will not be acted upon and the prior values will remain for the purpose of identification.\*\*\*

☐ 1. Patient Number

☐ 2. Patient Initials (Enter a dash if no middle initial)

☐ All Visits ☐ Base

**Demographics**

☐ 1. Gender

☐ 2. Date of Birth

☐ 3. Race

☐ 4. Screening Date

☐ 5. Height

**Family History**

☐ 6. Marital Status

☐ 7. Does the patient have any children?

Save Save As Delete

Listings Report: [new] Open Submit

Done Internet

Select listing options

Select data items



# Laboratory Data

---

- Can be imported into InForm
- Can be entered directly into eCRF as with other data
- Import tool used to map and load external data
  - Agree to data format, define mapping, execute program
  - Can run rules against imported data at the time of import; queries generated as if data put in directly
- Customized programming required for each lab used; efficiencies gained with imports from central laboratories



# Data Coding

---

- Coding for items using external coding tools
- Exported data run against dictionary using coding engine (SAS, Clintrial)
- Multiple dictionaries available
- Code can be imported back into InForm, but must predefine specifications for form and process

