PHASE FORWARD™

InForm 4.6

Principal Investigator Training

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**Overview of this course**

InForm 4.6 Principal Investigator Training is a .5 day course designed to show you how to perform the tasks associated with reviewing electronic clinical data in InForm trials.

**Objectives**

After completing this course, you should be able to:

- Log on to an InForm trial and manage a user profile.
- Review clinical data in an InForm trial.

**Prerequisites**

You should have experience with all of the following:

- Medical industry concepts and terminology.
- Clinical trials processes and procedures.
- Using a personal computer and a mouse.
- Microsoft Windows operating system.
- Microsoft Internet Explorer.
- Microsoft Excel.

**Audience**

This course is intended for clinical trial professionals who are responsible for reviewing electronic clinical data. This includes:

- Clinical Data Managers (CDM).
- Principal Investigators (PI).
- Other sponsor and CRO staff.
This lesson discusses concepts and terminology surrounding InForm trials.

**Objectives**

After completing this lesson, you should be able to:

- Discuss InForm concepts and terminology.
- Describe InForm software features.
Examining a typical InForm trial environment

The InForm software from Phase Forward Incorporated is a Web-based electronic data capture tool that enables site staff to enter patient data into electronic Case Record Forms. Trial data are automatically stored and maintained in a database via the Internet.

Examining InForm trials

The following illustration shows you how a typical InForm trial gathers and stores clinical data:

1. The clinical research coordinator (CRC) logs on to an InForm trial using a Web browser.
2. The CRC completes and submits electronic case record forms (eCRF) over the Internet.
3. The InForm system stores the clinical data from the eCRFs in the InForm trial database.
4. The InForm system then evaluates the clinical data and automatically sends queries on questionable data to the CRC.
5. The CRC answers automatic queries.
6. The clinical research associate (CRA) performs analysis on the clinical trial data.
7. The CRA sends queries to the CRC if there are questions on clinical data items.
Introducing InForm trial concepts and terminology

The following table describes common InForm trial terms:

<table>
<thead>
<tr>
<th>Term</th>
<th>What it means</th>
</tr>
</thead>
</table>
| CRC      | The **Clinical Research Coordinator** is a user based at a site. The CRC typically has access only to the site where he/she works. Responsibilities include:  
  ▪ Data entry into the eCRF.  
  ▪ Query resolution and management. |
| PI       | The **Principal Investigator** may have similar access as the CRC although their primary responsibilities include:  
  ▪ Data review.  
  ▪ Signing a Case Book or eCRF. |
| CRA      | The **Clinical Research Associate** or Monitor is a sponsor user with read-only access to the data. Responsibilities include:  
  ▪ Monitoring activities.  
  ▪ Query generation and closure.  
  ▪ Source Data Verification.  
  ▪ Freezing eCRFs. |
| CDM      | The **Clinical Data Manager** is a sponsor user with read-only access to all sites in the trial. Responsibilities include:  
  ▪ Generating and closing queries.  
  ▪ Locking eCRFs. |
| eCRF     | An **electronic Case Report/Record Form** that a CRC completes for a patient as a result of a visit to a site. |
| CRB      | The **Case Record Book** is a complete set of all forms or pages that a CRC must complete for a patient in a trial. |
| Regular form | Also known as a flat form, an eCRF designed to capture data in a single visit only. |
| Common form | An eCRF designed to gather data across two or more visits where all the data gathered is visible in every visit where the form occurs. There are two types of forms that can gather cumulative data:  
  ▪ Add Entry forms  
  ▪ Repeating forms |
| Hyperlink | Underlined text that allows you to jump to another page or location in a trial by a single mouse click. |
| InForm portal | This is an optional Web portal for InForm clinical trials that is integrated with the Home page that you see at login. The InForm portal provides access to important information about the trial such as announcements, reports, and trial documents. |

Examining site user activities

Typical InForm trial site user activities include:

▪ Obtaining an InForm site user name and password.  
▪ Registering patients into a trial.  
▪ Entering and changing clinical data on eCRFs.  
▪ Answering queries on clinical data.  
▪ Preparing for monitoring visits.
Examining sponsor user activities

Typical InForm trial sponsor user activities include:

- Obtaining an InForm sponsor user name and password.
- Reviewing clinical data queries.
- Performing source verification.
- Signing electronic case record forms.
- Transferring patients from one site to another.
- Running standard reports.
- Producing ad hoc reports (discussed in the InForm Reporting and Analysis Training course).
Examining the user activation process

To become an InForm trial user, you must perform the following tasks:

- Obtain a private email address for corresponding with the Help Desk and Sponsor representatives.
- Complete InForm Site and Sponsor training.
- Obtain the following from your Sponsor:
  - The Web address (URL) for the trial.
  - Your InForm trial user name.
  - An initial password.
- Determine secret information to use in case you forget your password:
  - A personal hint question.
  - The answer to your personal hint question.

Examining InForm trial security features

Your user name and password comprise your secure access to an InForm trial. Keep the following in mind:

- To secure your password from improper use:
  - Never write down your password.
  - Never store your password where others can see it.
  - Use a combination of letters and numbers (alphanumeric).
- Passwords expire after a pre-defined number of days after the date of creation.
- InForm requires re-identification (log back in) after a pre-defined number of minutes of:
  - Inactivity
  - Continuous activity
- Your user account may be deactivated after a pre-defined number of failed login attempts.

Note: If the InForm trial logs you out after some period of inactivity or continuous activity, you can pick up where you left off by logging back on. Any data that you had entered but not submitted is retained.
**What if I forget my password**

If you forget your password, the InForm software provides a mechanism that allows you to provide the answer to your secret hint question so that you can automatically receive a new password. This is what you must do:

1. Set up a hint question on the password administration page.
2. If you forget your password after attempting to log in, click the **Forgot your password?** link below the **Log In** button to access the **Forgot Password** page.
3. Enter the answer to your hint question in the **Your Answer** field then click the **Get New Password** button.
4. InForm software logs you on to the trial and you receive a new password via email.
5. Change your password from the one you received in the email message.

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**Caution:** Failing the above, you must contact Phase Forward Support and provide answers to all the following questions.
- Full Name
- Site Name
- Site Address
- Site Number
- 3 last digits from Username
  (or User role if alphanumeric format is not used for Username)
Getting Around in an InForm Trial

This lesson shows you how to use the many navigation features provided in an InForm trial.

Objectives

After completing this lesson, you should be able to:

- Describe InForm trial navigation features.
- Access and reorder patients on the Case Books for Site screen.
- Perform visit navigation.
- Perform form navigation.
- Perform at-will changes to your user profile.
Examining InForm trial navigation features

InForm trials provide many navigation features that you can click to get around during clinical data entry:

- The **Time and Events Navigation Arrow** lets you quickly access the Time and Events schedule for a patient.
- The **Visit Timeline** (visit ruler) allows access to the visits for a patient.
- **Tabs** allow you to display forms in a visit.
- **Icons** not only give you access to major trial components but also show you the status of visits, eCRFs, and other trial components.
- **Hyperlinks** (underlined text) and **Hot Spots** (data values) allow you to jump to trial-specific help or to change pages respectively.
- **Navigation** features include the **Navigation** pane that gives you access to the major functions in a trial, the **Patient search** feature, and **Apply** controls that give you access to eCRF actions (**Print Preview**, **Mark SV Ready**, **Clear CRF**).

**Hint:** You can identify the navigation features on a page when your mouse pointer changes to this 🗺 as you move it around.
Examining the navigation features on the Case Books for Site page

When you click the **Patients** button in the **Navigation** pane, the InForm software displays the **Case Books for Site** page that features:

- **Navigation buttons** give you access to the major functions in an InForm trial.
- The **Patient search** field allows you to type a patient number to quickly access the Time and Events Schedule for that patient.
- The following **icons**:
  - **Reorder Patients** button that allows you to resequence the list of patients displayed on the **Case Record Book For Site** page.
  - **Traffic light** icons that give you access to patient visits.
- The **Status** filter that lets you display only those patients who are **Enrolled**, **Randomized**, **Complete**, or **Dropped**.
- The **Highlight** checkboxes allow you to highlight the traffic lights for visits that are **Started**, **Incomplete**, have **Queries**, are **Frozen**, and/or **Locked**.
- **Hyperlinks** (underlined text) in the **Patient** and **Status** column that allow you to jump to the **Time and Events Schedule** for a patient.
- A **Page Indexer** that allows you to view subsequent pages of patients when the list of patients is longer than a single page.
Examining visit and form navigation features

When you click a traffic light icon in the Case Books for Site page, the InForm software gives you access to the forms in that visit. The visit page features:

- The **Time and Events Navigation** arrow lets you quickly access the Time and Events schedule for a patient.
- The **Visit Navigation Timeline** gives you access to each visit for a patient.
- The **eCRF tabs** allow you to select a form to work on. Tabs containing a (!) indicate that the form is incomplete or that there are open queries.
- The following **icons** provide additional navigation options:
  - At the top right of the page, there are two navigation mode icons (if this feature is active):
    - ![Visit Navigation Mode](image) **Visit Navigation Mode** allows you to display a **visit page indexer** to perform visit navigation for a patient.
    - ![Form Navigation Mode](image) **Form Navigation Mode** allows you to display a **form page indexer** to perform form navigation for a patient.
  - In the form header to the right of the patient identifier, there is a **Comment** icon ![Comment](image) that allows you to enter a form-level comment.
  - To the right of each form item question, you can find icons:
    - ![Comment](image) The **Comment** icon allows you to enter an item-level comment.
    - ![Reset Item Values](image) The **Reset Item Values** icon (for items where no data have been submitted) allows you to clear the item value so that you can enter another.
    - ![View Item Audit History](image) The **View Item Audit History** icon (for items where data have been submitted) allows you to view what, when, and by whom data was entered.
    - ![View Item Queries](image) The **View Item Queries** icon allows you to review the queries for an item and their resolution
  - **Hyperlinks** (underlined text) provide navigation capabilities for:
    - Item questions (if provided by your clinical trial designer) gives you access to trial-specific help (which you can also access by clicking the **Documents** button in the **Navigation** pane).
    - The most recently visited forms (a standard feature).
- **Hot Spots** on submitted data (a standard feature) allow you to access the **Data Value(s)** page where you can change the original data.
- **Navigation buttons** give you access to the major functions in an InForm trial.
- The **Patient search** field allows you to type a patient number to quickly access the Time and Events Schedule for that patient.
Examining the navigation features on the home page

When you first log on to your InForm trial or click the Home button in the Navigation pane, the Home Page displays:

- **Navigation buttons** give you access to the major functions in an InForm trial.
- The **Patient search** field allows you to type a patient number to quickly access the Time and Events Schedule for that patient.
- The patient Go controls allow you to access the formset for a selected patient in a selected visit.
Preparation an InForm Trial for Review

This lesson discusses how to prepare eCRFs for review by the trial sponsors.

Objectives

After completing this lesson, you should be able to:

- Describe typical preparation activities for a sponsor visit.
- Mark forms and case books ready for source verification.
- Describe the Investigator signature process.
- Sign eCRFs and the CRB.
Examining source verification activities

Source verification of eCRFs typically occurs in the following activities:

- Site users mark the eCRFs/CRBs that are ready for source verification.
- Sponsors can freeze eCRF/CRBs to prevent changes to the data.
- Sponsors compare the data on the eCRFs with the source documents and indicate the items that have been verified.
- Sponsors can issue queries where necessary.
- Investigators sign the eCRFs/CRBs that have completed source verification.

Note: Remember that when a sponsor selects Create Query In Candidate State, only sponsor users are able to view the query and respond.

Examining the signature status in a trial

As a site user, you can review the signature status of eCRFs and CRBs for your site by accessing the Required Signatures page. You can access the Required Signatures page by clicking the Signatures button in the Navigation pane. You can find the following features on this page:

- Five filters that control what you see in the signatures list:
  - The Patient Filter drop-down lets you display designated signing eCRFs for all patients or for a selected patient.
  - The Site Filter drop-down lets you display designated signing eCRFs for all sites or for a selected site.
  - The Type Filter drop-down lets you display all designated signing eCRFs or you can limit the list to those that are designated for a single eCRF or for the entire CRB.
  - The Status Filter drop-down lets you display all designated signing eCRFs regardless of status or you can limit the eCRFs listed to those that are signed or unsigned.
  - The CRF/CRB Status Filter drop-down lets you display all designated signing eCRFs or list only those at a certain stage of completion.

- Status of All Signatures column displays icons representing the status of the signatures for the eCRF or CRB:
  - One or more required signatures are missing.
  - All required signatures are present.
  - The CRB can not be signed in this state.
  - One or more signatures for the CRF are missing.
• All required signatures for the CRB are present.
• The **Sign** hyperlink to access the **Sign Form** page for an eCRF.
• The **Sign Book** hyperlink to access the **Sign Form** page for a CRB.

- The **View** signature details hyperlink gives you access to the **Signature** page for a selected eCRF.
- The **Page Indexer** lets you navigate from page to page of designated signing eCRFs when there are too many eCRFs to display on a single page.
- **Hyperlinked column headings** that you can click to sort the designated signing eCRFs listed.
Examining how investigators sign eCRFs and CRBs

Investigators sign an eCRF or a CRB once the eCRF or the CRB is complete for a patient and the data are not expected to change.

Examining where a trial requires signatures

Your InForm trial is set up with specific eCRFs designated as signature forms. The signature on a single eCRF can represent that:

- The clinical data is reviewed, accurate, and/or complete.
- The Case Record Book is complete.

**Hint:** By convention, the eCRF for signing the Case Record Book is the Study Completion Form, or the final eCRF in the trial.

How do investigators sign eCRFs and CRBs

Investigators can sign an eCRF or CRB by navigating through the Signatures page or through the Time and Events schedule.

**Caution:** A signature becomes invalid if the data on the signed eCRF is subsequently changed.

Examining signature tools for investigators

As an investigator, there are two types of signature pages that you can access:

- The Required Signatures for Site page to review a summary of your required signatures.
- The Affidavit page to apply an electronic signature to a signature eCRF.

Examining the Required Signatures for Site page

As an investigator, you can review the status of eCRFs and CRBs that require a signature by accessing the Required Signatures page. You can access the Required Signatures page by clicking the Signatures button in the Navigation pane. You can find the following features on this page:

- Five filters that control what you see in the signatures list:
  - Status of All Signatures column displays icons representing the status of the signatures for the eCRF or CRB:
    - One or more required signatures are missing.
    - All required signatures are present.
- The CRB cannot be signed in this state.
- One or more signatures for the CRF are missing.
- All required signatures for the CRB are present.
- The Sign hyperlink to access the Sign Form page for an eCRF.
- The Sign Book hyperlink to access the Sign Form page for a CRB.

- The View signature details hyperlink gives you access to the Signature page for a selected eCRF.

- The View All Signature Information button let’s you display a summary of all required signatures (in addition to yours). Once you click the View All Signature Information button, the InForm software relabels the button to View My Signatures so that you can toggle back to the original view.

- The Page Indexer lets you navigate from page to page of signing eCRFs when there are too many eCRFs to display on a single page.

- Hyperlinked column headings that you can click to sort the designated signing eCRFs listed.

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Filter Dropdown Lists
Status of Signatures
View Details Hyperlink

Column Hyperlinks
Page Indexer
View All Sigs Button
Examining the Affidavit page

The Affidavit page allows you to sign an eCRF or Case Record Book. You can access the Affidavit page by clicking the Sign link for an eCRF on the Required Signatures for Site page. You can find the following features on this page:

- The **clinical data items** on the signature eCRF. There must be data in at least one item before the eCRF is available for signing.
- The **Signature List** displays the sponsor users who have signed the eCRF.
- The **Affidavit Statement** describes the meaning of a signature on the eCRF.
- The **User name** textbox is where you can type your InForm trial user ID which comprises the first part of the electronic signature.
- The **Password** textbox is where you can type your InForm trial password which comprises the second part of the electronic signature.
Performing End-Of-Trial Activities

This lesson shows sponsors how to sign the forms and case record books and how to produce data export listings on the clinical data in an InForm trial.

Objectives

After completing this lesson, you should be able to:

- Describe end-of-trial activities.
- Lock eCRFs and Case Record Books.
- Produce clinical data export listings.
Examining sponsor end-of-trial activities

Sponsor end-of-trial activities consist of:

- Locking eCRFs and CRBs.
- Signing eCRFs and CRBs.
- Producing clinical data export listings.
- Running standard reports.
- Producing ad hoc reports (discussed in the InForm Reporting and Analysis Training course).

Locking eCRFs and CRBs

Locking data enables you to permanently prevent changes in eCRFs permanently at the end of a study. The following table describes the activities that you can and can not perform when you lock an eCRF or Case Record Book:

<table>
<thead>
<tr>
<th>You can</th>
<th>You can not</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sign an eCRF</td>
<td>Add/Update Data</td>
</tr>
<tr>
<td>Sign a CRB</td>
<td>Add/Update Comments</td>
</tr>
<tr>
<td></td>
<td>Answer Queries</td>
</tr>
<tr>
<td></td>
<td>Mark SV Ready</td>
</tr>
</tbody>
</table>
Signing eCRFs and CRBs

Electronic signatures in InForm trials replace the handwritten signatures of paper CRFs. Designated investigator(s) at your site have the rights to sign the Case Record Book and/or eCRFs.

Hint: Signing should not occur until:
- All data entry is complete.
- Source verification is complete.
- All queries are answered and closed.

When you can sign eCRFs and CRBs

You can sign a signature eCRF as soon as there is at least one data item entered on the eCRF right through until after the CRB is frozen and/or locked.

What an electronic signature conveys

An Affidavit page on which the Investigator signs indicates what the signature conveys. The signature meaning varies from trial to trial. Typically, a signature could mean that:

- Data entry is complete.
- Source verification has been performed.
- All queries are resolved and closed.

How electronic signatures become invalid

The InForm software automatically invalidates electronic signatures when a user enters either of the following on a signature eCRF:

- New or updated clinical data.
- One or more comments.
**Producing data export listings**

The InForm software provides the Listings Export Tool where you can configure and execute clinical data extracts to a Microsoft Excel spreadsheet (which you can save) for selected clinical data. You can use Listings reports for:

- Review purposes
- Interim analysis

Through the Listings Export Tool, you can define selection criteria to output and recall the specifications (by name) for reuse:

- **Global** (or public) selection criteria specifications.
- **Private** selection criteria specifications.
Examining the InForm trial locking features

You can lock individual eCRFs, all the eCRFs in a visit, or complete CRBs using the features described in this topic.

Examining the Lock eCRF feature

You can lock an individual eCRF by clicking the Lock button in the bottom left of the page for an eCRF.

Note: The Lock CRF button appears on eCRFs that contain clinical data.
Examining the lock visit feature

You can lock a complete visit by selecting Lock Visit from the Actions drop-down list in the bottom left of the page.

Examining the lock CRB feature

You can lock a complete CRB by clicking the Lock CRB button in the bottom left of the page for a selected CRB.

**Note:** The Lock CRB button appears on Case Record Books that contain clinical data.
Examining the Listings Export Tool

The Listings Export Tool enables you to produce data export listings of clinical data items. The InForm software stores the report output in a Microsoft Excel spreadsheet that you can save. The following describes the features of the Listings Export Tool:

- The Set/clear all checkboxes button allows you to select all the data items in a trial. You can then deselect the items that you do not want to include in the Excel spreadsheet.
- The report settings checkboxes let you specify report run options:
  - Save the report as a Global (public) listing that is visible to all users who have rights to the Listings page.
  - Include HTTP Links to eCRF data in the Excel spreadsheet.
  - Include Comments on the items and eCRFs in the Excel spreadsheet.
- The site filter drop-down list allows you to select a single site or all sites to include in the Excel spreadsheet.
- The visit checkboxes allow you to select or deselect the visits to include for an eCRF in the report.
- The report selection feature allows you to:
  - Select a saved report from the Listings Report drop-down list.
  - Click the Open button to retrieve a report.
- The report disposition feature allows you to:
  - Click the New button to begin configuring a new report.
  - Click the Save button to save the currently configured report.
  - Click the Save As button to save the currently configured report to a different name.
  - Click the Delete button to delete the opened report.
- The item checkboxes allow you to select or deselect the items to include in the report.
Set/Clear Check Boxes

Report Settings

Site Filter Dropdown

Item Check Boxes

Report Selection

Visit Check Boxes

Caution: Avoid selecting all data items for a listing. This can severely impact system and database performance.
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