HALF-PINT
Data Entry Training
Part 2: InForm

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Outline

- *Part 1: Screening & Tracking (see Part 1 slide set)*
  - *I. Welcome and objectives*
  - *II. Screening and tracking procedures*
- Part 2: InForm
  - III. Introduction to InForm data management system
  - IV. *HALF-PINT* case report forms flowchart
  - V. Data entry demonstration
  - VI. Data entry certification process
  - Appendix. InForm reference slides

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Part 2.
InForm

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III. Introduction to InForm

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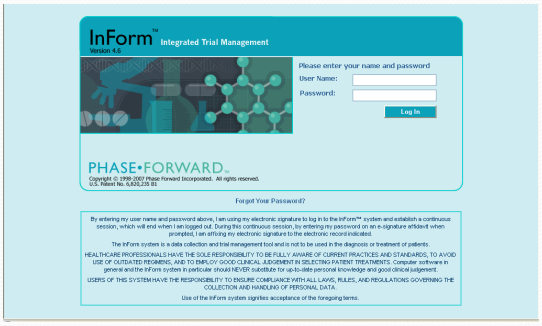
InForm Data Management System

- Web-based data entry system
- There are 2 versions of InForm:
  - **Training** version (for data entry training and certification)
  - **Production** version (for real study data entry)



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InForm Requirements

- InForm Version 4.6 is compatible with PCs only; it is not compatible with MACs
- Internet Explorer is the only web browser supported by InForm
  - Internet Explorer 6 and 7 supported
  - Internet Explorer 8 can be used if run in "compatibility mode"

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InForm Display Panes

Navigation pane: displays your username and buttons corresponding to the different actions you can do

Content pane: displays the Patient List, the Time and Events schedule, or eCRFs (electronic case report forms)

Content-specific pane: displays additional functionality and navigation options

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InForm Patient List

- Click the Patients button to access the Patient List
- The Patient List is a log of the patients entered into the database
- The Patient List also summarizes the status of eCRFs

- Click on an underlined patient ID link to access the Time and Events Schedule for a patient

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InForm Time and Events Schedule

- The Time and Events Schedule lists all eCRFs for a particular patient
- The traffic lights indicate the status of an eCRF

Traffic lights:

Blank: the eCRF has not been started

Green: the eCRF is complete with no open queries

Yellow: the eCRF is incomplete

Red: the eCRF has open queries

- Click on a traffic light to access an eCRF

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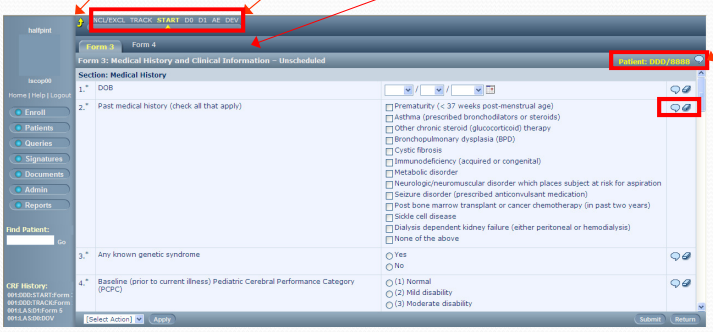
Exploring eCRFs in InForm

Click the yellow arrow to return to the Time and Events Schedule

Timeline

Tabs: there may be several tabs, one for each eCRF in a group of eCRFs



Patient Study ID Number

Icons:

Quote bubble: allows you to insert a comment

Eraser: allows you to reset an item (before submitting)

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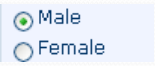
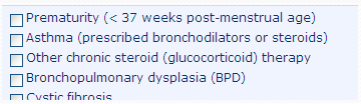
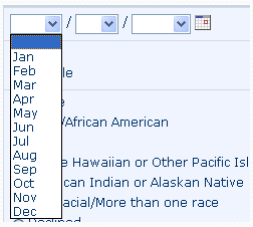
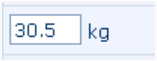
Types of Data Entry Fields

Radio buttons: you can select one option from two or more options; they are mutually exclusive	
Check lists: you can select multiple options from two or more options; they are not mutually exclusive	
Drop-down lists: you can select a value from a list of prespecified options	
Text boxes: you can type in text or numeric data; numeric data is entered as integers or decimals (for example, 5 or 5.2)	

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IV. *HALF-PINT* Case Report Forms Flowchart

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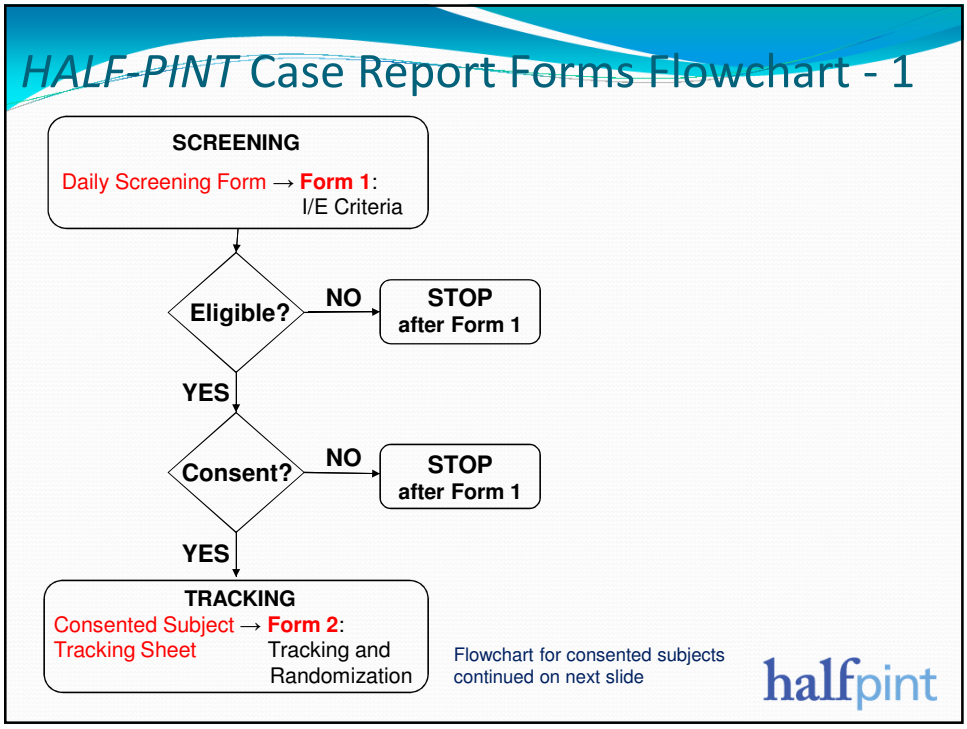
HALF-PINT Case Report Forms Flowchart - 1
SCREENING
Daily Screening Form → Form 1: I/E Criteria
Eligible?
NO
STOP after Form 1
YES
Consent?
NO
STOP after Form 1
YES
TRACKING
Consented Subject → Form 2: Tracking Sheet
Tracking and Randomization
Flowchart for consented subjects continued on next slide
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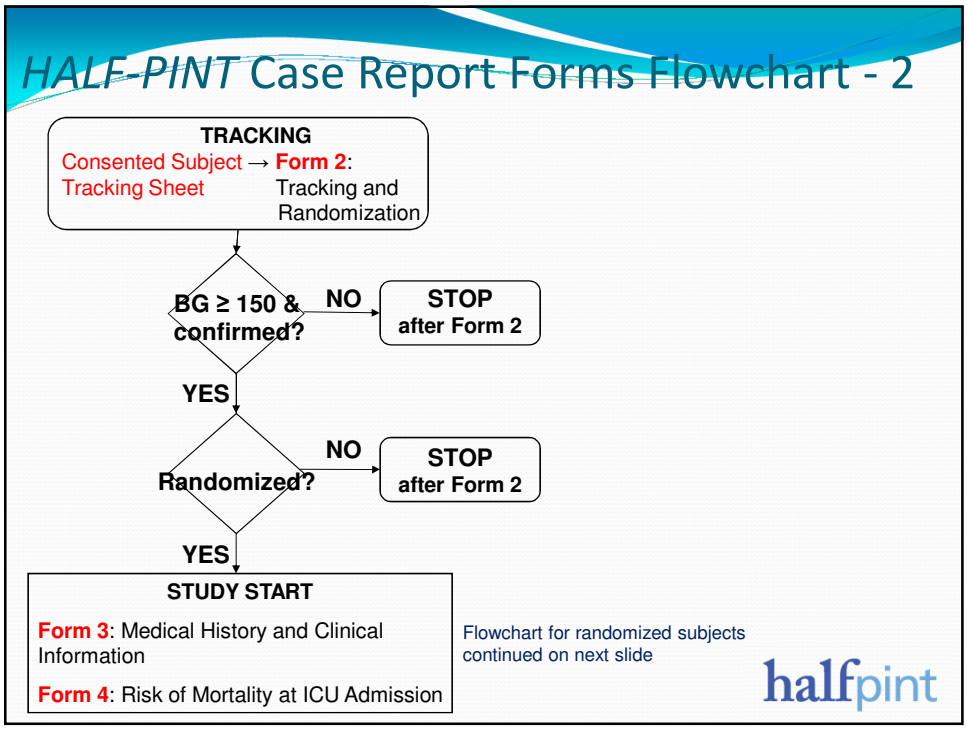
HALF-PINT Case Report Forms Flowchart - 2
TRACKING
Consented Subject → Form 2: Tracking Sheet
Tracking and Randomization
BG ≥ 150 & confirmed?
NO
STOP after Form 2
YES
Randomized?
NO
STOP after Form 2
YES
STUDY START
Form 3: Medical History and Clinical Information
Form 4: Risk of Mortality at ICU Admission
Flowchart for randomized subjects continued on next slide
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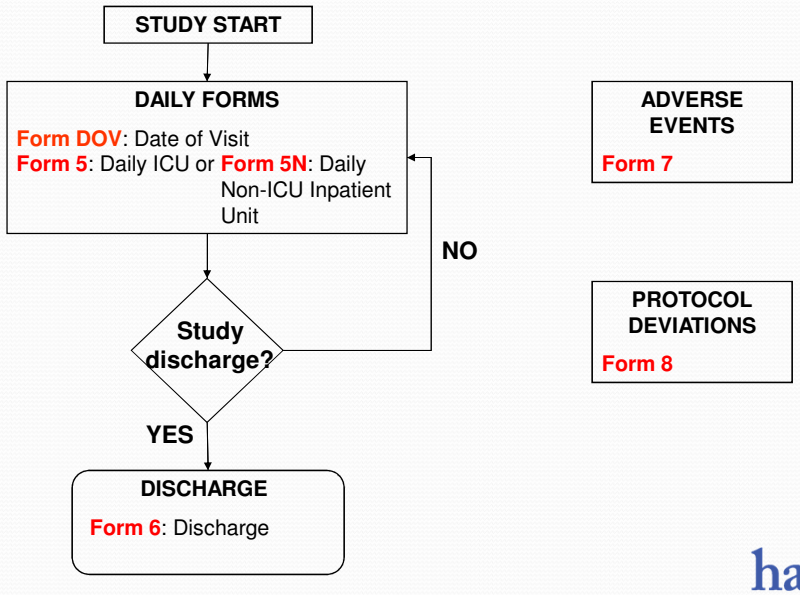
HALF-PINT Case Report Forms Flowchart - 3



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HALF-PINT Study Discharge Criteria

- Reasons for *HALF-PINT* study discharge (end of daily data collection):
- 1. Related to primary outcome (study-defined ICU discharge): Subject is study discharged when all of the following are true for 24 consecutive hours:
  - Extubated
  - Off non-invasive ventilation that provides ≥ 5 cm H_2O or reached ventilatory settings used prior to the illness that led to this ICU admission
  - Not on intravenous vasopressor or inotropes (i.e., dopamine or dobutamine > 5 mcg/kg/min, or any dose of epinephrine, norepinephrine, milrinone, or vasopressin if used to treat hypotension)
- 2. Other reason: Subject can also be study discharged if:
  - Family/team have decided to limit/redirect from aggressive ICU technological support
  - Withdrawal of consent
  - Hospital discharge
  - Study Day 28
  - Subject has new cardiac surgery

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V. Data Entry Demonstration

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VI. Data Entry Certification

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Certification Process

- When requested, the DCC will e-mail each individual a mock patient data packet and a username/password for the InForm **training** database
- The individual is to enter the mock patient data into the InForm **training** database
- The DCC will assess each individual's data entry and issue queries
- Once the queries are answered and the data entry is corrected, the DCC will assign the individual a username/password for the InForm **production** database

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Data Entry Expectations

- Screening/eligibility data for the previous week are to be entered by Monday at 5pm your local time
  - Complete InForm **Form 1** (Inclusion/Exclusion Criteria) for all screened patients meeting inclusion criteria in the past week
  - Complete InForm **Form 2** (Tracking and Randomization) for all subjects for whom tracking was discontinued or who were randomized during past week
- Other data (daily forms, etc.) are to be entered into InForm within one week of occurrence
- The timeliness of data entry is addressed through weekly e-mails and monthly/quarterly reports ("Site Performance Metrics")

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Source Documentation

- All data entered into InForm must have source documentation = must be part of the medical record
- Consent
  - If the CHB IRB is your site's IRB of record, you will have to include a copy of the consent form in the subject's medical record
  - Other sites can follow this procedure or document the date/time of consent and enrollment into *HALF-PINT* in the medical record, depending on local IRB practice
- Pediatric Cerebral Performance Category (PCPC) and Pediatric Overall Performance Category (POPC)
  - These assessments must be based on documentation in the medical record to assure an audit trail

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Source Documentation

- Each site will create a "formal data plan" to provide source documentation for data verification
- The DCC will provide a template which sites can use to develop their formal data plan
- The formal data plan may include:
  - PICU admission date/time
  - Extubation date/time
  - End of non-invasive ventilation
- The site monitor will follow your site's formal data plan when verifying source documentation during your site monitoring visits

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Questions?
Comments?

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Appendix. InForm Reference Slides

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InForm Reference Slides

- Starting a new patient/ System Screening/ System Enrollment
- Conditional & compound questions
- Skip instructions
- Submitting data
- Queries
- Conditional forms (e.g., Daily ICU Form 5, Discharge Form 6)
- Repeating forms (e.g., Adverse Event Form 7, Protocol Deviation Form 8)
- Deleting forms

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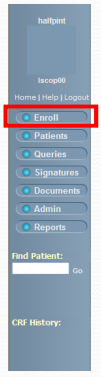
Starting a New Patient

- Click the Enroll button.
- Note: here, "Enroll" means that you are entering data for a new patient into the database, regardless of whether that patient will be enrolled in the *HALF-PINT* study.



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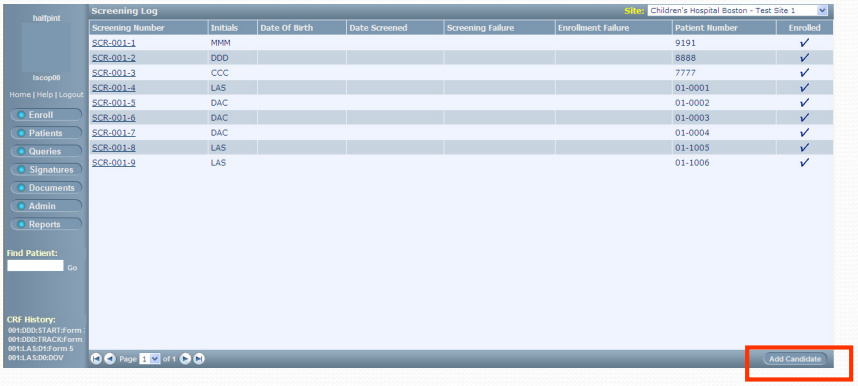
System Screening

- The Enroll button brings you to the Screening Log page.
- Click the Add Candidate button.



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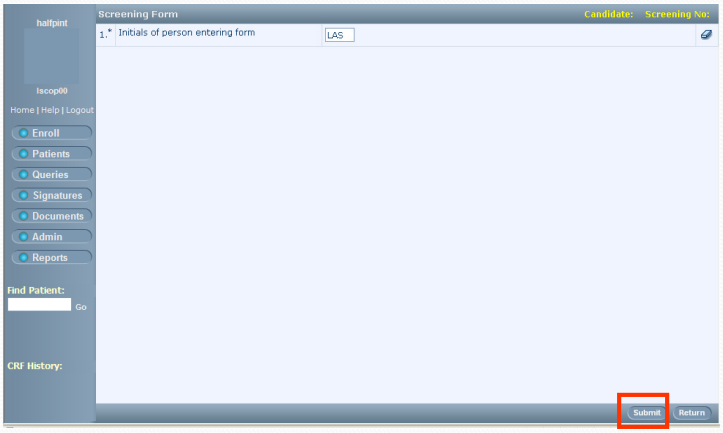
System Screening (continued)

- Enter your initials
- Click the Submit button to return to the Screening Log page.



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System Enrollment

- Click Enroll. Again, "Enroll" means that you are entering data for a new patient, regardless of whether that patient will be enrolled in the *HALF-PINT* study.

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System Enrollment (continued)

- Enter the Patient Study ID Number
  - The DCC will mail a binder containing the Patient Study ID log to each site.
  - The binder should be kept in a safe and secure location.
  - Data entry personnel will use the ID log to look up the final/tracking digit corresponding to the Sequential Study ID Number recorded on the Daily Screening Form Log.

- Click the Submit button

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System Enrollment (continued)

- Click through the next two screens:
  - Click the Enroll button
  - Click the Go to First Visit button
- On the Subject ID page, Patient Study ID Number should be filled in automatically. (You can edit it here if necessary.)
- When starting a new patient, you should always continue to this point before stopping. After you get to this point, you can easily pick up from where you left off.
- You are now ready to enter data from the Daily Screening Form into InForm, specifically in Form 1: Inclusion/Exclusion Criteria.

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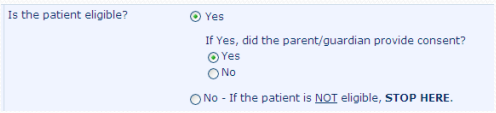
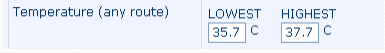
Conditional & Compound Questions

- Conditional questions
  - Some responses require that follow-up questions, or conditional questions, must also be answered.



- Compound questions
  - Some items contain multiple questions that must be answered.



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Skip Instructions

- Sometimes, certain questions or sections of a data form are not applicable and should be skipped
- InForm does not allow for the programming of skip patterns
- Take note of **Bolded** text to help guide your data entry

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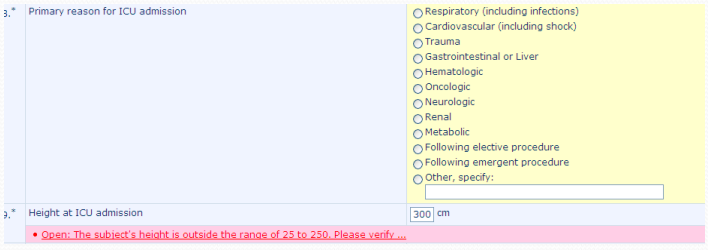
Submitting Data

- When starting a new form, enter all data or as much data as possible
- Then click the Submit button at the bottom right
- After you submit the form for the first time, scroll back through the form to check for:
  - Unanswered questions (yellow highlight)
  - Open queries (pink highlight and red text)



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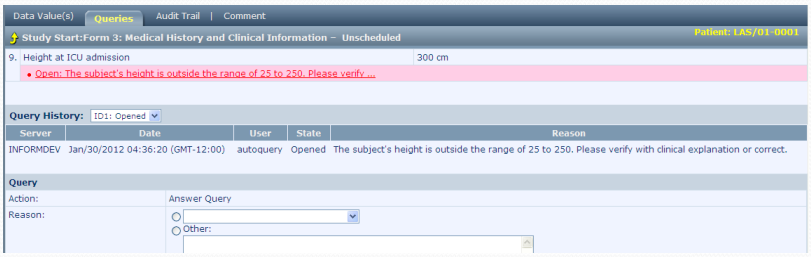
Queries

- Automated queries will appear if you fail to answer certain questions, answer a question that should be skipped, or enter out-of-range data.
- Click on the underlined text or the query flag to open the query. Read the entire query text.
  - Example #1: out-of-range data



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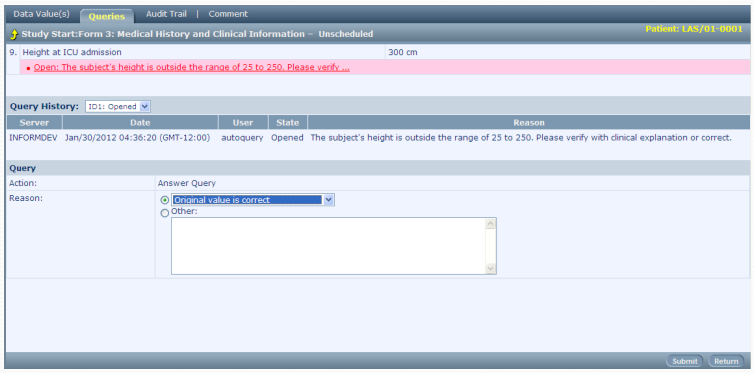
Queries (continued)

- Click on the Data Value(s) tab. If necessary, enter a new value and reason for change. Or enter a reason to justify the current answer as shown below. Then click the Submit button.



- If the query relates to another question, review your answer to the other question. If necessary, edit the other question in order to resolve the query.

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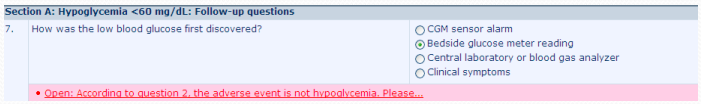
Queries (continued)

- Queries continued -
  - Example #2: answering a question that should be skipped
  - Depending on the answer to a previous question, certain questions or sections should be skipped.



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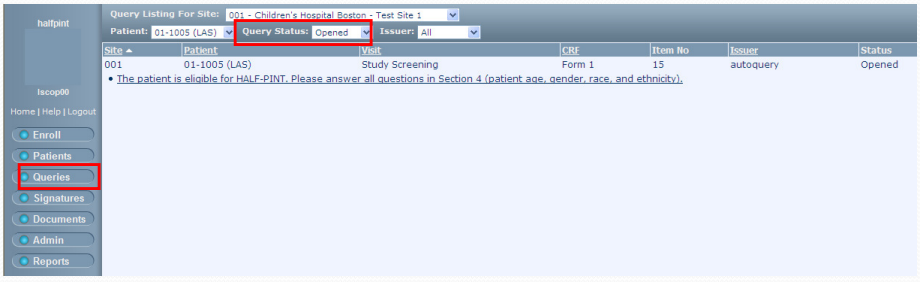
Queries (continued)

- Besides automated queries, queries will also be issued by the DCC
- Periodically check for new open queries by clicking the Queries button in the navigation pane, then by selecting "Opened" from the Query Status drop-down list



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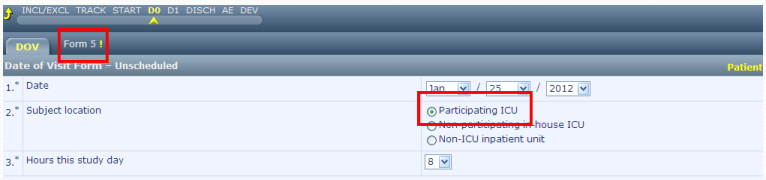
Conditional Forms

- Sometimes, new data forms are generated based on particular responses. Here are some examples:
  - Daily ICU Form 5 is generated if the DOV form subject location is answered "Participating ICU"
  - Discharge Form 6 is generated if one of the Form 5 or Form 5N study discharge questions is answered "Yes"



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Repeating Forms

- There are some forms you may need to complete more than once:
  - Adverse Event Form 7
  - Protocol Deviations Form 8
- To add a Form 7 or Form 8, click AE or DEV in the timeline at the top of the screen
- Then click the New button
- Complete the form, then click the Submit button

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Deleting Forms

- You may need to "delete" forms if entered in error (e.g., Non-ICU inpatient unit daily forms entered when PICU daily forms should have been, an event was determined not to be an adverse event)
- InForm does not allow forms to be completely removed
- There are 2 methods for "deleting" forms

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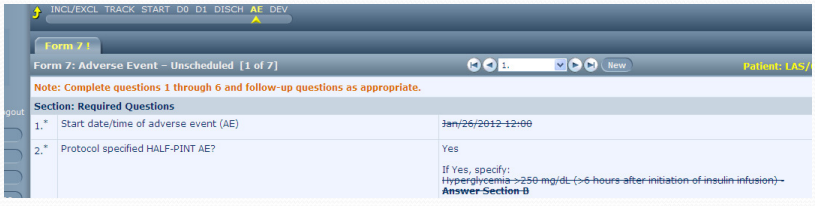
Deleting Forms (continued)

- Method #1 (for repeating forms only): Use the "Delete" button
  - Select "Delete" from the drop-down list at the bottom left
  - Click the "Apply" button
  - Scroll down and enter a "Reason for Change"
  - Finally, click the "Delete" button at the bottom right
  - The data entered in the form will then appear to be crossed out



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Deleting Forms (continued)

- Method #2 (for non-repeating forms): Enter a form-level comment
  - Click the quote bubble next to the Patient Study ID Number at the top right of the screen
  - Type in the comment “Form created in error”
  - Click the “Submit” button
  - The DCC will not analyze data from non-repeating forms marked with such comments

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