

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)

InForm™ Integrated Trial Management
version 4.6

Please enter your name and password

User Name:

Password:

[Forgot Your Password?](#)

PHASE FORWARD.
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U.S. Patent No. 8,045,019 B2

By entering my user name and password above, I am using my electronic signature to log in to the InForm™ system and establish a continuous session, which will end when I am logged out. During the continuous session, by entering my password or an e-signature without when prompted, I am affirming my electronic signature to the electronic record created.

The InForm system is a data collection and trial management tool and is not to be used in the diagnosis or treatment of patients. HEALTHCARE PROFESSIONALS HAVE THE SOLE RESPONSIBILITY TO BE FULLY AWARE OF CURRENT PRACTICES AND STANDARDS, TO AVOID USE OF OBSOLETE PRACTICES, AND TO EMPLOY SOUND CLINICAL JUDGMENT IN SELECTING PATIENT TREATMENTS. Computer software is general and the InForm system in particular should never substitute for up-to-date personal knowledge and good clinical judgment. USERS OF THIS SYSTEM HAVE THE RESPONSIBILITY TO INSURE COMPLIANCE WITH ALL LAWS, RULES, AND REGULATIONS GOVERNING THE COLLECTION AND HANDLING OF PERSONAL DATA.

Use of the InForm system signifies acceptance of the foregoing terms.

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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)

Site	Patient	Status	Study Screening	Tracking and Randomization	Study Start	Daily Event 0	Daily Event 1	Discharge	Adverse Event
001	01-0001 (LAS)	Complete							
001	01-0002 (DAC)	Enrolled							
001	01-0003 (DAC)	Enrolled							
001	01-0004 (DAC)	Enrolled							
001	01-1003 (LAS)	Enrolled							
001	01-1006 (LAS)	Enrolled							
001	7777 (CCC)	Not Complete							
001	8888 (DOO)	Enrolled							
001	9191 (NMM)	Enrolled							

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

Site	Patient	Status	Study Screening	Tracking and Randomization	Study Start	Daily Event 0	Daily Event 1	Discharge	Adverse Event
001	01-0001 (LAS)	Complete							
001	01-0002 (DAC)	Enrolled							
001	01-0003 (DAC)	Enrolled							
001	01-0004 (DAC)	Enrolled							
001	01-1003 (LAS)	Enrolled							
001	01-1006 (LAS)	Enrolled							
001	7777 (CCC)	Not Complete							
001	8888 (DOO)	Enrolled							
001	9191 (NMM)	Enrolled							

- 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)

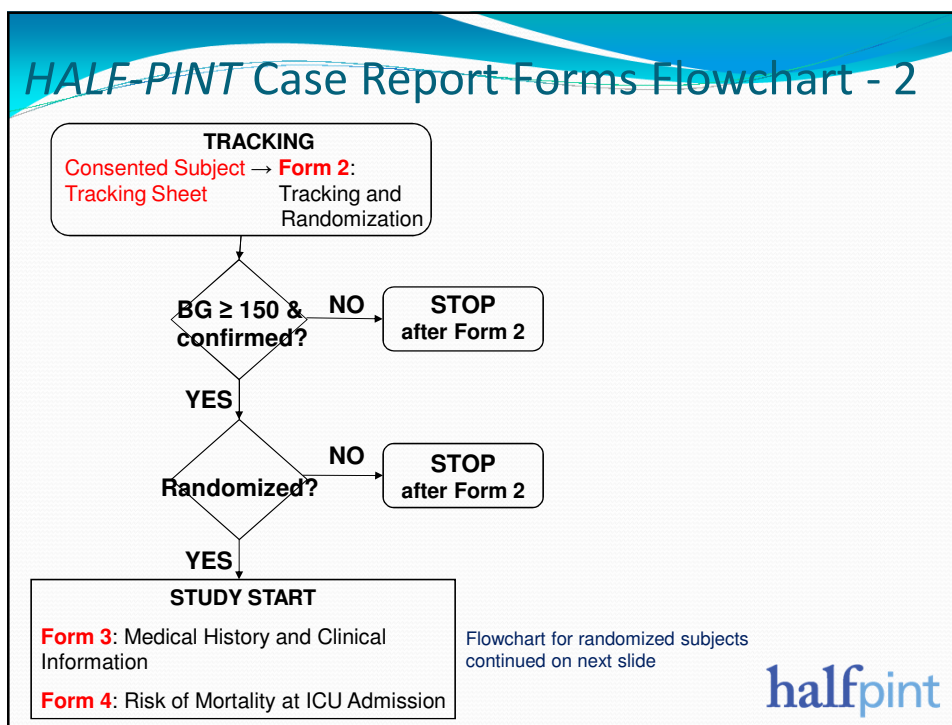
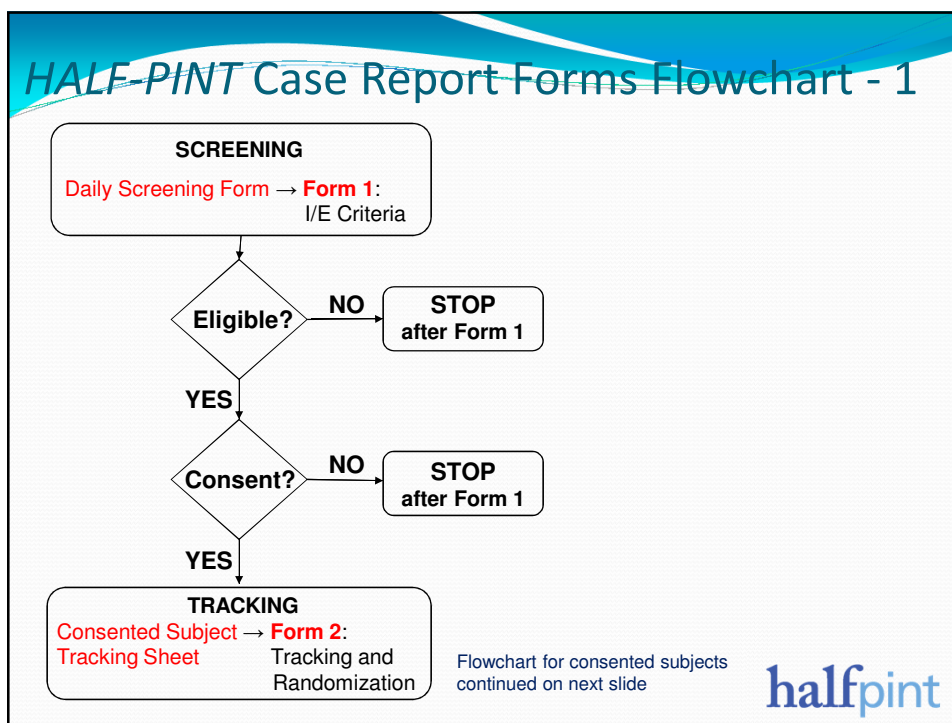
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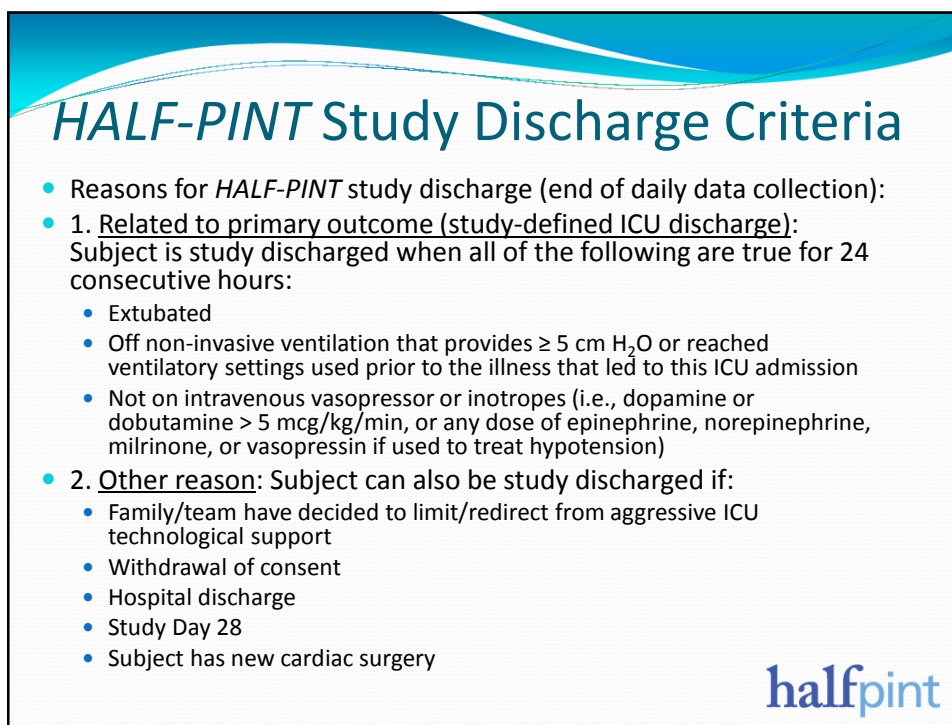
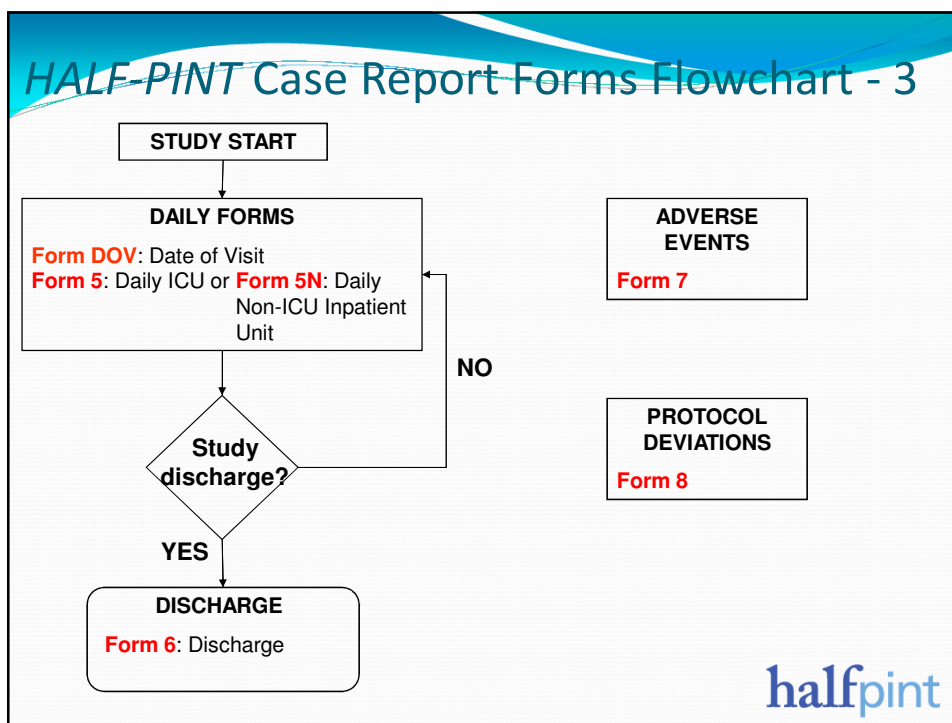


IV. *HALF-PINT* Case Report Forms Flowchart



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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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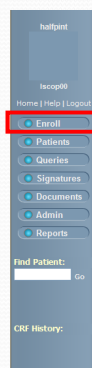
InForm Reference Slides

- 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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Screening Log Site: Children's Hospital Boston - Test Site 1

Screening Number	Initials	Date Of Birth	Date Screened	Screening Failure	Enrollment Failure	Patient Number	Enrolled
SCR-001-1	MMH					9191	✓
SCR-001-2	DOD					8888	✓
SCR-001-3	CCC					7777	✓
SCR-001-4	LAS					01-0001	✓
SCR-001-5	DAC					01-0002	✓
SCR-001-6	DAC					01-0003	✓
SCR-001-7	DAC					01-0004	✓
SCR-001-8	LAS					01-1005	✓
SCR-001-9	LAS					01-1006	✓

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Find Patient: Go

CRF History:
 001000-51 Add form
 001000-TRACK form
 001000-51 Form B
 001000-51 Form C

Page 1 of 1

Add Candidate

System Screening (continued)

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

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Screening Form Candidate: Screening No:

1. Initials of person entering form

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Find Patient: Go

CRF History:

Submit Return

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.

Screening Number	Initials	Date Of Birth	Date Screened	Screening Failure	Enrollment Failure	Patient Number	Enrolled
SCR-001-1	MMH					9191	✓
SCR-001-2	DDO					8888	✓
SCR-001-3	CCC					7777	✓
SCR-001-4	LAS					01-0001	✓
SCR-001-5	DAC					01-0002	✓
SCR-001-6	DAC					01-0003	✓
SCR-001-7	DAC					01-0004	✓
SCR-001-8	LAS					01-1003	✓
SCR-001-9	LAS					01-1006	✓
SCR-001-10	LAS						Enroll

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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.

Is the patient eligible? ☒ Yes

If Yes, did the parent/guardian provide consent?

☒ Yes

☐ No

☐ No - If the patient is NOT eligible, **STOP HERE**.

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

Temperature (any route)	LOWEST	HIGHEST
	35.7 C	37.7 C

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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

11.* Intubated/mechanically ventilated at time of consent

☐ Intubated and mechanically ventilated

If intubated, date/time of intubation:

/ / : : 24-hour clock

☐ Tracheostomy and mechanically ventilated

If tracheostomy, date/time of initiation of mechanical ventilation:

/ / : : 24-hour clock

☒ **No - If subject was not intubated or trached, skip to question 15.**

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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)

3.* Primary reason for ICU admission

☐ Respiratory (including infections)

☐ Cardiovascular (including shock)

☐ Trauma

☐ Gastrointestinal or Liver

☐ Hematologic

☐ Oncologic

☐ Neurologic

☐ Renal

☐ Metabolic

☐ Following elective procedure

☐ Following emergent procedure

☐ Other, specify:

3.* Height at ICU admission cm

• **Open: The subject's height is outside the range of 25 to 250. Please verify...**

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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

Data Value(s) | **Queries** | Audit Trail | Comment

Study Start: Form 3: Medical History and Clinical Information - Unscheduled Patient: LAX/01-0001

9. Height at ICU admission 300 cm

Open: The subject's height is outside the range of 25 to 250. Please verify ...

Query History: ID1: Opened

Server	Date	User	State	Reason
INFORMDEV	Jan/30/2012 04:36:20 (GMT-12:00)	autoquery	Opened	The subject's height is outside the range of 25 to 250. Please verify with clinical explanation or correct.

Query

Action: Answer Query

Reason: ☐ ☒ Other:

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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.

Data Value(s) | **Queries** | Audit Trail | Comment

Study Start: Form 3: Medical History and Clinical Information - Unscheduled Patient: LAX/01-0001

9. Height at ICU admission 300 cm

Open: The subject's height is outside the range of 25 to 250. Please verify ...

Query History: ID1: Opened

Server	Date	User	State	Reason
INFORMDEV	Jan/30/2012 04:36:20 (GMT-12:00)	autoquery	Opened	The subject's height is outside the range of 25 to 250. Please verify with clinical explanation or correct.

Query

Action: Answer Query

Reason: ☒ Original value is correct ☐ Other:

Submit Return

- 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.

Section A: Hypoglycemia <60 mg/dL: Follow-up questions

7. How was the low blood glucose first discovered?

☐ CGM sensor alarm
☒ Bedside glucose meter reading
☐ Central laboratory or blood gas analyzer
☐ Clinical symptoms

• Open: According to question 2, the adverse event is not hypoglycemia. Please...

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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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Query Listing For Site: 001 - Children's Hospital Boston - Test Site 1

Patient: 01-1005 (LAS) Query Status: Opened Issuer: All

Site	Patient	Visit	CRF	Item No	Issuer	Status
001	01-1005 (LAS)	Study Screening	Form 1	15	autoquery	Opened

• The patient is eligible for HALF-PINT. Please answer all questions in Section 4 (patient age, gender, race, and ethnicity).

Isop00

Home | Help | Logout

- Enroll
- Patients
- Queries**
- Signatures
- Documents
- Admin
- Reports

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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

INCID/EXCL TRACK START DO D1 AE DEV

DOV | Form 5 | **Form SN 1**

Form SN: Daily Non-ICU Inpatient Unit - Unscheduled Patient: LAS/01-100

Section: Study Discharge

1.* If the subject was on non-invasive ventilation prior to this illness, has the subject returned to that baseline level of support?

☒ Yes
☐ No
☐ Not on non-invasive ventilation prior to this illness

Enter a comment for the form

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