Institute for Clinical and Translational Science

ICTMS Community Informational Meeting

August 27th, 2024

Type in your ICTMS-related queries in the chat window or leave suggestions for future topics you'd like us to cover. Thanks!

Agenda

- ICTMS Expansion Project Update
- OnCore
  - Calendar & Budget Build – the BOS team approach
  - Duplicate enrollment check box
- eReg Updates
  - Training
  - External Monitor Access
- Announcements & Reminders

ICTMS Enterprise Expansion

Phase 1 Complete 2023

OnCore Expansion

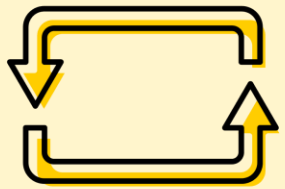
- Available for use by all research studies
- Centralizes participant & visit tracking
- Sponsor invoicing
- Sponsor Payment tracking
- Interfaces EPIC, HawkIRB, V estigo, ePost

Phase 2 Complete 2024

eReg Expansion

- Electronic Regulatory Binder
- Remote monitoring capability
- Electronic signatures
- Real-time document routing
- Enhance Compliance
- 21 CFR Part 11 Compliant

Phase 3
Kick-off Sept 16th, 2024



EDC Expansion

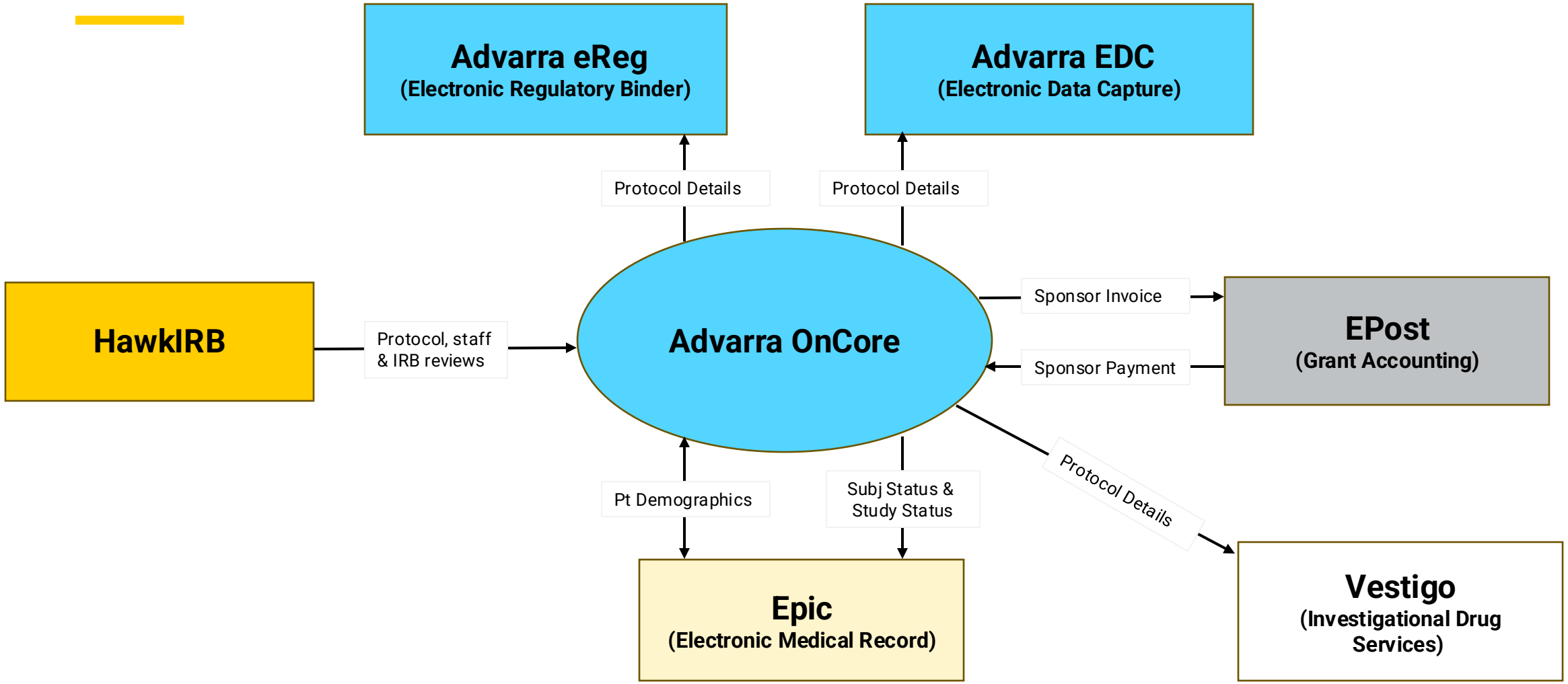
- Internal Electronic Data Capture
- Resource for Iowa Investigator Initiated Trials
- Multi-site Studies
- 21 CFR Part 11 Compliant

Phase 4 TBD

Epic Research Billing & CRPC Grid

- Automated identification and separation of sponsor, patient and insurance billable research procedures

ICTMS & its integrations



IOWA

About Advarra Electronic Data Capture (EDC)

- Software that stores subject data collected in clinical trials
- Effective management investigator – initiated, FDA regulated device or drug studies
- Maintain 21 CFR Part 11 compliance
- Integrated with OnCore
- Replaces paper records with electronic records
- Quicker access and availability for data analysis
- Robust reporting capability
- Include constraints to prevent inaccurate or illogical values

OnCore

BOS (Advarra Business Operational Services)

- **Iowa Institution Specific Build Guidelines for General Research - Highlights**
  - Build Blocking Queries – BOS team sends when:
    - Discrepancy between the documents provided
    - Sponsor settings to include a CRO
    - Conditional visits like home visits and phone calls
  - Build notes in email responses and in OnCore > PC Console > Documents tab

[External] Advarra Ticket Update Re: UIHC- GR- Calendar and Financial Build- 202402285 (Ticket Number 310875)

Shubhashini A (Support) <cal.bud@advarra.com>
To ICTMS Admin
Sandra

Reply | Reply All | Forward

Mon 8/26/2024 6:56 AM

Shubhashini A (Advarra Zendesk)
Aug 26, 2024, 6:55 AM CDT

Hello Team,

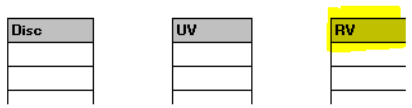
We have run into a Build Blocking Query for **Protocol 202402285**

Protocol Document Referred: 1404-0056_CTA_US_FE_12Aug2024_Sanchez
1404-0056_clinical-trial-protocol-version-01_01Dec2023_fully signed

Protocol Version: Version 1.0, 01 Dec 2023

Build Blocking Query 1. As per the CTA, the CRO (IQVIA) is mainly responsible for the payment, whereas in the OnCore instance, only the sponsor (Boehringer Ingelheim Pharmaceuticals) is added, not the CRO. Kindly add the CRO (IQVIA) to the instance for us to proceed with the build.

Build Blocking Query 2: As per the budget sheet **Remote Visit** has a separate visit milestone cost. Kindly let us know if we can handle this by adding a procedure line item and updating the cost with Pass-thru charge type accordingly. If not, please let us know how you would want us to create this additional Remote Visit as per the budget sheet.



Please have the Study Team review the above queries and provide a response for us to proceed with the build.

Thanks and Regards,
Shubhashini A | Research Associate - III- Business Operations Services
M +91-7358566109 | shubhashini.a@advarra.com
Advarra – Advancing Clinical Trials

IOWA

BOS (Advarra Business Operational Services)

- Calendar
  - Calendar source of truth is Schedule of Events
  - Visit & procedure labeling – should match SOE (occasionally you may find a duplicate ex. ECG/EKG and Electrocardiogram)
  - Amendments – visits or procedures removed will not be removed by BOS team. They will include "DELETE" in front of visit or procedure label the removed item.

BOS (Advarra Business Operational Services)

- Budget
  - Budget - source of truth is CTA or any budget documents other that CTA
  - Indirect rate for applicable clinical trials will be added as 30% unless otherwise defined in CTA
  - Indirect rate for Federal Studies will be added as 55.5% unless otherwise defined in the CTA
- Amendments
  - The reason for "DELETE" instead of removing is to avoid a prior link of visit or procedure to invoice.
  - If budget item removed in amendment BOS team will not delete item but will remove all triggers.

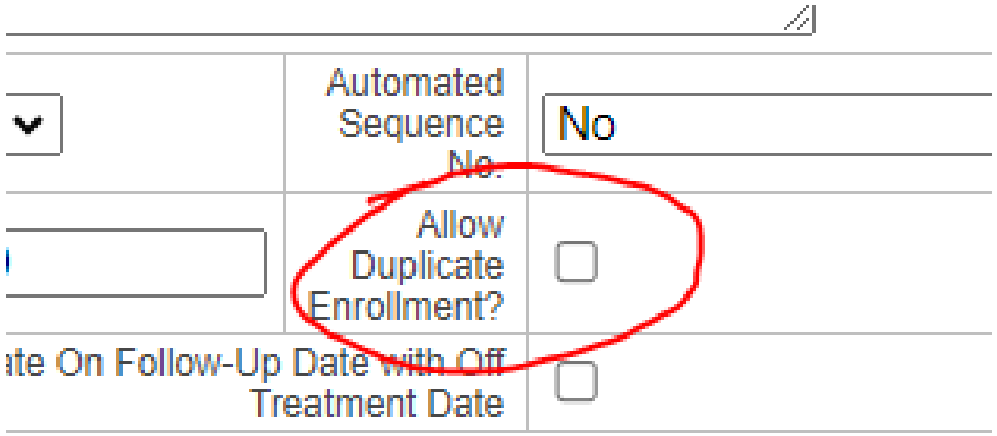
OnCore Financials Console

Inflation Multiplier	1.0
Overhead Rate %	
Indirect Rate %	30
Settings for Application of Indirect Charges	
Import From Charge Master?	N
Protocol?	N
Subject?	Y
Milestones?	Y
Cumulative?	N
Apply indirect charges during budgeting only?	N
No. of Cycles for Budget Calculations (Required If Specification is Open Ended)	
V1 (Unreleased Budget)	
Comments	

The complete BOS Build Guide for General Research is located on the ICTMS OnCore ICON site

Duplicate Enrollment

PC Console > Main > Management
- **Allow Duplicate Enrollment?**
- Not Selected by default



If Selected, Subject can be enrolled more than once
- If Subject Fails screening but is reenrolled and passes, the above checkbox needs to be checked to record that reenrollment while keeping fail record in OnCore.
- If not Selected then you will be unable to reenroll Subject.

TRAIN Reset/Upgrade

OnCore TRAIN environment Upgrade, Sept-Oct training cycle delayed:

1. September 1st TRAIN reset (**July 31st** last day of this training cycle)
2. September 2nd TRAIN Upgrade
3. **September 3rd & 4th** User Import and any other config changes
4. September 5th TRAIN Snapshot
5. **September 6th** (**Friday**), September-October Training cycle begins

September-October Training cycle delayed until Friday Sept 6th, possibly delayed further if necessary.

eReg

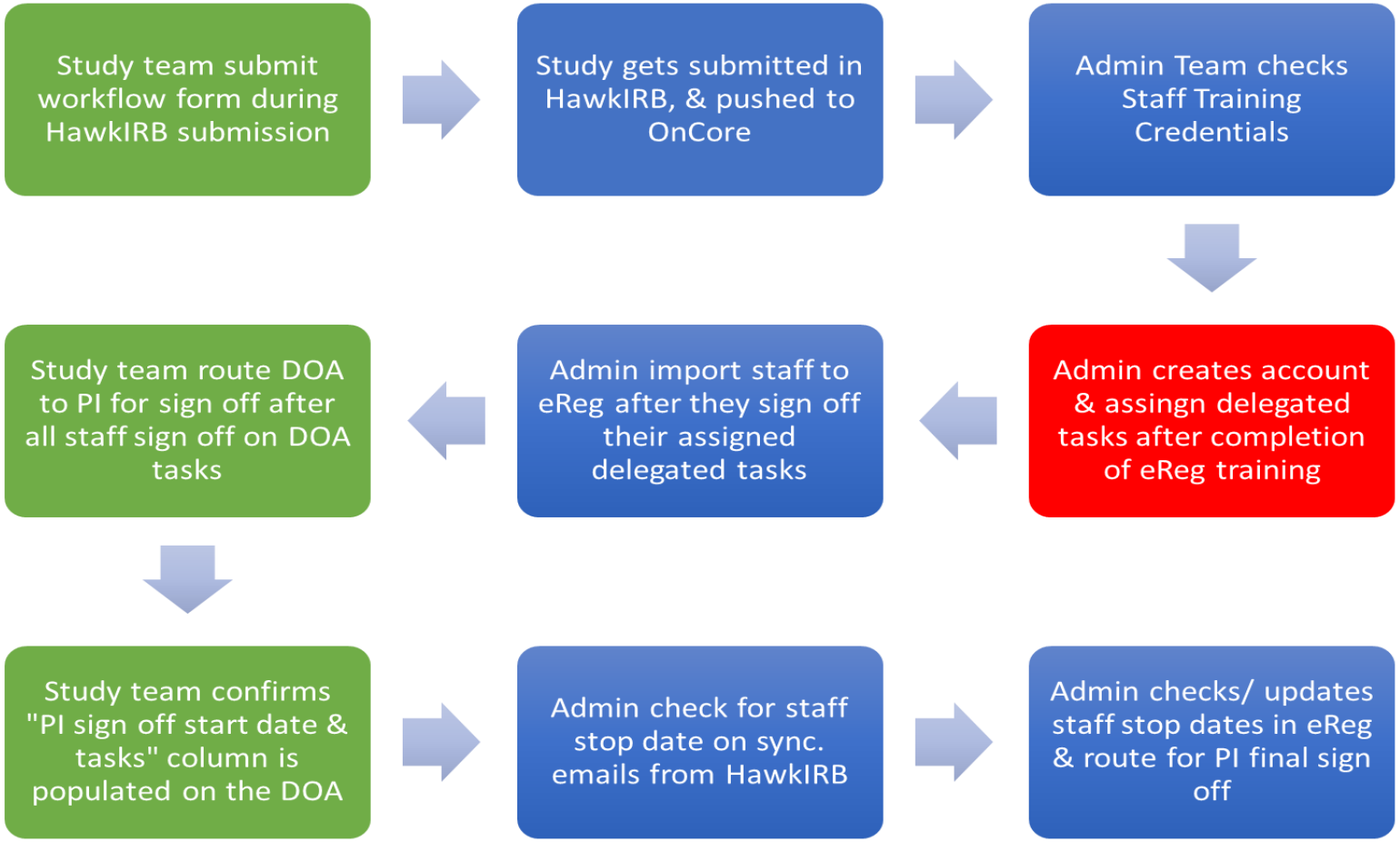
eReg Training Updates:

- **eReg Training is live: Link on ICTS website:** ICTMS eREG Training Registration
  - ICON/ Advarra University access with detailed training instructions provided to each trainee

- **Training Statistics (As of 8/27/2024):**

Signed up for Training	Completed Training	Pending Completion
125	91	34

eReg DOA Flowchart:



eReg Monitor Access:

- **eReg monitor access form - eReg review session:**
  - ICTS website (**Access Survey**)
- **Monitor access to eReg - 3 step process:**
  - Training - Advarra eReg 1300: Reviewer Curriculum
  - Submission of external Healthcare ID request to identity management
  - eReg account creation and review session access

Monitor Epic Access

❑ For Remote Epic CareLink access(Preferred Method)

- ➢ Accessed remotely or from monitor's own laptop onsite
- ➢ 5-7 business days to get access (this could be set up as soon as you know who your monitor is)
- ➢ Coordinator will set up the monitor session's review dates
- ➢ Monitor will need to sign the confidentiality form
- ➢ Confidentiality form can be accessed through **UI CareLink**

❑ For Temporary onsite Epic access

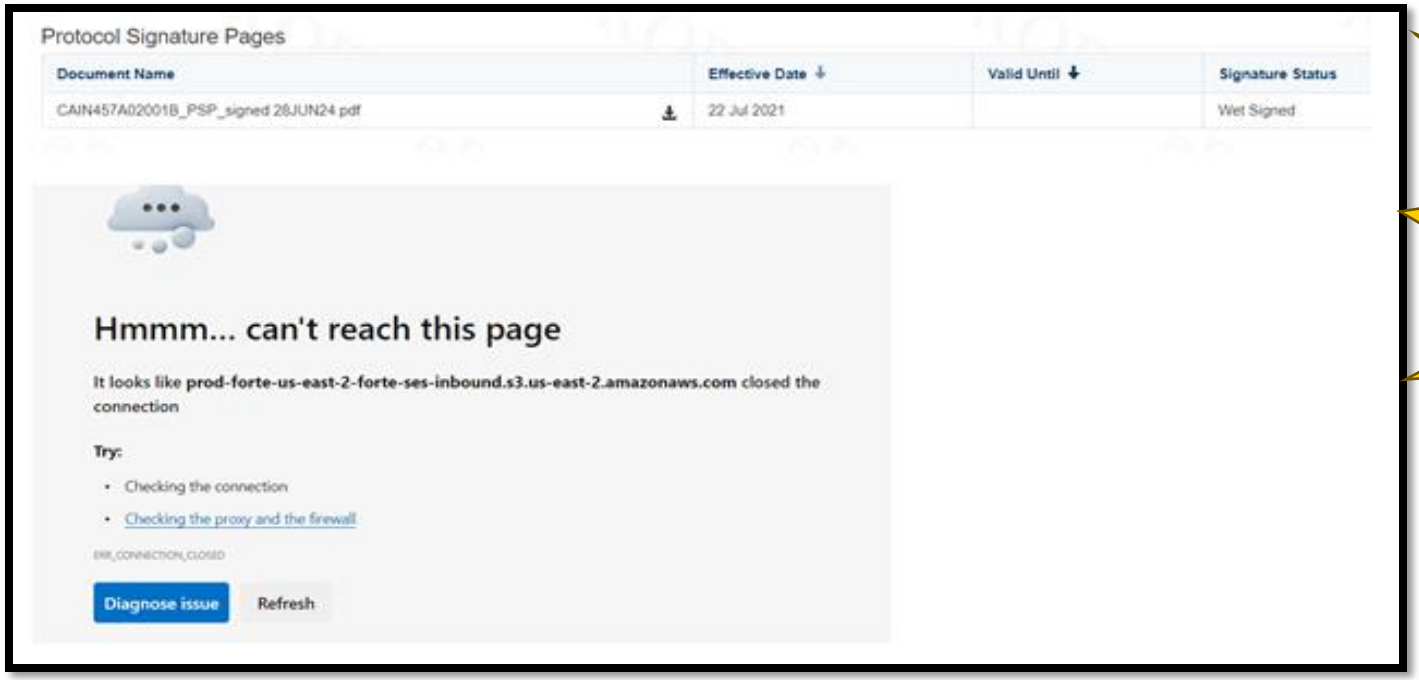
- ➢ On Site epic access needs to done with an ICTS laptop
- ➢ Lead time 1-2 days
- ➢ This will need to be requested for each monitor visit(a new log in will be issued for each visit)

❑ Contact for both type of access (kristy-mahan@uiowa.edu)

Review Session Common Errors:

Common errors experienced by monitors:

- Getting locked out of Iowa account
- Unable to download documents in a review session



Email us @ ictms-admin@uiowa.edu

Announcements/Reminders

HawkIRB & OnCore Integration

- **New Process** - Effective September 3rd HawkIRB will push staff name, staff role and staff start dates to OnCore at time of initial application submission.

- **Old Process** – Staff push to OnCore at time of application release.

- Any staff changes or additions to the HawkIRB application, during the review process, will update automatically at time of application release. If you need staff added before application release, for eReg purposes you should Email:
  - ictms-admin@uiowa.edu for General Research staff updates OR,
  - HCCC-RegDocProDevMon@healthcare.uiowa.edu or PRMC@uiowa.edu for Cancer Center

- Why did we make this change?
  - Allows for automatic sync with OnCore and the eReg system
  - Eliminates duplicate manual entry
  - Maintains consistency across all systems
  - HawkIRB is source of truth

Any staff changes made in HawkIRB after application release, will automatically update in OnCore and be available for import into eReg .

ICTMS OnCore Reminders

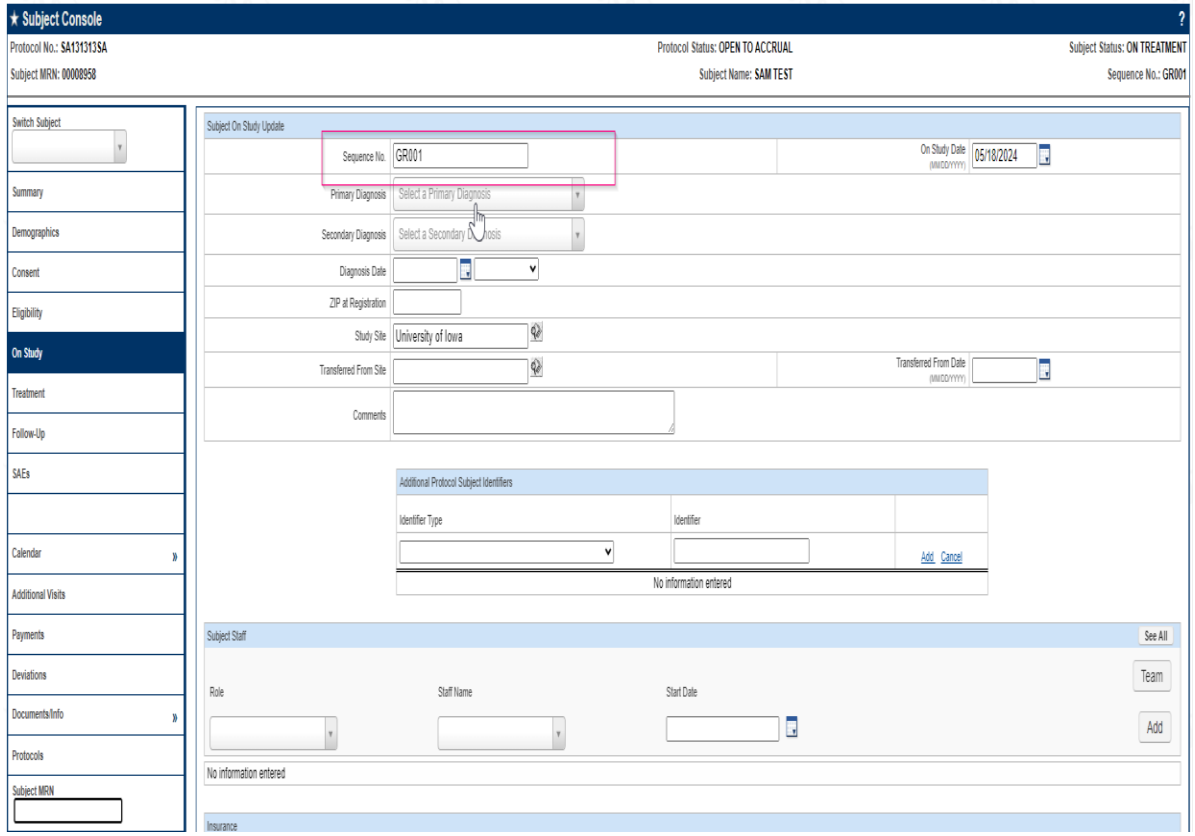
- **Inconsistent subject management in OnCore and Epic**
  - Active enrollments for deceased patients.
  - Active enrollments associated to completed studies.
  - Enrollments being maintained in Epic and OnCore.
  - Enrollments being maintained in Epic only and study exists in OnCore.

  - Best practice is to associate (register) and manage subject statuses in OnCore.
    - Reminder OnCore and Epic are synced. Study related changes you make to a subject record in OnCore will automatically flow over to Epic.

ICTMS OnCore Reminders

- Enter a subject sequence # in OnCore (aka participant ID)
  - *Subject Console > On Study tab*

- Why do these steps matter?
  - Research billing review
  - Future automation with billing grid
  - Upcoming Epic upgrade



Resources

Resources

More information about ICTMS

General Research ICTMS Resources | Institute for Clinical and Translational Science
HCCC I-CTMS Resources for Oncology Clinical Trials

Q & A Opportunities

Weekly Office Hours Wednesdays 9 - 10am
Monthly ICTMS Community Update

Support

General Research ictms-admin@uiowa.edu
HCCC oc-oncoreadmin@healthcare.uiowa.edu
Cherwell Ticket Support Request

Thank you

Sandra Ahrendsen
Josiah Argo
Shehzad Gill

ictms-admin@uiowa.edu

➔ Institute for Clinical and Translational Science (uiowa.edu)