

IOWA

Institute for Clinical and Translational Science

ICTMS

Community Informational Meeting

July 23, 2024



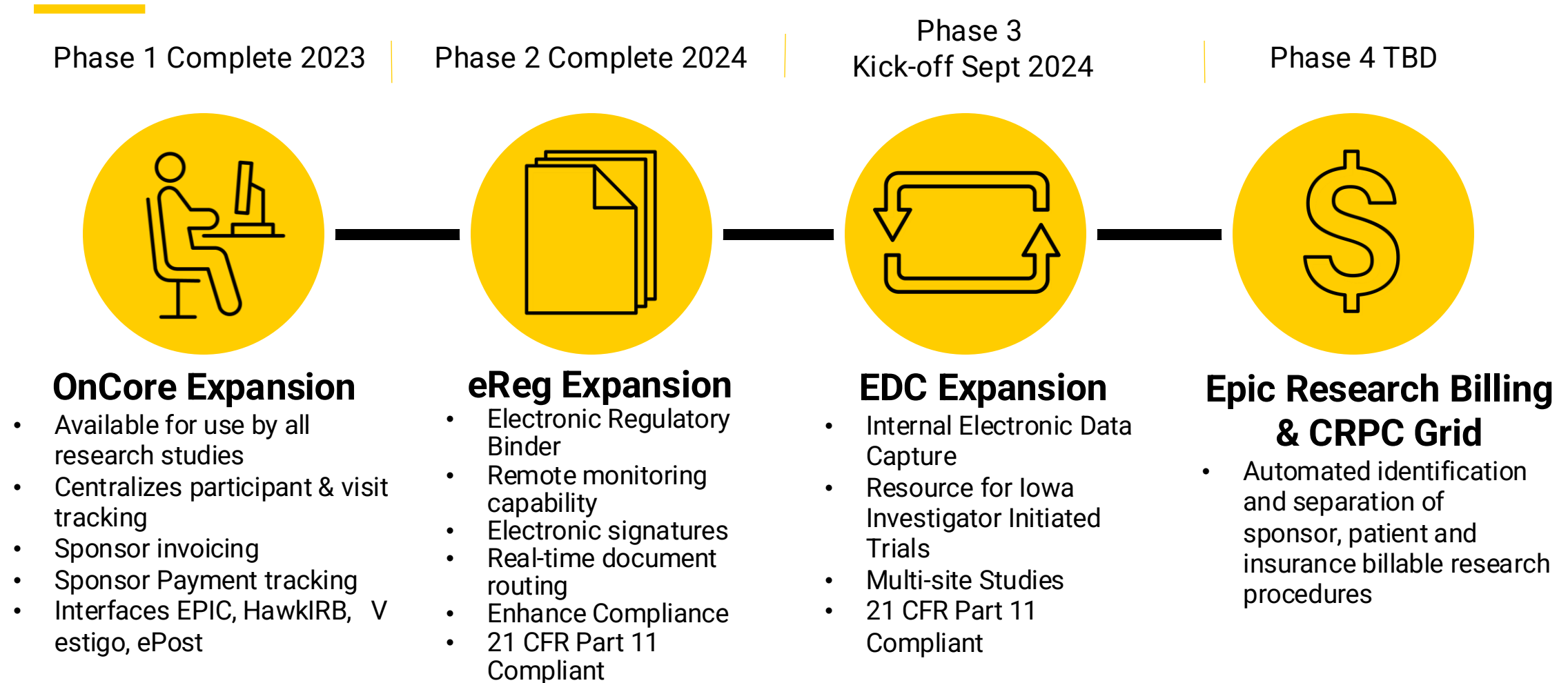
Type in the chat your favorite summertime dessert and/or barbeque dish?



Agenda

- ICTMS Expansion Project Update
- OnCore
 - Invoice integrations and workflows
- eReg Updates
 - Training
 - External Monitor Access
- Announcements & Reminders

ICTMS Enterprise Expansion



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

ICTMS OnCore utilization

General Research

# general research studies currently OTA in OnCore	246
# OTA budgets available (released) for invoicing in OnCore	80
# invoices with sponsor payments applied in OnCore	121

Holden Comprehensive Cancer Center

# oncology studies currently OTA in OnCore	258
# OTA budgets available (released) for invoicing in OnCore	58
# invoices with sponsor payments applied in OnCore	87

Data range 01/01/2000 thru 7/22/2024

OnCore Invoice Integrations

Required fields to invoice in OnCore

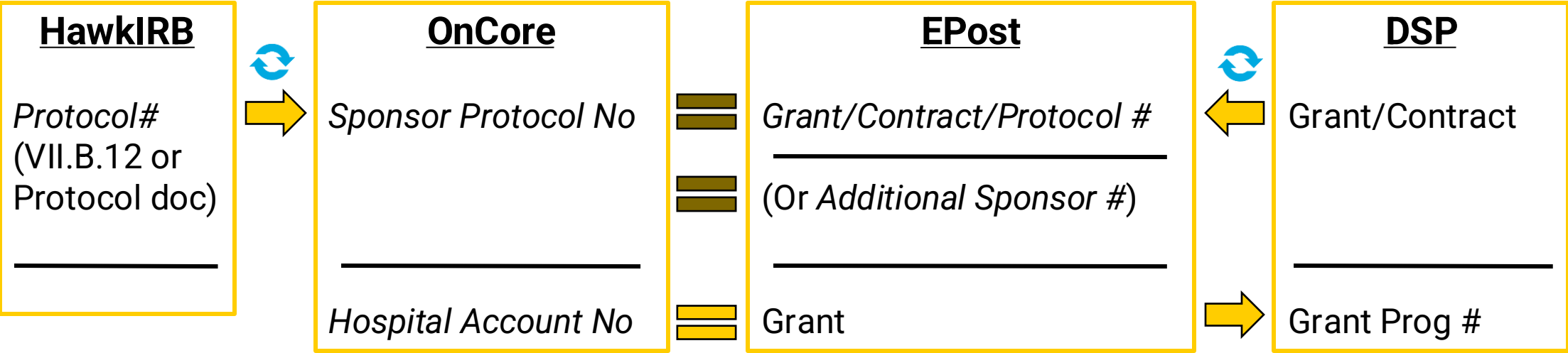
PC Console > Main

- *Management* tab
 - **Hospital Account No**
- *Staff* tab
 - **Primary Financial Analyst**
 - **GR Primary Research Coordinator**
- *Sponsor* tab
 - **Sponsor Protocol No**

Financials Console

- *Parameters* tab
 - **Bill To**
- *Invoice* tab > [Invoice]
 - **Bill To**
 - **Invoice No** (format 00-[Hospital Account No])
 - **Invoice Date** (At or after budget release date)

Equivalent & Invoice Validated Fields



: Field is equivalent in respective systems.

: Field is, or has alternate field that is, equivalent in respective systems.

: Field is equivalent, w/ one acting as source of truth (Arrow direction indicates Data flow).

: Data (ideally) syncs from one system to the other.

What this means for you

- Answer HawkIRB question VII.B.12 with the **Sponsor Protocol No**, to ensure it makes it into OnCore.
 - Can often be found in Protocol document
- Use **Sponsor Protocol No** for **Grant/Contract** field in *DSP*
- Input the **Grant Prog #** from *DSP* into **Hospital Account No** field in *OnCore* prior to budget release

This should help ensure there are no validation issues when Invoicing in OnCore!

—
eReg

eReg Training

- ❑ eReg Training is live: Link on ICTS website [ICTMS eREG Training Registration](#)
- ❑ Users will choose from the following roles when signing up for training
 - **Document Signer training** (Blood Bank/ Lab , Clinical Unit Lead, Pharmacy IDS etc.)
(Approx. 23 min)
 - **Regulatory Manager training** (Highest level access) (Approx. 290 min or 4.83 hrs.)
 - **Regulatory Coordinator training** (Approx. 252 min or 4.20 hrs.)
 - **Clinical Research Coordinator training** (Approx. 252 min or 4.20 hrs.)
 - **Principal Investigator and Sub-Investigator training** (Approx. 56 min)

eReg Training (Advarra University Tips):

- **Complete
all required
Training Modules**

Advarra eReg 1100: Regulatory Manager Curriculum

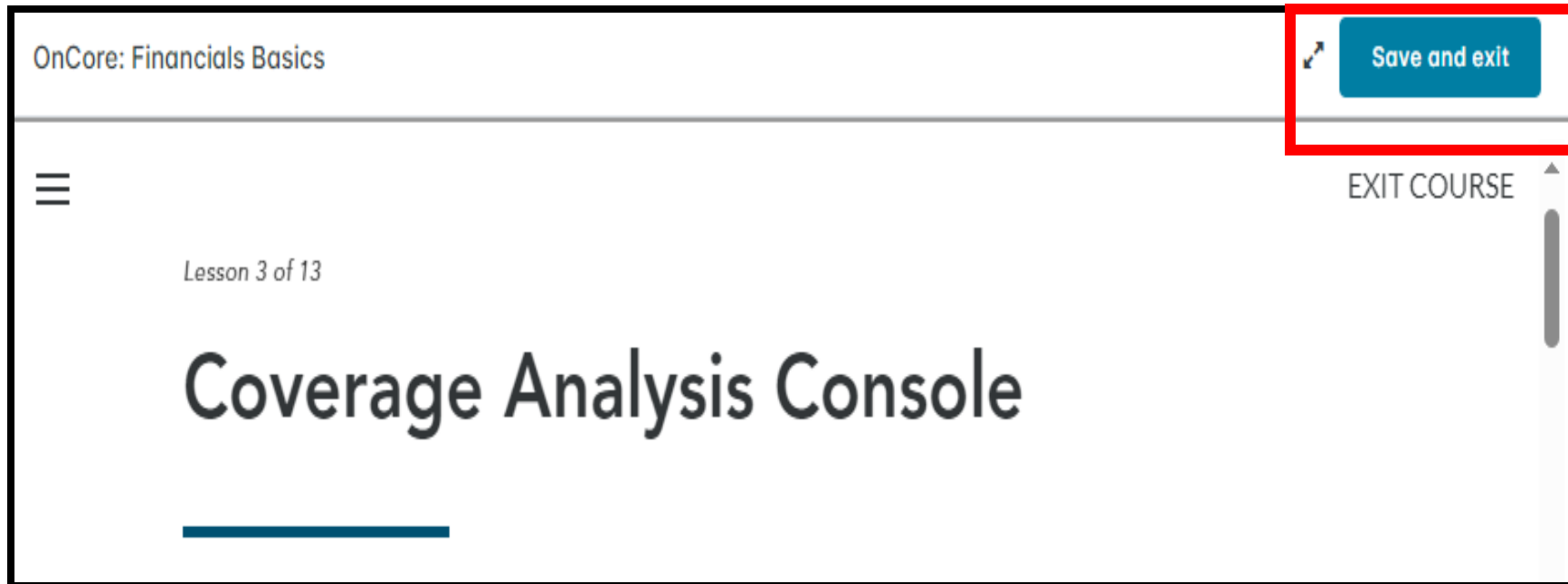
My Progress 28%

Course Description

- ✓ 1. Advarra eReg 100: Navigation
- ✓ 2. Advarra eReg 101: Setting and Resetting PIN
- ✓ 3. Advarra eReg 102: Reviewing and Signing Documents Electronically
- ✓ 4. Advarra eReg 103: Managing Contact Records
- ✓ 5. Advarra eReg 104: Maintaining Reference Lists
- 6. Advarra eReg 105: Managing Organization Records
- 7. Advarra eReg 106: Managing Regulatory Templates

eReg Training (Advarra University Tips) Cont'd:

➤ Save and Exit upon Module Completion



Required Course Enrollment/ Completion:

- Required Course Enrollment
- Role specific courses

The dashboard displays the following statistics:

- 16** Enrolled Courses
- 15** Completed Courses
- 1** Learning Paths

The course list includes:

- v. 6 Advarra eReg 1100: Regulatory Manager Curriculum**
In Progress · Last Entered 09 May 2022
- v. 3 OnCore 300: Basic Calendars**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 2 OnCore 320: Calendars Advanced**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 4 OnCore 400: Financials Basics**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 3 OnCore 410: Financials Advanced**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 1 OnCore 415: Overview of Financials Video**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 2 OnCore 450: Vendor Payables**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 1 OnCore 460: Coverage Analysis Console**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 1 OnCore 470: Budgeting Using the Financials Console**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date
- v. 1 OnCore 480: Post-Award Financials**
Not Started · Enrolled 14 Nov 2022 · Due date Set Date

Access for External Monitor:

- ❑ eReg monitor access form - ICTS website ([Access Survey](#)).
- ❑ Survey Submission as soon as your study is imported into eReg.
- ❑ Processing of External monitor account setup can take 1-2 weeks after the survey submission.
- ❑ Monitor access to eReg - 3 step process:
 - 1) Training - Advarra eReg 1300: Reviewer Curriculum
 - 2) Submission of external Healthcare ID request to identity management
 - 3) eReg account creation and review session

eReg Credentials :

- ❑ **Regulatory Manager role can manage credentials in eReg**

- ❑ **Required eReg credentials Include:**
 - **CV & Clinical License (PI & Sub-I only)**

 - **GCP (All roles)**

 - **Human Subject protection training (All roles)**

 - **Signature Sample(All roles)**

 - **IATA Certification (Data Mgr)**

How to access e-signed Documents in an eReg protocol

The screenshot displays a web interface for protocol management. On the left is a navigation sidebar with options like 'Document Inbox', 'Overview', 'Summary', 'Details', 'Staff', 'IRB Approvals and Correspondence', 'Delegation of Authority', 'Delegation of Authority Log', and 'Investigator's Brochure'. The main area is titled 'Protocol: SG100' and contains a 'Note to file' section. Below this is a table of document versions. A red box highlights the download icon in the 'Versions' column for the first document. A callout box points to the download icon with the text 'Unsigned Version of Document'. The table includes columns for 'Document Name', 'Versions', 'Effective Date', 'Valid Until', and 'Signature Status'. The first document is '20_ereg faqs, v4.0_2022.11.03 (5f043b20-1a96-4c6a-a259-31274199d615)_430079_284_47216_v4.pdf' with an effective date of 11 Jul 2024 and a signature status of 'Electronically Signed'. Action buttons for '+ New Document', '+ New Version', and 'Delete' are visible.

Document Name	Versions	Effective Date ↓	Valid Until ↓	Signature Status	
20_ereg faqs, v4.0_2022.11.03 (5f043b20-1a96-4c6a-a259-31274199d615)_430079_284_47216_v4.pdf	↓	11 Jul 2024	09 Oct 2024	Electronically Signed	+ New Version ✕ Delete

How to access e-signed Documents in an eReg protocol (cont'd)

Note to file for SG100

Versions

20_ereg faqs, v4.0_2022.11.03 (5f043b20-1a96-4c6a-a259-31274199d615)_430079_284_47216_v4.pdf

Details Edit

File	20_ereg faqs, v4.0_2022.11.03 (5f043b20-1a96-4c6a-a259-31274199d615)_430079_284_47216_v4.pdf
Effective Date	11 Jul 2024
Valid Until	09 Oct 2024
Comments	
Signature Requirement	Electronic Signature

Related Documents (0) > Add Related Document

Electronic Signature Routing

Electronic Signatures Needed

There are no electronic signatures still needed.

Electronically Signed 

Shehzad Gill (sgill1) Approved on 11 Jul 2024

Announcements/Reminders

Changes to ICTMS Intake Workflows form

Additional questions on include:

- Expedited calendar build options: **Yes/No**
 - **Yes** means we *may* start Calendar build before budget finalized and/or before IRB approval.
 - **No** means we will wait for IRB Approval and all Budget docs before starting build
- eReg: **Yes/No**
 - If Yes, additional information is gathered within form

Submit Workflows form as early as your Initial HawkIRB Submission

- Submit early if you want to use eReg and/or need expediated Calendar build
- Don't let lack of documentation stop you from submitting, we will route it for those later!

Business Operational Services

Are you requesting the calendar build team (BOS) to add the subject visit calendar to the I-CTMS (OnCore)?

The Subject Visit Calendar is the schedule of events setup in the I-CTMS matching the protocol documents. This is used to track all subject visits directly in the I-CTMS.

Yes

Are you requesting the BOS team to build the study budget into the I-CTMS (OnCore)?

The BOS (Business Operational Services) team is a third party including calendar and budget builder experts. Iowa research teams and the I-CTMS Admin Team works closely with the BOS team to complete each calendar and or budget build.

Yes

Would you like to expedite the Calendar build by starting it ASAP?

"Yes" indicates calendar build may begin before budget negotiation and contract completion. "No" indicates calendar build will wait until all budget and contract negotiations are finalized, with relevant documents attached in Workflow.

No

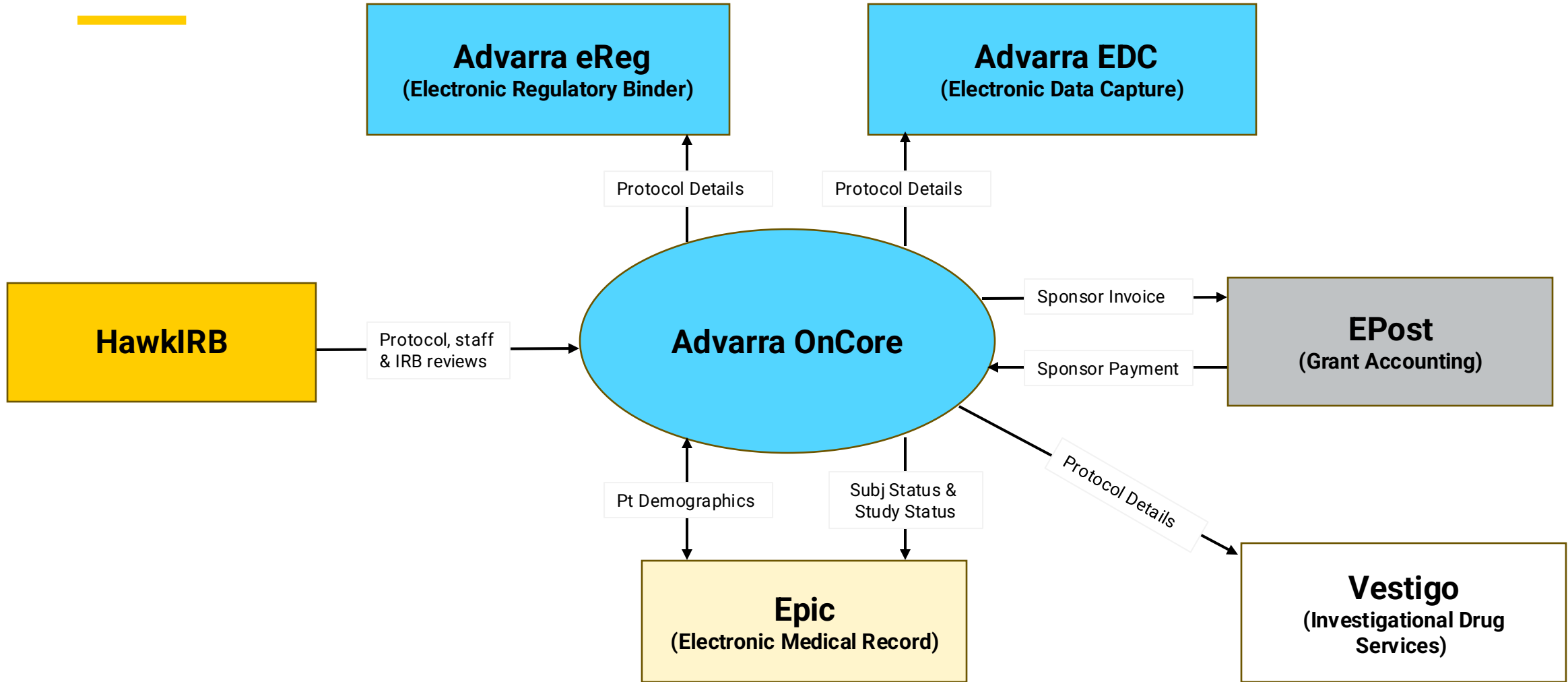
Electronic Regulatory Binder (eReg)

Is this study using eReg (Electronic Regulatory Binder)?

No

If you need to request access to ICTMS OnCore and/or eReg go to [I-CTMS \(OnCore\) Resources](#) | [Institute for Clinical and Translational Science \(uiowa.edu\)](#) to complete the access request form.

ICTMS & its integrations



Resources

Resources

More information about ICTMS

General Research [ICTMS Resources | Institute for Clinical and Translational Science](#)
HCCC [ICTMS 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](#)

IOWA

Thank you

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→ [Institute for Clinical and Translational Science \(uiowa.edu\)](https://www.uiowa.edu/ictms)