Institute for Clinical and Translational Science

ICTMS Community Informational Meeting

July 23, 2024

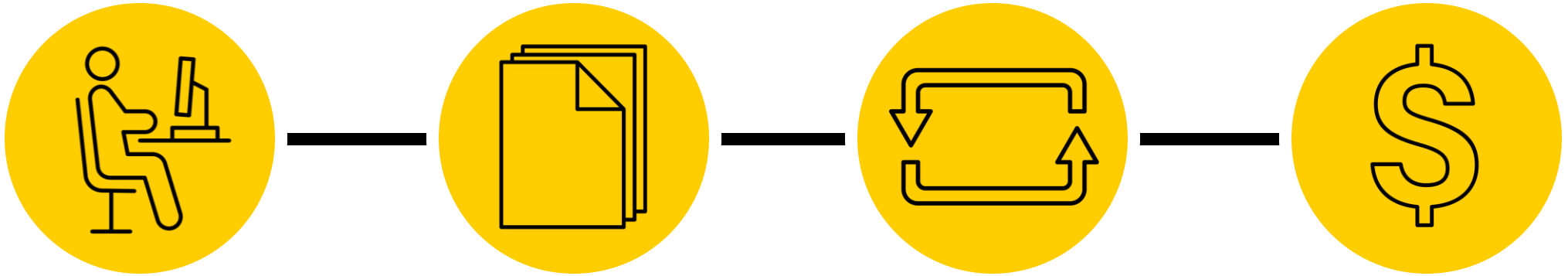
Type in the chat your favorite summertime dessert and/or barbeque dish?

Agenda

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

ICTMS Enterprise Expansion

Phase 1 Complete 2023 | Phase 2 Complete 2024 | Phase 3 Kick-off Sept 2024 | Phase 4 TBD



OnCore Expansion

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

eReg Expansion

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

EDC Expansion

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

Epic Research Billing & CRPC Grid

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

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

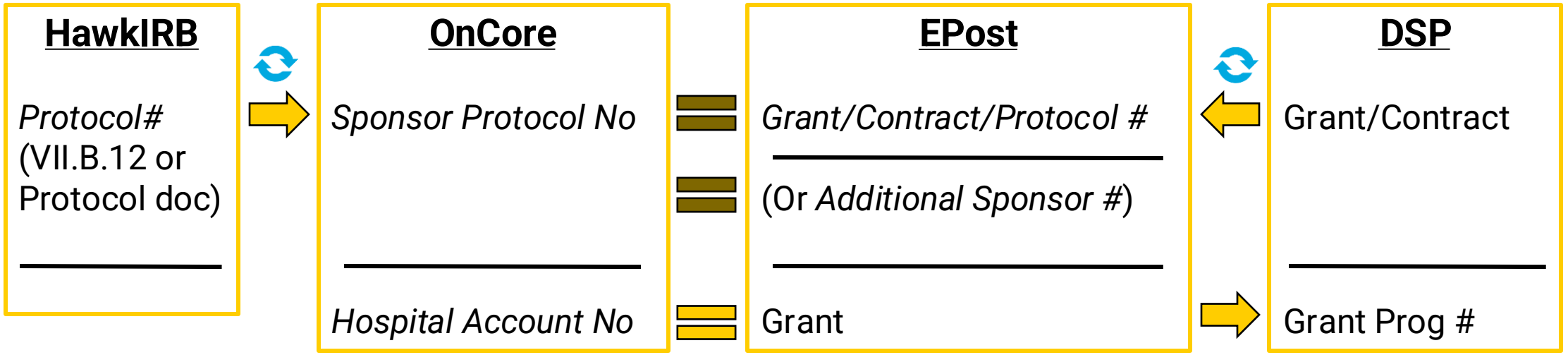
PC Console > Main

- *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!

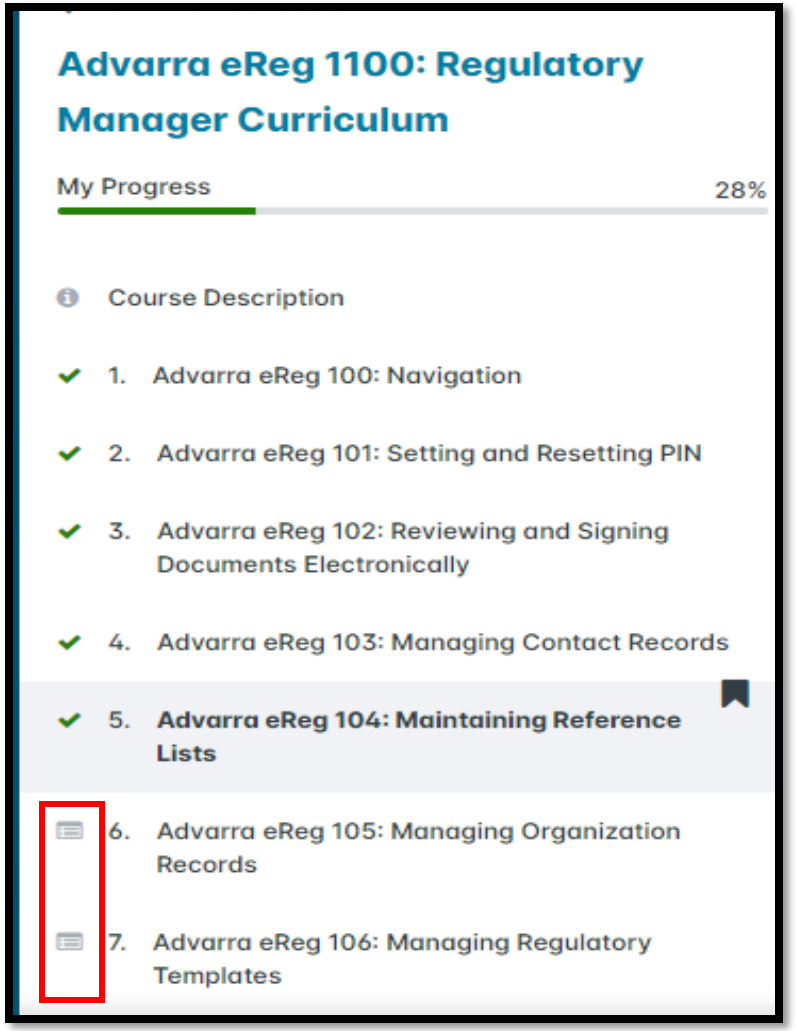
eReg

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)

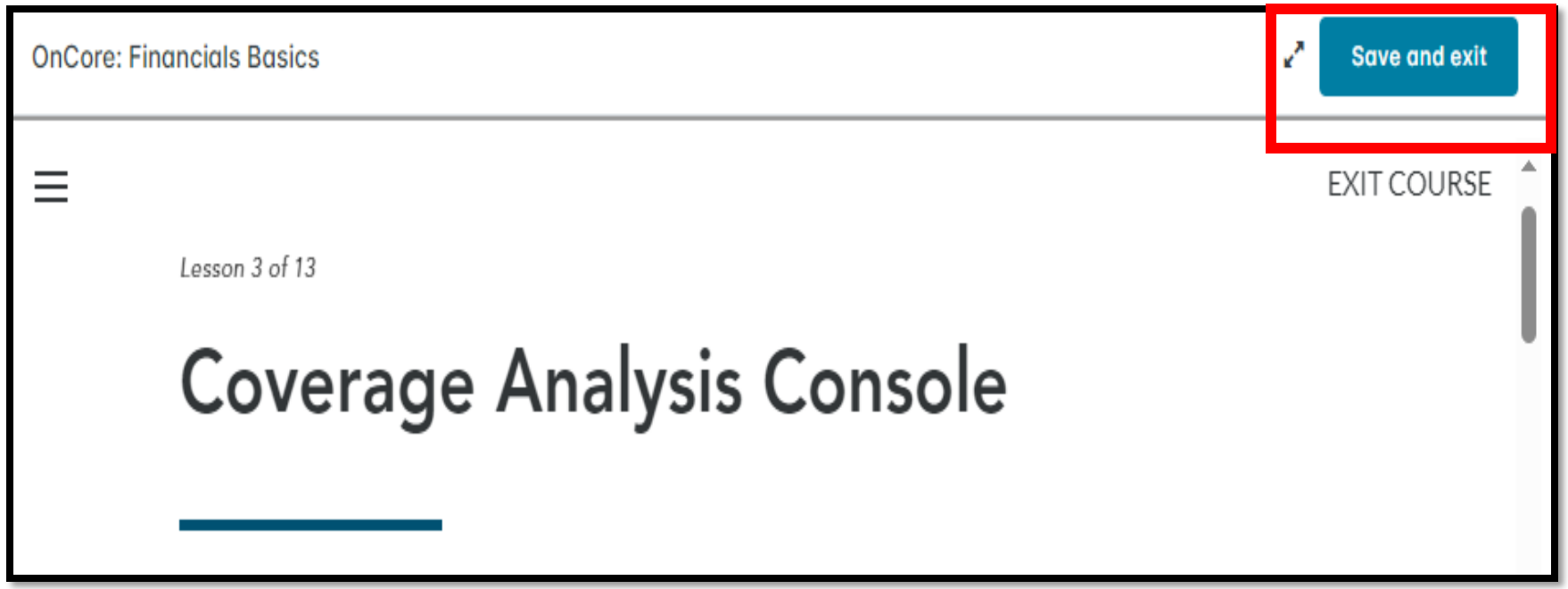
eReg Training (Advarra University Tips):

- **Complete all required Training Modules**



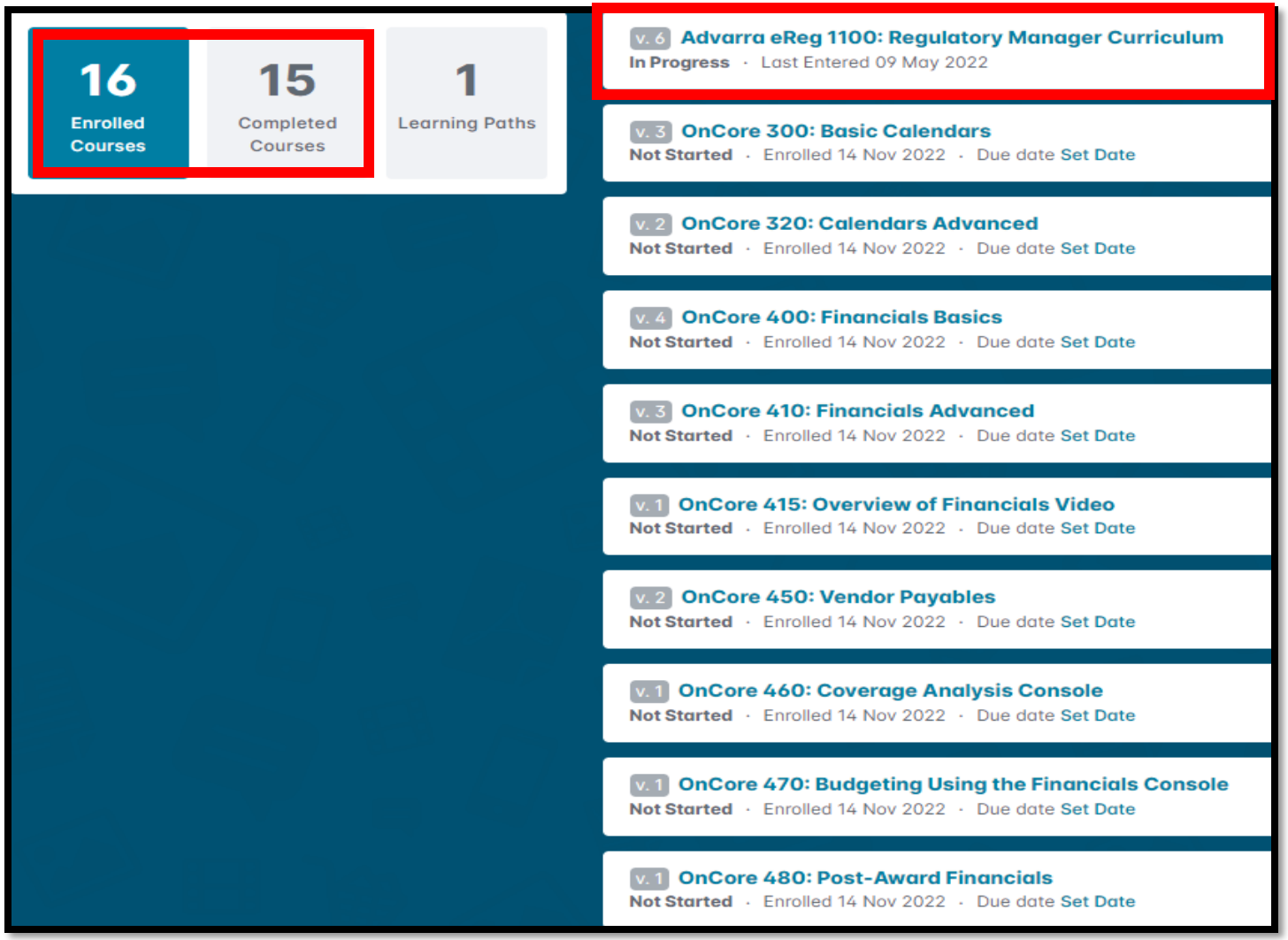
eReg Training (Advarra University Tips) Cont'd:

- **Save and Exit upon Module Completion**



Required Course Enrollment/ Completion:

- ❑ Required Course Enrollment
- ❑ Role specific courses



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

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

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

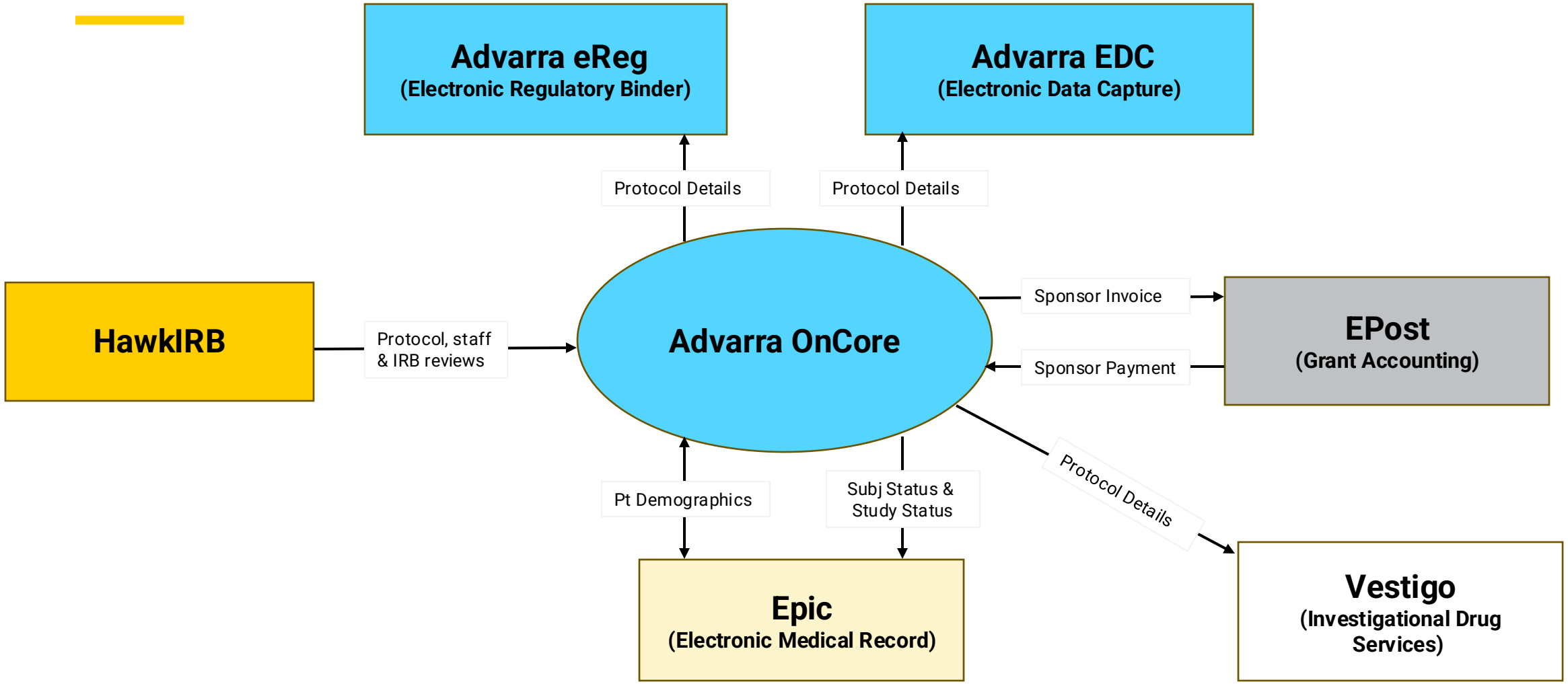
Are you requesting the calendar build team (BOS) to add the subject visit calendar to the I-CTMS (OnCore)?	The Subject Visit Calendar is the schedule of events setup in the I-CTMS matching the protocol documents. This is used to track all subject visits directly in the I-CTMS. Yes
Are you requesting 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



IOWA

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

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Josiah Argo
Shehzad Gill

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