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What is Advarra eSource + EDC?

SOM CTU CME Series - Clinical Research education series

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Accreditation

- The University of Virginia School of Medicine and School of Nursing awards **1.0 contact hour** for nurses who participate in this educational activity and complete the post activity evaluation.

- The University of Virginia School of Medicine and School of Nursing awards **1.0 hour of participation** (consistent with the designated number of *AMA PRA Category 1 Credit(s)™* or ANCC contact hours) to a participant who successfully completes this educational activity. The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

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Activity Code

- Activity Code: **24764**
- Instructions for claiming credits/contact hours can be found here.

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Who we are

Research and Clinical Trial Analytics

A multi-disciplinary team of specialists in human subject research data who support the School of Medicine's research community across the globe. Together we work to provide innovative solutions and find the best tools, systems and processes to reach your research goals.

We are a remote team that reports up through the University Health System Analytics and Reporting Team (ART) of the Quality and Performance Improvement (QPI) Department.

Director: Christine Kelly-Fisher

Manager: Deb Green

Advarra EDC Team

- Harrison Miller
- Misha Zemmel
- Rob Pates

Website: Research Clinical Trials Analytics – Advarra-EDC

Other applications and services on our team:

- **Advarra EDC Presentation today!**
- **MuSIC**
- **REDCap**
- **UVA Health Data (Data Requests, Cosmos, Epic Tools, EMERSE, OMOP, TriNetX)**
- **Caisis**
- **Cancer Research Data Mart (CRDM)**
- **CRConnect2/CRC2**

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1. What is Advarra EDC
2. How Advarra EDC streamlines studies
3. How to get started
    a. Access & Requirements per protocol
    b. Entering new subjects
    c. Overview of subject in study
4. How to submit a request for Full-Service & Cost

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1. What is Advarra EDC

What is Advarra eSource + EDC

- This is an Electric Data Capture (EDC) The application is an eSource option for Clinical Trials eliminating paper entry by providing real time remote data entry.
- This direct data capture system allows for quick data transfer into electronic health records avoiding with out the need for additional transcription
- The web based format allows for multiple digital devices to collect the information into the application
- Scales for increasingly complex studies that may include, more subjects than originally calculated, additional research institutions, and increase of study scope.

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Advarra EDC Features

- Is the electronic data capture system that was originally Oncore data capture
- It is a web based data collection application that works with investigator led studies
- Templated eCRF designer
- Allows for flexible data collection
- Quick standard reports
- Data is easy for researchers to access
- Decentralized studies allowing for better security

- Improved data integrity
- Auditing and Role-Based Access

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2. How Advarra eSource + EDC streamlines studies

Best use cases for Advarra EDC

- Primary use for investigator-initiated trials (IITs) for quick data submission replacing the need for paper entry
- Version based updates maintaining data integrity
- Quick fit-for-purpose replacement of EMR data collection reducing cost
- Advarra EDC is compliant with 21 CFR Part 11 for quick Audit turn around
- Clinical data is in one secure location that can be accessed easily by researchers
- Allows for real time access to data
- Working with external institutions has never been easier
- Seamless data collection with Biostats teams

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3. How to get started

How to request access

- Work with your study manager for requesting access to Advarra University for training
- Over 50 different types of classes to learn from
- Complete the assigned trainings
- Access will be provided to assigned study approved from manager once training is completed

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CRC View in Advarra EDC

Ongoing Forms

Name	Calendar Version	Form Status	Open Queries
Protocol Deviation V2	Version 1	In Progress	0
CTC AE CRF V6	Version 1	In Progress	0

Visits

+ Add Segment + Additional Visit

Visit Name	Visit Date	Planned Dates	Calendar Version	Visit Status
Primary				1 visit
Screening	01 Nov 2024	01 Nov 2024	Version 1	In Progress
On study ✖				1 visit
Visit 1	11 Nov 2024	09 Nov 2024 - 13 Nov 2024	Version 1	In Progress

Attachments

+ New Attachment

Description	Is Certified Copy?	Versions	Attachment	Version Date
No records found.				

Activate Windows
Go to Settings to activate Windows.

TEST FORMS – Not Real Data

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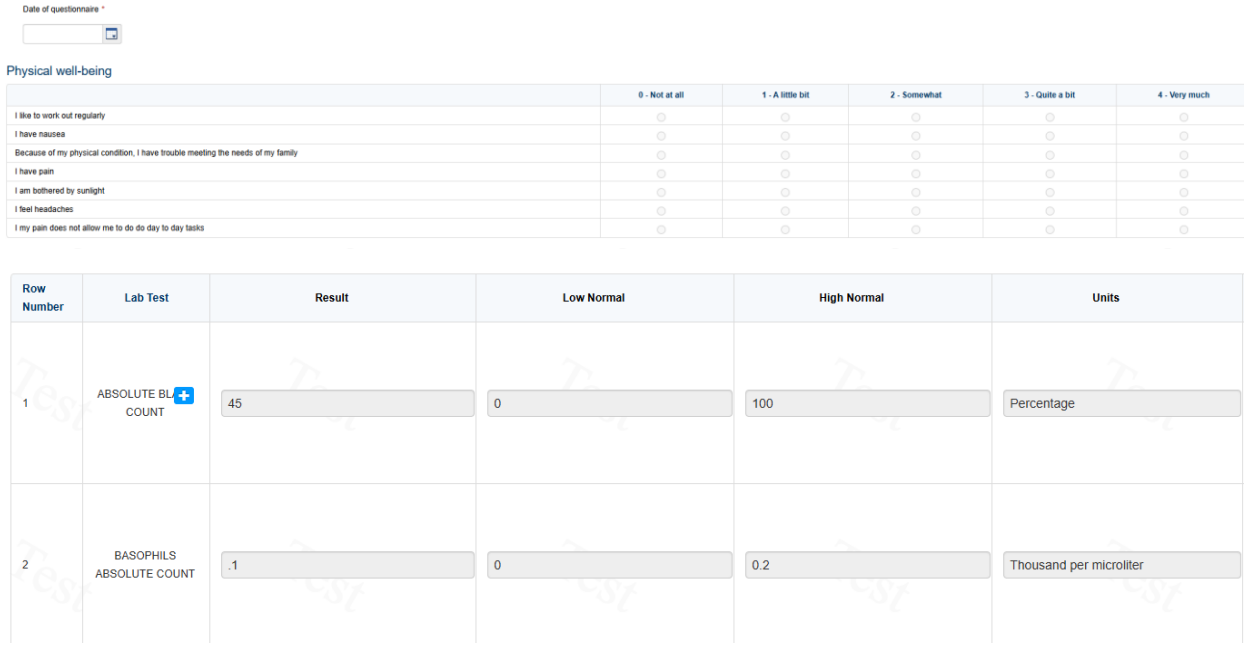
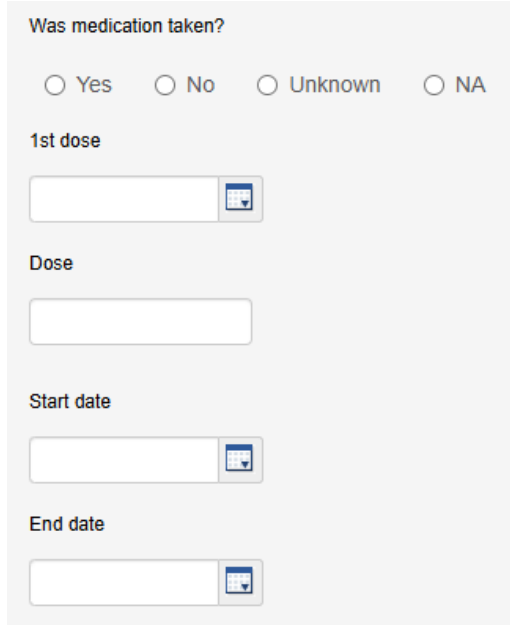
Types of forms Advarra EDC


Date of questionnaire *

Physical well-being

	0 - Not at all	1 - A little bit	2 - Somewhat	3 - Quite a bit	4 - Very much
I like to work out regularly					
I have nausea					
Because of my physical condition, I have trouble meeting the needs of my family					
I have pain					
I am bothered by sunlight					
I feel headaches					
I my pain does not allow me to do do day to day tasks					

Row Number	Lab Test	Result	Low Normal	High Normal	Units
1	ABSOLUTE BL COUNT	45	0	100	Percentage
2	BASOPHILS ABSOLUTE COUNT	.1	0	0.2	Thousand per microliter


Was medication taken?

Yes No Unknown NA

1st dose

Dose

Start date

End date

TEST FORMS – Not Real Data

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4. Submit a request for Full-Service

Requirements for Full-Service Advarra EDC

1.1. Email RCTA EDC Team to request Full-Service for a cost estimate: researchedc@uvahealth.org

2. Requirements:

- IRB approval/assurance document
- Meeting with the Study Investigator

3. The RCTA EDC Team will provide you a cost estimate for your work effort

- Cost is $100/hour

4. After the cost estimate is signed by your team, your work will be prioritized within current workload of assigned staff member

5. Full-Service means, our team will gather requirements from you, train researcher, and submit to you for review and validation.

6. Customer is Invoiced for services provided

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Questions?

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