OSIRES

ORD Strategic Initiative for Research & EHR Synergy

The New Electronic Health Record and What the Transition Means to the Research Office and the Non Profit Corporation

NAVREF/ACOS-R Meeting

Sept 20, 2023

Molly Klote, MD

Deputy CRADO-Enterprise Support

VA

U.S. Department of Veterans Affairs

Electronic Health Record Modernization

Roadmap

OSIRES
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- **Who is OSIRES?**
- Current state of EHR Modernization program
- Understanding EHR deployment related to research
- Understanding Sustainment

ORD Strategic Initiative for Research and EHR Synergy

OSIRES
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- OSIRES is comprised of **VHA ORD employees** committed to the understanding of the EHR as it relates to research
- They are **advocates** to make sure the system meets the needs of researchers, research offices, NPCs and sponsors
  - Where the system can't be changed they work to find ways to get to yes
- Coordinating with EHR Clinical Councils to leverage workflows
- Tirelessly working to **HELP YOU** get ready for transition
- They are **NOT ORACLE CERNER**
- Led by Maria Souden (also Director VIReC)

- Takeaway: **OSIRES = FRIEND Answer their questions!!!**

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Program Office Support

- ORD-funded since 2019
- >$10 million investment, currently 11 dedicated FTE

Leadership

- Molly Klote - ORD Deputy CRADO & OSIRES Executive Champion
- Maria Souden, OSIRES Director
- Hannah Gelman, Program Manager
- Ashley Morris, Research Deployment Manager

Field Implementation & Support

- Andrea Goubeaux
- Carolyn DePalma
- Sandra Pineros
- Kaitlin Leonard
- Natassia Boening
- Jeanette Spitz

Subject Matter Experts

- Isaac Purton, EHRM-IO Research Solution Expert
- Eileen Wilbur, research pharmacy, investigational meds
- Lindsey Jarrett, systems strategy (contractor)
- Jimmy Pontzer, CSP, informatics & pharmacy operations
- Jennifer Sporleder, CSP liaison

Research & EHRM Ecosystem

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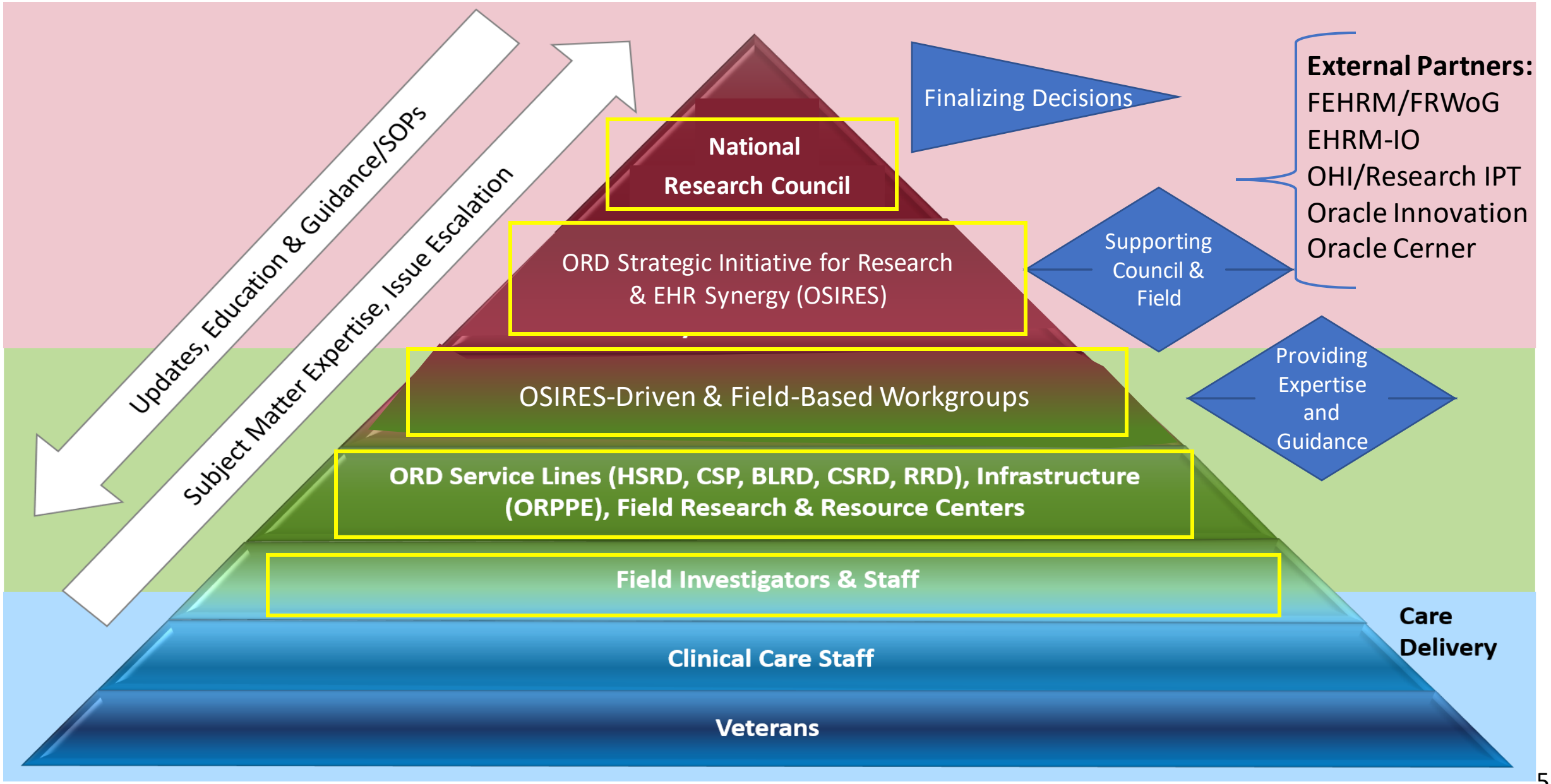

OSIRES EXPERIENCE

- VAMCs in **VISNs 10, 12, and 20** have previously begun research deployment preparation, but have been halted:
  - Ann Arbor, Battle Creek, Boise, Chillicothe, Cincinnati, Cleveland, Dayton, Detroit, Indianapolis, Milwaukee, Portland, Puget Sound

- Work with R&D and the field at these sites has helped OSIRES to **identify system gaps and supportive processes** for deployment

- OSIRES has learned what is needed to help a facility's research program/investigators be ready to go live

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CURENT STATE: RESET

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- **Mann-Grandstaff (Spokane, WA)** has been using VA's new Cerner-based EHR since October 24, 2020.
  - Mann-Grandstaff has the **only research study currently live** in the new EHR.
    - Just charting, not using ordering or PowerTrials
- **Four additional facilities** have been using the new EHR since 2022:
  - Columbus, OH; White City, OR; Roseburg, OR; Walla Walla, WA
- March 16, 2023 – 6 cases of catastrophic harm including 4 deaths reported to Congress in connection to the EHR transition
- **April 2023 – RESET announced**
  - No additional sites will go live until the current 5 sites can show significant safety and operational improvements

FHCC Lovell North Chicago

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- Level 1c* facility
- DOD-VA joint campus
- Scheduled to go-live on March 9th, 2024
  - DODs last deployment
  - 28 Research studies
    - 9 require Data Collection Worksheets (DCWs) in order to be in the EHR for research

* Facilities with medium-high volume, medium risk patients, some complex clinical programs and medium sized research and teaching programs

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What to Expect During Deployment

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- Oracle Cerner Current State Review (CSR) meeting kicks off process ~18 months before go-live
- Oracle Cerner-led Workshops start ~ 12 months before scheduled go-live
  - Be aware of non-research workshops
- OSIRES-led meetings around workshops include:
  - Survey to identify which studies go into the EHR
  - Support for study onboarding into the new system – completion of Data Collection Workbooks (DCWs)

Differences from VistA

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- Differences in the Oracle Cerner EHR will entail changes or new processes for:
  - Research billing
  - Research access and roles in EHR
  - EHR research ordering, documentation
  - EHR research enrollment, scheduling

Local R&D and NPC Responsibilities
Early in deployment

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- ❑ Oversee full completion of the VAIRRS Project Cover Sheet for all active studies
- ❑ When your site is contacted for an Oracle Cerner led Current State Review, ensure the following groups are represented and invited:
  - NPC Representative
  - Oncology Research Representative
  - Research Pharmacist
  - CSP Representative
  - AO/ACOS-R
  - Senior research coordinators who can speak about multi-site studies, Point of Care research, and various study protocols
  - Staff member familiar with research billing
- ❑ After the CSR, begin to formulate a group (CSI) who can assist with deployment activities.
- ❑ Attend meetings held by the ORD OSIRES team

Thinking about Your Current State Impact (CSI) team

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Your CSI Team should consist of:

- ✓The CSI team will be the individual(s) attending meetings and completing day to day deployment activities.
- ✓One POC 50% time for 18 months (not the ACOS-R or AO)
  - ✓ A staff member with local authority and credibility, who gets responses when they send an email, is strongly recommended.
- ✓Coordinator-type team members with excellent organizational and tracking skills and time/FTE will attend meetings and complete needed tasks.
- ✓Project manager-type team members will track and manage the higher-level activities and overall status of the transition.

What Can R&D and NPCs do to Prepare Research Studies for Deployment of the New EHR?

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- ❑ Make sure all your studies have completed a cover sheet in VAIRRS.
  - The Project Cover Sheet in VAIRRS identifies studies which may need PowerTrials and includes information for Oracle Cerner EHR role assignment.
- ❑ Begin considering who may make up your site's CSI team and who can serve as the single POC
- ❑ Be prepared to receive and respond to a lot of communication.
  - Responses to emails from OSIRES Research Application Analysts are *critical.*
  - Note that not all Oracle Cerner communication will be research-specific.
- ❑ Be prepared to offer protected time to your research team to complete tasks needed for study onboarding
  - Consider additional clinical/administrative support

Data Collection Worksheets (DCWs)

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- Excel worksheets collecting study information for PowerTrials build

Function needed	PowerTrials DCWs Required		
	Protocol	Pre-screening	PowerPlan
Track protocol	x		
Screen for eligibility	x	x	
Place research orders	x		x

- Study team is walked through build to verify accuracy
- Up through Go-Live: done by Cerner
  - After Go-Live: done by VA staff through Research Application Analysts (new positions)
- OSIRES research pharmacist will provide some information for investigational medications to create the drug file in the system

The "POWERS"

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PowerChart

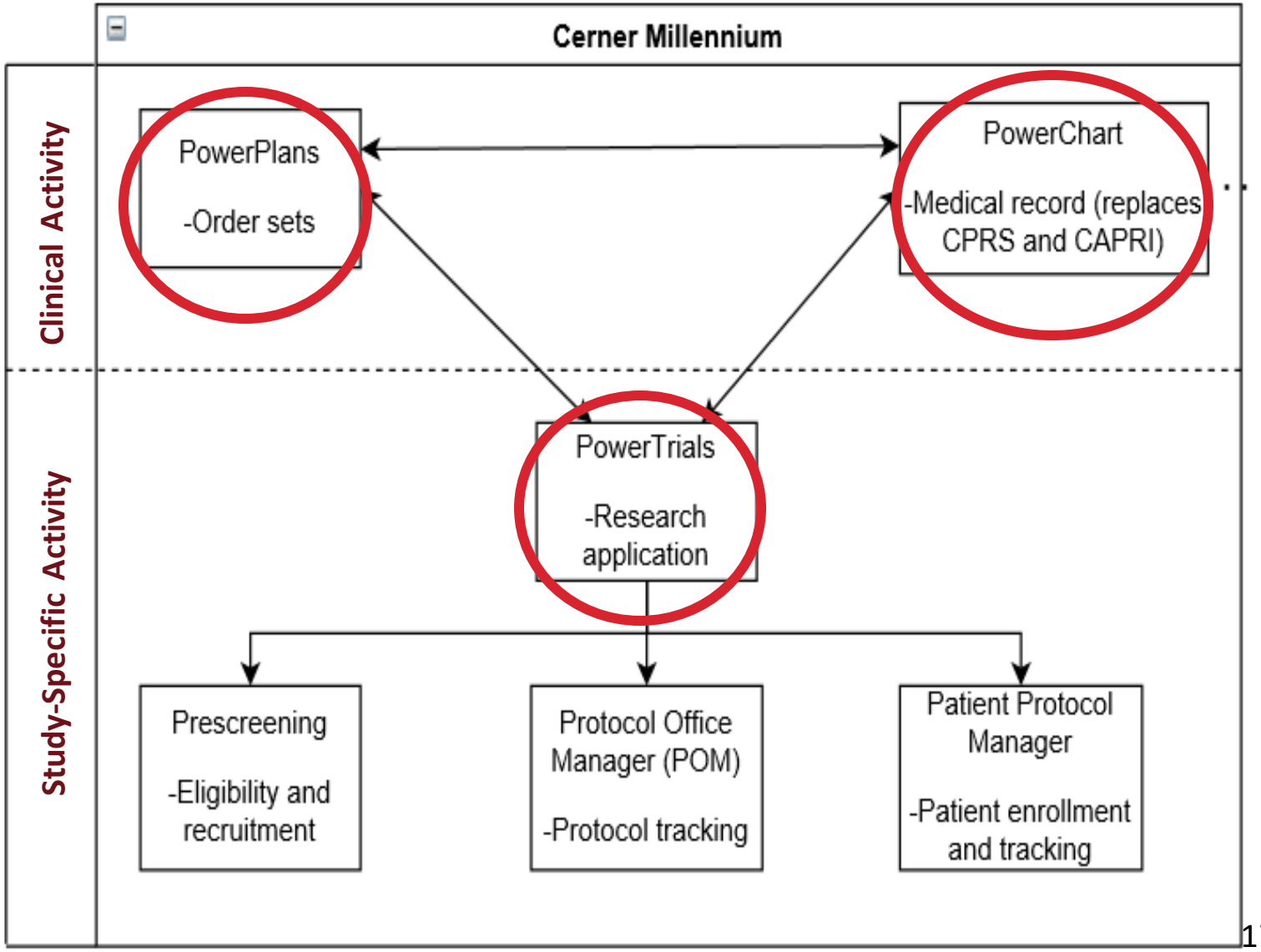
- Main EHR application for clinical interactions such as viewing, documenting, scheduling, and ordering in the chart.

PowerPlans

- EHR application for order sets.
- Required especially for investigational drugs and oncology treatment.
- Designates research orders for which patient should not be billed

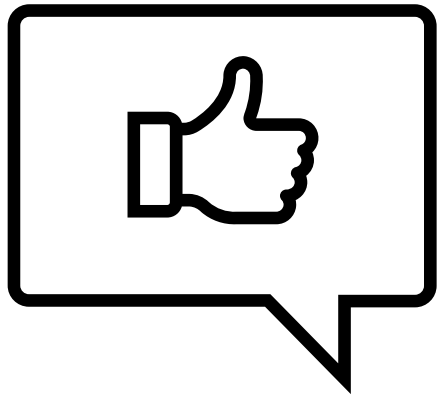
PowerTrials

- Research-specific EHR application that builds a study record in the EHR to connect clinical activity to a study and a patient.



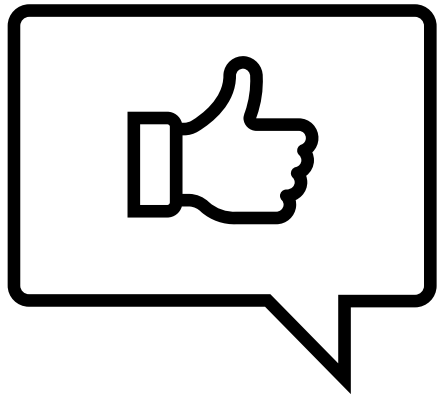
Does a Protocol Need to Be Entered into PowerTrials?

- Yes, if study needs any of the following:
  - A PowerPlan
  - Pre-screening
  - Research Flag/SmartZone alert for research study enrollment
  - To enroll patients within PowerTrials for the purposes of:
    - Research Flag/SmartZone flag visibility
    - (possible) Supporting alert suppression



Does a Study Need a PowerPlan?

- Will this project need to enter orders? This may include labs, diagnostics, investigational drugs, scans, pregnancy tests, imaging, etc.
- What type of orders will your project need? (Usual Care only, Clinical Trial orders only, Both)
    - If orders are placed, how are they billed?
- Will your project prescribe investigational drugs? (Yes/No)



Supporting research needs throughout the local deployment process

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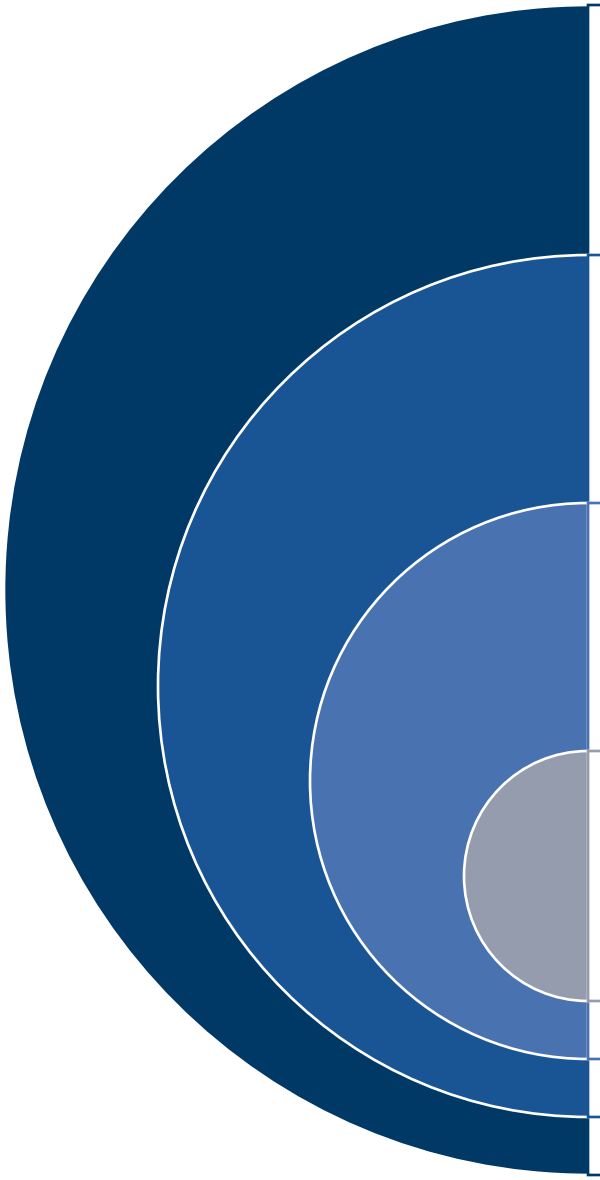

OSIRES Deployment and RAA Teams	• Assist local R&D and study teams with deployment preparation • Act as a bridge for questions, concerns, and issue escalation
R&D Administration + NPCs	• Serve as points of contact regarding site needs, issues, and risks during deployment • Develop teams and processes to support implementation at the local site
Study Researchers	• Respond to requests for information about study protocols and needs • Complete study-specific forms (e.g., DCWs) if needed
Oracle Cerner Consulting Team	• Build and validate PowerPlans and Prescreening rules as required for individual studies • Support discovery and development for local site processes and needs (e.g., orders)

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Local Sustainment

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- Post Go-Live there will be a need for:
  - Amendments to ongoing studies
    - Amending DCWs and PowerPlans (OSIRES RAAs)
      - Track any changes and communicate needs
      - Time to do this work
      - Support to do this work
  - New studies/New Investigators
    - Training
    - Creating DCWs
      - Time to do this work
      - Support to do this work

Additional Research EHRM Information

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ORDResearchApplicationAnalyst@va.gov

- For questions, concerns, and assistance with transition activity
- Include this distribution group on any correspondence, implementation managers, or Oracle/Cerner regarding research transition activities

R&D and NPC Manual for the EHR Transition (CSI Team)

- Provides operations guidance for R&D and NPC Leadership to assist transition efforts
- Questions about the Manual can be directed to ORDResearchApplicationAnalyst@va.gov
- R&D Manual for the EHR Transition - Home (sharepoint.com)

Researcher Resource Guide

- For all researchers to keep up to date on important information about transition
- https://dvagov.sharepoint.com/sites/VHAPugResearch/RRG/SitePages/EHRM-and-research.aspx

QUESTIONS??

For more information:

ResearchEHRMHelp@va.gov