Using Technology and Outreach to Fuel Diversity in VA Research

Maria Souden, MSI, PhD David Thompson, DBA Kousick Biswas, PhD

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- Overview of EHR Transition for Research
  Maria Souden, MSI, PhD
- ORD Research Volunteer Program
  David Thompson, DBA
- Clinical Trials Management Solution
  Kousick Biswas, PhD

The EHR Transition for Research: Status of Deployment and Anticipated Impacts

Maria Souden, PhD

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- HSRD VA Information Resource Center Director (VIReC)

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Where are we in the rollout?
Recently adjusted VA EHR Deployment Schedule*

OSIRES ORD Strategic Initiative for Research & EHR Synergy

- Mann-Grandstaff (Spokane) has been using VA's new electronic health record (EHR) since October 24, 2020. Since then, four additional Medical Centers have deployed (see table below).
- To meet site and system readiness needs, EHRM recently announced a revised deployment schedule.

VISN	Facility	FY 2022
20	**Walla Walla, WA**	**Deployed 3/26/22**
10	**Columbus, OH**	**Deployed 4/30/22**
20	**White City, OR**	**Deployed 6/11/22**
20	**Roseburg, OR**	**Deployed 6/11/22**
20	Boise, ID	~~July 23, 2022~~ POSTPONED

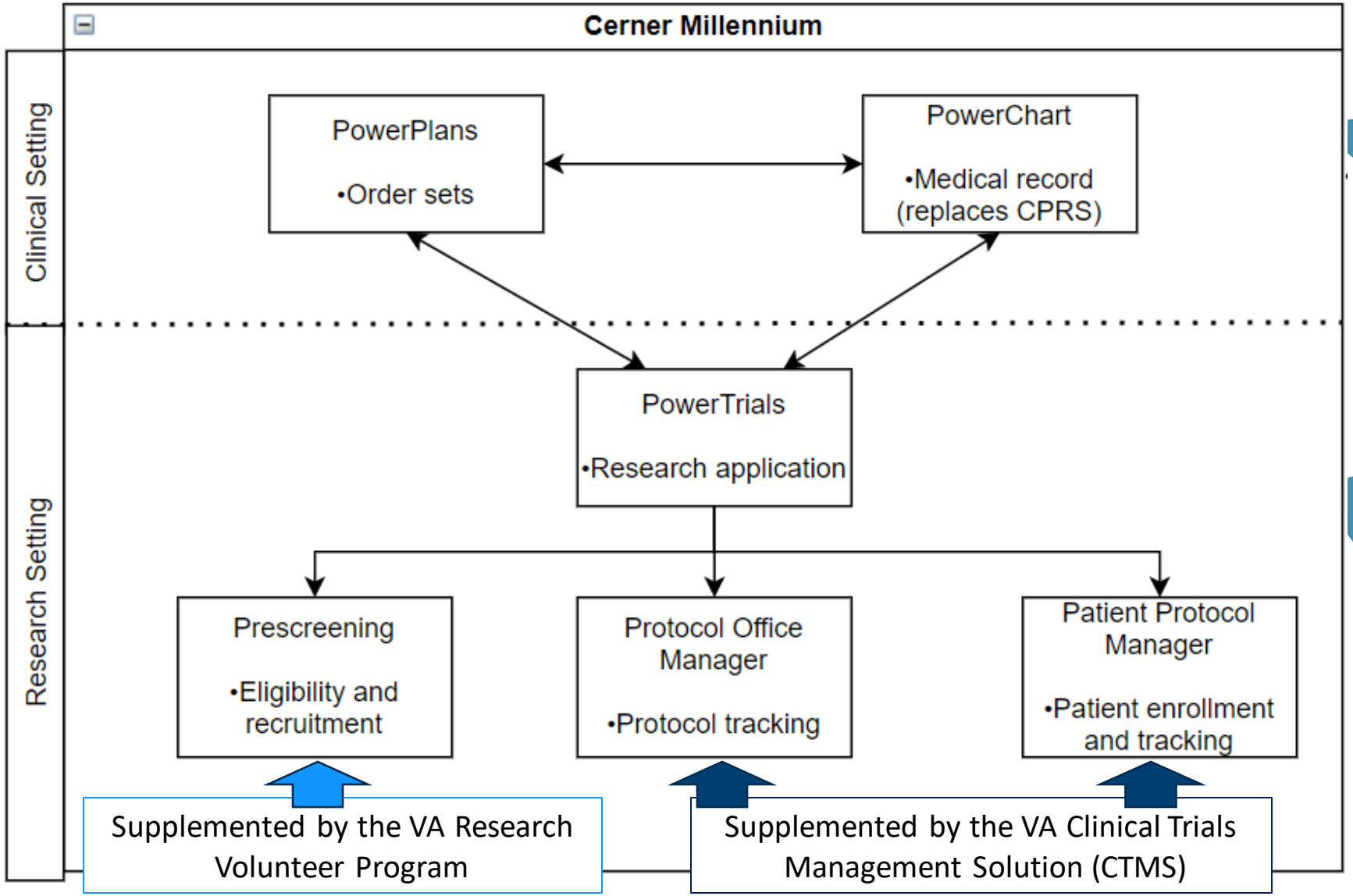
VISN	Facility	FY 2023**
10	Ann Arbor, MI (with Battle Creek, Lutz, and Saginaw)	January 28, 2023
20	Puget Sound, WA (incl. Seattle and American Lake)	March 4, 2023
10	Cincinnati/Dayton/Ft Thomas	March 25, 2023
20	Portland, OR (with Vancouver, WA)	April 22, 2023

Green = large research presence
Yellow = smaller research

****Additional research sites planned for second half of FY23: Detroit, Milwaukee, Madison, Cleveland, Indianapolis, Hines, Jesse Brown**

All dates are provisional, contingent on site and system readiness, and contract status.

How is research conducted within the new Oracle/Cerner EHR?



PowerChart & PowerPlans
Clinical applications used by research to place orders and add notes

PowerTrials
Research-specific component of the O/C platform that incorporates clinical research processes and information into the EHR

When does a study use PowerTrials?

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- Required when:
  - Placing orders (PowerPlans)
  - Using PowerTrials pre-screening
- Benefits:
  - Tracking features
    - Protocol Office Manager (POM) for tracking protocol
    - Patient Protocol Manager (PPM) for tracking enrollment
  - Integration of research into EHR/clinical care

See EHRM and research RRG page for more information and resources

How can PowerTrials *potentially* support research?

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1. Prescreening: Identify, screen, and support recruitment of patients that meet eligibility criteria
2. Facilitating communication between clinical care and research:
   - Clinicians can see details about patient participation in clinical research
   - Study teams can get notifications about clinical events
3. Tracking – studies can create reports including number of prescreened patients, enrolled patients, patients in each study stage, etc.
4. Separating charges for research-related tests and procedures from clinical care
5. Improved billing
   - Study team can set up uniform charging to research accounts per protocol and/or sponsor.
   - Works with PowerPlans so study teams can attach research orders to a research charge

What issues is ORD currently working with Cerner and EHRM-IO to ensure the new EHR is ready for research?

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- PowerPlan creation
  - Inadequate scope of Cerner contract
    - Need to build in-house to ensure proper sustainment (new studies and changes)
  - Populating for optimal ordering and billing
- Building investigational medications in the National Drug File
  - More complex process in this system
  - Increasing capacity to build and sustain research medications
- Billing and charge delineation
  - Differentiating research orders from Standard of Care
  - Accurate accounting of study participants and procedures for sponsor billing
- Improving implementation of complex PowerPlans
  - Particularly oncology trials involving regimens and/or time offsets

How is research done with data generated from the new Oracle/Cerner EHR?

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- Data populated into new EHR at five live sites are being syndicated back to the Corporate Data Warehouse (CDW)
- Available in the Millennium-native format in CDW Work2
  - Dramatically different from current CDW model
- CDW Work2 data are integrated with current VistA CDW into CDW Work3
  - Familiar model - useful for understanding translation between the two, but incomplete due to differences
- Future data model will be more Millennium-centric
- Data quality and data knowledge are evolving and changing; patience and flexibility will be required

How will researchers obtain data generated from the new Oracle/Cerner EHR?

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- Right now, data generated by the new EHR at the existing five sites are available for use by approved projects
- Data are requested and provisioned through current processes (DART)
- VINCI's Data Services Team will assist projects in identifying the best data to meet study needs
- Studies in process can email VINCI@va.gov and ask for a data needs assessment
- Other questions about Research and EHRM data ResearchEHRMHelp@va.gov

How will study activities be affected by the new EHR?

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ORD Strategic Initiative for Research & EHR Synergy

Study Need	EHR Utilization		
	Interact with PowerChart	Interact with PowerTrials*	Use syndicated data from the new EHR
Screen patients for eligibility	Optional	Optional	Optional
Enter notes into the patient chart	Required	Optional	
Create encounters or appointments	Required	Optional	
Place orders for tests, medications, procedures	Required	Required	
Retrospective or observational data study	Optional	Optional	Required
Use custom data collection templates/alerts	Implementation/capabilities unknown		
Modify clinical reminders and alerts	Implementation/capabilities unknown		

What can R&D and field do to prepare? (1. research using EHR)

OSIRES ORD Strategic Initiative for Research & EHR Synergy

*** Affected: Sites within a year of deployment, multi-site studies using the EHR for the conduct of research***

- Ensure studies are up-to-date in VAIRRS and have accurately completed a project cover sheet and where appropriate the IRB information sheet.
- Study activities/administration may be affected by the deployment in ways that may be unexpected **(e.g., ordering, documentation, recruitment)**. Studies with complex EHR interaction should reach out to ResearchEHRMHelp@va.gov.
- Studies **with certain EHR needs (e.g., ordering, billing)** may need to use PowerTrials. The OSIRES deployment support team will work with studies to prepare for this well in advance of go-live.
- **Stay aware of and respond to outreach from OSIRES and the Research Sub-Council** to connect with study staff – this is how study needs will be identified and supported.

* Investigators *conducting multisite studies at upcoming deployment sites* may also want to be in touch with local site staff to be updated on deployment activities and anticipate their impact.

What can R&D and field do to prepare? (2. Research using EHR data)

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Affected: all VISNs, all sites using national data

All studies using national data will be increasingly affected as go-lives continue/accelerate.

- Research and analytic staff can engage in a range of activities:


Microsoft
verPoint Presentat

- Become familiar with **Data Education and Knowledge Resources** being created across VA (see Resource Summary presentation – linked left)


Adobe Acrobat
Document

- **Request Millennium data** for appropriate studies to prepare for using the new data (see VINCI Provisioning document – linked left)
- **Identify an experienced VA data** programmer/analyst to train as an EHRM data "expert-in-residence," participating in organizational data learning and assessment activities (ResearchEHRMHelp@va.gov)

ORD Research Volunteer Program
David Thompson, DBA

- What is the Research Volunteer Program
- Creating the Research Volunteer Registry
- Access and Use of the Registry

What is the Research Volunteer Program?

VA-wide, centrally managed, program to link research volunteers to VHA research resources and research opportunities.

Why are we starting this Research Volunteer Program?

VA research is done to improve Veteran healthcare and well-being that relies on Veterans taking part. The program will put Veterans in touch with VHA research that matters to them.

What is the goal of the program?

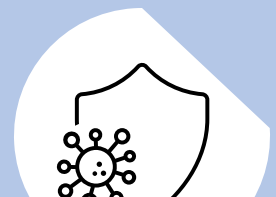
Creating and sustaining a modernized connection between VHA Research and Research Volunteers

Research Volunteers: VHA Combatting COVID-19

How the VHA and Veteran Volunteers helped combat COVID-19.

57,000
Volunteers

20
VA Study Sites



1 in 10
Real Impact

VHA Research Volunteer Program/Volunteer Registry

Volunteer Experience

User Friendly, Veteran-focused.

Increased Access to Trials

Veterans access research important to them across VHA.

Optimize Valuable Data

VA data works to improve Veteran care.

Diversity, Equity, and Inclusion

Improve accessibility of research to all Veterans.

Veteran Research Community

Improve information sharing and research visibility

Study Completion and Results

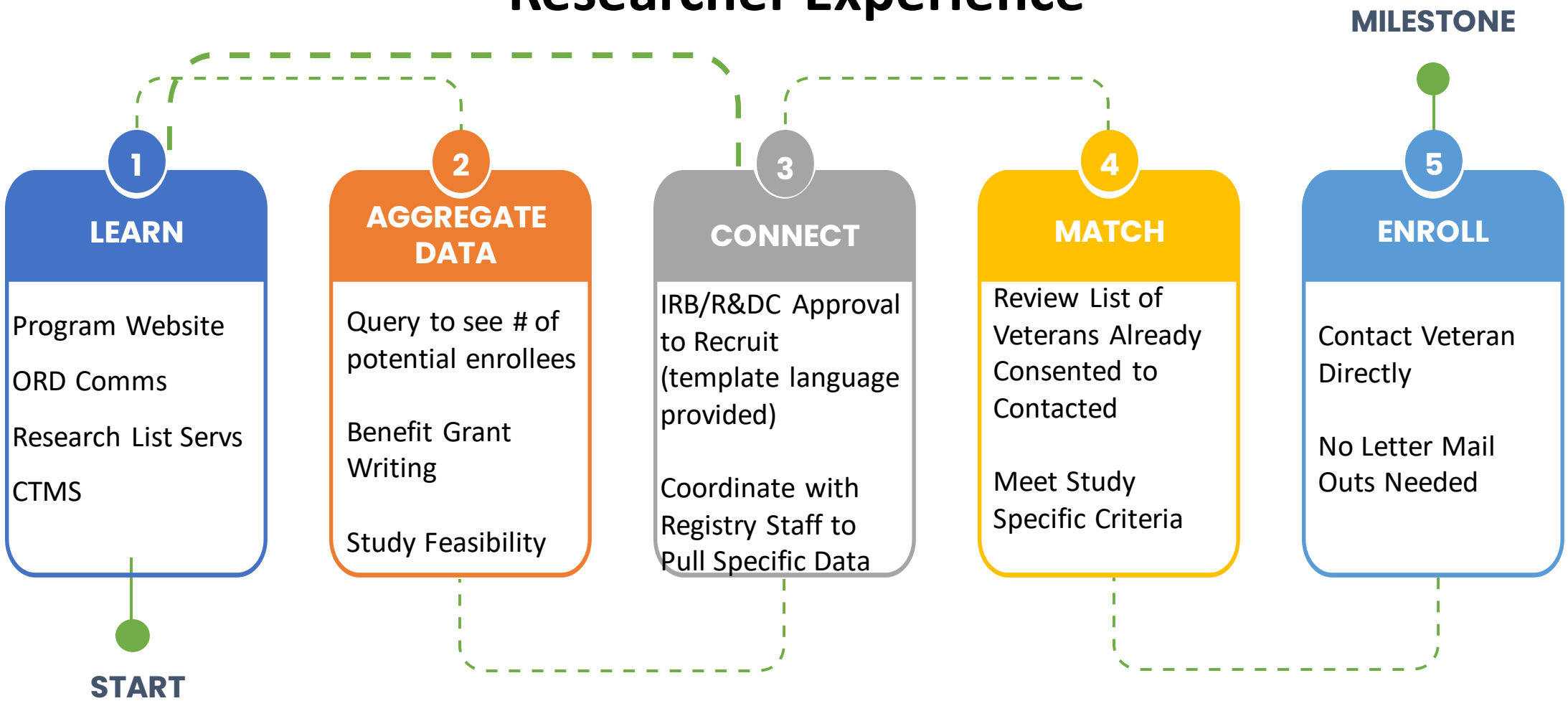
Reduce study delays and cancellations so research results benefit Veterans.

Research Volunteer Registry

Veteran's Enrollment to Participation

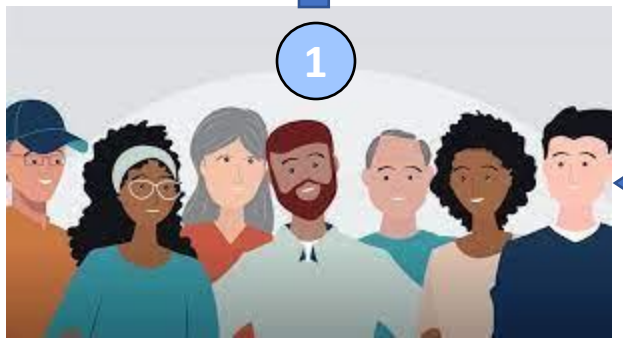
Research Volunteer Registry

Researcher Experience



From Research to Health Care

VA Research Volunteer Program



Veterans, families and friends

VA Researchers

Clinical Trials Management Solution Kousick Biswas, PhD

- Conducting/Managing Clinical Trials
- Interfacing with VA Registry
- Interfacing with VA's New EHR

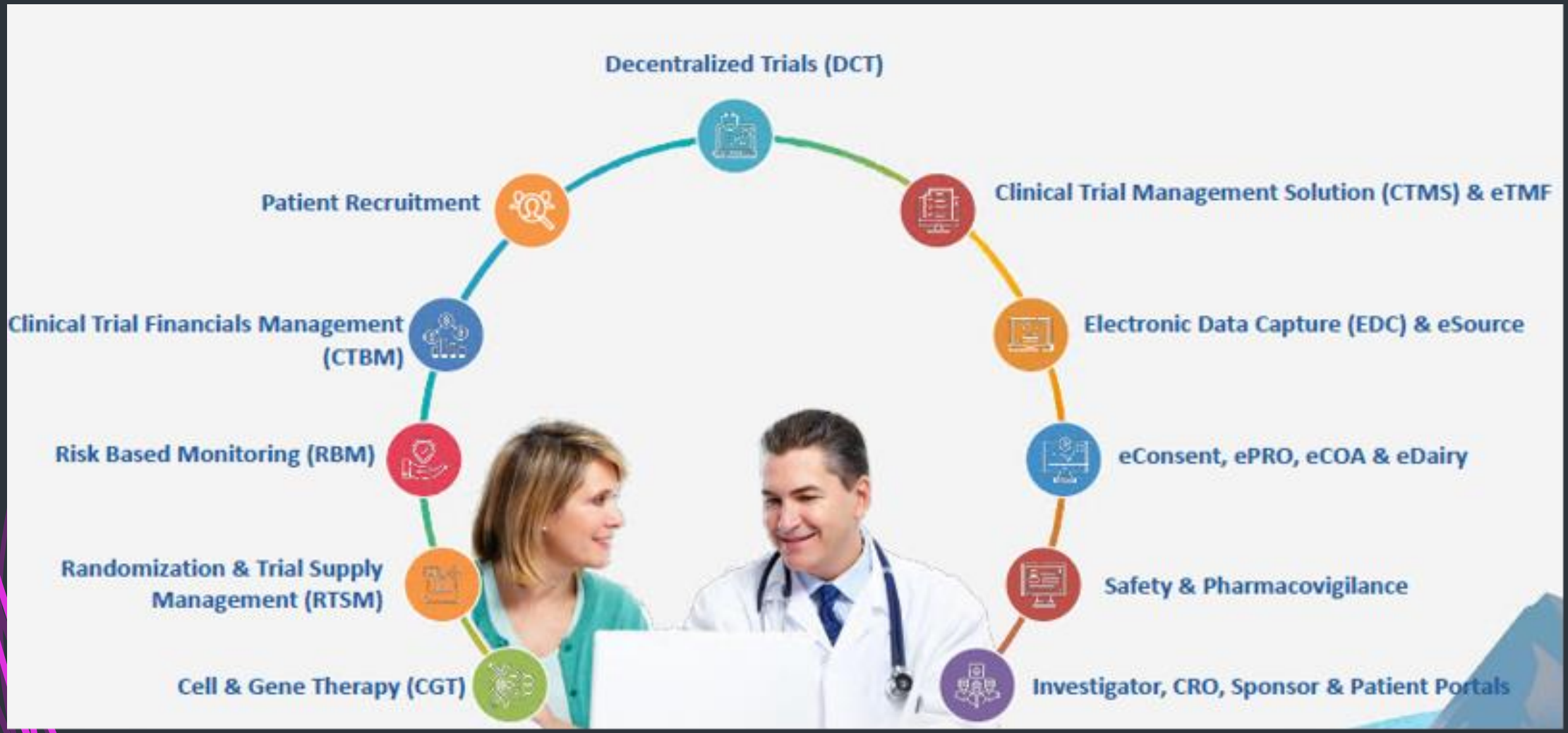
Clinical Trial Management Solution (CTMS)

- Vendor: Cloudbyz
- Platform: Salesforce Community
- ATO: FISMA High
- Solution: Enterprise – for ORD funded clinical trials
  - Exception – Can be used for trials funded by other sponsors, only if, approved by the sponsor
- POC @ ORD:
  - Mary (Molly) Klote, MD, Dep CRADO - ES
  - Kousick Biswas, Ph.D., Director, CSP Coordinating Center, Perry Point, MD
  - Angela Foster, ORPPE
- Estimated "GO LIVE" date: Spring/Summer 2023

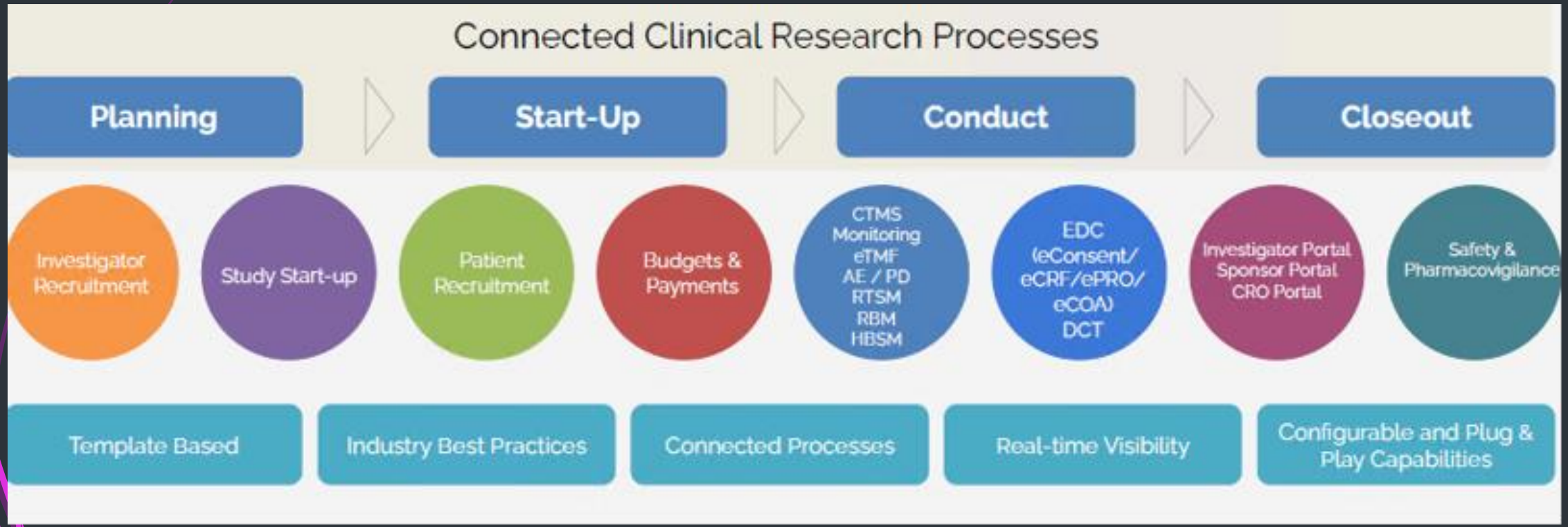
Clinical Trial Management Solution (CTMS)

- Portals:
  - Investigator Portal
  - Sponsor Portal
  - CRO Portal
  - Patient Portal
- Modules:
  - eConsent, Trial Administration, Patient Recruitment, eTMF (electronic Trial Management Files), RTSM (Randomization and Trial Supply Management), EDC (Electronic Data Capture), ePRO (electronic Patient Reported Outcomes), Reporting

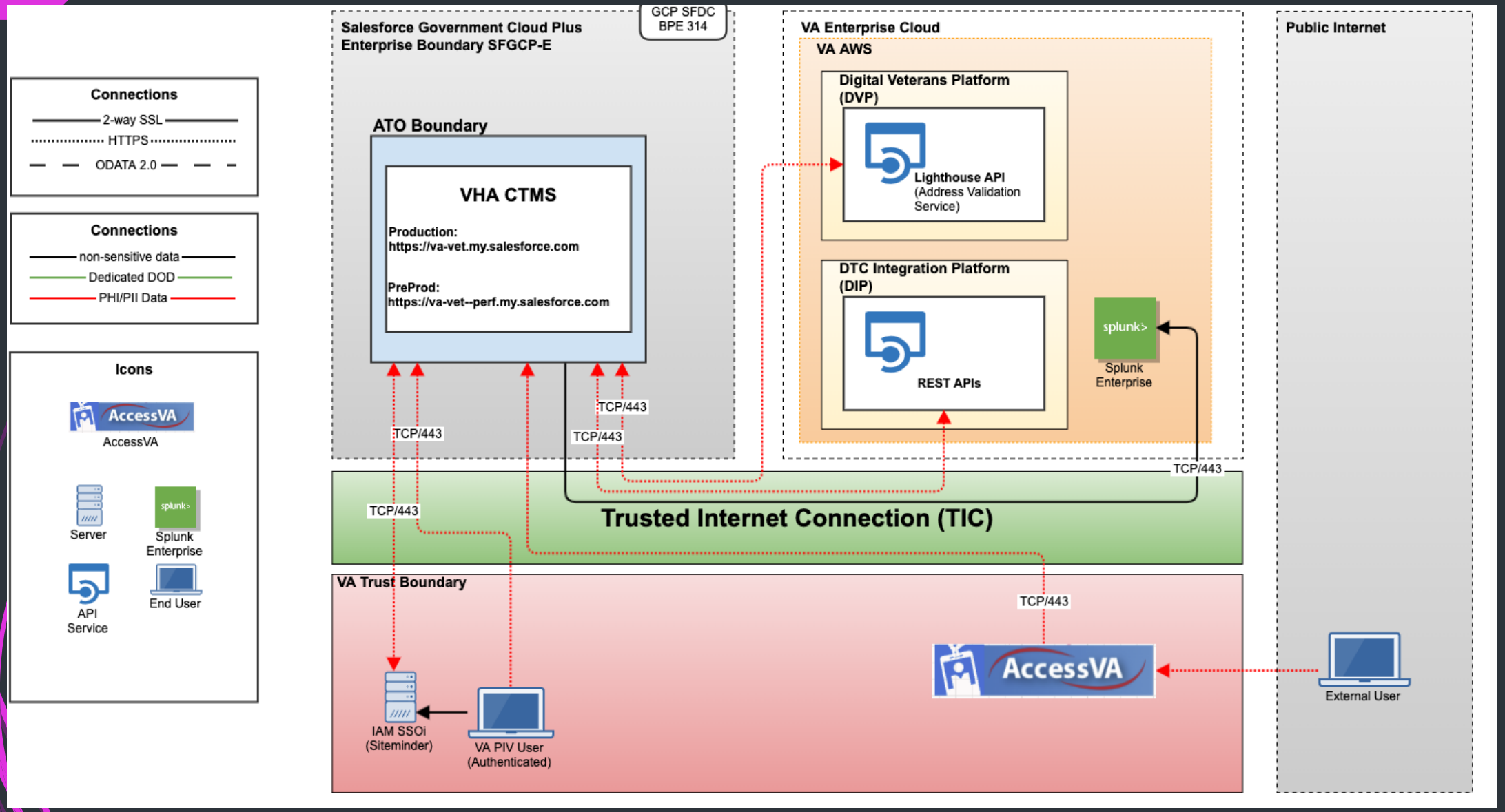
Clinical Trial Management Solution



Connected Clinical Research Processes

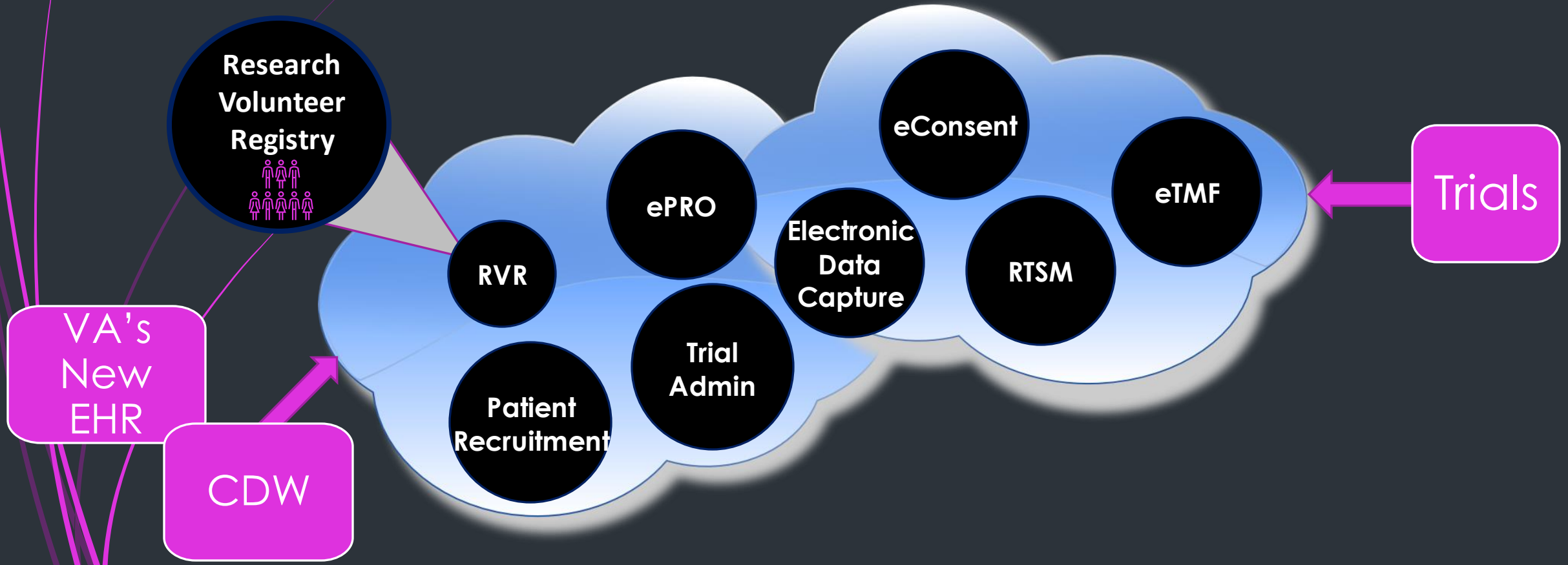


CTMS Architectural Diagram



Clinical Trial Management Solution (CTMS)

Integrations



Thank you

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CTMS - Kousick.Biswas@va.gov; Angela.Foster@va.gov

Research Volunteer Program - ResearchVolunteer@va.gov

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