The Department of Veterans Affairs
Point of Care Clinical Trial and Precision Oncology Programs:

Using Electronic Medical Record Systems and Health System Data in Support of Clinical Trials and Learning Healthcare System Activities

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The VA Cooperative Studies Program

VISN 1 Clincial Trail Network

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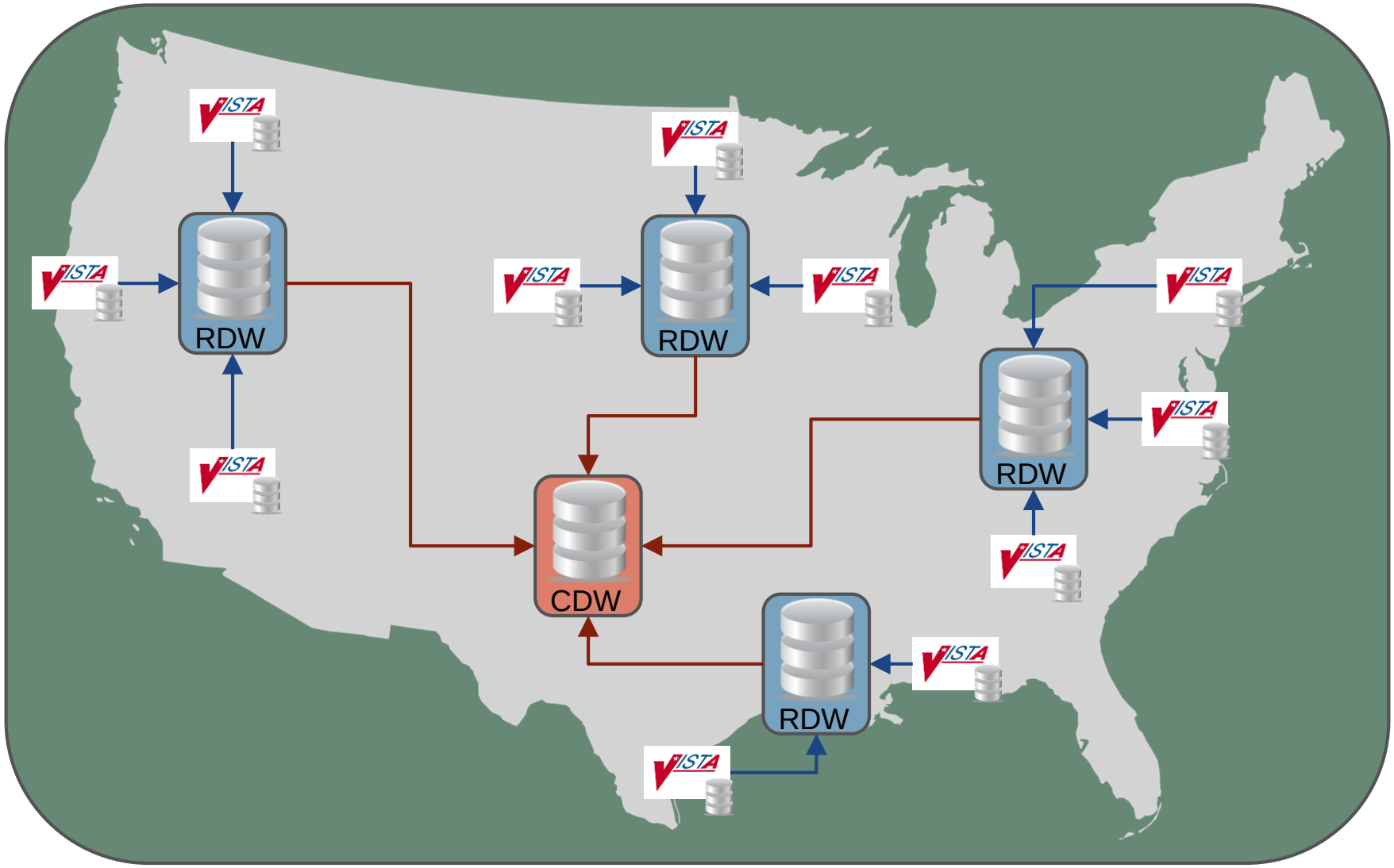
The VA VistA/CPRS National EHR



Exemplars

- Insulin Study
  - Randomization to sliding scale or weight based insulin regimens
  - Recruitment from EHR without a registry or data warehouse

- Diuretic Comparison Study
  - Randomization to hydrochlorothiazide or chlorthalidone
  - Recruitment from Corporate Data Warehouse

- Precision Oncology Program
  - DNA targeted sequence with subsequent enrollment into matched clinical trial
  - Recruitment from the Precision Oncology Clinical Data Repository

Endocrine Medication Menu

Done

Diabetes Medications

Insulin Options:

1. **No preference for insulin regimen. Consider enrollment in an inpatient study of Weight Based vs. Sliding Scale protocols.**
   To choose option 1 **Click HERE**
2. **Weight Based insulin protocol.**
   Weight Based Insulin protocol **Click HERE**
3. **Sliding Scale or other inpatient insulin regimen.**
   Other Inpatient Insulin Orders **Click HERE**

Portland Protocol (ICU Patients)

Portland Protocol **Click HERE**

Oral Hypoglycemics

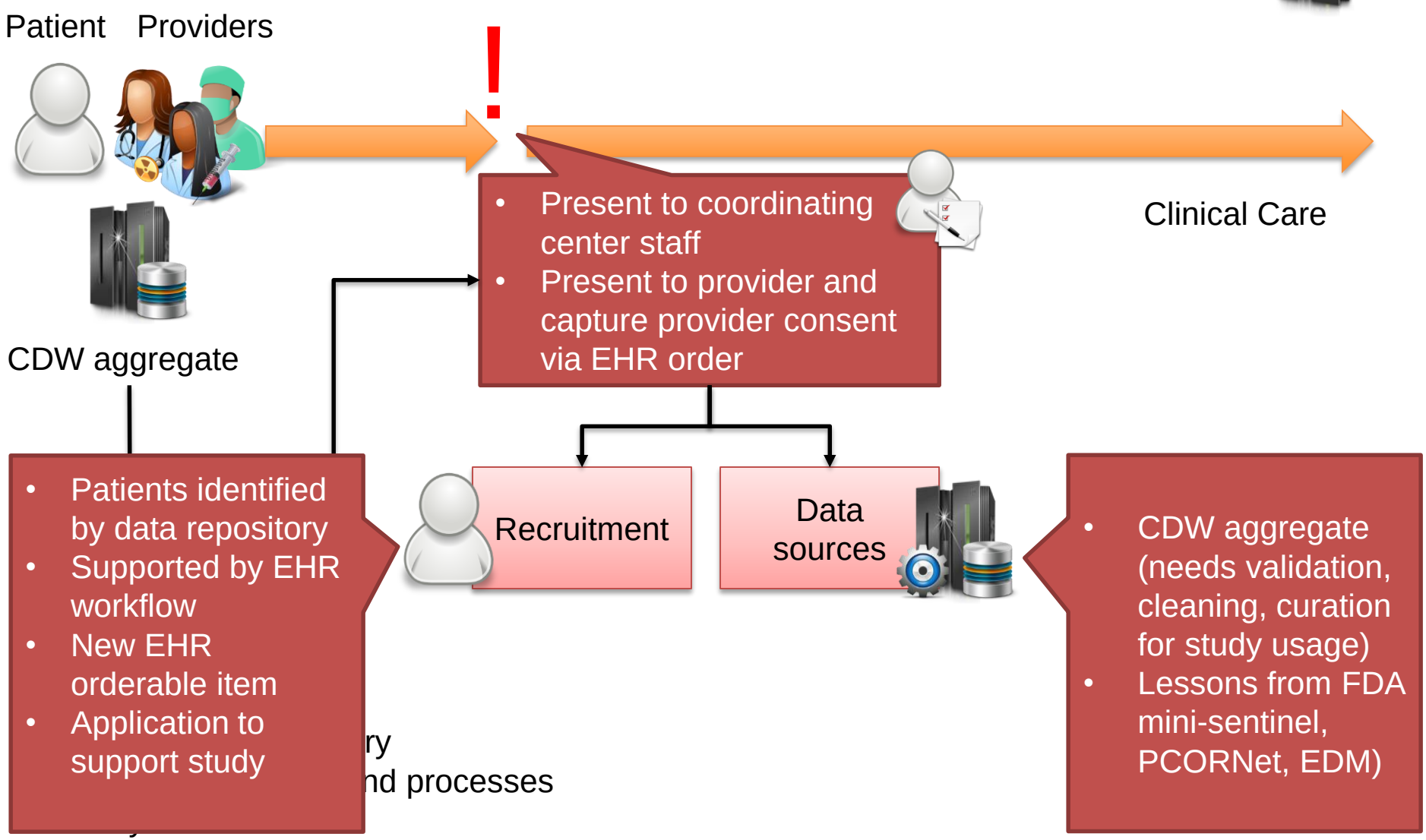
Oral Diabetes Medications Menu **Click HERE**

Thyroid Medications

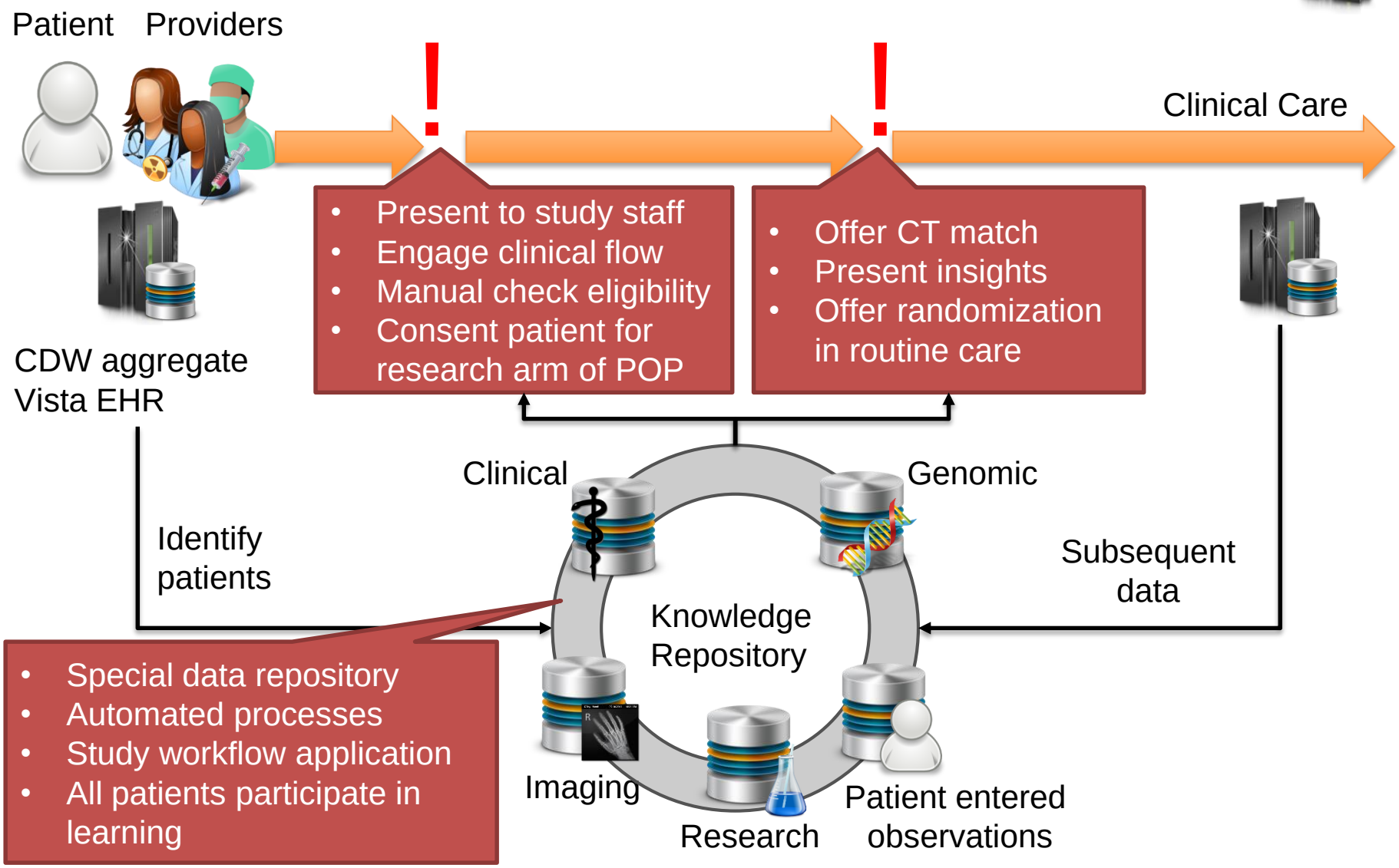
Thyroid Medications Menu **Click HERE**

Steroids (under construction)

Workflow of the POC DCP



Workflow of the POP (and rLHS)



Major Barriers and Solutions

- Technical
  - –Phenotype identification compromised by data
    - •Unstructured
    - •Not administrative data
    - •Drives enrollment criteria and outcome selection
    - •
  - –Corporate Data Warehouse
    - •Not validated
      - –Data Wiki (Mini Sentinel)
    - •Data interpretation issues
    - •Missing data elements
    - •Missing data fields

    - •Macro data use
    - •Micro data use

Major Barriers and Solutions

- Research versus Learning
  - –Ownership by clinical care providers and administration
  - –Types of questions that are asked
- Cultural
  - –Researcher mentality (Silo)
  - –Clinical autonomy
  - –Patient preference
  - –Perception of patient preference
- Site support
  - –Alternative provider incentive
- Regulatory
  - – Engagement in Research

Major Barriers and Solutions

- Informed consent
  - –Data repository requires waiver if not operational
  - –Obtained centrally by phone
  - –Equates to risk mitigation
  - –HIPAA authorization through mail
- Implementation of Intervention
  - –Workflow in EHR (vs parallel ecosystem)
  - –Conversion to decision support (T2 translation gap)
- SAE monitoring
  - –Surveillance through data review (vs parallel ecosystem)
  - –Detected late
  - –Risk based
  - –Drives intervention possibilities

Generalizability

- Reduction of barriers to patient participation = better enrollment
- Locally selfish