DATA AND DOCUMENT ESSENTIALS IN CLINICAL RESEARCH MANAGEMENT

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26Sep2025; CAN-TAP ECHO

Overview

- **Roles Reminders**
- Data
- Documents
- Quick Wins

Roles Reminders

Sponsor

- Individual, company, institution, or organization which **takes responsibility for the initiation, management, and/or financing of a clinical trial** (across all sites).
- Can appoint a delegate.

PI

- Leader of the site study team who is **responsible for the overall conduct of the clinical trial and trial participants** (at a given site in a study).
- Can appoint a delegate.

Site Study Team

- Contains all the **individuals that are listed on the delegation log for a given site**.
- Includes front-line or patient-facing staff, and back-end data and regulatory staff.

Vendor/CRO/Service Provider

- Individual, company, institution, or organization that **provides a service used by either the sponsor or the investigator to fulfil trial-related activities**, such as:
  - trial oversight/conduct,
  - regulatory/ethical compliance,
  - data management,
  - participant/study intervention management,
  - etc.

REB/IRB/IEC

- An **independent body of medical and non-medical members that ensure the protection of human trial participants** by:
  - reviewing and approving the trial protocol,
  - investigator qualifications,
  - facilities, and
  - informed consent procedures.

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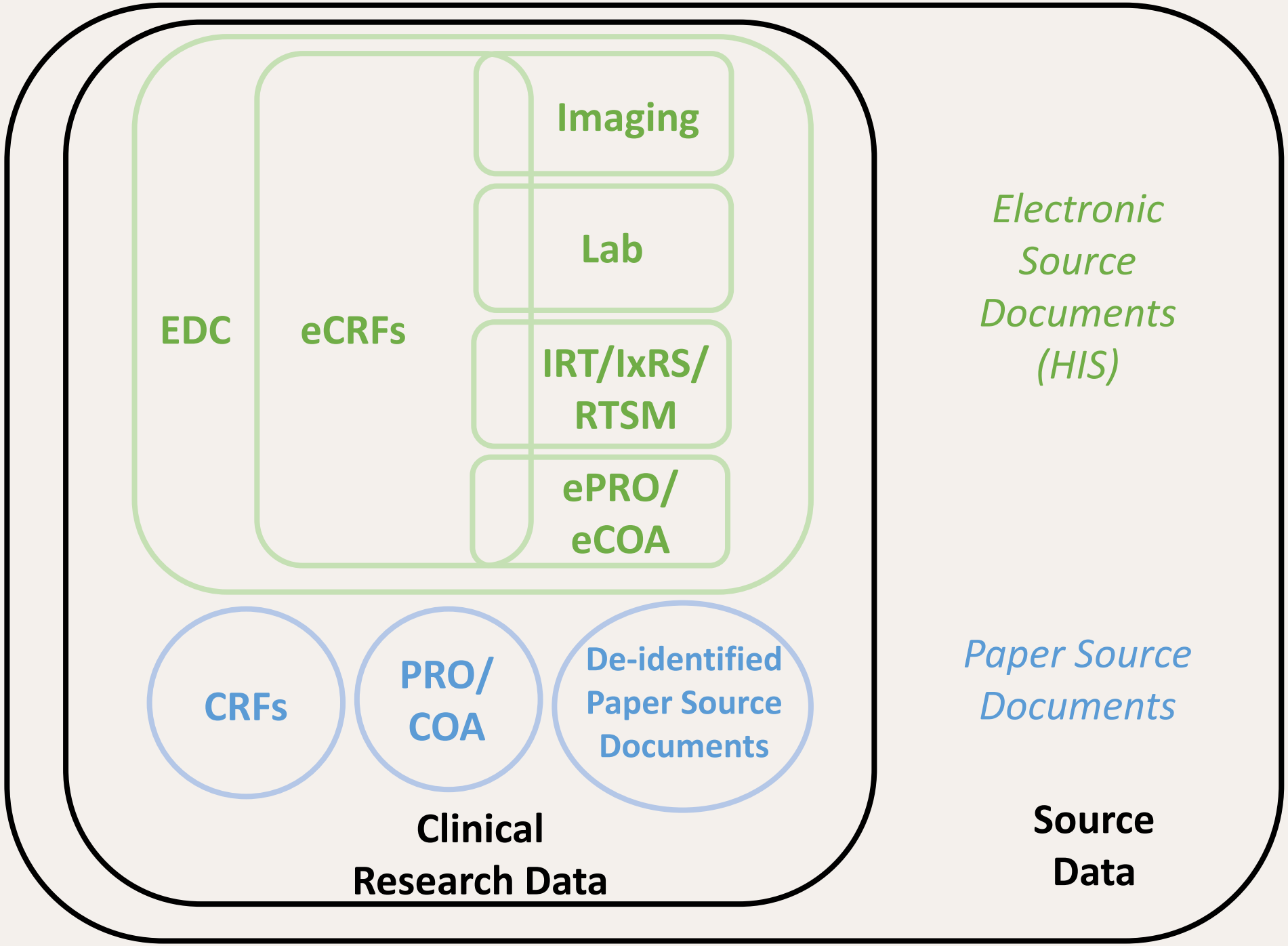
Data

Source Data

- All **information in original records** (and certified copies of original records) **of clinical findings/results, observations, or other activities** in a clinical trial, necessary for the reconstruction and evaluation of the trial
- Collected internally*
- First place data is written down or typed

Clinical Research Data

- Data collected per **clinical research protocol**, used to evaluate **safety and efficacy of protocol intervention**
- Must match source data
- Must be approved for external release
- First place protocol-specific data is written down or typed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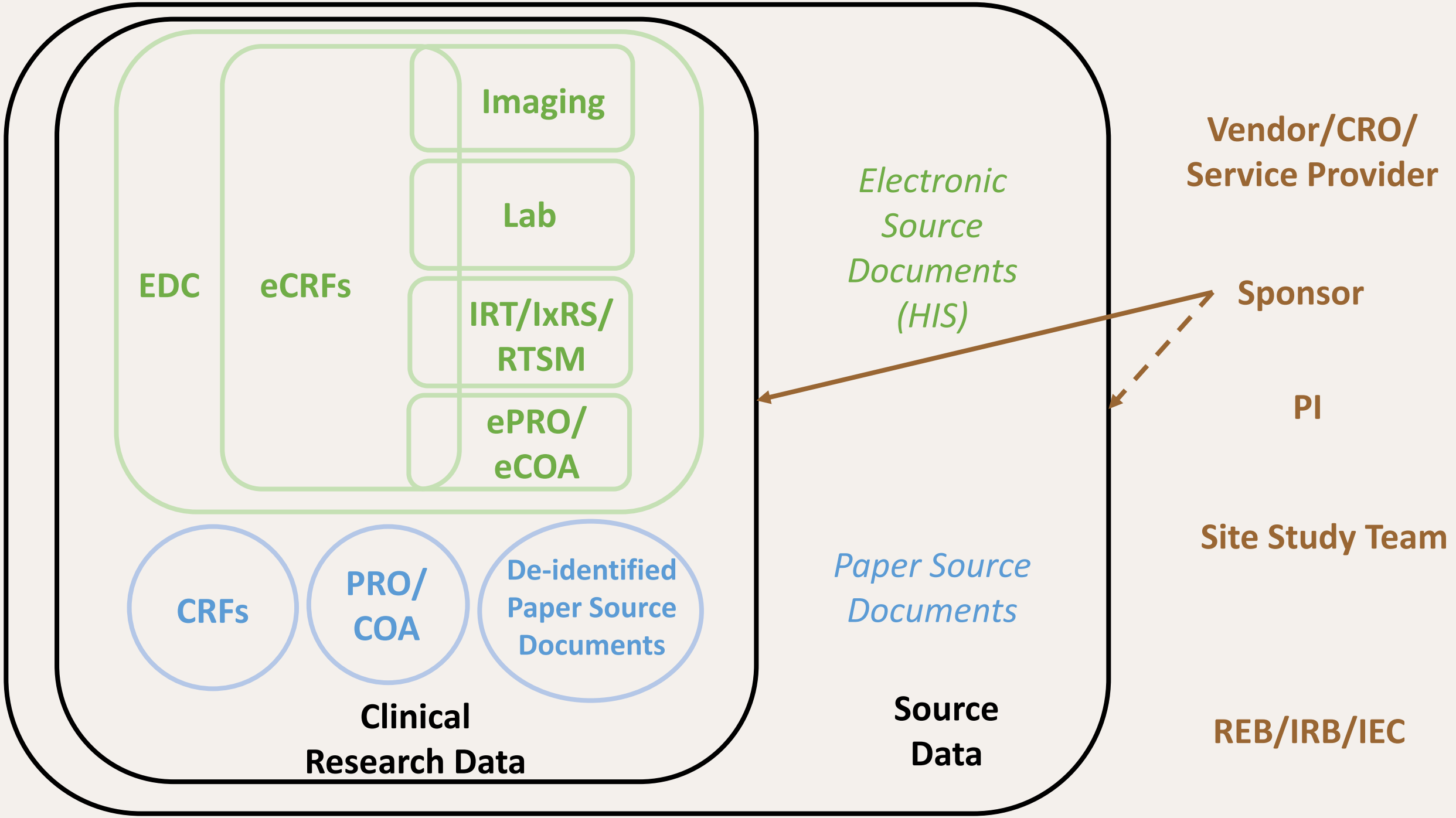
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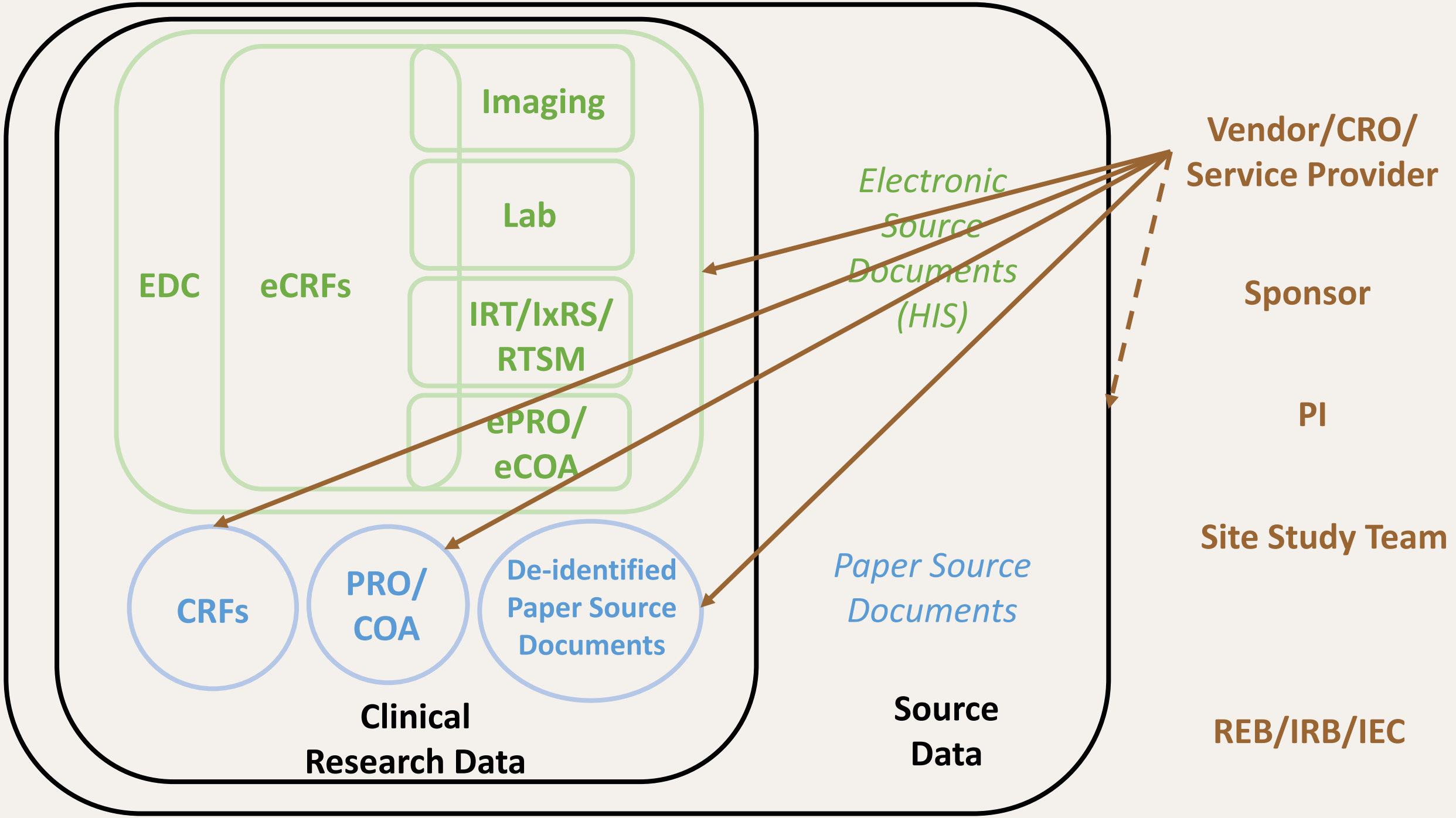
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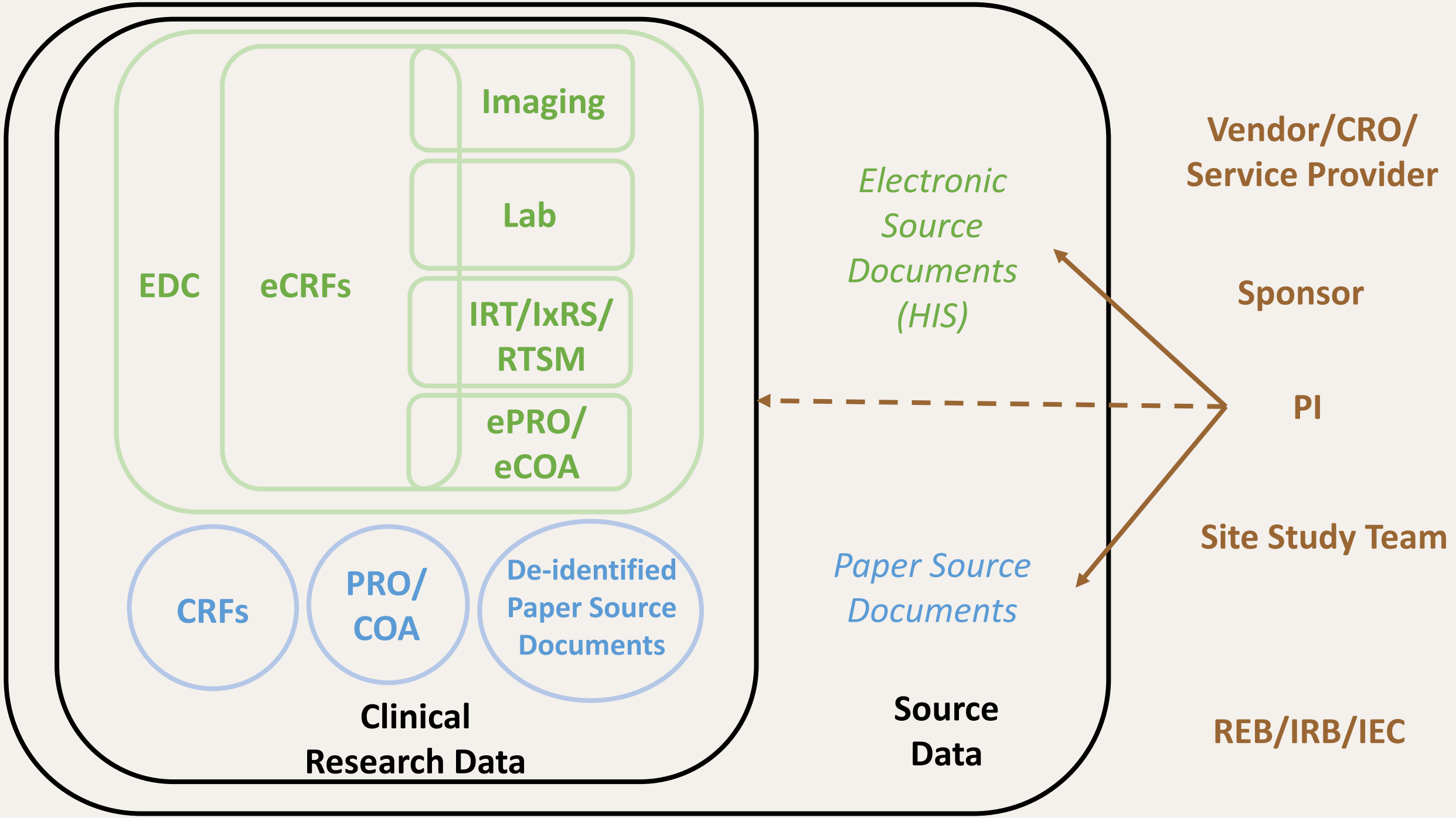
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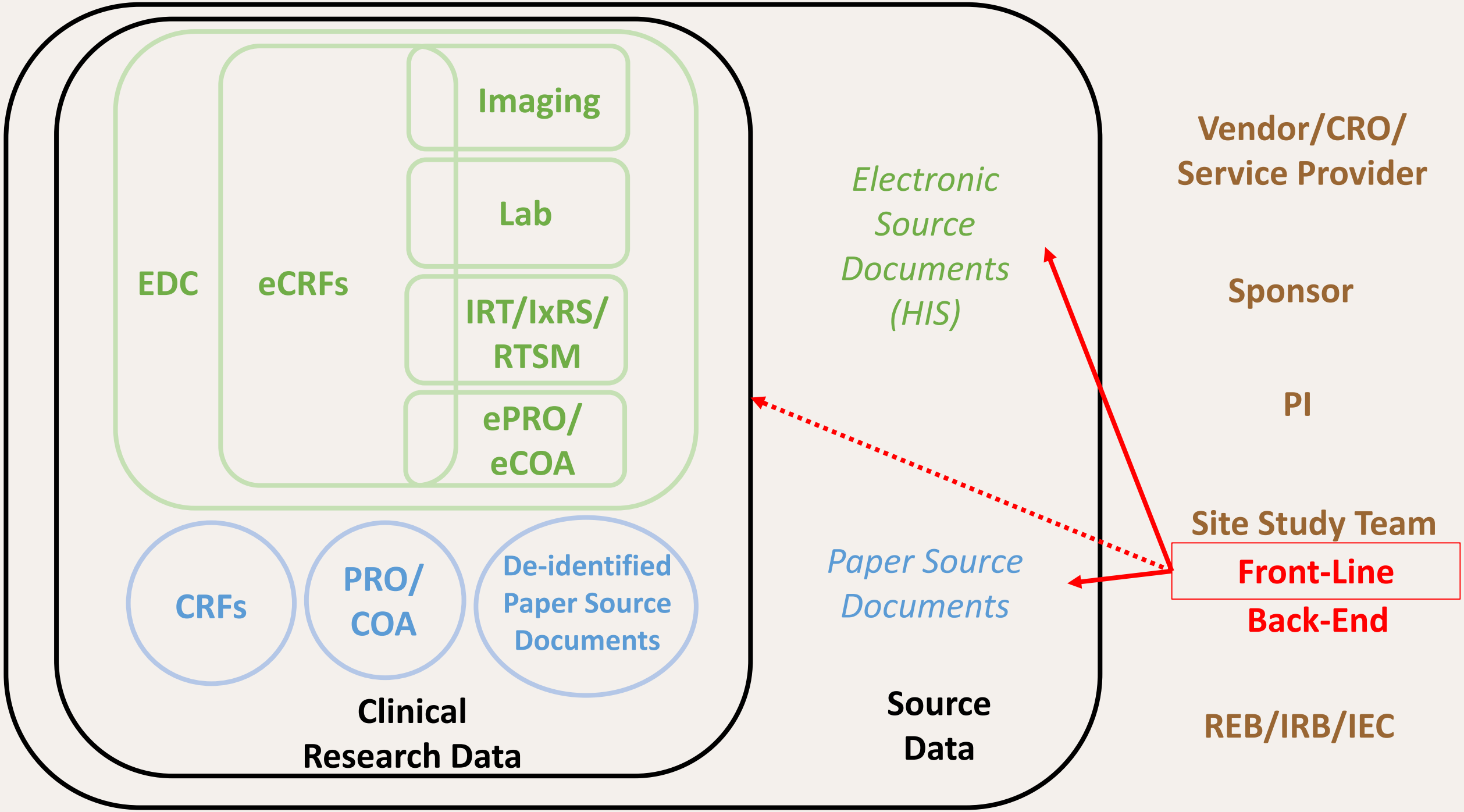
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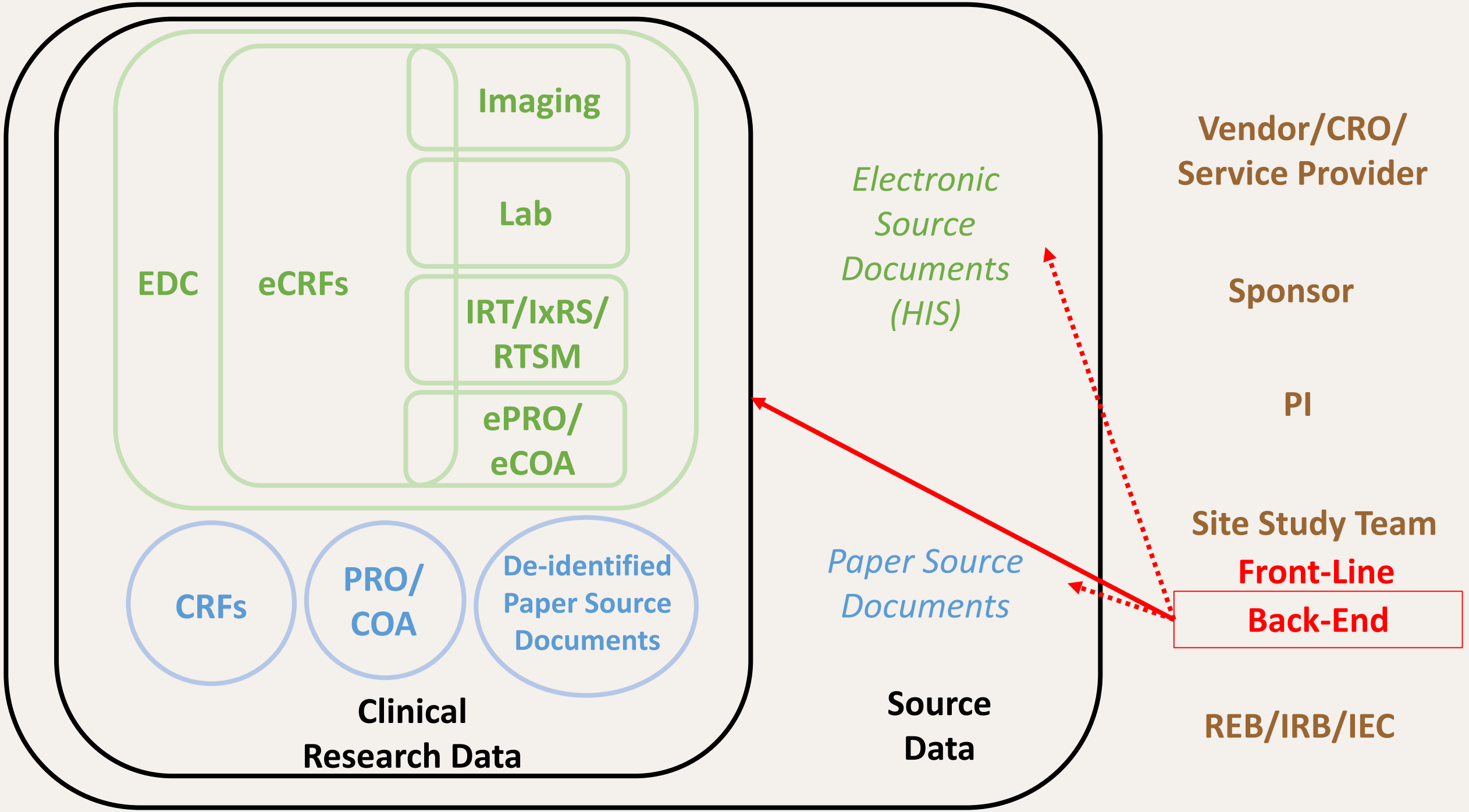
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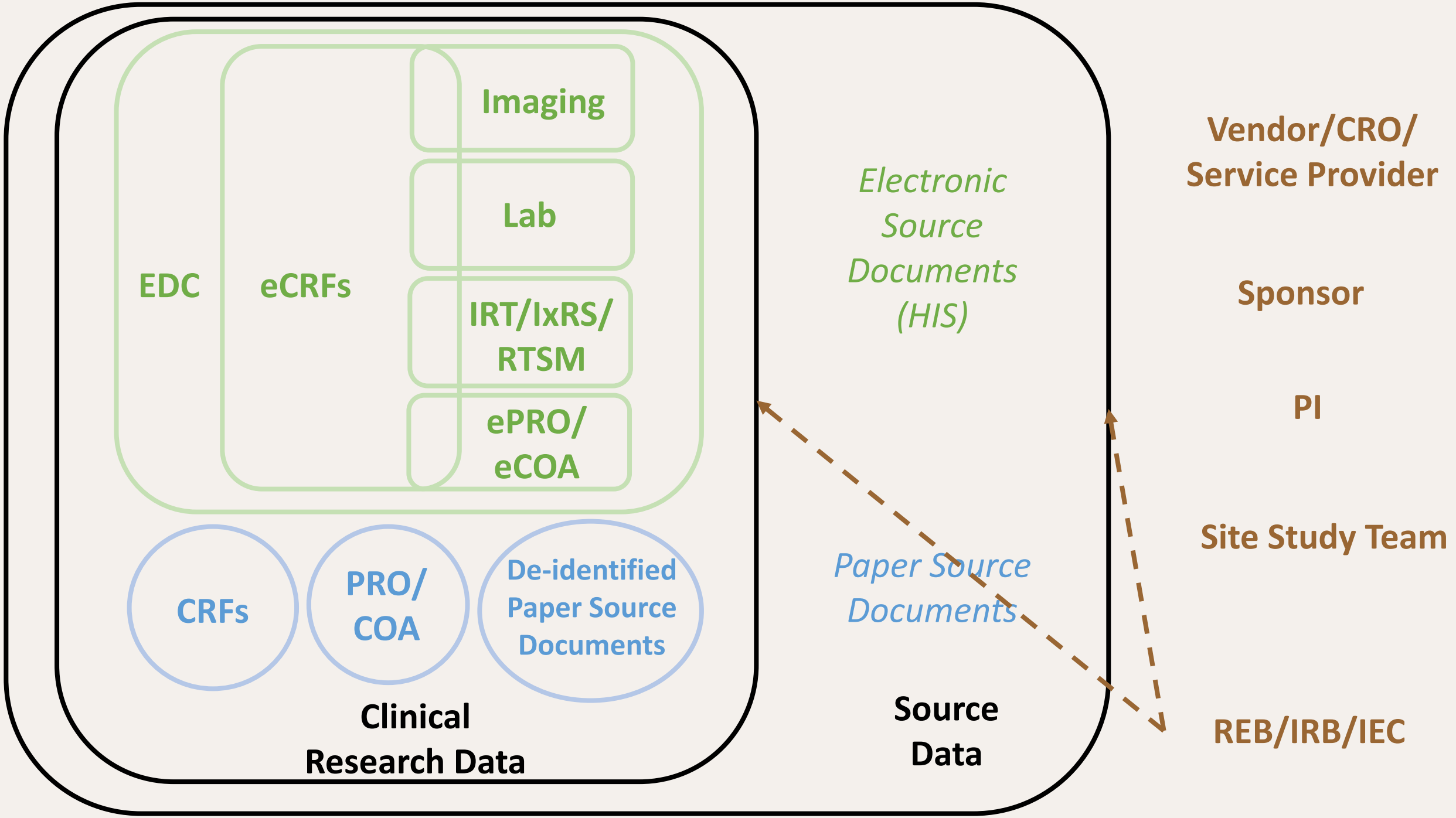
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Study File Basics

- **Regulatory binder required for regulated trials** (interventional, prospective, above minimal risk studies)
- Regulatory binder is a centralized/organized repository and tracking tool for **essential documents** (not participant-specific)
  - Demonstrates compliance with regulations, GCP, protocol
  - Serves as reference for auditor, monitors and study personnel for management/oversight
  - Provides a clear written record to enable evaluation/recreation of all study events
  - Can be stored/managed across departments
  - Should follow clearly labelled structure, typically standardized and written into SOPs, with a list of essential documents and their locations
  - Can be electronic, paper, or hybrid

TMF-Sponsor

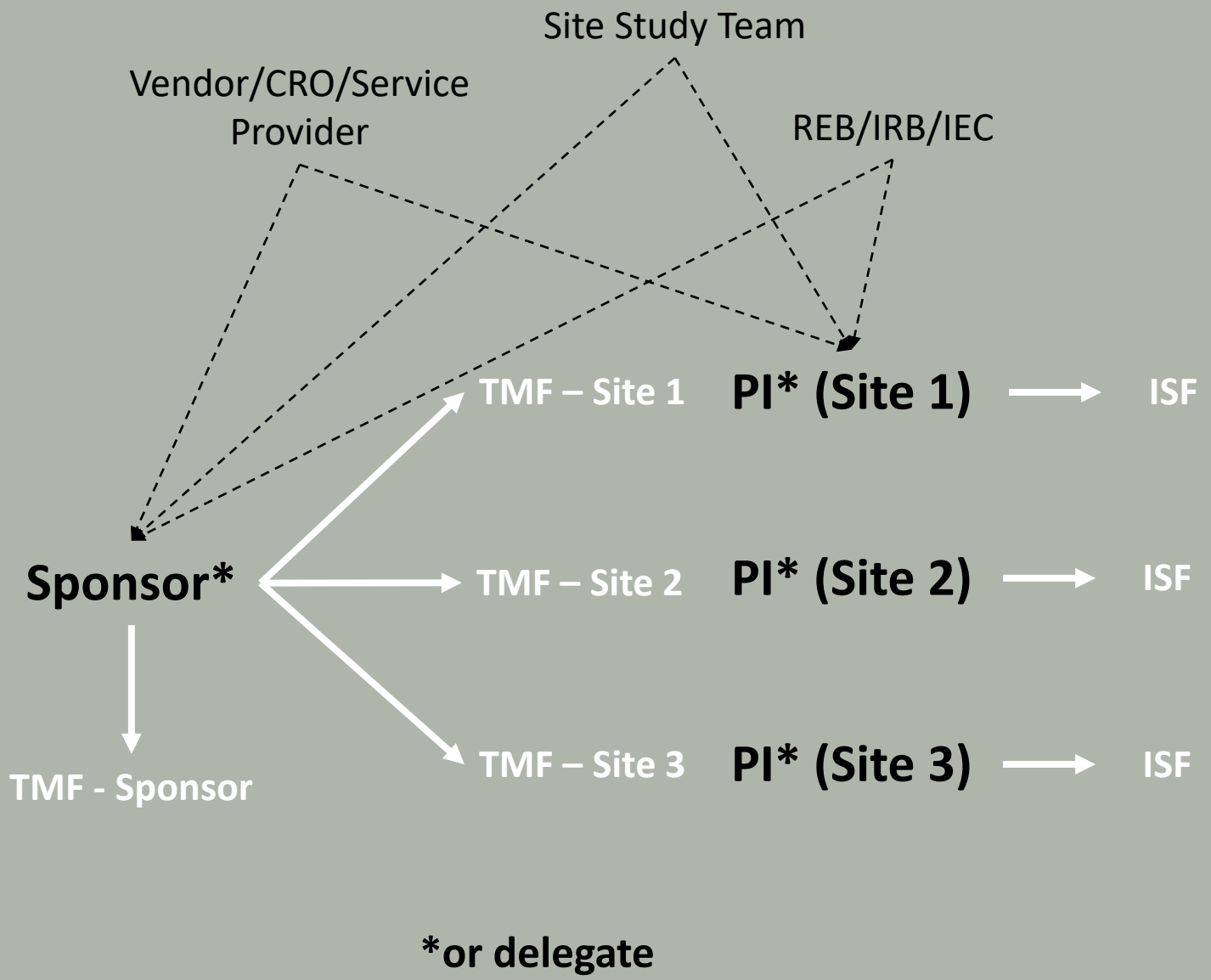
- Centralized collection of **essential documents** required for sponsor role and responsibilities
- Demonstrates **proper trail conduct** and **compliance** with GCP/regulations

TMF-Site

- Centralized collection of **essential documents** from all participating sites

ISF

- A collection of **essential documents** maintained at a clinical trial site
- Serves as evidence of investigator's **compliance** with protocol/GCP/regulations



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Quick Wins

Pay attention to paper

- 95% of patient source document findings were on paper source
- 50% of these findings were due to presence of blank spaces

Don’t forget to document

- 95% of insufficient/inappropriately filed correspondence was related to regulatory essential documents (not patients)

Try to track

- 40% of findings were related to missed, delayed, deficient essential documents
- Most of these findings can be mitigated by comprehensive tracking practices

Thank you! Questions?

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