RAPID Phase 1 Deliverables
Use Cases, Flow Diagrams

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Use Cases: Background & Rationale

- Why Use Cases? To provide RAPID Working Groups (clinical, informatics, and GUDID) a reference point (and boundaries) for selecting clinical terminology to be developed into data concepts (i.e., when are data encountered, data uses, data interchange, analytics, etc.)
- Use cases selected to span clinical care, registries, clinical trials, and regulatory contexts
- Use cases are a traditional informatics instrument – a translation layer between data producers (clinicians), data management (HIT vendors), and data users (analytics)
- Note that: use cases are archetypes to help level set the utility and applicability of the RAPID core data set (i.e., use cases are hypothetical, not definitional)

Use Case 1

- Pre-Market Registry Based Trial
  - Summary: Registry-based trial to assess the safety and efficacy of Device X (new technology) vs. Device Y (approved technology) [or OPC (objective performance criteria)] in pts 40-85 with a fem-pop stenosis experiencing any PAD sxs
  - Study design: single-blind, registry-embedded, 1:1 randomized controlled clinical trial of 500 pts, evaluating device performance and acute / intermediate / long-term outcomes (CV endpoints, limb endpoints, functional measures, QOL measures)
  - Success criteria:
    1. Overall study is acceptable to FDA to modify the device label
    2. Study operations, processes are acceptable to industry sponsor
    3. Trial utilizes RAPID core data elements, UDI, and linkages to GUDID

Use Case 1

- Pre-Market Registry Based Trial (~8 pages of detail)
  - Project summary
  - Rationale and background
    - Rationale for embedded registry-based trial
  - Methodology
    - Hypothesis
    - Inclusion / exclusion criteria
  - Study flow
    - Baseline / screening
    - Procedure
    - Follow-up
  - Assessments matrix

Use Case 2

- Post-Market Surveillance Study
  - Summary: Registry-based analysis for post-market surveillance of an FDA-approved Drug-Coated Balloon (DCB), to provide event estimates (e.g. acute limb ischemia)
  - Study design: prospective, open-label, multicenter, observational, single-arm analysis of pts in a PAD registry treated with the DCB following post market approval. The registry will contain pts from 20 sites across the US. There are no exclusion criteria.
  - Success criteria:

1. Study design, data collection methods, data quality, and results are acceptable to FDA to satisfy post-approval requirements
2. Study operations, processes are acceptable to the industry sponsor
3. Trial utilizes RAPID core data elements, UDI, and linkages to GUDID

Use Case 3

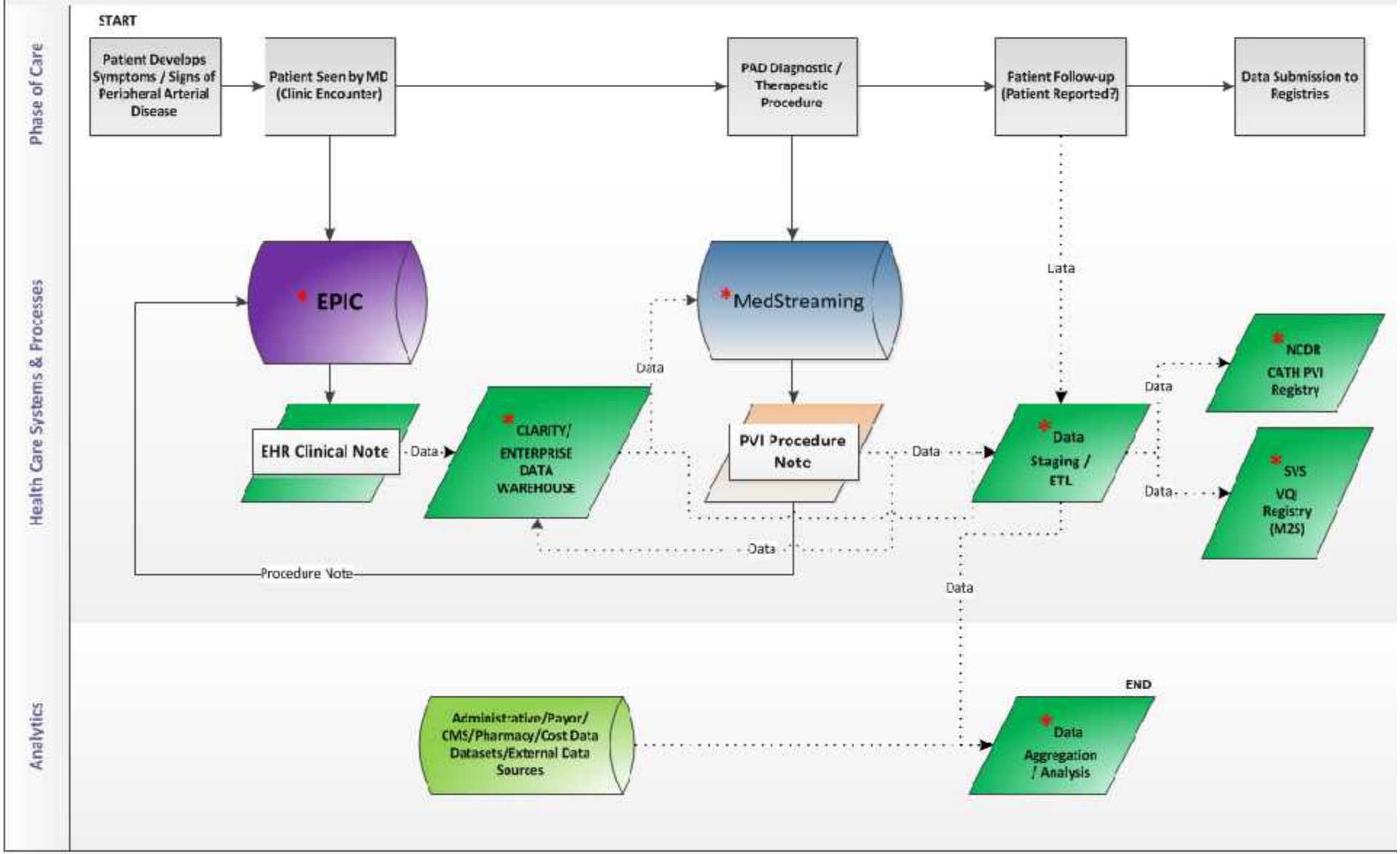
- RCT of Adjunctive Pharmacology
  - Summary: Randomized clinical trial (RCT) assessing safety and efficacy of 1 versus 6 months of dual antiplatelet therapy (DAPT) following infrainguinal revascularization. The RCT will be broad enough for subgroup analyses of different device technologies, anatomic segments, and symptom classifications.
  - Study design: Registry-embedded, multicenter, randomized, double-blind clinical trial enrolling 5000 pts scheduled to undergo endovascular revascularization for PAD
  - Success criteria:

1. Study identifies the optimal duration of dual-antiplatelet therapy (DAPT) following LE PAD revascularization
2. Study operations, processes are acceptable to the industry sponsor
3. Trial utilizes RAPID core data elements, UDI, and linkages to GUDID

Workflow Diagrams: Background & Rationale

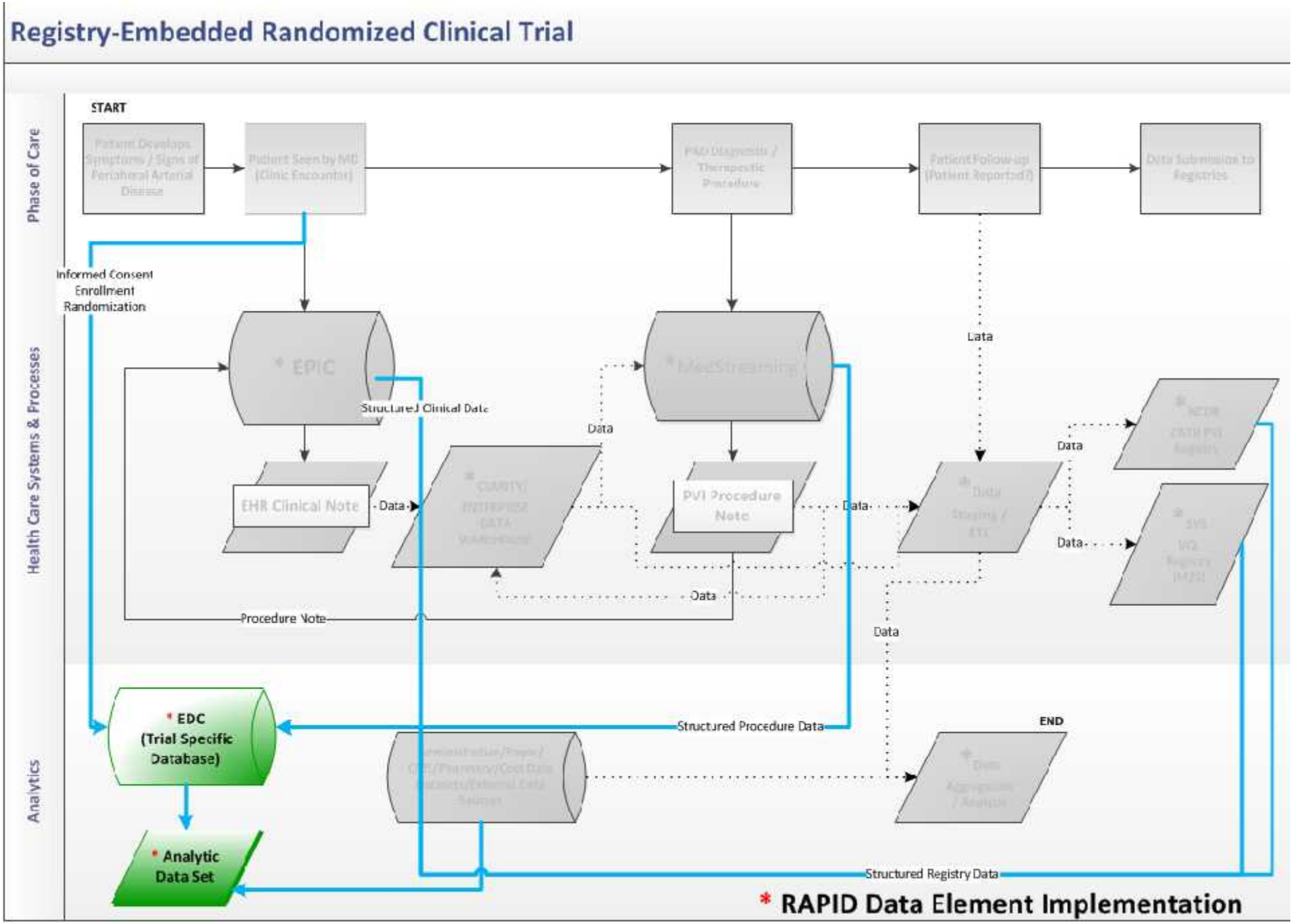
- Why Workflow Diagrams? To provide a reference for understanding how the RAPID common data elements are intended to be integrated into various data streams
- Workflow / data flow diagrams selected to span clinical care, registries, clinical trials, and regulatory contexts
  - Clinical care (with reporting to registries)
  - Registry-embedded clinical trial
  - Medical device surveillance
- Workflow diagrams are another classical informatics instrument – to illustrate integration of workflow (people, places, systems) with data flow, from data producers (clinicians) via data management (HIT systems) to data users (analytics)

RAPID Data Elements Demonstration Project

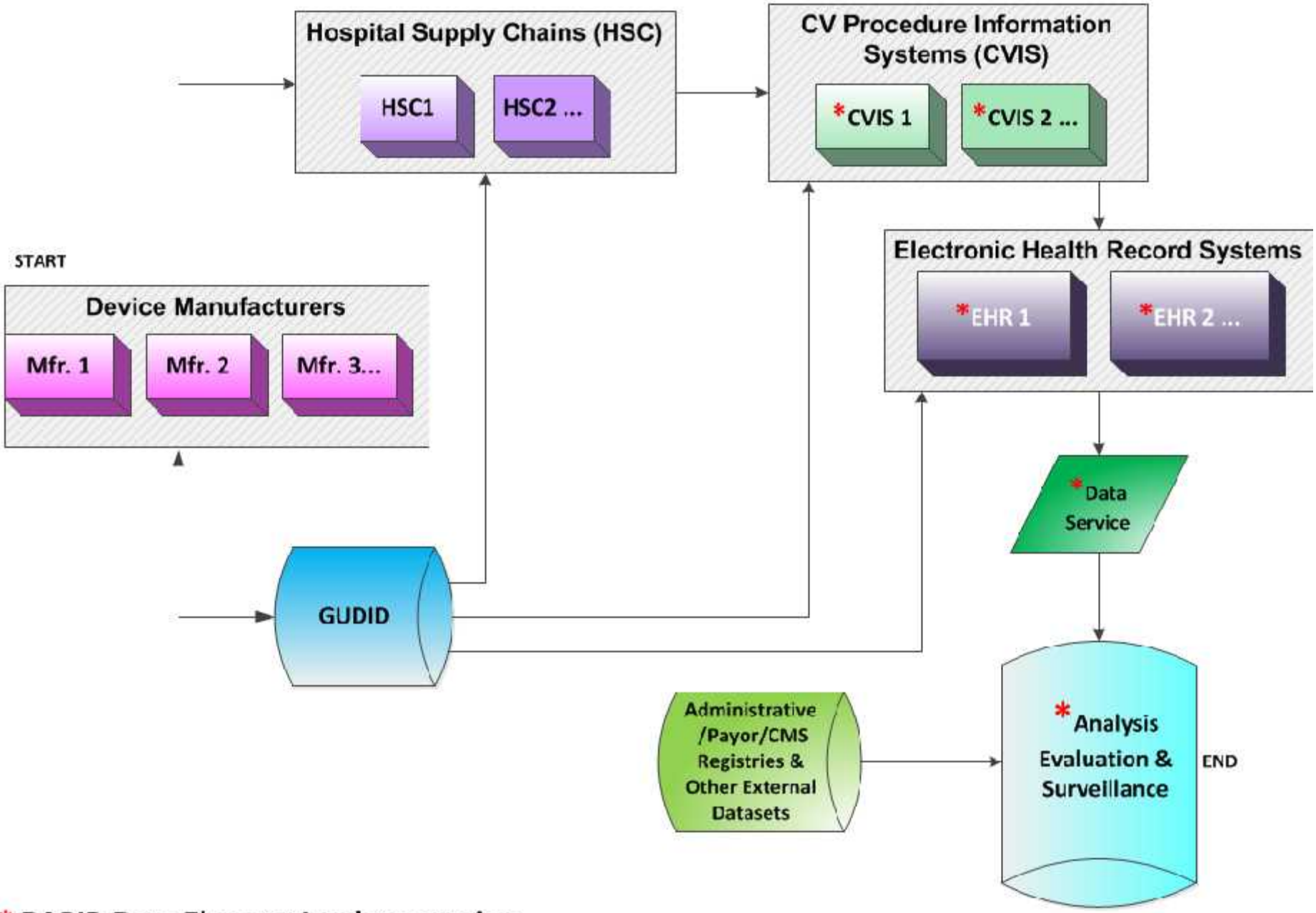


* RAPID Data Element Implementation

Registry-Embedded Randomized Clinical Trial



National Medical Device Evaluation/Surveillance System



* RAPID Data Element Implementation

RAPID Project Plan

- Phase II opportunities:
  - Build out the informatics formalisms of the RAPID core data elements
  - Incorporate RAPID CDEs into clinical documentation systems (CVIS, EHR systems)
  - Incorporate RAPID CDEs into PVI registries (CathPVI, SVS, ICVR)
  - Facilitate the creation of an interoperability profile to move data from CVIS/EHR to PVI registries
  - Introduce structured reporting into PVI clinical care (more on this in a bit …)