

## **RAPID Information and WorkFlow Diagrams**

In each diagram, the red asterisk (\*) indicates systems, where the RAPID core data elements are implemented. Semantically and syntactically interoperable data is collected, extracted and reported.

### **RAPID Data Elements Demonstration Project**

This workflow provides a visual representation of the information collected at the point of care for utilization and reporting across the continuum through device evaluation. The process starts with patient presentation in clinic for a routine visit (top left) and continues through the analysis of their data for device evaluation in an analysis data set (bottom right). The resulting structured dataset supports pre- and post-market surveillance, quality improvement/assurance, and evaluation of clinical outcomes and device performance.

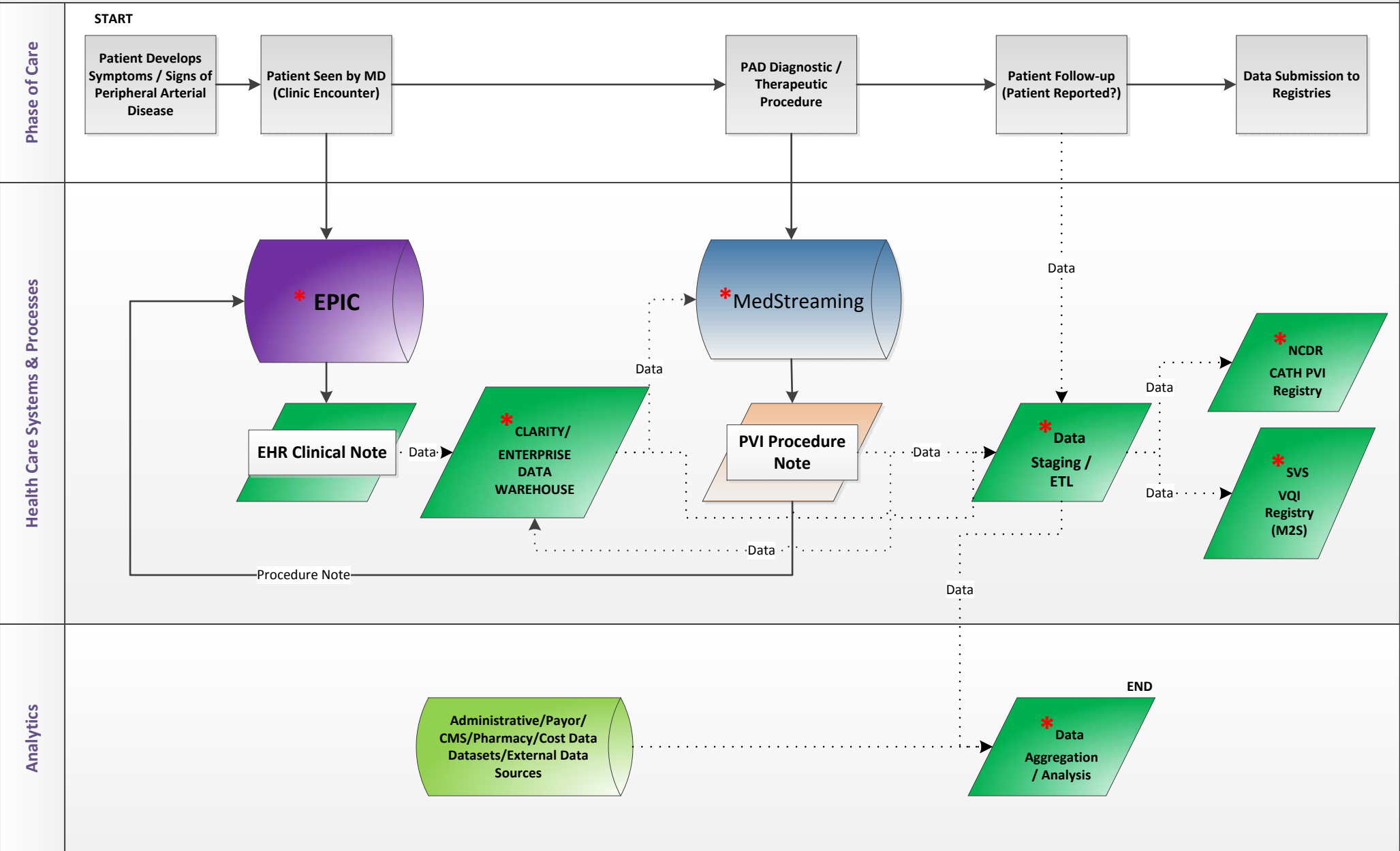
### **National Medical Device Evaluation/Surveillance System**

This workflow represents implementation of RAPID core data elements at a variety of points in the total product life cycle. Starting with Device Manufacturers on the top left and continuing across to the bottom right where devices are associated with individual patients in EHR's & clinical procedure information systems, data from the core data set can be extracted & utilized for device evaluation and safety surveillance.

### **Registry-Embedded Clinical Trial**

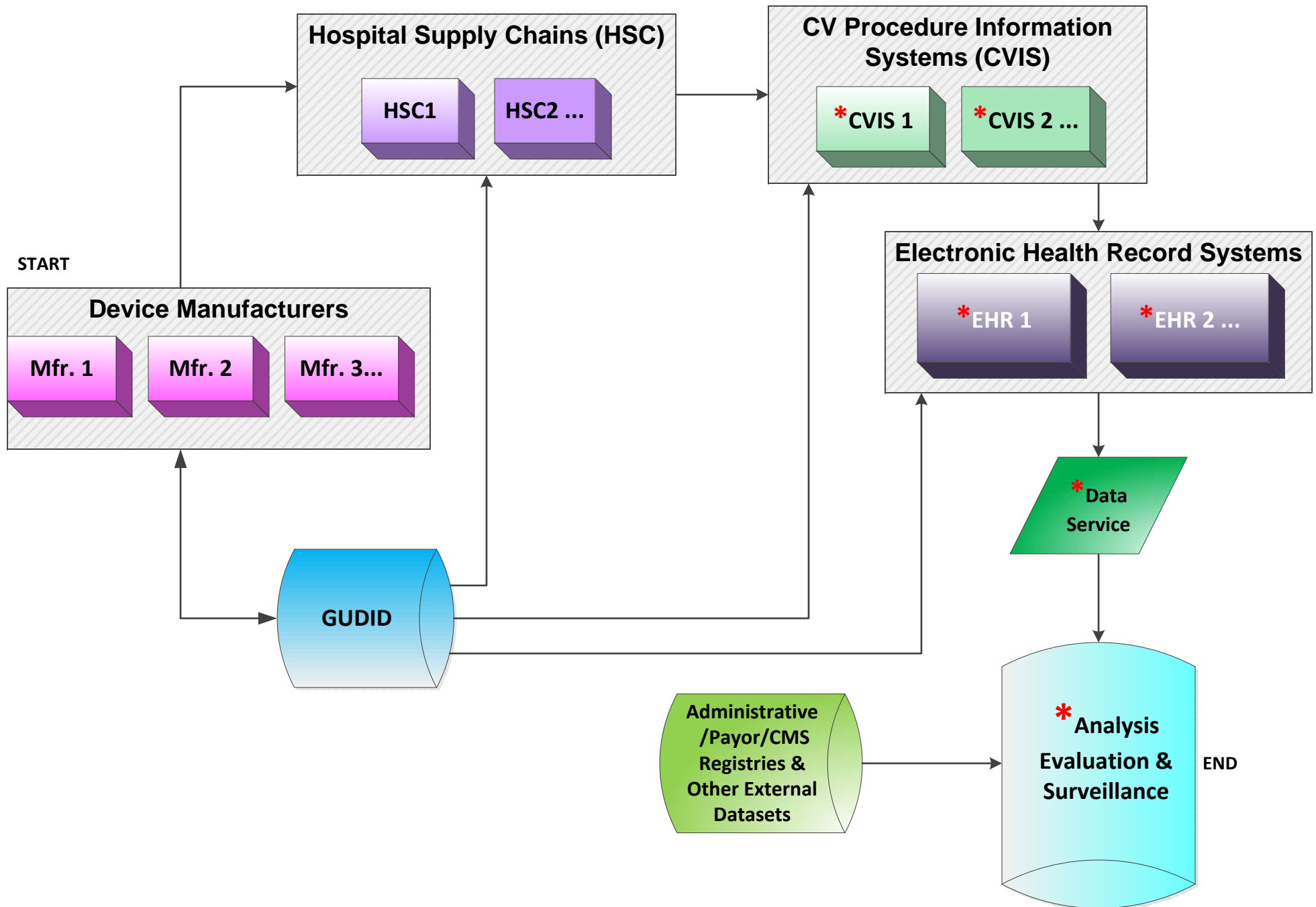
This workflow represents implementation of the RAPID core data set as part of a clinical trial that is integrated into a routine, care delivery process. The flow of RAPID Core Data point of care in the top left through analysis in the bottom right is illustrated. Additionally, core data flow from a patient registry into a clinical trial's electronic data capture system where it is used to support research operations such as patient enrollment, randomization, informed consent and study-specific data collection efforts is illustrated.

# RAPID Data Elements Demonstration Project



**\* RAPID Data Element Implementation**

# National Medical Device Evaluation/Surveillance System

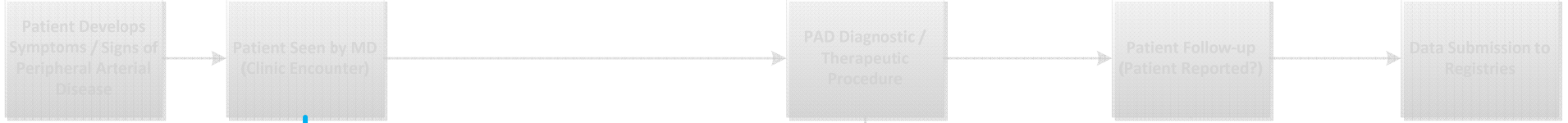


\* RAPID Data Element Implementation

# Registry-Embedded Clinical Trial

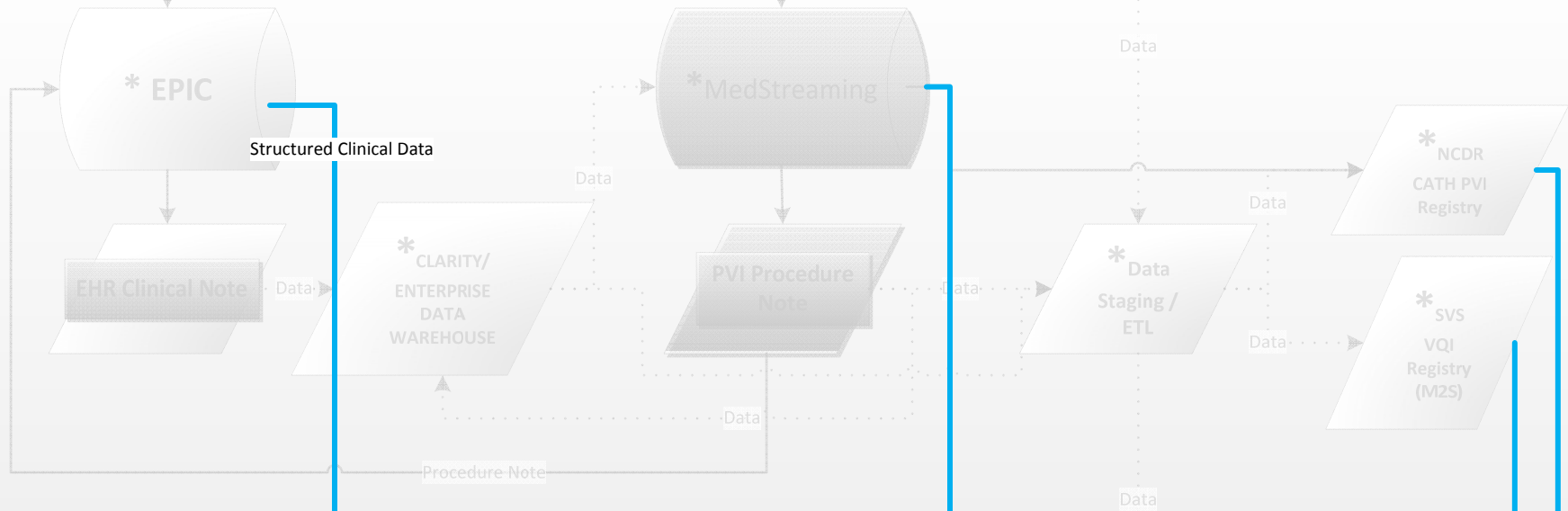
Phase of Care

START

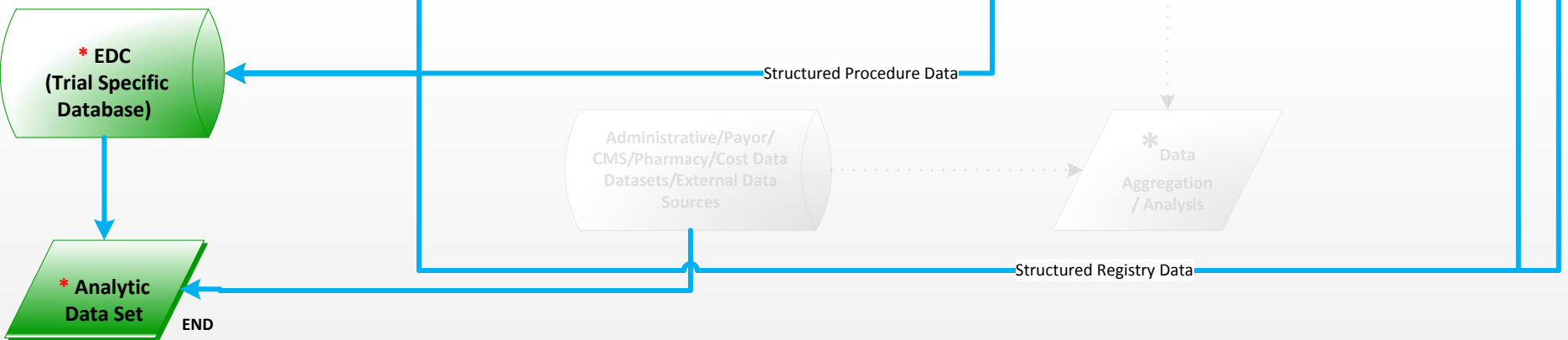


Health Care Systems & Processes

Informed Consent  
Enrollment  
Randomization



Analytics



**\* RAPID Data Element Implementation**