Point-of-Care Medical Device Tracking (PMDT) Integration Profile

PROBLEM

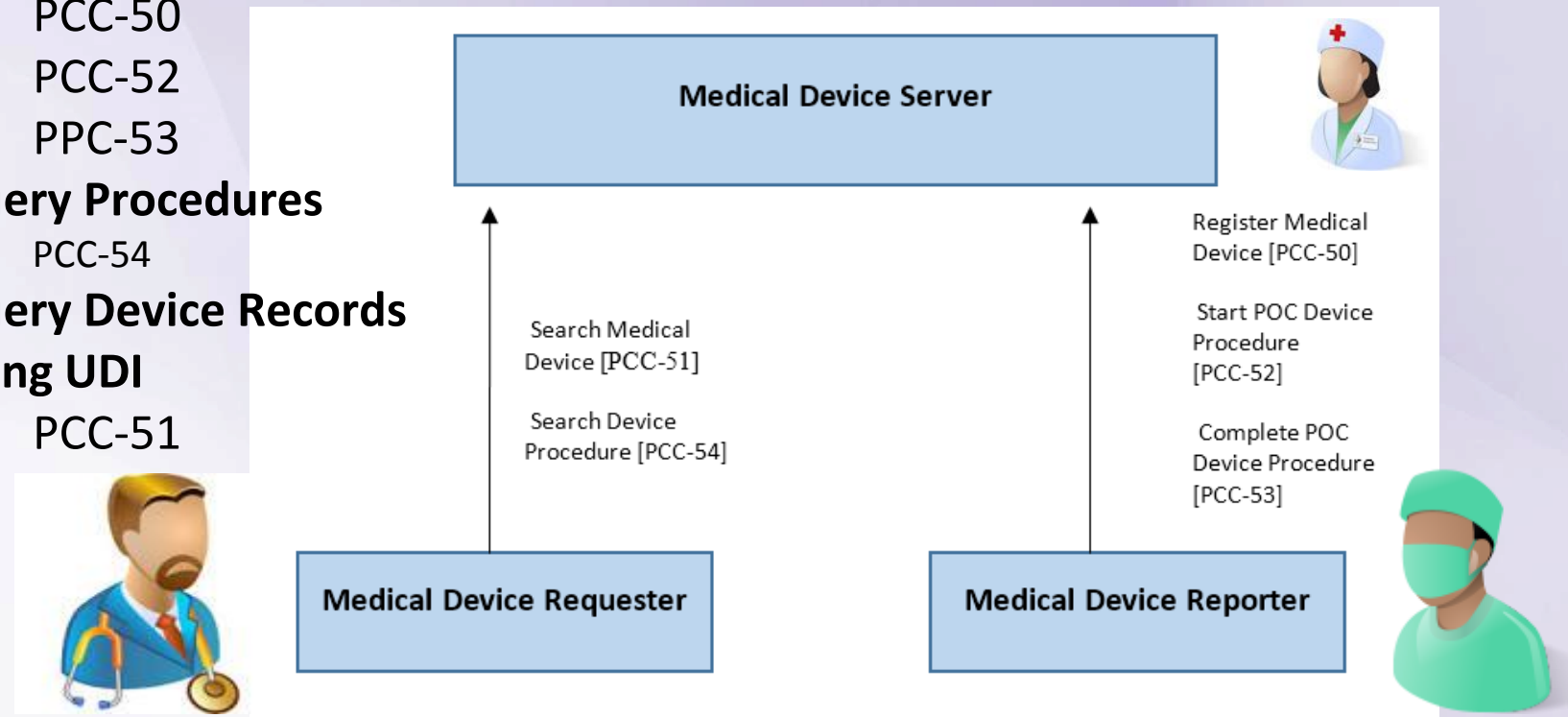
- **Implantable medical devices are costly and concerns about illegitimate (i.e., counterfeit, stolen) products has become a global issue**
- **Post-market surveillance of implantable medical devices can be challenging**
- **Implantable medical device adverse events and recalls pose a patient safety issue**
- **Acquiring medical device data used at the point-of-care is difficult to retrieve for reuse at a later time**

VALUE PROPOSITION

- **Closes the loop on data acquisition at the point-of-care to support reporting of medical device data**
  - Medical device data used for:
    - Continuum of care (e.g., Discharge Summary, Referrals)
    - Registries (e.g., Total Joint Registry)
    - Payers (e.g., government provided, private insurance)
  - Can associate a medical device used for monitoring a disease or symptom of a disease (e.g., vital sign monitors, pulse oximeters, blood glucose monitors) to a patient for querying the device or procedure using the UDI
- **Increase patient safety**
  - Traceability of medical devices (avoid use of counterfeit or illegitimate products)
  - Quality issues identified (e.g., recalls, adverse events)
- **Increase accurate medical device data capture at the point-of-care**
  - Eliminates human error from manual medical device data entry

Actors and Transactions

- **Tracking Implantable Medical Devices and Tissues (e.g., Orthopedic, Cardiovascular, etc.)**
  - PCC-50 + PCC-53
- **Track Procedures using a Medical Device (e.g., glucose monitor, vital sign monitor) at the point-of-care for accuracy**
  - PCC-50
  - PCC-52
  - PPC-53
- **Query Procedures**
  - PCC-54
- **Query Device Records using UDI**
  - PCC-51



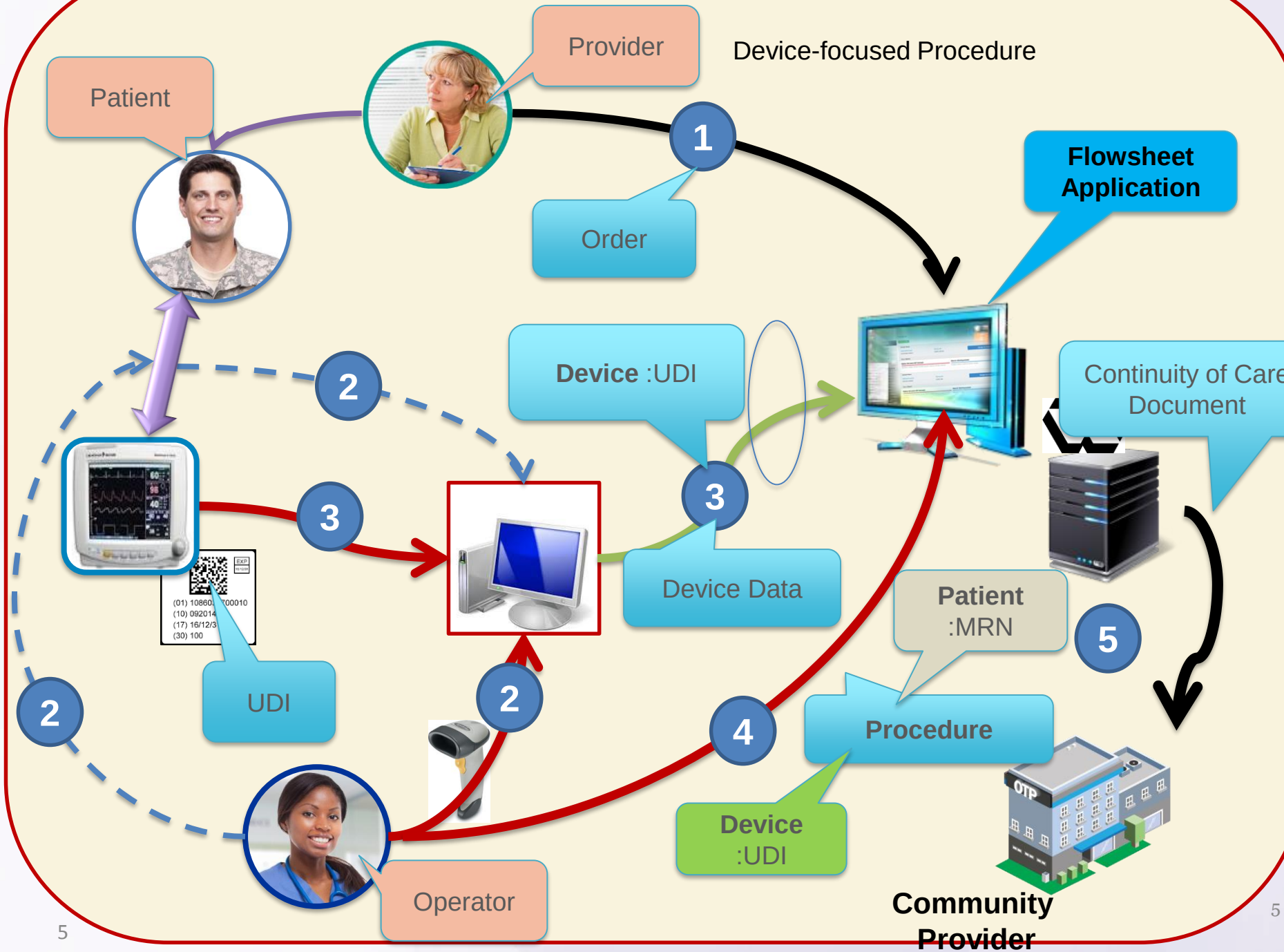
PMDT Technical Highlights

- **Content Profiles use HL7 FHIR STU3 profiles (i.e., StructureDefinition Resource) to record information about medical devices (including implantable/life-supporting/life-sustaining device and tissues that use US FDA UDI)**
  - Device Resource
  - Procedure Resource – to document procedures using focal devices and references to Patient
  - FHIR uses RESTful services (HITTP/HTTPS) to create/update and query records
- **Provides new capabilities to the point-of-care systems to enhance patient safety and effectiveness**
  - Tracking device use in the context of procedures and associated medical devices and POC procedures with the correct patient record
  - Managing identity information for devices and patients at the point-of-care
- **Supports US FDA UDI and transitions**
  - Both human-readable(i.e., manually entered or processed) and AIDC (i.e., scanned) using ASCII and extended character sets.

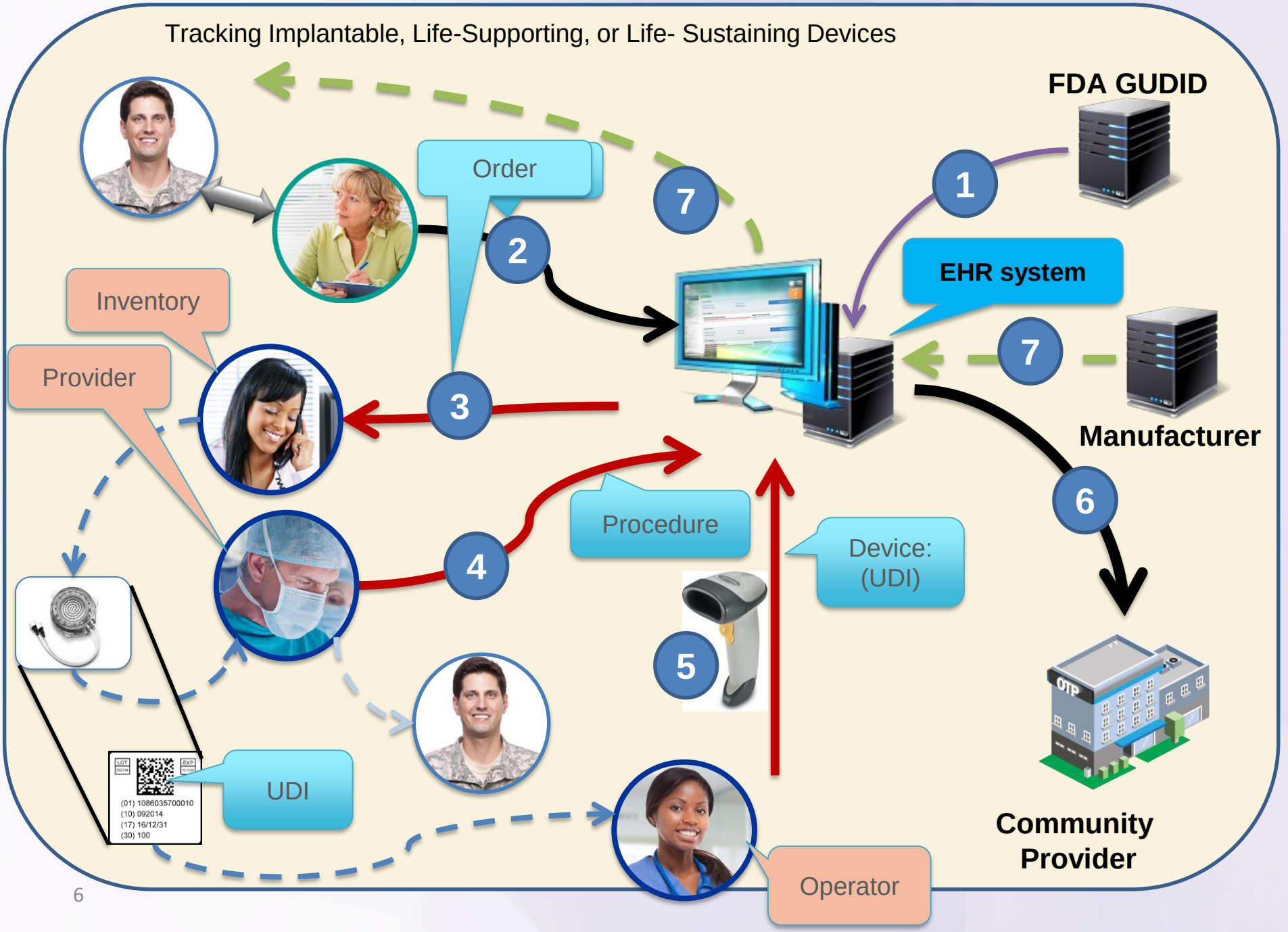
Point-of-Care Medical Device Tracking

Value Proposition:

- **Closes the loop on data acquisition at the point-of-care to support reporting of medical device data**
  - Implantable medical devices (e.g., total knees, screws, rods, defibrillators, etc.)
  - Medical devices used for diagnostic or monitoring a disease or symptom of a disease (e.g., vital sign monitors, pulse oximeters, blood glucose monitors)
- **Increase patient safety**
  - Traceability of medical devices (avoid use of counterfeit or illegitimate products)
  - Acquire the device UDI at the time of a procedures, at the point-of-care to avoid associating an implant or other device data with the patient
  - Timely resolution of recalls or adverse events involving implantable devise
- **Increase accurate medical device data capture at the point-of-use**
  - Eliminates human error from manual data entry
  - Associates the patient to their devices in the context of a well-defined procedure (i.e. start-to-end or completion date/time)


Device-focused Procedure
Provider
Patient
1
Order
Flowsheet Application
2
Device :UDI
3
Continuity of Care Document
3
Device Data
UDI
2
2
4
Patient :MRN
5
Procedure
Device :UDI
Operator
Community Provider

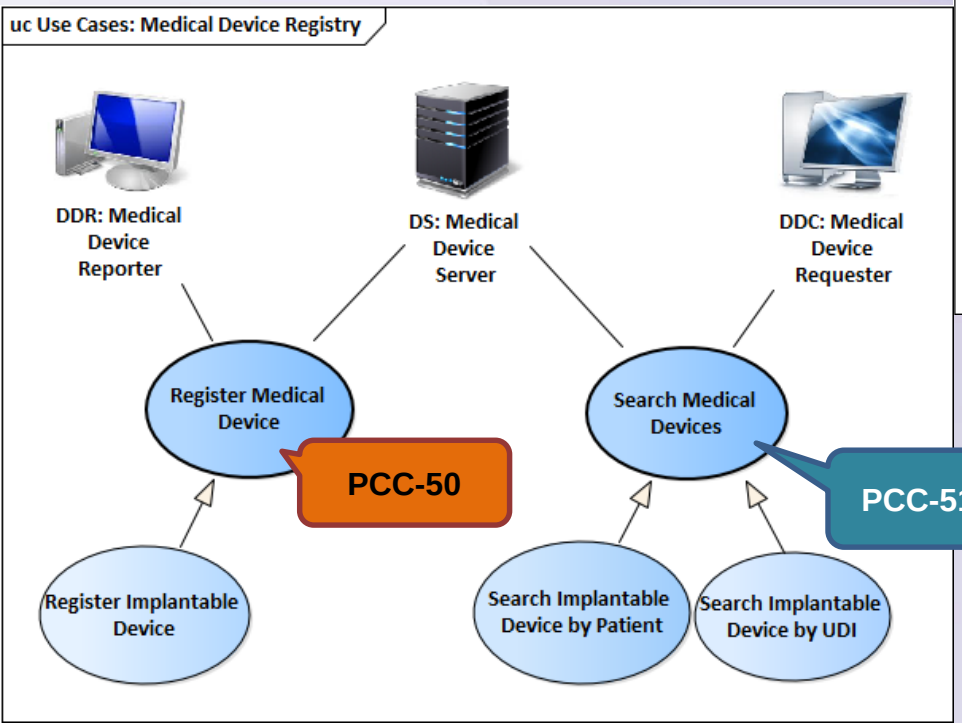
5

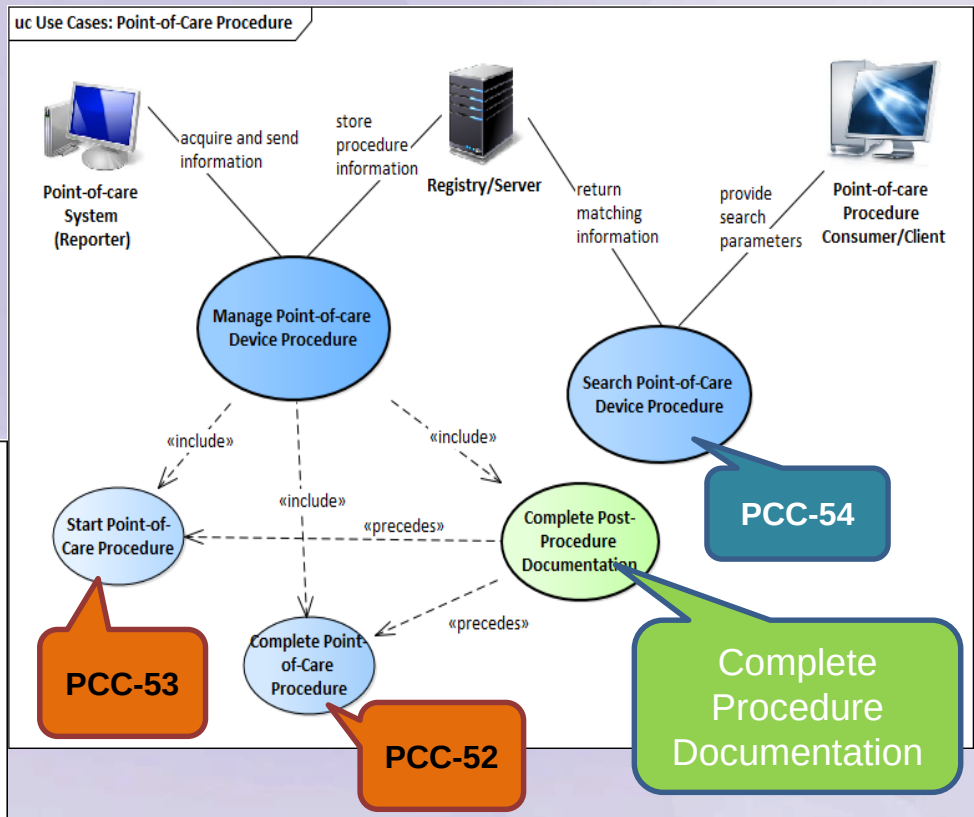

Tracking Implantable, Life-Supporting, or Life- Sustaining Devices
FDA GUDID
Order
1
2
3
4
5
6
7
7
EHR system
Inventory
Provider
Procedure
Device: (UDI)
Manufacturer
Community Provider
UDI
(01) 1086035700010
(10) 092014
(17) 16/12/31
(30) 100
Operator

Point-of-Care Medical Device Tracking

Use Case Analysis:

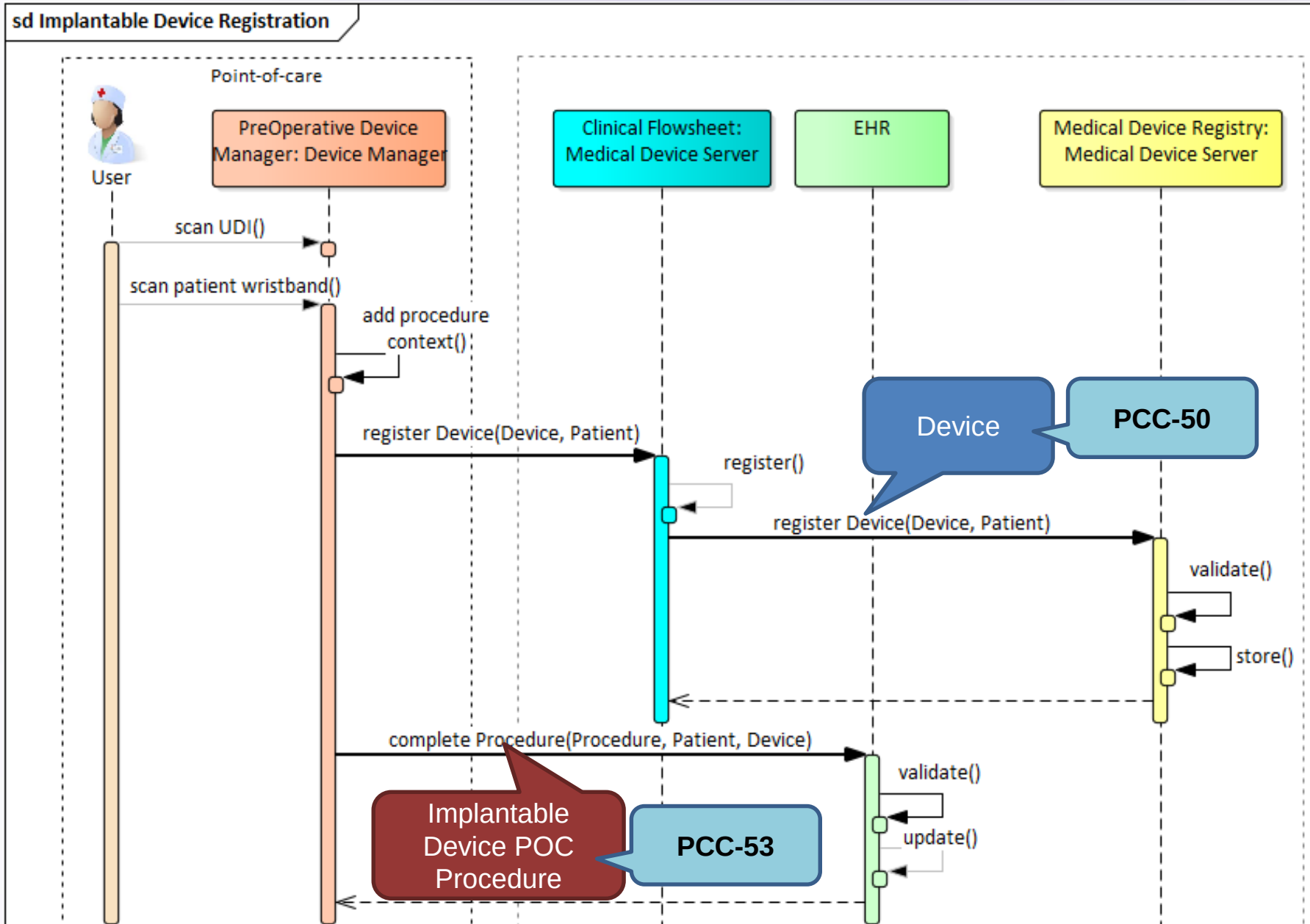
- Document procedures and track Implantable Medical Device or Tissue using the FDA UDI at the point-of-care



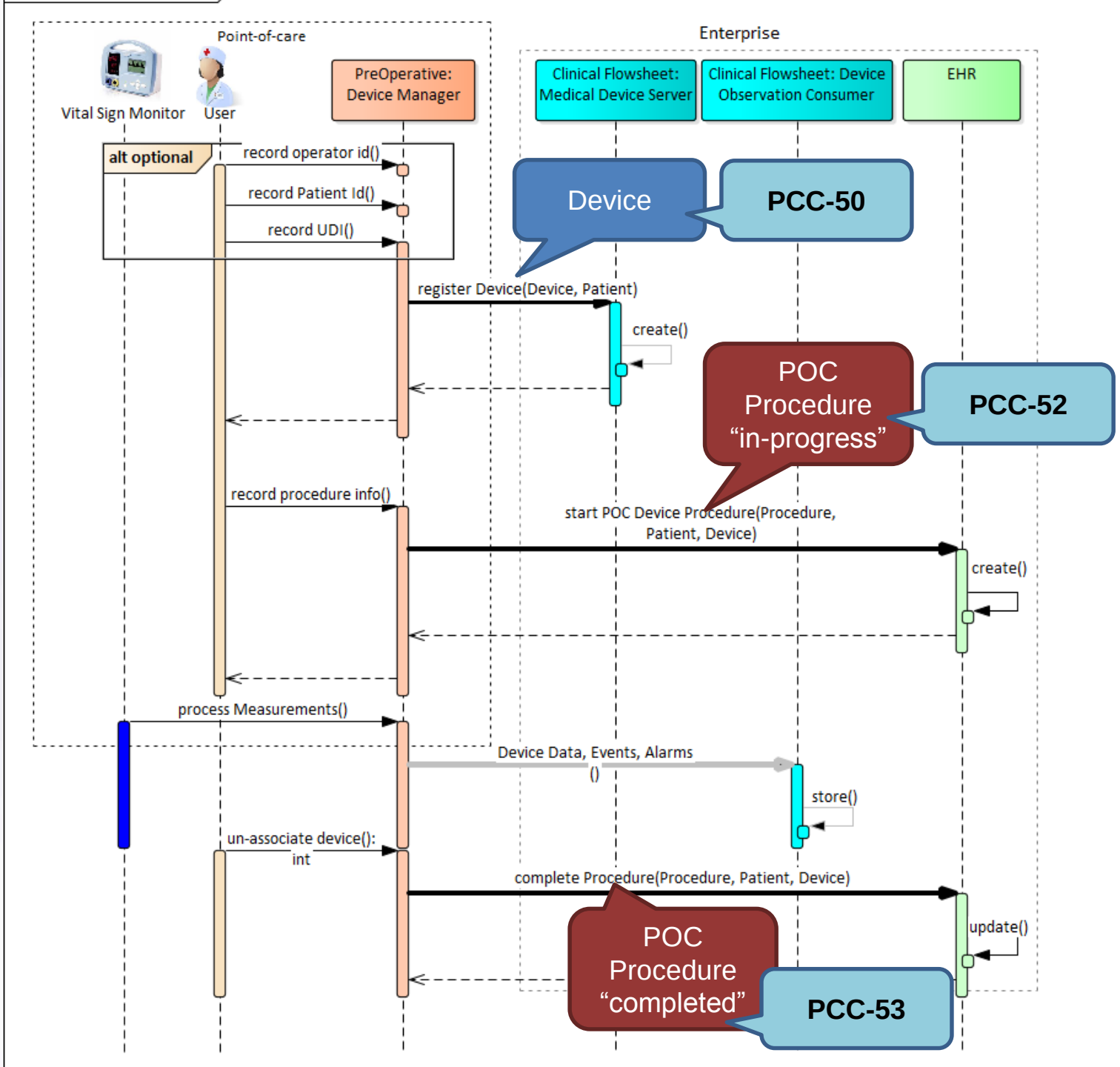


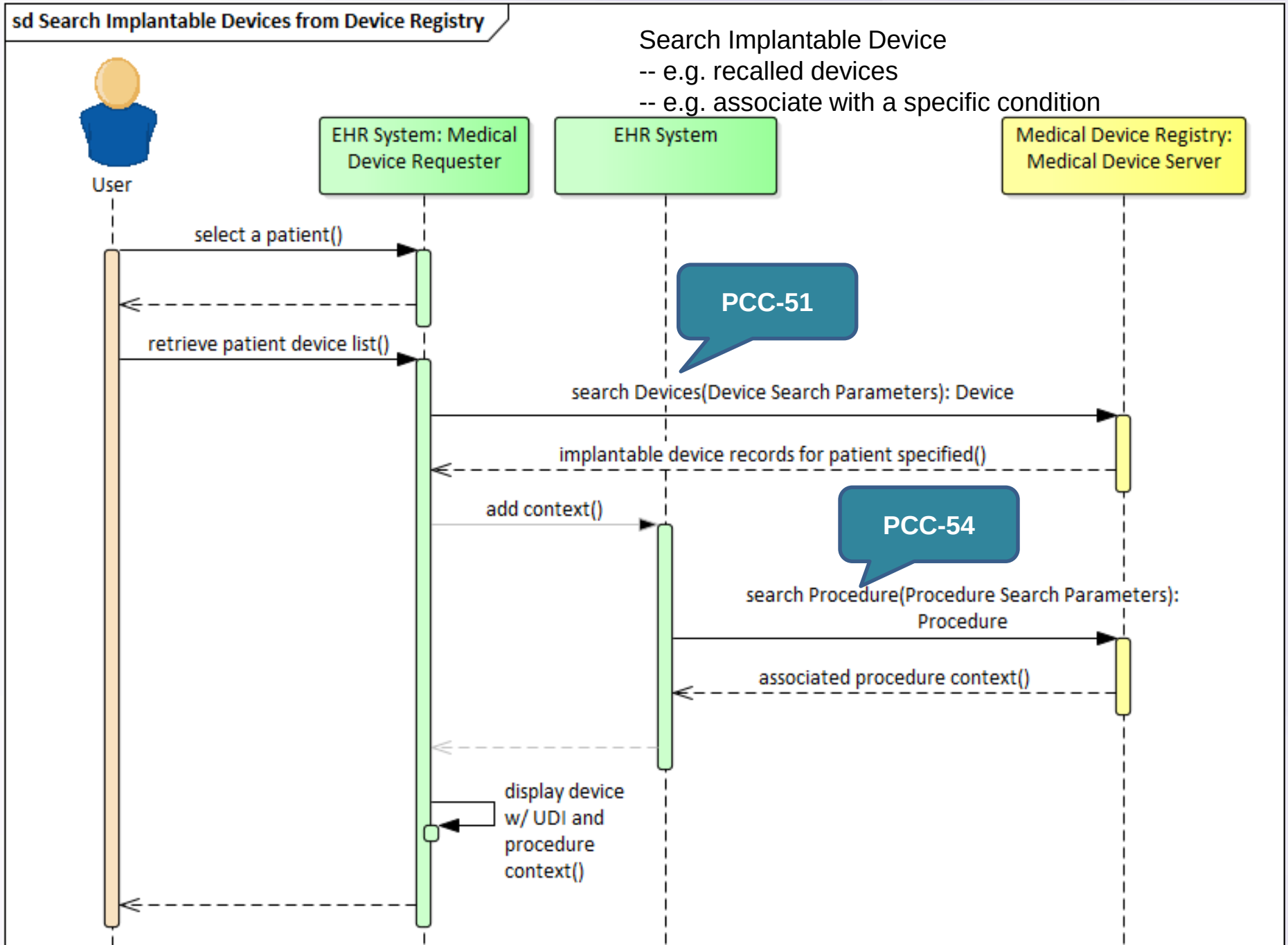
- Document treatment, diagnostic, and health procedures at the point-of-care

Implantable Device Registration

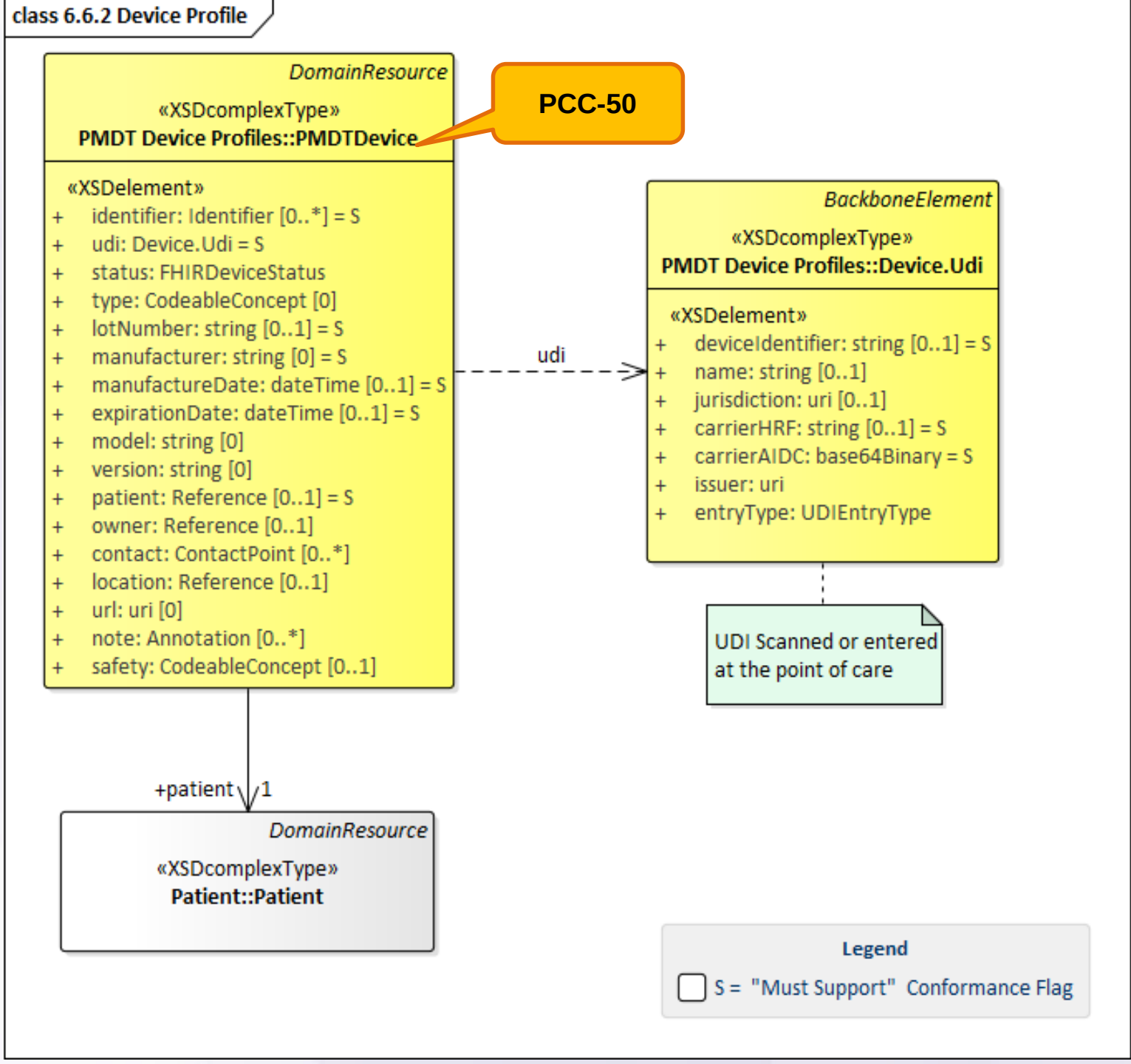


Point-of-Care Procedures Start → Complete

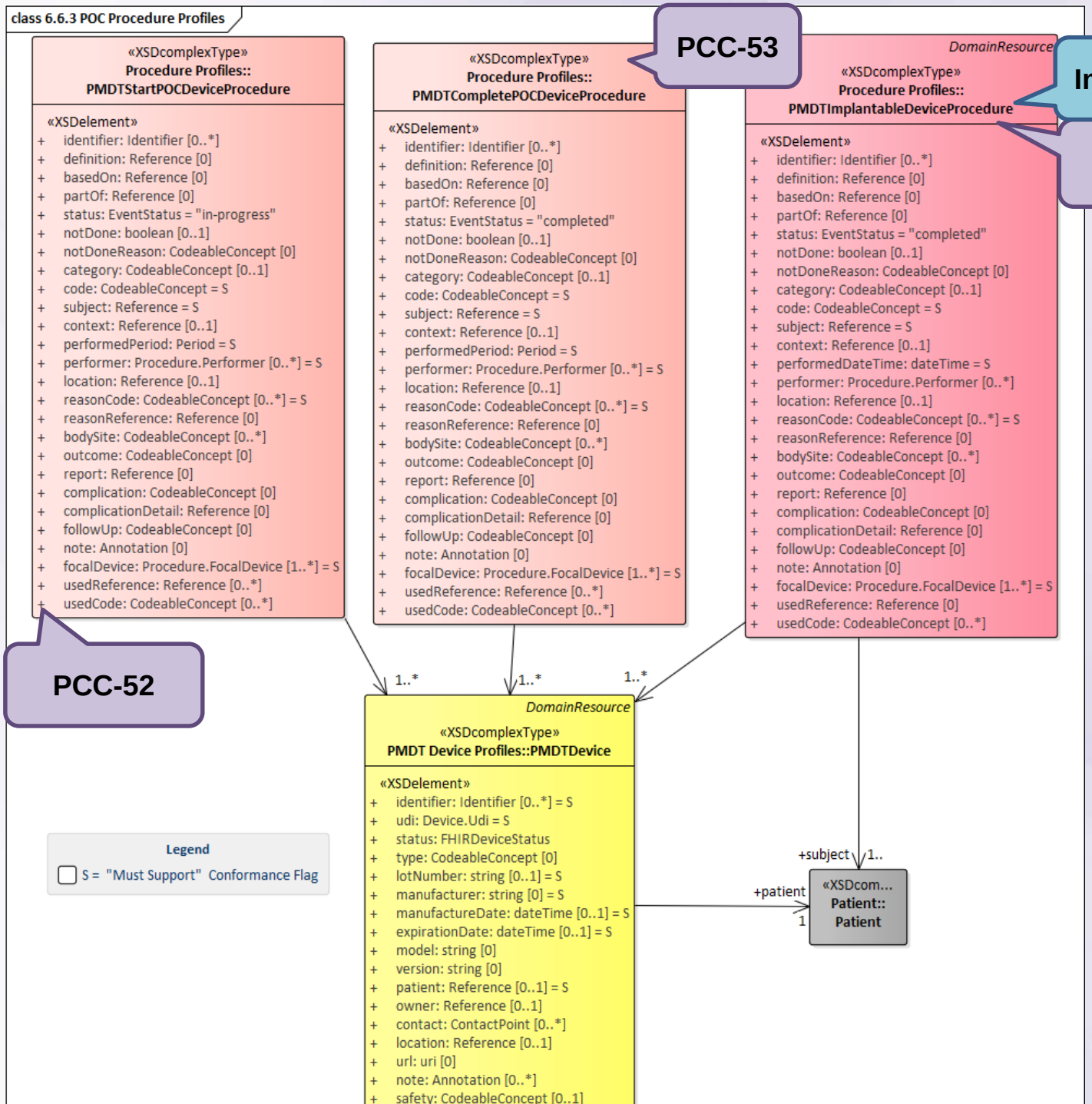



sd Search Implantable Devices from Device Registry
Search Implantable Device
-- e.g. recalled devices
-- e.g. associate with a specific condition
User
EHR System: Medical Device Requester
EHR System
Medical Device Registry: Medical Device Server
select a patient()
PCC-51
retrieve patient device list()
search Devices(Device Search Parameters): Device
implantable device records for patient specified()
add context()
PCC-54
search Procedure(Procedure Search Parameters): Procedure
associated procedure context()
display device w/ UDI and procedure context()

Content Profiles: Device



Content Profiles: Procedure



Content Profiles: Search Parameters