

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

## PROBLEM

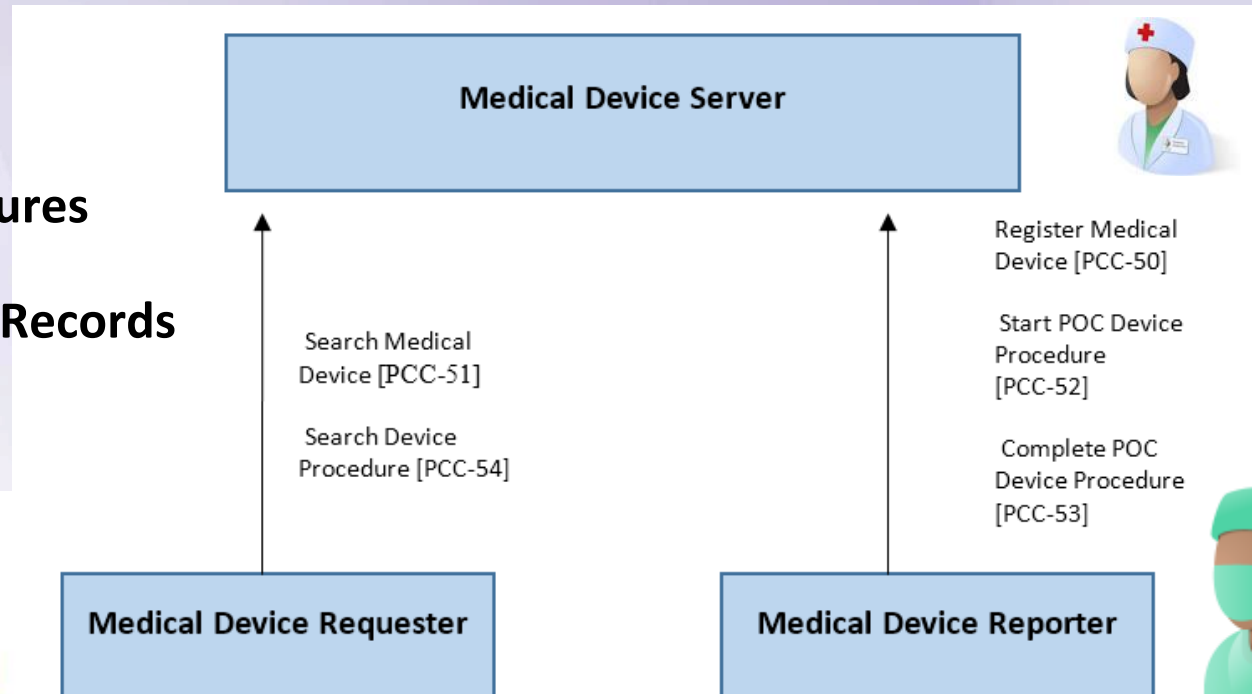
- **Implantable medical devices are costly and concerns about illegitimate (i.e., counterfeit, stolen) products has become a global issue**
- **Post-market surveillance of implantable medical devices can be challenging**
- **Implantable medical device adverse events and recalls pose a patient safety 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



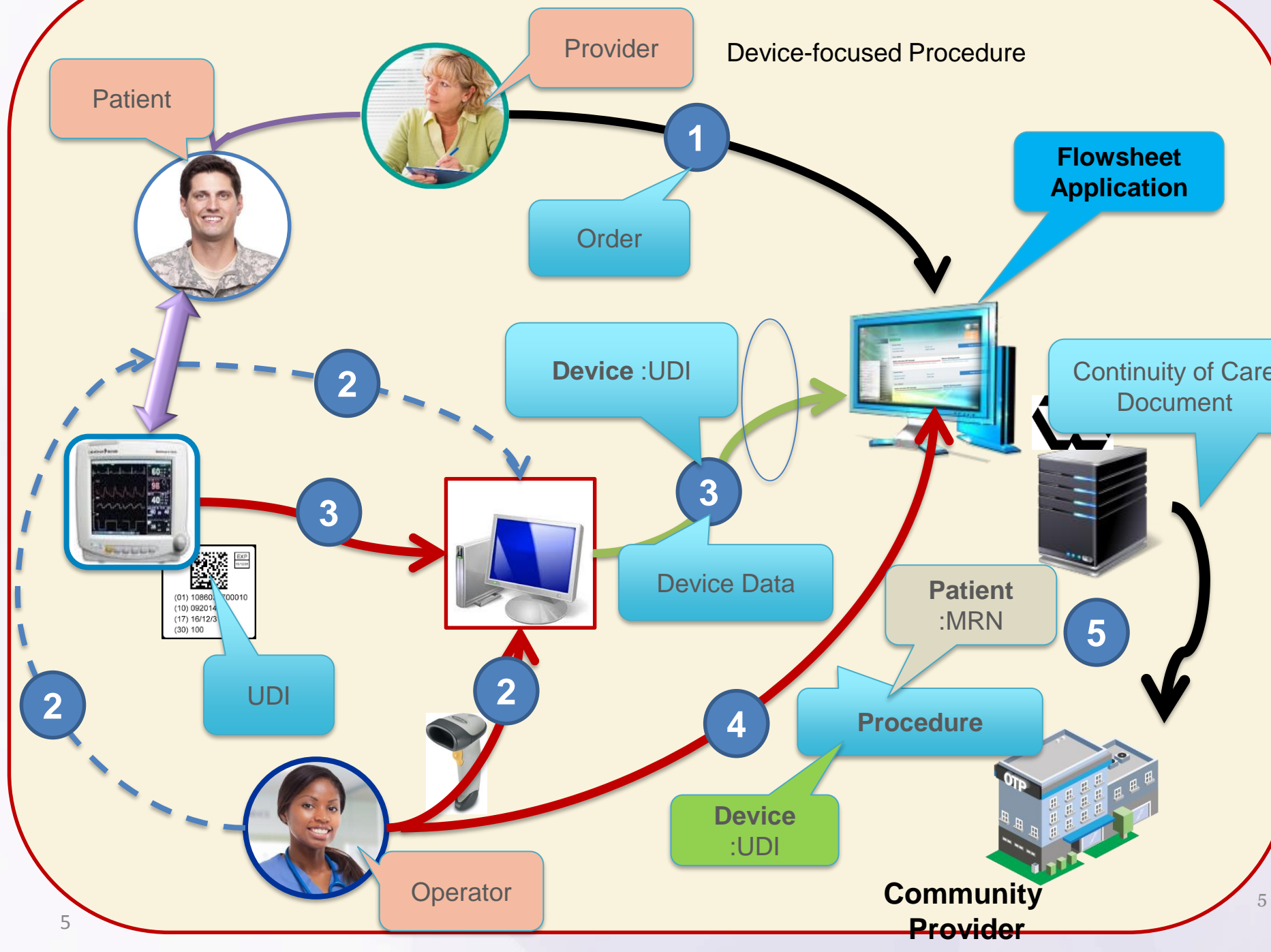
# PMDT Technical Highlights

- **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.

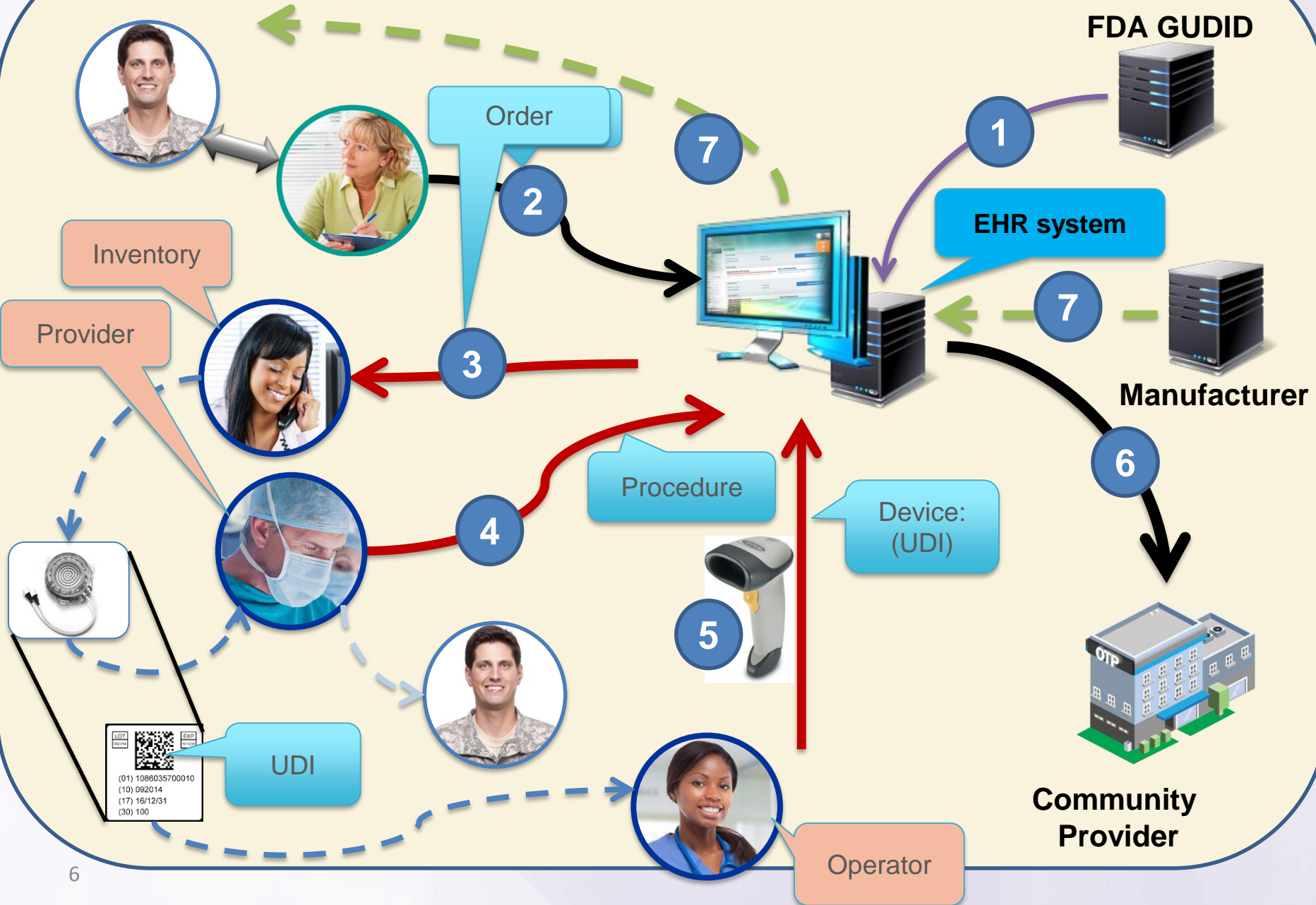
# Point-of-Care Medical Device Tracking

## 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 procedure, 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 devices
- **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)



# Tracking Implantable, Life-Supporting, or Life-Sustaining Devices



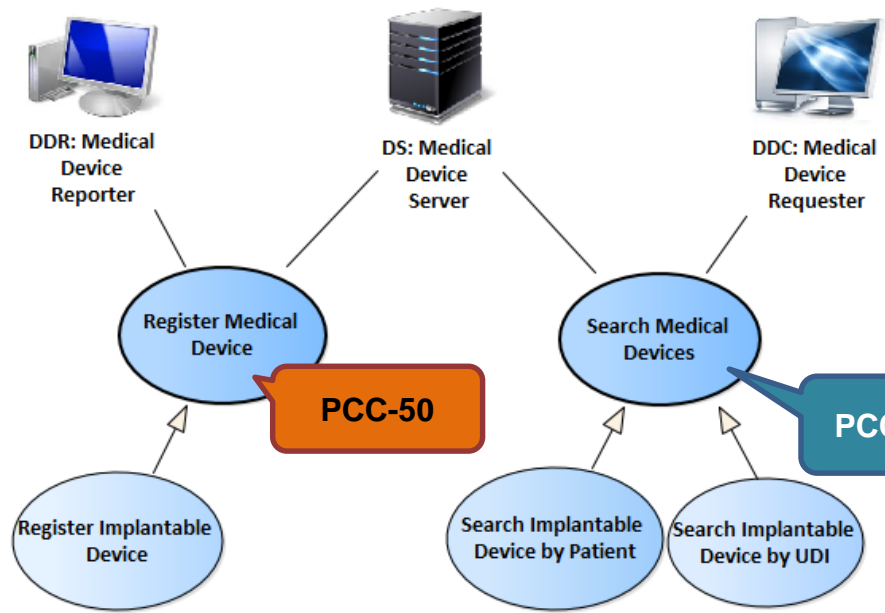


## Point-of-Care Medical Device Tracking

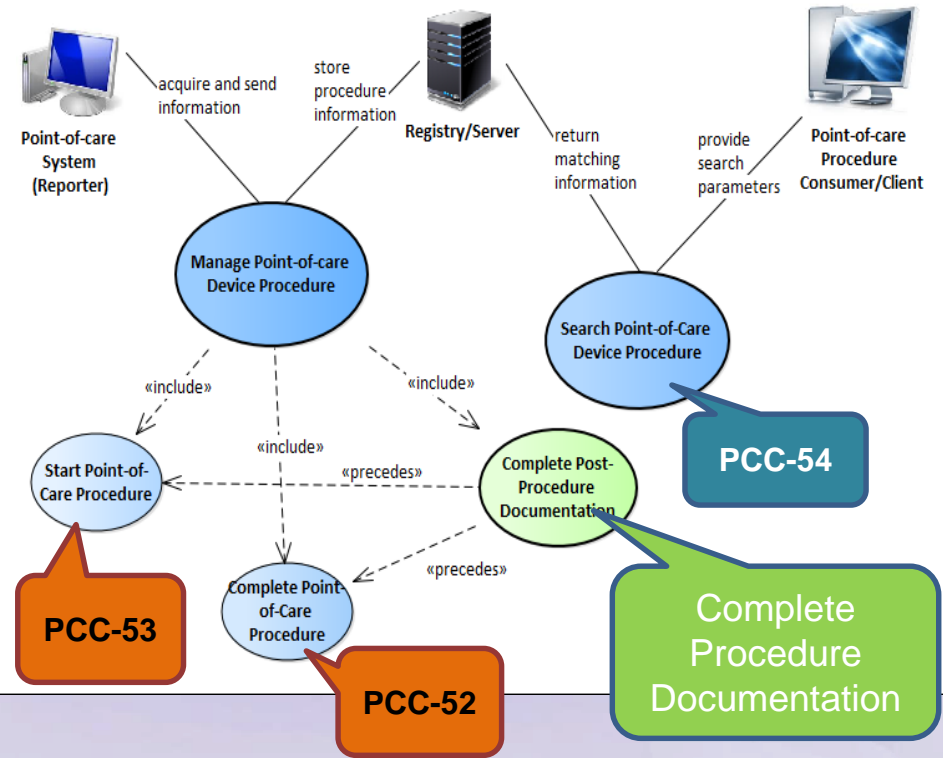
### Use Case Analysis:

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

uc Use Cases: Medical Device Registry



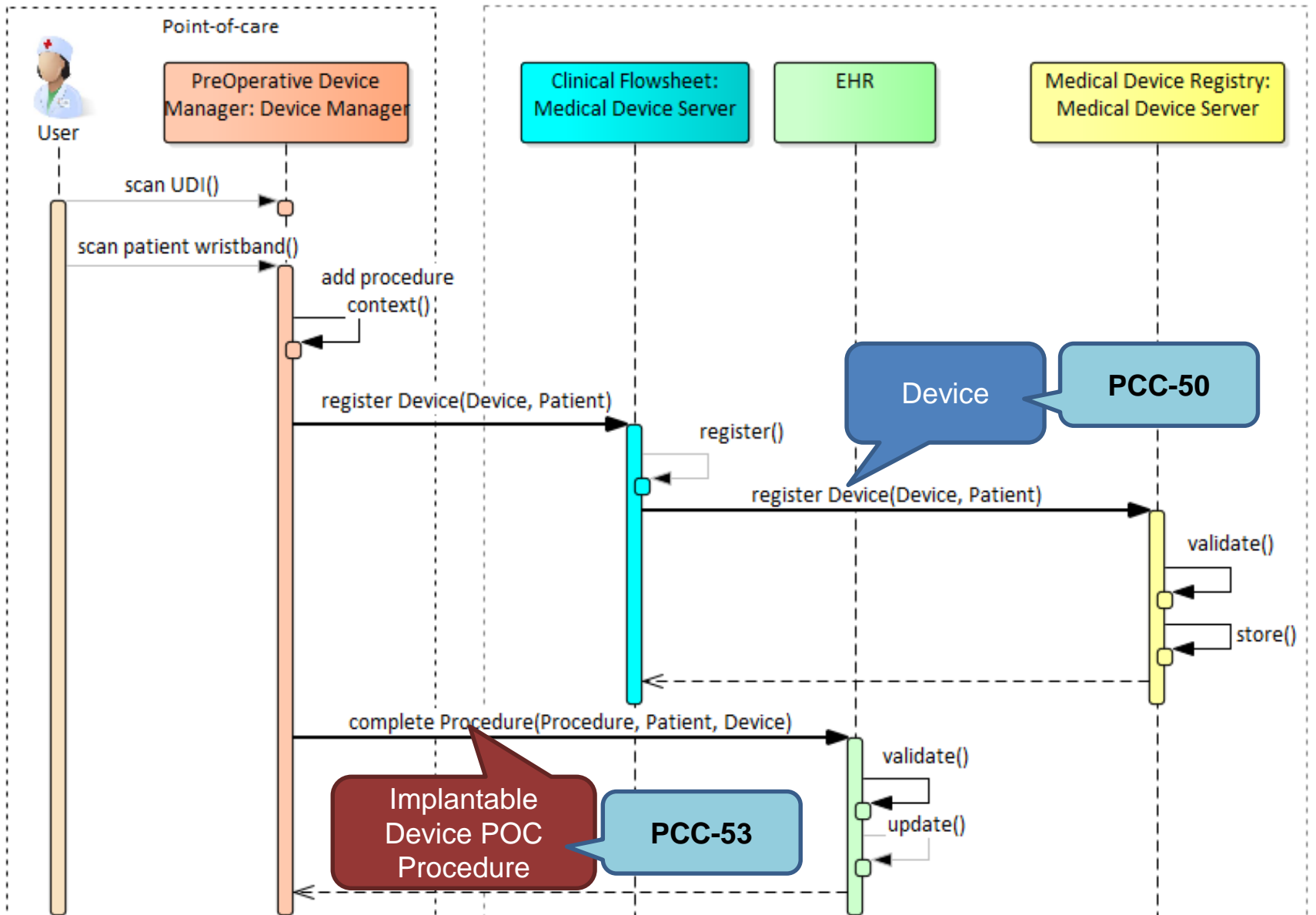
uc Use Cases: Point-of-Care Procedure



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

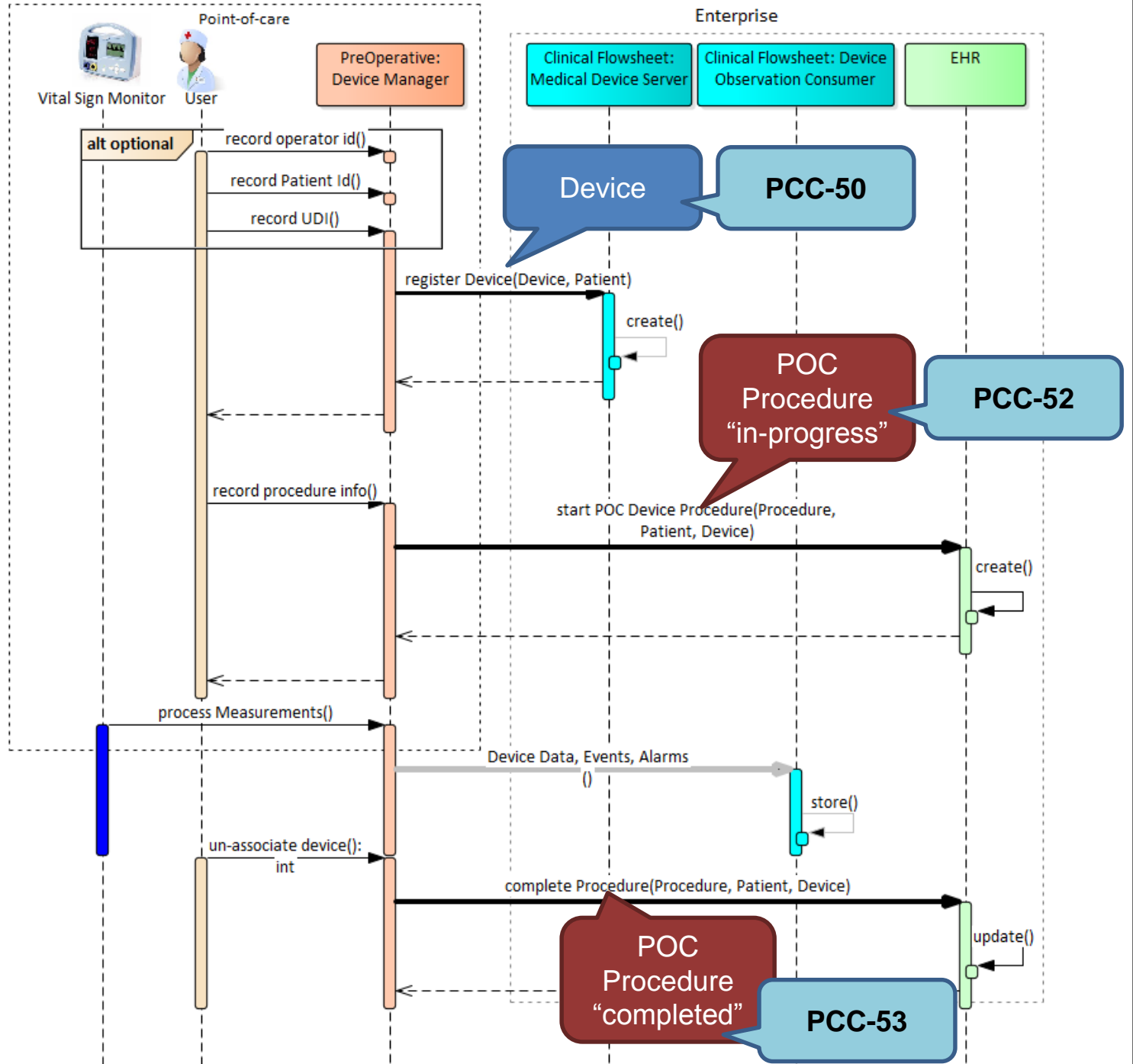
# Implantable Device Registration

sd 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()

retrieve patient device list()

search Devices(Device Search Parameters): Device

implantable device records for patient specified()

add context()

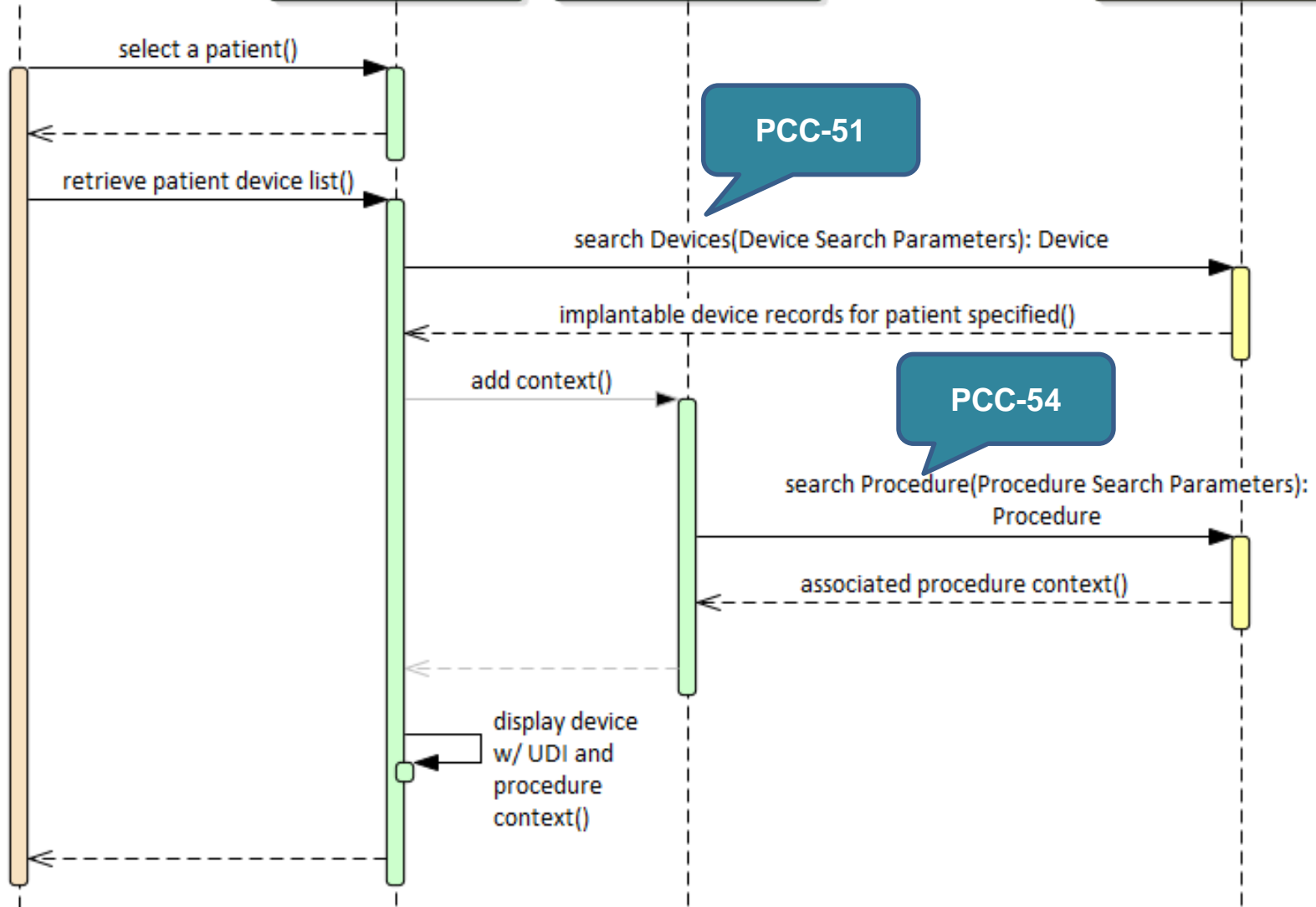
search Procedure(Procedure Search Parameters): Procedure

associated procedure context()

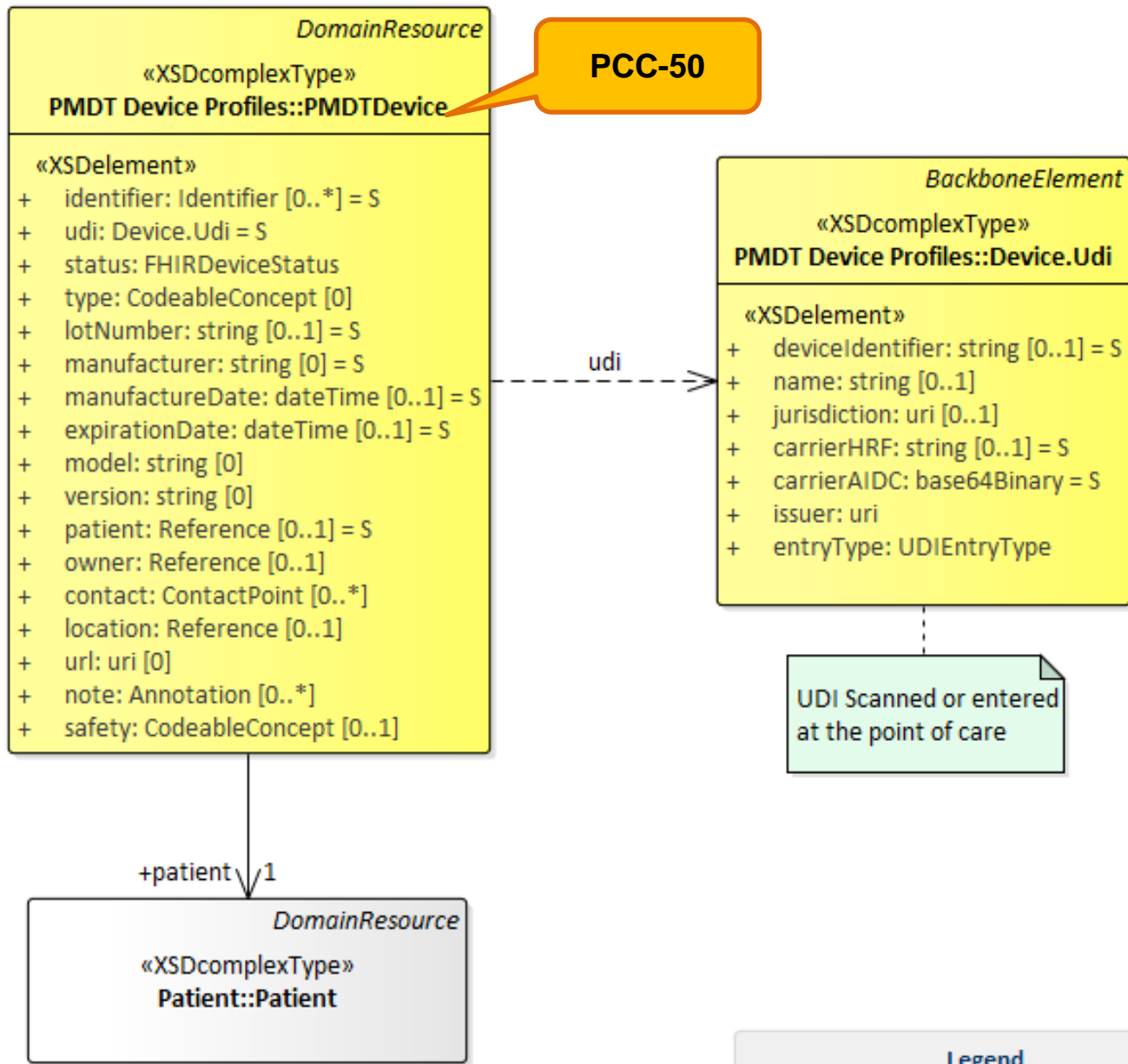
display device w/ UDI and procedure context()

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# Content Profiles: Device



PCC-50

UDI Scanned or entered at the point of care

Legend  
 S = "Must Support" Conformance Flag

# Content Profiles: Procedure

class 6.6.3 POC Procedure Profiles

```

«XSDcomplexType»
Procedure Profiles::
PMDTStartPOCDeviceProcedure

«XSDelement»
+ identifier: Identifier [0..*]
+ definition: Reference [0]
+ basedOn: Reference [0]
+ partOf: Reference [0]
+ status: EventStatus = "in-progress"
+ notDone: boolean [0..1]
+ notDoneReason: CodeableConcept [0]
+ category: CodeableConcept [0..1]
+ code: CodeableConcept = S
+ subject: Reference = S
+ context: Reference [0..1]
+ performedPeriod: Period = S
+ performer: Procedure.Performer [0..*] = S
+ location: Reference [0..1]
+ reasonCode: CodeableConcept [0..*] = S
+ reasonReference: Reference [0]
+ bodySite: CodeableConcept [0..*]
+ outcome: CodeableConcept [0]
+ report: Reference [0]
+ complication: CodeableConcept [0]
+ complicationDetail: Reference [0]
+ followUp: CodeableConcept [0]
+ note: Annotation [0]
+ focalDevice: Procedure.FocalDevice [1..*] = S
+ usedReference: Reference [0..*]
+ usedCode: CodeableConcept [0..*]
    
```

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**Legend**

S = "Must Support" Conformance Flag

```

«XSDcomplexType»
Procedure Profiles::
PMDTCompletePOCDeviceProcedure

«XSDelement»
+ identifier: Identifier [0..*]
+ definition: Reference [0]
+ basedOn: Reference [0]
+ partOf: Reference [0]
+ status: EventStatus = "completed"
+ notDone: boolean [0..1]
+ notDoneReason: CodeableConcept [0]
+ category: CodeableConcept [0..1]
+ code: CodeableConcept = S
+ subject: Reference = S
+ context: Reference [0..1]
+ performedPeriod: Period = S
+ performer: Procedure.Performer [0..*] = S
+ location: Reference [0..1]
+ reasonCode: CodeableConcept [0..*] = S
+ reasonReference: Reference [0]
+ bodySite: CodeableConcept [0..*]
+ outcome: CodeableConcept [0]
+ report: Reference [0]
+ complication: CodeableConcept [0]
+ complicationDetail: Reference [0]
+ followUp: CodeableConcept [0]
+ note: Annotation [0]
+ focalDevice: Procedure.FocalDevice [1..*] = S
+ usedReference: Reference [0..*]
+ usedCode: CodeableConcept [0..*]
    
```

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```

«XSDcomplexType»
DomainResource
Procedure Profiles::
PMDTImplantableDeviceProcedure

«XSDelement»
+ identifier: Identifier [0..*]
+ definition: Reference [0]
+ basedOn: Reference [0]
+ partOf: Reference [0]
+ status: EventStatus = "completed"
+ notDone: boolean [0..1]
+ notDoneReason: CodeableConcept [0]
+ category: CodeableConcept [0..1]
+ code: CodeableConcept = S
+ subject: Reference = S
+ context: Reference [0..1]
+ performedDateTime: dateTime = S
+ performer: Procedure.Performer [0..*]
+ location: Reference [0..1]
+ reasonCode: CodeableConcept [0..*] = S
+ reasonReference: Reference [0]
+ bodySite: CodeableConcept [0..*]
+ outcome: CodeableConcept [0]
+ report: Reference [0]
+ complication: CodeableConcept [0]
+ complicationDetail: Reference [0]
+ followUp: CodeableConcept [0]
+ note: Annotation [0]
+ focalDevice: Procedure.FocalDevice [1..*] = S
+ usedReference: Reference [0]
+ usedCode: CodeableConcept [0..*]
    
```

Implantable

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```

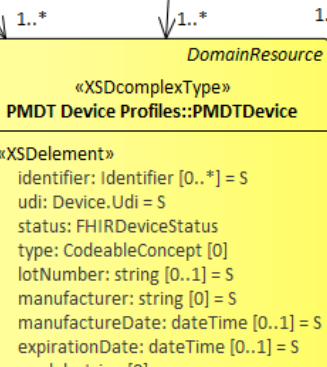
DomainResource
«XSDcomplexType»
PMDT Device Profiles::PMDTDevice

«XSDelement»
+ identifier: Identifier [0..*] = S
+ udi: Device.Udi = S
+ status: FHIRDeviceStatus
+ type: CodeableConcept [0]
+ lotNumber: string [0..1] = S
+ manufacturer: string [0] = S
+ manufactureDate: dateTime [0..1] = S
+ expirationDate: dateTime [0..1] = S
+ model: string [0]
+ version: string [0]
+ patient: Reference [0..1] = S
+ owner: Reference [0..1]
+ contact: ContactPoint [0..*]
+ location: Reference [0..1]
+ url: uri [0]
+ note: Annotation [0..*]
+ safety: CodeableConcept [0..1]
    
```

```

«XSDcom...»
Patient::
Patient

+subject 1..
+patient 1
    
```



# Content Profiles: Search Parameters

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class 6.1.17 FHIR Content Module: Search Parameters

## Device Search::Device Search Parameters

- + device-name: string
- + identifier: token
- + location: reference
- + manufacturer: string
- + model: string
- + organizatoin: reference
- + patient: reference
- + status: token
- + type: token
- + udi-carrier: string
- + udi-di: string
- + url: int

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## Point-of-Care Procedure Search : :Procedure Search Parameters

- + date: date\_
- + identifier: token
- + patient: reference
- + status: token
- + code: token