

Central Registry for Traceability (CRT)

HL7 FHIR Cookbook Version 0.1

Created by



This document is provided to you free of charge by

SMALS Fonsnylaan 20 – 1000 Brussel 20, Avenue Fonsny – 1060 Bruxelles

All are free to circulate this document with reference to the URL source.

1	Doc	cument ma	nagement	3
	1.1	Docume	nt history	3
2	Pur	pose of thi	s document	4
	2.1	Introduc	tion to the central registry for traceability	5
3	Fun	nctional des	cription of the Web services	7
	3.1	HL7 FHIR	® introduction	7
	3.1	.1 FHI	R® approach	7
		3.1.1.1	Patient	7
		3.1.1.2	ServiceRequest	10
		3.1.1.3	Procedure	12
		3.1.1.4	Practitioner	15
		3.1.1.5	Organization	18
		3.1.1.6	Device	21
		3.1.1.7	SupplyDelivery	23
		3.1.1.8	Bundle	26
		3.1.1.9	Composition	28
	3.2	CRT REST	⁻ methods	31
	3.2	.1 POS	ST /surgicalNotifications	32
		3.2.1.1	Schematic composition message	33
		3.2.1.2	Cardinalities of the FHIR [®] resources in message	33
		3.2.1.3	Full example for Implantation	34
		3.2.1.4	Full example for explantation (implant removal)	39
	3.2	.2 PU	۲/surgicalNotifications/{surgicalNotificationId}	42
		3.2.2.1	Schematic composition message	43
		3.2.2.2	Cardinalities of the FHIR [®] resources in message	44
		3.2.2.3	Full example	44
	3.2	.3 GET	surgicalNotifications	44
		3.2.3.1	Schematic composition message	45
		3.2.3.2	Cardinalities of the FHIR [®] resources in message	45
		3.2.3.3	Full example	46
4	Ref	erences		51
	4.1	Table of	figures	51
	4.2	Table of	ISON samples	51



1 Document management

1.1 Document history

Version*	Date	Author	Description of changes / remarks
0.1	20/04/2020	Patrick Moons	Initiation
0.2	25/06/2020	Sofiane Moualhi	update

Note that due to the fact that FHIR is a "next generation" standard framework, it is constantly subject to evolution.



2 Purpose of this document

This document describes the HL7 FHIR[®] message structure of the different methods of the REST Web services as offered to actors in the medical sector for the central registry for traceability.

This document is complementary to the cookbook explaining the different CRT REST Webservices methods that can be used with the system.

Only methods transferring medical information are converted into the HL7 FHIR[®] format. This document will give a detailed description of these HL7 FHIR[®] conversions for the following methods :

POST /surgicalNotifications This method creates surgical notification of implants. The request part of the method will contain the message.

• POST /surgicalNotifications/{surgicalNotificationId}

This method creates surgical notification for removal of implants based on an existing implantation notification. The request part of the method will contain the message.

• GET /surgicalNotifications

This method returns surgical notifications by searching on one of its identifiers. The response part of the method will contain the message.

• **PUT /surgicalNotifications/{surgicalNotificationsId}** This method updates surgical notifications by its identifier. The request part of the method will contain the message.

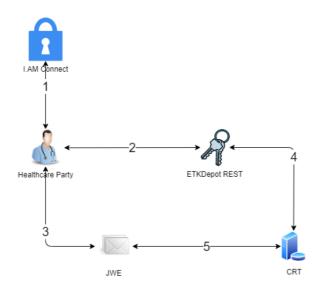
The messages will contain one single element containing the message in HL7 FHIR[®] JSON format This element will be signed using the private key of the sender, and encrypted using the public key of the recipient.

This public key can be retrieved from ETKDepot Rest. The sender of the message knows the recipient and the messages are sent directly in a synchronous way. At least 1 key must be defined for the recipient so that the sender can encrypt the message to be sent.

Messages sent to the system must be encrypted with the public key specific for the application "CRT".



Here is a high-level schema of the flow :



1. To use the endpoints, the client has to contact the I.AM Connect service to get a secure token containing his identification.

2. CRT REST endpoints require content signing and encryption. Therefore the client needs to sign its message using its private key then encrypt it using CRT public key

3. The client sends (CRUD) implant and removal notifications to CRT.

4. CRT will decrypt the message using its private key then validate the signature with the client's public key.

5. CRT provides the client answers

More details can be found in the cookbook *Central Registry Traceability (CRT) - REST Cookbook Version 1.0.pdf*

2.1 Introduction to the central registry for traceability

The main purpose of the Central Registry for Traceability (CRT) is to trace all implantable medical devices that are distributed in Belgium. This goal is achieved by allowing the healthcare actors to notify implantations and explantations, along with a series of relevant data concerning these interventions. These data are fed into this registry by two means: a Web application and a Web service (the subject of this manual).

Web application

The Web application is designed for specialists who do not have a dedicated hospital system to register implants. It allows for a more comprehensive gathering of medical information than the Web service.

The information that is captured includes some details on the prescription, delivery and the procedure itself. Procedure details contain the list of implants that where implanted or explanted during the procedure.

All this information is mandatory. For more details, see the user-guide of the Web application.

The Web application makes all of the registry's hospitalizations available to specialists by means of a search.



Web services

The REST Webservices are designed for specialists who have a dedicated (hospital) information system. The details of the medical information remain in the patient's file at the hospital, and the registry represents a summary of this information.

The integration with the dedicated information system will make a submission transparent for the specialist.



3 Functional description of the Web services

3.1 HL7 FHIR[®] introduction

3.1.1 FHIR[®] approach

FHIR[®] is a standard for health care data exchange, published by HL7[®]

The philosophy behind FHIR[®] is to use a base set of resources that, either by themselves or when combined, satisfy a majority of use cases. These use cases are usually implemented by combining resources together through the use of resource references, in other words resources referencing one another.

Overview of FHIR® resources used in CRT

The best place to start is to list the resources used by the Central Registry of Traceability and look at the definition of each resource to see what it looks like, give some background about the scope and usage and about the resource content.

The resource content described hereafter will be limited to the elements that are:

- mandatory in the HL7 FHIR[®] specification
- made mandatory through the profiling of the resource by eHealth for the standardized Belgian FHIR[®] context
- mandatory to the CRT back-end system
- •

<u>Remarks:</u>

- 1. All FHIR® resources MUST be described in JSON format
- 2. Elements of enumerated type (e.g. gender in Patient resource further on) values must be:
 - o entered in lower-case (e.g. *male, female, other, unknown*)
 - \circ without spaces
- 3. Extra resource elements delivered in a message by the client application are possible, but will be ignored in CRT processing.

3.1.1.1 Patient

This resource contains demographics and other administrative information about an individual receiving care or other health-related services.

A patient can be a Belgian patient or a foreign patient (provided he has an SSIN, Social Security Identification Number)



Detailed information for the patient can be found at <u>HL7 FHIR® Patient</u>.



3.1.1.1.1 Scope and usage

The data in the Resource covers the "who" information about the patient: its elements are focused on the demographic information necessary to support the administrative, financial and logistic procedures. A Patient record is generally created and maintained by each organization providing care for a patient.

3.1.1.1.2 Resource content by example

```
ł
  "resourceType": "Patient",
  "id": "7c24c922-eab8-41ca-b668-2b3c3f9c7fcf",
  "identifier": [
      Ł
         "system": "https://www.ehealth.fgov.be/standards/fhir/Nam
                    ingSystem/ssin",
         "value": "67031804978"
     }
  1,
  "meta": {
     "profile": [ "https://www.ehealth.fgov.be/standards/fhir/Struct
                    ureDefinition/be-patient"
     1
  },
  "name": [
      {
         "family": "Shiver",
         "given": [
             "Claude"
         1
     }
  1,
  "deceasedDateTime": "2019-11-19T10:27:59+00:00"
  "gender": "male"
```

JSON 1- Patient resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource you are describing	11	<string> <i>Patient</i></string>
identifier	An identifier - identifies some entity uniquely and unambiguously. Typically this is used for business identifiers.	1*	Only the first identifier will be treated
ldentifier.system	Establishes the namespace for the value - that is, a URL that describes a set values that are unique.	11	<uri> https://www.ehealth.fgov.be/s tandards/fhir/NamingSystem/s sin</uri>
Identifier.value	The portion of the identifier typically relevant to the user and which is unique within the context of the system.	11	<string></string>



Must be a valid Belgian SSIN¹ number

Metadata about the resource		
The profile can be used to indicate which version(s) of FHIR [®] a resource conforms to.	11	<uri> https://www.ehealth.fgov.be/s tandards/fhir/StructureDefiniti on/be-patient</uri>
A name associated with the individual.	1*	
The part of a name that links to the genealogy.	11	<string> The patient's last names tags are mandatory in the FHIR® message. However, in the checks done by the CRT, this tag will be ignored.</string>
Given name.	1*	<string> The patient's first names tags are mandatory in the FHIR® message. However, in the checks done by the CRT, this tag will be ignored.</string>
Administrative Gender - the gender that the patient is considered to have for administration and record keeping purposes.	11	<string> The patient's sex is mandatory in the FHIR® message. However, in the checks done by the CRT, this tag will be ignored one of enumeration (http://hI7.org/fhir/administrat ive-gender) : <i>male</i> <i>female</i> <i>other</i> <i>unknown</i></string>
Indicates if the individual is deceased or not	01	<datetime> If the patient is deceased this date will be returned. If there is no deceased date for the patient, the element will be omitted in the <i>Patient</i> resource.</datetime>
	The profile can be used to indicate which version(s) of FHIR® a resource conforms to. A name associated with the individual. The part of a name that links to the genealogy. Given name. Administrative Gender - the gender that the patient is considered to have for administration and record keeping purposes. Indicates if the individual is	The profile can be used to indicate which version(s) of FHIR* a resource conforms to.11A name associated with the individual.1*The part of a name that links to the genealogy.11Given name.1*Administrative Gender - the gender that the patient is considered to have for administration and record keeping purposes.11

¹ Social Security Identification Number, an identifier that corresponds to his or her 11-digit National Register number (INSS). This number has the following structure:



^{*} the first 6 digits correspond to the date of birth in the format YYMMDD, where YY=# year, MM= # month, DD= # day;

^{*} the next 3 digits correspond to the daily counter of births; this is an even number for women and an odd number for men;

^{*} the last 2 digits correspond to a control number.

The format is YYYY-MM-DDThh:mm:ss+00:00, e.g. 2019-11-19T10:27:59+00:00

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.1.1.2 ServiceRequest

This resource describes a record of a request for service such as diagnostic investigations, treatments, or operations to be performed.

Detailed information for the *ServiceRequest* can be found at <u>HL7 FHIR®</u> <u>ServiceRequest</u>.

3.1.1.2.1 Scope and usage

ServiceRequest is a record of a request for a procedure to be performed on a patient. The procedure will lead to a *Procedure* such as a clinical intervention (implantation or implant removal). The principal intention of *ServiceRequest* is to support ordering procedures for one patient. The *ServiceRequest* resource allows requesting only a single procedure.

3.1.1.2.2 Resource content by example

```
Ł
  "resourceType": "ServiceRequest",
  "id": "45b71058-3a2e-4cb4-94f3-29da4c5c303e",
  "status": "completed",
  "intent": "order",
  "code": {
      "coding": [
          ł
              "system": "http://snomed.info/sct",
              "code": "782902008",
              "display": "Implantation procedure (procedure)"
          }
     1
   },
   "subject": {
     "reference": "urn:uuid:Patient 1"
   },
   "authoredOn": "2019-11-19T10:27:59+00:00",
   "requester": {
      "reference": "urn:uuid:Practitioner_2"
   },
   "bodySite": [
     {
          "text": "Pectoral region"
      }
   1
```



}

JSON 2- ServiceRequest resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource	11	<string></string>
			ServiceRequest
status	The status of the order.	11	<string> The activity described by the request has been fully performed. <i>completed</i></string>
intent	Whether the request is a proposal, plan, an original order or a reflex order.	11	<string> The request represented a request/demand and authorization for action by a Practitioner. order</string>
code	What is being requested/ordered	11	
code.coding	Code defined by a terminology system	11	
code.coding.system	Identity of the terminology system	11	<uri> The SNOMED CT multilingual clinical healthcare terminology system is used http://snomed.info/sct</uri>
code.coding.code	Code in syntax defined by the system	11	<string> <i>Must be one of following :</i> • 782902008 - implantation procedure • 284101009 - removal of implant</string>
code.coding.display	A representation of the meaning of the code in the system.	01	<string></string>
subject	On whom or what the service is to be performed. This is usually a human patient.	11	
subject.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to a Patient resource also included in the	11	<string></string>



	FHIR [®] bundle delivered by the client.		
authoredOn	Date request signed; when the request transitioned to being actionable.	11	<datetime> The format is YYYY-MM- DDThh:mm:ss+00:00, e.g. 2019-11-19T10:27:59+00:00</datetime>
requester	The individual who initiated the request and has responsibility for its activation.	11	
requester.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to a Practitioner resource also included in the FHIR [®] bundle delivered by the client.	11	<string></string>
bodysite	Location in the body of the implant.		
bodysite.text	A textual representation of the bodylocation	01	<string></string>

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.1.1.3 Procedure

This resource describes the action that was performed on a patient. In our case it will be a physical intervention; an operation of the type implant or of the type removal of implant.



Detailed information for the *Procedure* can be found at <u>HL7 FHIR® Procedure</u>.

3.1.1.3.1 Scope and usage

This resource is used to record the details of an activity that is performed on a patient as part of the provision of care. Examples include surgical procedures, diagnostic procedures, etc... Procedures may be performed by a healthcare professional. This resource provides summary information about the occurrence of the procedure.



3.1.1.3.2 Resource content by example

```
{
   "resourceType": "Procedure",
   "id": "f9f8e333-f3ed-4e6b-88f4-c14570eed65e",
   "basedOn": [
        {
            "reference": "urn:uuid:ServiceRequest 1"
        },
    1
   "status": "completed",
   "subject": {
       "reference": "urn:uuid:Patient 1"
    },
   "performedDateTime": "2019-11-19T10:27:59+00:00",
    "performer": [
        Ł
            "actor": {
                "reference": "urn:uuid:Practitioner 1"
            },
            "onBehalfOf": {
                "reference": "urn:uuid:Organization 1"
            }
       }
   1,
    "focalDevice": [
        ł
            "manipulated": {
                "reference": "urn:uuid:Device_1"
            }
       }
   1
```

JSON 3- Procedure resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource	11	<string> <i>Procedure</i></string>
basedOn	A reference to the ServiceRequest resource that contains details of the request for this procedure.	1*	Only the first identifier will be treated
basedOn.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to the ServiceRequest resource also included in the FHIR®	11	<string></string>



	bundle delivered by the client.		
status	A code specifying the state of the procedure.	11	<string> The event has now concluded. <i>completed</i></string>
subject	On whom or what the service is to be performed. This is usually a human patient.	11	
subject.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to the Patient resource also included in the FHIR [®] bundle delivered by the client.	11	<string></string>
performedDatetime	When the procedure was performed	11	<datetime> The format is YYYY-MM- DDThh:mm:ss+00:00, e.g. 2015-02-07T13:28:17+00:00</datetime>
performer	The people who performed the procedure	1*	Only the first occurrence of performer will be registered into the CRT registry
performer.actor	The reference to the practitioner	11	
performer.actor.refe rence	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to a Practitioner resource also included in the FHIR [®] bundle delivered by the client.	11	<string></string>
performer.onBehalf Of	Organization the practitioner was acting for	11	
performer.onBehalf Of.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves	11	<string></string>



	to the location where the resource is found. In practice this will be the absolute reference to a Practitioner resource also included in the FHIR [®] bundle delivered by the client.			
focalDevice	The implanted or removed device.	1*		
focalDevice.manipul ated	The device used during the procedure	11		
focalDevice.manipul ated.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to a Device resource also included in the FHIR [®] bundle delivered by the client.	11	<string></string>	

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.1.1.4 Practitioner

This resource describes a person who is directly or indirectly involved in the provisioning of healthcare.



Detailed information for the Practitioner can be found at HL7 FHIR®

3.1.1.4.1 Scope and usage

Practitioner covers all individuals who are engaged in the healthcare process and healthcare-related services as part of their formal responsibilities and this Resource is used for attribution of activities and responsibilities to these individuals. Practitioners include (but are not limited to): physicians, dentists, pharmacists, etc...

3.1.1.4.2 Resource content by example





"resourceType": "Practitioner",



```
"id": "42581db2-ede2-4a06-a217-ea60440a7055",
"identifier": [
    ł
        "system": "https://www.ehealth.fgov.be/standards/fh
                    ir/NamingSystem/ssin",
        "value": "68031905678"
    }
1,
"meta":{
    "profile": [
        "https://www.ehealth.fgov.be/standards/fhir/Str
         uctureDefinition/be-practitioner"
    1
},
"name": [
    ł
       "family": "Kidmann",
        "given": [
            "Nicole"
        1
    }
1
```

JSON 4 - Practitioner resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource you are describing	11	<string> <i>Practitioner</i></string>
identifier	An identifier - identifies some entity uniquely and unambiguously. Typically this is used for business identifiers.	11	
Identifier.system	Establishes the namespace for the value - that is, a URL that describes a set values that are unique.	11	<uri> <i>Must either be one of the</i> <i>following two possibilities:</i> 1) If we want to identify the practitioner by his SSIN² number: <i>https://www.ehealth.fgov.be/s</i> <i>tandards/fhir/NamingSystem/s</i> <i>sin</i> 2) If we want to identify the practitioner by his NIHII³ number:</uri>

² Social Security Identification Number, an identifier that corresponds to his or her 11-digit National Register number (INSS). This number has the following structure:

- * the first 6 digits correspond to the date of birth in the format YYMMDD, where YY=# year, MM= # month, DD= # day;
- * the next 3 digits correspond to the daily counter of births; this is an even number for women and an odd number for men;
- * the last 2 digits correspond to a control number.

³ Number assigned by the National Institute for Health and Invalidity Insurance, identifying an organization in the health care sector (e.g. hospital). Note: A NIHII number can also be assigned to certain professionals in the health care sector (e.g. doctors). These numbers consist of 8 digits, to which 3 digits are added depending on the specialization in a medical domain.



			https://www.ehealth.fgov.be/s tandards/fhir/NamingSystem/ nihdin
Identifier.value	The portion of the identifier typically relevant to the user and which is unique within the context of the system.	11	<string> Must either be one of the following two possibilities: 1) if we want to identify the practitioner by his SSIN number: a valid Belgian SSIN number 2) If we want to identify the practitioner by his NIHII number : a valid NIHII number. Both 8 and 11 digits NIHII numbers are accepted.</string>
meta	Metadata about the resource	11	
meta.profile	The profile can be used to indicate which version(s) of FHIR [®] a resource conforms to.	11	<uri> https://www.ehealth.fgov.be/s tandards/fhir/StructureDefiniti on/be-practitioner</uri>
name	A name associated with the individual.	1*	
name.family	The part of a name that links to the genealogy.	11	<string></string>
name.given	Given name.	1*	<string></string>

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.1.1.5 Organization

This resource describes a (in)formally recognized grouping of people or organizations formed for the purpose of achieving some form of collective action. Includes companies, institutions, corporations, departments, community groups, healthcare practice groups, payer/insurer, etc.

H 2 Organization.

Detailed information for the Organization can be found at HL7 FHIR®

3.1.1.5.1 Scope and usage

The *Organization* resource is used for collections of people that have come together to achieve an objective.



3.1.1.5.2 Resource content by example



JSON 5 - Organization resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource	11	<string> Organization</string>
identifier	An identifier - identifies some entity uniquely and unambiguously. Typically this is used for business identifiers.	11	
identifier.system	Establishes the namespace for the value - that is, a URL that describes a set values that are unique.	11	<uri> <i>Must either be one of the</i> <i>following two possibilities:</i> 1) If we want to identify the Organization by its NIHII⁴ number : <i>https://www.ehealth.fgov.be/</i> <i>standards/fhir/NamingSystem</i></uri>

⁴ Number assigned by the National Institute for Health and Invalidity Insurance, identifying an organization in the health care sector (e.g. hospital). Note: A NIHII number can also be assigned to certain professionals in the health care sector (e.g. doctors). These numbers consist of 8 digits, to which 3 digits are added depending on the specialization in a medical domain.



			<pre>/nihdi 1) If we want to identify the Organization by its CBE⁵ number : https://www.ehealth.fgov.be/ standards/fhir/NamingSystem /cbe</pre>
identifier.value	The portion of the identifier typically relevant to the user and which is unique within the context of the system.	11	<string> Must either be one of the following two possibilities: 1) If we want to identify the Organization by its NIHII number : a valid NIHII number. Both 8 and 11 digits NIHII numbers are accepted. 2) If we want to identify the Organization by its CBE number : a valid CBE 10 digits number IF Pharmacist must be the head pharmacist of a pharmacy</string>
meta	Metadata about the resource	11	
meta.profile	The profile can be used to indicate which version(s) of FHIR [®] a resource conforms to.	11	<uri> https://www.ehealth.fgov.be/ standards/fhir/StructureDefini tion/be-organization</uri>
type	Kind of organization.	11	
type.coding	Code defined by a terminology system	11	
type.coding.system	Identity of the terminology system	11	<uri> The Healthcare Party Type: https://www.ehealth.fgov.be/ standards/fhir/NamingSystem /CD-HCPARTY</uri>
type.coding.code	Value identifies the type of health care party.	11	<string> orghospital - If we are identifying a hospital orgpharmacy - If we are identifying a pharmacy: </string>
Name	Name used for the organization	01	<string></string>
		Leger	nd

⁵ Number assigned by the Crossroads Bank of Enterprises, identifying an enterprise having activities in Belgium.



Green	Fixed values(s)	
Red	Constraint	
Pink	Element only in output	

3.1.1.6 Device

This resource describes a type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device.

Detailed information for the Device can be found at <u>HL7 FHIR® Device</u>.

3.1.1.6.1 Scope and usage

Device is an administrative resource that tracks individual instances of a device and their location. It is referenced by other resources for recording which device performed an action such as a procedure or an observation, referenced when prescribing and dispensing devices for patient use or for ordering supplies, and used to record and transmit Unique Device Identifier (UDI) information about a device such as a patient's implants.

3.1.1.6.2 Resource content by example

```
ł
    "resourceType": "Device",
    "id": "841e1c90-85ae-4e03-b80b-f7b1b1bfa9eb",
    "identifier": [
        Ł
            "system": "https://www.ehealth.fgov.be/standar
                       ds/fhir/NamingSystem/nihdi",
            "value": "000001694629"
        },
        Ł
            "type": "SADMI-PRODUCTREFERENCE",
            "value": "FJ748T"
        },
            "type": "RCT-TECHNICALID",
            "value": "83e155ca-bd87-4010-8e74-6bc19ce1183a"
        },
    1,
    "status": "active",
    "manufacturer": "Volkswagen",
    "deviceName": [
        {
            "name": "Dieteren",
            "type": "manufacturer-name"
        },
        Ł
            "name": "Passat",
            "type": "model-name"
        }
    1,
```



JSON 6 - Device resource

element id	definition	cardinality	value(s)
resourceType	The name of the resource	11	<string> Device</string>
id	Persistent identifier	11	<string></string>
identifier	An identifier - identifies some entity uniquely and unambiguously. Typically this is used for business identifiers.	1*	
identifier.system	Establishes the namespace for the value - that is, a URL that describes a set values that are unique.	<mark>01</mark>	<uri> <i>Must be the following:</i> 1) If we want to identify the <i>Device</i> by its NIHII⁶ number : <i>https://www.ehealth.fgov.be/</i> <i>standards/fhir/NamingSystem</i> /nihdi</uri>
identifier.type	Establishes the type for the value - that is, a (coded) type for the identifier that can be used to determine which identifier to use for a specific purpose.	<u>01</u>	<string> Must be one of the following: • rct-technicalid - If we want to identify the Device by its technical identification known in CRT • sadmi-productreference - If we want to identify the Device by its SADM product reference (only returned when in output !!)</string>
identifier.value	The portion of the identifier typically relevant to the user and which is unique within the context of the system.	11	<string> <i>Must be one of the following</i> <i>possibilities:</i> 1) If we want to identify the <i>Device</i> by its NIHII number : a valid NIHII number. Both 8 and 11 digits NIHII numbers are accepted. 2) If we want to identify the <i>Device</i> by its technical-id know to CRT : a UUID valid string.</string>

⁶ The NIHII implant notification code is a unique identifier for a medical device (an implant) and is attributed by the NIHDI when registering this medical device.



manufacturer Name of device manufacturer 11 <stringative strina="" stringative="" stringative<="" th=""><th>e want to identify the by its product nce: a string</th></stringative>	e want to identify the by its product nce: a string
entifierUDIStatusStatus of the device availability01 <string: </string: Must bile act device manufacturermanufacturerName of device manufacturer11 <string: </string: manufacturerdeviceNameThe name of the device as given by the manufacturer11 <string: </string: manufacturerdeviceName.nameThe name of the device11 <string: </string: manufacturerdeviceName.type11 <string: </string: manufacturerdeviceName.type11 <string: </string: manufacturerdeviceName.type11 <string: </string: manufacturerdeviceName.type11 <string: </string: manufacturer	
availability Must be availability • act device ina manufacturer Name of device manufacturer 11 deviceName The name of the device as given by the manufacturer 11 deviceName.name The name of the device deviceName.type 11 deviceName.type 11 viceName.type 11 viceName.type 11 viceName.type 11 viceName.type 11	>
manufacturer manufacturer deviceName The name of the device as given by the manufacturer 1* deviceName.name The name of the device 11 deviceName.type 11 <string:< td=""> is refer 1 1 deviceName.type 11 1</string:<>	> e one of the following: rive – for implanted vices active – for removed vices
deviceName.name The name of the device 11 <string: deviceName.type 11 <string: the name of the device 11 <string: the name of the device 11 <string: the name of the device 11 <string: the type is refer udi use</string: </string: </string: </string: </string: 	>
deviceName.type 11 <string: The typ is refer <i>udi</i></string: 	>
The typ is refer • udi • use	>
• ma	be of name the device red by. i-label-name er-friendly-name tient-reported-name inufacturer-name odel-name

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.1.1.7 SupplyDelivery

This resource describes the record of delivery of what is supplied.

Detailed information for the *SupplyDelivery* can be found at <u>HL7 FHIR®</u> <u>SupplyDelivery</u>.

⁷ The UDI-DI is a unique numeric or alphanumeric code specific to a model of device. The UDI-DI allows for the unequivocal identification if the device. It is assigned by the manufacturer in compliance with the rules of the issuing entity.



3.1.1.7.1 Scope and usage

The scope of the supply resource is for supplies used in the healthcare process. This includes supplies specifically used in the treatment of patients as well as supply movement within an institution (transport a set of supplies from materials management to a service unit (nurse station).

3.1.1.7.2 Resource content by example

```
{
   "resourceType": "SupplyDelivery",
   "id": "5alf3a26-32ad-4023-9cef-8592d78f8cb9",
   "status": "completed",
   "suppliedItem": {
        "quantity": {
           "value": "2"
        },
        "itemReference": {
            "reference": "urn:uuid:Device 2"
        }
   },
    "occurrenceDateTime": "2019-11-19T10:27:59+00:00",
    "supplier": {
       "reference": "urn:uuid:Organization 2"
    },
    "receiver": [
       -{
            "reference": "urn:uuid:Practitioner 3"
        }
   1
```

JSON 7 - SupplyDelivery resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource	11	<string> SupplyDelivery</string>
status	A code specifying the state of the dispense event.	11	<string> completed Supply has been delivered ("completed").</string>
suppliedItem	The item that is delivered or supplied	11	
suppliedItem.quant ity	Amount dispensed	11	
suppliedItem.quant ity.value	The numerical amount dispensed	11	<numerical></numerical>
suppliedtItem.item Reference	Reference of the device supplied	11	



suppliedtItem.item Reference.referenc e	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to a Device resource also included in the FHIR [®] bundle delivered by the client.	11	<string></string>
occurrenceDateTim e	Date and time when event occurred	11	<datetime> The format is YYYY-MM- DDThh:mm:ss+00:00, e.g. 2015-02-07T13:28:17+00:00</datetime>
supplier	The individual responsible for dispensing the medication, supplier or device.	11	
supplier.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to an Organization resource (pharmacy) also included in the FHIR [®] bundle delivered by the client.	11	<string></string>
receiver	Identifies the person who picked up the Supply.	1*	Only the first occurrence of receiver will be registered into the CRT registry
receiver.reference	A reference to a location at which the other resource is found. The reference is the absolute URL that resolves to the location where the resource is found. In practice this will be the absolute reference to a Practitioner (pharmacyst) resource also included in the FHIR [®] bundle delivered by the client.	11	<string></string>

Legend



Green	Fixed values(s)	
Red	Constraint	
Pink	Element only in output	

3.1.1.8 Bundle

Bundles are used as a container for a collection of resources.



Detailed information for the *Bundle* can be found at <u>HL7 FHIR® Bundle</u>.

3.1.1.8.1 Scope and usage

One common operation performed with *Bundle* resources is to gather a collection of resources into a single instance with containing context. In FHIR[®] this is referred to as "bundling" the resources together. These resource bundles are useful for a variety of different reasons, including:

- Returning a set of resources that meet some criteria as part of a server operation e.g. a search operation
- Grouping a self-contained set of resources to act as an exchangeable and persistent collection with clinical integrity e.g. a clinical document
- Creating/updating/deleting a set of resources on a server as a single operation

3.1.1.8.2 Resource content by example

"resourceType": "Bundle", "id": "9991a0fa-8bc8-48e0-add8-cf08123c7424", "meta": { "source": "UZGent" }, "type": "transaction", "timestamp": "2015-02-07T13:28:17+00:00", "entry": [ł "fullUrl": "urn:uuid:Patient_1", "resource" : { . . . the resource }, "request": { "method": "POST", "url": "Patient" } } 1

JSON 8 - Bundle resource



element id	definition	cardinality	value(s)
resourceType	The name of the resource	11	<string> Bundle</string>
id	Persistent identifier for the bundle	11	<string></string>
meta	Metadata about the resource	11	
meta.source	Identifies where the resource comes from: i.e. the name of the system that composed the bundle	11	<uri> In the context of the implant registry, the sender of the message is always a hospital or a specialist working in a private practice.</uri>
type	Indicates the purpose of this bundle - how it is intended to be used.	11	<string> transaction - The bundle is a transaction - intended to be processed by a server as an atomic commit → incomming request searchset - The bundle is a list of resources returned as a result of a search/query interaction, operation, or message → outgoing response </string>
timestamp	When the bundle was assembled.	11	<datetime> The format is YYYY-MM- DDThh:mm:ss.sss+zz:zz, e.g. 2015-02- 07T13:28:17.295+00:00</datetime>
entry	Entry in the bundle - will have a resource or information	1*	
entry.fullUrl	URI for resource (Absolute URL server address or URI for UUID/OID).	11	<uri> The identifier that other resources will use to reference this resource.</uri>
entry.resource	The resource in the bundle	11	<string> SHOULD be a resource of following type: • ServiceRequest • Patient • Procedure • Practitioner • Organization • Device • SupplyDelivery • Composition</string>



			Other types of resource will be skipped and thus not be treated by the CRT registry system
entry.request	Information on how process this resource entry as part of the transaction	11	MUST be present when type of bundle = 'transaction'
entry.request.meth od	The HTTP action to be executed for this entry	11	<string> MUST be : POST</string>
entry.request.url	The URL for this entry, relative to the root (the address to which the request is posted)	11	<string> <i>MUST be the name of the</i> <i>resource :</i> <i>e.g. Patient</i></string>

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.1.1.9 Composition

This resource describes a set of healthcare-related information that is assembled together into a single logical package that provides a single coherent statement of meaning, establishes its own context and that has clinical attestation with regard to who is making the statement. A *Composition* defines the structure and narrative content necessary for a document.

•••• ===

Detailed information for the *Composition* can be found at <u>HL7 FHIR® Composition</u>.

3.1.1.9.1 Scope and usage

A *Composition* is the basic structure from which FHIR[®] Documents - immutable bundles with attested narrative - are built. A single logical composition may be associated with a series of derived documents, each of which is a frozen copy of the composition. In RCT we will halt at composition level for delivering notification information from the registry.



CRT – Manual for using the webservices

```
1
},
"subject": { "reference": "#Patient-1" },
"date": "2013-02-01T12:30:02Z",
"author": [
   { "reference": "#Patient-1" }
1,
"title": "Notification Summary",
"confidentiality": "N",
"section": [
   {
       _____",
       "code": {
       "coding": [
          -{
              "system": "http://snomed.info/sct",
              "code": "116154003",
"display": "Patient (person)"
          }
       1
       },
       "entry": [
          - {
              "reference": "#Patient-1"
          }
       1
  }
1
```

JSON 9 - Composition resource

element id	definition	cardinality	value(s)
id	Persistent identifier	11	<string></string>
resourceType	The name of the resource	11	Composition
contained	Contained, inline Resources (see definitions of all resources above)	1*	<resource> SHOULD be a resource of following type: • ServiceRequest • Patient • Procedure • Practitioner • Organization • Device • SupplyDelivery Other types of resource will be skipped and thus not be treated by the CRT registry system</resource>
status	The status of the composition	11	<string> preliminary final - This version of the composition is complete and verified </string>



			amendedentered-in-error
type	Kind of composition (LOINC if possible)	11	
type.coding	Terminology system defining Kind of composition	11	
type.coding.system	Identity of the terminology system	11	<uri> http://loinc.org LOINC encoding system</uri>
type.coding.code	Value identifies the type of composition.	11	<string> <i>57080-4</i> - Implanted medical device Narrative</string>
subject	Who and/or what the composition is about	11	
subject.reference	Reference to the contained Patient resource	11	<string></string>
date	Composition editing time	11	<datetime> The format is YYYY-MM- DDThh:mm:ss+00:00, e.g. 2015-02- 07T13:28:17+00:00</datetime>
author	Who and/or what authored the composition	11	
author.reference	Reference to the contained Patient resource	11	<string></string>
title	Human Readable name/title of the composition	11	<string> Notification Summary</string>
confidentiality	Confidentially code for the composition	01	one of enumeration U L M N – normal R V
section	Composition is broken into sections	1*	
section.title	Human readable label for section	11	<string></string>
section.code	Classification of section (recommended)	11	
section.code.codin g	Code defined by a terminology system	11	
section.code.codin g.system	Identity of the terminology system	11	<uri> http://snomed.info/sct</uri>



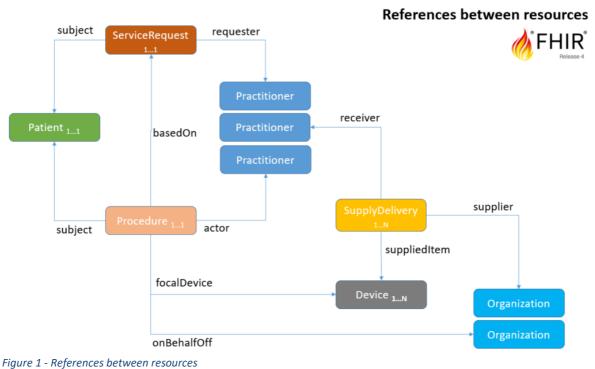
section.code.codin g.code	Value identifies the context of the section	11	<string> 116154003 - Patient (person) 373655009 - Medical service (procedure) 370852006 - Recording of devices implanted during operative procedure </string>
section.code.codin g.display	Human Readable code value text	11	
section.entry	A reference to data that supports this section; i.e. a reference to contained resources	0*	
section.entry.refer ence	Reference to contained resources	11	<string></string>

Legend	
Green	Fixed values(s)
Red	Constraint
Pink	Element only in output

3.2 CRT REST methods

Whenever a client application executes a CRT REST method, a collection of resources will be received from or delivered to that client application. In order to handle these collections, HL7 FHIR uses *Bundle* and *Composition* resources. These *Bundle* and *Composition* resources are to be seen as containers for holding other resources. Inside these containers the resources are linked together. Independent of the method invoked by the client, the general scheme for linking resources in the CRT context is :





rigure 1 - Rejerences between resources

3.2.1 POST /surgicalNotifications

This method allows healthcare actors to notify the <u>implantation</u> of different implants to the registry.

This method allows healthcare actors to also notify the <u>removal</u> of different implants to the registry. Only the removal of implants that have been previously notified as "implanted" will be accepted by the registry. Removal of implants that are implanted but have never been notified cannot be registered into the registry.

Since we must refer to implanted medical devices already notified to CRT in the past, we provide a reference of that previous implantation using a technical ID parameter with the method. This parameter has "type": "RCT-TECHNICALID" and "value": "83e155ca-bd87-4010-8e74-6bc19ce1183a" (as example).

The request part of the method will contain the message. Only one FHIR[®] message a time is allowed to be reported. This single FHIR[®] message always concerns a single patient getting a single implantation. The message itself is a bundle collection of different FHIR[®] resources.

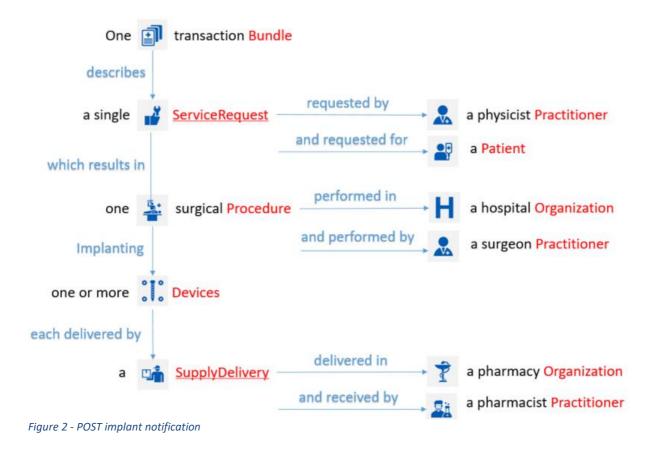
The FHIR[®] resources needed to compose a valid implantation notification into the registry will be described hereafter. Of each FHIR[®] resource the cardinality will be given; this is the number of times that FHIR[®] resource can occur in the message.

At the end of the chapter, a full example of a valid FHIR® request/response will be included.



At the end of the chapter, a full example of a valid FHIR[®] request/response will be included.

3.2.1.1 Schematic composition message



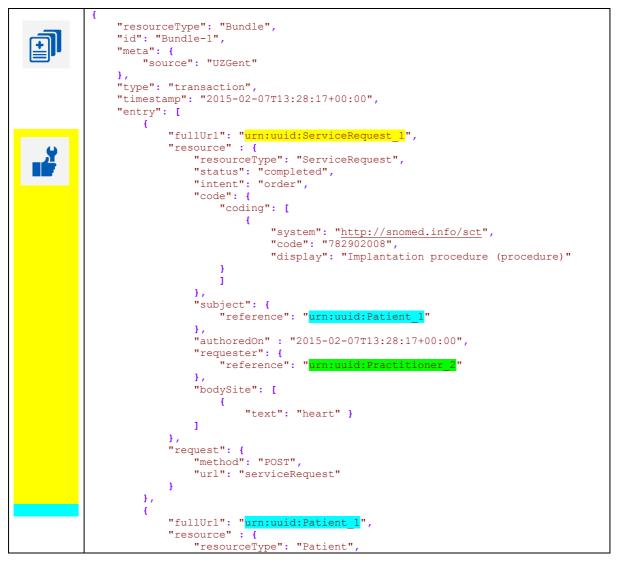
3.2.1.2 Cardinalities of the FHIR® resources in message

Resource	Cardinality	Remark
Bundle	1	Wrapper or container which contains all the resources used in the implant notification
ServiceRequest	1	Only one implant <i>ServiceRequest</i> a time is possible
Procedure	1	One and only one (surgical) procedure associated with the <i>ServiceRequest</i> ; <i>ServiceRequest</i> and <i>Procedure</i> must exist together

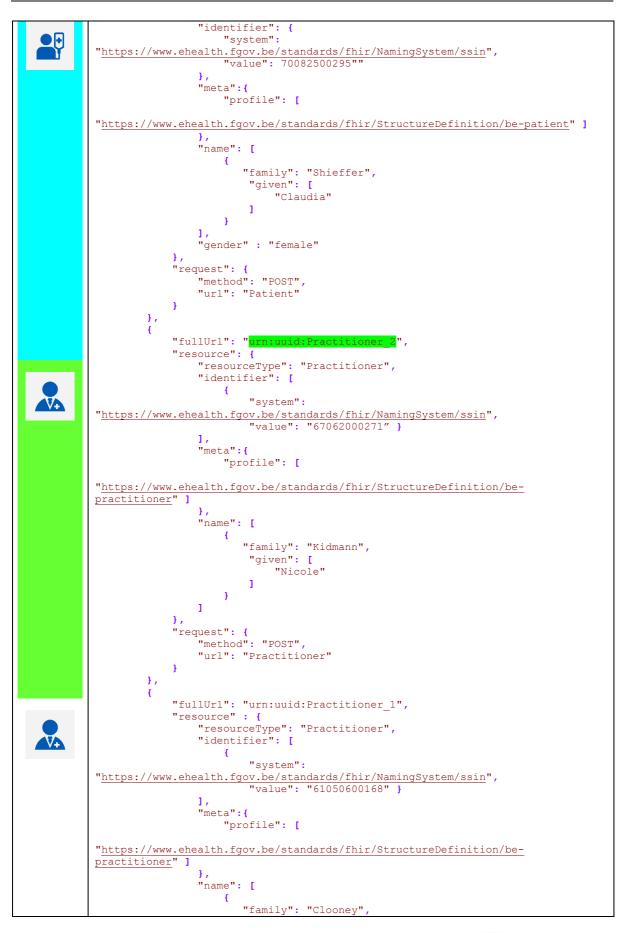


• • • Device	1N	One or more devices implanted into the patient. Multiple implants possible, at least 1 required.
SupplyDelivery	1N	Same cardinality as <i>Device</i> ; for each Device a <i>SupplyDelivery</i> must exist one device -> one delivery
Patient	1	The only patient subject of the implantation
/ 💐 Practitioner	1M	Requester, performer and pharmacist can all be different persons or all be the same person.
H / T Organization	1K	The hospital and pharmac(ies) could be the same or all be different.

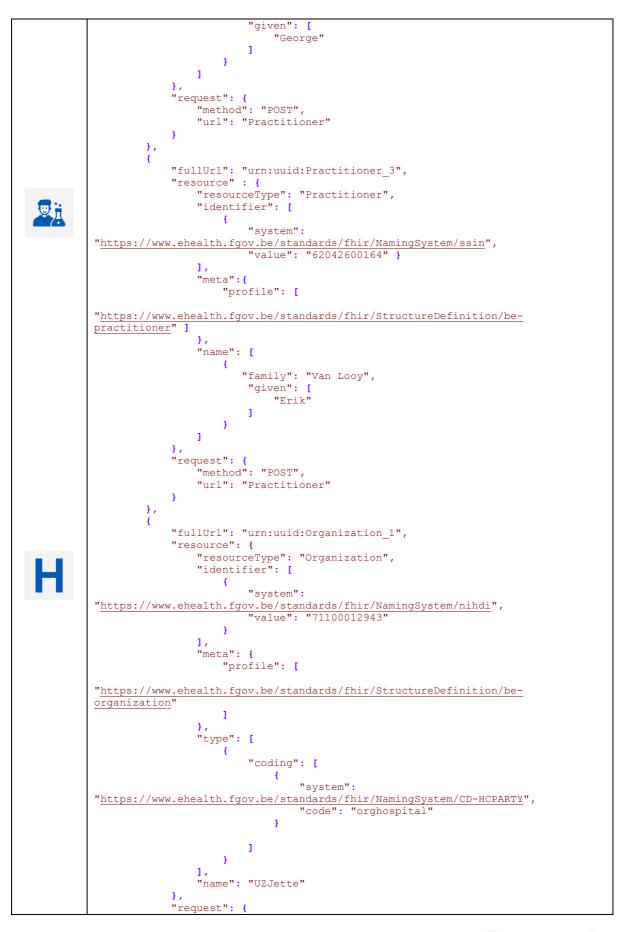
3.2.1.3 Full example for Implantation



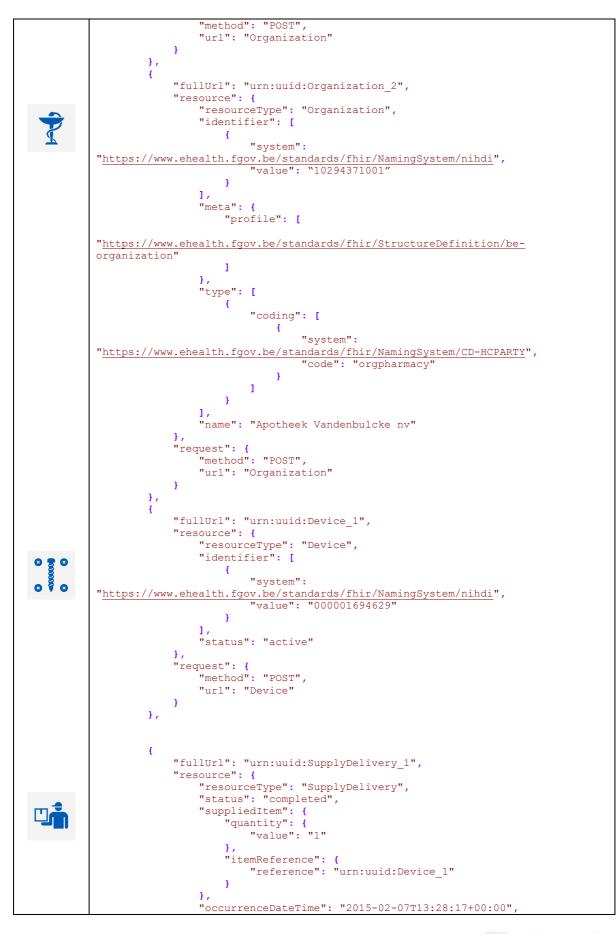




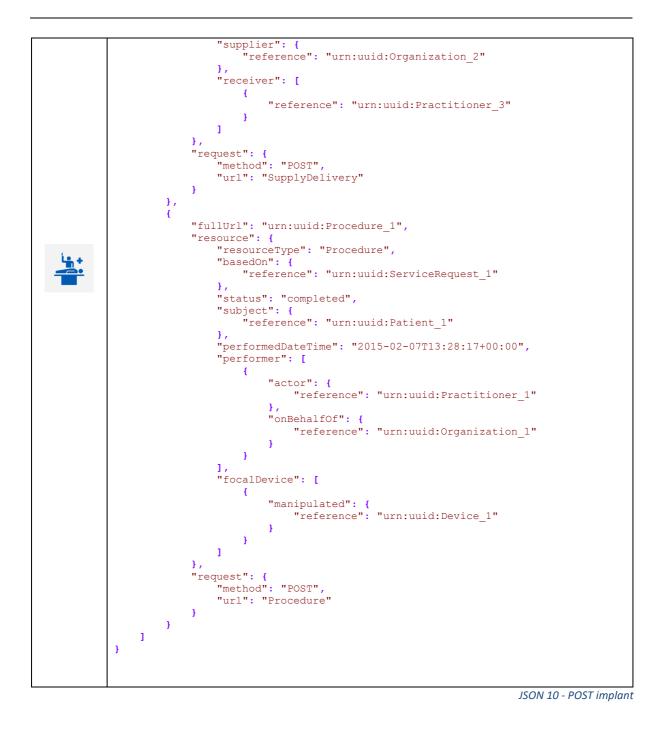






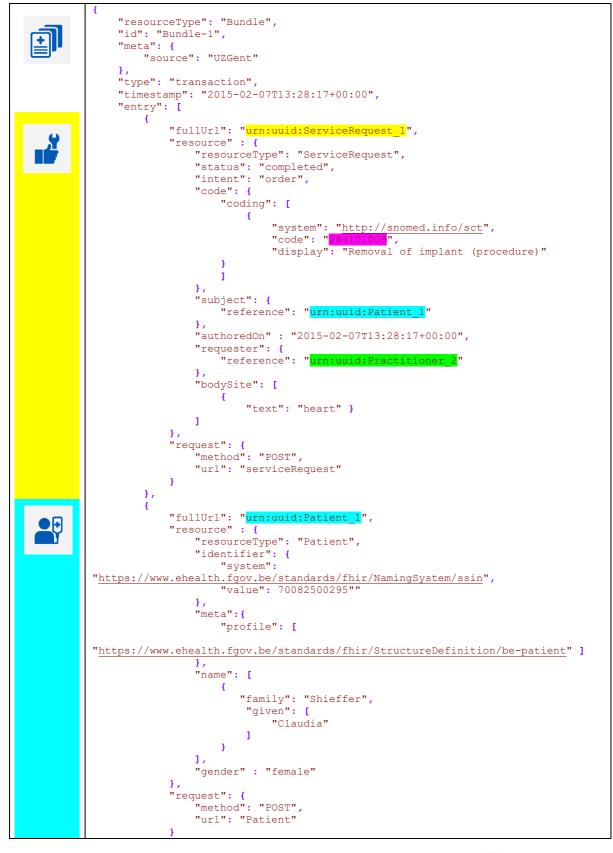




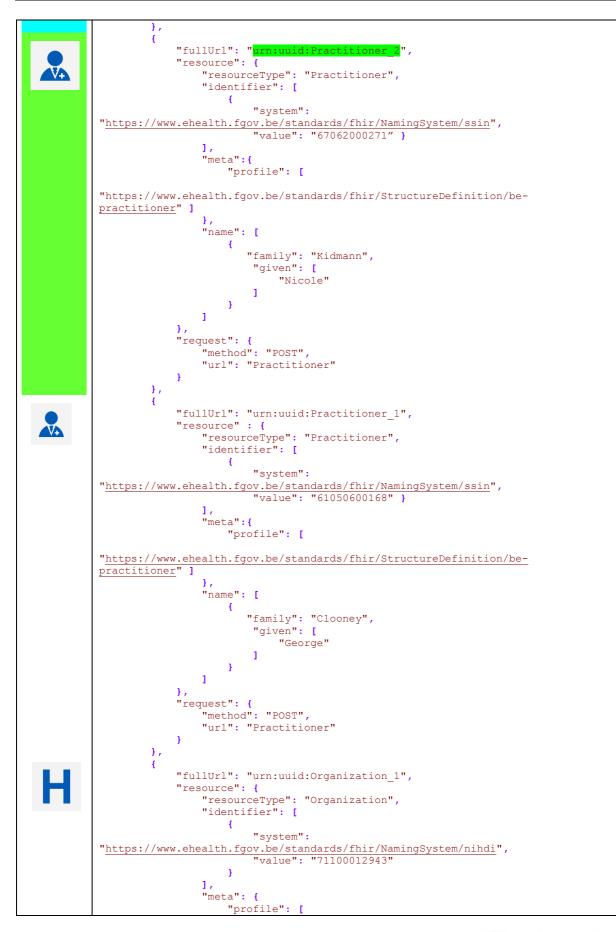




3.2.1.4 Full example for explantation (implant removal)















3.2.2 PUT /surgicalNotifications/{surgicalNotificationId}

This method allows healthcare actors to update existing surgical notifications (implant or implant removal notifications) by its identifier.

This method is to be seen as performing two steps :

- 1. The old *surgicalNotifications* referenced by the *surgicalNotificationId* is logically deleted in the registry and thus leaving a historical trace.
- 2. A new *surgicalNotifications* is created with a new *surgicalNotificationId* returned in output.

Schematically this gives us :

If an old erroneous notification in the registry as given below . . .



. . . is corrected by the method

PUT /surgicalNotifications/201910303220266

... this will result in the following situation in the registry ...

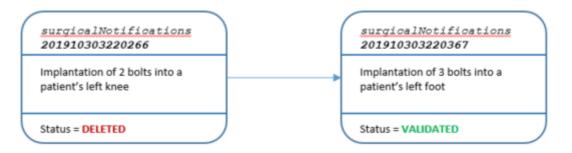


Figure 3 - PUT implant/removal notification



The path parameter *surgicalNotificationsId* in the method references the notification to be corrected. The request part of the method contains the modified notification message.

The collection of FHIR[®] resources needed to compose a valid modification notification into the registry system will be described hereafter. Of each FHIR[®] resource the cardinality will be given; this is the number of times that resource can occur in the message.

At the end of the chapter, a full example of a valid FHIR[®] request/response will be included.

3.2.2.1 Schematic composition message

Depending on the type of the existing message to change in the CRT registry, the message schematic will be :

- either the one of an <u>implantation</u>
- either the one of a <u>removal</u>



3.2.2.1.1 Schematic composition implant message

For this we refer to the use case 3.2.1.1

3.2.2.1.2 Schematic composition removal message

For this we refer to the use case 1.1.1.1

3.2.2.2 Cardinalities of the FHIR® resources in message

Depending on the type of the existing message to change in the CRT registry, the message, the cardinalities for the FHIR[®] resources will be :

- either the one of an <u>implantation</u>
- either the one of a <u>removal</u>

3.2.2.2.1 Cardinalities of the FHIR® resources in implant message

For this we refer to the use case 3.2.1.2

3.2.2.2.2 Cardinalities of the FHIR® resources in removal message

For this we refer to the use case 1.1.1.1

3.2.2.3 Full example

Depending on the type of the existing message to change in the CRT registry, the full message will be :

- either the one of an implantation
- either the one of a <u>removal</u>

3.2.2.3.1 Full example implant message

For this we refer to the use case 3.2.1.3

3.2.2.3.2 Full example removal message

For this we refer to the use case 3.2.1.4

3.2.3 GET /surgicalNotifications

This method allows healthcare actors to retrieve surgical notifications from the registry. By providing parameters to the retrieval method, searches can be performed in a variety of ways: search by notification identifier, retrieve all notifications for a given patient, retrieve all notifications of patients given a specific medical device, perform date ranges on the query result etc... Our goal is not to explain the correct usage of these parameters (see eHealth documentation of CRT), instead we will focus on the results returned by this method.

The result will be a *Bundle*, a collection of zero, one or more *Compositions* (hence notifications). A *Composition* on its turn is a set of healthcare-related information assembled together into a single logical package that provides a single coherent statement of meaning.

The response part of the method will contain the message. The collection of FHIR[®] resources returned from the registry system will be described hereafter. Of each FHIR[®] resource the cardinality will be given; this is the number of times that FHIR[®] resource can occur in the message.



At the end of the chapter, a full example of a valid FHIR[®] response will be included.

3.2.3.1 Schematic composition message

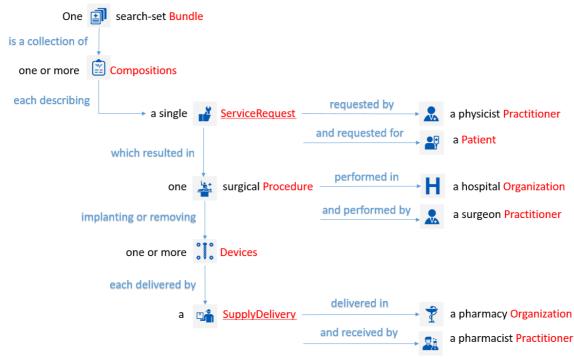


Figure 4 - GET implant/removal notification(s)

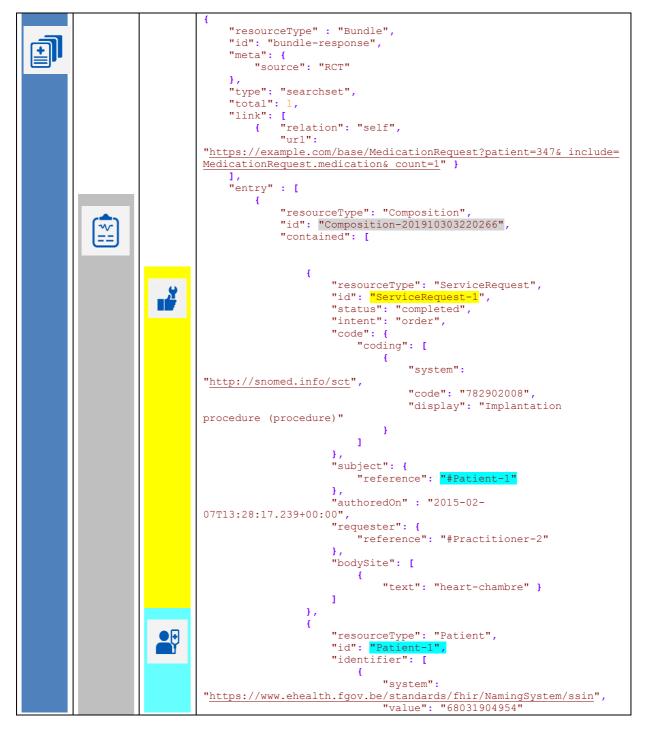
3.2.3.2 Cardinalities of the FHIR® resources in message

Resource	Cardinality	Remark
Bundle	1	Searchset wrapper or container which contains the composition(s) describing the implant/implant removal notification(s)
Composition	1X	One or more <i>Compositions</i> are returned in the <i>Bundle</i> depending on the search performed.
ServiceRequest	1X	One or more explant/implant ServiceRequest(s) – one and only one for each Composition
Procedure	1X	One or more (surgical) <i>Procedure</i> (s); one and only one for each <i>ServiceRequest</i>
• • • Device	1N	One or more <i>Devices</i>
SupplyDelivery	1N	Same cardinality as <i>Device</i> ; for each <i>Device</i> a <i>SupplyDelivery</i> must exist one device -> one delivery. Only present when the <i>Composition</i> is an implant.

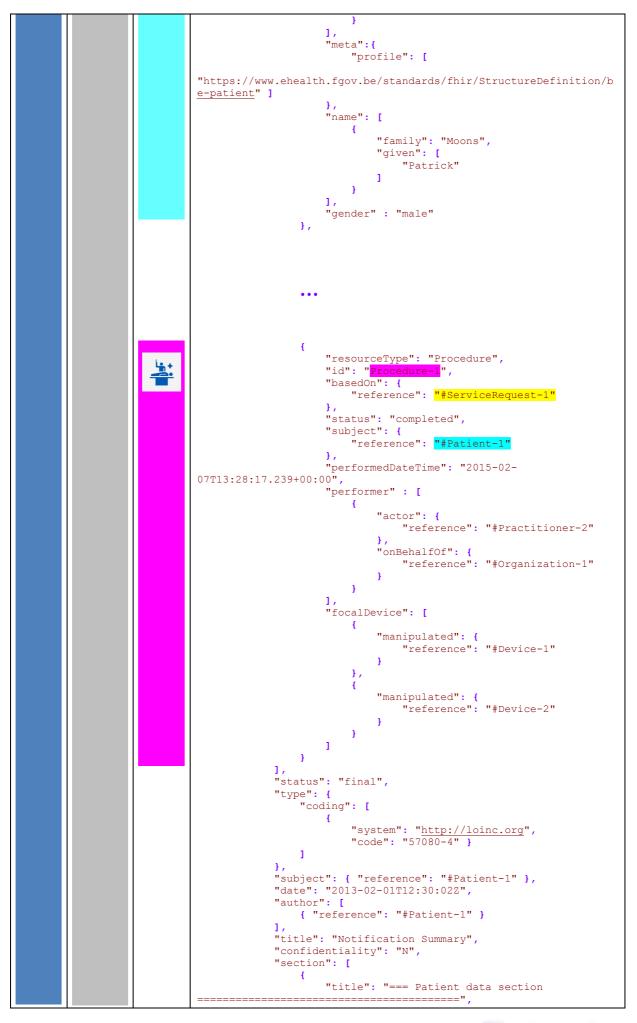


Patient	1X	One or more <i>Patient</i> subject(s) – one and only one for each <i>ServiceRequest</i>
/ Practitioner	1M	Requester, performer and pharmacist can all be different persons or all be the same person. Numbers can vary for each <i>Composition</i> .
H / T Organization	1K	The hospital and pharmac(ies) could be the same or all be different. Numbers can vary for each <i>Composition</i> .

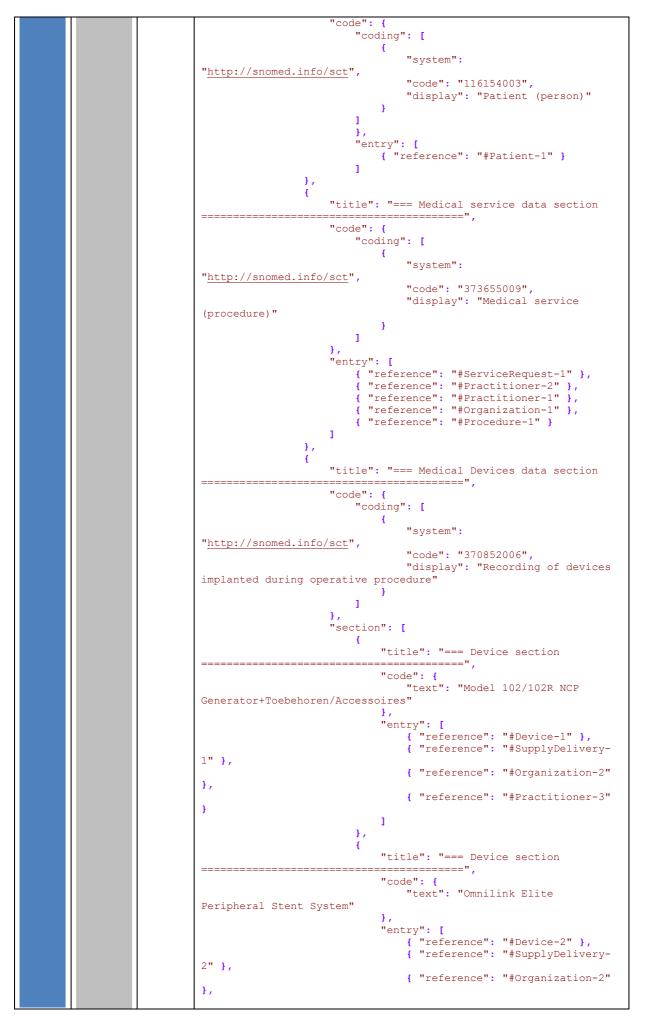
3.2.3.3 Full example



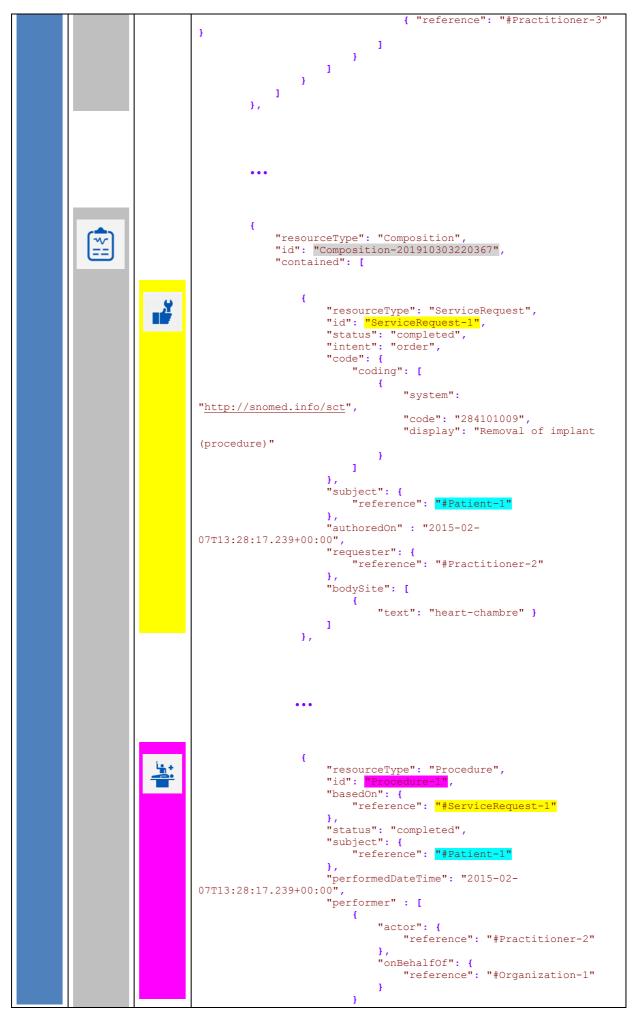




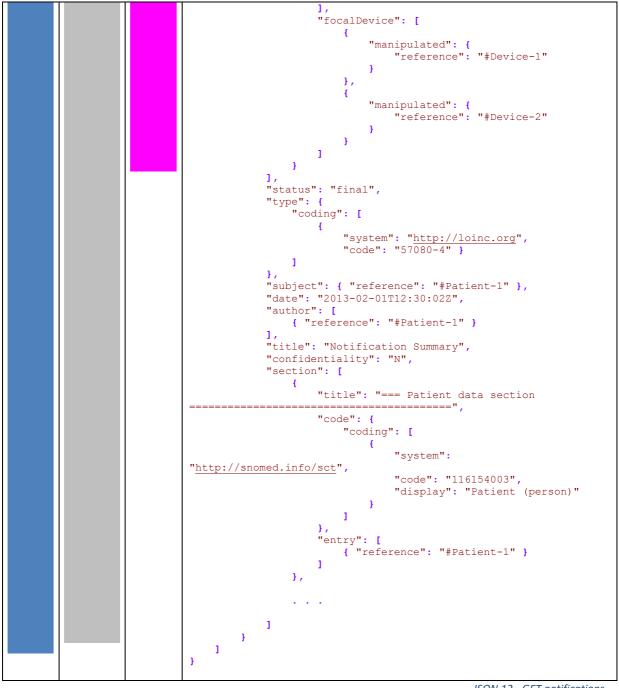












JSON 12 - GET notifications



4 References

4.1 Table of figures

Figure 1 - References between resources	32
Figure 2 - POST implant notification	33
Figure 3 - POST implant removal notification	39
Figure 4 - PUT implant/removal notification	42
Figure 5 - GET implant/removal notification(s)	

4.2 Table of JSON samples

JSON 1- Patient resource	8
JSON 2- ServiceRequest resource	11
JSON 3- Procedure resource	13
JSON 4 - Practitioner resource	17
JSON 5 - Organization resource	19
JSON 6 - Device resource	22
JSON 7 - SupplyDelivery resource	24
JSON 8 - Bundle resource	26
JSON 9 - Composition resource	29
JSON 10 - POST implant	
JSON 11 - POST implant removal	42
JSON 12 - GET notifications	50

