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Complemento 2.2 all'allegato 5 dell'ordinanza del DFI del 22 marzo 2017 sulla cartella informatizzata
del paziente

Profili d'integrazione nazionale secondo l'articolo 5
capoverso 1 lettera c OCIP-DFI

Audit Trail Consumption (CH:ATC)

Complemento 2.2 all'allegato 5 OCIP-DFI : Adeguamenti nazionali

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1 Introduction

Il presente documento è stato creato per adempiere i disciplinamenti svizzeri dell'ordinanza sulla cartella informatizzata del paziente (OCIP; RS 816.11). L'OCIP e l'OCIP-DFI (RS 816.111) sono pubblicate nella Raccolta ufficiale (in italiano, francese e tedesco)¹.

La cartella informatizzata del paziente (CIP) si basa su un sistema che prevede numerose comunità IHE-XDS, in cui il paziente non accorda solo il consenso per la costituzione e l'utilizzo della sua cartella, ma stabilisce esplicitamente anche regole per l'accesso tramite un apposito portale per pazienti.

Il paziente e, se disponibile, il suo rappresentante devono potere consultare i verbali contenuti nella cartella informatizzata presso qualsiasi comunità e comunità di riferimento mediante un apposito portale per pazienti e in una forma leggibile. Questo profilo CH:ATC definisce i requisiti in materia di audit trail consumption che una comunità deve soddisfare in vista dell'audit trail per il paziente.

This document fulfils the Swiss regulations of the Ordinance on the Electronic Patient Record (EPRO, SR 816.11). The EPRO and the EPRO-FDHA (SR 816.111) are published in Official Compilation of Federal Legislation (available in German, French and Italian)¹.

The Swiss Electronic Health Record (EPR) depends on an IHE XDS and multi-community based system where the patient not only consents to the creation and use of the record, but does so by explicitly defining access rules through a patient portal.

Patients – and, if existing, their representatives – have the right to access the audit trail within the EPR circle of trust. The access to the audit trail will be provided by certified web access portals for patients. This profile CH:ATC defines the audit trail consumption requirements which a community has to meet in order to provide a patients audit trail.

¹ German: <https://www.admin.ch/opc/de/classified-compilation/20111795/index.html>; French: <https://www.admin.ch/opc/fr/classified-compilation/20111795/index.html>; Italian: <https://www.admin.ch/opc/it/classified-compilation/20111795/index.html>.

2 Volume 1 – Integration Profiles

2.1 Overview

This profile defines the audit trail consumption requirements a community has to provide for a patient's audit trail.

The profile CH:ATC defines and precises the actors and Retrieve Audit Event [ITI-81] of the IHE ITI Supplement Add RESTful Query to ATNA²³ and defines the content of the Audit Messages. The different types of the Audit Messages are based on the requirements for Document and Access Policy management as well as the entry of healthcare professionals into a group in order to achieve the Swiss regulation needs on the audit trail access by patients. These Audit Event types differ from the Audit Events which have also to be logged according to the ATNA requirements.

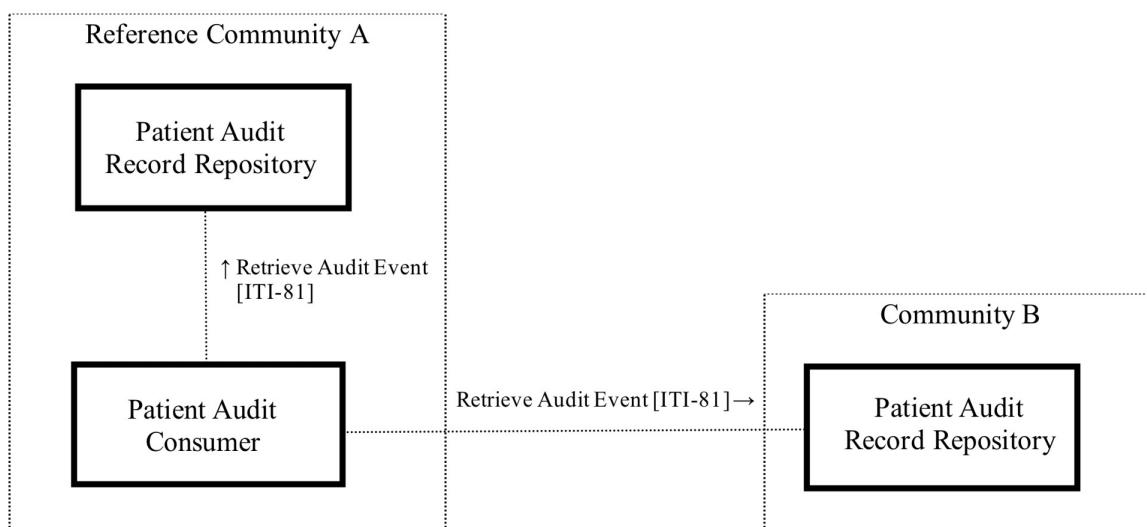


Figure 1: CH:ATC Overview within the Swiss EPR circle of trust

Each community shall provide one endpoint to a Patient Audit Record Repository which can be queried according to the Retrieve Audit Event [ITI-81] RESTful Query transaction. A reference community shall implement a Patient Audit Consumer which will query all Patient Audit Record Repositories, aggregate the results and provide it to the patient.

How the Patient Audit Record Repository generates or collects the specified Audit Events within the community is outside the scope of this profile.

² IHE IT Infrastructure Technical Framework Supplement Add RESTful ATNA (Query and Feed), Revision 3.3, July 2, 2021.

³ https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_RESTful-ATNA_Rev2.2_TI_2017-07-21.pdf.

2.2 Actors, Transactions and Content Modules

Figure 2 shows the actors directly involved in the CH:ATC Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines.

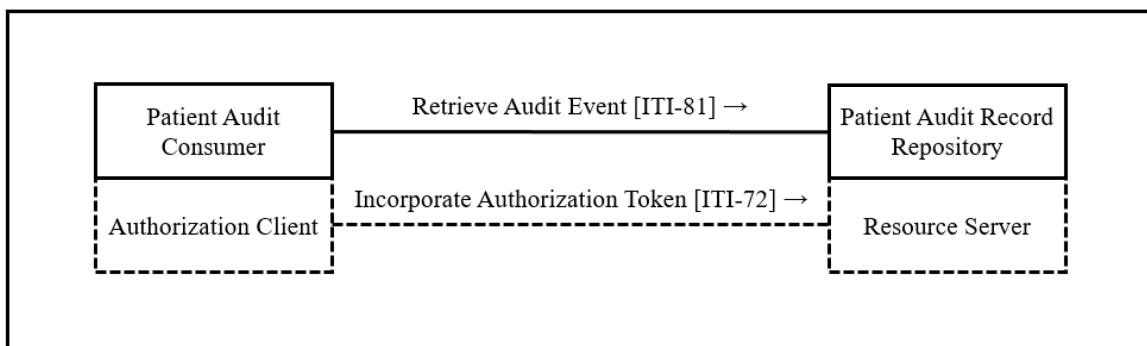


Figure 2: CH:ATC Actor diagram

Table 1 lists the transactions for each actor directly involved in the CH:ATC Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

| Actors | Transactions | Initiator or Responder | Opt | Reference |
|---------------------------------|-------------------------------|------------------------|-----|--------------|
| Patient Audit Consumer | Retrieve Audit Event [ITI-81] | Initiator | R | CH:ATC 2.2.3 |
| Patient Audit Record Repository | Retrieve Audit Event [ITI-81] | Responder | R | CH:ATC 2.2.2 |

Table 1: CH:ATC Profile - Actors and Transactions

2.2.1 Actor Descriptions and Actor Profile Requirements

The actors defined in this profile are based on the IHE ITI TF-2⁶ and the IHE ITI Supplement Add RESTful Query to ATNA⁴ actors. This section documents any additional requirements on the profile's actors required in the Swiss EPR context.

2.2.2 Patient Audit Record Repository

For the actor Patient Audit Record Repository the actor Audit Record Repository in IHE ITI Supplement Add RESTful Query to ATNA⁴ is relevant.

The Patient Audit Record Repository shall support the Retrieve Audit Message Option from the Audit Record Repository (IHE ITI TF-1⁵, chapter 9.2.3) with the search capabilities as defined in IHE ITI TF-2⁶, chapter 3.81 and the Audit Message Formats defined in Volume 3 – Content Profiles.

2.2.3 Patient Audit Consumer

For the actor Patient Audit Consumer the actor Audit Consumer in IHE ITI Supplement Add RESTful Query to ATNA⁷ is relevant.

The Patient Audit Consumer queries a Patient Audit Record Repository for Audit Events defined by this profile. The Patient Audit Consumer shall support the Retrieve Audit Message Option from the Audit Consumer (ITI TF-1⁸, chapter 9.2.3).

⁴ IHE IT Infrastructure Technical Framework Supplement Add RESTful ATNA (Query and Feed), Revision 3.3, July 2, 2021.

⁵ IHE IT Infrastructure (ITI) Technical Framework, Volume 1, Revision 19.0, June 17, 2022.

⁶ IHE IT Infrastructure (ITI) Technical Framework, Volume 2, Revision 19.0, June 17, 2022.

⁷ IHE IT Infrastructure Technical Framework Supplement Add RESTful ATNA (Query and Feed), Revision 3.3, July 2, 2021.

⁸ IHE IT Infrastructure (ITI) Technical Framework, Volume 1, Revision 19.0, June 17, 2022.

The Patient Audit Consumer should filter duplicate AuditEvents for display (e.g. Document Retrieval Audit Event for the same document access are in multiple Patient Audit Record Repositories, because the requesting and responding community need to make the AuditEvent available).

Subsequent processing like translation of the coded elements into the users preferred language and display of the query result is not defined in this profile.

2.3 Integration Profile Options

| CH:ATC Actor | Option name |
|---------------------------------|--------------------------------|
| Patient Audit Consumer | Aggregate Audit Message Option |
| Patient Audit Record Repository | - |

Table 2: Actors and Options

The aggregate Audit Message Options allows the Patient Audit Consumer to aggregate results from multiple Patient Audit Record Repositories. A reference community shall support at least one Patient Audit Consumer with this Option.

2.4 Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to all*** of the requirements for the grouped actor.

| CH:ATC Actor | Grouping Condition | Actor to be grouped with | Reference |
|---------------------------------|--------------------|--|------------------------------------|
| Patient Audit Consumer | Required | ATNA – Secure Node | Amendment 1 of Annex 5 EPRO-FDHA |
| | Required | CT – Time Client | IHE ITI TF-1 ⁸ |
| | Required | IUA – Authorization Client | IHE ITI Suppl IUA ⁹ |
| | Optional | CH:CPI – CPI Consumer | Amendment 2.3 of Annex 5 EPRO-FDHA |
| Patient Audit Record Repository | Required | ATNA – Secure Node | Amendment 1 of Annex 5 EPRO-FDHA |
| | Required | CT – Time Client | IHE ITI TF-1 ⁸ |
| | Required | CH:ADR – Authorization Decision Consumer | Amendment 2.1 of Annex 5 EPRO-FDHA |
| | Required | IUA – Resource Server | IHE ITI Suppl IUA ¹⁰ |

Table 3: Actor Grouping

Section 2.6 describes the groupings required for security considerations.

2.5 Overview – Use Cases

Activities related to the EPR are audited for specific document and access policy management events as well as entry events of healthcare professionals into a group and stored in the communities.

This profile supports the following Use Cases:

- A patient can request protocols of the activities related to his EPR.
- A patient representative can request a protocol of the activities related to the patients delegated EPR.

⁹ IHE ITI Technical Framework Supplement Internet User Authorization (IUA), Revision 2.2, June 17, 2022.

¹⁰ IHE ITI Technical Framework Supplement Internet User Authorization (IUA), Revision 2.2, June 17, 2022.

2.6 Security Considerations

The transaction is used to exchange sensitive information and requires authentication and authorization. This profile requires all actors to be grouped with Secure Node or Secure Application implementing the "STX: TLS 1.2 floor using BCP195 Option" defined in the IHE ITI TF-¹¹, chapter 3.19.6.2.3.

Access control shall be implemented by grouping the CH:ATC Audit Consumer and Audit Record Repository with the Authorization Client and Resource Server from the IUA trial implementation profile using the SAML Token option (see IHE ITI Supplement IUA¹⁰, chapter 3.72.4.3.2). As defined therein, the CH:ATC Audit Consumer and Audit Record Repository shall implement the Incorporate Authorization Token [ITI-72] transaction to convey the XUA token.

The CH:ATC Patient Audit Record Repository shall be grouped with CH:ADR, i.e. the CH:ATC Patient Audit Record Repository shall use the CH:ADR Authorization Decision Request transaction to authorize the transaction and enforce the authorization decision retrieved from CH:ADR Authorization Decision Response.

¹¹ IHE IT Infrastructure (ITI) Technical Framework, Volume 2, Revision 19.0, June 17, 2022.

3 Volume 2 – Transactions

3.1 Constraints on Retrieve ATNA Audit Event [ITI-81]

The Retrieve ATNA Audit Event [ITI-81] transaction is defined in IHE ITI TF-2¹¹ and the IHE ITI Supplement Add RESTful Query to ATNA¹². The following rules shall be applied for the CH:ATC profile.

3.1.1 Message Semantics

The Retrieve ATNA Audit Event message shall be a HTTP GET request sent to the Patient Audit Record Repository. This message is a FHIR search (see <http://hl7.org/fhir/R4/search.html>) on AuditEvent Resources (see <http://hl7.org/fhir/R4/auditevent.html>). This "search" target is formatted as:

```
<scheme>://<authority>/<path>/AuditEvent?date=ge[start-time]&date=le[stop-time]&<query>
```

where:

- a. <scheme> shall be https.
- b. <query> shall include the entity.identifier as defined in 3.1.2 and may include additional ATNA Search parameters. If entity.identifier is not included an HTTP response code 400 - Bad Request shall be returned.

3.1.2 Additional ATNA Search Parameters

The Patient Audit Consumer shall not use the following parameters in a query parameters: address, patient.identifier, source, type, user, outcome. The Patient Audit Consumer may use other parameters as listed in Retrieve Audit Event [ITI-81].

entity.identifier is a parameter of token type. This parameter specifies unique identifier for the object. The parameter value should be identified in accordance to the entity type;

For example:

<https://example.com/ARRservice/AuditEvent?date=ge2020-03-22&date=le2025-03-22&entity.identifier=urn:oid:2.16.756.5.30.1.127.3.10.3|5678>

The Audit Record Repository shall match this parameter with the AuditEvent.entity.what.identifier field that is of type identifier (ParticipantObjectID in DICOM schema).

For the CH:ATC profile the entity.identifier has to be the EPR-SPID:

entity.identifier=urn:oid:2.16.756.5.30.1.127.3.10.3|<<<value EPR-SPID>>>

3.1.3 Message Semantics for Response

The returned AuditEvent FHIR resources in the Bundle shall conform the CH:ATC AuditEvent profile, see section 4.

3.1.4 Security Considerations

The transaction is used to exchange sensitive information and requires authentication and authorization. This profile requires all actors to be grouped with Secure Node or Secure Application implementing the "STX: TLS 1.2 floor using BCP195 Option" defined in the IHE ITI TF-2¹³, chapter 3.19.6.2.3.

Access control shall be implemented by grouping the CH:ATC Audit Consumer and Audit Record Repository with the Authorization Client and Resource Server from the IUA trial implementation profile using the SAML Token option (see IHE ITI Supplement IUA¹⁴, chapter 3.72.4.3.2). As defined

¹² IHE IT Infrastructure Technical Framework Supplement Add RESTful ATNA (Query and Feed), Revision 3.3, July 2, 2021.

¹³ IHE IT Infrastructure (ITI) Technical Framework, Volume 2, Revision 19.0, June 17, 2022.

¹⁴ IHE ITI Technical Framework Supplement Internet User Authorization (IUA), Revision 2.2, June 17, 2022.

therein, the CH:ATC Audit Consumer and Audit Record Repository shall implement the Incorporate Authorization Token [ITI-72] transaction to convey the XUA token.

The actors shall implement the Incorporate Authorization Token [ITI-72] transaction with SAML token option, using the base64url encoded SAML assertion defined in XUA to the authorization header of the HTTP1.1 GET request with key "Bearer" as follows:

GET /example/url/to/resource/location HTTP/1.1

Authorization: "Bearer" fFBGRNJru1FQd[...omitted for brevity...]44AzqT3Zg

Host: examplehost.com

The CH:ATC Patient Audit Record Repository shall be grouped with CH:ADR, i.e. the CH:ATC Patient Audit Record Repository shall use the CH:ADR Authorization Decision Request transaction to authorize the transaction and enforce the authorization decision retrieved from CH:ADR Authorization Decision Response.

3.1.5 Security Audit Considerations

An audit event as specified in section 4.4 Access Audit Trail Content Profile shall be returned by a query to Patient Audit Record Repository after the Patient Audit Record Repository has been queried by a Patient Audit Consumer.

4 Volume 3 – Content Profiles

There are four different categories of Audit Events in the context of the EPR:

- a. Document management (e.g. a document has been uploaded to the EPR of a patient or a list of document metadata has been retrieved)
- b. Policy management (e.g. a patient has given a healthcare professional access rights to his EPR)
- c. Access Patient Audit Record Repository by a patient or representative (a patient viewed the Audit Trail for the Audit Record Repository)
- d. Notification of the patient about the entry of healthcare professionals into a group

Each category is described as a content profile. These content profiles are based on the AuditEvent Resource, <http://hl7.org/fhir/R4/auditevent.html>.

The AuditEvent Resource has mapping rules to the DICOM audit message format, see FHIR Table 6.4.7.2, <http://hl7.org/fhir/R4/auditevent-mappings.html> which allows to map to ATNA.

4.1 Audit Trail Consumption Event Types

The following Audit Trail Consumption Event Types are defined and SHALL be supported, see EprAuditTrailConsumptionEventTypes from Codesystem 2.16.756.5.30.1.127.3.10.7.

| Type | Description | Profile Ref | Opt Community |
|----------------------------|---|-------------|-------------------------------------|
| ATC_DOC_CREATE | Document upload | 4.2 | R |
| ATC_DOC_READ | Document retrieval | 4.2 | R |
| ATC_DOC_UPDATE | Document or Document Metadata update | 4.2 | R |
| ATC_DOC_DELETE | Document removal | 4.2 | R |
| ATC_DOC_SEARCH | Document search | 4.2 | R |
| ATC_POL_CREATE_AUT_PART_AL | Authorize participants to access level/date | 4.3 | R, (NP if not reference community) |
| ATC_POL_UPDATE_AUT_PART_AL | Update access level/date of authorized participants | 4.3 | R, (NP: if not reference community) |
| ATC_POL_REMOVE_AUT_PART_AL | Remove authorization for participants to access level/date | 4.3 | R, (NP: if not reference community) |
| ATC_POL_DEF_CONFLEVEL | Set or update the default Confidentiality Level for new documents | 4.3 | R, (NP: if not reference community) |
| ATC_POL_DIS_EMER_USE | Disabling Emergency Access | 4.3 | R, (NP: if not reference community) |
| ATC_POL_ENA_EMER_USE | Enabling Emergency Access | 4.3 | R, (NP: if not reference community) |
| ATC_POL_INCL_BLACKLIST | Assign a Healthcare Professional to Blacklist | 4.3 | R, (NP: if not reference community) |
| ATC_POL_EXL_BLACKLIST | Exclude a Healthcare Professional from Blacklist | 4.3 | R, (NP: if not reference community) |
| ATC_LOG_READ | Accessing the Patient Audit Record Repository | 4.4 | R |
| ATC_HPD_GROUP_ENTRY_NOTIFY | Entry of healthcare professionals into a group | 4.6 | R |

Table 4: Audit Trail Consumption Event Types

4.2 Document Audit Event Content Profile

This content profile describes Audit Event related to Document Management. The following Data Elements shall be provided:

| Data Element | Description | Property/Value |
|--|--|---|
| Event Type | Document upload Document retrieval Document or Document Metadata update Document removal Document search | |
| Event Date and Time | | UTC |
| Participants | | |
| Initiator | Patient | Name |
| | Representative of patient | Name UAP-ID or EPR-SPID |
| | Authorized Healthcare Professional | Name GLN |
| | Assistant of a Healthcare Professional | Name GLN |
| | Technical User | Name Identifier |
| | Document Administrator | Name UAP-ID |
| Responsible ¹⁵ | Patient | Name |
| | Healthcare Professional | Name GLN |
| Groups where Healthcare Professional is member | | Name of Group OID |
| Purpose of Use | | NORM, EMER, AUTO, DICOM_AUTO |
| Patient | Involved patient | EPR-SPID |
| Document ¹⁶ | type of document | typeCode ¹⁷ (SNOMED CT code) |
| | reference to document | uniqueId ¹⁸ repositoryUniqueId ¹⁹ homeCommunityId ²⁰ |
| | title of document | title ²¹ |

Table 5: Document Audit Event Data Elements

This profile defines the content of the document audit events which a community has to provide for a patient's audit trail. This profile builds on AuditEvent (<http://hl7.org/fhir/R4/auditevent.html>).

¹⁵ If different from Initiator (Representative of patient acting on behalf of a patient then patient is responsible).

¹⁶ Required for Document upload, Document retrieval, Document or Document Metadata update and Document removal but not for Document search.

¹⁷ Annex 3 EPRO-FDHA, chapter 2.6 type of document (2.16.756.5.30.1.127.3.10.1.27).

¹⁸ IHE IT Infrastructure (ITI) Technical Framework, Volume 3, Revision 19.0, June 17, 2022, chapter 4.2.3.2.26, DocumentEntry.uniqueId.

¹⁹ IHE IT Infrastructure (ITI) Technical Framework, Volume 3, Revision 19.0, June 17, 2022, chapter 4.2.3.2.18, DocumentEntry.repositoryUniqueId.

²⁰ IHE IT Infrastructure (ITI) Technical Framework, Volume 3, Revision 19.0, June 17, 2022, chapter 4.2.3.2.12, DocumentEntry.homeCommunityId.

²¹ IHE IT Infrastructure (ITI) Technical Framework, Volume 3, Revision 19.0, June 17, 2022, chapter 4.2.3.2.24, DocumentEntry.title.

| Name | Flags | Card. | Type | Description & Constraints |
|--------------------------------|-------|-------|--|--|
| AuditEvent | I | 0..* | AuditEvent | Document Audit Trail Content Profile ch-atc-dae-1: subtype needs to be fixed to ValueSet DocumentAuditEventType |
| type | | 1..1 | Coding | Type/identifier of event Binding: AuditEventID (extensible): Type of event. |
| Slices for subtype | | 1..* | Coding | More specific type/id for the event Slice: Unordered, Open by value:system |
| subtype:DocumentAuditEventType | | 1..1 | Coding | DocumentAuditEventType Binding: DocumentAuditEventType (required): Document Audit Event Type |
| system | | 1..1 | uri | Identity of the terminology system Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.7 |
| recorded | | 1..1 | instant | Time when the event was recorded |
| purposeOfEvent | | 1..1 | CodeableConcept | The purposeOfUse of the event Binding: EprPurposeOfUse (required): EprPurposeOfUse |
| agent | | 1..* | BackboneElement | Participants |
| role | | 1..1 | CodeableConcept | Agent role in the event Binding: EprParticipant (required): EprParticipant |
| who | | 0..1 | Reference(PractitionerRole Practitioner Organization Device Patient RelatedPerson) | Identifier of who |
| name | | 1..1 | string | Human-meaningful name for the agent |
| requestor | | 1..1 | boolean | Whether user is initiator |
| Slices for entity | I | 0..* | BackboneElement | Data or objects used Slice: Unordered, Open by value:type.code, value:role.code sev-1: Either a name or a query (NOT both) |
| entity:Patient | | 1..1 | BackboneElement | Patient |
| what | | 1..1 | Identifier | Patient Id (EPR-SPID) |
| identifier | | 1..1 | uri | The namespace for the identifier value Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.3 |
| type | | 1..1 | Coding | Type of entity involved |
| code | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 1 |
| role | | 1..1 | Coding | What role the entity played |
| code | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 1 |
| entity:Document | | 0..1 | BackboneElement | Document |
| what | | 1..1 | Identifier | XDSDocumentEntry.uniqueId |
| identifier | | 1..1 | Coding | Type of entity involved |
| code | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 2 |
| role | | 1..1 | Coding | What role the entity played |
| code | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 3 |
| Slices for detail | | 0..* | BackboneElement | Additional Information about the entity Slice: Unordered, Open by value:type |
| detail:repositoryUniqueId | | 1..1 | BackboneElement | repositoryUniqueId |
| type | | 1..1 | string | Name of the property Fixed Value: Repository Unique Id |
| value | | 1..1 | base64Binary | Property value |
| detail:homeCommunityID | | 1..1 | BackboneElement | homeCommunityID |
| type | | 1..1 | string | Name of the property Fixed Value: homeCommunityID |
| value | | 1..1 | base64Binary | Property value |
| detail:EprDocumentTypeCode | | 1..1 | BackboneElement | EprDocumentTypeCode |
| type | | 1..1 | string | Name of the property Fixed Value: EprDocumentTypeCode |
| value | | 1..1 | base64Binary | Property value |
| entity:Query | | 0..1 | BackboneElement | Query |
| what | | 1..1 | Identifier | XDSQueryEntry.uniqueId |
| identifier | | 1..1 | Coding | Type of entity involved |
| code | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 2 |
| role | | 1..1 | Coding | What role the entity played |
| code | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 24 |

Table 6: StructureDefinition for Document Audit Event Profile

The mapping from the Document Audit Event Resource to the Data Elements is as follows:

| DocumentAuditEvent | CH:ATC Data Element/Property |
|----------------------------------|---|
| AuditEvent | |
| subtype (DocumentAuditEventType) | Event Type |
| recorded | Event Date and Time |
| purposeOfEvent | PurposeOfUse |
| agent | Participants |
| role | role (PAT, HCP, ASS, REP, TCU, DADM, GRP) |
| who.identifier | Identifier if applicable |
| name | Name |
| requestor | if participant is Initiator |
| entity | |
| entity (Patient) | Patient |
| what.identifier | EPR-SPID |
| entity (Document) | Document |
| what.identifier | uniqueId |
| detail (repositoryUniqueId) | repositoryUniqueId |
| detail (homeCommunityID) | homeCommunityID |
| detail (EprDocumentTypeCode) | typeCode |
| detail (title) | title |
| entity (Query) | Query |
| what.identifier | Stored Query ID (UUID) |

Table 7: Mapping Document Audit Event to Data Elements

4.2.1 Example of a Document Audit Event: Document upload

| | |
|---------------------------------|---|
| Event | Upload |
| Resource title of Document | Upload |
| Resource: type of Document | Austrittsbericht von Julia Helfe-Gern |
| Resource: reference to Document | Nicht näher bezeichnetes Dokument (SOMED CT: 419891008)) |
| Event Date and Time | uniqueID |
| Participant, Initiator | 10.10.2020 18:29 |
| Participant, Responsible | Julia Helfe-Gern representing Jakob Wieder-Gesund |

Table 8: Uploading a Record Artifact by a patient representative (atc-doc-create-rep-pat.xml)

```

<AuditEvent xmlns="http://hl7.org/fhir">
  <id value="atc-doc-create-rep-pat"/>
  <meta>
    <profile value="http://fhir.ch/ig/ch-atc/StructureDefinition/DocumentAuditEvent" />
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">Upload of Record Artifact 10.10.2020 18:29 from Julia Helfe-Gern on behalf of Jakob Wieder-Gesund
    </div>
  </text>
  <type>
    <system value="http://dicom.nema.org/resources/ontology/DCM"/>
    <code value="110106"/>
  
```

```
        <display value="Export"/>
    </type>
    <subtype>
        <system value="urn:oid:2.16.756.5.30.1.127.3.10.7"/>
        <code value="ATC_DOC_CREATE"/>
        <display value="Document upload"/>
    </subtype>
    <action value="C"/>
    <recorded value="2020-10-10T16:29:00Z"/>
    <outcome value="0"/>
    <purposeOfEvent>
        <coding>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.5"/>
            <code value="NORM"/>
            <display value="Normal Access"/>
        </coding>
    </purposeOfEvent>
    <agent>
        <role>
            <coding>
                <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
                <code value="PAT"/>
                <display value="Patient"/>
            </coding>
        </role>
        <name value="Jakob Wieder-Gesund" />
        <requestor value="false" />
    </agent>
    <agent>
        <role>
            <coding>
                <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
                <code value="REP"/>
                <display value="Representative"/>
            </coding>
        </role>
        <userId>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
            <value value="761322222222222222" />
        </userId>
        <name value="Julia Helfe Gern" />
        <requestor value="true" />
    </agent>
    <source>
        <identifier>
            <system value="urn:ietf:rfc:3986"/>
            <!-- oid of system generating this audit event -->
            <value value="urn:oid:7.8.9.10.11"/>
        </identifier>
    </source>
    <entity>
        <!-- Patient -->
        <what>
            <identifier>
                <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
```

```
        <value value="761337610469261945" />
    </identifier>
</what>

<type>
    <system value=" http://terminology.hl7.org/CodeSystem /au-
dit-entity-type"/>
        <code value="1"/>
        <display value="Person"/>
</type>
<role>
    <system value=" http://terminology.hl7.org/CodeSystem /ob-
ject-role"/>
        <code value="1"/>
        <display value="Patient"/>
</role>
</entity>
<entity>
    <!-- Document -->
    <what>
        <identifier>
            <type>
                <coding>
                    <system value="urn:uuid:2e82c1f6-a085-4c72-9da3-
8640a32e42ab"/>
                        <code value="IHE XDS Metadata"/>
                        <display value="XDSDocumentEntry.uniqueId"/>
                    </coding>
                </type>
                <system value="urn:ietf:rfc:3986"/>
                <value value="urn:oid:1.2.3.4.5"/>
            </identifier>
        </what>
        <type>
            <system value=" http://terminology.hl7.org/CodeSystem /au-
dit-entity-type"/>
                <code value="2"/>
                <display value="System Object"/>
            </type>
            <role>
                <system value=" http://terminology.hl7.org/CodeSystem /ob-
ject-role"/>
                    <code value="3"/>
                    <display value="Report"/>
            </role>
            <detail>
                <type value="Repository Unique Id" />
                <value value="MS4yLjM=" />
                <!-- base64 of OID eg 1.2.3 == -->
            </detail>
            <detail>
                <type value="homeCommunityID" />
                <value value="NS42LjcuOA==" />
                <!-- base64 of OID URN homeCommunityId e.g. 5.6.7.8 -->
            </detail>
```

```

<detail>
  <type value="EprDocumentTypeCode" />
  <value value=" NDE5ODkxMDA4" />
  <!-- base64 typeCode 419891008 -->
</detail>
<detail>
  <type value="title"/>
  <valueBase64Binary value="QXVzdHJpdHRzYmVyaWN-
odCB2b24gSnVsaWEgSGVsZmUtr2Vybg=="/>
  <!-- base64 title Austrittsbericht von Julia Helfe-Gern
-->
</detail>
</entity>
</AuditEvent>

```

Listing 1: Example of a document audit event

4.2.2 Example of a Document Audit Event: Document search

| | |
|--------------------------|--|
| Event | Search for documents |
| Event Date and Time | 10.10.2020 18:49 |
| Participant, Initiator | David Mustermann |
| Participant, Responsible | representing Dr. med. Sabine Musterfrau |
| Participant, Group | Kardiologie Universitätsspital Musterstadt |
| Purpose of event | Emergency Access |

Table 9: Example of a Document Audit Event: Document search

```

<AuditEvent xmlns="http://hl7.org/fhir">
  <id value="atc-doc-search"/>
  <meta>
    <profile value="http://fhir.ch/ig/ch-atc/StructureDefinition/DocumentAuditEvent" />
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml"> Search for documents 10.10.2022 18:49 Dr. med. Sabine Musterfrau requesting documents in Emergency Access from Kardiologie Universitätsspital Musterstadt
    </div>
  </text>
  <type>
    <system value="http://dicom.nema.org/resources/ontology/DCM"/>
    <code value="110106"/>
    <display value="Export"/>
  </type>
  <subtype>
    <system value="urn:oid:2.16.756.5.30.1.127.3.10.7"/>
    <code value="ATC_DOC_SEARCH"/>
    <display value="Document search"/>
  </subtype>
  <action value="E"/>
  <recorded value="2022-10-10T18:49:00Z"/>
  <outcome value="0"/>
  <purposeOfEvent>
    <coding>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.5"/>
      <code value="EMER"/>
    </coding>
  </purposeOfEvent>

```

```
        <display value="Emergency Access"/>
    </coding>
</purposeOfEvent>
<agent>
    <role>
        <coding>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
            <code value="HCP"/>
            <display value="Healthcare professional"/>
        </coding>
    </role>
    <name value="Dr. med. Sabine Musterfrau" />
    <requestor value="true" />
</agent>
<agent>
    <role>
        <coding>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.14"/>
            <code value="GRP"/>
            <display value="Group"/>
        </coding>
    </role>
    <who>
        <identifier>
            <value value="urn:oid:1.1.1.1.1"/>
        </identifier>
    </who>
    <name value="Kardiologie Universitätsspital Musterstadt"/>
    <requestor value="false" />
</agent>
<source>
    <observer>
        <identifier>
            <system value="urn:ietf:rfc:3986"/>
            <value value="urn:oid:7.8.9.10.11"/>
        </identifier>
    </observer>
</source>
<entity>
    <!-- Patient -->
    <what>
        <identifier>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
            <value value="761337610469261945" />
        </identifier>
    </what>
    <type>
        <system value="http://terminology.hl7.org/CodeSystem/au-
dit-entity-type"/>
        <code value="1"/>
        <display value="Person"/>
    </type>
    <role>
        <system value="http://terminology.hl7.org/CodeSystem/ob-
ject-role"/>
```

```
<code value="1"/>
<display value="Patient"/>
</role>
</entity>
<entity>
    <!-- Query -->
    <what>
        <identifier>
            <system value="urn:ietf:rfc:3986" />
            <value value="urn:uuid:14d4deb8f97-4251-9a74-
a90016b0af0d" />
            <!-- Stored Query Id: https://pro-
files.ihe.net/ITI/TF/Volume2/ITI-18.html#3.18.4.1.2.4 -->
        </identifier>
    </what>
    <type>
        <system value="http://terminology.hl7.org/CodeSystem/au-
dit-entity-type"/>
        <code value="2"/>
        <display value="System Object"/>
    </type>
    <role>
        <system value="http://terminology.hl7.org/CodeSystem/ob-
ject-role"/>
        <code value="24"/>
        <display value="Query"/>
    </role>
</entity>
</AuditEvent>
```

Listing 2: Example of a document audit event

4.3 Policy Audit Event Content Profile

This content profile describes Audit Events related to Policy Management. The following Data Elements shall be provided:

| Data Element | Description | Property/Value |
|-----------------|---|--|
| Event Type | Authorize participants to access level/date | |
| | Update access level/date of authorized participants | |
| | Remove authorization for participants to access level/date | |
| | Set or update the default Confidentiality Level for new documents | |
| | Disabling Emergency Access | |
| | Enabling Emergency Access | |
| | Assign a Healthcare Professional to Blacklist | |
| | Exclude a Healthcare Professional from Blacklist | |
| Event Date Time | | UTC |
| Participants | | |
| Initiator | Patient | Name |
| | Representative of patient | Name UAP-ID or EPR-SPID |
| | Authorized Healthcare Professional ²² | Name GLN |
| | Assistant of a Healthcare Professional ⁷ | Name GLN |
| | Policy Administrator | Name UAP-ID |
| Responsible | Patient | Name |
| | Healthcare Professional ⁷ | Name GLN |
| Patient | Involved patient | EPR-SPID |
| Resource | Resource Role | HCP, GRP or REP |
| | Healthcare Professional | Name GLN |
| | Group of Healthcare Professional | Name of Group OID |
| | Representative of patient | Name UAP-ID or EPR-SPID |
| | AccessLevel ²³ | one of urn:e-health-suisse:2015:policies:access-level: normal, restricted, delegation-and-restricted, delegation-and-normal, full |
| | AccessLimitedToDate ⁸ | Date |
| | ProvideLevel ²⁴ | one of urn:e-health-suisse:2015:policies:provide-level: normal, restricted, secret |

Table 10: Policy Audit Event Data Elements

²² Healthcare Professional or Assistant of Healthcare Professional can only be a participant for the first Event Type (Authorize participants to access level).

²³ Access Level and the date if the access is limited (AccessLimitedToDate) are required for the first two Event Types (Authorize, update Authorization participants to access level/date), for the other Event Types these parameters do not need to be specified.

²⁴ Provide Level is only relevant for the Event Type Default Confidentiality Level for new Documents.

This content profile defines the document audit events which a community has to provide for a patients audit trail. This profile builds on AuditEvent (<http://hl7.org/fhir/R4/auditevent.html>).

| Name | Flags | Card. | Type | Description & Constraints |
|------------------------------|-------|-------|--|--|
| AuditEvent | I | 0..* | AuditEvent | Policy Audit Trail Content Profile |
| type | | 1..1 | Coding | ch-atc-pae-1: subtype needs to be fixed to ValueSet PolicyAuditEventType |
| subtype | | 1..* | (Slice Definition) | Type/identifier of event |
| subtype:PolicyAuditEventType | | 1..1 | Coding | Binding: AuditEventID (extensible) |
| system | | 1..1 | uri | More specific type/id for the event |
| recorded | | 1..1 | instant | PolicyAuditEventType |
| agent | | 1..* | BackboneElement | Binding: PolicyAuditEventType (required) |
| role | | 1..1 | CodeableConcept | Identity of the terminology system |
| who | | 0..1 | Reference(PractitionerRole Practitioner Organization Device Patient RelatedPerson) | Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.7 |
| name | | 1..1 | string | Time when the event was recorded |
| requestor | | 1..1 | boolean | Participants |
| entity | I | 0..* | (Slice Definition) | Agent role in the event |
| entity:Patient | | 1..1 | BackboneElement | Binding: EprParticipant (required) |
| what | | | | Identifier of who |
| identifier | | 1..1 | Identifier | Human-meaningful name for the agent |
| system | | 1..1 | uri | Whether user is initiator |
| type | | 1..1 | Coding | Data or objects used |
| code | | 1..1 | code | Slice: Unordered, Open by value:type.code |
| role | | 1..1 | Coding | sev-1: Either a name or a query (NOT both) |
| code | | 1..1 | code | Patient |
| entity:Resource | | 0..1 | BackboneElement | Patient Id (EPR-SPID) |
| what | | | | The namespace for the identifier value |
| identifier | | 0..1 | Identifier | Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.3 |
| type | | 1..1 | Coding | Type of entity involved |
| code | | 1..1 | code | Symbol in syntax defined by the system |
| role | | 1..1 | Coding | Fixed Value: 1 |
| code | | 1..1 | code | What role the entity played |
| entity:Resource | | 0..1 | BackboneElement | Symbol in syntax defined by the system |
| what | | | | Fixed Value: 1 |
| identifier | | 0..1 | Identifier | What role the entity played |
| type | | 1..1 | Coding | Binding: EprParticipant (required) |
| code | | 1..1 | code | Descriptor for entity |
| role | | 1..1 | Coding | Identifier. HCP (GLN), Group (OID) |
| name | I | 1..1 | string | Type of entity involved |
| detail | | 0..* | (Slice Definition) | Symbol in syntax defined by the system |
| detail:AccessLevel | | 0..1 | BackboneElement | Fixed Value: 2 |
| type | | 1..1 | string | What role the entity played |
| value | | 1..1 | base64Binary | AccessLevel if subtype is Create or Update |
| detail:AccessLimitedToDate | | 0..1 | BackboneElement | The type of extra detail provided in the value. |
| type | | 1..1 | string | Fixed Value: AccessLevel |
| value | | 1..1 | base64Binary | one of urn:e-health-suisse:2015:policies:access-level: normal,restricted,delegation-and-restricted,delegation-and-normal or full |
| detail:ProvideLevel | | 0..1 | BackboneElement | AccessLimitedToDate if subtype is Create or Update |
| type | | 1..1 | string | Name of the property |
| value | | 1..1 | base64Binary | Fixed Value: AccessLimitedToDate |
| detail:ProvideLevel | | 0..1 | BackboneElement | date in Property value |
| type | | 1..1 | string | ProvideLevel if subtype is ATC_POL_DEF_CONFLEVEL |
| value | | 1..1 | base64Binary | Name of the property |
| type | | 1..1 | string | Fixed Value: ProvideLevel |
| value | | 1..1 | base64Binary | one of urn:e-health-suisse:2015:policies:provide-level: normal, restricted or secret |

Table 11: StructureDefinition for Policy Audit Event Profile

The mapping from the Document Audit Event Resource to the Data Elements is as follows:

| PolicyAuditEvent | CH:ATC Data Element/Property |
|--------------------------------|---|
| AuditEvent | |
| subtype (PolicyAuditEventType) | Event Type |
| recorded | Event Date and Time |
| agent | Participants |
| role | role (PAT, HCP, ASS, REP, GRP, PADM) |
| who.identifier | Identifier if applicable |
| name | Name |
| requestor | if participant is Initiator |
| entity | |
| entity (Patient) | Patient |
| what.identifier | EPR-SPID |
| entity (Resource) | Resource |
| what.identifier | Identifier: GLN for HCP, OID for Group |
| role | Role (HCP, REP, GRP) |
| name | Name of HCP, Group or Representative of Patient |
| detail (AccessLevel) | AccessLevel |
| detail (AccessLimitedToDate) | AccessLimitedToDate |
| detail (ProvideLevel) | ProvideLevel |

Table 12: Mapping Policy Audit Event to Data Elements

4.3.1 Examples

| | |
|--|--|
| Event Resource: HCP | Create EPR-Access Level "delegation-and-restricted" till 31.12.2020 08:00 to Dr. med. Hans Allzeitbereit 22.09.2020 09:47 Jakob Wieder-Gesund |
| Event Date and Time Participant Initiator | |

Table 13: Example Create Delegation and Restricted access for a healthcare professional (atc-pol-create-acc-right.xml)

```

<AuditEvent xmlns="http://hl7.org/fhir">
  <id value="atc-pol-create-acc-right"/>
  <meta>
    <profile value="http://fhir.ch/ig/ch-atc/StructureDefinition/PolicyAuditEvent" />
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">22.09.2020 09:47:  
Jakob Wieder-Gesund created Access Level delegation-and-restricted  
till 31.12.2020 08:00 to Dr. med. Hans Allzeitbereit
    </div>
  </text>
  <type>
    <system value="http://dicom.nema.org/resources/ontology/DCM"/>
    <code value="110106"/>
    <display value="Export"/>
  </type>
  <subtype>

```

```
<system value="urn:oid:2.16.756.5.30.1.127.3.10.7"/>
<code value="ATC_POL_CREATE_AUT_PART_AL"/>
<display value="Authorize participants to access level/date"/>
</subtype>
<action value="C"/>
<recorded value="2020-10-09T07:47:00Z"/>
<outcome value="0"/>
<agent>
  <role>
    <coding>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
      <code value="PAT"/>
      <display value="Patient"/>
    </coding>
  </role>
  <name value="Jakob Wieder-Gesund" />
  <requestor value="true" />
</agent>
<source>
  <identifier>
    <system value="urn:ietf:rfc:3986"/>
    <!-- oid of system generating this audit event -->
    <value value="urn:oid:7.8.9.10.12"/>
  </identifier>
</source>
<entity>
  <!-- Patient -->
  <what>
    <identifier>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
      <value value="761337610469261945" />
    </identifier>
  </what>
  <type>
    <system value=" http://terminology.hl7.org/CodeSystem /au-dit-entity-type"/>
    <code value="1"/>
    <display value="Person"/>
  </type>
  <role>
    <system value=" http://terminology.hl7.org/CodeSystem /ob-ject-role"/>
    <code value="1"/>
    <display value="Patient"/>
  </role>
</entity>
<entity>
  <!-- Resource -->
  <what>
    <identifier>
      <system value="urn:oid:2.51.1.3" />
      <value value="7601000234438" />
    </identifier>
  </what>
  <type>
```

```

        <system value="http://terminology.hl7.org/CodeSystem/object-type"/>
            <code value="2"/>
            <display value="System Object"/>
        </type>
        <role>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
            <code value="HCP"/>
            <display value="Healthcare professional"/>
        </role>
        <name value="Dr. med. Hans Allzeitbereit" />
        <detail>
            <type value="AccessLevel" />
            <value value="dXJuOmUtaGVhbHRoLXN1aXNzZToyMDE1OnBvbGljaWV-
zOmFjY2Vzcy1sZXZlbDpkZWx1Z2F0aW9uLWFuZC1yZXN0cm1jdGVk" />
            <!-- base64 of urn:e-health-suisse:2015:policies:access-
level:delegation-and-restricted -->
        </detail>
        <detail>
            <type value="AccessLimitedToDate" />
            <value value="MjAyMC0xMi0zMVQwODowMDowMFo=" />
            <!-- base64 of 2020-12-31-->
        </detail>
    </entity>
</AuditEvent>

```

Listing 3: Example of a create delegation and restricted access for a healthcare professional audit event

| | |
|---|---|
| Event Resource: Representative Event Date and Time Participant Initiator | Create Julia Helfe Gern 22.09.2020 09:48 Jakob Wieder-Gesund |
|---|---|

Table 14: Example Create for a representative (atc-pol-create-rep.xml)atc-pol-create-acc-right.xml)

```

<AuditEvent xmlns="http://hl7.org/fhir">
    <id value="atc-pol-create-rep"/>
    <meta>
        <profile value="http://fhir.ch/ig/ch-atc/StructureDefinition/PolicyAuditEvent" />
    </meta>
    <text>
        <status value="generated"/>
        <div xmlns="http://www.w3.org/1999/xhtml">22.09.2020 09:48:
        Jakob Wieder-Gesund authorized Julia Helfe Gern as a representative
        </div>
    </text>
    <type>
        <system value="http://dicom.nema.org/resources/ontology/DCM"/>
        <code value="110106"/>
        <display value="Export"/>
    </type>
    <subtype>
        <system value="urn:oid:2.16.756.5.30.1.127.3.10.7"/>
        <code value="ATC_POL_CREATE_AUT_PART_AL"/>
        <display value="Authorize participants to access level/date"/>
    </subtype>

```

```
</subtype>
<action value="C"/>
<recorded value="2020-10-09T07:48:00Z"/>
<outcome value="0"/>
<agent>
    <role>
        <coding>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
            <code value="PAT"/>
            <display value="Patient"/>
        </coding>
    </role>
    <name value="Jakob Wieder-Gesund" />
    <requestor value="true" />
</agent>
<source>
    <identifier>
        <system value="urn:ietf:rfc:3986"/>
        <!-- oid of system generating this audit event -->
        <value value="urn:oid:7.8.9.10.12"/>
    </identifier>
</source>
<entity>
    <!-- Patient -->
    <what>
        <identifier>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
            <value value="761337610469261945" />
        </identifier>
    </what>
    <type>
        <system value=" http://terminology.hl7.org/CodeSystem /audit-entity-type"/>
        <code value="1"/>
        <display value="Person"/>
    </type>
    <role>
        <system value=" http://terminology.hl7.org/CodeSystem /object-role"/>
        <code value="1"/>
        <display value="Patient"/>
    </role>
</entity>
<entity>
    <!-- Resource -->
    <type>
        <system value="http://hl7.org/fhir/object-type"/>
        <code value="2"/>
        <display value="System Object"/>
    </type>
    <role>
        <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
        <code value="REP"/>
        <display value="Representative"/>
    </role>

```

```

<name value="Julia Helfe Gern" />
</entity>
</AuditEvent>

```

Listing 4: Example of a create for a representative audit event

4.4 Access Audit Trail Content Profile

This content profile describes Audit Event related to Accessing the Audit Trail of a Patient from a Patient Audit Record Repository. The following Data Elements shall be provided:

| Data Element | Description | Property/Value |
|---------------------|--------------------------------------|------------------------------------|
| Event Type | | Access Audit Trail |
| Event Date and Time | | UTC |
| Participants | | |
| Initiator | Patient Representative of patient | Name Name UAP-ID or EPR_SPID |
| Responsible | Patient | Name |
| Patient | Involved patient | EPR-SPID |

Table 15: Access Audit Trail Data Elements

This content profile defines the access audit trail event, which a community has to provide for a patient's audit trail. This profile builds on AuditEvent (<http://hl7.org/fhir/R4/auditevent.html>).

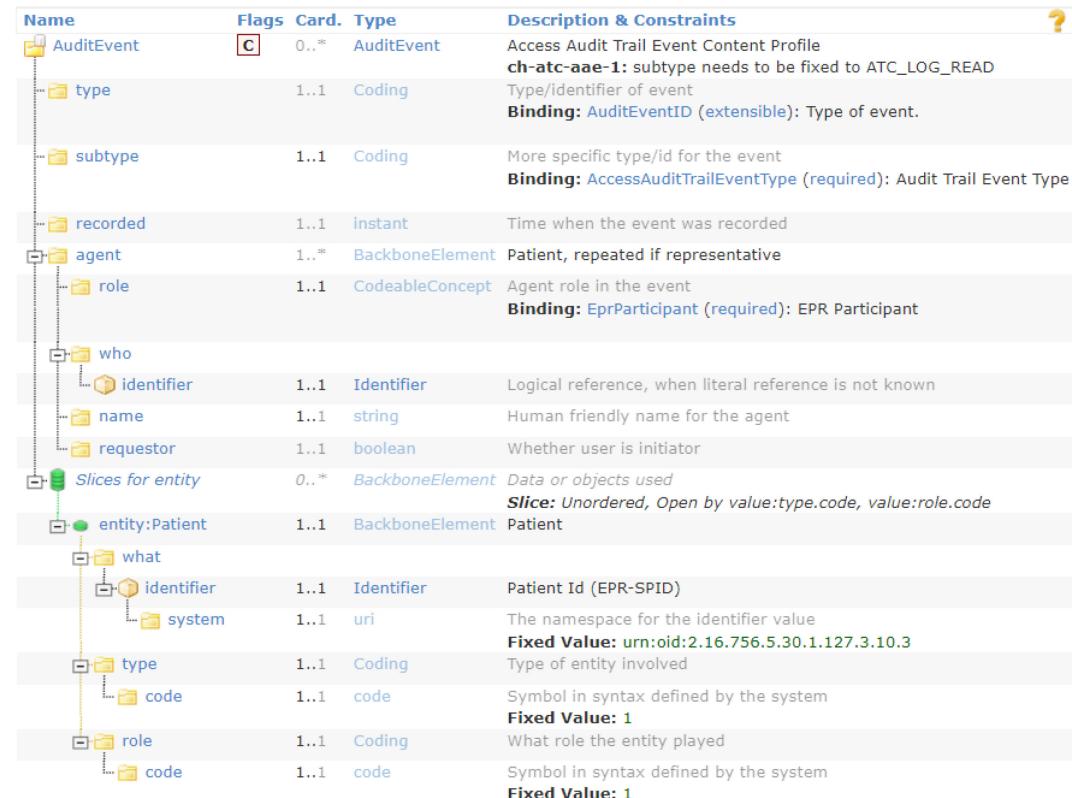


Table 16: StructureDefinition for Access Audit Trail Event Profile

The mapping from the Access Audit Trail Event Resource to the Data Elements is as follows:

| AccessAuditTrailEvent | CH:ATC Data Element/Property |
|-------------------------------------|-------------------------------------|
| AuditEvent | |
| subtype (AccessAuditTrailEventType) | Event Type |
| recorded | Event Date and Time |
| agent | Participants |
| role | role (PAT, REP) |
| who.identifier | Identifier if applicable |
| name | Name |
| requestor | if participant is Initiator |
| entity | |
| entity (Patient) | Patient |
| what.identifier | EPR-SPID |

Table 17: Mapping Access Audit Trail Event to Data Elements

4.4.1 Example

| | |
|-------------|---------------------|
| Event | Access Audit Trail |
| Patient | Jakob Wieder-Gesund |
| Timestamp | 22.09.2020 10:47 |
| Participant | Jakob Wieder-Gesund |

Table 18: Example Log Access (atc-log-read.xml)

```

<AuditEvent xmlns="http://hl7.org/fhir">
  <id value="atc-log-read"/>
  <meta>
    <profile value="http://fhir.ch/ig/ch-atc/StructureDefinition/AccessAuditTrailEvent" />
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">Jakob Wieder-Gesund
has viewed the audit trail 22.09.2020 10:47
    </div>
  </text>
  <type>
    <system value="http://dicom.nema.org/resources/ontology/DCM"/>
    <code value="110106"/>
    <display value="Export"/>
  </type>
  <subtype>
    <system value="urn:oid:2.16.756.5.30.1.127.3.10.7"/>
    <code value="ATC_LOG_READ"/>
    <display value="Accessing the Patient Audit Record Repository"/>
  </subtype>
  <action value="C"/>
  <recorded value="2020-09-22T08:47:00Z"/>
  <outcome value="0"/>

```

```
<agent>
  <role>
    <coding>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
      <code value="PAT"/>
      <display value="Patient"/>
    </coding>
  </role>
  <name value="Jakob Wieder-Gesund" />
  <requestor value="true" />
</agent>
<source>
  <identifier>
    <system value="urn:ietf:rfc:3986"/>
    <!-- oid of system generating this audit event -->
    <value value="urn:oid:7.8.9.10.11"/>
  </identifier>
</source>
<entity>
  <!-- Patient -->
  <what>
    <identifier>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
      <value value="761337610469261945" />
    </identifier>
  </what>
  <type>
    <system value="http://terminology.hl7.org/CodeSystem/audit-entity-type"/>
    <code value="1"/>
    <display value="Person"/>
  </type>
  <role>
    <system value="http://terminology.hl7.org/CodeSystem/object-role"/>
    <code value="1"/>
    <display value="Patient"/>
  </role>
</entity>
</AuditEvent>
```

Listing 5: Example of a log access audit event

4.5 HPD Group Entry Audit Event Content Profile

This content profile describe the Audit Event related to the entry of a healthcare professional into a HPD group for which the patient is notified. The following Data Elements shall be provided:

| Data Element | Description | Property/Value |
|--------------------------|---|----------------------|
| Event Type | Patient notified of Healthcare Professionals added to a group | |
| Event Date and Time | | UTC |
| Notification Service | | Name |
| Patient | Notified patient | EPR-SPID |
| Healthcare Professionals | Healthcare professionals | Name GLN |
| Group | Group where Healthcare Professionals are added as members | Name of Group OID |

Table 19: HPD Group Entry Audit Event Elements

This profile defines the content of the HPD group entry audit event. This profile builds on AuditEvent (<http://hl7.org/fhir/R4/auditevent.html>).

| Name | Flags | Card. | Type | Description & Constraints |
|-------------------------------|-------|-------|-----------------|---|
| AuditEvent | C | 0..* | AuditEvent | HPD Audit Trail Content Profile ch-atc-pae-1: subtype needs to be fixed to ValueSet HpdAuditEventType |
| type | | 1..1 | Coding | Type/identifier of event Binding: AuditEventID (extensible): Type of event. |
| Slices for subtype | | 1..* | Coding | More specific type/id for the event Slice: Unordered, Open by value:system |
| subtype:HpdAuditEventType | | 1..1 | Coding | HPD Audit Event Type Binding: HpdAuditEventType (required): HPD Audit Event Type |
| system | | 1..1 | uri | Identity of the terminology system Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.7 |
| recorded | | 1..1 | instant | Time when the event was recorded |
| agent | | 1..1 | BackboneElement | Notification service |
| who | | 1..1 | Identifier | Logical reference, when literal reference is not known |
| identifier | | 1..1 | string | Name of notification service |
| name | | 1..1 | boolean | Whether user is initiator |
| Slices for entity | | 0..* | BackboneElement | Data or objects used Slice: Unordered, Open by value:role.code |
| entity:Patient | | 1..1 | BackboneElement | Patient |
| what | | 1..1 | Identifier | Patient Id (EPR-SPID) |
| identifier | | 1..1 | uri | The namespace for the identifier value Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.3 |
| system | | 1..1 | Coding | Type of entity involved |
| type | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 1 |
| code | | 1..1 | Coding | What role the entity played |
| role | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 1 |
| code | | 1..1 | uri | Identity of the terminology system Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.6 |
| system | | 1..1 | string | Symbol in syntax defined by the system Fixed Value: HCP |
| entity:HealthcareProfessional | | 1..* | BackboneElement | Healthcare professional (HCP) |
| what | | 1..1 | Identifier | Identifier: HCP (GLN) |
| identifier | | 1..1 | uri | The namespace for the identifier value Fixed Value: urn:oid:2.51.1.3 |
| system | | 1..1 | Coding | Type of entity involved |
| type | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 1 |
| code | | 1..1 | Coding | What role the entity played |
| role | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 1 |
| code | | 1..1 | uri | Identity of the terminology system Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.6 |
| system | | 1..1 | string | Symbol in syntax defined by the system Fixed Value: HCP |
| name | | 1..1 | string | Healthcare professional name |
| entity:Group | | 1..1 | BackboneElement | Group |
| what | | 1..1 | Identifier | Identifier for Group (OID) |
| identifier | | 1..1 | Coding | Type of entity involved |
| system | | 1..1 | code | Symbol in syntax defined by the system Fixed Value: 3 |
| type | | 1..1 | Coding | What role the entity played |
| code | | 1..1 | uri | Identity of the terminology system Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.14 |
| system | | 1..1 | string | Symbol in syntax defined by the system Fixed Value: GRP |
| name | | 1..1 | string | Group name |

Table 20: StructureDefinition for HPD Group Entry Audit Event Content Profile

The mapping from the HPD Group Entry Audit Event Resource to the Data Elements is as follows:

| HpdAuditEvent | CH:ATC Data Element/Property |
|---------------------------------|--------------------------------------|
| AuditEvent | |
| subtype (HpdAuditEventType) | Event Type |
| recorded | Event Date and Time |
| agent | Notification service |
| who.identifier | Identifier if applicable |
| name | Name |
| requestor | If notification service is Initiator |
| entity | |
| entity (Patient) | Patient |
| what.identifier | EPR-SPID |
| entity (HealthcareProfessional) | Healthcare Professional |
| what.identifier | Identifier for HCP (GLN) |
| name | Name of HCP |
| entity (Group) | Group |
| what.identifier | Group OID |
| name | Name of Group |

Table 21: Mapping HPD Group Entry Audit Event to Data Elements

4.5.1 Example

| | |
|--------------------------|--|
| Event | Group entry of healthcare professional: |
| Healthcare professionals | Dr. med. Sabine Musterfrau |
| Timestamp | 10.10.2020 10:05 |
| Participant, Group | Kardiologie Universitätsspital Musterstadt |
| Patient | Jakob Wieder-Gesund |

Table 22: Example group entry of healthcare professionals

```

<AuditEvent xmlns="http://hl7.org/fhir">
    <id value="atc-hpd-group-entry-notify"/>
    <meta>
        <profile value="http://fhir.ch/ig/ch-atc/StructureDefinition/HpdAuditEvent" />
    </meta>
    <text>
        <status value="generated"/>
        <div xmlns="http://www.w3.org/1999/xhtml">
            10.10.2020 10:05: Healthcare professional Dr. med. Sabine Musterfrau has been added to Group Kardiologie Universitätsspital Musterstadt and patient Jakob Wieder-Gesund has been notified
        </div>
    </text>
    <type>
        <system value="http://dicom.nema.org/resources/ontology/DCM"/>
        <code value="110106"/>
        <display value="Export"/>
    </type>

```

```
</type>
<subtype>
    <system value="urn:oid:2.16.756.5.30.1.127.3.10.7"/>
    <code value="ATC_HPD_GROUP_ENTRY_NOTIFY"/>
    <display value="HPD Group Entry Notification"/>
</subtype>
<action value="C"/>
<recorded value="2022-10-10T10:05:00Z"/>
<outcome value="0"/>
<agent>      <name value="Notifikations-Dienst" />
    <requestor value="false" />
</agent>
<source>
    <observer>
        <identifier>
            <system value="urn:ietf:rfc:3986"/>
            <value value="urn:oid:7.8.9.10.11"/>
        </identifier>
    </observer>
</source>
<entity>
    <!-- Patient -->
    <what>
        <identifier>
            <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
            <value value="761337610469261945" />
        </identifier>
    </what>
    <type>
        <system value="http://terminology.hl7.org/CodeSystem/audit-entity-type"/>
        <code value="1"/>
        <display value="Person"/>
    </type>
    <role>
        <system value="http://terminology.hl7.org/CodeSystem/object-role"/>
        <code value="1"/>
        <display value="Patient"/>
    </role>
</entity>
<entity>
    <!-- Healthcare professional -->
    <what>
        <identifier>
            <system value="urn:oid:2.51.1.3"/>
            <value value="7601000050717"/>
        </identifier>
    </what>
    <type>
        <system value="http://terminology.hl7.org/CodeSystem/audit-entity-type"/>
        <code value="1"/>
        <display value="Person"/>
    </type>
```

```
<role>
    <system value="urn:oid:2.16.756.5.30.1.127.3.10.6"/>
    <code value="HCP"/>
    <display value="Healthcare professional"/>
</role>
<name value="Dr. med. Sabine Musterfrau"/>
</entity>
<entity>
    <!-- Group Entry -->
    <what>
        <identifier>
            <value value="urn:oid:1.1.1.1.1"/>
        </identifier>
    </what>
    <type>
        <system value="http://terminology.hl7.org/CodeSystem/au-
dit-entity-type"/>
        <code value="3"/>
    </type>
    <role>
        <system value="urn:oid:2.16.756.5.30.1.127.3.10.14"/>
        <code value="GRP"/>
    </role>
    <name value="Kardiologie Universitätsspital Musterstadt"/>
</entity>
</AuditEvent>
```

Listing 6: Example of a HPD group entry audit event

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