



Revisionsentwurf zur Ergänzung 2 zu Anhang 5 der Verordnung des EDI vom
22. März 2017 über das elektronische Patientendossier

Nationale Integrationsprofile nach Artikel 5 Absatz 1 Buchstabe c
EPDV-EDI

Audit Trail Consumption (CH:ATC)

Änderungsnachweis seit Inkrafttreten 15. April 2017

Die Anpassungen der Anhänge zur EPDV-EDI werden durch das BAG laufend vorgenommen und die Zwischenstände durch eHealth Suisse der Öffentlichkeit zugänglich gemacht. Der Nachweis ermöglicht eine Vorschau auf eine mögliche künftige Version der normativen Spezifikationen.

Bis zur Inkraftsetzung der revidierten Verordnung gilt formell die Ausgabe, welche am 15. April 2017 in Kraft getreten ist.

Bezüglich der zu verwendenden Metadaten gilt aktuell die Version 1.2 des Revisionsentwurfs zum Anhang 3 der EPDV-EDI. Dieser entspricht den publizierten Value Sets der Version 201704.x-beta auf ART-DECOR, abrufbar unter: <http://art-decor.org/art-decor/decor-project--ch-epr->

Die von eHealth Suisse publizierte Programmierhilfe enthält die aktuellen Verweise auf die Stable/Beta-Versionen im JSON Format: https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2017/D/180131_Anleitung_Zugang_Metadaten_und_Synonymen_v1.2_d.pdf

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Profile: CH:ATC

Anpassungen:

Version	Datum	Ticket	Vorgenommene Anpassung
1.0.0	18.6.2018		Resolved open issues CH:ATC_014 and CH:ATC_015, Release
0.9.7	12.6.2018		Resolved open issues CH:ATC_006 and CH:ATC_013
0.9.6	11.6.2018		Integrated CH:XUA (A5E1), Version 1.3 from 31.5.2018
0.9.5	01.6.2018		Release candidate for FOPH, AG TSI
0.9.4	30.5.2018		Feedback from workshop/telco
0.9.3	29.5.2018		ImplementationGuide published
0.9.2	28.5.2018		Feedback from workshop
0.9.1	23.5.2018		Integrated Feedback from AG TSI, Samples
0.9.0	15.5.2018		Initial Draft for AG TSI
0.8.1	11.5.2018		Initial Draft for FOPH

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1 Introduction

Das elektronische Patientendossier (EPD) basiert auf einem System mit mehreren IHE XDS-Gemeinschaften, in welchem die Patientin oder der Patient nicht nur die Zustimmung zur Erstellung und Verwendung ihres oder seines Dossiers gibt, sondern auch explizit Zugangsregeln durch ein Zugangsportal für Patientinnen und Patienten festlegt.

Patientinnen und Patienten müssen die Möglichkeit haben, die Protokolldaten zu ihrem elektronischen Patientendossier aus allen Gemeinschaften und Stammgemeinschaften in einer für sie lesbaren Form im Patientenportal der Stammgemeinschaft einzusehen. Dieses Profil CH:ATC definiert die Audit-Trail-Anforderungen, die eine Gemeinschaft für einen Patienten-Audit-Trail bereitstellen muss.

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 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 provide for a patients audit trail

1.1 Definitions of terms

For the definition of terms, refer to SR 816.111.11: Authorization Decision Request (CH:ADR) and Privacy Policy Query (CH:PPQ). The same definition of terms is also valid for the present document.

Open Issues

CH:ATC_002: Each community needs to publish an URL for querying the Patient Audit Record Repository.

Fully qualified endpoint, corresponding to the other endpoints to the CPI, equivalent to the other endpoint setup. Attribute needs to be created in CH:CPI.

CH:ATC_003: The grouping with the CH:ADR Authorization Decision Consumer actor requires an update of the CH:ADR profile and the policy stack

The transaction ITI-81 needs to be added in the Authorization Decision Request (CH:ADR) and the policy stack must be extended to support enforcement that only the patient and delegate of the patient can access the audit log.

Closed Issues

CH:ATC_001: Shall EPRS-PID or MPI-PID specified in the queries/Patient Audit Record Repository?

Patient Audit Record Repository requires EPR_SPID. Policy Repository has also only the EPR_SPID in the policies. Since Patient Audit Record Repository is grouped with CH:ADR the EPR_SPID has to be provided by the Patient Audit Consumer in the http Header, therefore EPR_SPID is specified.

CH:ATC_004: There are current requirements in CH:ATNA which contradicts or are not necessary anymore if CH:ATC is specified for Audit Trail Consumption.

Current position of FOPH is that how the Audit Messages for CH:ATC are generated is out of scope for this profile. The AuditEvent Resource has been profiled in such a way that most part of the information can be derived from a DICOM message as defined in CH:ATNA.

The ATC profile contradicts with CH:ATNA (except 1a, 1b which are in collision with DICOM/IHE) and the following points should be considered to **be removed or adapted** in CH:ATNA:

1. AuditMessage/ActiveParticipant

- a. UserID format conflicts with DICOM format (loginName@domain-name see http://dicom.nema.org/medical/dicom/current/output/chtml/part15/sect_A.5.2.html#sect_A.5.2.1)
- b. UserName is in conflict with ITI XUA (Vol 2.b 3.40.4.2 ATNA Audit encoding) where alias "<"user"@<"issuer">" is requested as format. Submit Change Proposal (CP) for IHE?
- c. RoleIDCode should not be xds_author_Role but role for CH-EPR actors (RoleIDCode element is 0..n), to be decided to replace xds_authorRole and use CH-EPR actors or at least add it and leave xds_authorRole

2. AuditMessage/AuditSourceIdentification

- a. @AuditEnterpriseSiteID When presenting to the user, the GLN details MUST be provided: Presenting to the user is not applicable to the CH:ATNA profile.
- b. @AuditSourceID equivalent to above

3. AuditMessage/ParticipantObjectIdentification

- a. @ParticipantObjectSensitivity: Drop requirements on CNE.2 (language specific*) and CNE.7 (publication of valueset):
- b. ParticipantObjectDescription (type: xs:token) drop requirement, reference*
- c. ParticipantObjectID: when ParticipantObjectIdentification is describing a patient with a patient related AuditEvent transaction

and that transaction is grouped with XUA, the EPR_SPID shall be added in this element. Format patient ID in HL7 CX.

4. CodedValueType

- a. displayName, original Text: Drop requirement for language support in users preferred language*

* Actors providing the Audit Event records cannot access the preferred language of the intended recipient (patient or delegate), therefore the information in the Audit Event is coded and the textual display needs to be generated by a Patient Portal for the recipients preferred language.

AG TSI decided on June 6th that CH:ATNA will be resolved with this conflicts.

CH:ATC_005: The AuditEvent messages profile requires the Values from 2.16.756.5.30.1.127.3.10.5 (PurposeOfUse) and 2.16.756.5.30.1.127.3.10.6 (eHealth Suisse EPR Actors), which are defined in A5E2 and are not available in Art-Decor.

Done, see [EprPurposeOfUse](#), [EprActors](#).

CH:ATC_006: It is not clear/possible how to get to the group name, roles technical system/admin and identifiers from the XUA token into the Patient Audit Record Repository.

Group name can be resolved through HPD, identifier of group has to be specified. REP: EPR-SPID or UAP-ID, ASS: GLN or UAP-ID, Technical User: X.509 ID or other.

CH:ATC_007: Audit Event Type Codes should be modeled in CH-EPR (Art-Decor)

[EprAuditTrailConsumptionEventTypes](#). OID 2.16.756.5.30.1.127.3.10.7
(Registration in refdata to be done).

CH:ATC_008: Audit Events in respect to Policy Management

Example for Audit Events for creating/deleting/updating Access Rights from a patient to a Healthcare Professional with the possibility to propagate his rights (see 816.11, Art 4g) and for a representative should be created. Done, see samples in Content Profiles.

CH:ATC_009: Implementation Guide for Audit Event Profiles

Implementation Guide (ch-atc.zip) will be downloadable officially at https://ehealthsuisse.ihe-europe.net/docs/reference_documents/, current build version of Implementation Guide: <http://build.fhir.org/ig/ahdis/ch-atc/index.html>

CH:ATC_010: Actor naming of CH:ATC Audit Consumer, Audit Record Repository?

Should it not be a specialized actor instead of the same names as in RESTful ATNA? Renamed actors to Patient Audit Record Repository and Patient Audit Consumer.

CH:ATC_011: Further information for DocumentEntry in detail type/value pair

To provide further information about a Document or Policy Audit Event additional information has to be provided (currently repositoryUniqueId, homeCommunityId, EprDocumentTypeCode). They are provided with detail.type and detail.value pairs. This works and follows IHE TF Vol 2b mapping for ATNA, however the value have to be specified in base64 which is not readable/structured. An extension could be made as an alternative, but decision was made to not pursue.

CH:ATC_012: Canonical URL for ImplementationGuide Artefacts?

The FHIR Artefacts (ImplementationGuide/StructureDefinition/ValueSets) need a canonical URL (needs not to be resolved in a web browser). Currently fhir.ch is used. This has only impact on the conformance resources and validation.

CH:ATC_013: Code for identifying an agent as a Group

Groups where a Healthcare Professional is member have to be specified in the AuditEvent. This is specified as an agent Element. To differentiate the different agent roles (HCP, PAT etc) a code is need to identify a group. Can code GRP for group be introduced in Codesystem 2.16.756.5.30.1.127.3.10.6? A new Code System EprAgentRole with oid 2.16.756.5.30.1.127.3.10.8 (needs to be registered in refdata).

CH:ATC_014: Narrative text of coded Audit Event?

The AuditEvent contains structured data. A narrative of the coded Audit Event must be provided.

CH:ATC_015: Anhang 2 der EPDV-EDI: Zertifizierungsvoraussetzungen SR 816.111.1 needs to be adjusted for CH:ATC

- 2.10.3 c, 2.10.5 – search not required for CH:ATC, decision made by FOPH, AG TSI
- 2.10.9 add CH:ATC
- 4.6.2 d reference CH:ATC Actors also

CH:ATC_016: AuditEvent with successful outcome

The AuditEvent types provided by FOPH describe audit events with a successful outcome. This profile does not specify this explicitly, but it is clear from the defined AuditEvent Types.

2 Volume 1 – 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 transaction [ITI-81] of the IHE IT Infrastructure Technical Framework Supplement Add RESTful Query to ATNA¹ and defines the content of the Audit Messages. The different types of the Audit Messages are based on the requirements for Document and Policy Access management 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 IHE / CH:ATNA requirements.

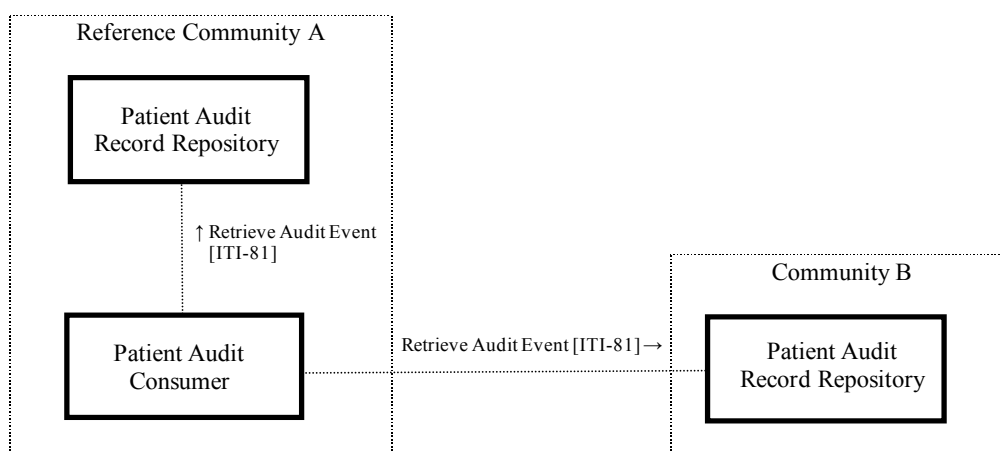


Figure 1 CH:ATC Overview within the Swiss EPR circle of trust

Each community must provide one endpoint to a Patient Audit Record Repository which can be queried according to the [ITI-81] RESTful Query transaction. A reference community must 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 Document and Policy Access management Audit Events within the community is outside the scope of this profile.

¹ http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_RESTful-ATNA.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.

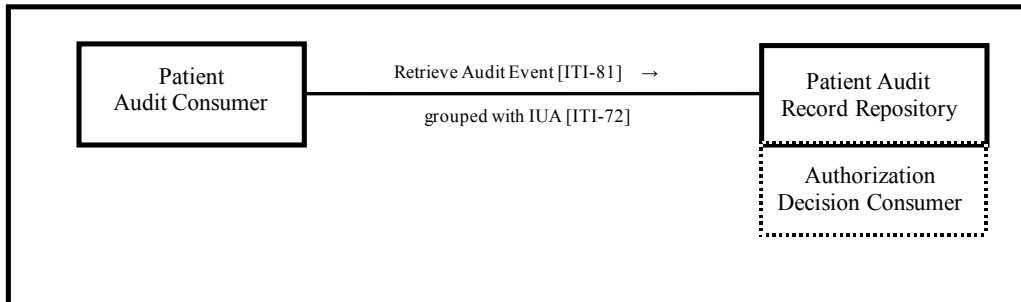


Figure 2 CH:ATC Actor diagram

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 2.2.1.1
Patient Audit Record Repository	Retrieve Audit Event [ITI-81]	Responder	R	CH:ATC 2.2.1.2

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 IT Infrastructure Technical Framework and the IHE IT Infrastructure Technical Framework Supplement Add RESTful Query to ATNA actors. This section documents any additional requirements on the profile’s actors required in the Swiss EPR context.

2.2.1.1 Patient Audit Record Repository

For the actor Patient Audit Record Repository the actor Audit Record Repository in IHE IT Infrastructure Technical Framework Supplement Add RESTful Query to ATNA is relevant.

The Patient Audit Record Repository shall support the Retrieve Audit Message Option from the Audit Record Repository (ITI TF-1: 9.2.3) with the search capabilities as defined in ITI TF- 2c: 3.81 and the Audit Message Formats defined in Volume 3 – Content Profiles.

2.2.1.2 Patient Audit Consumer

For the actor Patient Audit Consumer the actor Audit Consumer in IHE IT Infrastructure Technical Framework Supplement Add RESTful Query to ATNA 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-1: 9.2.3).

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

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 must 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.

ATC Actor	Grouping Condition	Actor to be grouped with	Reference
Patient Audit Consumer	Required	CH:ATNA - Secure Node	SR 816.11 Annex 5, Extension 1
	Required	CH:CT - Time Client	SR 816.11 Annex 5, Extension 1
	Required	IUA - Authorization Client	IHE ITI Suppl IUA
	Optional	CH:CPI – CPI Consumer	SR 816.11 Annex 5, Extension 2
Patient Audit Record Repository	Required	CH:ATNA - Secure Node	SR 816.11 Annex 5, Extension 1
	Required	CH:CT - Time Client	SR 816.11 Annex 5, Extension 1
	Required	CH:ADR – Authorization Decision Consumer	SR 816.11 Annex 5, Extension 2
	Required	IUA - Resource Server	IHE ITI Suppl IUA

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 policy access management events 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.

2.6 Security Considerations

The transaction is used to exchange sensitive information and requires authentication and authorization. Grouping of the actors with the ATNA profile is required to ensure TLS Mutual-Authentication, Integrity and Confidentiality.

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 3.72.4.1.2.1 in IHE-ITI-Supplement IUA). As defined therein, the CH:ATC Audit Consumer and Audit Record Repository shall implement the ITI-72 Incorporate Authorization Token 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.

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 in the IHE IT Infrastructure Technical Framework and the IHE IT Infrastructure Technical Framework Supplement Add RESTful Query to ATNA. 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/STU3/search.html>) on AuditEvent Resources (see <http://hl7.org/fhir/STU3/auditevent.html>). This “search” target is formatted as:

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

where:

- **<scheme>** shall be https.
- **<query>** shall include the patient.identifier as defined in 3.1.2 otherwise an HTTP response code 400 - Bad Request shall be returned.

3.1.2 Additional ATNA Search Parameters

patient.identifier is a parameter of `token` type. This parameter specifies the identifier of the patient involved in the event as a participant. The value of this parameter can contain the namespace URI (that represents the assigning authority for the identifier) and the identifier.

For example: `http://example.com/ARRservice/AuditEvent?date=ge2020-03-22&date=le2025-03-22&patient.identifier=urn:oid:2.16.756.5.30.1.127.3.10.3|5678`

The Patient Audit Record Repository shall match this parameter only with the `AuditEvent.agent.identifier` field that represents the patient. The Patient Audit Record Repository shall not match this parameter with other fields in the AuditEvent Resource. (The patient identifier can be used in other audit event fields; the objective of this constraint is to force the repository to respond only with audit records for which the identifier specified in the query plays the role of the patient identifier, and not with all the audit records that involve this identifier in other roles).

For the CH:ATC profile the patient.identifier has to be the EPR-SPID, eg:
`patient.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. Grouping of the actors with the ATNA profile is required to ensure TLS Mutual-Authentication, Integrity and Confidentiality

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 3.72.4.1.2.1 in IHE-ITI-Supplement IUA). As defined therein, the CH:ATC Audit Consumer and Audit Record Repository shall implement the ITI-72 Incorporate Authorization Token transaction to convey the XUA token.

The actors shall implement the ITI-72 transaction with SAML token option, using the base64 encoded SAML assertion defined in CH:XUA to the authorization header of the HTTP1.1 GET request with key IHE-SAML as follows:

```
GET /example/url/to/resource/location HTTP/1.1
Authorization: IHE-SAML_fFBGRNJrulFQd[...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 generated.

4 Volume 3 – Content Profiles

Audit Events in the context of the EPR which must be made available for the audit trail fall in three different categories:

- Document management (e.g. a document has been uploaded in the EPR for a patient)
- Policy management (e.g. a patient has given a healthcare professional access rights to his EPR)
- Access Patient Audit Record Repository by a patient or representative (a patient viewed the Audit Trail for the Audit Record Repository)

Each category is described as a content profile. These content profiles are based on the AuditEvent Resource, <http://hl7.org/fhir/STU3/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/STU3/auditevent-mappings.html> which allows to map to CH:ATNA.

4.1 Audit Trail Consumption Event Types

The following Audit Trail Consumption Event Types are defined and MUST 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_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

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 must be provided:

Data Element	Description	Property/Value
Event Type	Document upload Document retrieval Document or Document Metadata update Document removal	
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 or UAP-ID
	Technical User	Name Identifier
	Administrative User	Name UAP-ID
Responsible ²	Patient	Name
	Healthcare Professional	Name GLN
Groups where Healthcare Professional is member		Name of Group OID
PurposeOfUse		Regular or Emergency Access
Patient	Involved patient	EPR-SPID
Document	type of document	typeCode ³ (SNOMED CT code)
	reference to document	uniqueId ⁴ repositoryUniqueId ⁵ homeCommunityID ⁶

Table 5 Document Audit Event Data Elements

² If different from Initiator (Representative of patient acting on behalf of a patient then patient is responsible)

³ SR 816.11, Annex 3, 3.11 type of document (2.16.756.5.30.1.127.3.10.1.27)

⁴ IHE TF ITI Vol 3, 4.2.3.2.26 DocumentEntry.uniqueId

⁵ IHE TF ITI Vol 3, 4.2.3.2.18 DocumentEntry.repositoryUniqueId

⁶ IHE TF ITI Vol 3, 4.2.3.2.12 DocumentEntry.homeCommunityId

This profile defines the content of the document audit events which a community has to provide for a patients audit trail. This profile builds on AuditEvent (<http://hl7.org/fhir/STU3/auditevent.html>).

Name	Flags	Card.	Type	Description & Constraints
AuditEvent		0..*		Document Audit Trail Content Profile
id	Σ	1..1	id	Logical id of this artifact
text		1..1	Narrative	A human-readable narrative that contains the summary of the Audit Event.
type	Σ	1..1	Coding	Type/identifier of event Binding: Audit Event ID (extensible)
subtype	Σ		Coding	Slice: Unordered, Open by value:system
subtype	Σ	1..1	Coding	DocumentAuditEventType Binding: DocumentAuditEventType (required)
system		1..1	uri	Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.7
recorded	Σ	1..1	instant	Time when the event was recorded
purposeOfEvent	Σ	1..1	CodeableConcept	The purposeOfUse of the event Binding: EprPurposeOfUse (required)
agent		1..*	BackboneElement	Participants
role	Σ	1..1	CodeableConcept	Agent role in the event Binding: EprParticipant (required)
userId	Σ	0..1	Identifier	Unique identifier for the user
name	Σ	1..1	string	Human-meaningful name for the agent
requestor	Σ	1..1	boolean	Whether user is initiator
entity	I		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	Σ	1..1	BackboneElement	Patient
identifier	Σ	1..1	Identifier	Patient ID in HL7 CX format, EPR-SPID
type	Σ	1..1	Coding	Type of entity involved
code	Σ	1..1	code	Fixed Value: 1
role	Σ	1..1	Coding	What role the entity played
code	Σ	1..1	code	Fixed Value: 1
entity	Σ	1..1	BackboneElement	Document
identifier	Σ	1..1	Identifier	XDSDocumentEntry.uniqueId
type	Σ	1..1	Coding	Type of entity involved
code	Σ	1..1	code	Fixed Value: 2
role	Σ	1..1	Coding	What role the entity played
code	Σ	1..1	code	Fixed Value: 3
detail	Σ		BackboneElement	Slice: Unordered, Open by value:type
detail	Σ	1..1	BackboneElement	repositoryUniqueId
type	Σ	1..1	string	Name of the property Fixed Value: Repository Unique Id
value	Σ	1..1	base64Binary	Property value
detail	Σ	1..1	BackboneElement	homeCommunityID
type	Σ	1..1	string	Name of the property Fixed Value: homeCommunityID
value	Σ	1..1	base64Binary	Property value
detail	Σ	1..1	BackboneElement	EprDocumentTypeCode
type	Σ	1..1	string	Name of the property Fixed Value: EprDocumentTypeCode
value	Σ	1..1	base64Binary	Property value

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, AST, REP, TCU, ADM, GRP)
userId	Identifier if applicable
name	Name
requestor	if participant is Initiator
entity	
entity (Patient)	Patient
identifier	EPR-SPID
entity (Document)	Document
identifier	uniqueId
detail (repositoryUniqueId)	repositoryUniqueId
detail (homeCommunityID)	homeCommunityID
detail (EprDocumentTypeCode)	typeCode

Table 7 Mapping Document Audit Event to Data Elements

4.2.1 Example Document Audit Event

Event	Upload
Resource: type of Document	Birth certificate (SOMED CT: 444561001)
Resource: reference to Document	uniqueId
Event Date and Time	10.10.2020 18:29
Participant, Initiator	Julia Helfe-Gern
Participant, Responsible	representing Jakob Wieder-Gesund

Table 8 Uploading a Birth certificate 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 Birth certificate
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>
</AuditEvent>
```

```

</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>
  <userId>
    <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
    <value value="761337610469261945" />
  </userId>
  <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>
  <name value="Julia Hilfe 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 -->
  <identifier>
    <value
value="761337610469261945^^^&2.16.756.5.30.1.127.3.10.3&ISO"/>
  </identifier>

```

```
<type>
  <system value="http://hl7.org/fhir/object-type"/>
  <code value="1"/>
  <display value="Person"/>
</type>
<role>
  <system value="http://hl7.org/fhir/object-role"/>
  <code value="1"/>
  <display value="Patient"/>
</role>
</entity>
<entity>
  <!-- Document -->
  <identifier>
    <type>
      <coding>
        <system value="urn:uuid:2e82c1f6-a085-4c72-9da3-8640a32e42ab"/>
        <code value="IHE XDS Metadata"/>
        <display value="XSDocumentEntry.uniqueId"/>
      </coding>
    </type>
    <system value="urn:ietf:rfc:3986"/>
    <value value="urn:oid:1.2.3.4.5"/>
  </identifier>
  <type>
    <system value="http://hl7.org/fhir/object-type"/>
    <code value="2"/>
    <display value="System Object"/>
  </type>
  <role>
    <system value="http://hl7.org/fhir/object-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="NDQ0NTYxMDAx" />
    <!-- base64 typeCode 444561001 -->
  </detail>
</entity>
</AuditEvent>
```

4.3 Policy Audit Event Content Profile

This content profile describes Audit Events related to Policy Management. The following Data Elements must 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 ⁷	Name GLN
	Assistant of a Healthcare Professional ⁷	Name GLN or UAP-ID
	Administrative User	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 ⁸	one of urn:e-health-suisse:2015:policies:access-level: normal, restricted, delegation-and-restricted, delegation-and-normal, full
	AccessLimitedToDate ⁸	UTC

⁷ Healthcare Professional or Assistant of Healthcare Professional can only be a participant for the first Event Type (Authorize participants to access level).

⁸ Access Level and the date if the access is limited are only relevant for the first two Event Types (Authorize and update Authorization participants to access level/date).

	ProvideLevel ⁹	one of urn:e-health-suisse:2015:policies:provide-level: normal, restricted, secret
--	---------------------------	---

Table 9 Policy Audit Event Data Elements

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/STU3/auditevent.html>).

Name	Flags	Card.	Type	Description & Constraints
AuditEvent		0..*		Policy Audit Trail Content Profile
id	Σ	1..1	id	Logical id of this artifact
text		1..1	Narrative	A human-readable narrative that contains the summary of the Audit Event.
type	Σ	1..1	Coding	Type/identifier of event Binding: Audit Event ID (extensible)
subtype	Σ		Coding	Slice: Unordered, Open by value:system
subtype	Σ	1..1	Coding	PolicyAuditEventType Binding: PolicyAuditEventType (required) Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.7
system		1..1	uri	
recorded		1..1	instant	Time when the event was recorded
agent		1..*	BackboneElement	Participants
role	Σ	1..1	CodeableConcept	Agent role in the event Binding: EprParticipant (required)
userId		0..1	Identifier	Unique identifier for the user
name	Σ	1..1	string	Human-meaningful name for the agent
requestor		1..1	boolean	Whether user is initiator
entity	I		BackboneElement	Data or objects used Slice: Unordered, Open by value:type.code sev-1: Either a name or a query (NOT both)
entity	Σ	1..1	BackboneElement	Patient
identifier		1..1	Identifier	Patient ID in HL7 CX format, EPR-SPID
type	Σ	1..1	Coding	Type of entity involved
code		1..1	code	Fixed Value: 1
role	Σ	1..1	Coding	What role the entity played
code		1..1	code	Fixed Value: 1
entity	Σ	0..1	BackboneElement	Resource (HCP, Group, Representative of Patient)
identifier		0..1	Identifier	Identifier. HCP (GLN), Group (OID)
type	Σ	1..1	Coding	Type of entity involved
code		1..1	code	Fixed Value: 2
role	Σ	1..1	Coding	What role the entity played Binding: EprParticipant (required)
name	I	1..1	string	Descriptor for entity
detail	I		BackboneElement	Slice: Unordered, Open by value:type
detail	I	0..1	BackboneElement	AccessLevel if subtype is Create or Update
type		1..1	string	The type of extra detail provided in the value. 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	I	0..1	BackboneElement	AccessLimitedToDate if subtype is Create or Update
type		1..1	string	Name of the property Fixed Value: AccessLimitedToDate
value		1..1	base64Binary	date in Property value
detail	I	0..1	BackboneElement	ProvideLevel if subtype is ATC_POL_DEF_CONFLEVEL
type		1..1	string	Name of the property Fixed Value: ProvideLevel
value		1..1	base64Binary	one of urn:e-health-suisse:2015:policies:provide-level: normal, restricted or secret

Table 10 StructureDefinition for Policy Audit Event Profile

⁹ Provide Level is only relevant for the Event Type Default Confidentiality Level for new Documents.

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, AST, REP, GRP, ADM)
userId	Identifier if applicable
name	Name
requestor	if participant is Initiator
entity	
entity (Patient)	Patient
identifier	EPR-SPID
entity (Resource)	Resource
identifier	Identifier if applicable
name	Name of HCP, Group or Representative of Patient
detail (AccessLevel)	AccessLevel
detail (AccessLimitedToDate)	AccessLimitedToDate
detail (ProvideLevel)	ProvideLevel

Table 11 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
Event Date and Time	22.09.2020 09:47
Participant Initiator	Jakob Wieder-Gesund

Table 12 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"/>
  </subtype>
</AuditEvent>
```



```
    <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>
    <userId>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
      <value value="761337610469261945" />
    </userId>
    <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 -->
    <identifier>
      <value
value="761337610469261945^^^&2.16.756.5.30.1.127.3.10.3&ISO"/>
      </identifier>
    <type>
      <system value="http://hl7.org/fhir/object-type"/>
      <code value="1"/>
      <display value="Person"/>
    </type>
    <role>
      <system value="http://hl7.org/fhir/object-role"/>
      <code value="1"/>
      <display value="Patient"/>
    </role>
  </entity>
  <entity>
    <!-- Resource -->
    <identifier>
      <system value="urn:oid:2.51.1.3" />
      <value value="7601000234438" />
    </identifier>
    <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="HCP"/>
      <display value="Healthcare professional"/>
    </role>
    <name value="Dr. med. Hans Allzeitbereit" />
    <detail>
      <type value="AccessLevel" />
      <value
value="dXJuOmUtaGVhbHRoLXN1aXNzZToyMDE1OnBvbG1jaWVzOmFjY2Vzcy1sZXZlbDpkZWxlZ2F0aw9uLWFl
uZC1yZXN0cm1jdGVk" />
      <!-- base64 of urn:e-health-suisse:2015:policies:access-level:delegation-
and-restricted -->
    </detail>
  </entity>
```

```

    <type value="AccessLimitedToDate" />
    <value value="MjAyMC0xMi0zMVQwODowMDowMFo=" />
    <!-- base64 of 2020-12-31T08:00:00Z -->
  </detail>
</entity>
</AuditEvent>

```

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

Table 13 Example Create for a representative (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 Hilfe 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>
  <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>
    <userId>
      <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
      <value value="761337610469261945" />
    </userId>
    <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 -->
    <identifier>
      <value value="761337610469261945^^^&2.16.756.5.30.1.127.3.10.3&ISO"/>
    </identifier>
  </entity>

```

```
    <system value="http://hl7.org/fhir/object-type"/>
    <code value="1"/>
    <display value="Person"/>
  </type>
  <role>
    <system value="http://hl7.org/fhir/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>
```

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 must be provided:

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

Table 14 Access Audit Trail Data Elements

This content profile defines the access audit trail event which a community has to provide for a patients audit trail. This profile builds on AuditEvent ((<http://hl7.org/fhir/STU3/auditevent.html>)).

Name	Flags	Card.	Type	Description & Constraints
AuditEvent		0..*		Access Audit Trail Event Content Profile
id	Σ	1..1	id	Logical id of this artifact
text		1..1	Narrative	A human-readable narrative that contains the summary of the Audit Event.
type	Σ	1..1	Coding	Type/identifier of event Binding: Audit Event ID (extensible)
subtype	Σ		Coding	Slice: Unordered, Open by value:system
subtype	Σ	1..1	Coding	AccessAuditTrailEventType Binding: AccessAuditTrailEventType (required)
system		1..1	uri	Fixed Value: urn:oid:2.16.756.5.30.1.127.3.10.7
recorded	Σ	1..1	instant	Time when the event was recorded
agent		1..*	BackboneElement	Patient, repeated if representative
role	Σ	1..1	CodeableConcept	Agent role in the event Binding: EprParticipant (required)
userId	Σ	0..1	Identifier	Unique identifier for the user
name	Σ	1..1	string	Human-meaningful name for the agent
requestor	Σ	1..1	boolean	Whether user is initiator
entity	I		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	Σ	1..1	BackboneElement	Patient
identifier	Σ	1..1	Identifier	Patient ID in HL7 CX format, EPR-SPID
type	Σ	1..1	Coding	Type of entity involved
code	Σ	1..1	code	Fixed Value: 1
role	Σ	1..1	Coding	What role the entity played
code	Σ	1..1	code	Fixed Value: 1

? Documentation for this format

Table 15 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)
userId	Identifier if applicable
name	Name
requestor	if participant is Initiator
entity	
entity (Patient)	Patient
identifier	EPR-SPID

Table 16 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 17 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>
</AuditEvent>
```

```
<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>
  <userId>
    <system value="urn:oid:2.16.756.5.30.1.127.3.10.3" />
    <value value="761337610469261945" />
  </userId>
  <name value="Jakob Wieder-Gesund" />
  <requestor value="true" />
</agent>
<source>
  <identifier>
    <system value="urn:ietf:rhc:3986"/>
    <!-- oid of system generating this audit event -->
    <value value="urn:oid:7.8.9.10.11"/>
  </identifier>
</source>
<entity>
  <!-- Patient -->
  <identifier>
    <value
value="761337610469261945^^&2.16.756.5.30.1.127.3.10.3&ISO"/>
    </identifier>
  <type>
    <system value="http://hl7.org/fhir/object-type"/>
    <code value="1"/>
    <display value="Person"/>
  </type>
  <role>
    <system value="http://hl7.org/fhir/object-role"/>
    <code value="1"/>
    <display value="Patient"/>
  </role>
</entity>
</AuditEvent>
```

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