Terminology Operations Concept & Operations Manual

Version 2.4

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Version	Change Date	Description	Name
1.1	18-September-2020	Initial Version	René Tielsch-Nebel
1.2	30-September-2020	Inclusion of newly uploaded Terminologies	Abdul Mateen
1.3	21-October-2020	Reformatted, added definition & features of Ontoserver with Terminologies. Also updated with more Terminologies	Abdul Mateen
1.4	27-October-2020	Added Access to the terminology server from external partner	Jonathan Okereke
1.5	27-October-2020	Title, Formatting, figures labels	Abdul Mateen
1.6	28-October-2020	Added Syndication feed section	Abdul Mateen
1.7.	4- January-2021	Implementation of an Allowed-list as an alternative authentication mechanism for accessing the terminology server.	Jonathan Okereke
1.8.	7-June- 2022	Added maintenance windows and adjusted code system overview table	Rene Tielsch-Nebel, Muhammad Adnan
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2.3	13.1.2023	Added details GÉANT certificate	Muhammad Adnan
2.4.	5.1.2024	Adjusted email addressing	Rene Tielsch-Nebel

Table of Content

1.   Summary

This document describes the operations of the terminology service hosted at the MeDIC at the University Clinic, Cologne, available for the members of the Medical informatics initiative (MI-I) located in Germany.

2.   Environment Description

2.1.   Ontoserver

Ontoserver is a clinical terminology server, which is based on the HL7 Fast Health Interoperability Resources (FHIR) standard. It has been developed by the Australian E-Health Research Council at CSIRO with the aim to overcome some of the challenges that have hindered adoption of standardized clinical terminologies. It queries, searches, filters and ranks standard clinical terminologies such as SNOMED CT.

Increasing adoption of terminologies is an important goal because it will not only help to improve the quality of clinical data, but will also lead to a better clinical decision support and thereby ultimately to better patient outcomes. A key use case for Ontoserver is to translate clinical descriptions of a phenotype into a standardized terminology with associated codes. This is achieved through fast, incremental searches, and context-specific result ordering.

Possibility to search clinical terminologies by using Ontoserver enforces the greater use of standardized, coded medical data in clinical praxis. This would also largely contribute to diminish further use of natural language in clinical praxis, which is often difficult to compute and prone to variation. Standardization of medical data also facilitates the development of genotype-phenotype databases and supports the sharing of these datasets – vital to yielding the benefits of clinical genomics to health systems.

Some of Ontoserver's key features include: Out-of-the-box support for SNOMED CT, LOINC and OWL ontologies, such as the Human Phenotype Ontology (HPO); a fast, prefix-based search algorithm to ensure that users can easily find content and are not discouraged from entering coded data; the use of the HL7 FHIR Terminology Services standard; a syndication mechanism to facilitate keeping terminologies up to date across multiple instances; a full implementation of SNOMED CT's Expression Constraint Language (ECL) syntax for querying concepts, which enables sophisticated data analytics, as well as support for SNOMED CT's Post Coordinated Expressions (PCEs) for combining codes into computable concepts.

2.2. Syndication feed

A syndication feed offers a possibility to import code systems directly from another Ontoserver so thus the user does not have to do that by himself. The Ontoserver works with a pull model which means that you have to specify the syndication feed source and execute a pull request for each code system you want to import. In addition to that, Ontoserver also supports "preloading" resources via a remote Atom feed via the atom.preload.feedLocation setting in docker-compose.yml. Further details and Postman collection can be provided on request.

2.3.   Shrimp

Shrimp is a complementary tool, which is developed by CSIRO. It works as a clinical terminology search, visualization, and exploration tool. It runs in a browser, and communicates with Ontoserver instance using the RESTful FHIR Terminology API. The

endpoint of the UI can be manually specified via an entry box, so that a local Ontoserver instance can be used as well. Shrimp is available at:

https://ontoserver.csiro.au/shrimp/ (for communicating with Ontoserver instances via HTTPS) and http://ontoserver.csiro.au/shrimp (for communicating with insecure Ontoserver instances via HTTP)

2.4. Snapper

Snapper enables the creation and maintenance of the FHIR terminology resources i.e. CodeSystem, ValueSet, and ConceptMap. Snapper is available at:

https://ontoserver.csiro.au/snapper2/

Similarly to Shrimp, an insecure HTTP endpoint for Snapper is also available to support the use of insecure (development) instances

3. Access to Terminology Server

The central instance of the terminology server running at the UKK is accessed through secured and encrypted communication over TCP HTTPS, port 443 as it is using transport layer security, SSL/TLS.

The SSL/TLS transport security ensures that the transfer of packet data between host servers and clients is based on asymmetric (public/private key) encryption and therefore prevents network security vulnerabilities like eavesdropping and man-in-middle attack. The public key of the central instance is cryptographically signed by a CA within the Deutsches Forschungsnetz, DFN, Public Key Infrastructure and GÉANT is the collaboration of European National Research and Education Networks (NRENs)..

The terminology server is intended to be used across Germany by different Pilot projects within the Medical Informatics consortium (like HiGHmed, MIRACUM, DIFURE, SMITH, NUM-FDPG) and other private healthcare institutions.

There are currently two access schemes available, namely:

- Access using DFN certificate / GÉANT
- Access through an Allowed-list (formerly called Whitelist)

3.1. Access using DFN certificate

This service uses the Deutsches Forschungsnetz Public Key Infrastructure, DFN-PKI, for mutual TLS User/Client authentication and GÉANT User/Client certificate.

This mechanism (mTLS) ensures that the User browser or Client machine is authenticated before access is granted as the service can either be accessed as a User (web browser) or as a Client (API service call). This authentication is carried out during the handshake phase, before

application data is transferred.

In order to access the service as a User, a DFN User certificate (DFN profile: User) is requirement while to access the service as a Client, a DFN Client certificate (DFN profile: 802.1X Client) is required.

More information about the DFN certificate profiles are available at: https://www.pki.dfn.de/fileadmin/PKI/anleitungen/DFN-PKI-Zertifikatprofile_Global.pdf

However, if a User/Client attempts to access the web address of the terminology server (https://terminology-highmed.medic.medfak.uni-koeln.de) without the required DFN certificate, the authentication server will return HTTP error code 400 (Bad Request) and this will display the server error page shown below in Figure 1.

Welcome to the terminology service of the Medical Informatics Initiative, Germany.

This service uses the Deutsches Forschungsnetz Public Key Infrastructure, DFN-PKI, for mutual TLS User/Client authentication.

If you see this page, you will need to request for a DFN User/Client certificate from your institution (Local DFN-PKI subscriber-service) before you can access this service.

Certificate profiles required:
- User certificate or
- 802.1X Client certificate.

More information about the DFN certificate profiles are available here.

For support, contact the MeDIC Cologne support team:
support-medic@uni-koeln.de

Thank you !

Figure 1 : Error page (HTTP Status 400) of terminology server in absence of DFN certificate

Please check with your local IT department how to apply for a certificate that fulfils the aforementioned criteria.

Process is the same as far as getting the GÉANT certificate, more details are available on the following link:

https://security.geant.org/trusted-certificate-services/

Also, your local IT department will be able to provide you more detail about obtaining the certificate.

3.2. Access as a User

After obtaining the DFN User certificate from the "Local DFN-PKI subscriber-service" of your institution. In order to use the certificate and associated private key in most modern browsers, it should be converted to a PKCS (.PFX or .P12) format as the certificate is delivered by DFN as a .PEM format.

Use the command below to convert from .pem to .p12 format:

```
openssl pkcs12 -export -out certificate.p12 -in certificate.pem -inkey
privateKey.pem
```

- openssl – the command for executing OpenSSL, available by default on most UNIX-based systems. When using Windows 10, using Windows Subsystem for Linux is the easiest way to access OpenSSL.
- pkcs12 – the file utility for PKCS#12 files in OpenSSL
- -export -out certificate.p12 – export and save the P12 file as *certificate.p12*
- -in certificate.pem – use *certificate.pem* as the certificate the private key will be combined with
- -inkey privateKey.key – use the private key file *privateKey.key* as the private key to combine with the certificate.
  An alternative, java-based and Free/Open-Source graphical tool to convert between different certificate formats is available at https://keystore-explorer.org/

The certificate can then be uploaded in a web browser (e.g. Google Chrome and other Chromium-based Browsers) as below:

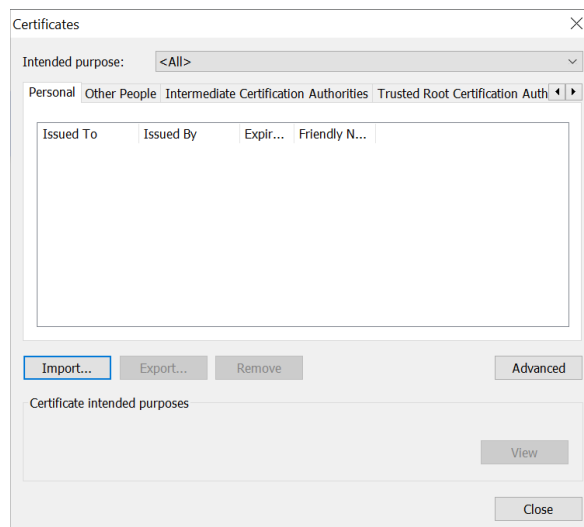**Chrome -> Settings -> Security -> Manage certificates -> Import**

Figure 2: Certificates import wizard

In Mozilla Firefox, the corresponding dialog is available at Preferences → Privacy & Security → Certificates (bottom of the page) → View Certificates → Your Certificates → Import

Upon successful authentication, the terminology server processes the request and should return a successful status code if the request can be processed correctly.

3.3. Access as a Client

Just like the User certificate, the DFN client certificate is also delivered as .PEM format.

However, this certificate can be used directly (as .pem format) without the need to convert to any other certificate format.

It is also important to serve the certificate with the complete certificate chain as delivered by DFN.

For optimal experience, it is advisable to serve the certificate from a reverse-proxy server (like NginX or Apache) with SSL enabled and points to the remote server located at https://terminology-highmed.medic.medfak.uni-koeln.de as shown below:

```
1. location /koeln/ {
2.     proxy_pass https://terminology-highmed.medic.medfak.uni-koeln.de:443/;
3.     proxy_ssl_certificate /etc/pki/ontoserver/certs/cert-with-chain.pem;
4.     proxy_ssl_certificate_key /etc/pki/ontoserver/certs/private.pem;
5.     proxy_ssl_protocols TLSv1.2 TLSv1.3;
6.     proxy_ssl_ciphers HIGH:!aNULL:!MD5;
7.     proxy_ssl_trusted_certificate /etc/pki/ontoserver/chain/chain.pem;
8.     proxy_ssl_verify on;
9.     proxy_ssl_verify_depth 5;
10.}
```

3.4. Access through a Allow-list

This authentication scheme is specifically designed for Healthcare institutions that are not part of the DFN. Such as private institutions or non-research organizations.

Most research institutions in Germany are already part of the DFN and can obtain the required certificate(s). However, for institutions that are not part of the DFN or that can not obtain the certificates, a Whitelist is used to authenticate and verify the digital signature of the client machine.

3.4.1. Requirement for the Allowed-list

To be admitted into the Allowed-list, a request email has to be sent by the Head or PI (Principal investigator) of the requesting institute or department. This mail should be sent to the Support-team (See Section 4 below).

Upon approval of the request, the requesting party has to send a Static or Dedicated IP address of the machine (client) that needs to access the terminology server.

For machines on the Allowed-list, the terminology server can be reached at :

https://terminology.medic.medfak.uni-koeln.de/

The base URL of the FHIR API is:
https://terminology.medic.medfak.uni-koeln.de/fhir

and the "CapabilityStatement" can been seen at:
https://terminology.medic.medfak.uni-koeln.de/fhir/metadata

4. Servicedesk & Support

The Terminology Server is accessible round the clock (24 x 7). The service desk can be reached from Mon-Fri 08:00 am - 05:00 pm, excluded the Bank holidays of NRW.

The Service desk is reachable at:

Email: Medic-Terminologie-Support@uk-koeln.de

Copy to: team@mail.mii-termserv.de

Response Time: Requests are answered within a day.

Maintenance Windows:

a) Terminology updates for LOINC and SNOMED CT will be handled monthly – Fri 14:00 – 17:00 with a downtime. Including OS patches.
b) Terminology updates of other Terminologies w/o downtime will be handled during the operations hours Monday to Friday at service hours
c) Terminology Server, Ontoserver update is scheduled Fri 08:00 – Friday 17:00 quarterly (last week of March, June, Sept, 2nd week of Dec)

The lead times to communicate the changes is 5 weekdays

The maintenance windows will be communicated to MII and NUM partners.

- office@medizininformatik-initiative.de
- diz@medizininformatik-initiative.de
- mii-num-diz-all@lists.fau.de

Documentation for Terminology Server

The documentation for terminology server could be found at:

https://www.uk-koeln.de/forschung/medical-data-integration-center-medic/dokumente-formulare/

- Dokumentation des Terminologieservers (Operations model and terminologies)

- Vereinbarungserklärung, um Zugang zum Terminologieserver zu erhalten (Access)

5. Code Systems

The Terminology Server has following Code Systems available:

5.1. LOINC

LOINC (Logical Observation Identifiers Names and Codes) is the universal standard for identifying health measurements, observations, and documents. It is now ubiquitous in health data systems worldwide and is an essential ingredient of system interoperability.

The update information is currently not available, this section will be updated later.

5.2. SNOMED CT

SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) is a systematically organized computer processible collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting. SNOMED CT is considered to be the most comprehensive, multilingual clinical healthcare terminology in the world. The primary purpose of SNOMED CT is to encode the meanings that are used in health information and to support the effective clinical recording of data with the aim of improving patient care.

Updates are coming often in March and September, conversion time from the native files to FHIR compatible format (Terminology Server compatible) is not known yet. Typically, it can be done in a month.

5.3. ICD-O-3

The International Classification of Diseases for Oncology (ICD-O) is a domain-specific extension of the International Statistical Classification of Diseases and Related Health Problems for tumor diseases. This classification is widely used by cancer registries. It is currently in its third revision (ICD-O-3).

ICD-O-3 is used principally in tumor or cancer registries for coding the site (topography) and the histology (morphology) of neoplasms, usually obtained from a pathology report.

5.4. ICD-10-WHO

ICD-10 is the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO). It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. Work on ICD-10 began in 1983, became endorsed by the Forty-third World Health Assembly in 1990, and was first used by member states in 1994.

The Terminology can be downloaded from DIMDI website:

https://www.dimdi.de/dynamic/de/klassifikationen/downloads

5.5.   ICD-10-GM

Germany's ICD-10 German Modification (ICD-10-GM) is based on ICD-10-AM. ICD-10-GM was developed between 2003 and 2004, by the German Institute for Medical Documentation and Information abbreviated as DIMDI.

The Terminology can be downloaded from DIMDI website:

https://www.dimdi.de/dynamic/de/klassifikationen/downloads

5.6.   OPS

The Operation and Procedure Code (OPS) is the official classification for coding operations, procedures and general medical measures.

The OPS is currently revised annually on the basis of a transparent proposal procedure under the leadership of the BfArM.

The Terminology can be downloaded from DIMDI website:

https://www.dimdi.de/dynamic/de/klassifikationen/downloads

5.7.   ATC

Anatomical Therapeutic Chemical (ATC)-Classification with defined daily doses (DDD). In the ATC-Classification substances are divided into different groups according to the organ or organ system which they affect and their chemical, pharmacological and therapeutic properties.

5.8.   Available code systems and value sets

Vendor	Status	Description
LOINC	Alive	Production, Test
SNOMED CT	Alive	Production, Test
ICD-O-3	Alive	Production, Test
ICD-10-gm	Alive	Production, Test
ICD-10-who	Alive	Production, Test
OPS	Alive	Production, Test
ATC	Alive	Production, Test
Administrative Gender	Alive	Production, Test
DICOM Controlled Terminology Definitions	Alive	Production, Test
Parameter-Codes-eCRF	Alive	Production, Test
Frailty-Score	Alive	Production, Test
Gender Amtlich DE	Alive	Production, Test
SOFA-Score	Alive	Production, Test

Status:

- Alive : Up and running, full operational
- Update : Currently Updated
- Down : Not available from outside (Reason given within comment)

The Version of the code systems could be obtained from Website:

https://www.uk-koeln.de/forschung/medical-data-integration-center-medic/nutzung-des-medics/

There are two files located:

- Code system: CentralTS_CS_XXXXX.pdf
- Value sets: CentralTS_VS_XXXXX.pdf

6. Customization and adding an additional Code System

Request for the addition of a terminology from other partner sites for different use cases or different projects (CORD) etc. can be requested as described in chapter 4.