Requirements Integrated Process Data Model
Deliverable D1.2
Sopheon (Ed.)

June 2011

Contributors	Affiliation
Luuk Groenewegen	CeTIM/LIACS
Christoph Stettina	CeTIM/LIACS
Roger Erens	Zorggemak
Peter Eshuis	Philips
Huub Rutten	Sopheon
Elsemiek ten Pas	Sopheon

Table of contents

1. Introduction

This deliverable D1.2 aims at describing the requirements for the integrated process model. It is closely related to the Edafmis deliverables D2.2 *Requirements and Design – Operational Execution* and D1.3 *Integrated Reference Model*.

- D2.2 describes the requirements for the separate systems.
- In D1.3 the focus is on how the various components of the integrated system architecture "logically" work. The underlying data models are visualised there.

Therefore in this deliverable we concentrate on the high level requirements for data representation.

Background:

WP1's main objective: to deliver the conceptual data model (Reference Model) allowing to define and execute a clinical pathway for (semi-) automated intervention; where possible the WP will reuse existing industrial standards, however will develop related to additional needs; to deliver the protocol handling system that creates and manages the protocol in the form of a program that executes the clinical pathway; this can be used and evaluated during experimenting and prototyping.

> *It is clear that the conceptual and technical integration of various data producing and absorbing devices around the clinical pathway and the precise interpretation of their various datasets are conditional for meaningful communication and cooperation. This cannot be realised without having an agreed Reference Model, that allows for a stable and unambiguous "deep" definition of the clinical pathway "program", however while still allowing source systems to stick to their proprietary software languages. Therefore the WP will need close cooperation with those partners that deliver a device to the workflow such as the ERP system, the mobile scan exchanging system, the intervention system, the protocol management system, to agree the input/output schemata.*

There are 4 dimensions or perspectives on the research route to the objective mentioned above. Together they form the structure that are imperative for all the deliverables of Workpackage 1, including deliverable D1.2 *Requirements Integrated Process Data Model*. These dimensions are represented in the tasks as described in the project description as follows:

Task 1.1 Clinical pathway representation

> *This Task will deliver those models that define the medical aspects of the diagnosis and treatment of a disease. To do so it needs to establish the "language" in terms of function and form that can be used to express these aspects, both at a human level and at a technical (software) level. How to express the basic or starting configuration? The models will contain property-value combinations as well as rules that manage the behaviour of the treatment instruction. On one hand it should enable for medical experts to express their detailed definitions, on the other hand it should ensure the right data collection during diagnosis and intervention and the consequences thereof. For example to stop the treatment or to change strategy. The Clinical Pathway models will be tested by producing a Clinical pathway program, that will be used for prototyping and experiments in the integrated Edafmis environment.*

Task 1.2 Process data representation

> *This tasks focuses on the flow-aspects of the diagnosis and intervention procedures. It will model the sequence and conditional aspects of activities and events in a way that we can*

consider the Clinical Path to be a "secured" workflow. It will define in detail when which data sets should be pushed out to or pulled in from the various devices and tools participating in the process. The task will deliver the conceptual interface requirements as well as the common reference model.

Task 1.3 Patient data representation

New and existing imaging modalities make an increasing amount of potentially important information available for any given patient. Furthermore, systems for image-guided minimal invasive surgery and therapy are increasingly being used in order to safely navigate surgical instruments into the human body for improved patient treatment. Essential questions in multi-modal navigation are: What information is needed for optimal surgical planning and guidance in the operating theatre? How should all this multi-modal information be presented to the surgeon? And how can technology ensure that information displayed in the navigation system represents an accurate picture of the intra-operative anatomy throughout the operation?

Task 1.4 Dynamic patient model representation

When the patient is in the Intervention phase the body will be monitored on a continuous basis from various perspectives, in parallel. The dynamic patient model instructs or suggests the intervention systems what to do and what not to do within certain tolerance margins. This task should define the patient model dynamics as a set of probable data combinations (patterns) that might appear and have preprogrammed logical consequences. It also should define how to handle "uncertain" or "unexpected" combinations of monitoring data. These rules need to be expressed in the Clinical Pathway software and executed by the Intervention System.

This deliverable is structured according to the workpackage tasks.

2. Clinical Pathway Representation

Requirements:

a. Roles of people and devices, events and statuses of the pathway should be distinctively laid out clearly according to the Paradigm method.

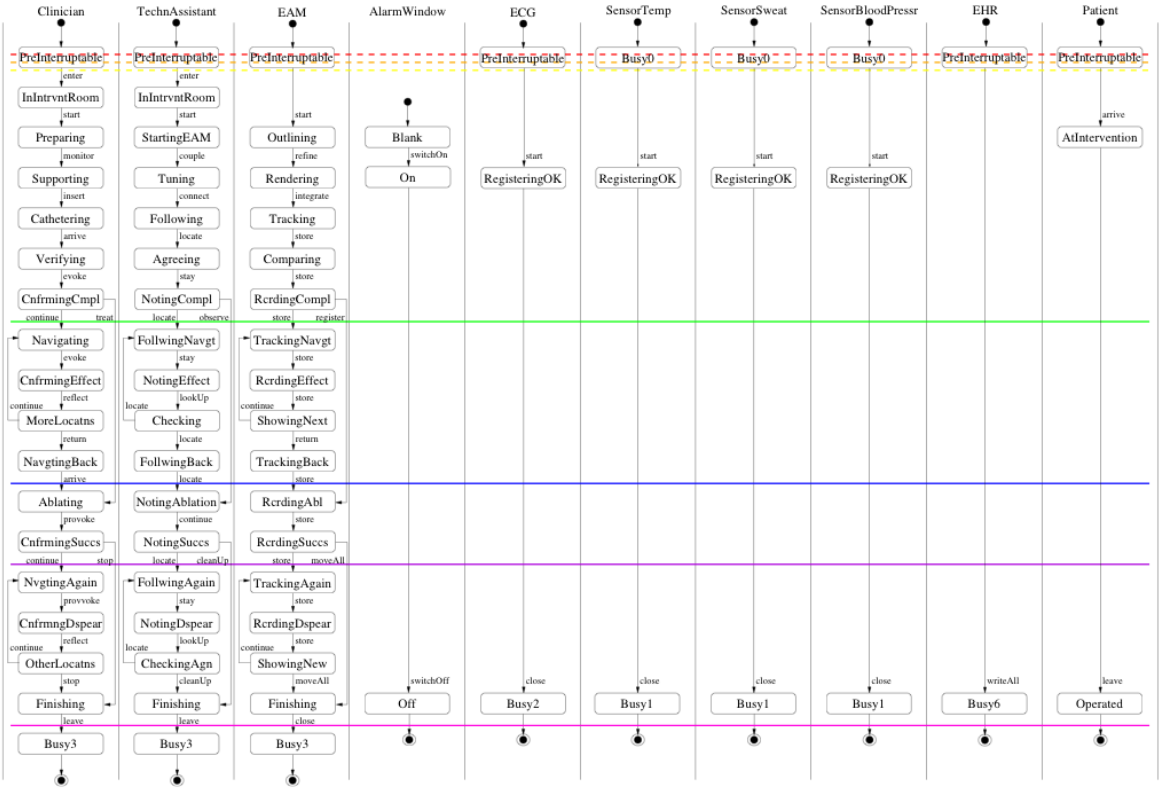

Figure 1: Step-wise collaboration in Paradigm

(See Edafmis deliverable D1.3, section 2.3 for an explanation of Paradigm)

b. The method should clarify multiple phases or stages and have clear stage changers.

c. The pathway should be presented in a formal, approved medical protocol so that the human roles (doctors, nurses) can easily read and understand, according to standard templates and terminology; the protocol serves as the instruction how to perform the clinical pathway.

d. The pathway description should include the decision support needed, continuously or at certain points of action; it contains the calculation rules that are used to calculate data from sensors or other devices.

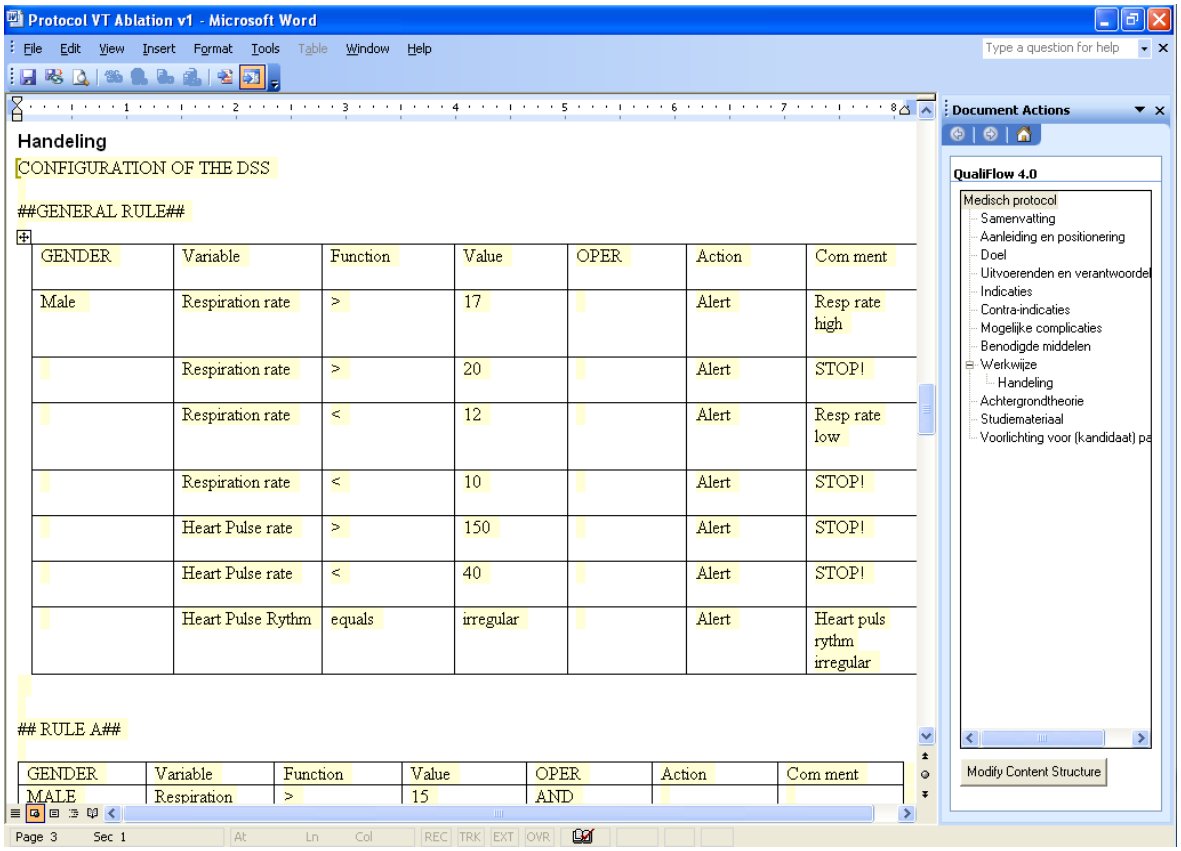

Figure 2: Representation of rules in the protocol

3. Process Data Representation

Requirements:

For Edafmis in the end we do not have process data requirements, because there is no automation of the workflow, the process. The original idea was to see if we would need workflow to execute a clinical pathway. But that is not the case for the use cases we have. In fact we have a computer-assisted, machine-aided workflow, not a fully automated workflow.

We do have data representation requirements for the systems involved in the integrated architecture, but the flow of events and actions itself is completely under manual control of the doctor. This means that the doctor activates the devices, activates a protocol, activates the patient data to be used.

The devices involved deliver data or/and read data in. The requirements for these are described in the other sections of this chapter.

4. Patient Data Representation

We distinguish between static patient data and dynamic patient model data. This chapter is about the static data. These data are per definition historical data during an operation and are delivered by the EHR system. The project (partner Zorggemak) has looked into the standardisation of the data representation with a view of being integrated in a treatment process, with other systems around the patient, in our case the DSS (Decision Support System); see the Appendix for the detailed description.

Requirements:

a. Extracts of the EHRs that are in use in the hospital environment should be collected and sent in an HL7v3 XML-format or as an HL7v2-message (making use of the CEN/ISO 13606 standards).

The patient information items that have to be obtained from the Virtual EHR are listed below:

data item	archetype source	data type	data domain	units of measure
person name/details[family name]	openEHR-DEMOGRAPHIC-PARTY_IDENTITY.person_name.v1	DV_TEXT	-	-
patient birth_date	openEHR-DEMOGRAPHIC-ITEM_TREE.person_details.v1	DV_DATE	-	-
patient gender	openEHR-DEMOGRAPHIC-ITEM_TREE.person_details.v1	DV_CODED_TEXT	“male”, “female”, “intersex or indeterminate”, “not declared/inadequately described”	-
patient weight	openEHR-EHR-OBSERVATION.body_weight.v1	C_DV_QUANTITY	<|0.0..1000.0|>	kg

b. The meaning of the parameters used should be unambiguous.

c. The Mobile Dicom app should be able to receive a Dicom image from the PACS and visualise it clearly on a mobile device screen, possibly including "comments" or "notes" (spoken or written).

Figure 3: Example of Dicom image on an iPad

5. Dynamic Patient Model

The dynamic patient model means the state of the patient during operation. We have different sources of data that "describe" the state of the patient "live": various sensors connected to the patient like ECG, blood pressure monitor, pulse rate monitor.

Requirements

a. The continuously measuring sensors should present their results in binary format -- these can be reused with supplier specific protocols by the Decision Support System, and by other monitors.

b. The EP Navigator system should show the doctor the exact location of the device inserted in the body during the intervention (eg a needle, laser burner, catheter). The data should be represented as 3D images on a 3D screen, real time.

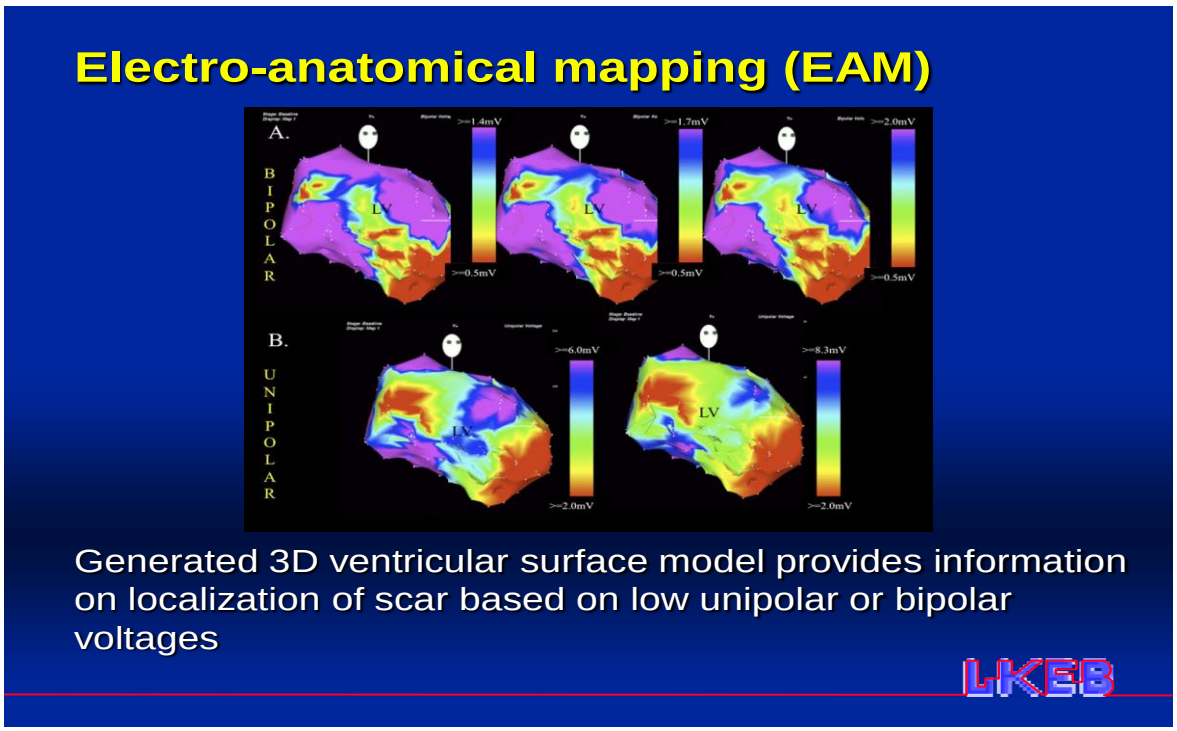

Figure 4: Example of 3D images used during VT ablation

c. The 3D screen of EP Navigator should have a small Alert window, where the DSS presents alerts for the doctor, in case the state of the patient is not what it should be following the rules as set in the medical protocol. The alerts should be presented set as "messages" that are unambiguous and clear.

d. The DSS is connected to the devices over APIs and applies real time the rules to their measurements (see point a.). It should send its generated alerts to the 3D screen of EP Navigator.

e. The DSS should maintain a log with information about the calculations done and the data used at which precise moment. It should present this information if required.

Appendix

The way patient information data can be transmitted in an HL7-CDA-CCD type of format is exemplified below. Example 1 shows an XML-file that is constructed using various archetypes such as edafmis-EHR-COMPOSITION.report.v1. This XML file also refers to an XML-file containing the patients' demographic data. This data is kept seperately from the medical data for security reasons. Example 2 contains an example of such a demographic datafile.

The XML-files mentioned above have been created with the use of archetypes which act as a kind of 'instruction sheets'. The ZorgGemak-openEHR-Kernel retrieves these 'instruction sheets' during run-time from an archetype-repository and 'molds' the data accordingly. ZorgGemak has created the following archetypes for the Edafmis project:

- edafmis-EHR-COMPOSITION.report.v1
  This archetype is a generic container archetype to carry information for use inside the edafmis project. It can contain a reference to the patients' demographic data and has multiple slots available for
  - edafmis-EHR-GENERIC-ENTRY.admission.v1
    This admission GENERIC_ENTRY archetype was designed for representing the HL7-CDA-CCD data for the Edafmis-project.
- edafmis-demographic-PERSON.person.v1
  This archetype contains the details of a person such as gender, date of birth, date of death, marital status, nationality. It also has slots available for
  - edafmis-demographic-PARTY_IDENTITY.identity_person_name.v1
    This archetype has various possibilities for storing names, like first name, last name, preferred name, etc.
  - edafmis-demographic-PARTY_IDENTITY.identity_identifier.v1
    This archetype is used to store information about the names of organisations.
  - edafmis-demographic-ADDRESS.address.v1
    This archetype contains information about the physical addresses
    edafmis-demographic-ADDRESS.telephone.v1
    This archetype contains information about the telephone number

Example 1: XML-file constructed using various archetypes

composition.xml[1] shows an XML-file that is constructed using various archetypes such as edafmis-EHR-COMPOSITION.report.v1. This XML file also refers to patient.xml, an XML-file containing the patients' demographic data.

Here we only show a small first part of the file composition.xml:

[1] http://edafmis.org/Projects/530/Work%20Packages/Work%20Package%201/Related%20Documents/composition.xml

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<COMPOSITION>
  <archetype_details>
    <archetype_id>
      <value>edafmis-EHR-COMPOSITION.report.v1</value>
    </archetype_id>
    <rm_version>v1.0</rm_version>
  </archetype_details>
  <archetype_node_id>at0000</archetype_node_id>
  <name>
    <charset>
      <code_string>ISO-8859-1</code_string>
      <terminology_id>
        <value>IANA_character-sets</value>
      </terminology_id>
    </charset>
    <language>
      <code_string>en</code_string>
      <terminology_id>
        <value>ISO_639-1</value>
      </terminology_id>
    </language>
    <value>encounter report</value>
  </name>
  <category>
    <charset>
      <code_string>ISO-8859-1</code_string>
      <terminology_id>
        <value>IANA_character-sets</value>
      </terminology_id>
    </charset>
    <language>
      <code_string>en</code_string>
      <terminology_id>
        <value>ISO_639-1</value>
      </terminology_id>
    </language>
    <value>event</value>
    <defining_code>
      <code_string>433</code_string>
      <terminology_id>
        <value>openehr</value>
      </terminology_id>
    </defining_code>
  </category>
  <composer xsi:type="partyIdentified" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <external_ref>
      <id xsi:type="hierObjectID">
        <value>e6e91ce1-7697-474d-844b-fd18426643b0</value>
      </id>
      <namespace>DEMOGRAPHIC</namespace>
      <type>PARTY</type>
    </external_ref>
    <name>party name</name>
  </composer>
  <content xsi:type="genericEntry" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <archetype_details>
      <archetype_id>
        <value>edafmis-EHR-GENERIC_ENTRY.admission.v1</value>
      </archetype_id>
      <rm_version>v1.0</rm_version>
    </archetype_details>
    <archetype_node_id>at0000</archetype_node_id>
    <name>
      <charset>
        <code_string>ISO-8859-1</code_string>
        <terminology_id>
          <value>IANA_character-sets</value>
        </terminology_id>
      </charset>
      <language>
        <code_string>en</code_string>
```

```
      <terminology_id>
        <value>ISO_639-1</value>
      </terminology_id>
    </language>
    <value>HL7-CDA-CCD</value>
  </name>
  <data>
    <archetype_node_id>at0001</archetype_node_id>
    <name>
      <charset>
        <code_string>ISO-8859-1</code_string>
        <terminology_id>
          <value>IANA_character-sets</value>
        </terminology_id>
      </charset>
      <language>
        <code_string>en</code_string>
        <terminology_id>
          <value>ISO_639-1</value>
        </terminology_id>
      </language>
      <value>identity-details</value>
    </name>
    <items>
      <items xsi:type="cluster">
        <archetype_node_id>at0010</archetype_node_id>
        <name>
          <charset>
            <code_string>ISO-8859-1</code_string>
            <terminology_id>
              <value>IANA_character-sets</value>
            </terminology_id>
          </charset>
          <language>
            <code_string>en</code_string>
            <terminology_id>
              <value>ISO_639-1</value>
            </terminology_id>
          </language>
          <value>Personal Physicians HealthCare Continuity of Care Document</value>
        </name>
```

Example 2: XML-file with demographic data

patient.xml[2] contains an example of demographic data. The patient data is kept separately from the medical data in composition.xml for security reasons.

Here we only show a small first part of the file patient.xml:

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<PERSON>
  <archetype_details>
    <archetype_id>
      <value>edafmis-demographic-PERSON.person.v1</value>
    </archetype_id>
    <rm_version>v1.0</rm_version>
  </archetype_details>
  <archetype_node_id>at0000</archetype_node_id>
  <name>
    <charset>
      <code_string>ISO-8859-1</code_string>
      <terminology_id>
        <value>IANA_character-sets</value>
      </terminology_id>
    </charset>
    <language>
      <code_string>en</code_string>
      <terminology_id>
        <value>ISO_639-1</value>
      </terminology_id>
    </language>
    <value>person-person</value>
  </name>
  <uid xsi:type="hierObjectID" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <value>1.7.8.4</value>
  </uid>
  <contacts>
    <contacts>
      <archetype_node_id>at0022</archetype_node_id>
      <name>
        <charset>
          <code_string>ISO-8859-1</code_string>
          <terminology_id>
            <value>IANA_character-sets</value>
          </terminology_id>
        </charset>
        <language>
          <code_string>en</code_string>
          <terminology_id>
            <value>ISO_639-1</value>
          </terminology_id>
        </language>
        <value>persoon-&gt;contact-adres</value>
      </name>
      <addresses>
        <addresses>
          <archetype_details>
            <archetype_id>
              <value>edafmis-demographic-ADDRESS.address.v1</value>
            </archetype_id>
            <rm_version>v1.0</rm_version>
          </archetype_details>
          <archetype_node_id>at0000</archetype_node_id>
          <name>
            <charset>
              <code_string>ISO-8859-1</code_string>
              <terminology_id>
```

2 http://edafmis.org/Projects/530/Work%20Packages/Work%20Package%201/Related%20Documents/patient.xml

```
          <value>IANA_character-sets</value>
        </terminology_id>
      </charset>
      <language>
        <code_string>en</code_string>
        <terminology_id>
          <value>ISO_639-1</value>
        </terminology_id>
      </language>
      <value>contact-&amp;gt;adres-woning</value>
    </name>
    <details xsi:type="itemList" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
      <archetype_node_id>at0001</archetype_node_id>
      <name>
        <charset>
          <code_string>ISO-8859-1</code_string>
          <terminology_id>
            <value>IANA_character-sets</value>
          </terminology_id>
        </charset>
        <language>
          <code_string>en</code_string>
          <terminology_id>
            <value>ISO_639-1</value>
          </terminology_id>
        </language>
        <value>adres</value>
      </name>
      <items>
        <items>
          <archetype_node_id>at0003</archetype_node_id>
          <name>
            <charset>
              <code_string>ISO-8859-1</code_string>
              <terminology_id>
                <value>IANA_character-sets</value>
              </terminology_id>
            </charset>
            <language>
              <code_string>en</code_string>
              <terminology_id>
                <value>ISO_639-1</value>
              </terminology_id>
            </language>
            <value>adres-straat</value>
          </name>
          <value xsi:type="dvText">
            <charset>
              <code_string>ISO-8859-1</code_string>
              <terminology_id>
                <value>IANA_character-sets</value>
              </terminology_id>
            </charset>
            <language>
              <code_string>en</code_string>
              <terminology_id>
                <value>ISO_639-1</value>
              </terminology_id>
            </language>
            <value>Alden Road</value>
          </value>
        </items>
```