

**Title:** The CogNIAM Conceptual Models for Two Laboratory Test Examples

**Date:** 2012-08-29

**Source:** Denise Warzel and PNA Group

**Dear WG2 Members:**

**The following document was prepared by PNA for use to review the Fact Based Modelling approach. My question to the experts was given two examples of a small information model, what would it look like if described using FBM? My goal is to assess whether or not 19763-12 Information Model CD could be used to register a FBM.**

**I draw your attention to the information model on page 18, section 2.5. The rest of the paper is interesting – it is how they arrived at the FBM – but that process is out of scope for our work. The question is really whether the information models represented on page 18 can be recorded using 19763-12? If not, would a reasonable modification to the Part 12 allow the FBM to be registered?**

**Our goal is to standardize a metamodel for registering information models, regardless of the technique used to create the information model. The goal is interoperability, IMHO the kind of information model, or the technique in which it was produced, is important metadata to help someone understand the information model, and should be included as attributes of the model.**

**In Krakow, please be prepared to discuss whether or not WG2 thinks that a new part of 19763 is needed in order to support registration of FBMs, or whether changes to the 19763-12 draft might be able to accommodate these kinds of models.**

**Sincerely,**

**Denise Warzel**

**WG2 Convenor**

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# The CogNIAM Conceptual Models

for

## Two Laboratory Test Examples

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### Summary

At the FBM telecon of June 14th 2012, it was agreed that each of the three FBM approaches present in the telecon, CogNIAM, DOGMA and ORM would use its method to come to a conceptual model, based on the input presented by Serge Valera on the telecon screen. The input was used in a discussion with Denise Warzel, chairperson of the ISO SC32/WG2, at the June 2012 Berlin meeting.

The screens shown by Serge Valera contained two views on a laboratory test. Each of these views has been taken as input for the CogNIAM method. This document shows how the CogNIAM procedure focuses on the usage of concrete examples for the communication with the subject matter expert to arrive at a conceptual model.

### 1 Introduction

This working paper is part of a series of three. Each of the FBM approaches CogNIAM, DOGMA and ORM will take the same input and will apply their procedure on the input to arrive at a validated conceptual schema. This document records the intermediate and final results of applying the CogNIAM procedure on the examples. Section 2 focuses on the first example, while in section 3 the second example is highlighted. Section 4 provides a reflection on both test cases.

### 2 Laboratory test example 1

In Figure 2-1, the original form as provided by Serge Valera, is presented. This form serves as baseline for application of the CogNIAM procedure.

<b>LaboratoryTest</b>	
Columns	
<b>PK : testNumber</b>	<b>: int</b>
<b>person</b>	<b>: varchar</b>
cancerLaboratoryTestValue	: varchar
cholesterolLaboratoryTestValue	: varchar

Figure 2-1: LaboratoryTest, version 1, baseline.

## 2.1 Step 1: Concrete examples

The CogNIAM procedure starts with the development of concrete examples for the form provided. Why?

- a) Because a populated form appears more frequently than an empty form,
- b) Because a subject matter expert is more familiar with a concrete example.

The concrete example is used in the communication with the SME to assess the correctness of the example.

The first question asked to the SME by the CogNIAM analyst is:

*Is this form (see Figure 2-2) representative for a laboratory test in your hospital?*

<b>Laboratory Test</b>	
<b>testNumber</b>	<b>00123456</b>
<b>person</b>	<b>J. Smith</b>
cancerLaboratoryTestValue	7.4
cholesterolLaboratoryTestValue	3.2

Figure 2-2: LaboratoryTest, version 1, baseline example.

The answer of the subject matter expert (SME) on the first example was:

*This is not representative for our hospital.*

CogNIAM analyst asks:

*Can you please specify what is missing or incorrect in the concrete example?*

Answer of the SME:

- a) Lab test reports contain meaningful names for the kind of tests performed, e.g. HDL-Cholesterol, LDL-Cholesterol, Prostate Specific Antigen (PSA), HbA1c.
- b) Each of our lab tests contains the date-time the sample is taken.
- c) Each form contains the name of our hospital laboratory.
- d) We refer to our clients as 'patients', not 'persons'.

CogNIAM analyst asks:

*Do I understand correctly that the form used in your hospital (Maastricht University Hospital) contains one or more test results, i.e. not restricted to 2? Figure 2-3 is a concrete illustration of my question.*

MUMC Clinical Chemical Laboratory	
Laboratory Test	
Test Number	00123456
Patient	J. Smith
Specimen Date/Time	02-Jul-2012 11:50
PSA	7.4
HDL Cholesterol	1.3
LDL Cholesterol	2.0

Figure 2-3: LaboratoryTest, version 1, increment 1.

Answer SME:

*Figure 2-3 is a step in the right direction, but it is not yet complete; in our form, we present for each kind of test the unit in which the result is expressed. i.e. for HDL-Cholesterol and LDL-Cholesterol the unit is mmol/l, for Prostate Specific Antigen it is ug/l and for HbA1c it is mmol/. Furthermore, the name of the patient is used, but also the unique identifier of the patient as used in our hospital, is put after the name, to avoid integrity problems.*

*And finally, we refer to the report as a "Laboratory Sample", not a "Laboratory Test" since any number of tests can be performed on the given sample and we refer to those specific tests as our "Lab tests".*

**Use of highlighting in Figure 2-3:**

Highlighting is used in this document as a service to the reader. In general it is used to focus the reader's attention to the information that has been modified, when comparing the figure to a previous figure (or figures). For the first two figures, for each highlighted cell the reason for highlighting will be given.

- a) The cell labelled "MUMC Clinical Chemical Laboratory" has been highlighted because the SME has noted that the laboratory reports always contain the name of their hospital laboratory, i.e. context has been added (answer c. above)
- b) The cell labelled "Patient" has been highlighted because the SME has noted that they refer to their clients as patients, not persons (answer d. above).
- c) The cell labelled "Specimen date/time" (and the corresponding date/time cell) has been highlighted because the SME has noted that the laboratory report contains the date/time the example has been taken (answer b. above)
- d) the cells with the names of actual laboratory tests (PSA, HDL Cholesterol and LDL Cholesterol) have been highlighted because the analyst want to know whether the SME agrees with the situation where a laboratory report can contain numerous tests, i.e. not limited to just 2 as in the previous figure.

CogNIAM analyst asks:

*Is the form shown in Figure 2-4 a representative example covering all the answers you have given?*

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	65123456	
<b>Patient</b>	J. Smith	123444789
Specimen Date/Time	02-Jul-2012 11:50	
Lab Test	Result	Unit
PSA	7.4	ug/L
HDL Cholesterol	1.3	mmol/L
LDL Cholesterol	2.0	mmol/L

Figure 2-4: LaboratoryTest, version 1, increment 2.

Answer SME:

Yes it is.

**Use of highlighting in Figure 2-4:**

- a) The cell labelled “Laboratory Sample” has been highlighted because the SME has noted that the laboratory reports are referred to as samples, not tests.
- b) The cell labelled “Sample Number” has been highlighted because there has been a change in the contents.
- c) The cell with contents “123444789” has been highlighted because the SME has noted that patients are not only identified by their name but by a unique patient identifier as well (this is a newly added cell, as compared to the previous figure).
- d) The cells labeled “Lab Test”, “Result” and “Unit” have been highlighted because they have been newly introduced by the analyst. The function of these cells is to act as header for the actual test data that is displayed in the lines below them. Also, the introduction of the term ‘Lab Test’ is in line with the information provided by the SME
- e) The cells with contents ‘ug/L’, ‘mmol/L’ and ‘mmol/L’ have been highlighted because they have been newly added, based on the information from the SME that for each laboratory test result, the corresponding unit is displayed.

CogNIAM analyst:

*I have one more question to ask you at this moment. Could you please tell me whether you have a specific format for each result, e.g. HDL-Cholesterol 1.30 and Amylase 90?*

Answer of the SME:

*Of course, we have a different format for each result although some results may share the same format.*

CogNIAM analyst:

*Does Figure 2-5 contain a representative filled form?*

<b>MUMC Clinical Chemical Laboratory</b>		
<b>Laboratory Sample</b>		
<b>Sample Number</b>	<b>65123456</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA	7.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-5: LaboratoryTest, version 1, increment 3.

Answer of the SME:

Yes.

We now have a concrete example of a Laboratory Sample that the SME agrees with.

## 2.2 Step 2: Verbalization of the concrete example

The next step in the CogNIAM protocol is to provide the verbalization of the approved concrete example. This verbalization is produced by the SME as if he were speaking to a colleague over the phone. The result is given in the box below.

**It is important to explicitly specify the context: This information is to be interpreted within the context of the MUMC Clinical Chemical Laboratory and within the year 2012.**

*The Laboratory Sample with sample number 65123456 is for the patient identified by patient number 123444789, with name J. Smith, whereby the specimen was taken on 02-Jul-2012 11:50.*

*Laboratory Sample 65123456 has a result of 7.4 for lab test PSA, expressed in unit ug/L,  
 has a result of 1.30 for lab test HDL Cholesterol, expressed in unit mmol/L,  
 has a result of 2.00 for lab test LDL Cholesterol, expressed in unit mmol/L and  
 has a result of 90 for lab test Amylase, expressed in U/L.*

Figure 2-6: LaboratoryTest, version 1, verbalization.

### 2.3 Step 3: Adding examples to determine the constraints

The next step in the procedure consists of producing more concrete examples to determine the constraints. For each example, the SME is asked whether the specific example or the combination of examples is permitted and if not, why it is not permitted.

Each example will contain one deviation with respect to the original example.

#### 2.3.1 Deviation 1: Change of sample number

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123457</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA	7.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-7: LaboratoryTest version 1, increment 3, deviation on sample number.



The CogNIAM analyst asks:

*Is this a permitted example?*

The SME answers:

*Yes it is. Every laboratory sample is given a unique number within a year. Every year in January, the system starts with assigning number 10000000 to the next new Laboratory Sample.*

Based on the SME answer, the CogNIAM analyst provides another example to the SME to ensure correct understanding and asks:

*Are the examples of Figure 2-7 and Figure 2-8 permitted to coexist in the register at the same time?*

The SME Answers:

*No, they are not. Each sample number is unique within a year*

<b>MUMC Clinical Chemical Laboratory</b>		
<b>Laboratory Sample</b>		
<b>Sample Number</b>	<b>65123457</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA	8.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	88	U/L

*Figure 2-8: LaboratoryTest version 1, increment 3, deviation on sample number (2).*

Based on the answer given by the SME, the following examples will have unique sample numbers, but will focus on other aspects of deviation.

### **2.3.2 Deviation 2: Change of patient**

The next concrete example presented by the CogNIAM analyst to the SME is of a different patient, taken on the same date, with the same test results.

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123458</b>	
<b>Patient</b>	<b>F. Mills</b>	<b>123444799</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA	8.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	88	U/L

Figure 2-9: LaboratoryTest version 1, increment 3, deviation of patient.

The CogNIAM analyst asks the SME:

*Knowing the first example, is this example permitted?*

The SME answers:

*Yes it is.*

### 2.3.3 Deviation 3: Change of date

The next concrete example is a laboratory sample for the same patient, but taken on another date.

<b>MUMC Clinical Chemical Laboratory</b>		
<b>Laboratory Sample</b>		
<b>Sample Number</b>	<b>65123459</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	30-Jul-2012 09:20	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA	7.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-10: LaboratoryTest version 1, increment 3, deviation of date.

The CogNIAM analyst asks the SME:

*Is this example permitted?*

The SME answers:

Yes.

### 2.3.4 Deviation 4: change of lab test value

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123455</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
Lab Test	Result	Unit
PSA	4.7	ug/L
HDL Cholesterol	1.85	mmol/L
LDL Cholesterol	2.10	mmol/L
Amylase	88	U/L

Figure 2-11: LaboratoryTest version 1, increment 3, deviation of lab test results

For the example given, the SME answers that at the same time, for the same patient, this is highly unlikely, but since it is a different sample, still possible.

2.3.5 Deviation 5: Lab test name not given

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123454</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
Lab Test	Result	Unit
	7.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-12: LaboratoryTest version 1, increment 3, deviation: lab test name not given.

The CogNIAM analyst asks:

*Is this example permitted?*

The SME answers:

*No this is not permitted. You cannot have a test without the lab test name.*

2.3.6 Deviation 6: Lab test value not given

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123453</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA		ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-13: LaboratoryTest version 1, increment 3, deviation: lab test value not given.

For this example, the SME answers:

*This is not allowed, for each lab test, its result is administered.*

### 2.3.7 Deviation 7: Unit not given

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123452</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
PSA	7.4	
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-14: LaboratoryTest version 1, increment 3, deviation: lab test unit not given.

The CogNIAM analyst asks the SME:

*Is this example permitted?*

The SME answers:

*It is not allowed to have a lab test without its specified unit. Moreover, each lab test has exactly one unit associated.*

2.3.8 Deviation 8: no lab test given

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	<b>65123451</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>

Figure 2-15: LaboratoryTest version 1, increment 3, no lab test provided.

The CogNIAM analyst asks the SME:

*Is this example permitted?*

The SME answers:

*What is the value of no test? Therefore, this is not permitted.*



2.3.9 Deviation 9: the same patient id, but different patient names

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	25123456	
<b>Patient</b>	J. Smith	123444789
Specimen Date/Time	02-Jul-2012 11:50	
Lab Test	Result	Unit
PSA	7.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-16: LaboratoryTest version 1, increment 3, patient name different (1).

MUMC Clinical Chemical Laboratory		
Laboratory Sample		
<b>Sample Number</b>	35123456	
<b>Patient</b>	M. Davis	123444789
Specimen Date/Time	02-Jul-2012 11:50	
Lab Test	Result	Unit
PSA	7.4	ug/L
HDL Cholesterol	1.30	mmol/L
LDL Cholesterol	2.00	mmol/L
Amylase	90	U/L

Figure 2-17: LaboratoryTest version 1, increment 3, patient name different (2).

The CogNIAM analyst presents the combination of both examples to the SME and asks:

*Is this combination of examples permitted?*

The SME answers:

*Although this is highly unlikely, it is permitted. Nevertheless, the system produces the advice to the quality manager to investigate the situation. The patient might have obtained permission from the official authorities to modify his or her name.*

Based on the answers given, the CogNIAM analyst produces a text with the following content:

- 1 *Each Laboratory Sample in the (context of) MUMC is given an 8 digit number(called Sample*
- 2 *Number) that is unique over time when concatenated with the year in which the test sample*
- 3 *was taken.*
- 4 *Each Laboratory Sample consists of one or more Lab Tests. Each Laboratory Sample has at*
- 5 *most one of a specific Lab Test.*
- 6 *Each year the numbering for the Laboratory Sample commences at 10000000 and this provides*
- 7 *room for many years to come.*
- 8 *The date/time that each Laboratory Sample is taken is also registered in the format dd-Mmm-*
- 9 *yyyy hh:mm (e.g. 02-Jul-2012 10:30).*
- 10 *Each patient for whom a Laboratory Sample is taken, has been assigned a 9-digit number that*
- 11 *identifies the patient within the context of the MUMC; of each patient the first initial and last*
- 12 *name is also known; in case somebody is brought into the hospital without the name being*
- 13 *known, e.g. after a very serious car accident, he is assigned a patient number and provisionally*
- 14 *given the name G. Luck.*
- 15 *Each Laboratory Sample contains at least one specific Lab Test, including the name, value and*
- 16 *unit. Each of these tests is available in an approved register, also being the single source for the*
- 17 *unit and format.*

*Figure 2-18: LaboratoryTest version 1, textual description.*

In the CogNIAM approach, the text given above is the main document communicated to the subject matter experts. However, this document is always accompanied by the relevant definitions, which are presented below.

## **2.4 Concept definitions**

### **Laboratory Sample**

A specific specimen of body fluids or tissues, on which Lab Tests can be performed, in the context of the MUMC Clinical Chemical Laboratory.

### **Lab Test**

Identifier name given to a test performed on a Laboratory Sample.

### **Result**

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Value of a Lab Test.

**Unit**

Code that represents the unit of measure for a Lab Test Result.

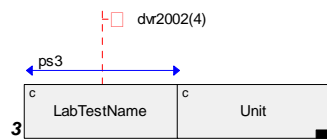
**Format**

Control string to be used when representing the Result of a Lab Test. Typically contains information on the number of decimal places used to display a Lab Test Result.

## 2.5 Fact type diagrams

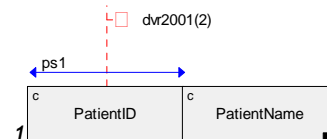
This section contains the CogNIAM representation of the fact types and associated integrity and derivation rules:

### Laboratory test



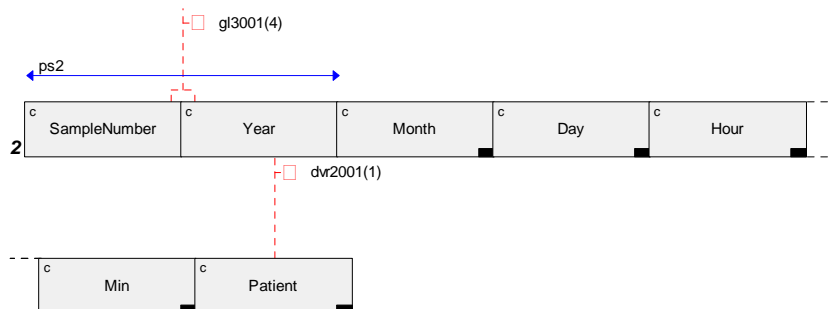
- 3: Within the collection of all laboratory tests, test name <LabTestName> identifies a specific laboratory test.  
8: Laboratory test <LabTestName> has the unit: <Unit> associated.

### Patient



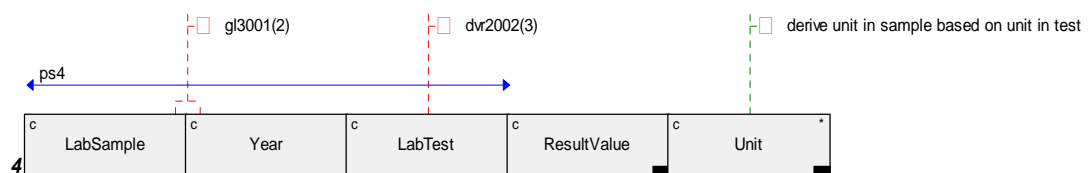
- 1: Within the collection of all patients, a specific patient is identified by means of patient ID <PatientID>.  
3: Patient <PatientID> is called <PatientName>.

### Laboratory sample



- 4: Within the collection of samples, the combination of Sample number <SampleNumber> and year <Year> identifies a specific laboratory test sample.  
5: The laboratory sample <SampleNumber> taken in <Year>, is taken on <Month> <Day> <Hour> <Min>.  
6: The laboratory sample <SampleNumber> <Year> was taken for patient <Patient>.

### Lab test result in laboratory sample



- 9: In laboratory sample <LabSample> <Year>, laboratory test <LabTest> has result value <ResultValue>.  
10: In Laboratory <LabSample> <Year>, associated with labtest <LabTest>, the unit <Unit> is specified.  
□ derive unit in sample based on unit in test: Unit = f(LabTest, Laboratory test.Unit, Laboratory test.LabTestName)

### 3 The second lab test case

The document received as input to develop the second version of the lab test case is given in Figure 3-1.

<b>LaboratoryTest</b>	
Columns	
<b>PK</b>	<b>testNumber : int</b>
<b>person</b>	<b>: varchar</b>
<b>testNature</b>	<b>: varchar</b>
<b>testValue</b>	<b>: varchar</b>

Figure 3-1 LaboratoryTest, version 2, baseline

A concrete example following these rules corresponding with the contents of Figure 3-1 is given in Figure 3-2.

<b>MUMC Clinical Chemical Laboratory</b>		
<b>Laboratory Sample</b>		
<b>Sample Number</b>	<b>65123456</b>	
<b>Patient</b>	<b>J. Smith</b>	<b>123444789</b>
Specimen Date/Time	02-Jul-2012 11:50	
<b>Lab Test</b>	<b>Result</b>	<b>Unit</b>
<testNature>	<testValue>	<testUnit>

Figure 3-2 LaboratoryTest, version 2, increment 1

This kind of representation is a typical IT look with little regards for the meaning. In technical jargon it is called mixed semantics and mixed mode data typing. For communication with subject matter experts this view of the problem should be completely ignored, is the recommendation of the CogNIAM community of practice. A CogNIAM conceptual domain model can be developed for this view using the same procedure as used in section 2.

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## 4 Review

In this paper we have applied the CogNIAM procedure to the two examples provided by Serge Valera. In section 2 the first example has been diligently developed into a Conceptual Model expressed in an almost controlled natural language model, including the concept definitions as well as the CogNIAM diagrammatical notation. Every step from the concrete example to the final Conceptual Domain Model including every intermediate result are presented.