APPLIED COMPUTER SCIENCES
Institute for eHealth

FH | JOANNEUM
University of Applied Sciences

Use of LOINC and UCUM in CDISC SDTM and SEND

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Use of LOINC in Healthcare

- Healthcare uses HL7 Standards for exchange
- HL7: Health Level 7
  - Worldwide organization
  - With headquartes in the USA
  - Develops semantic and syntactic standards for healthcare

  - Major groups of standards:
    - HL7-v2: bar delimited exchange format
    - HL7-v3: XML based exchange format

HL7 v2

- Messages between systems
  - Mostly between systems in the same hospital
    - E.g. Lab results from Lab to Hospital Information System
  - Sometimes also between hospitals / other organizations
    - E.g. immunization information

HL7-v2 example
Laboratory Result

```
MSH|^~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PID|||555-44-4444||EVERYWOMAN^EVE^E^^^^L|JONES|19620320|F|||153 FERNWOOD DR.^
^STATESVILLE^OH^35292||(206)3345232|(206)752-121||||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE|||200202150730|||||||||
555-55-5555^PRIMARY^PATRICIA P^^^^MD^^|||||||||F||||||444-44-4444^HIPPOCRATES^HOWARD H^^^^MD<cr>
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN||^182|mg/dl|70_105|H|||F<cr>
```

Usage of LOINC in healthcare

- Used in HL7-v2 messages

```
MSH|^~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PID|||555-44-4444||EVERYWOMAN^EVE^E^^^^L|JONES|19620320|F|||153 FERNWOOD DR.^
^STATESVILLE^OH^35292||(206)3345232|(206)752-121||||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE|||200202150730|||||||||
555-55-5555^PRIMARY^PATRICIA P^^^^MD^^|||||||||F||||||444-44-4444^HIPPOCRATES^HOWARD H^^^^MD<cr>
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN||^182|mg/dl|70_105|H|||F<cr>
```

- MSH: message header
- GHH LAB: sender
- GHH OE: receiver
- 200202150930: Datetime
- ORU^R01: message type: Observation Result - unsollicited

HL7-v2 example
Laboratory Result - Details

```
MSH|^~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PID|||555-44-4444||EVERYWOMAN^EVE^E^^^^L|JONES|19620320|F|||153 FERNWOOD DR.^
^STATESVILLE^OH^35292||(206)3345232|(206)752-121|||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE|||200202150730|||||||||
555-55-5555^PRIMARY^PATRICIA P^^^^MD^^|||||||||F||||||444-44-4444^HIPPOCRATES^HOWARD H^^^^MD<cr>
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN||^182|mg/dl|70_105|H|||F<cr>
```

- OBR: Observation Request
- 15545^GLUCOSE: "please execute Glucose test with test code 15545"

HL7-v2 example
Laboratory Result - Details

```
MSH|^~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PID|||555-44-4444||EVERYWOMAN^EVE^E^^^^L|JONES|19620320|F|||153 FERNWOOD DR.^
^STATESVILLE^OH^35292||(206)3345232|(206)752-121||||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE|||200202150730|||||||||
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN||^182|mg/dl|70_105|H|||F<cr>
```

- OBX: Observation Result
- 1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN
- Meaning:
  - I have executed test with LOINC Code 1554-4 which is a glucose test, 12 hours calory fasting as a mass concentration as a point in time, in serum or plasma as a quantitative test

LOINC is not only lab tests …

```
OBR|1|||^CDC VAERS-1 (FDA) Report|||20010316|
OBX|1|NM|21612-7^Reported Patient Age^LN||05|mo^month^ANSI|
OBX|1|TS|30947-6^Date form completed^LN||20010316|
OBX|2|FT|30948-4^Vaccination adverse events and treatment, if any^LN|1|fever of 10
loss of appetite|
OBX|3|CE|30949-2^Vaccination adverse event outcome^LN|1|E^required emergency room/
OBX|4|CE|30949-2^Vaccination adverse event outcome^LN|1|H^required hospitalization
OBX|5|NM|30950-0^Number of days hospitalized due to vaccination adverse event^LN|1
OBX|6|CE|30951-8^Patient recovered^LN||Y^Yes^ HL70239|
OBX|7|TS|30952-6^Date of vaccination^LN||20010216|
OBX|8|TS|30953-4^Adverse event onset date and time^LN||200102180900|
OBX|9|FT|30954-2^Relevant diagnostic tests/lab data^LN||Electrolytes, CBC, Blood cu
OBR|2|||30955-9^All vaccines given on date listed in #10^LN|
OBX|1|CE30955-9&30956-7^Vaccine type^LN|1|08^HepB-Adolescent/pediatric^CVX|
OBX|2|CE|30955-9&30957-5^Manufacturer^LN|1|MSD^Merck^MVX|
OBX|3|ST|30955-9&30959-1^Lot number^LN|1|MRK12345|
OBX|4|CE|30955-9&30958-3^ Route^LN|1|IM^Intramuscular ^HL70162|
OBX|5|CE|30955-9&31034-2^Site^LN|1|LA^Left arm^ HL70163|
OBX|6|NM|30955-9&30960-9^Number of previous doses^LN|1|01I
OBX|7|CE|CE|30955-9&30956-7^Vaccine type^LN|2|50^DTaP-Hib^CVX|
OBX|8|CE|30955-9&30957-5^ Manufacturer^LN|2|WAL^Wyeth_Ayerst^MVX|
OBX|9|ST|30955-9&30959-1^Lot number^LN|2|W46932777|
OBX|10|CE|30955-9&30958-3^ Route^LN|2|IM^Intramuscular^HL70162|
```

HL7-v2 example Laboratory Result

- 1554-5^GLUCOSE^POST 12H CFST :MCNC:PT:SER/PLAS:QN
- Test is very granular

- From the LOINC manual:

Table 7: Example Nature of Challenge

Type	Description
CFst	Calorie fast. No caloric intake (food) for the period specified in the time part of the term, e.g., POST 12H CFst
Exercise	Exercise undertaken as challenge (can be quantified)
FFst	Fluid "fast." No fluid intake for the period specified

HL7-v2 example Laboratory Result

- LOINC code details:

LOINC Number	1554-5
Component	Glucose^post 12H CFst
Property	MCnc
Time Aspect	Pt
System	Ser/Plas
Scale Type	Qn
Class	CHAL
Source	AT
Date Last Changed	20010124
Change Type	MAJ
Status	ACTIVE
Molar Mass	180.2
Class Type	1
Chemical Name Synonyms	CORN SUGAR, D GLUCOPYRANOSE, D GLUCOSE, D GLUCOSE, DEXTROSE, GLU, GRAPE SUGAR,
Units Required	Y
Related Names v2.05	Glu; Gluc; Glucoseur; p 12h fast; Mass concentration; Level; Point in time; Random; SerPl; SerPlas; SerP; Serum; SR; Plasma; Pl; Plsm; Quantitative; QNT; Quant; Quan; PST; After; PC; Fast; Calorie Fast; Fasting; CHEMISTRY.CHALLENGE TESTING; CHEMISTRY.CHALLENGE TESTING; GTT; Glu tol; Glucose tolerance
Short Name	Glucose p 12h fast SerPl-mCnc
Order OBS	Both
Example Units	mg/dL
Long Common Name	Glucose [Mass/volume] in Serum or Plasma --12 hours fasting

DOES CDISC USE LOINC ?

Well, somehow …

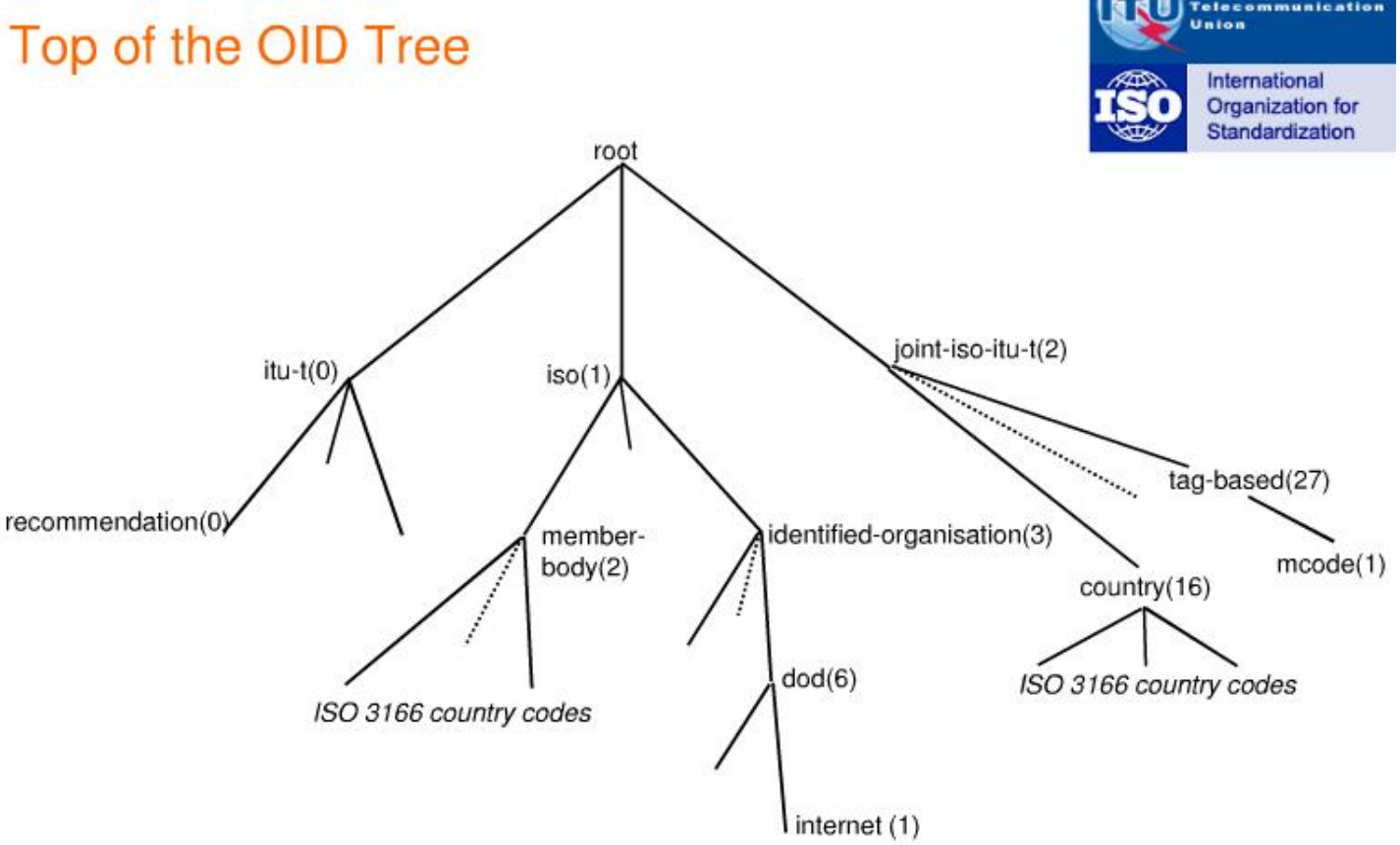
--LOINC	LOINC Code	Char	Synonym Qualifier of --TESTCD	Logical Observation Identifiers Names and Codes (LOINC) code for the topic variable such as a lab test.

Source: Study Data Tabulation Model v.1.3

OIDs: object identifiers

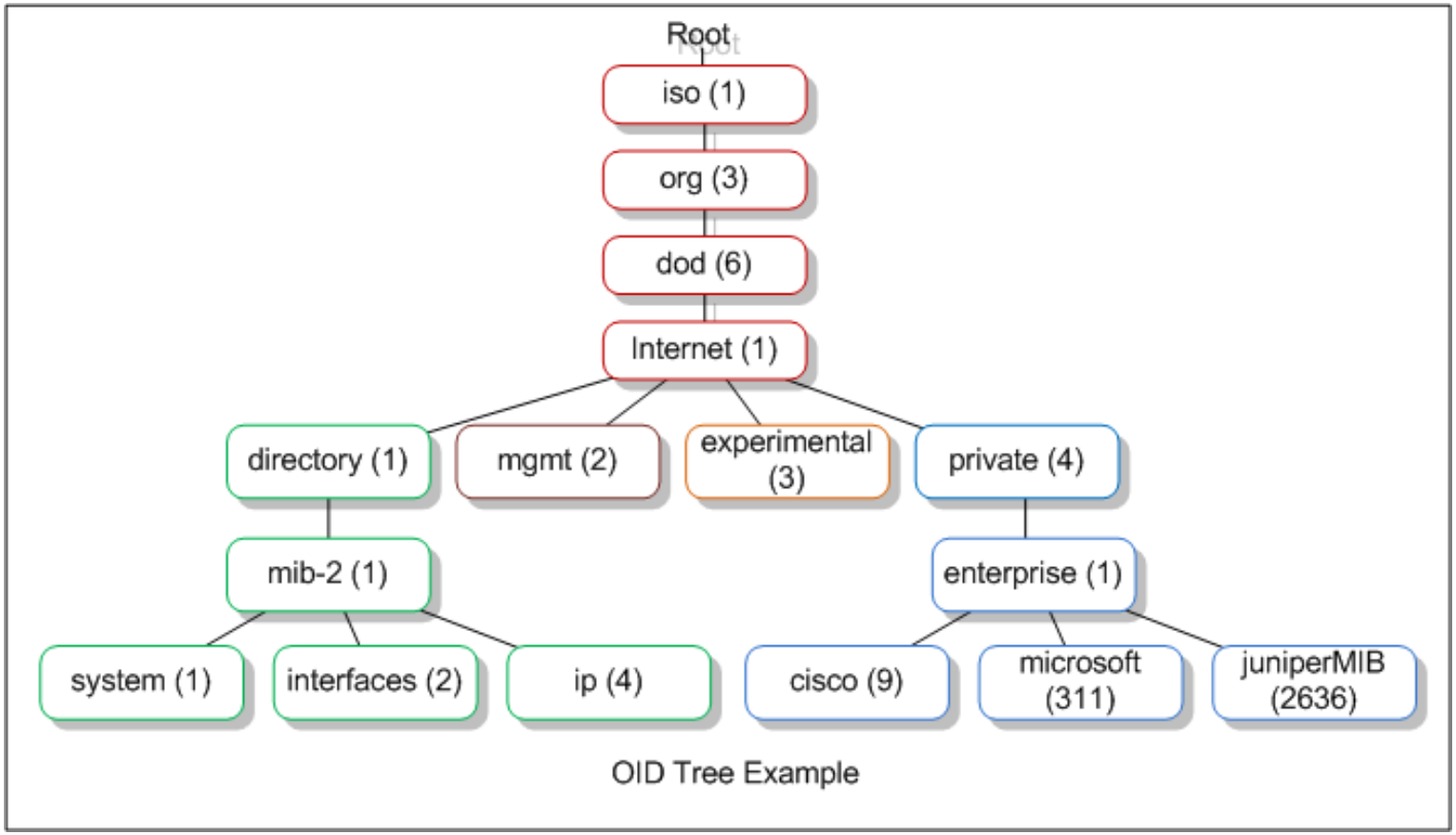
- Object identifiers used in healthcare
  - But not only there
- Tree structure
- An organization that has an OID is allowed to assign further OIDs to …
  - Associated (sub)organizations
  - Documents
  - Persons
  - …

OID tree structure



ITU = International Telecommunication Union (www.itu.int)

OID tree structure



Microsoft = 1.3.6.1.4.1.311

OID ISO country codes and ISO-3166-1

1.2.840 = ISO USA
1.2.40 = ISO Österreich
1.2.276 = ISO Deutschland
1.2.756 = ISO Schweiz

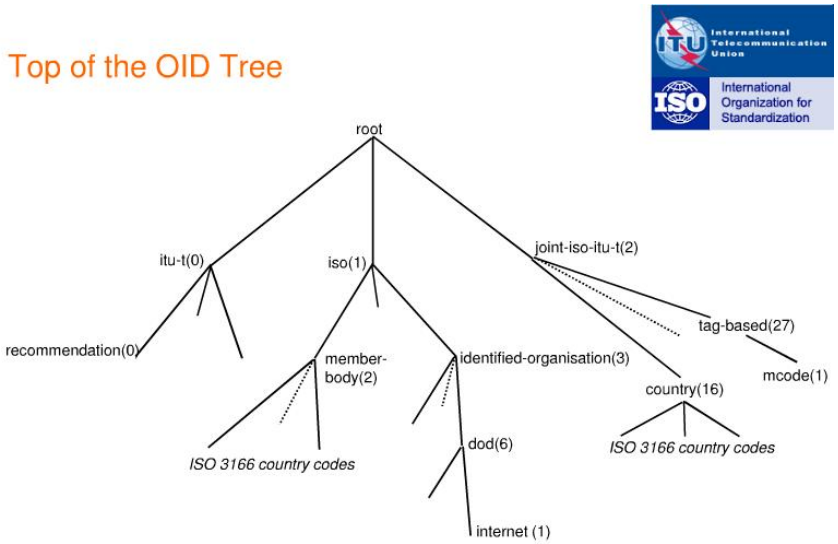
Nigeria	NG	NGA	566
Niue	NU	NIU	570
Nördliche Marianen	MP	MNP	580
Norfolkinsel	NF	NFK	574
Norwegen	NO	NOR	578
Oman	OM	OMN	512
Österreich	AT	AUT	040
Pakistan	PK	PAK	586
Palau	PW	PLW	585
Panama	PA	PAN	591
Papua-Neuguinea	PG	PNG	598
Paraguay	PY	PRY	600
Peru	PE	PER	604
Philippinen	PH	PHL	608
Pitcairninseln	PN	PCN	612

Die Ojekt-Identifikatoren werden als OID abgekürzt. OID sind weltweit eindeutige Kennzeichungen für Objekte und sind in ISO/IEC 9834/1 normiert. Ein Beispiel: Die OID 1.2.756.5.30.1.104.1.2.1 ist die SoH-Personalnummer, eingesetzt bei der Solothurner Spitäler AG. Sie bedeutet eine eindeutig zuordbare Personalnummer. Die Kombination von OID (= Iden-

OIDs Germany

- 1.2.276 = ISO Germany
- But! 2.16.840.1.113883.2.6 = HL7 Germany

2.16.840 = USA
2.16.840.1 = US Organization
2.16.840.1.113883 = HL7 USA



HL7 Austria

- OID = 2.16.840.1.113883.2.16

Superior references

- 2.16.840.1.113883 - Health Level Seven, Inc. (HL7)
- 2.16.840.1 - US company arc
- 2.16.840 - USA
- 2.16 - Joint assignments by country
- 2 - ISO/ITU-T jointly assigned OIDs
- Top of OID tree

Subsidiary references (single level)

- 2.16.840.1.113883.2.3 - HL7 Australia
- 2.16.840.1.113883.2.4 - HL7 Netherlands Affiliate
- 2.16.840.1.113883.2.8 - HL7 France Affiliate
- 2.16.840.1.113883.2.10 - HL7 ARGENTINA

Organisations can assign OIDs based on their own OID - ELGA Austria

(Elektronische Gesundheitsakte)

- eHealth-Austria: 1.2.40.0.34
- ELGA CDA Implementierungsleitfaden: 1.2.40.0.34.7.1.1
- ELGA CDA Implementierungsleitfäden Entlassungsbrief (Ärztlich): 1.2.40.0.34.7.2.1

7 = "Documents"

OIDs and Coding Systems

- OID = Maschine-readable and unique
- Each Coding System used in healthcare has an OID
- ICD-10 = 2.16.840.1.113883.6.3
- SNOMED-CT = 2.16.840.1.113883.6.96
- LOINC = 2.16.840.1.113883.6.1

Use of LOINC in EHRs (HL7-CDA)

Domäne	OID	Beispiel Identifikation	Beispiel Syntax HL7 V3
SNOMED-CT	2.16.840.1.113883.6.96	Asthma	<code code="195967001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Asthma" />
LOINC	2.16.840.1.113883.6.1	History of present Illness	<code code="10164-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Anamnese" />
Laborauftrag im Krankenhaus X	2.16.840.1.113883.2.16.1.99.3	A-123456	<id extension=" A-123456" root="2.16.840.1.113883.2.16.1.99.3" />

Use of LOINC in EHRs (HL7-CDA)

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet type="text/xsl" href="VHITG-CDA-V3.xsl"?>
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:sciphox="urn::sciphox-org/sciphox"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <id extension="60467,36049" root="1.2.276.0.58"/>
  <code code="11488-4" codeSystem="2.16.840.1.113883.6.1" displayName="Consultation note"/>
  <title>Arztbrief aus DURIA auf CDA Rel 2 Basis</title>
  <effectiveTime value="20060924"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
  <languageCode code="de"/>
  <setId extension="D1" root="2.16.840.1.113883.3.933"/>
  <versionNumber value="1"/>
  <recordTarget>
    <!--- Patienten-Daten -->
    <patientRole>
```

LOINC Code 11488-4 in codeSystem 2.16.840.1.113883.6.1

LOINC Number	11488-4
Component	Consultation note
Property	Find
Time Aspect	Pt
System	{Setting}
Scale Type	Doc
Method Type	{Provider}
Class	DOC.CLINRPT
Source	CJM
Date Last Changed	20110829

In the same CDA …

```
<!-- Laborwerte auf CDA Level 2 -->
<section>
  <code code="18723-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>24.09.2006: Laborwerte</title>
  <text>
    <paragraph>Wir berichten kurz zusammenfassend über die Laborergebnisse des obigen Patienten.
```

LOINC Number	18723-7
Component	Hematology studies
Property	Cmplx
Time Aspect	-
System	^Patient
Scale Type	Set
Class	ATTACH.LAB

In the same CDA …

```
<code code="24317-2" codeSystem="2.16.840.1.113883.6.1"/>
<statusCode code="completed"/>
<effectiveTime value="200609241025"/>
<component>
  <observation classCode="OBS" moodCode="EVN">
    <code code="789-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="ERY Erythrozyten">
      <originalText>
        <reference value="#LAB20060924001"/>
      </originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime>
      <center value="200609241025"/>
    </effectiveTime>
    <value xsi:type="PQ" value="4.37" unit="10*12/l"/>
```

Hey! A UCUM Unit!

LOINC Number	789-8
Component	Erythrocytes
Property	NCnc
Time Aspect	Pt
System	Bld
Scale Type	Qn
Method Type	Automated count
Class	HEM/BC

Does CDISC use Object Identifiers? (OIDs)

- The CDISC Organization does not have an OID
- So CDISC coding systems (like CT) do not have an OID either
- So CDISC-CT Code is only valid … within CDISC
  - And can e.g. not be stored in an EHR …
- Why?

Use of LOINC in SDTM and SEND

- From the SDTM-IG 3.1.3:

LBLOINC	LOINC Code	Char	*	Synonym Qualifier	1. Dictionary-derived LOINC Code for LBTEST. 2. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm

MBLOINC	LOINC Code	Char	*	Synonym Qualifier	1. Dictionary-derived LOINC Code for MBTEST. 2. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm

- Dictionary-derived (!!!)
- Permissible

Use of LOINC in SDTM and SEND

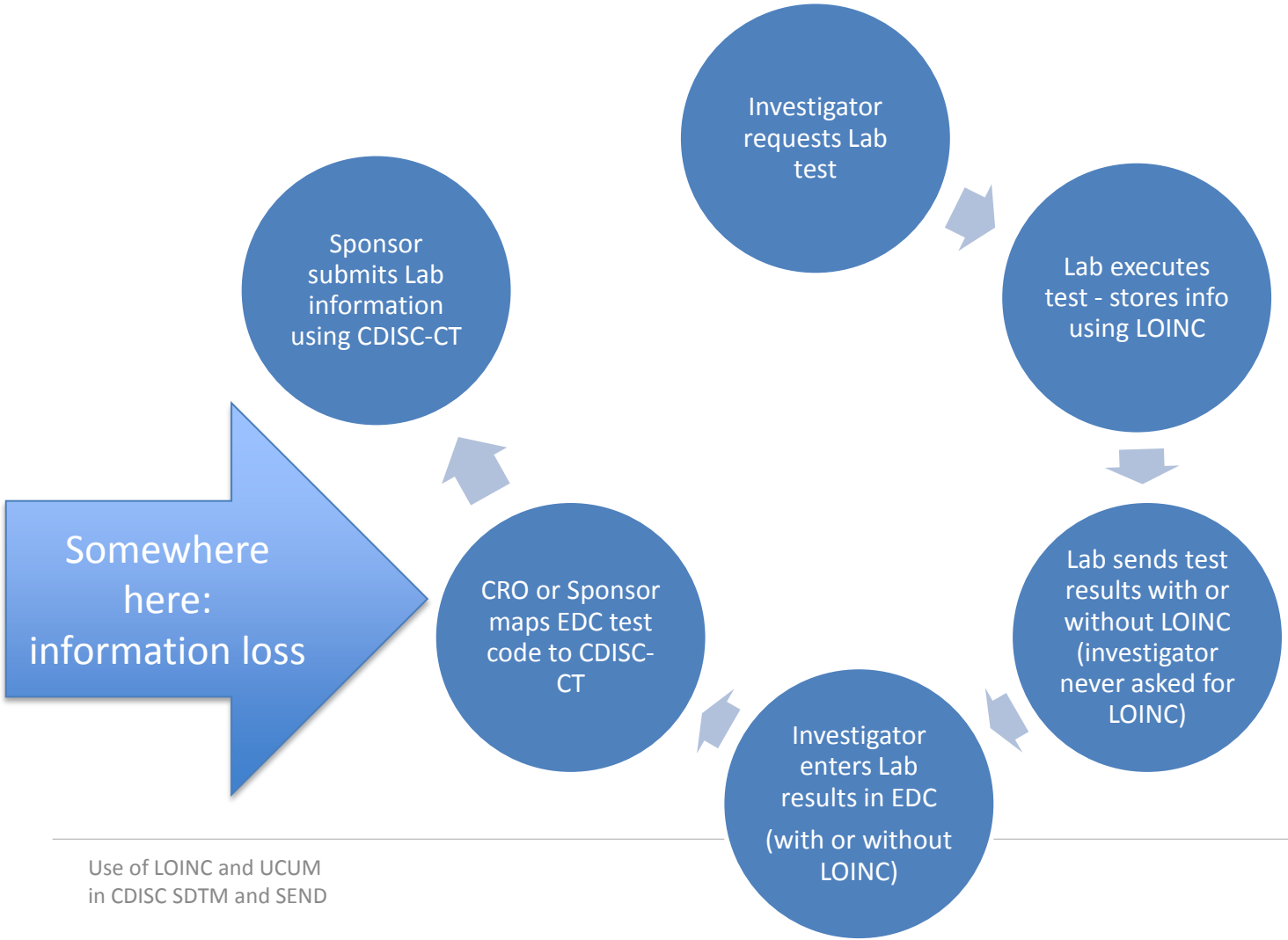
- --LOINC should not be used in:
  - EG (ECG Test Results)
  - IE (Inclusion/Exclusion Exceptions)
  - PE (Physical Examination)
  - QS (Questionnaires)
  - SC (Subject Characteristics)
  - DA (Drug Accountability)

--LOINC is permissible

- Description says:
  "Dictionary-derived LOINC Code for LBTEST"
  - Meaning: "from the value of LBTEST", look for a LOINC code in the dictionary"
  - This is however impossible, as there is a 1:n relationship
  - So sponsors do not use LBLOINC
- However, the LOINC code is in the LIS, HIS or EHR!

LIS = Laboratory Information System - HIS = hospital information system

LBLOINC in SDTM - possible process



CDISC decided to develop its own CT for Laboratory tests

- LBTESTCD

LBTESTCD	Lab Test or Examination Short Name	Char	(LBTESTCD)

Topic	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g."1TEST"). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ALT, LDH.

CDISC-CT for Lab tests

- Latest version: 2013-07-08
  - 975 test codes
- LOINC
  - > 70000 test codes
- CDISC-CT cannot be mapped well to LOINC
  - We tried …
  - Granularity is completely different

CDISC-CT versus LOINC for Lab tests
An example

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU
1	ABC	LB	ABC-001-001	1	ALB	Albumin	CHEMISTRY		30	g/L
2	ABC	LB	ABC-001-001	2	ALP	Alkaline Phosphatase	CHEMISTRY		398	IU/L
3	ABC	LB	ABC-001-001	3	ALP	Alkaline Phosphatase	CHEMISTRY		350	IU/L
4	ABC	LB	ABC-001-001	4	ALP	Alkaline Phosphatase	CHEMISTRY			
5	ABC	LB	ABC-001-001	5	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L
6	ABC	LB	ABC-001-001	6	LYMLE	Lymphocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%
7	ABC	LB	ABC-001-001	7	NEUT	Neutrophils	HEMATOLOGY	DIFFERENTIAL	5.1	10^9/L
8	ABC	LB	ABC-001-001	8	PH	pH	URINALYSIS		7.5	
9	ABC	LB	ABC-001-001	9	ALB	Albumin	CHEMISTRY			
10	ABC	LB	ABC-001-001	10	CHOL	Cholesterol	CHEMISTRY		229	mg/dL
11	ABC	LB	ABC-001-001	11	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L
12	ABC	LB	ABC-001-001	12	PROT	Protein	URINALYSIS		MODERATE	

Source: CDISC SDTM-IG 3.1.3

CDISC-CT versus LOINC for Lab tests

CDISC CT Code (LBTESTCD)	CDISC CT Name (LBTEST)	Nr. of LOINC Codes
ALB	Albumin	51 (++)
ALP	Alkaline Phosphatase	12 (++)
WBC	Leukocytes	81 (++)
LYMLE	Lymphocytes	24 (++)
NEUT	Neutrophils	33 (++)
PH	pH	3
CHOL	Cholesterol	21 (++)
PROT	Protein	36 (++)

++ : Exclusing similar tests, e.g. excluding "Cholesterol crystals".

CDISC-CT versus LOINC
Example GLUC (Glucose)

- LBTESTCD = GLUC
- 68 LOINC Codes

5,6493	6300-8	Glucose	MCnc	Pt	Amnio fld	Qn	
5,6493	2339-0	Glucose	MCnc	Pt	Bld	Qn	
5,6493	2341-6	Glucose	MCnc	Pt	Bld	Qn	Test strip manual
5,6493	2340-8	Glucose	MCnc	Pt	Bld	Qn	Test strip.automated
5,6493	15074-8	Glucose	SCnc	Pt	Bld	Qn	
5,6493	72516-8	Glucose	SCnc	Pt	Bld	Qn	Test strip.automated
5,6493	41651-1	Glucose	MCnc	Pt	BldA	Qn	
5,6493	39481-7	Glucose	SCnc	Pt	BldA	Qn	
5,6493	32016-8	Glucose	MCnc	Pt	BldC	Qn	
5,6493	41653-7	Glucose	MCnc	Pt	BldC	Qn	Glucometer
5,6493	51596-5	Glucose	SCnc	Pt	BldC	Qn	
5,6493	14743-9	Glucose	SCnc	Pt	BldC	Qn	Glucometer
5,6493	47995-6	Glucose	SCnc	Pt	BldCo	Qn	
5,6493	41652-9	Glucose	MCnc	Pt	BldV	Qn	
5,6493	39480-9	Glucose	SCnc	Pt	BldV	Qn	
5,6493	2344-0	Glucose	MCnc	Pt	Body fld	Qn	
5,6493	14745-4	Glucose	SCnc	Pt	Body fld	Qn	
5,6493	40366-7	Glucose	SRat	24H	Body fld	Qn	
5,6493	2342-4	Glucose	MCnc	Pt	CSF	Qn	
5,6493	14744-7	Glucose	SCnc	Pt	CSF	Qn	
5,6493	2343-2	Glucose	MCnc	Pt	Dial fld	Qn	
5,6493	45297-9	Glucose	SCnc	24H	Dial fld	Qn	
5,6493	15075-5	Glucose	SCnc	Pt	Dial fld	Qn	
5,6493	12629-2	Glucose	MCnc	24H	Dial fld prt	Qn	
5,6493	12628-4	Glucose	MCnc	Pt	Dial fld prt	Qn	

OK, but we have LBCAT, LBMETHOD …

- LBCAT, LBSCAT, LBMETHOD, LBSPEC do not have controlled terminology!

	LBTESTCD	LBCAT	LBSPEC	LBMETHOD	LBLOINC
Sponsor 1	GLUC	CHEMISTRY	BLD	QUANT	2339-0
Sponsor 2	GLUC	CHEM	WHOLE BLOOD	ENZYMATIC	15074-8
Sponsor 3	GLUC	CHEMI	BLOOD	HEXOKINASE	2339-0

Where these the same test?

Use of LOINC by the FDA

- Even if there is consistency in LBCAT, LBMETHOD, … within a study or even a submission, how can FDA reviewers compare different submissions?
- If LBLOINC was made "expected" instead of "permissible" they could.

Arguments heard against using LOINC in FDA submissions

- Preclinical is not well covered by LOINC
  - => make separate LBTESTCD-CT for SEND
- Not each combination of 5 variables has a test code
  - => see following slides
- LOINC does not always make a distinction between Serum and Plasma
  - => Does CDISC?

Once upon a time …
CDISC tried …

- 2005 Document by LOINC: "Common LOINC codes used in clinical research"
  - http://loinc.org/discussion-documents/CDISCcommonLOINCtests20050214.pdf
- Never updated afterwoods
- No mapping with CDISC-CT

Common LOINC codes used in clinical research

LOINC® Codes for Common CDISC tests

The following table is a subset of the LOINC® database terms that have been identified by 3 central laboratories as the most frequently used terms in clinical trials. This is a small representation of the LOINC® codes and it is recommended that you use the RELMA® mapping tool to search the database.

Please visit the LOINC® web site (www.loinc.org) for more information about LOINC® and to download the complete set of LOINC® codes and the RELMA® mapping tool.

Explanation of fields:
Unique LOINC® code is a numeric code with a mod 10-check digit.
The fully specified LOINC® name consists of 6 fields:

1. Component (analyte) being measured
2. Property observe red (e.g. mass concentration, volume, number fraction)
3. Timing of the measurement (point in time or collected over 24 hours)
4. System (specimen)
5. Scale of measurement (quantitative, ordinal, nominal)
6. Method (where applicable)

REMARK:
The CDISC-CT Code is not mentioned

The LOINC® short name is an abbreviation of the fully specified LOINC® name consisting of less than 30 characters. The short names are unique, but are subject to change as better algorithms for generating them are developed. It is recommended that the short name be included along with the LOINC® code as the 2nd part of the HL7 CE data type in Hl7 messages.

LOINC® code	Fully Specified LOINC® Name						LOINC® short name
	Component	Property	Time Aspect	System	Scale	Method	
ALLERGY							
25638-8	EOSINOPHIL CATIONIC PROTEIN	MCNC	PT	SER	QN		ECP-mCnc
CELLMARKERS							
27011-6	CELLS.CD14	NCNC	PT	BLD	QN		CD14 Cells # Bld
8111-7	CELLS.CD14/100 CELLS	NFR	PT	BLD	QN		CD14 Cells % Bld
20402-4	CELLS.CD16+CD56+	NCNC	PT	BLD	QN		CD16+CD56+ Cells # Bld
18267-5	CELLS.CD16+CD56+/100 CELLS	NFR	PT	BLD	QN		CD16+CD56+ Cells % Bld
8116-6	CELLS.CD19	NCNC	PT	BLD	QN		CD19 Cells # Bld
8117-4	CELLS.CD19/100 CELLS	NFR	PT	BLD	QN		CD19 Cells % Bld
8122-4	CELLS.CD3	NCNC	PT	BLD	QN		CD3 Cells # Bld
8124-0	CELLS.CD3/100 CELLS	NFR	PT	BLD	QN		CD3 Cells % Bld

Common LOINC codes used in clinical research

LOINC® code	Fully Specified LOINC® Name						LOINC® short name
	Component	Property	Time Aspect	System	Scale	Method	
2753-2	PH	SCNC	PT	SER/PLAS	QN		pH SerPl-sCnc
2756-5	PH	SCNC	PT	UR	QN		pH Ur-sCnc
13539-2	PHOSPHATE	SCNC	PT	UR	QN		Phosphate Ur-sCnc
14879-1	PHOSPHATE	SCNC	PT	SER/PLAS	QN		Phosphate SerPl-sCnc
14881-7	PHOSPHATE	SRAT	24H	UR	QN		Phosphate 24H Ur-sRate
21458-5	PHOSPHATE	MCNC	24H	UR	QN		Phosphate 24H Ur-mCnc
25973-9	PHOSPHATE	SCNC	24H	UR	QN		Phosphate 24H Ur-sCnc
2775-5	PHOSPHATE	MCNC	PT	DIAF	QN		Phosphate Diaf-mCnc
2777-1	PHOSPHATE	MCNC	PT	SER/PLAS	QN		Phosphate SerPl-mCnc
2778-9	PHOSPHATE	MCNC	PT	UR	QN		Phosphate Ur-mCnc
2779-7	PHOSPHATE	MRAT	24H	UR	QN		Phosphate 24H Ur-mRate
21476-7	POTASSIUM	SCNC	24H	UR	QN		Potassium 24H Ur-sCnc
2823-3	POTASSIUM	SCNC	PT	SER/PLAS	QN		Potassium SerPl-sCnc
2828-2	POTASSIUM	SCNC	PT	UR	QN		Potassium Ur-sCnc
2829-0	POTASSIUM	SRAT	24H	UR	QN		Potassium 24H Ur-sRate
14890-8	PROGESTERONE	SCNC	PT	SER/PLAS	QN		Progest SerPl-sCnc
2839-9	PROGESTERONE	MCNC	PT	SER/PLAS	QN		Progest SerPl-mCnc
2842-3	PROLACTIN	MCNC	PT	SER/PLAS	QN		Prolactin SerPl-mCnc
2857-1	PROSTATE SPECIFIC AG	MCNC	PT	SER/PLAS	QN		PSA SerPl-mCnc
21482-5	PROTEIN	MCNC	24H	UR	QN		Prot 24H Ur-mCnc
2885-2	PROTEIN	MCNC	PT	SER/PLAS	QN		Prot SerPl-mCnc
2889-4	PROTEIN	MRAT	24H	UR	QN		Prot 24H Ur-mRate
2890-2	PROTEIN/CREATININE	MCRTO	PT	UR	QN		Prot/creat Ur-mRto
25977-0	PYRIDINOLINE	SCNC	24H	UR	QN		PYD 24H Ur-sCnc
25129-8	PYRIDINOLINE/CREATININE	SCRTO	PT	UR	QN		PYD/creat Ur-sRto
13967-5	SEX HORMONE BINDING GLOBULIN	SCNC	PT	SER	QN		SHBG Ser-sCnc
21525-1	SODIUM	SCNC	24H	UR	QN		Sodium 24H Ur-sCnc
2951-2	SODIUM	SCNC	PT	SER/PLAS	QN		Sodium SerPl-sCnc
2955-3	SODIUM	SCNC	PT	UR	QN		Sodium Ur-sCnc
2956-1	SODIUM	SRAT	24H	UR	QN		Sodium 24H Ur-sRate
16257-8	SODIUM URATE CRYSTALS	ACNC	PT	CALC	ORD	INFRARED SPECTROSCOPY	Na Urate Cry Calc Ql IR
2963-7	SOMATOTROPIN	MCNC	PT	SER/PLAS	QN		GH SerPl-mCnc
2965-2	SPECIFIC GRAVITY	RDEN	PT	UR	QN		Sp Gr Ur Qn
14913-8	TESTOSTERONE	SCNC	PT	SER/PLAS	QN		Testost SerPl-sCnc
2986-8	TESTOSTERONE	MCNC	PT	SER/PLAS	QN		Testost SerPl-mCnc
14914-6	TESTOSTERONE.FREE	SCNC	PT	SER/PLAS	QN		Testost Free SerPl-sCnc
2991-8	TESTOSTERONE.FREE	MCNC	PT	SER/PLAS	QN		Testost Free SerPl-mCnc
11061-9	THROMBOXANE BETA 2	MRAT	24H	UR	QN		TXB2 24H Ur-mRate
3016-3	THYROTROPIN	ACNC	PT	SER/PLAS	QN		TSH SerPl-aCnc
14921-1	THYROXINE	SCNC	PT	SER/PLAS	QN		T4 SerPl-sCnc
27980-2	THYROXINE BINDING GLOBULIN	SCNC	PT	SER/PLAS	QN		T4BG SerPl-sCnc
3021-3	THYROXINE BINDING GLOBULIN	MCNC	PT	SER/PLAS	QN		T4BG SerPl-mCnc
32215-6	THYROXINE FREE INDEX	ACNC	PT	SER/PLAS	QN		FTI SerPl-aCnc
14920-3	THYROXINE.FREE	SCNC	PT	SER/PLAS	QN		Free T4 SerPl-sCnc
3024-7	THYROXINE.FREE	MCNC	PT	SER/PLAS	QN		Free T4 SerPl-mCnc
22674-6	TRANSFERRIN	SCNC	PT	SER/PLAS	QN		Transferrin SerPl-sCnc
3034-6	TRANSFERRIN	MCNC	PT	SER/PLAS	QN		Transferrin SerPl-mCnc
30248-9	TRANSFERRIN RECEPTOR.SOLUBLE	MCNC	PT	SER/PLAS	QN		sTfR SerPl-mCnc
3040-3	TRIACYLGLYCEROL LIPASE	CCNC	PT	SER/PLAS	QN		Lipase SerPl-cCnc
14927-8	TRIGLYCERIDE	SCNC	PT	SER/PLAS	QN		Trigl SerPl-sCnc
2571-8	TRIGLYCERIDE	MCNC	PT	SER/PLAS	QN		Trigl SerPl-mCnc

An alterntive for the LB domain

- For usage in case the source data comes from a HIS, LIS or EHR
- Recently proposed to CDISC
  - But with little prospect of being accepted
- Based on usage of LOINC and UCUM instead of CDISC-CT

HIS = Hospital Information System

The alternative proposal

- Make LBLOINC expected
- Remove current LBCAT, LBSCAT, LBSPEC, LBMETHOD
- Add (LOINC) LBPROP (property measured), LBTIMEAS (time aspect), LBSYSTEM (system), LBSCALE (scale), LBCLASS (class), LBMETHOD (method, when applicable)

The alternative proposal

Sponsor	LBLOINC	LBCOMP	LBPROP	LBTIMEAS	LBSYSTEM	LBSCALE	LBCLASS
Sponsor 1	2339-0	Glucose	MCnc	Pt	Bld	Qn	CHEM
Sponsor 2	15074-8	Glucose	SCnc	Pt	Bld	Qn	CHEM
Sponsor 3	2339-0	Glucose	MCnc	Pt	Bld	Qn	CHEM

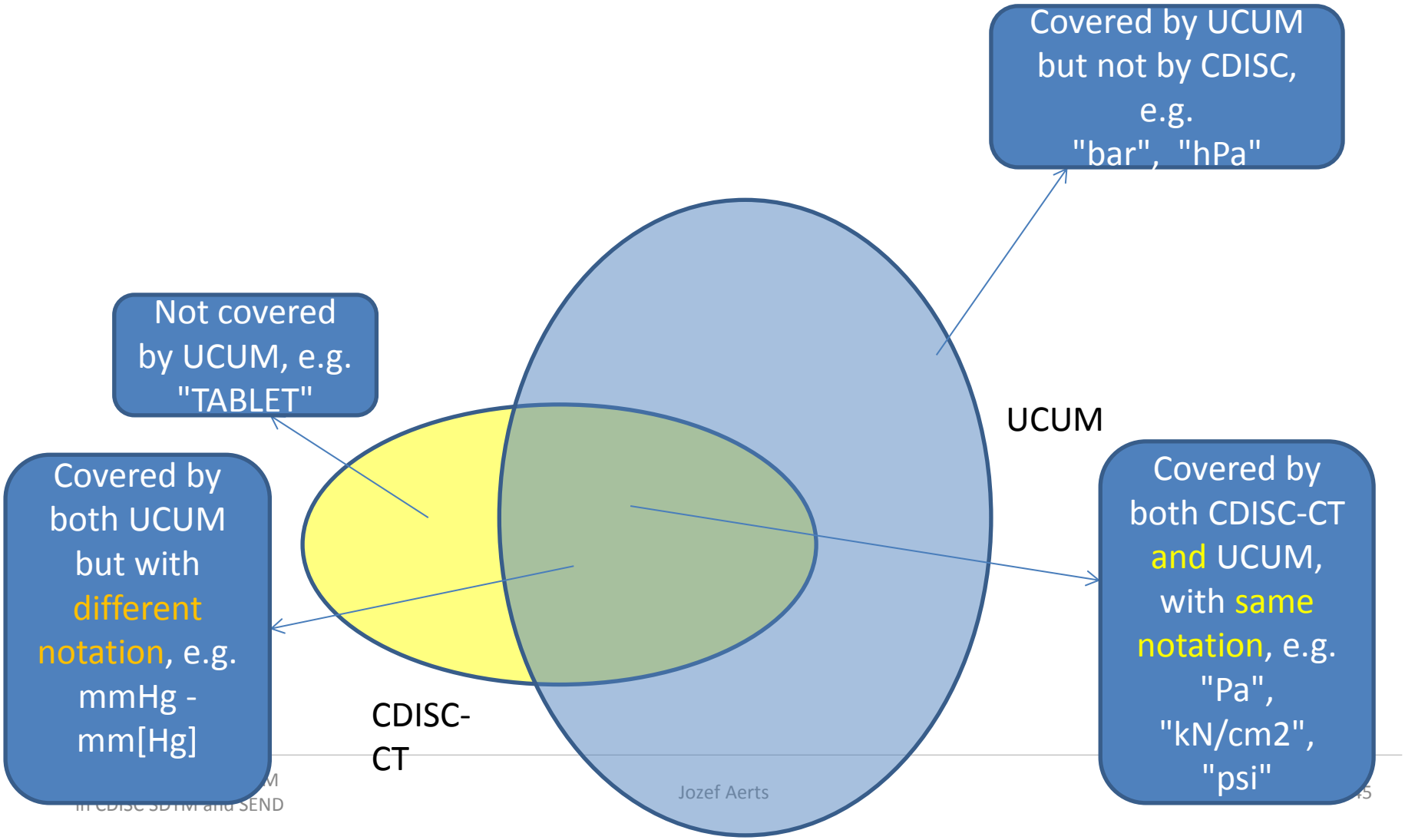
Valid LOINC combination without LOINC code

LBLOINC	LBCOMP	LBPROP	LBTIMEAS	LBSYSTEM	LBSCALE	LBCLASS
11217-7	Hexaporphyrin	MRat	24H	Urine	Qn	CHEM
30529-9	Hexaporphyrin	ACnc	Pt	Urine	Ord	CHEM
	Hexaporphyrin	MRat	12H	Urine	Qn	CHEM
50856-4	Hexaporphyrin	SRat	24H	Urine	Qn	CHEM

Use of UCUM in CDISC

- CDISC has own CT [UNIT]
- Is a list, not a system
- Latest version (July 2013) contains 516 "units"
- The list grows and grows …

CDISC claims to use a subset of UCUM



Some differences

Property	CDISC	UCUM
(blood) pressure	mmHg	mm[Hg]
pressure	cm H2O	cm[H2O]
count	10^9/l	10*9/l
cell count	cells/uL	{cells}/ul
energy	Joule	J
time	Years	a
non-SI length	ft	[ft_i]
non-SI length	IN	[in_i]

Code	CDISC meaning	UCUM meaning
bar	Dosing unit (e.g. bar of chocolate)	pressure

CDISC [UNIT] list is problematic

- CDISC-CT contains:
  - ug/g/day,
  - ug/g/h
  - ug/g/min
  - ug/g Creatinine
- But not
  - ug/g

CDISC-CT [UNIT] mixes up object and unit

- Object = what is measured
  - E.g "cells", "creatinine"
- Unit = "ug/g"
- CDISC-CT: "ug/g Creatinine"

- UCUM:
  - {cre} ug/g
  - or ug/g

CDISC-CT [UNIT] dosing "units"

- Dosing units: ampule, tablet, bar, bottle, capsule, can, cylinder

Unit	AMPULE	Ampule Dosing Unit	A dosing measurement based on the ampule unit.(NCI)
Unit	BAG	Bag Dosing Unit	A dosing measurement based on the bag unit.(NCI)
Unit	BAR	Bar Dosing Unit	A dosing measurement based on the bar unit.(NCI)
Unit	BOLUS	Bolus Dosing Unit	A dosing measurement based on the bolus unit.(NCI)
Unit	BOTTLE	Bottle Dosing Unit	A dosing measurement based on the bottle unit.(NCI)
Unit	BOX	Box Dosing Unit	A dosing measurement based on the box unit.(NCI)
Unit	CAN	Can Dosing Unit	A dosing measurement based on the can unit.(NCI)
Unit	CAPSULE	Capsule Dosing Unit; cap	A dosing measurement based on the capsule unit.(NCI)
Unit	CARTRIDGE	Cartridge Dosing Unit	A dosing measurement based on the cartridge unit.(NCI)
Unit	COAT	Coat Dosing Unit	A dosing measurement based on the coat unit.(NCI)
Unit	CONTAINER	Container Dosing Unit	A dosing measurement based on the container unit.(NCI)
Unit	CYLINDER	Cylinder Dosing Unit	A dosing measurement based on the cylinder unit.(NCI)
Unit	DISK	Disk Dosing Unit	A dosing measurement based on the disk unit.(NCI)
Unit	DRUM	Drum Dosing Unit	A dosing measurement based on the drum unit.(NCI)

CDISC-CT [UNIT] dosing "units"

- Is a "dosing unit" a "unit"?

- Suggestion to make this a separate codelist has been turned down

Why CDISC does not want to accept/support UCUM

- Investigators are unfamiliar with UCUM notation (e.g. "mm[Hg]" versus "mmHg")
- SEND "units" are not covered by UCUM
- Some "special" units used in clinical research are not covered by UCUM
- Investigators, sponsors, reviewers would need to learn UCUM

- Not invented at CDISC …

LOINC and UCUM for CDISC submissions - proposals

- Allow different "flavor" of LB domain (e.g. "LBLOINC" for cases where the laboratory information comes from LIS, HIS or EHR)

- For these cases, allow UCUM units to be used (documented in define.xml - "ExternalCodeList")

LOINC and UCUM for CDISC submissions - why we need this

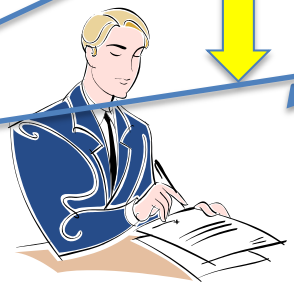
Investigator requests lab test

Lab executes test

Test results in LIS

Test results in HIS

Test results in EDC



Test results in eCRF

Test results in EHR

The end?

- I don't think so …

The long and winding road to interoperability …