



Using an MDR to Manage Lab Test Specifications

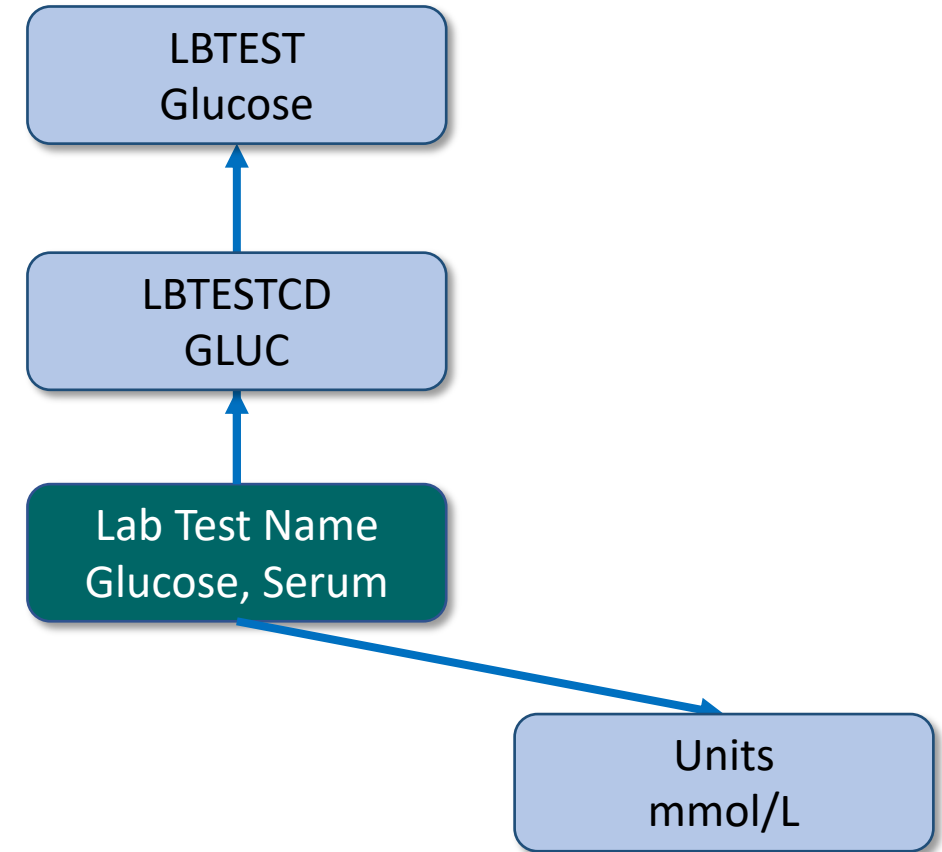
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Outline

- Lab Specification Scenario
- LOINC Requirement
- Lab Metadata in an MDR
- Benefits of MDR Managed Lab Specs

Lab Specification Scenario

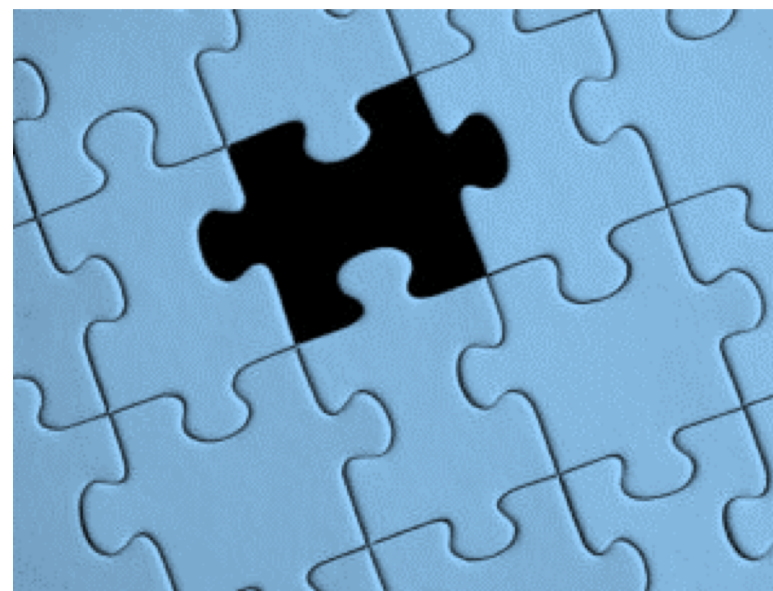
Study Design



Lab Data Received

Unique ID	CDISC Test Name	CDISC Test Code	Specimen Material Name	Category	Sub-Category	Method	Conventional Units	SI Units
LABID	LBTEST	LBTESTCD	LBSPEC	LBCAT	LBSCAT	METHOD	CNVU	SIU
10006	Alanine Aminotransferase	ALT	SERUM	LIVER AND KIDNEY FUNCTION	LIVER FUNCTION TESTS	SPECTROPHOTOMETRY	U/L	U/L
10007	Glucose	GLUC	PLASMA	CHEMISTRY	GLUCOSE TESTS	PHOTOMETRY	mg/dL	mmol/L
10008	Glucose	GLUC	URINE	URINALYSIS	URINE CHEMISTRY	DIPSTICK	mg/dL	mmol/L

- Lab ID or Name
- LBTEST
- LBTESTCD
- UNITS

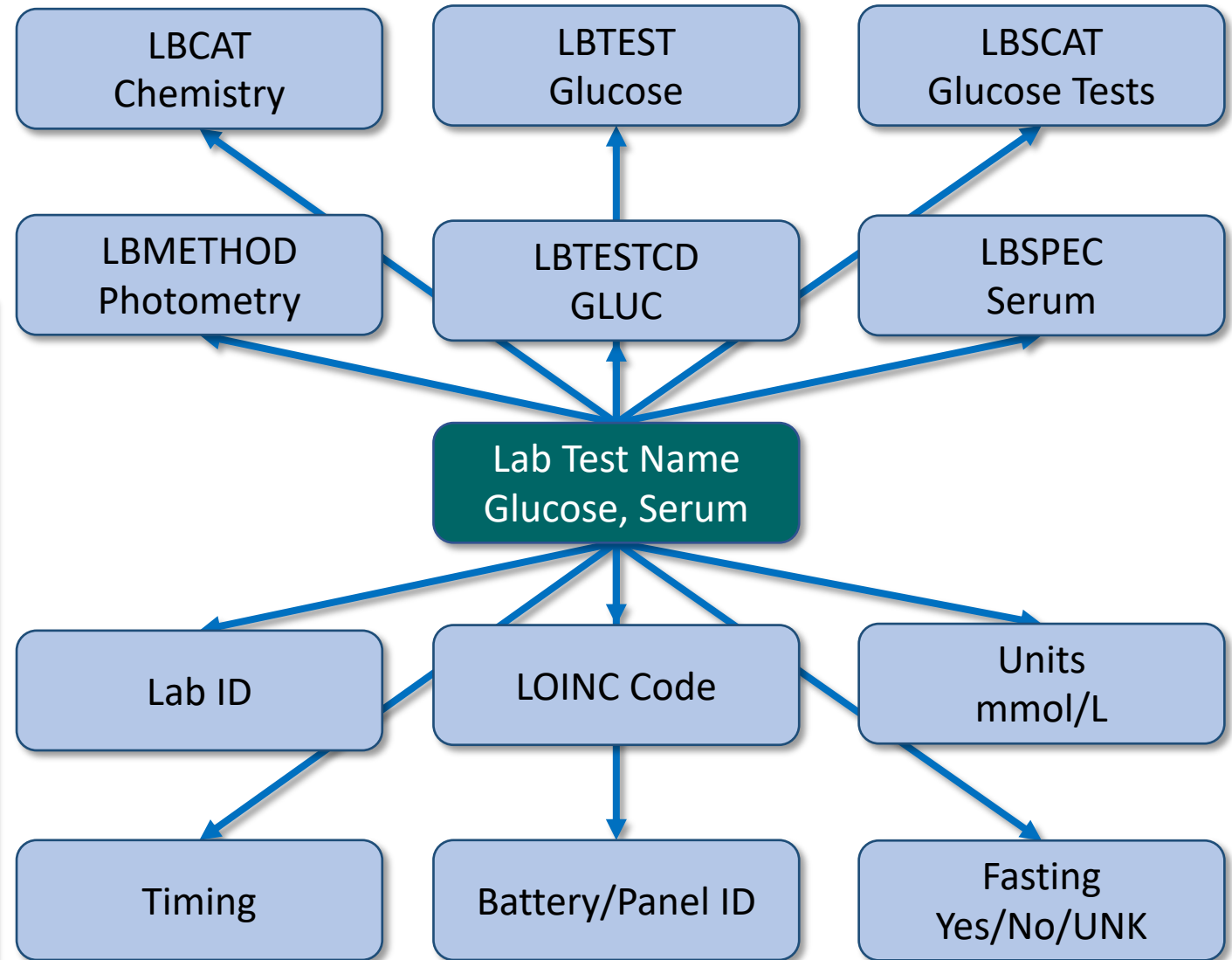


Study Design

What I really mean is.....

Blood sugar level

- With specimen type of Serum
- Using method of photometry
- With units of mmol/L
- Included in a Battery or Panel
- With a Company Lab ID
- Measured at a certain time
- With the patient fasting
- With a lab test name of Glucose, Serum
- Mapped to CDISC LBTEST = Glucose
- Mapped to CDISC LBTESTCD = GLUC

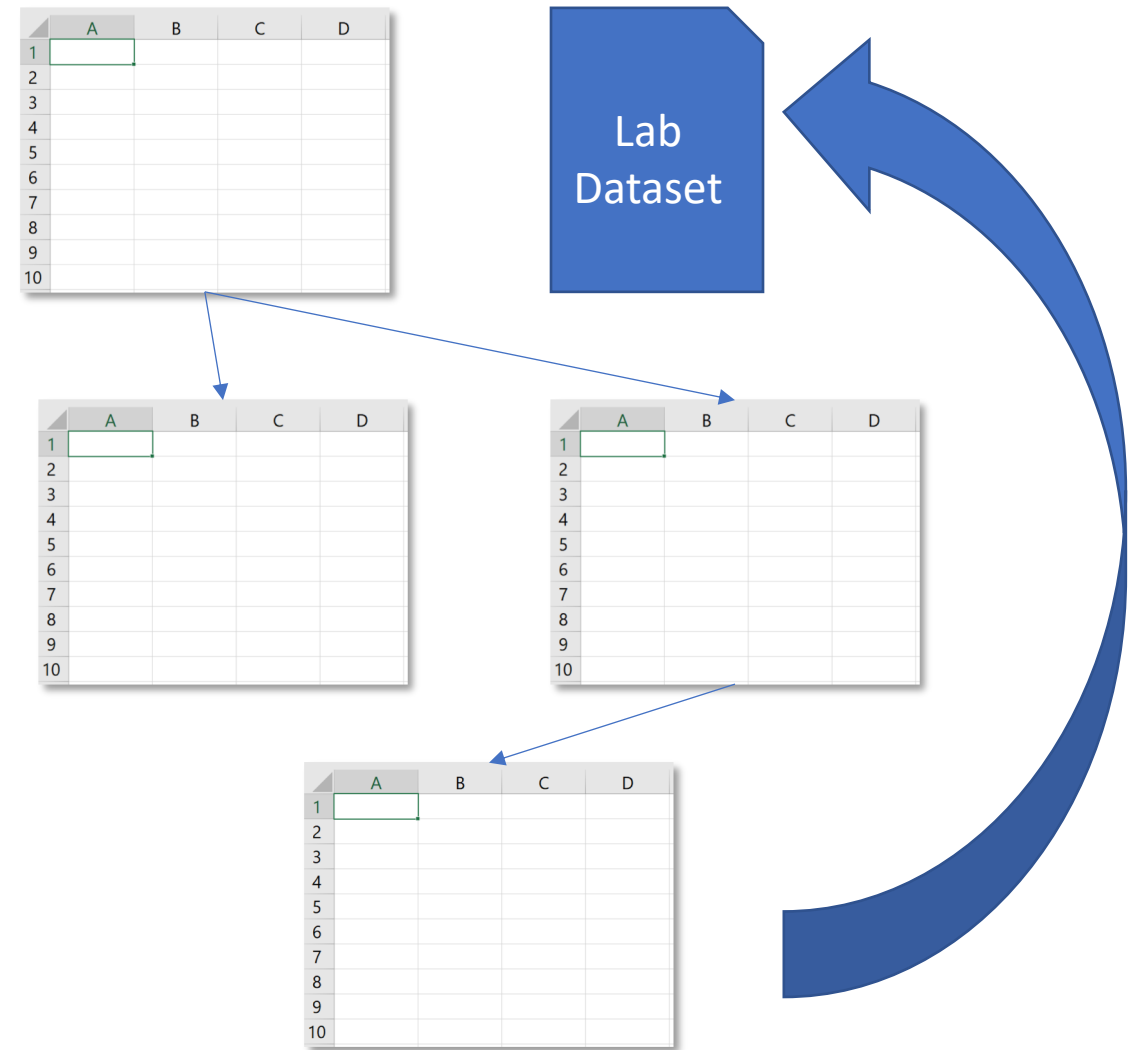


Managing the Lab Test Specs

- Manage the lab tests in a spreadsheet, sometimes in multiple spreadsheets
 - List all the attributes of the lab tests
- Share the spreadsheet on Sharepoint

Spreadsheet Management

- Study teams download the specifications
 - Make a copy and add all the labs needed for the study
- Share with the lab vendor
- Multiple Copies
- Lab vendor has multiple specifications



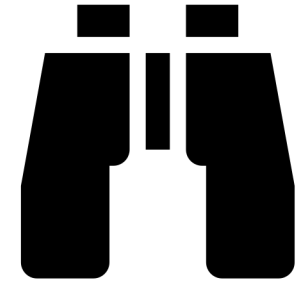
What's the problem

- Having multiple copies of a spreadsheet or loose governance of the standards in the spreadsheet can lead to poor quality lab data, or need for rework or investigation to determine the context.
- Governance processes to manage lab standards, adhering to controlled terminology in the lab standards
- Visibility to what lab tests are being used across the sponsor is not known, no impact analysis to changing or new lab specifications
- No audit trail of changes to specifications
- Ability to extend, add new attributes,
 - Addition of LOINC codes are a new requirement coming in 2020.
 - New types of lab tests that require new attributes

LOINC Requirement

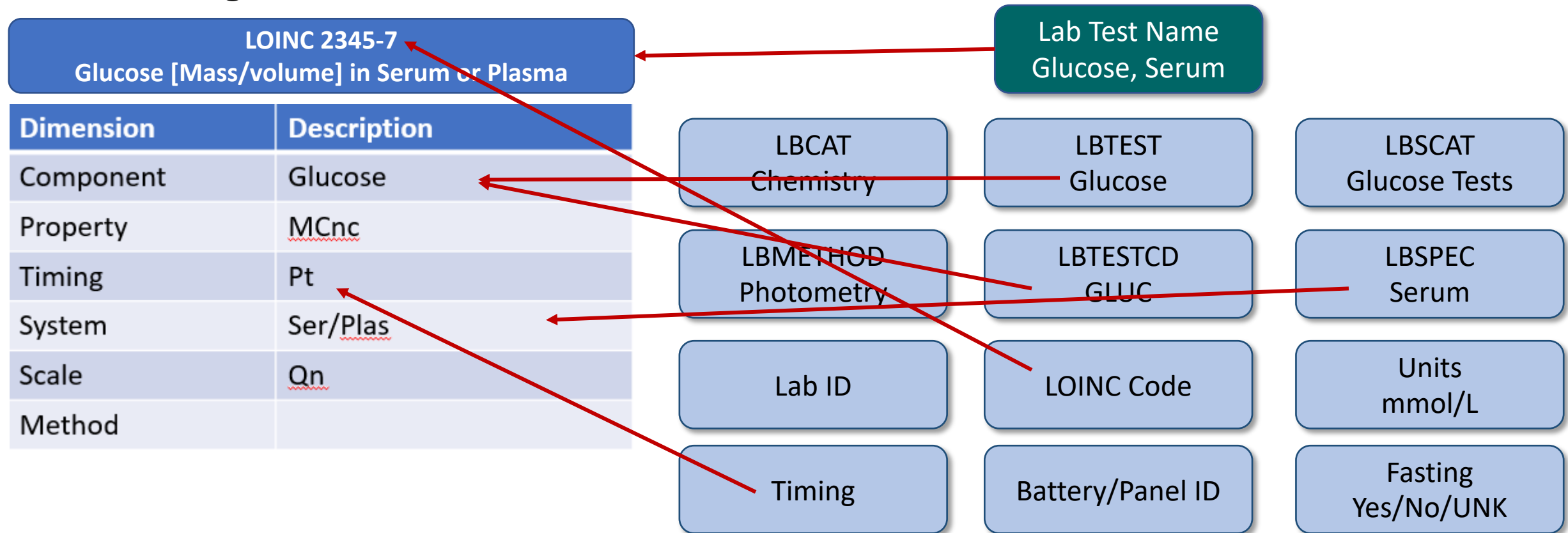
FDA LOINC Requirement

- LOINC Requirement
 - The FDA Data Standards Catalog includes the requirement to populate the LBLOINC variable in the LB Domain for study data submitted to the FDA
 - The requirement for LOINC codes begins for studies that start after March 15, 2020 for NDAs, ANDAs and certain BLAs, and on March 15, 2021 for certain INDs.
- With the introduction of LOINC code requirement it is more important than ever to have a set of lab test specifications and an organization and process and tools to support it.
- While it is not until next year, companies will need to come up with a strategy to add, approve and manage LOINC mappings for lab tests



LOINC Mapping

- Mapping LOINC dimensions and lab test specifications may not always be straight-forward



LOINC Working Group

- Sponsors should include LOINC codes for any test where a valid LOINC code exists for new trials' electronic submissions per the FDA Data Standards Catalog requirement dates.*
 - The most specific LOINC code should always be used without over-specifying details that are not known by the sponsor, such as method or scale.*
- CDISC Lab Working Group has assessed over 2000 common lab tests and assigned LOINC codes*

*Source: Recommendations for the Submission of LOINC Codes in Regulatory Applications to the U.S. Food and Drug Administration, November 2017

LOINC Mapping Tools

Regenstrief LOINC Mapping Assistant (RELMA) - Map Local Terms for "SAMPLE"

File Tools HIPAA Lab Auto Mapper View Help

Welcome dpringenbach log out

Search Mapping View All Working Set Terms Hierarchy & Search Limits Part Search Answer List Search

glucose Units Search

Use Lab Automapper Search Lab Terms Only

Ro	Score	LOINC	Component	Property	TI...	System	Sc...	M...	ExUC...	ExU...	Rank	SIR...	LForms	Com...	Co...	Class	LongName	ShortName	Type
1	1/2	32318-8	Glucose	SCnc	Pt	XXX	Qn		mmo...	mm...						CHEM	Glucose [Moles/volume] in Unspecified specimen	Glucose XXX-sCnc	1
2	1/3	2345-7	Glucose	MCnc	Pt	Ser/Plas	Qn		mg/dL	mg...	4			141	17	CHEM	Glucose [Mass/volume] in Serum or Plasma	Glucose SerPl...	1
3	1/3	2339-0	Glucose	MCnc	Pt	Bld	Qn		mg/dL	mg...	13			32	2	CHEM	Glucose [Mass/volume] in Blood		
4	1/3	2349-9	Glucose	PrThr	Pt	Urine	Ord				116	116		12	5	CHEM	Glucose [Presence] in Urine		
5	1/3	2342-4	Glucose	MCnc	Pt	CSF	Qn		mg/dL	mg...	550			20	15	CHEM	Glucose [Mass/volume] in Cerebral spinal f		
6	1/3	2350-7	Glucose	MCnc	Pt	Urine	Qn		mg/dL	mg...	1730			16	9	CHEM	Glucose [Mass/volume] in Urine		
7	1/3	41652-9	Glucose	MCnc	Pt	BldV	Qn		mg/dL	mg...				1	1	CHEM	Glucose [Mass/volume] in Venous blood		
8	1/3	54486-6	Glucose	MCnc	Pt	Water	Qn		g/L	g/L						CHEM	Glucose [Mass/volume] in Water		
9	1/3	35662-6	Glucose	MCnc	XXX	Urine	Qn		mg/dL	mg...				1	1	CHEM	Glucose [Mass/volume] in Urine collected		
10	1/3	14744-7	Glucose	SCnc	Pt	CSF	Qn		mmo...	mm...		550		49	6	CHEM	Glucose [Moles/volume] in Cerebral spinal		

Units Specimen Methodless Lab Terms Only Battery My Subset

Community Mapping Display for LOINC 2345-7

2345-7 Glucose [Mass/volume] in Serum or Plasma

NAME Fully-Specified Name: Component Property Time AspeSystem Scale Method
Glucose MCnc Pt Ser/Plas Qn

Mappings from the LOINC Community

Battery Code	Battery Name	Local Code	Local Test Name	Units	Language	Institution
		GLU	GLUCOSE		English (US)	ACL Laboratories
		3216	GLUCOSE		English (US)	DIA TEK USA
		3216	GLUCOSE		English (US)	DIA TEK USA
		82436	GLUCOSE SERUM		English (US)	DIA TEK USA
		82436	GLUCOSE SERUM		English (US)	DIA TEK USA
		230025	Glucose	mg/dL	English (US)	DIA TEK USA
22900	Comprehensive Metabolic Panel	230025	Glucose	mg/dL	English (US)	DIA TEK USA
22910	Basic Metabolic Panel	230025	Glucose	mg/dL	English (US)	DIA TEK USA
22950	Renal Profile	230025	Glucose	mg/dL	English (US)	DIA TEK USA
23040	Glucose	*FBS	GLUCOSE, FASTING	mg/dL	English (US)	Firelands Regional Medical Center
		*FBS WT LOSS	GLUCOSE, FASTING WT LOSS	mg/dL	English (US)	Firelands Regional Medical Center
		*GLUR	GLUCOSE,RANDOM	mg/dL	English (US)	Firelands Regional Medical Center
		EBS	GLUCOSE, FASTING	mg/dL	English (US)	Firelands Regional Medical Center
		GLUCOSE	EMPLOYEE SCR	mg/dL	English (US)	Firelands Regional Medical Center
		FGLU	GLUCOSE, FASTING	mg/dL	English (US)	Firelands Regional Medical Center
		GLUGITF	FASTING GLUCOSE-GLU TOLREANCE	mg/dL	English (US)	Firelands Regional Medical Center
		GLUR	GLUCOSE,RANDOM	mg/dL	English (US)	Firelands Regional Medical Center
BMETPN	BASIC METABOLIC PANEL	GLU	GLUCOSE	MG/DL	English (US)	Florida Hospital Orlando
GMETPN	COMP METABOLIC	GLU	GLUCOSE	MG/DL	English (US)	Florida Hospital Orlando

Although LOINC mapping tools exist (e.g. Regenstrief LOINC Mapping Assistant pictured), the Working Group recommends that sponsors not attempt to derive a mapping to LOINC as they create the SDTM files. Lab test names are notoriously ambiguous, and making assumptions in the mapping process without confirming with the test performer can lead to serious data quality issues. It is best to work with lab providers, CDISC and Regenstrief

Lab Metadata in an MDR

Modeling Lab Metadata

Unique ID	CDISC Test Name	CDISC Test Code	Specimen Material Name	Category	Sub-Category	Method	Conventional Units	SI Units
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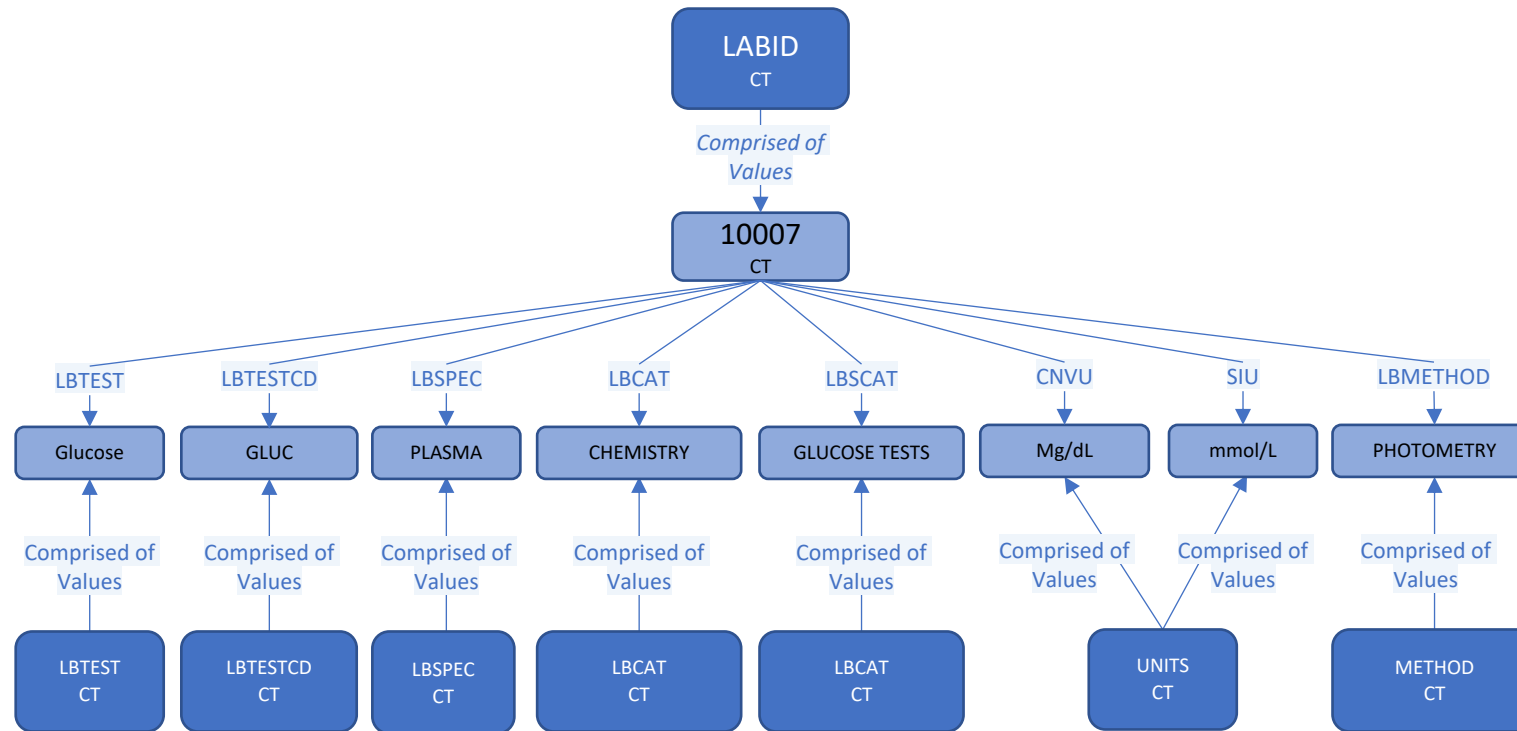


Each column is a list of controlled terminology

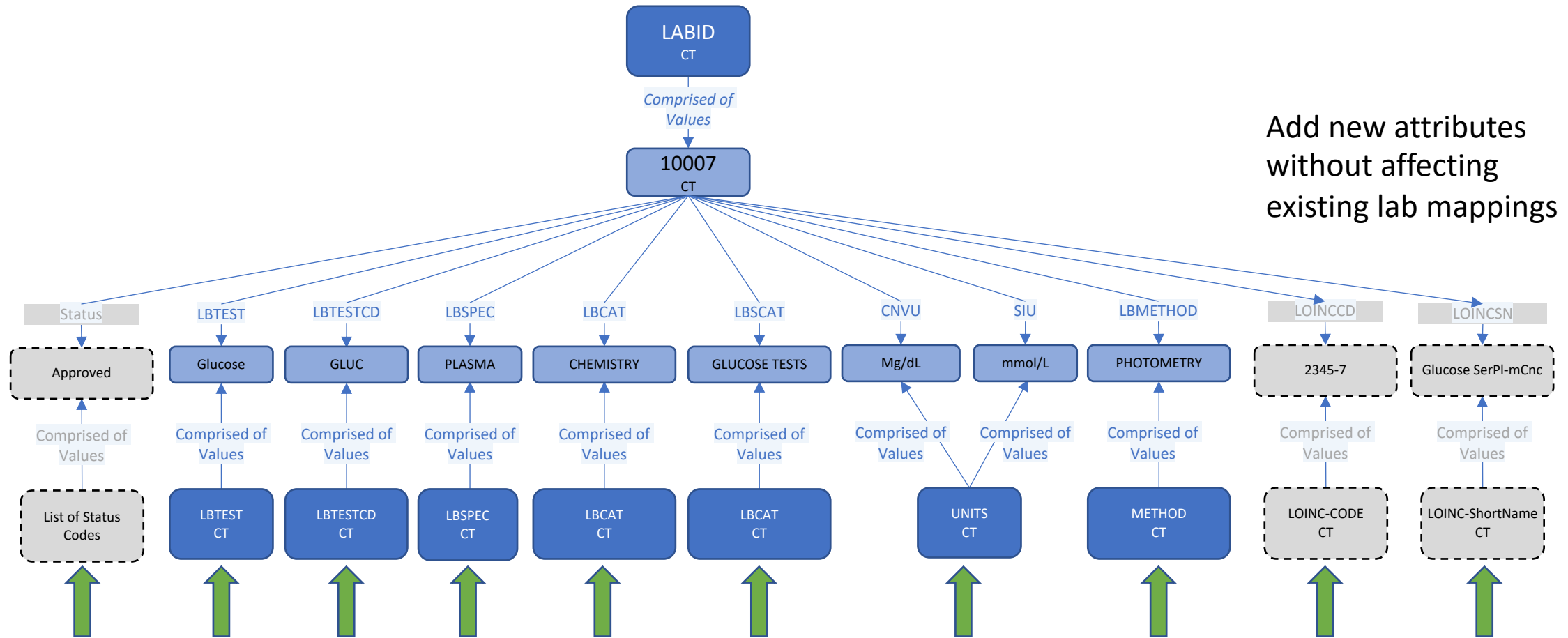


Each row is a unique lab test with a set of related items of multiple controlled terminologies

Modeling Lab Metadata



Extending the Model



Update CT without affecting the existing lab mappings



Benefits of MDR-Managed Lab Specifications

Benefits of Managing Lab Metadata in an MDR

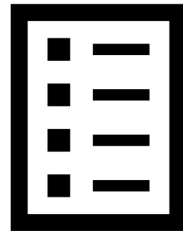
- Accessibility

- Most MDR's have web based user interfaces making the lab specifications accessible to global users



- Traceability / Audit Trail

- Any changes to lab specifications will be captured in an audit trail. Track changes with versioning capabilities in an MDR



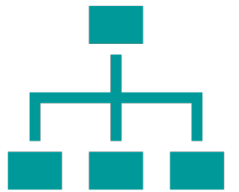
- Governance / Control

- Workflows aid in governance and approval processes as well as in adding new lab model extensions



- Extensibility

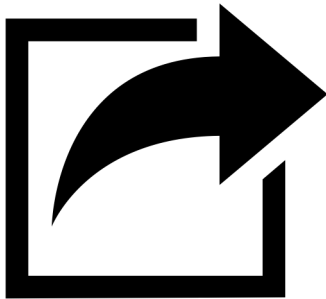
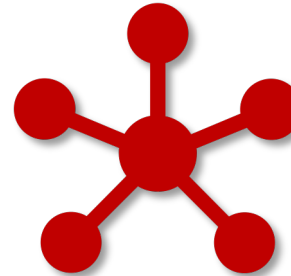
- Update lab specification attributes for changing requirements in the future (e.g. LOINC)



Benefits of Managing Lab Metadata in an MDR

- Impact Analysis

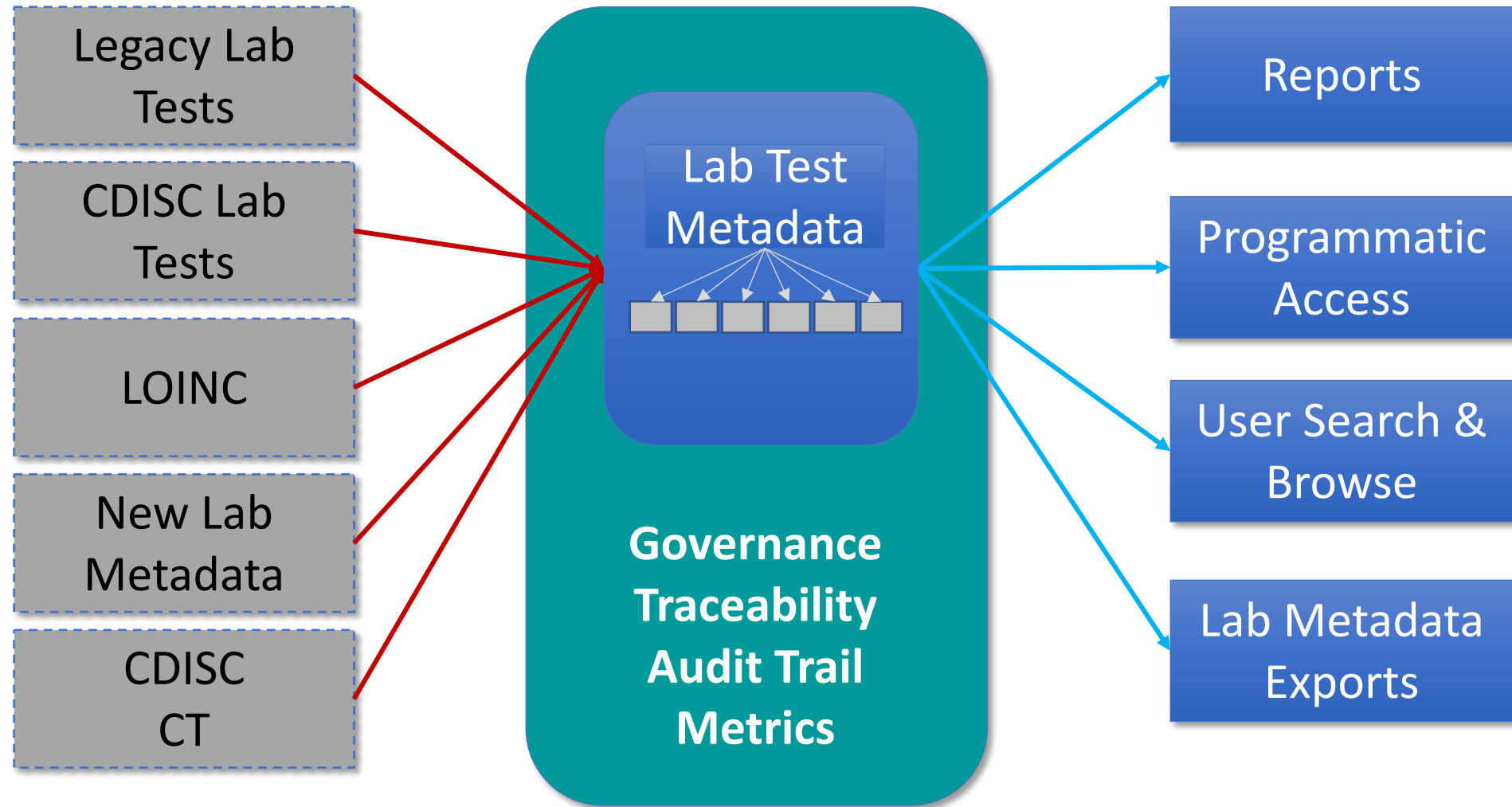
- Understand the impact of changes to lab specifications, changes to LOINC code status or mappings or changes to CDISC CT.



- Conformance Checking

- Enable automated lab data conformance checking with programmatic access to the latest lab standards.

Benefits of Lab Metadata in an MDR



Conclusions

- Lab test specifications are a complex set of related attributes. The attributes are subject to controlled terminologies.
 - Lab test specifications are difficult to manage using only a spreadsheet.
 - Managing related sets of metadata is the strength of an MDR
- Managing lab test specifications as metadata in a metadata repository can provide benefits of increased accessibility to lab standards, and increased governance and control.
- An MDR can provide added benefits of impact analysis, audit trails and improved conformance checking capability.

Questions?

