

A photograph of a bronze statue of a man in a long tunic, holding a large, ornate circular shield. The statue is set against a bright blue sky with some white clouds. The shield features a relief of a face. The statue is positioned on the right side of the image, with its right arm raised.

BRIDG Activities, Clinical Data Elements and the role of MDR

Basel, 21. March 2008

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Key question

- **How to develop and maintain an internal data element registry**
 - Supporting data integration
 - Supporting SDTM submissions

Three strategic decisions

- Specify the set of data elements for Novartis Development analogous to SDTM data elements (extend SDTM for Novartis).
- Use a ISO 11179 MDR¹⁾-based system to register the data elements with.
- Introduce an Analysis Model for Novartis Development analogous to the BRIDG²⁾ model mapping the data elements to unambiguously defined concepts.

1) ISO/IEC 11179, Information Technology -- Metadata registries (MDR)

2) Biomedical Research Integrated Domain Group

1 - Specify DE analogue to SDTM

2.2.3 The Findings Observation Class

Table 2.2.3: Findings — Topic and Qualifier Variables, One Record per Finding (--TESTCD)

Variable Name	Variable Label	Type	Description
Topic Variable			
--TESTCD	Short Name of Measurement, Test or Examination	Char#	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLATELET, SYSBP, PR, EYEEXAM.
Qualifier Variables			
--TEST	Name of Measurement, Test or Examination	Char#	Verbatim name, corresponding to the topic variable, of the test or examination used to obtain the measurement or finding. Examples: Platelet Count, Systolic Blood Pressure, PR Interval, Eye Examination.
--MODIFY	Modified Term	Char	If the value of --TEST is modified as part of a defined procedure, then the modified text is placed here.
--CAT	Category	Char#	Used to define a category of related records. Examples: HEMATOLOGY, URINALYSIS, CHEMISTRY, HAMILTON DEPRESSION SCALE, SF36.
--SCAT	Subcategory	Char#	Used to define a further categorization level for a group of related records. Example: DIFFERENTIAL.
--POS	Position of Subject During Observation	Char#	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.
--BODSYS	Body System or Organ Class	Char#	Body System or Organ Class that is involved in an event or measurement from the standard hierarchy. Example: the Primary SOC in MedDRA.
--ORRES	Result or Finding in Original Units	Char	Result of the measurement or finding as originally received or collected.

Extend SDTM for Novartis => SDTM++

2.2.3 The Findings Observation Class

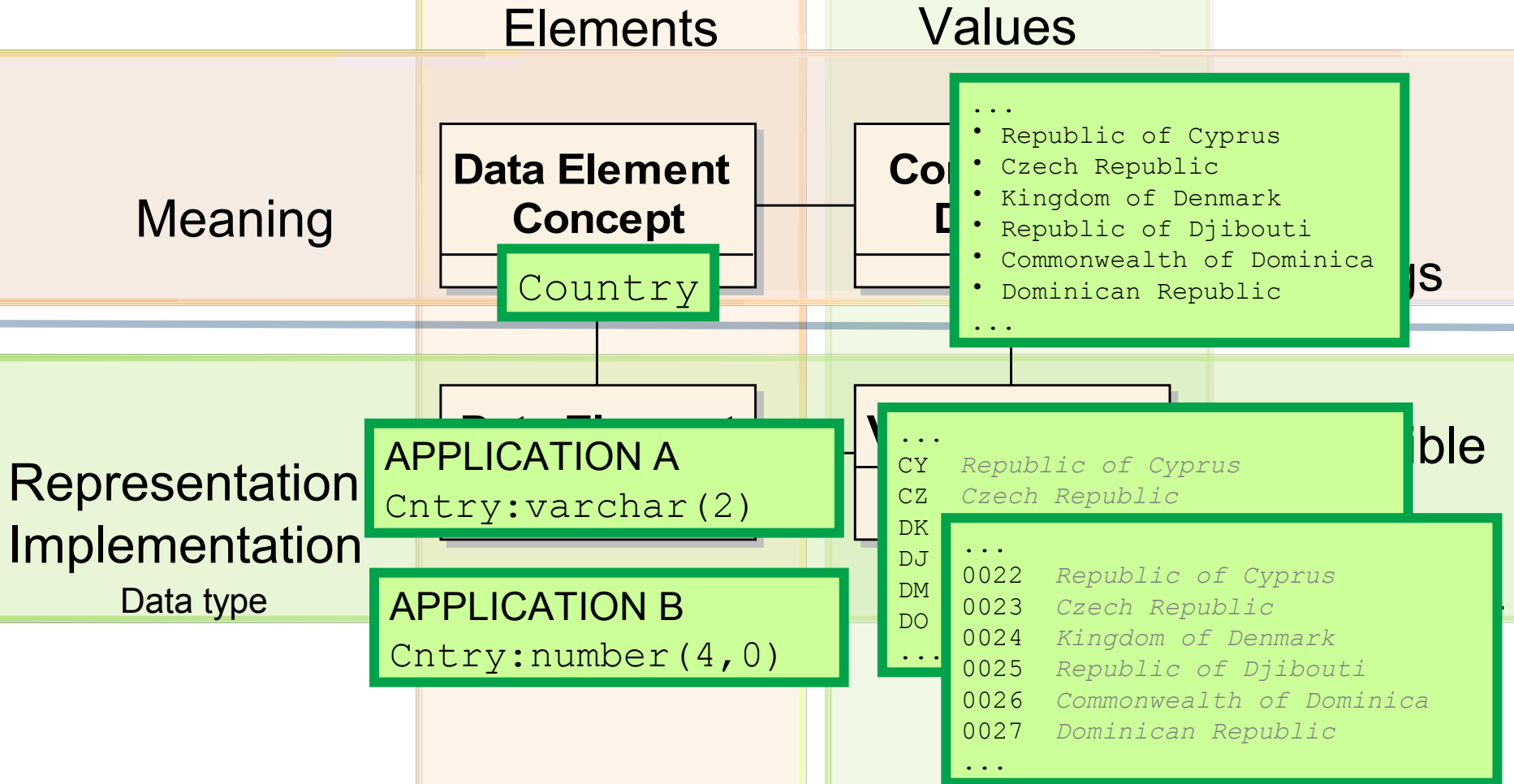
Table 2.2.3: Findings — Topic and Qualifier Variables, One Record per Finding (—TESTCD)

Variable Name	Variable Label	Type	Description
—TESTCD	Short Name of Measurement, Test or Examination	Char*	Short character value for —TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 3 characters. Examples: PLATELET, SYSBP, PR, EYEXAM.
Qualifier Variable:			
—TEST	Name of Measurement, Test or Examination	Char*	Verbatim name, corresponding to the topic variable, of the test or examination used to obtain the measurement or finding. Examples: Platelet Count, Systolic Blood Pressure, PR Interval, Eye Examination.
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—ORRES	Result or Finding in Original Units	Char*	Result of the measurement or finding as originally received or collected.

Additional attributes per DE

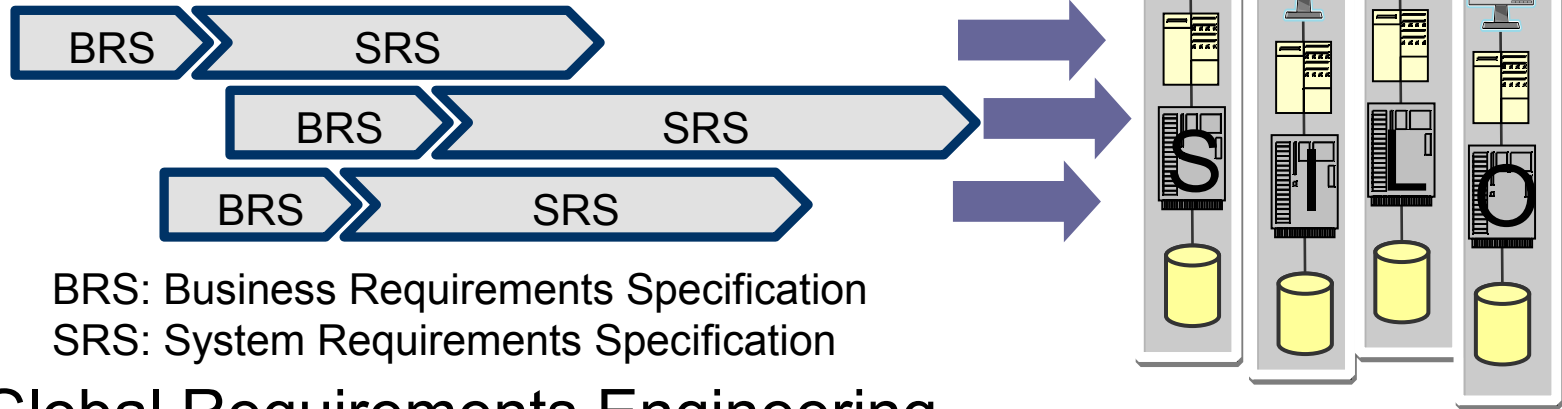
Additional DE's per Domain

2 - Register DEs in an MDR



AM – Global Requirements Gathering

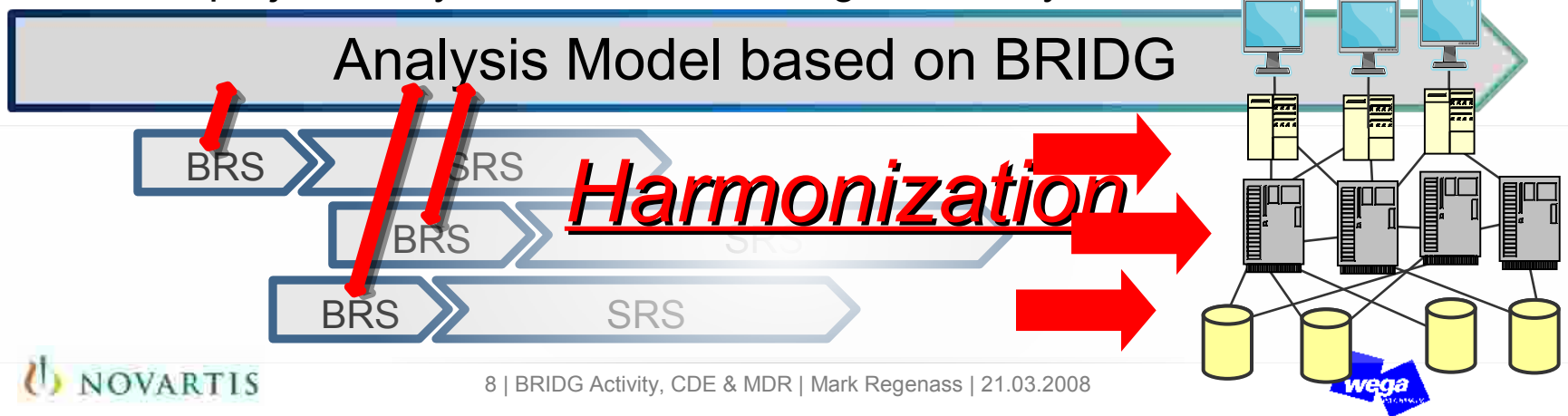
- Requirements Engineering per Project



BRS: Business Requirements Specification
SRS: System Requirements Specification

- Global Requirements Engineering

Business Requirements Specifications are obligated to harmonize their project analysis models with the global analysis model



Part of BRIDG is “generic”

These elements define business semantics precisely, explicitly and clearly.

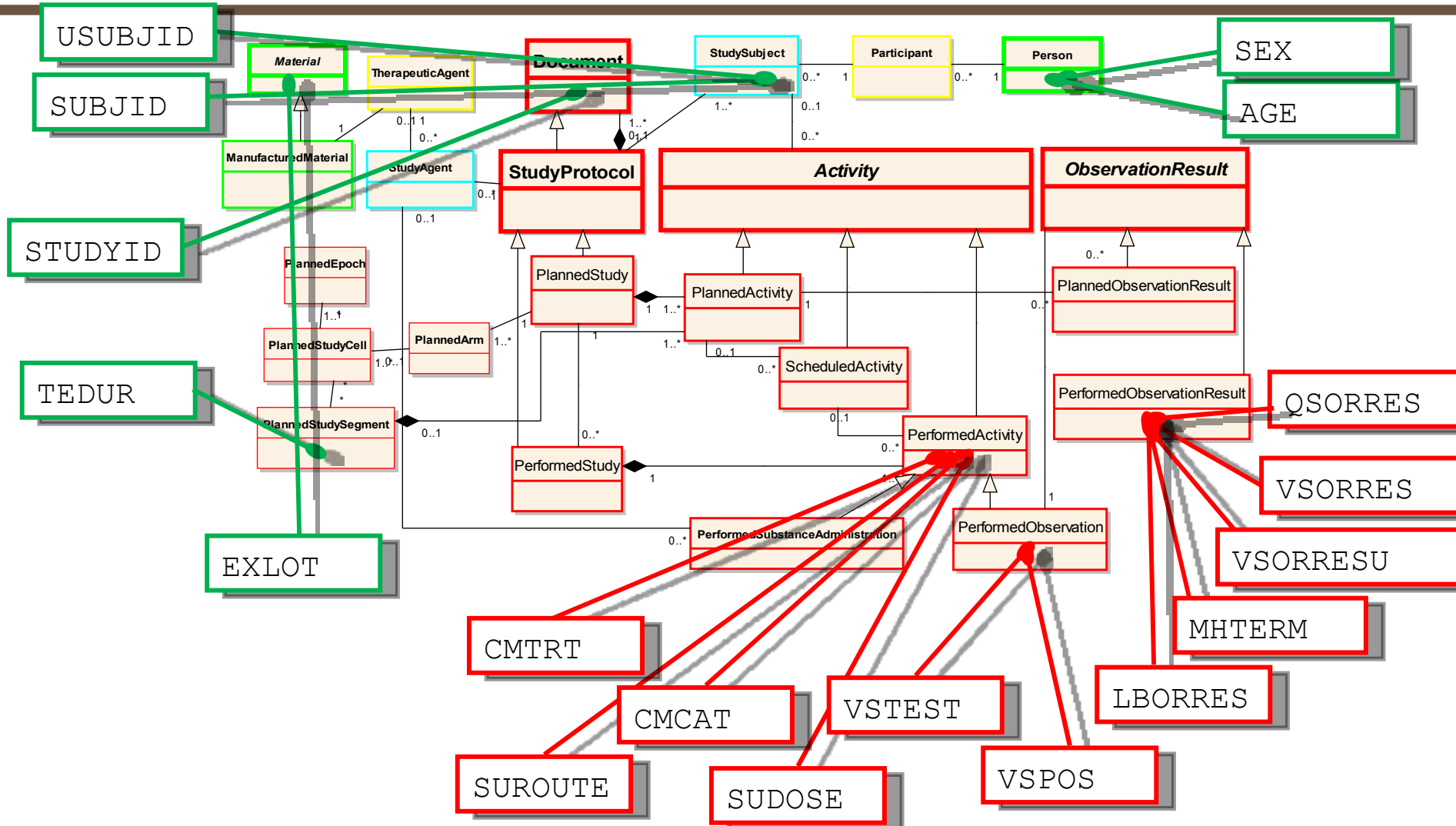
precise

These elements provide structures that can be used to further specify semantics

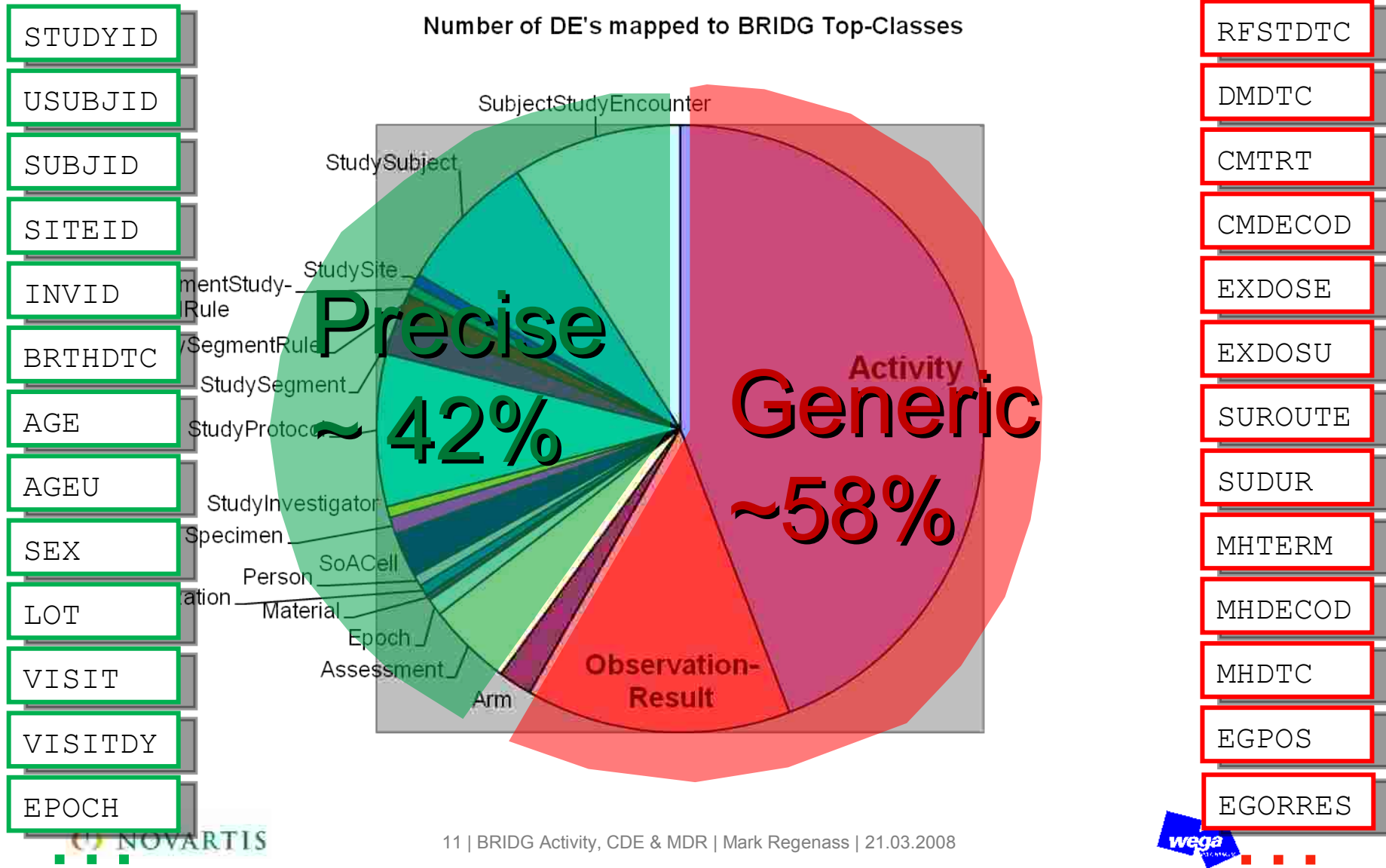
mainly activities and observation results

generic

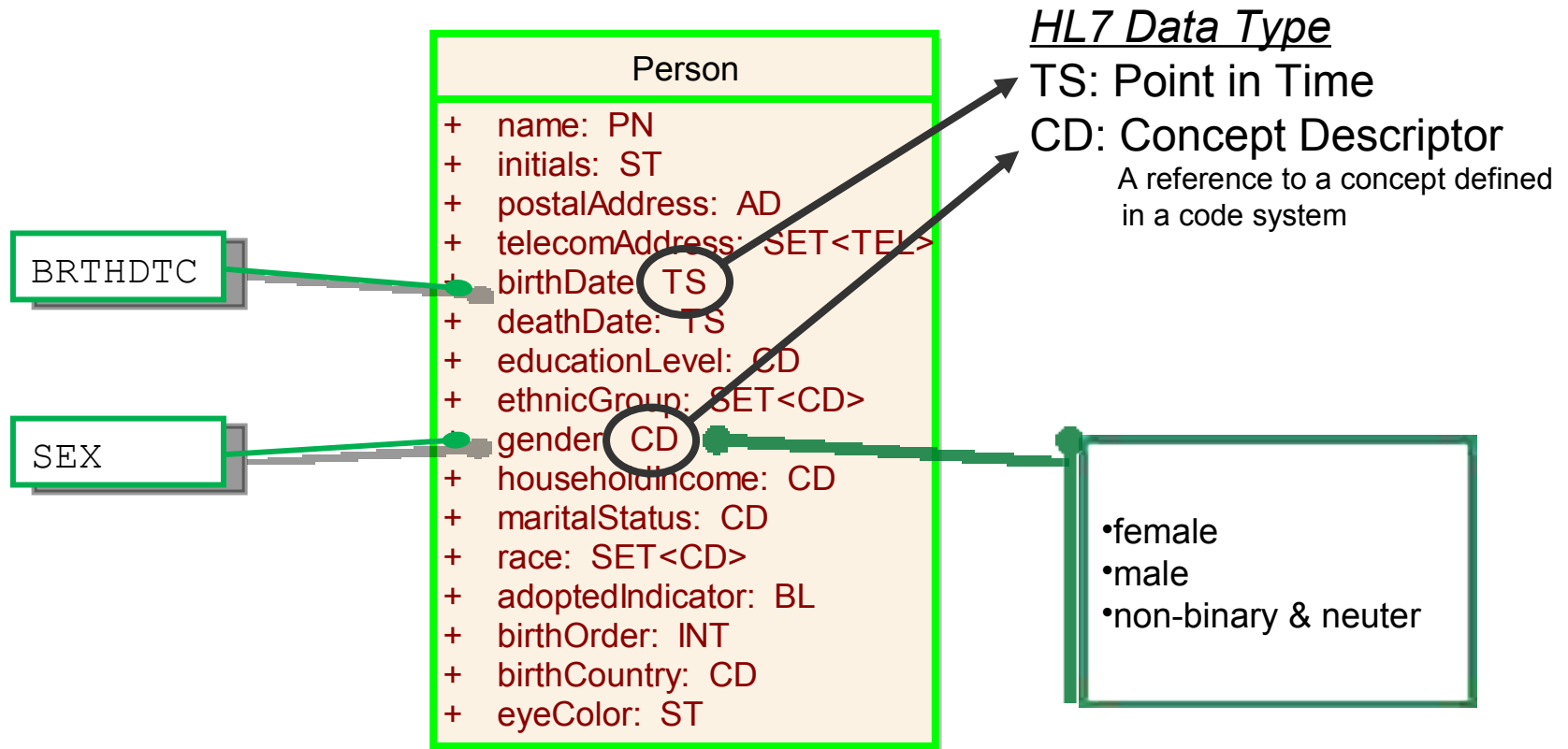
Mapping DE to BRIDG Release 1.1



Percentage share (mapping DE to BRIDG 1.1)

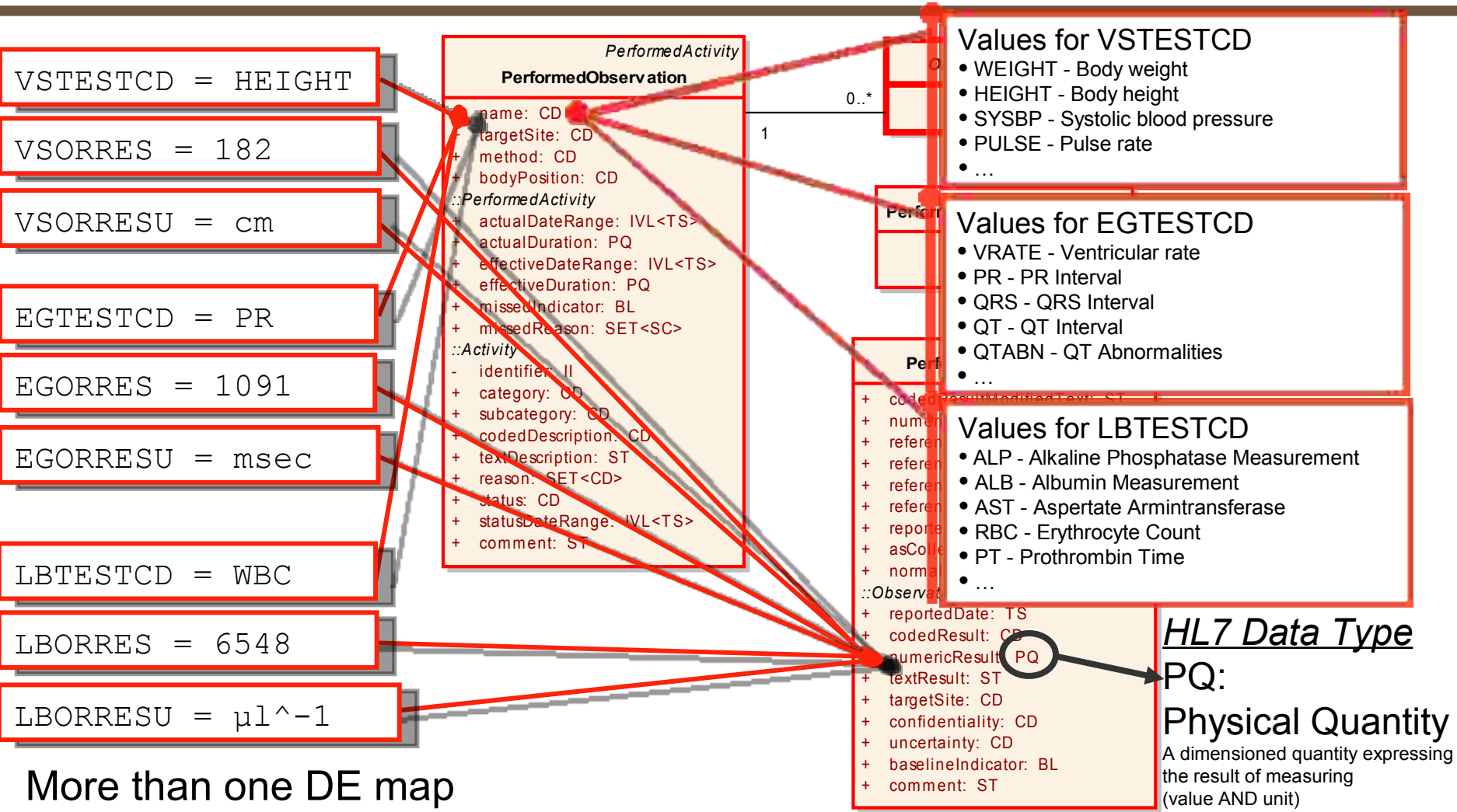


“Precise” – dedicated sets of value meaning



DE to attribute mapping is 1:1

“Generic” – multiple sets of value meanings



More than one DE map to one attribute

One attribute has several value domains

Registering in MDR – “precise” zone

2.2.3 The Challenge: Observative, CDEs

Code	Code Label	Description
SEX	Sex	Sex of the patient

DE

SEX

Person
+ gender: CD



Data Element
Concept

Conceptual
Domain

- female
- male
- non-binary & neuter

MDR

Data Element

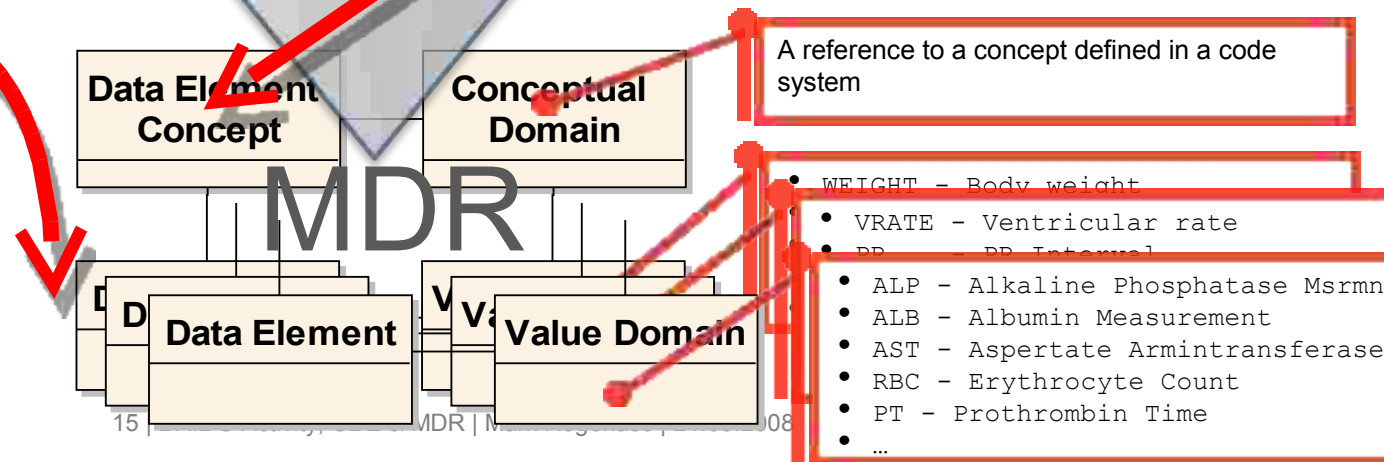
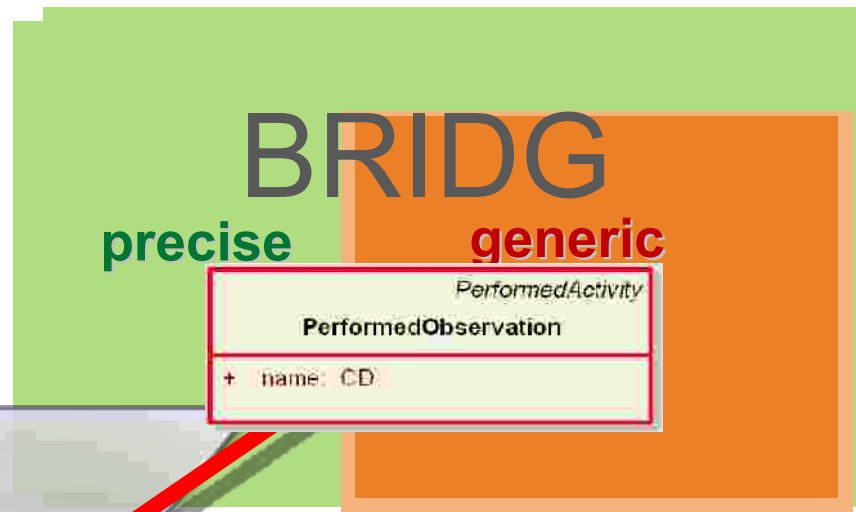
Value Domain

- F - female
- M - male
- N - non-binary & neuter

Registering in MDR – “generic” zone

2.2.3 The Bridge: Observation, Class

Code	Display Name	Definition
LBTESTCD	LBTESTCD	...



Conclusion

- SDTM needs to be extended to fully cover the need of data element definition from data collection onwards.
- Use of BRIDG as a source for unambiguous data element concepts requires 2 different types of mapping:
 - “precise”: one-to-one mapping between a DE and a BRIDG concept; business semantics precisely, explicitly and clearly defined.
 - “generic”: many DE fit within a single BRIDG concept, this BRIDG concept is providing structure to further specify semantics (mainly to define specific activities and observation results).
- An ISO 11179 based MDR can cover all requirements for data element registration only when applied with some flexibility.