

IHE APSR – the German view

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Background for HL7

- Communication requires that sender and recipient are responsible for validity of the information transmitted
- For communication both agree the model of meaning by defining the appropriate ontology
- Communication standard must take care for that (and only that)



Background for HL7

- All morphologic descriptions (including markers) may be valid for a variety of specific tumors
- No restrictions of the use of descriptors and markers for any diagnostic process
 - Her2neu in breast, gastric cancers and AEG
 - K-ras in colorectal and lung cancers
 - B-raf in melanomas, lung cancers and leukaemias
 - etc



Background for HL7

- HL7 Germany with advanced solutions for reporting to cancer registries and referral letters
- Generic TNM and ICD-O



Terminologies

consist of

- concepts
- terms
- relationships

for exact representation of pathologic data

Dudeck 2005



Anforderungen an Terminologien

- umfassend
- beliebig granulierbar
- Darstellbarkeit von Beziehungen
- **leicht anpassbar an neue medizinische Entwicklungen**
- Behandlung synonymmer Bezeichnungen
- In vielen Sprachen verfügbar

Dudeck 2005



Detailed Clinical Models (DCM)

„We believe the DCM pertains to any kind of clinical model that addresses the conceptual level, and which, for implementation needs to be transformed e.g. into an archetype or HL7 template.“

Goossen W. et al. Healthc Inform Res. 2010 December; 16(4): 201–214



Terminology considerations

- Generic models of meaning (DCM)

VS

- Perpetuated specific observations
- Multiaxial terminology
 - More post- than precoordination
- Support by CDA mechanisms



Terminology considerations

- Model of meaning → for communication
- Model of use → for data entry
- Organspecific templates
 - Very well suited for data entry
 - Well suited for communication
 - Not suited for system maintenance



PathLex

- Logical consequence of organ specific template approach
- Not driven by DCM
- Very valuable compilation of terms used in practice
- Unnecessary multiplication of terms



AP observation, organ specific



Figure 6.2.6.9.1-1 Conformance of an AP Observation

PathLex

Perineural invasion	Colon-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Esophagus-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Generic-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Larynx-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Lip, oral cavity-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Liver-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Lung-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Pancreas-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Pharynx-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Prostate-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Salivary gland-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Skin (melanoma)-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Stomach-Infiltrating malignant neoplasm-Perineural invasion
Perineural invasion	Thyroid-Infiltrating malignant neoplasm-Perineural invasion

...

Among 488 Element templates

414 are really generic,

among them **87 TNM,**

71 ICD-O-M,

43 ICD-O-C

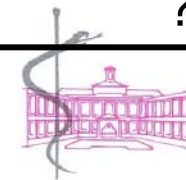


PathLex Value set for pTis

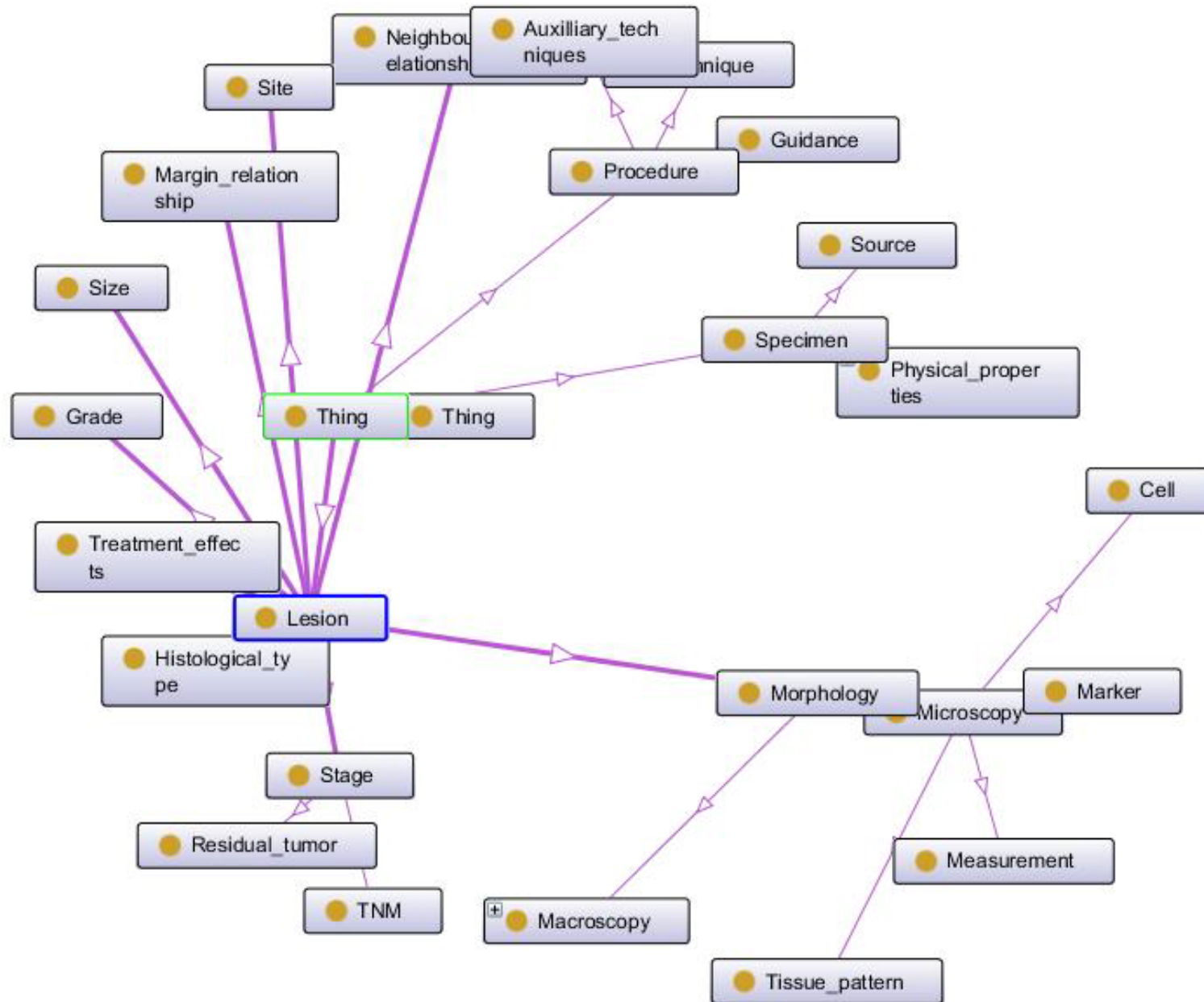
710	pTis (DCIS): Ductal carcinoma in situ	Breast-Infiltrating malignant neoplasm-pT-pTis (DCIS): Ductal carcinoma in situ
711	pTis (LCIS): Lobular carcinoma in situ	Breast-Infiltrating malignant neoplasm-pT-pTis (LCIS): Lobular carcinoma in situ
712	pTis (Paget): Paget disease of the nipple not associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma	Breast-Infiltrating malignant neoplasm-pT-pTis (Paget): Paget disease of the nipple not associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma
828	pTis: Carcinoma in situ	Stomach-Infiltrating malignant neoplasm-pT-pTis: Carcinoma in situ
949	pTis: Carcinoma in situ	Pancreas-Infiltrating malignant neoplasm-pT-pTis: Carcinoma in situ
982	pTis: Carcinoma in situ	Lung-Infiltrating malignant neoplasm-pT-pTis: Carcinoma in situ
1259	pTis: Carcinoma in situ	Lip, oral cavity-Infiltrating malignant neoplasm-pT carcinoma-pTis: Carcinoma in situ
1377	pTis: Carcinoma in situ	Larynx-Infiltrating malignant neoplasm-pT supra glottis carcinoma-pTis: Carcinoma in situ
1384	pTis: Carcinoma in situ	Larynx-Infiltrating malignant neoplasm-pT glottis carcinoma-pTis: Carcinoma in situ
1393	pTis: Carcinoma in situ	Larynx-Infiltrating malignant neoplasm-pT sub glottis carcinoma-pTis: Carcinoma in situ
1400	pTis: Carcinoma in situ	Larynx-Infiltrating malignant neoplasm-pT mucosal malignant melanoma-pTis: Carcinoma in situ
1635	pTis: Carcinoma in situ	Pharynx-Infiltrating malignant neoplasm-pT hypopharynx carcinoma-pTis: Carcinoma in situ
1645	pTis: Carcinoma in situ	Pharynx-Infiltrating malignant neoplasm-pT nasopharynx carcinoma-pTis: Carcinoma in situ
2261	pTis: Carcinoma in situ	Pharynx-Infiltrating malignant neoplasm-pT oropharynx carcinoma-pTis: Carcinoma in situ
868	pTis: Carcinoma in situ, intraepithelial (no invasion)	Colon-Infiltrating malignant neoplasm-pT-pTis: Carcinoma in situ, intraepithelial (no invasion)
869	pTis: Carcinoma in situ, invasion of lamina propria	Colon-Infiltrating malignant neoplasm-pT-pTis: Carcinoma in situ, invasion of lamina propria
1135	pTis: Carcinoma in situ: "flat tumor"	Urinary bladder-Infiltrating malignant neoplasm-pT-pTis: Carcinoma in situ: "flat tumor"
784	pTis: High-grade dysplasia	Esophagus-Infiltrating malignant neoplasm-pT-pTis: High-grade dysplasia
1062	pTis: Intratubular germ cell neoplasia (carcinoma in situ)	Testis-Infiltrating malignant neoplasm-pT-pTis: Intratubular germ cell neoplasia (carcinoma in situ)
1168	pTis: Melanoma in situ (ie, not an invasive tumor: anatomic level I)	Skin (melanoma)-Infiltrating malignant neoplasm-pT-pTis: Melanoma in situ (ie, not an invasive tumor: anatomic level I)

PathLex

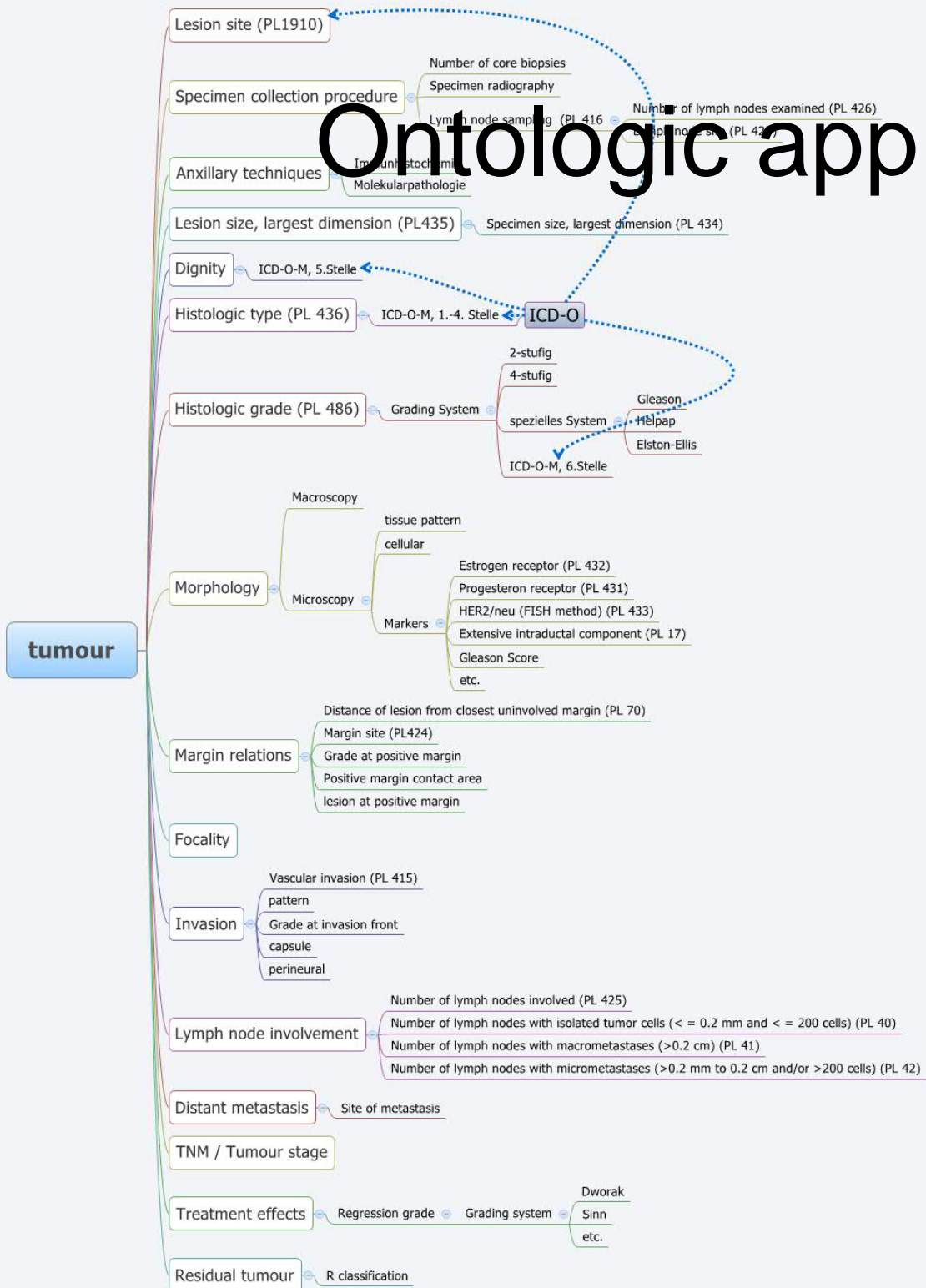
Value set name	PL Code	PL display name
Breast-Infiltrating malignant neoplasm-Histologic grade (Nottingham)	760	in size and shape, occasionally with very large and bizarre forms ?
Breast-Infiltrating malignant neoplasm-Histologic grade (Nottingham)	758	moderate variability in both size and shape Errors ?? ?
Breast-Infiltrating malignant neoplasm-Histologic grade (Nottingham)	759	Score 3: Vesicular nuclei, often with prominent nucleoli, exhibiting marked variation ?



Ontologic approach

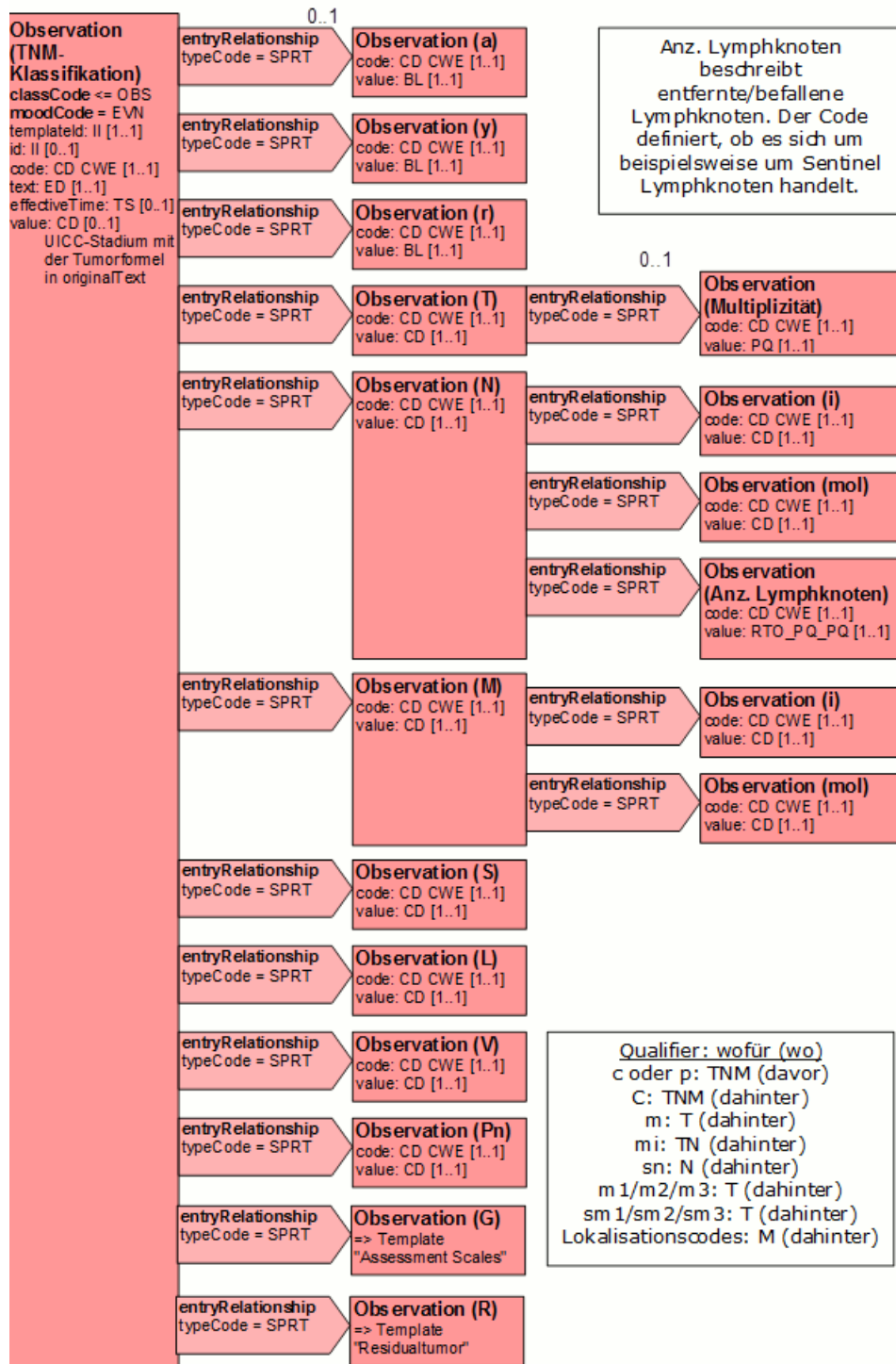


Ontologic approach



tumor

Stage



HL7 Generic model value set for

tnmT

Code	5th rev	6th rev	7th rev.
T0		x	x
TA	x	x	x
Tis	x	x	x
T1	x	x	x
T1mi	x	x	x
T1a	x	x	x
T1a1	x	x	x
T1a2	x	x	x
T1b	x	x	x
T1b1	x	x	x
T1b2	x	x	x
T1c	x	x	x
T1d			x
T2	x	x	x
T2a	x	x	x
T2a1			x
T2a2			x
T2b	x	x	x
T2c	x	x	x
etc.			

Generic models for tumor description

• Morphology

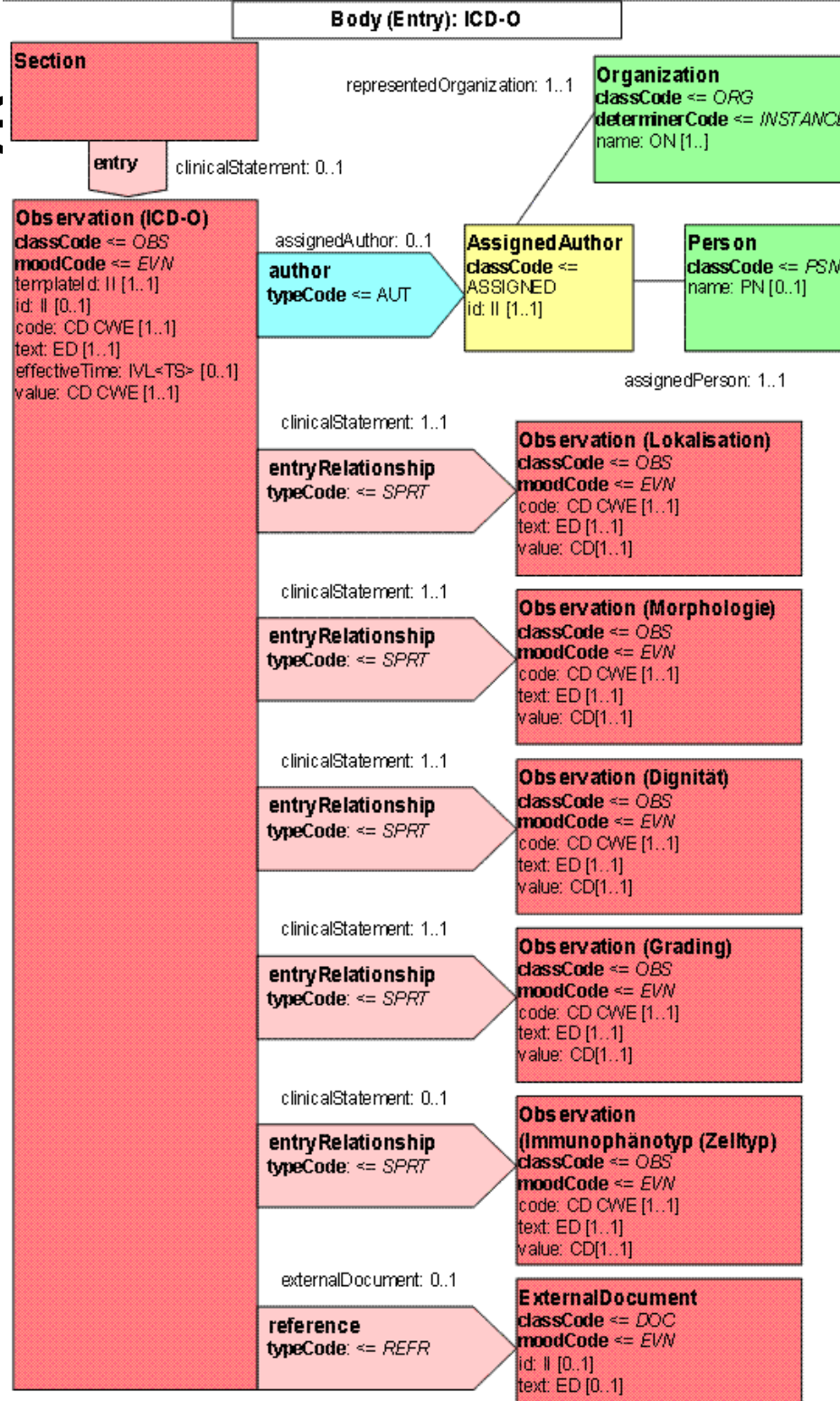
- Macroscopic
 - descriptive Value set
- Tissue pattern
 - descriptive Value set
 - measurement
 - Parameter PQ
- Cellular morphology
 - descriptive Value set
 - measurement
 - Parameter PQ
- Marker
 - morphology based
 - IHC
 - MP



Gen

tumor

ICD-O-M



Generic models for tumor description

- Site
 - lesion
 - localization system

- Margin relations
 - Distance
 - Site
 - Grade at positive margin
 - Positive margin contact area
 - Entity



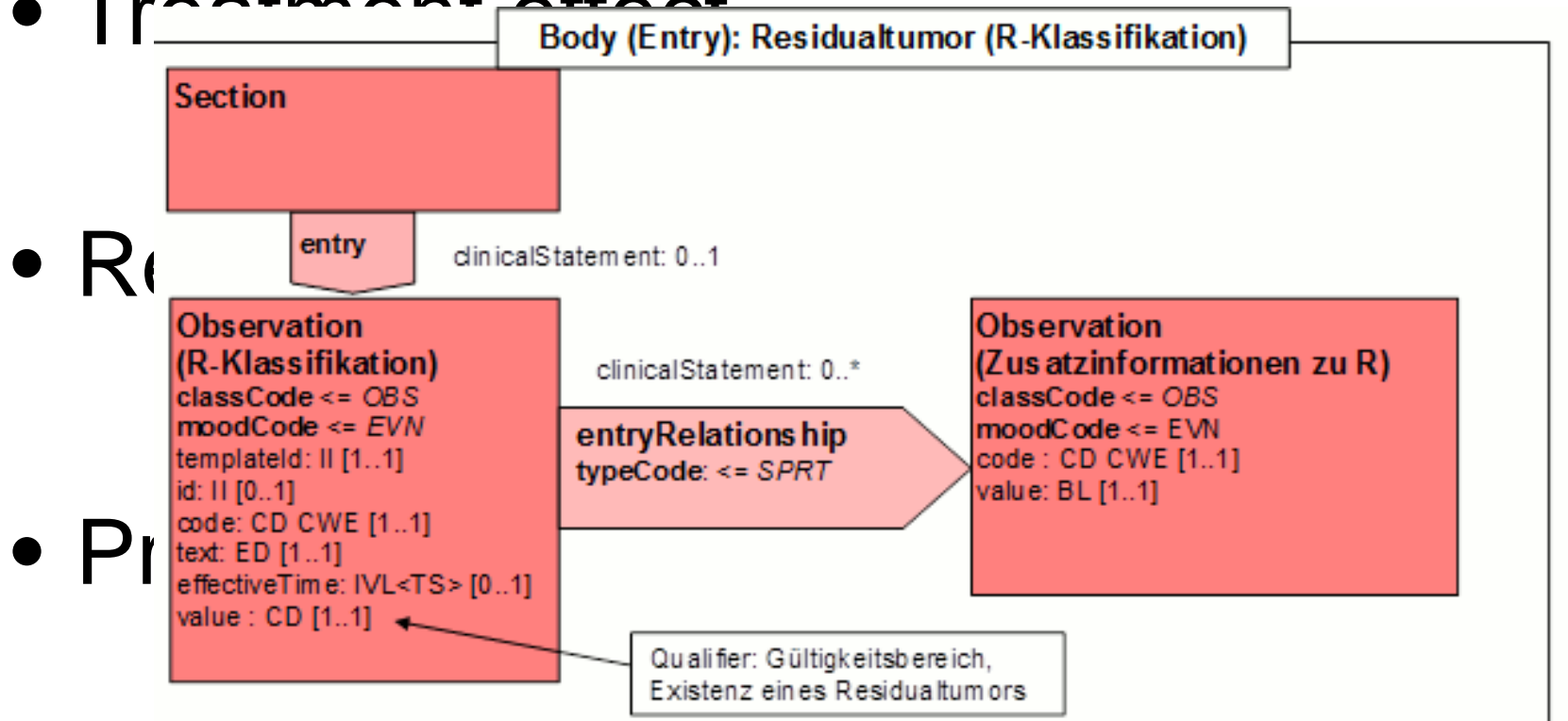
Generic models for tumor description

- Focality
 - lesion
- Invasion
 - pattern
 - grade at invasion front
 - capsule
 - perineural
 - vascular invasion
 - lymphovascular
 - venous



Generic models for tumor description

- Treatment effect



- Pr

- lymph node sampling
- guidance

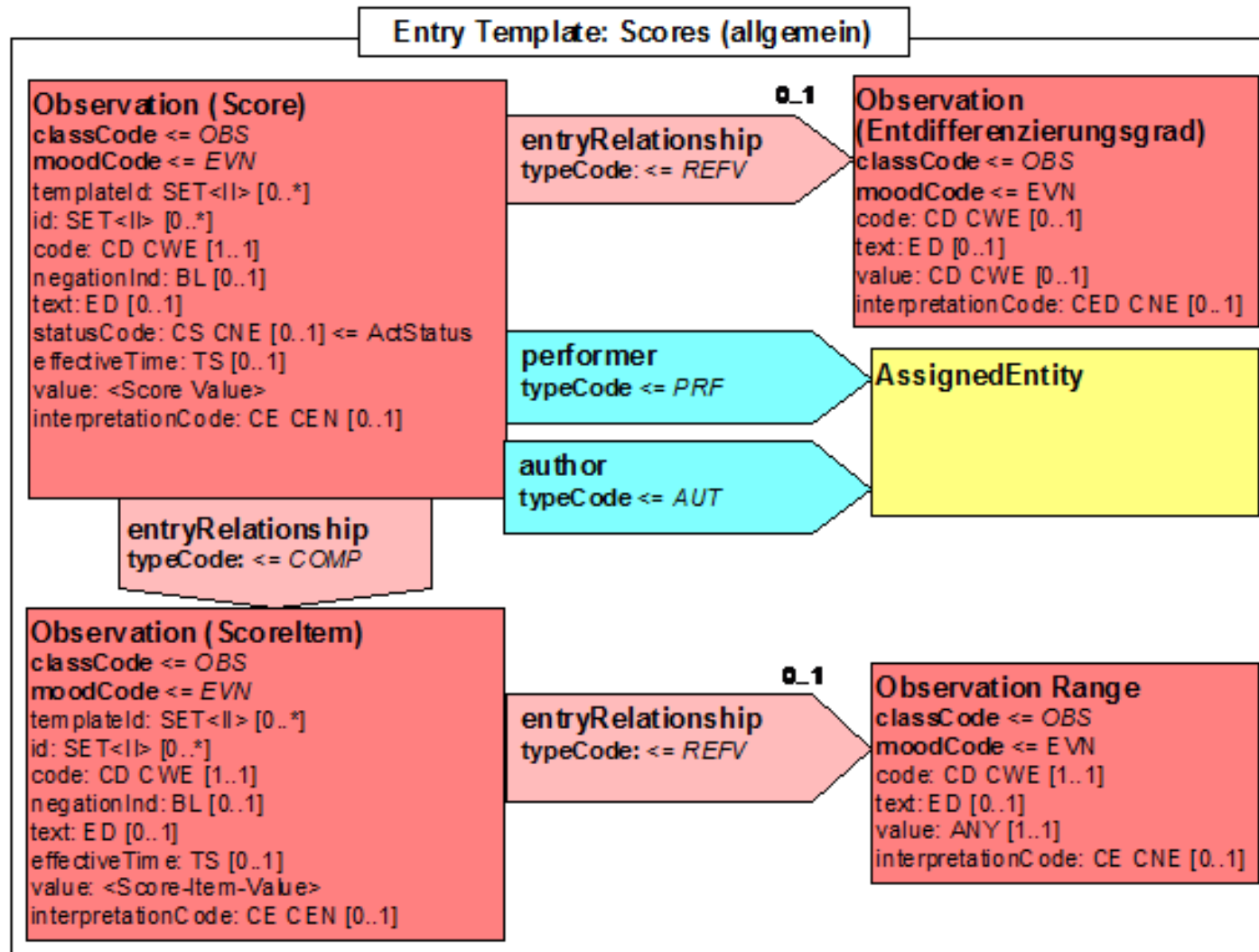


Assessment Scales

- All special grading systems
 - eg. Gleason score, Elson-Ellis malignancy grade, van Nuys classification, WHO nuclear grade of DCIS, Silverstein nuclear grade of DCIS, Helpap grading, risk classification of endoscopically removed T1 colorectal cancers,
- All agreed interpretations of IHC and MP
 - e.g. Allred and Remmele score, mismatch-repair defects, MSI low and high, Her-2-neu IHC score, Her-2-neu amplification, k-ras mutation, b-raf mutation, egfr mutation

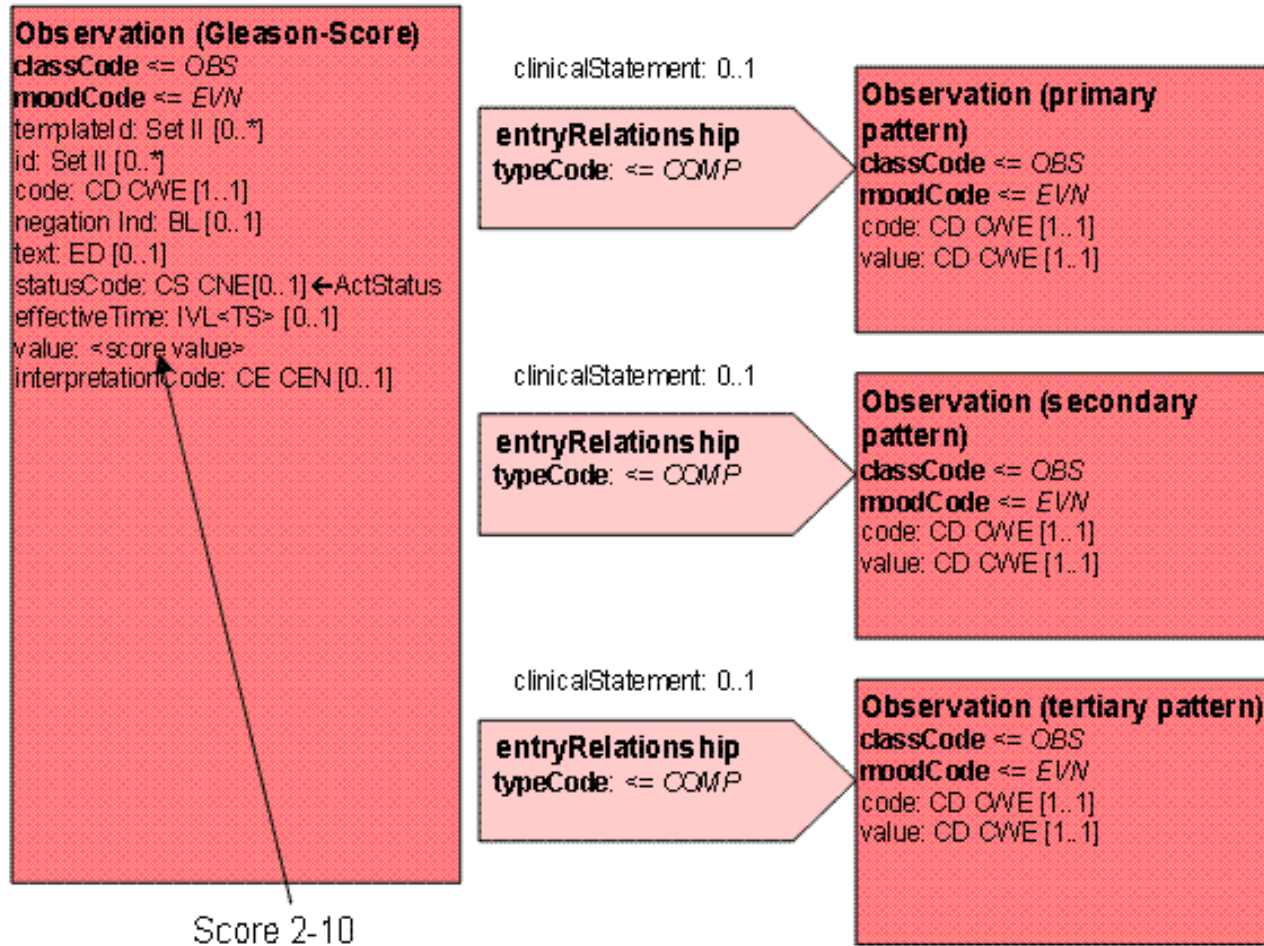


Assessment Scales



Assessment Scales

Entry template: Gleason-Score



Change proposal

- Open APSR 05 and replace by TNM / ICD-O-German, with consecutive changes in PathLex
- Cancel 4.1.2.2 Organ specific APSR document content modules, with consecutive changes in PathLex



AP observation, organ specific



Figure 6.2.6.9.1-1 Conformance of an AP Observation

Change proposal

- Generic document modules and templates only
- Ontology based relaunch of PathLex
 - according the models presented
 - for AP Observations
- Differentiation between terminology models, specimen and problem organizers



Change proposal

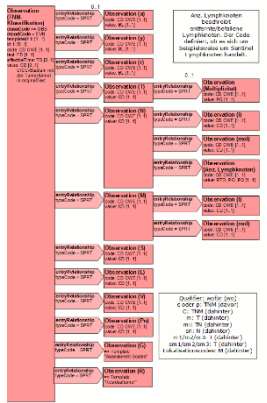
- Generic document modules and templates only
- Ontology based relaunch of PathLex
 - according the models presented
 - for AP Observations
- Differentiation between terminology models, specimen and problem organizers



Migration: old -> new

Generic templates (entity independent)

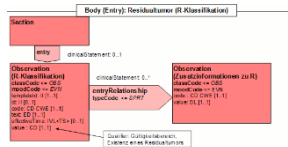
TNM
formula



ICD-C
morphology



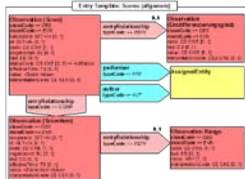
R
classifi-
cation



grade



scores



Entity
details

```

<?xml-stylesheet href="http://www.ascc.net/xml/schematron"
xmlns:cda="urn:hl7-org:v3" />
<ns prefix="cda" uri="urn:hl7-org:v3" />
<phase id="errors">
<active pattern="ReasonForReferralUncoded_Errors"/>
<active pattern="ReasonForReferralCoded_Errors"/>
</phase>
<pattern name='ReasonForReferralUncoded_Errors'>
<rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
<assert test='section'>
Error: The coded reason for referral module can only be used on a
section.
</assert>
<assert test='code[@code = "42349-1"]'>
Error: The section type code of the reason for referral section must be
42349-1
REASON FOR REFERRAL.
</assert>
<assert test='code[@codeSystem = "2.16.840.1.113883.6.1"]'>
Error: The section type code must come from the ICD-C code
system (2.16.840.1.113883.6.1).
</assert>
</rule>
</pattern>
</schema>
    
```

Entity-specific
schematron rules (for
validation)

These are the „old“
specific templates!

Advantages

- a few, easy to implement, generic templates
- Templates are reusable in other profiles
 - QRPH-Ca
 - XDS-MS
 - ...
- Separate validation using schematron
 - Easy to maintain, for IHE and vendors
- ...



Thank you for Attention ...
and Consideration !?



Change proposal

- ad PathLex
 - „Compression“ of terms repeatedly used
 - Use of assessment scales for further specification, transfer of PathLex codes
 - Use of specimen axis of SNOMED CT for Specimen Collection Procedures, cave differences between specimen and procedure (e.g. Thyroidectomies)



Change proposal

- ad PathLex
 - Organ specific templates as blueprint for data entry forms (checklist functionality)
 - Populated with generic terms
 - Use of specimen axis of SNOMED CT for Specimen Collection Procedures, cave differences between specimen and procedure (e.g. Thyroidectomies)



Definitionen

- **Terminologie**

- Fachbegriffe, einer Bezeichnung zugeordnet

- **Nomenklatur**

- plus Regeln für Bildung der Bezeichnung

- **Klassifikation**

- hierarchische Ordnung von Begriffen

- **Ontologie**

- formale, explizite Spezifikation einer Konzeptualisierung



Konzepte

Konzept ist ein abgrenzbarer klinischer Inhalt, der

- durch eine sich niemals ändernde Zahl (ConceptID) eineindeutig identifiziert wird
- eine eineindeutige Bezeichnung trägt (fully specified name)
- durch eine Menge von Beziehungen mit anderen Konzepten verbunden ist (Linkages)
- eine Menge von synonymen Bezeichnungen trägt

