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# Applying the FAIR guiding principles to clinical data management and re-use

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# FAIR principles

**Manifesto for sustainable use of scientific research objects (data, workflows, algorithms) by humans and their digital agents**

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- **R – Reusable** – Using exhaustive semantic annotations and metadata to reliably repurpose data, by preserving provenance, data production, and other contextual information.

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*European Commission and the G20 encourage researchers to embrace the FAIR principles*

# FAIR principles

- Current scope of FAIR: data-intensive science, optimised use of data acquired by public funding, idea of scientific data as a public good
- What if we include also clinical "big" data ?
  - Images, lab (low / high-throughput), bio-signals
  - All kinds of textual and coded data
  - Patient-generated data
- "FAIRify" data for primary and secondary use cases
  - Use of clinical data for scientific research
  - Other secondary uses (e.g. business intelligence)
  - Improved primary use (e.g. decision support, personalised data visualisation, coding support)

# Large-scale re-use of clinical data for various purposes

Electronic Health Record Systems

Clinical data prioritization / visualization

Clinical decision support

Business analytics / Prediction

Cohort builder

KAGes

Structured data  
Lab, Admin,  
QM, Registries

Unstructured data (text)

Staging Area

Semantic Enrichment

Clinical Data Warehouse

CDW

Medical Research Insights (MRI)

Connected Health Platform



LOINC®

SNOMED CT

Ontologies  
Terminologies

Text Mining  
De-Identification

averbis

CBmed

BIOMARKER RESEARCH



# Re-Defining the FAIR principles...

- ...for original patient data or data derived from patient data
- Contrasting current status with FAIR desiderata
- Requirements to implement FAIR principles for patient-related datasets:
  - Methods
  - Resources
  - Conditions

# FAIR – Findability

# FAIR – Findability

## Reality

- Clinical data / documents  
Identifiable and addressable  
even within closed systems  
difficult
- Retrieval of data from one  
patient or across several  
patients not supported by  
typical CIS
- Information retrieval across  
several CIS not supported
- No indexing of unstructured  
content

## Desiderata

- Clinical data / documents  
are assigned a globally  
unique and eternally  
persistent identifier
- Both database and free text  
search facilitates quick  
content retrieval with a  
single CIS
- Meta-search across several  
CIS is supported
- Semantic indexing reduces  
impact of language variety

# Ambiguous short forms

Patient?  
Pathologie?

rezent?  
rezidivierend?

Pat. mit rez.  
HWI und  
VUR

Harnwegsinfekt ?  
Hinterwandinfarkt?

Vesicoureteral  
reflux



# Synonyms and variants

Colon-Ca

Kolon-Ca

Kolon-  
karzinom

Colon-  
carcinom

Colon-  
Karzinom

Kolonkrebs

Dickdarm-  
krebs

Dickdarm-Ca

Malignom des  
Kolon

Dickdarm-  
karzinom

Dickdarm-Ca

Bösartige  
Neubildung  
am Dickdarm

Bösartiger  
Dickdarm-  
tumor

maligne  
Neoplasie des  
Dickdarms

Karzinom des  
Dickdarms

maligne NPL  
des Colon

# Common misspellings

Simvastatin

Sinvastatin

Simvastastin

Simvastain

Simvastad

Simbastatin

Simavstatin

Simavastatin

Simastatin

Symvastatin

Simvastation

Simvaststin

Simvatatin

Simvatin

Simvatstain

Simvstatin

# Failure of word indexing

... even with well-formed, non-abbreviated clinical language

**"Makroskopie: "Resektat nach Whipple": Ein noch nicht eröffnetes Resektat, bestehend aus einem distalen Magen mit einer kleinen Kurvaturlänge von 9,5 cm und einer großen Kurvaturlänge von 13,5 cm, sowie einem duodenalen Anteil von 14 cm Länge. 2 cm aboral des Pylorus zeigt die Dünndarmwandung eine sanduhrartige Stenose. Im Magen- und Duodenallumen reichlich zähflüssiger Schleim, sanguinolent; die Schleimhaut ist insgesamt livide. Auf lamellierenden Schnitten zähfestes weißliches, teilweise nodulär konfiguriertes Gewebe, ohne das Gallengänge manifest werden. Der distale Anteil des Ductus pancreaticus ist leicht erweitert und von der Papilla vateri aus 4,5 cm weit sondierbar, wobei er hier in einer peripankreatischen Narbenzone abbricht. Eine Gallengangsmündung läßt sich makroskopisch nicht abgrenzen. Die berichtete Duodenumstenose liegt 2,5 cm oral der Papilla vateri und steht mit der beschriebenen Narbenzone in direktem Zusammenhang.**

**Dokument is retrieved with:**

"Whipple", "Magen",  
"Pylorus"

**No hits for:**

"Pankreatikoduodenectomie", "Resektion",  
"Duodenum", "Zwölffingerdarm", "Pankreas",  
"Bauchspeicheldrüse", "Gallengang", "Pankreasgang",  
"Ductus pancreaticus", "Papille", "Magenresektion"

# FAIR – Accessibility



# Accessibility

## Reality

- Data are locked in silos, data import / export via costly custom procedures
- No transparent, secure, customisable authentication and authorization protocols
- Data access / exchange unclear. Bilateral agreements without a robust technical and regulatory framework. Informed consent for reuse of routine data missing
- Manual de-identification

## Desiderata

- Data are accessible by their identifiers using a standardized, free, secure communication protocol.
- The protocol allows for authentication and authorization procedures
- Multidimensional access policies, dependent on de-identification, types and frequencies of data values, granularity, privacy regulations, informed consent
- Automated de-identification

# De-identified narratives

AB\_ART  
Befund - Tumorambulanz

AB\_DATUM  
1997-05-22

FALL\_NR  
BBBBBBBBBB

PAT\_ALTER  
DDD

PAT\_GEB  
1000-01-01

PAT\_NAME  
Iris Leber


PAT\_NR  
1655583259

id  
772

ANAMNESE  
Pat. kommt zur Befundbesprechung.

Allergien: keine bek.  
Medika: Inhibace und Inhibace plus, Insulin, Berodual b.Bed.

DIAGNOSE  
Z.n. TE eines MM, Level IV, TD 3,5mm/Schulter re  
3/1997 (Histo:  
CCCC/CC: NE empf)  
Z.n. NE/Schulter re 5/07 (Narbengewebe)  
Z.n. Sentinelnode/Axilla re 5/1997 (1,2cm große Metastase des MM)  
mehrere. z.T. atvp. NZN/ges. Integument

| <input type="checkbox"/> | Annotations:             |  |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | LI, ML Date "1997-05-22" |   |
| <input type="checkbox"/> | LI, ML Date "1000-01-01" |   |
| <input type="checkbox"/> | LI, ML Name "Iris Leber" |   |
| <input type="checkbox"/> | LI, ML Date "3/1997"     |   |
| <input type="checkbox"/> | LI, ML Date "5/07"       |   |
| <input type="checkbox"/> | LI, ML Date "5/1997"     |   |
| <input type="checkbox"/> | LI, ML Date "27.03.1997" |   |
| <input type="checkbox"/> | LI, ML Date "29-05-1997" |   |

Delete selected annotations 8

# Coded, de-identified extracts

82271004|Injury of head region  
125593007|Facial injury  
262749000|Open wound of eyelid  
313261004|Open wound of chin  
7771000|Left side  
255473004|Symmetrical  
51440002|Right and left (qualifier value)  
301939004|Pupil constriction  
255510006|Slight  
366084008|Finding of ocular divergence  
399054005|Exotropia (disorder)  
8966001 |Left eye  
282977007|Does bend  
66019005|Extremity  
22253000 |Pain observations  
122545008|Stimulation  
80447000 |Aqueduct of Sylvius  
118592000 |Velocity  
255473004|Symmetrical  
17621005|Normal  
168733007 |Standard chest X-ray normal  
2004005|Normotensive



# FAIR – Interoperability / Reusability

# Interoperability / Reusability

## Reality


- Most content is in compact clinical language. Most structured content does not make use of semantic standards
- What clinical data means and how data are related limited to experts reading clinical text. Contexts are hidden, correct interpretation limited to insiders
- Data provenance often unclear
- Undefined licence regulations prevent data re-use

## Desiderata

- Content is represented using internationally sharable and "FAIRified" computable formalisms and vocabularies
- Context (time, certainty, authorship, purpose) is made explicit
- Data provenance allows estimation of data quality
- Data are released with clear usage licenses
- Data integration hubs consolidate and integrate heterogeneous data

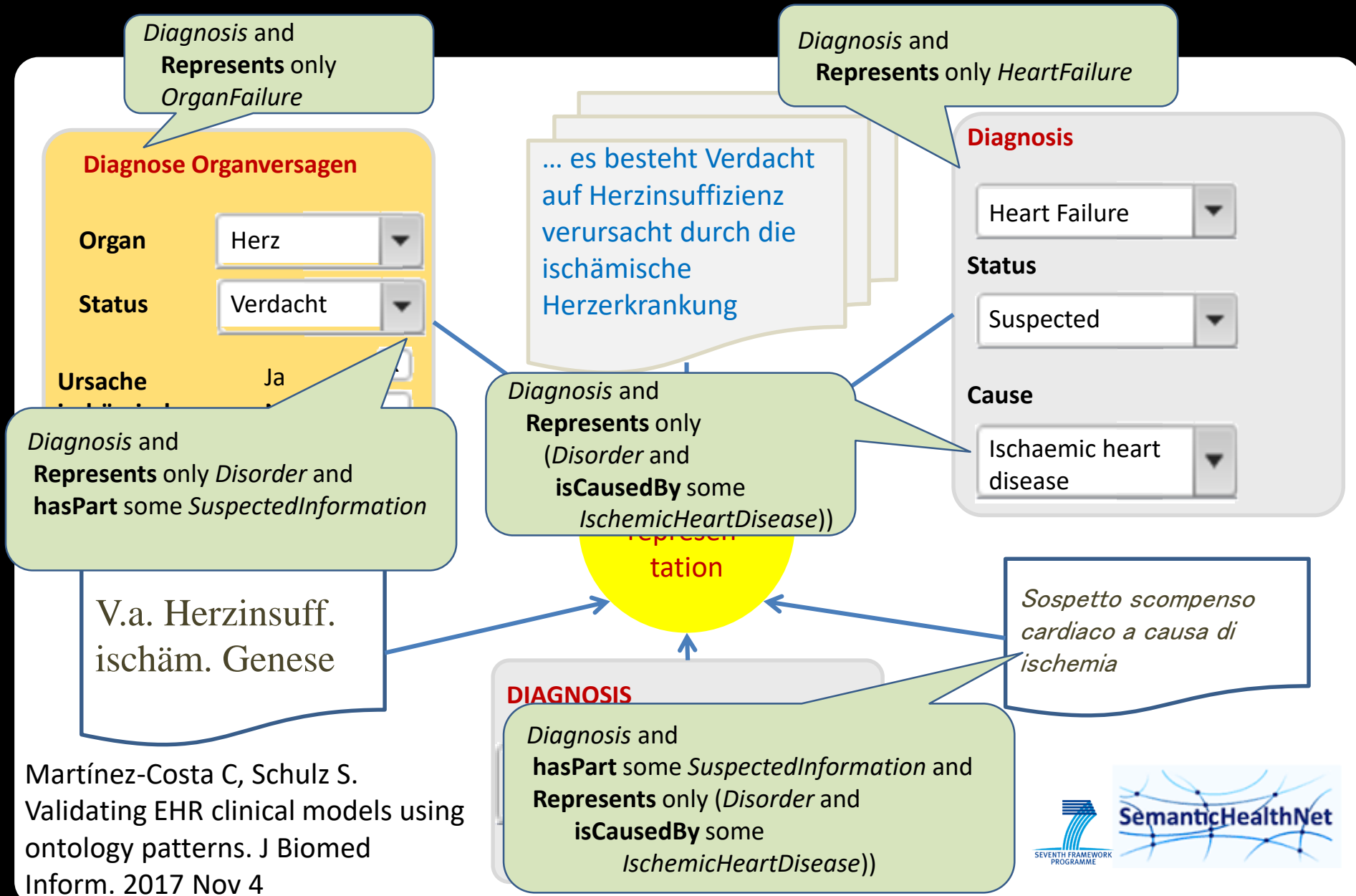
# Interoperability through common standards

St. p. TE eines  
exulc.  
sek.knot.SSM li US  
dors. 5/11 Level IV  
2,4 mm  
Tumordurchm.  
Sentinell LK ing.  
li. tumorfr.



| Code (SNOMED CT, LOINC)  | Value | Context                                      |
|--|-------|--|
| <b>254730000</b>   Superficial spreading malignant melanoma of skin    |       | 392521001<br>  History of                    |
| <b>301889008</b>   Excision of malignant skin tumor                    |       | 392521001<br>  History of                    |
| <b>47224004</b>   Skin of posterior surface of lower leg               |       |  |
| <b>7771000</b>   Left  |       |  |
| <b>81827009</b>   Diameter   | 2.41  |  |
| <b>258673006</b>   millimeter  |       |  |
| <b>258403002</b>   Lymph node level IV                                 |       |  |
| <b>94339008</b>   Secondary malignant neoplasm of inguinal lymph nodes |       | 15240007<br>  Current<br>2667000<br>  Absent |

# Interoperability through computable semantics



# Data provenance / context examples

- "94 kg"
  - reported by patient / measured in hospital
  - measured at admission / at discharge
  - target weight (e.g. after obesity treatment)
  - extracted from database / text mined from letter
- "G03.9 – Meningitis unspecified"
  - ICD code for billing – used for non-confirmed cases\*
  - ICD code from death certificate
  - ICD code resulting from text mining



# Challenges for clinical data "FAIRification"

# Challenges for clinical data "FAIRification"





# Standardisierung: Interoperabilität gewinnt an Fahrt

Dtsch Arztebl 2017; 114(47): A-2200 / B-1847 / C-1801

THEMEN DER ZEIT

Krüger-Brand, Heike E.



Die Einsicht wächst, dass grundlegende Standards für die Datenkommunikation im Gesundheitswesen unerlässlich sind. Einige Fortschritte gibt es zu vermelden.



# Challenges for clinical data "FAIRification"

- Standards
  - Terminologies (SNOMED CT, LOINC, WHO classifications, ISO IDMP standards, ...)
  - Information models (HL7, FIHR)
  - Clinical documents (HL7-CDA, IHE XDS.b)

**Medikationsplan Plus** - <http://egesundheit.nrw.de/projekt/medikationsplan-plus/>

**International Patient Summary** - <http://www.epsos.eu/epsos-services/patient-summary.html>

**LOINC User Group Deutschland** - <http://www.loinc.de>

**Identification of medicinal products**

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000645.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000645.jsp)

# Challenges for clinical data "FAIRification"

- Infrastructures and regulations
  - Data integration centres and digital health research platforms
  - Data safety and privacy policies
  - Involvement of all stakeholders

Consolidation of data sources allows for new research and treatment approaches in medicine  
[http://www.uni-mainz.de/presse/aktuell/2180\\_ENG\\_HTML.php](http://www.uni-mainz.de/presse/aktuell/2180_ENG_HTML.php)

TMF – Arbeitsgruppe Datenschutz [http://www.tmf-ev.de/Arbeitsgruppen\\_Foren/AGDS.aspx](http://www.tmf-ev.de/Arbeitsgruppen_Foren/AGDS.aspx)

# Challenges for clinical data "FAIRification"

- Resources
  - Local interface dictionaries for structured data entry and text mining, linked to terminology standards (e.g. crowdsourcing approaches)
  - Large training data for supervised / unsupervised learning → improving performance of clinical information extraction
    - de-identified clinical documents
    - document fragments
    - n-gram statistics

M. Kreuzthaler, S. Schulz. Detection of sentence boundaries and abbreviations in clinical narratives. BMC Medical Informatics and Decision Making 2015;15(Suppl 2):S4

S. Schulz - Building an experimental German user interface terminology linked to SNOMED CT SNOMED CT EXPO  
<https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=45525419>

# Challenges for clinical data "FAIRification"

- Collaborative users
  - Improved, personalised user interfaces of electronic health records:
    - Better data quality, more efficient use, higher degree of structured and coded content
- Basic research
  - Research on clinical language, lexicology, knowledge acquisition from big data
  - Ontologies and knowledge representation
- Translational research commons – bridging between health care and molecular biology

Schulz S, López-García P. Big data, medical language and biomedical terminology systems. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2015 Aug;58(8):844-852

Schulz S, Jansen L. Formal ontologies in biomedical knowledge representation. Yearb Med Inform. 2013;8:132-46.

Thank You!

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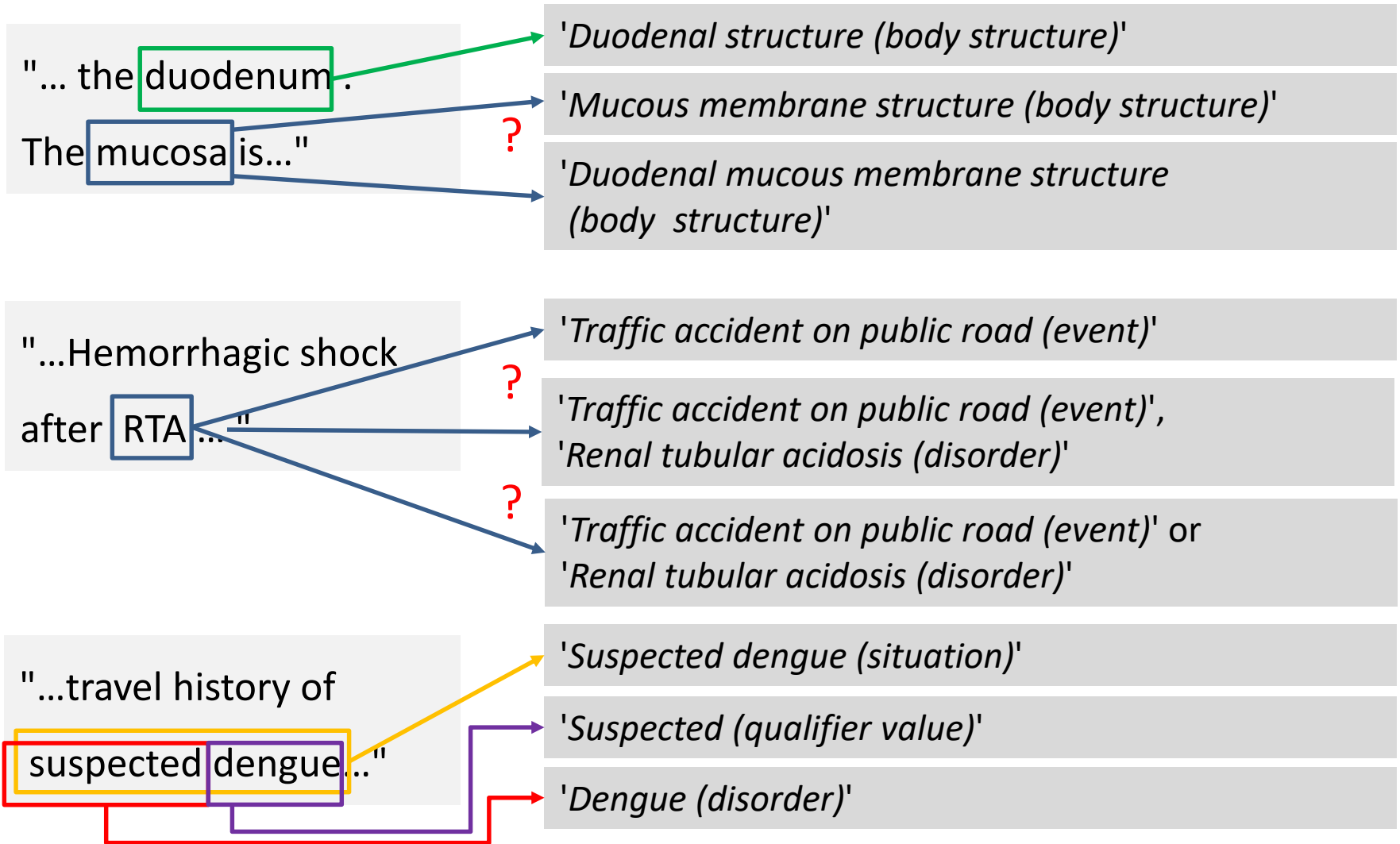


# Text fragments




13 Ventrikelfunktionsstörung I.  
13 rhythmusspezifischen  
13 konnte am ##.#.#### bei  
13 verabreichten  
13 RI  
13 Kontrolle INR  
13 elektrophysiologische Untersuchung.  
13 Bei neuerlich auftretenden  
13 #,# cm# und AINS I-II°  
13 sind für  
12 ###/###ms  
12 Ospexin #x#g  
12 als weitgehend  
12 und Zustand nach Implantation  
12 mit erhöhtem Risiko op-tauglich  
12 eines angiologischen  
12 als Kind  
12 HCT ##mg/###mg/##mg  
12 kardiolog. Kontrolluntersuchungen beim FA für  
12 Velputrin  
12 Über der Lunge  
12 Li. Vorhof einschließlich Herzohr frei

# Examples

## Clinical text SNOMED CT concepts (FSNs)



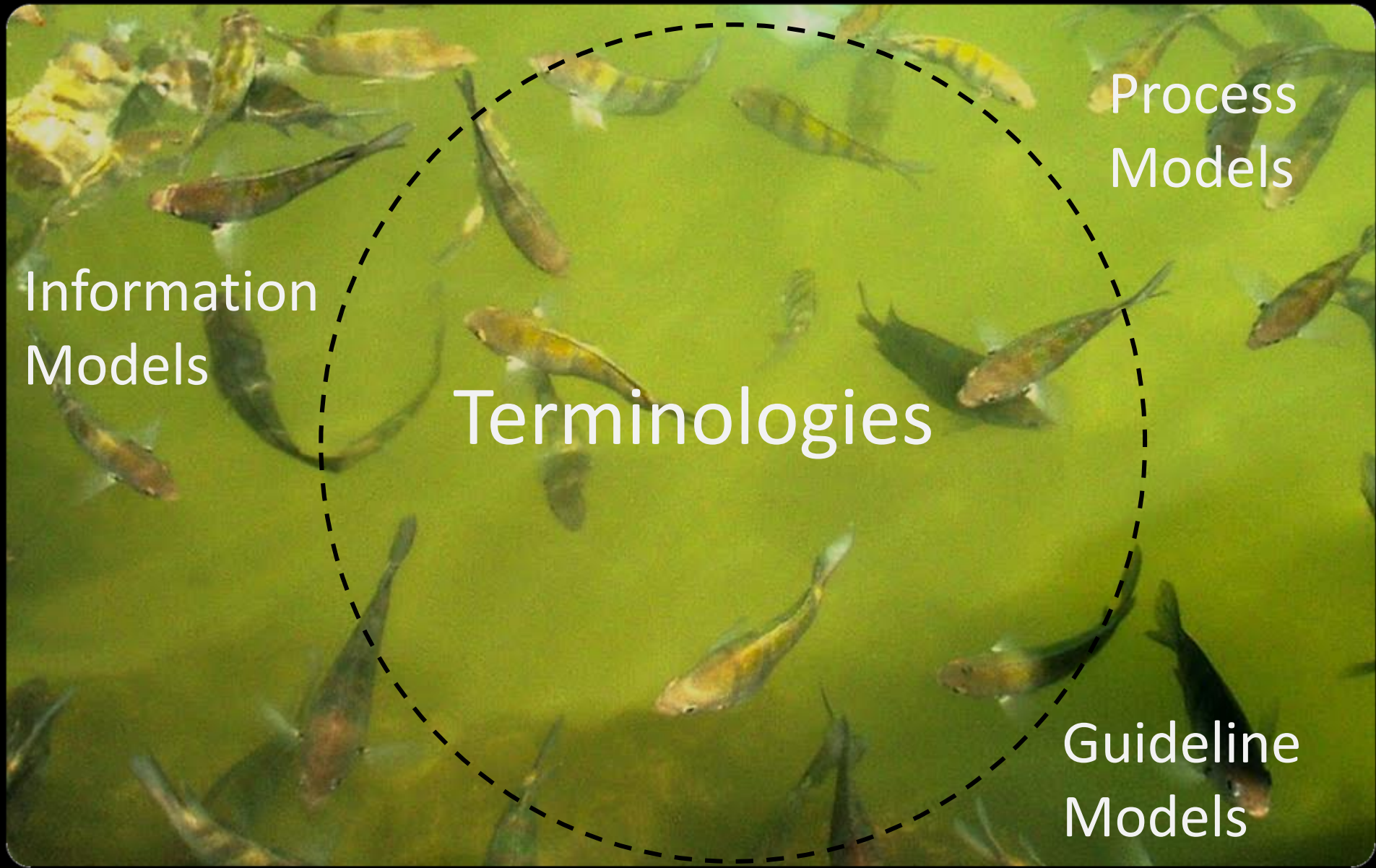
# Problem with large terminologies

| <b>Concept coverage [95% CI]</b>                                   | <b>SNOMED CT</b> |   |
|--|------------------|--|
| Text annotations – English   | .86 [.82-.88]    |  |
| <b>Term coverage [95% CI]</b>                                      | <b>SNOMED CT</b> |   |
| Text annotations – English   | .68 [.64; .70]   |  |
| <b>Inter annotator agreement<br/>Krippendorff's Alpha [95% CI]</b> | <b>SNOMED CT</b> |  |
| Text annotations   | .37 [.33-.41]    |  |

(similar results with alternative annotation task, using non-SNOMED UMLS extract)



# Ecosystem of semantic assets



Information  
Models

Terminologies

Process  
Models

Guideline  
Models



Information  
Models

Reference  
Terminologies

- ...describe and standardize a neutral, language-independent sense
- The meaning of domain terms
  - The properties of the objects that these terms denote
  - Representational units are commonly called "concepts"
  - RTs enhanced by formal descriptions = "Ontologies"

Guideline  
Models

Information  
Models

Core  
Reference  
Terminology

- Systems of non-overlapping classes in single hierarchies, for data aggregation and ordering.
- aka classifications, e.g. the WHO classifications
- Typically used for health statistics and reimbursement

Aggregation  
Terminologies  
(Classifications)

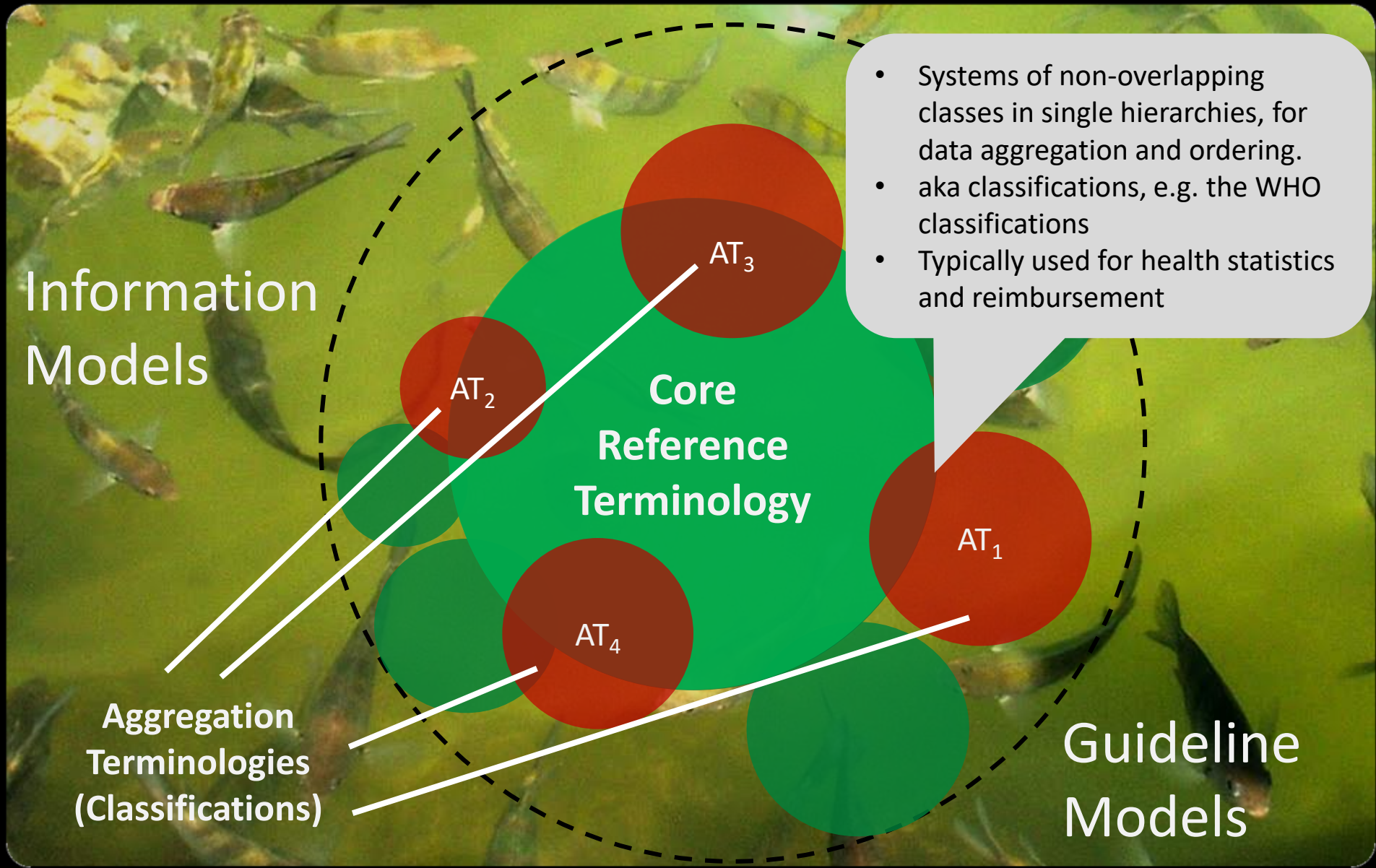
Guideline  
Models

AT<sub>2</sub>

AT<sub>3</sub>

AT<sub>1</sub>

AT<sub>4</sub>



- Reference and aggregation terminologies represent / organize the domain
- They are not primarily representations of language
- They use human language labels as a means to univocally describe the entities they denote, independently of the language actually used in human communication

- Systems of non-overlapping classes in single hierarchies, for data aggregation and ordering.
- aka classifications, e.g. the WHO classifications
- Typically used for health statistics and reimbursement

The diagram features a central green circle labeled "Core Reference Terminology". Surrounding it are four red circles labeled AT<sub>1</sub>, AT<sub>2</sub>, AT<sub>3</sub>, and AT<sub>4</sub>. These red circles overlap with the green circle and with each other. The entire set of circles is enclosed within a dashed black line. The background is a photograph of a pond with several goldfish swimming in green water.

## Core Reference Terminology

Guideline Models





Information  
Models

**User Interface  
Terminology  
(language specific)**

- Collections of terms used in written and oral communication within a group of users
- Terms often ambiguous.
- Entries in user interface terminologies to be further specified by language, dialect, time, sub(domain), user group.

Guideline  
Models

**User Interface Terminology  
(e.g. Portuguese)**

[chemistry]

"Ca"

"Cálcio"

[oncology]

"Ca"

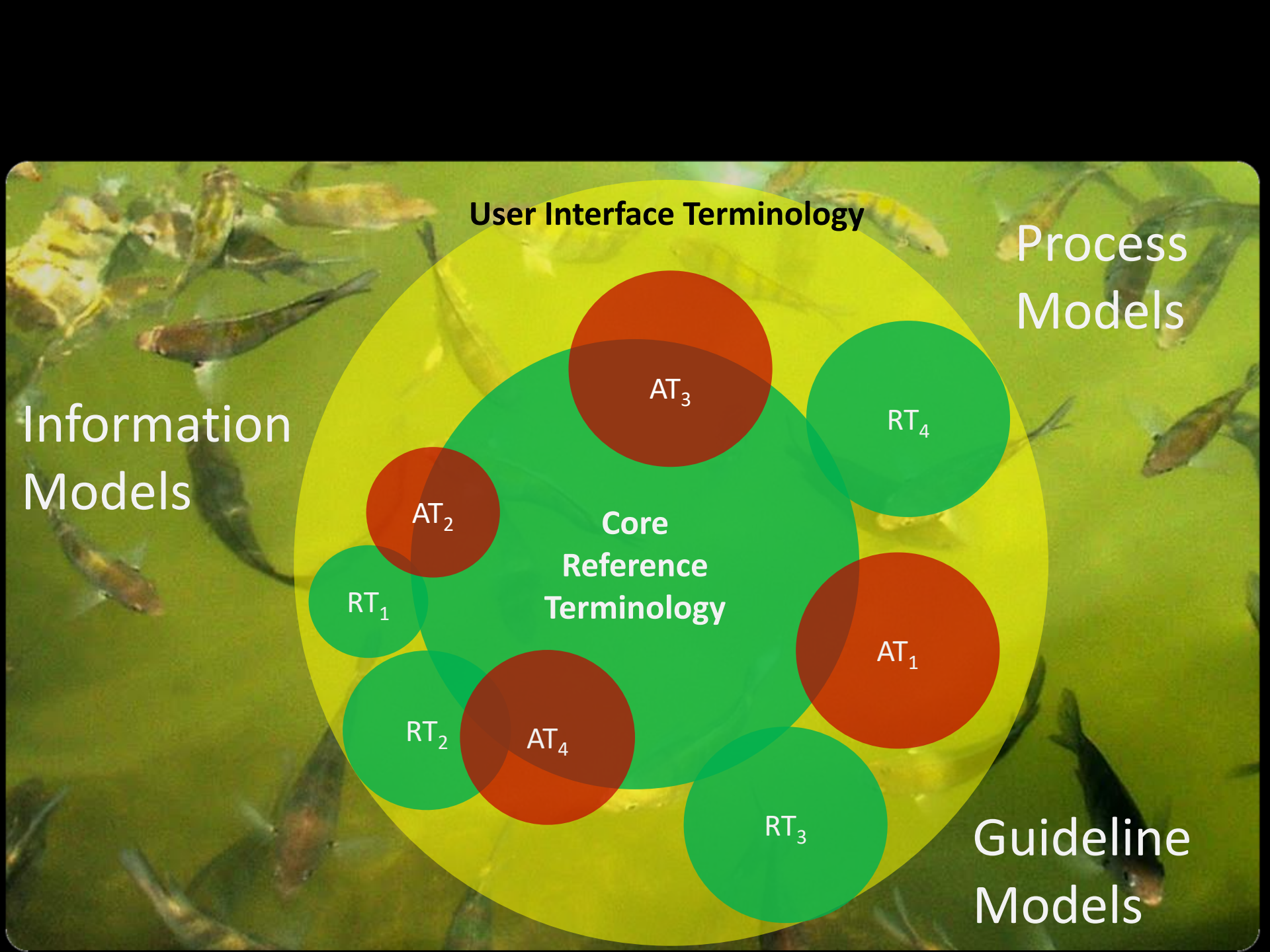
"Câncer"

"Carcinoma"

**Reference  
Terminology**

5540006 |  
Calcium  
(substance) |

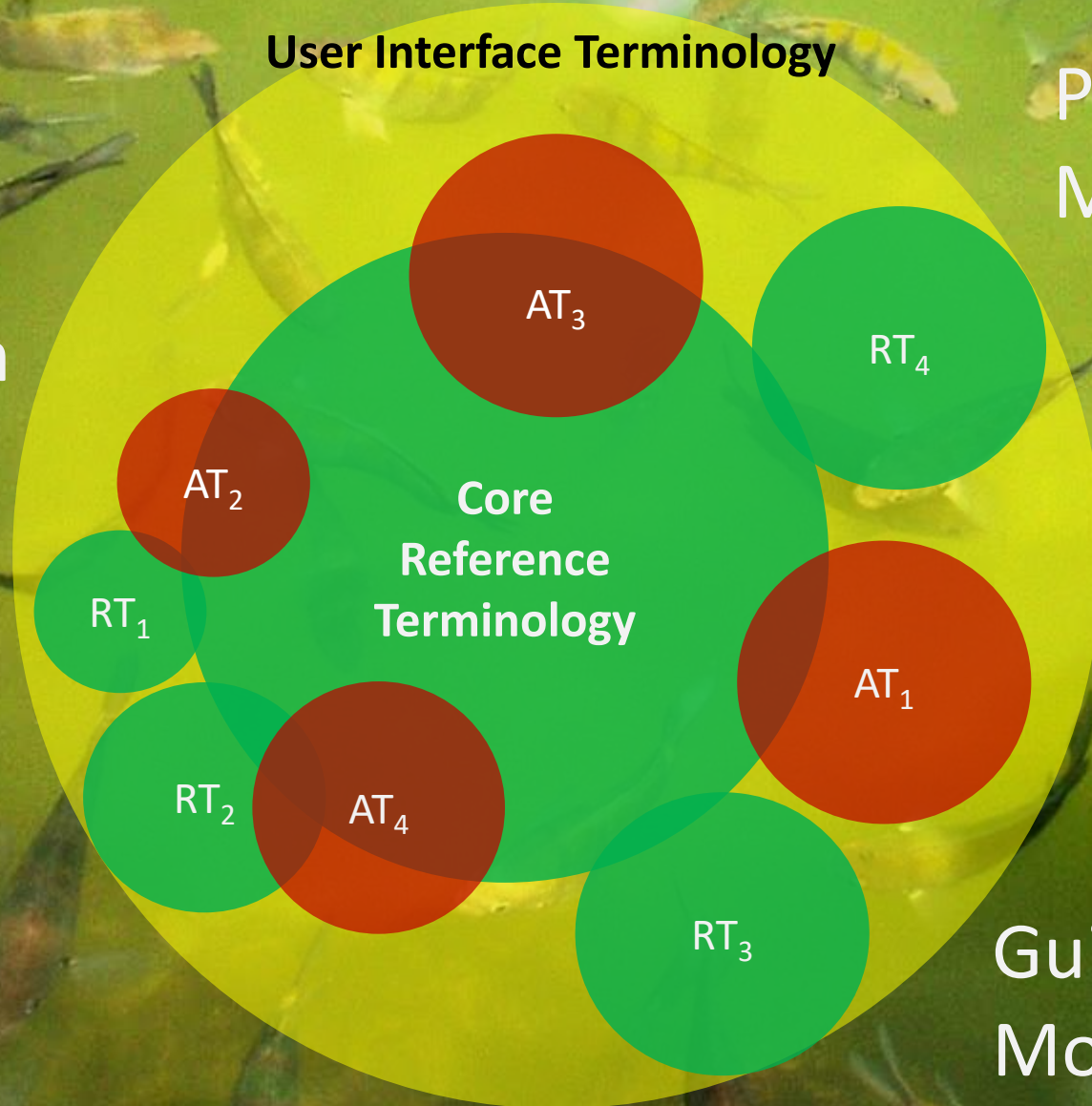
68453008 |  
Carcinoma  
(morphologic  
abnormality) |



**User Interface Terminology**

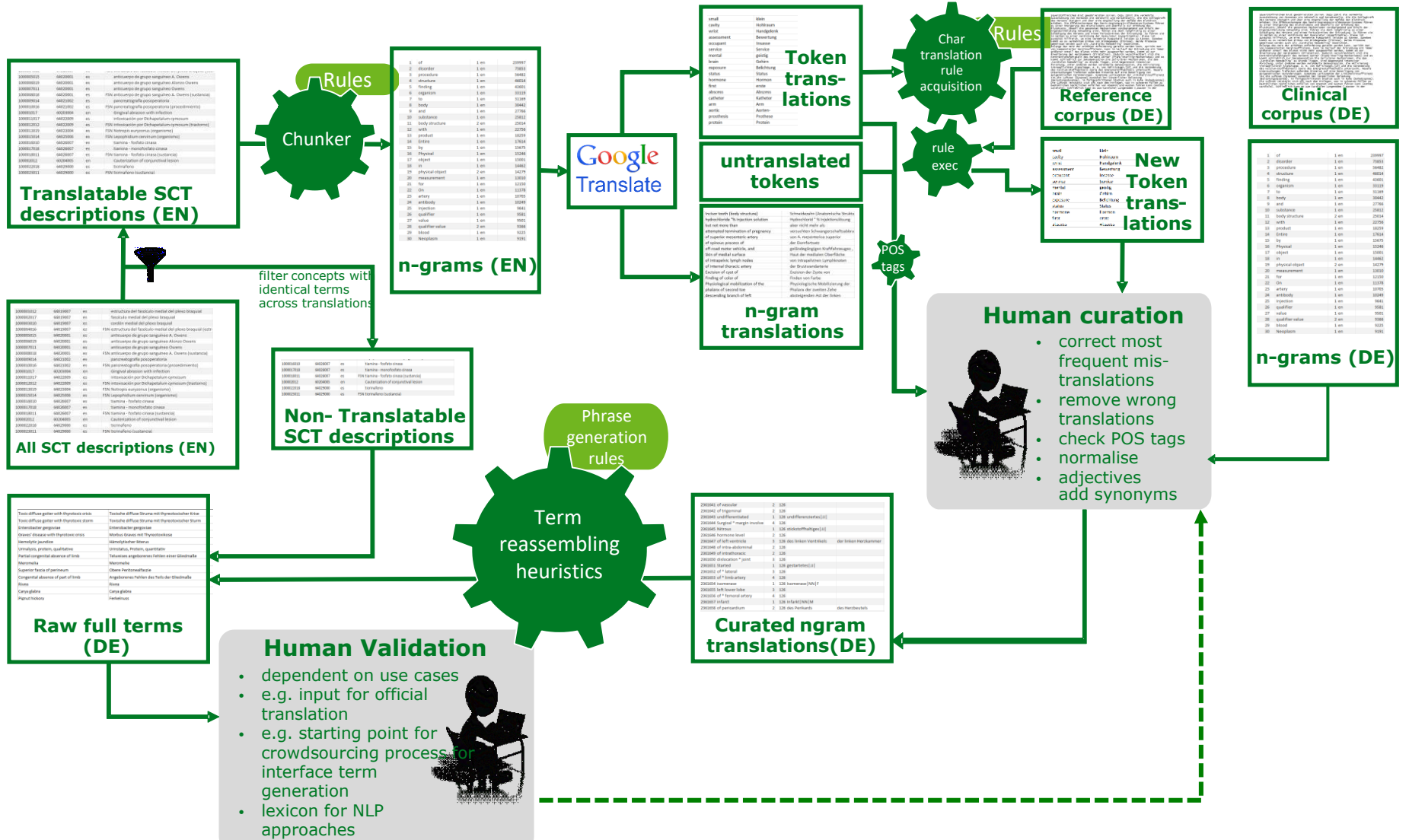
**Process Models**

**Information Models**



**Guideline Models**

# MUG-GIT: Creation of German Interface Terminologie for SNOMED CT



# ngram – core vocabulary

|                             |   |      |                               |                              |                            |
|-----------------------------|---|------|-------------------------------|------------------------------|----------------------------|
| vaginal                     | 1 | 1478 | vaginales JJ                  | Scheiden-                    |                            |
| fluoroscopic guidance       | 2 | 1477 | Durchleuchtungskontrolle NN F |                              |                            |
| disc                        | 1 | 1476 | Scheibe NN F                  |                              |                            |
| lower limb                  | 2 | 1473 | unteres JJ Extremität NN F    | Bein NN N                    |                            |
| brain                       | 1 | 1468 | Gehirn NN N                   | Hirn NN N                    | Encephalon NN N            |
| preparation                 | 1 | 1464 | Zubereitung NN F              | Aufbereitung NN F            | Präparation NN F           |
| method                      | 1 | 1463 | Verfahren NN N                | Methode NN F                 |                            |
| of bone                     | 2 | 1462 | des Knochens                  | _Knochen_                    |                            |
| Red                         | 1 | 1455 | rotes JJ                      |                              |                            |
| Monitoring                  | 1 | 1453 | Überwachung NN F              | Monitoring NN N              |                            |
| Computed                    | 1 | 1453 | berechnetes JJ                | Computer-                    |                            |
| phalanx                     | 1 | 1449 | Phalanx NN F                  |                              |                            |
| subsp.                      | 1 | 1449 |                               |                              |                            |
| anastomosis                 | 1 | 1447 | Anastomose NN F               | Anastomosierung NN F         |                            |
| vessel                      | 1 | 1446 | Blutgefäß NN N                | Gefäß NN N                   |                            |
| Computed tomography         | 2 | 1443 | Computertomographie NN F      |                              |                            |
| uterus                      | 1 | 1436 | Uterus NN M                   | Gebärmutter NN F             |                            |
| difficulty                  | 1 | 1432 | Schwierigkeit NN F            |                              |                            |
| elbow                       | 1 | 1429 | Ellbogen NN M                 | Cubitus NN M                 | Ellbogengelenk NN N        |
| high                        | 1 | 1429 | hohes JJ                      |                              |                            |
| food                        | 1 | 1423 | Lebensmittel NN N             | Speise NN F                  | Nahrungsmittel NN N        |
| Observation                 | 1 | 1423 | Beobachtung NN F              |                              |                            |
| using fluoroscopic          | 2 | 1422 |                               |                              |                            |
| unable                      | 1 | 1421 | unfähiges JJ                  |                              |                            |
| Peripheral                  | 1 | 1419 | peripheres JJ                 |                              |                            |
| unable to                   | 2 | 1418 | unfähig zu                    |                              |                            |
| Vascular                    | 1 | 1417 | vaskuläres JJ                 | Gefäß-                       |                            |
| using fluoroscopic guidance | 3 | 1416 | mit Durchleuchtungskontrolle  |                              |                            |
| Benign neoplasm             | 2 | 1415 | gutartiges JJ Neubildung NN F | gutartiges JJ Neoplasie NN F | benignes JJ Neoplasie NN F |

# Machine-generated Interface terms

|                     |           |                           |                                 |
|---------------------|-----------|---------------------------|---------------------------------|
| 20170315_240011_002 | 126952004 | Neoplasm of brain         | Gehirneubildung                 |
| 20170315_240011_003 | 126952004 | Neoplasm of brain         | Neubildung des Hirns            |
| 20170315_240011_004 | 126952004 | Neoplasm of brain         | Hirnneubildung                  |
| 20170315_240011_005 | 126952004 | Neoplasm of brain         | Neoplasie des Gehirns           |
| 20170315_240011_006 | 126952004 | Neoplasm of brain         | Gehirneoplasie                  |
| 20170315_240011_007 | 126952004 | Neoplasm of brain         | Neoplasie des Hirns             |
| 20170315_240011_008 | 126952004 | Neoplasm of brain         | Hirnneoplasie                   |
| 20170315_240011_009 | 126952004 | Neoplasm of brain         | Neoplasma des Gehirns           |
| 20170315_240011_010 | 126952004 | Neoplasm of brain         | Gehirneoplasma                  |
| 20170315_240011_011 | 126952004 | Neoplasm of brain         | Neoplasma des Hirns             |
| 20170315_240011_012 | 126952004 | Neoplasm of brain         | Hirneoplasma                    |
| 20170315_241010_001 | 126953009 | Neoplasm of cerebrum      | Neubildung des Großhirns        |
| 20170315_241010_002 | 126953009 | Neoplasm of cerebrum      | Neoplasie des Großhirns         |
| 20170315_241010_003 | 126953009 | Neoplasm of cerebrum      | Neoplasma des Großhirns         |
| 20170315_242015_001 | 126954003 | Neoplasm of frontal lobe  | Neubildung des Frontallappens   |
| 20170315_242015_002 | 126954003 | Neoplasm of frontal lobe  | Neubildung des Lobus frontalis  |
| 20170315_242015_003 | 126954003 | Neoplasm of frontal lobe  | Neoplasie des Frontallappens    |
| 20170315_242015_004 | 126954003 | Neoplasm of frontal lobe  | Neoplasie des Lobus frontalis   |
| 20170315_242015_005 | 126954003 | Neoplasm of frontal lobe  | Neoplasma des Frontallappens    |
| 20170315_242015_006 | 126954003 | Neoplasm of frontal lobe  | Neoplasma des Lobus frontalis   |
| 20170315_243013_001 | 126955002 | Neoplasm of temporal lobe | Neubildung des Temporallappens  |
| 20170315_243013_002 | 126955002 | Neoplasm of temporal lobe | Neubildung des Lobus temporalis |
| 20170315_243013_003 | 126955002 | Neoplasm of temporal lobe | Neoplasie des Temporallappens   |
| 20170315_243013_004 | 126955002 | Neoplasm of temporal lobe | Neoplasie des Lobus temporalis  |
| 20170315_243013_005 | 126955002 | Neoplasm of temporal lobe | Neoplasma des Temporallappens   |