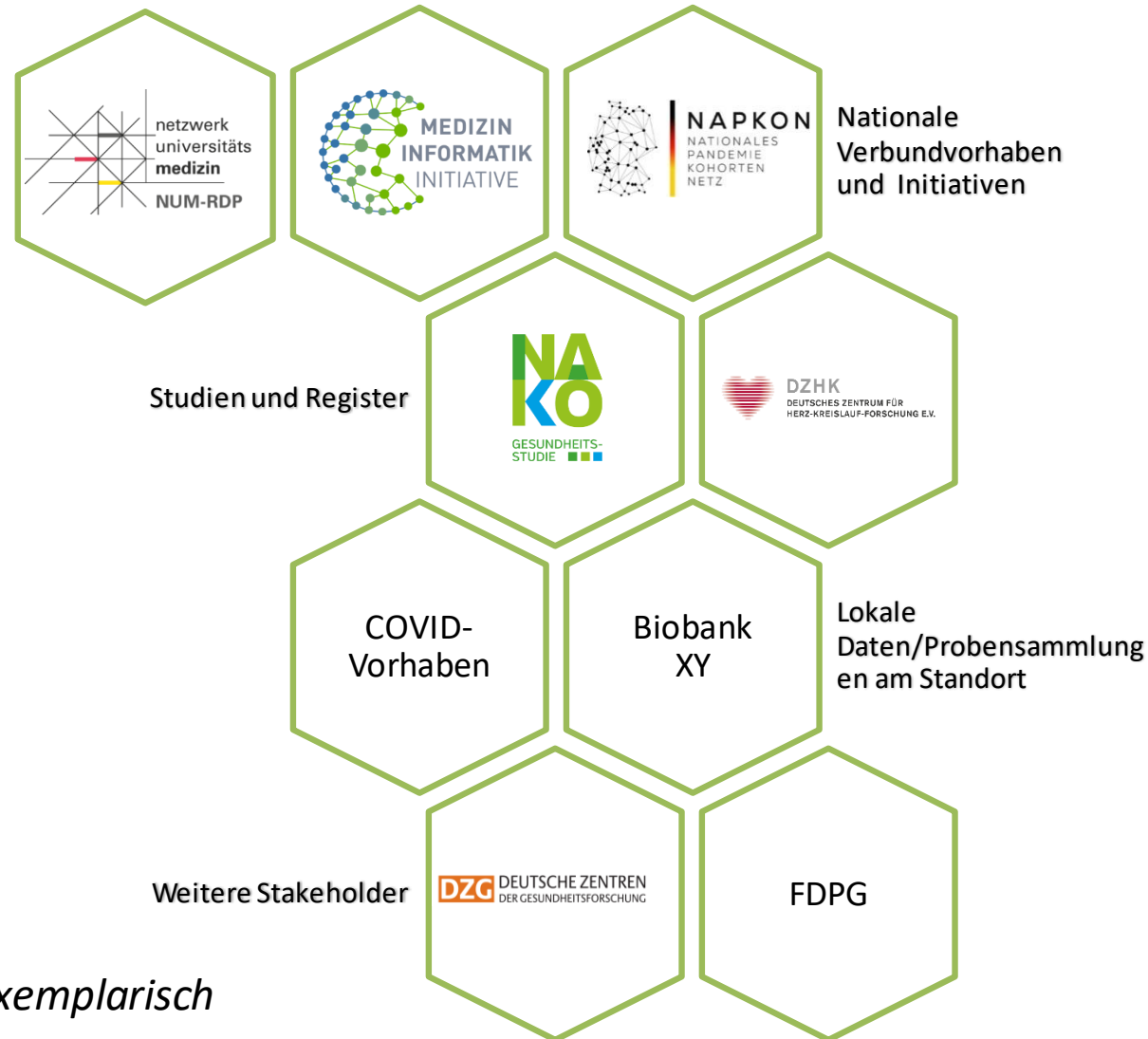# Bericht in der TMF AG Datenschutz

Semantische Abbildung von Einwilligungsinformationen mit dem Semantic Consent Code (SCC)

28.01.2025

TMF AG Datenschutz | Dr. Martin Bialke & Dr. Monika Kraus

1. Problemstellung
2. Methodik und Lösungsansatz
3. Erste Resultate
4. Zusammenfassung und Nächste Schritte

Nationale Verbundvorhaben und Initiativen
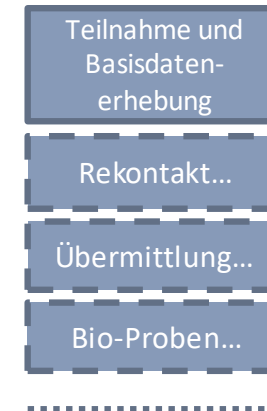
Studien und Register

Lokale Daten/Probensammlungen am Standort

COVID-Vorhaben

Biobank XY

Weitere Stakeholder

FDPG

Darstellung exemplarisch

monolithisch

All-in-One

[X] Einwilligung liegt vor

pragmatisch

Datenschutz & Studienteilnahme

Zusatz

[X] Studienmodul

[ ] Zusatzmodul

differenziert

Teilnahme und Basisdaten-erhebung
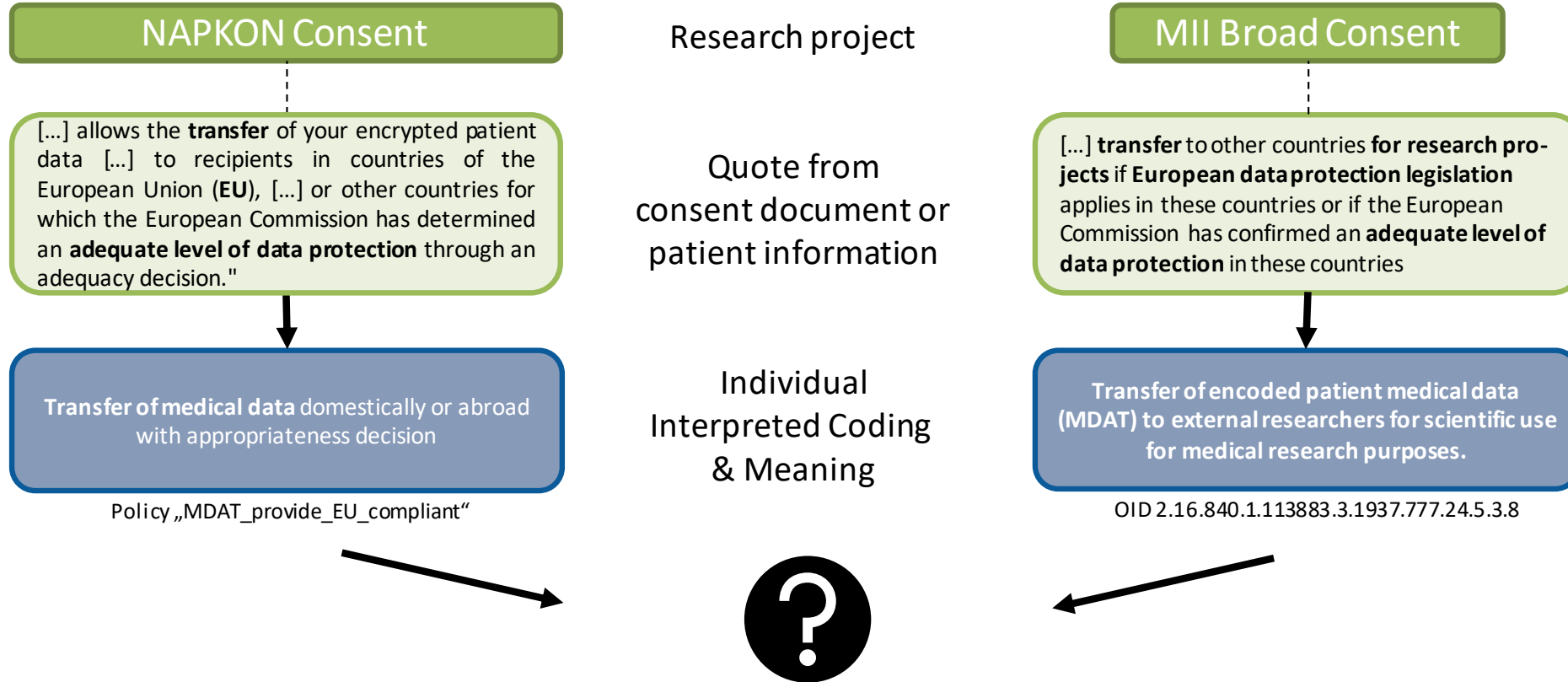
Rekontakt...

Übermittlung...

Bio-Proben...

[X] Basismodul

[X] Optionales Modul1

[X] Optionales Modul2

[ ] Optionales Modul2
...

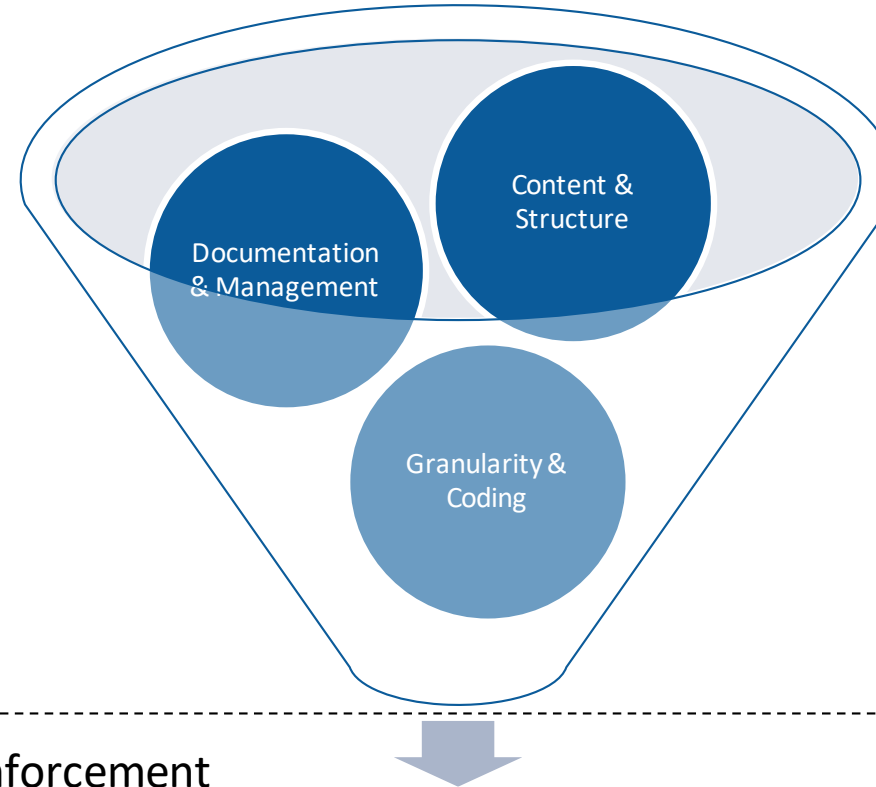| No.	Existing approach	Example(s)	Scope and limitations
1	Document-related	HL7 Consent Policy Rule Codes [13]	Each code focusses entire consent documents or rule sets, e.g. "Illinois Consent by Minors to Medical Procedures" [13]. Lack of granularity for the intended purpose.
2	Categorical	Standard Use Condition Consent Codes [14]	General application categories that allow the definition of inclusion and exclusion scenarios, e.g. "user-specific restrictions". Scope of granularity and combination of permission and denial is not suitable for the intended purpose.
3	Action-related	FHIR Consent Actions [15]	Defined set of permissible common data processing procedure actions, e.g. collect, access, etc. Limited granularity of permissible actions and applicable rules are unsuitable for the intended purpose.
4	Detailed policy-sets combining inclusion (permit) and exclusion (deny) criteria	IHE APPC Specification [16]	Focus on access control rules combining inclusion and exclusion scenarios and specific use cases/workflows, e.g. "Withhold consent to disclose to a specific provider organization". Scope of granularity and combination of permission and denial is unsuitable for the intended purpose.
5	Mapping of specific consents (per research project) based on explicit permission using individual consent policies (variant 1)	Consent Policies, identified by unique object identifiers (OIDs) [17]	Mapping of consent content to OIDs unambiguously refers to specific application context and document version (here: MII Broad Consent [10]). These MII OIDs focus on explicit permission. Their meaning is linguistically and semantically aligned. Re-use of this specific static mapping outside the MII scope is deliberately not intended.
6	Mapping of specific consents (per research project) based on explicit permission using individual consent policies (variant 2)	Consent policies identified by structured unique naming (TTP Policy Codes) [18] as applied in *research projects* DZHK/NAPKON/NUM NUKLEUS [8,19] and Trusted Third Party (TTP) of the University Medicine Greifswald	Structured identifiers and their meaning are project-specific and focus on explicit permission. Semantic assignment to consent texts requires considerable prior knowledge and expertise. Within the research project (e.g. DZHK [8]), however, they are suitable for mapping different study consents. Re-use outside the specific research project not envisaged. Nevertheless, naming of consent policies might provide orientation for similar use cases.
7	Meta data description for records	Focus on data use conditions allowing usage and access for research, as implemented in the project "Leipzig Health Atlas" [20] aligned with works of the MII [21]	Allocation of fine-grained rights for e.g. academic research, within the EU, with biomaterial. Simultaneous exclusion of certain matters, e.g. to recontact the patient concerned. Combination of inclusion and exclusion scenarios not suitable for intended purpose.

NAPKON Consent

Research project

MII Broad Consent

[…] allows the **transfer** of your encrypted patient data […] to recipients in countries of the European Union (**EU**), […] or other countries for which the European Commission has determined an **adequate level of data protection** through an adequacy decision."

Quote from consent document or patient information

[…] **transfer** to other countries **for research projects** if **European data protection legislation** applies in these countries or if the European Commission has confirmed an **adequate level of data protection** in these countries

Transfer of medical data domestically or abroad with appropriateness decision

Individual Interpreted Coding & Meaning

Transfer of encoded patient medical data (MDAT) to external researchers for scientific use for medical research purposes.

Policy „MDAT_provide_EU_compliant"

OID 2.16.840.1.113883.3.1937.777.24.5.3.8

Content & Structure

Documentation & Management

Granularity & Coding

Complex Input

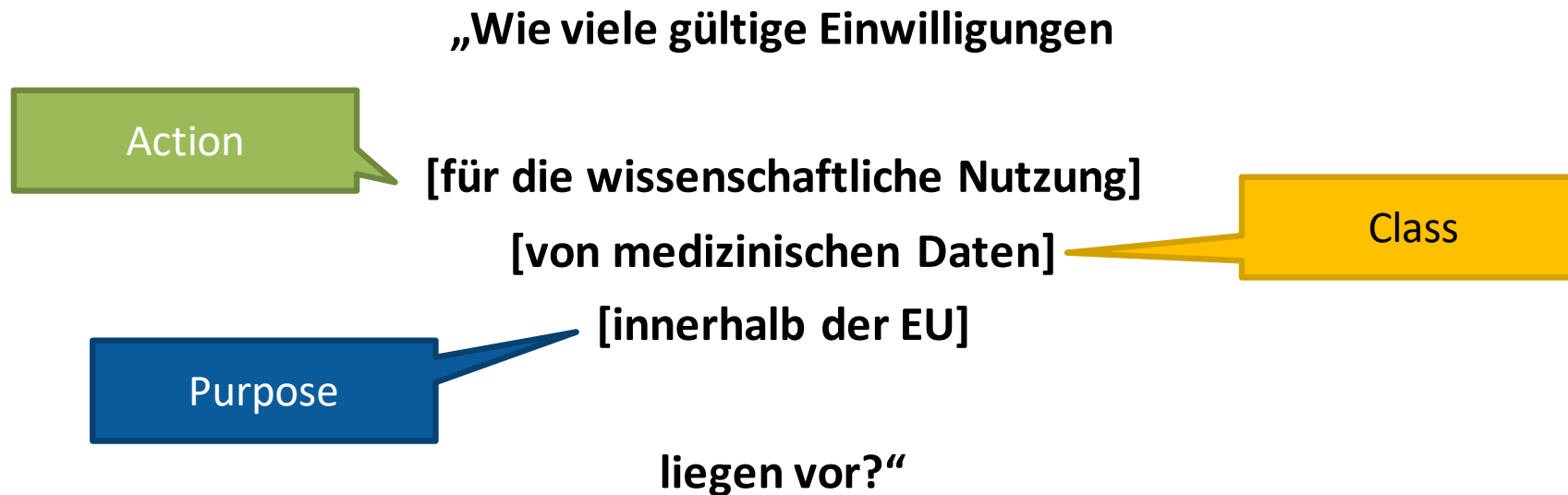- -

Simple Queriability/ Enforcement

„How many valid informed consents

allowing the scientific use of medical data within the EU exist?"

Wir benötigen eine einheitliche „semantische Sprache", um Einwilligungsinhalte zu beschreiben und „verständlich" zu machen.

„Wie viele gültige Einwilligungen

Action

[für die wissenschaftliche Nutzung]

Class

[von medizinischen Daten]

[innerhalb der EU]

Purpose

liegen vor?"

Methodik - Semantische Abstraktion

1. **Bestandsaufnahme**
   - Policy-Namen und Policy-Semantik auf Basis von MII, NUM-CODEX, NUM-NUKLEUS und DZHK

2. **Bestimmung semantischer Schnittmengen**

3. **Abstraktion der Gemeinsamkeiten bezogen auf**
   - **Klassen** (Daten-/Materialarten und Unterarten)
   - **Aktionen** (Zulässige Datenverarbeitungsschritte und ggf weitere relevante Tätigkeiten)
   - **Zweck** (Kontext-relevante weiteren Informationen
   - Angabe von Akteuren

4. **Abstimmung mit Techn. Commitee - Terminologien HL7 Deutschland bzgl. inhaltlicher und techn. Abbildbarkeit des Ansatzes**

Table 2

To semantically describe and encode the meaning of consent policies, a semantic code based on three axes (class, action, purpose) and one optional axis (actor) is applied.

Axis	Method of allocation	Description	Type of word	Example
class	data type in a separate but integrated data management system, e. g. patient identifying information or specimen	class combines data or material types and subtypes	acronym	person identifying information (PII or IDAT)
	Subclasses can be used to address relevant subsets of this data type, e.g. analysis data based on specimen	"Which data type is addressed with the policy?"		biomaterial (BIOMAT)
action	description of permissible activity resulting from a Consent Policy	action combines permitted processing steps and activities	verb	collect
		"What am I allowed to do?"		
purpose	specification of the application context of usage and/or scope of coverage of a Consent Policy	purpose combines further information relevant for – or – regarding the context	adjective and/or noun	timely_restricted
		"Why/What for/Where from/Where to/For whom/How/…?"		
actor	extendible categorisation of requestor of a consent request	specification of the Actor	acronym	DTU (data transfer unit)
		"Who is asking?"		

Technische Abbildung auf vier FHIR-basierte Codesysteme

- **Class**
  https://simplifier.net/ths-greifswald/consentpolicyclasscs

- **Action**
  https://simplifier.net/ths-greifswald/consentpolicyactioncs

- **Purpose**
  https://simplifier.net/ths-greifswald/consentpolicypurposecs

- Optional: Actor
  https://simplifier.net/ths-greifswald/consentpolicyactorcs

Vorteile

- Abbildbarkeit von Policies, Modulen und ganzen Vorlagen
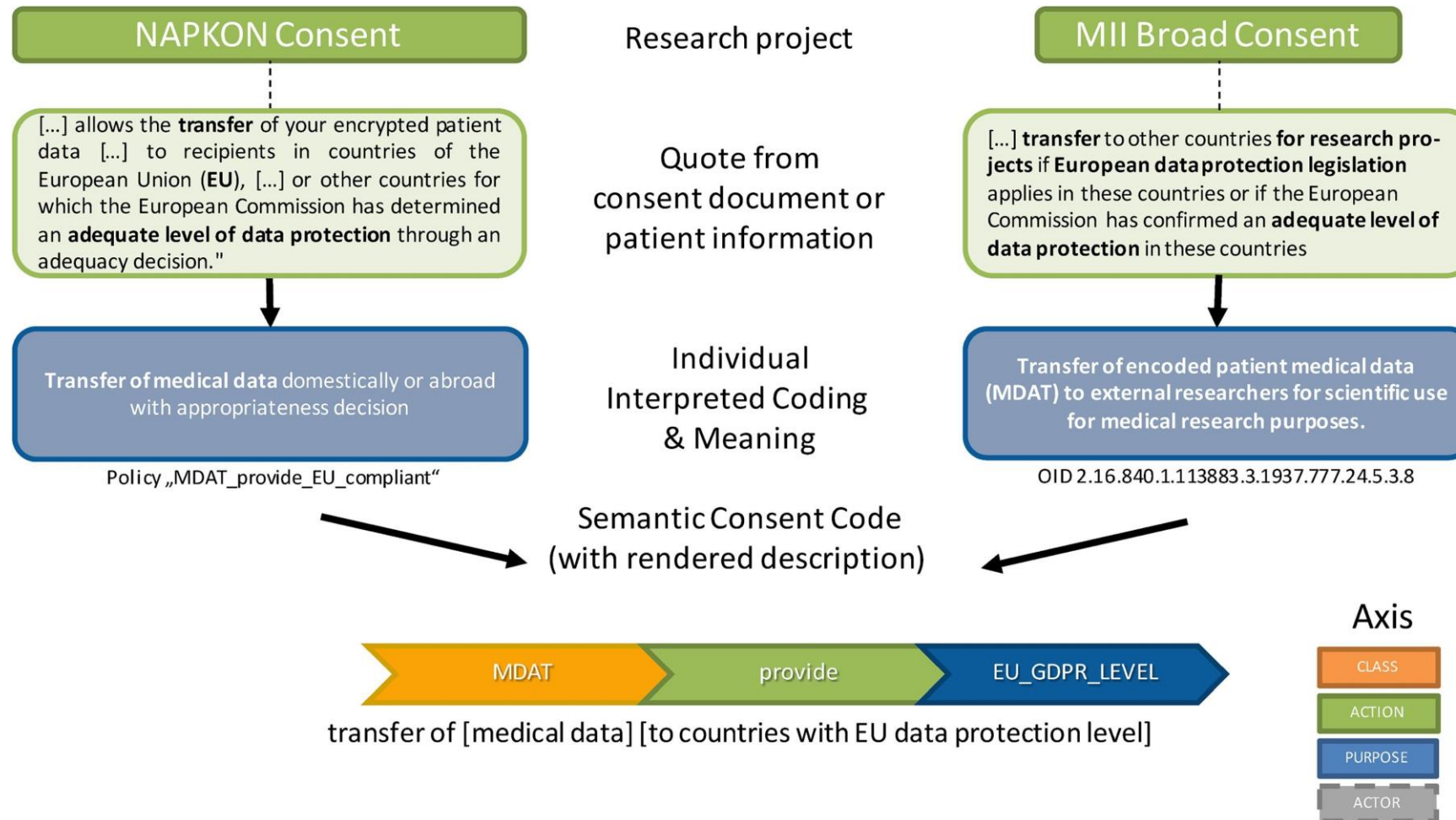
- Verwendung wie gehabt in FHIR Consent.Provision möglich

Semantic Consent Code (EN)

Perspektive/Perspective (CLASS)
BIOMAT
BIOMAT_analysed_data
BIOMAT_retrospective
BIOMAT_analysed_data_retrospective
BIOMAT_additional_sampling
PII
IMGDAT
HIDAT
HIDAT_HIPN
HIDAT_retrospective
MDAT
MDAT_GECCO83
MDAT_retrospective
BIOMAT_metadata

Tätigkeit/Activity (ACTION)
provide
transfer_ownership
view
collect
analyse_genetic
inform
store_process
contact
use
process
merge
query
supplement
link

Kontext/Context (PURPOSE)
health_state
general_practitioner
physician
CRO
third_parties
EU_GDPR_LEVEL
non_EU_GDPR_LEVEL
industry
health_records
monitoring
non_profit
pharma
project_specific
project_participation
death
timely_unrestricted
timely_restricted
once

Akteur/Actor (ACTOR)
LIMS
TTP
DTU
BDMS
RDP
DIC
FTTP

```json
{
    "code": "EU_GDPR_LEVEL",
    "display": "EU_GDPR_LEVEL",
    "designation": [
        {
            "language": "de-DE",
            "use": {
                "code": "900000000000003001",
                "system": "http://snomed.info/sct"
            },
            "value": "an Länder mit EU Datenschutzniveau"
        },
        {
            "language": "de-DE",
            "use": {
                "code": "900000000000013009",
                "system": "http://snomed.info/sct"
            },
            "value": "EU_DSGVO_NIVEAU"
        },
        {
            "language": "en-UK",
            "use": {
                "code": "900000000000003001",
                "system": "http://snomed.info/sct"
            },
            "value": "to countries with EU data protection level"
        }
    ]
}
```

Studierende aus THS Greifswald, Studentin von HMGU München

Zur Verfügung Stellung folgender Dokumente

- reale Einwilligungsdokumente
- SCC Code Version 1.0

Kurze Einleitung durch MB bzw. MK (ohne detailliertere Absprache)

Übersetzung der Texte in Semantic Consent Codes mit Fokus auf „inhaltliche Abdeckung"

Ergebnisse

- Manuell Abbildbarkeit /Anwendung erfolgreich bestätigt
- Dual language User Manual (GER, EN). (2024) https://ths-greifswald.de/scc/manual

Technische Grundlage

- Importierte SCC-ValueSets, MII Consent ValueSets, NUKLEUS Policies, …
- Junit Tests

Conversion Results

Note: For simplification only the results "with application of dialects" are listed.
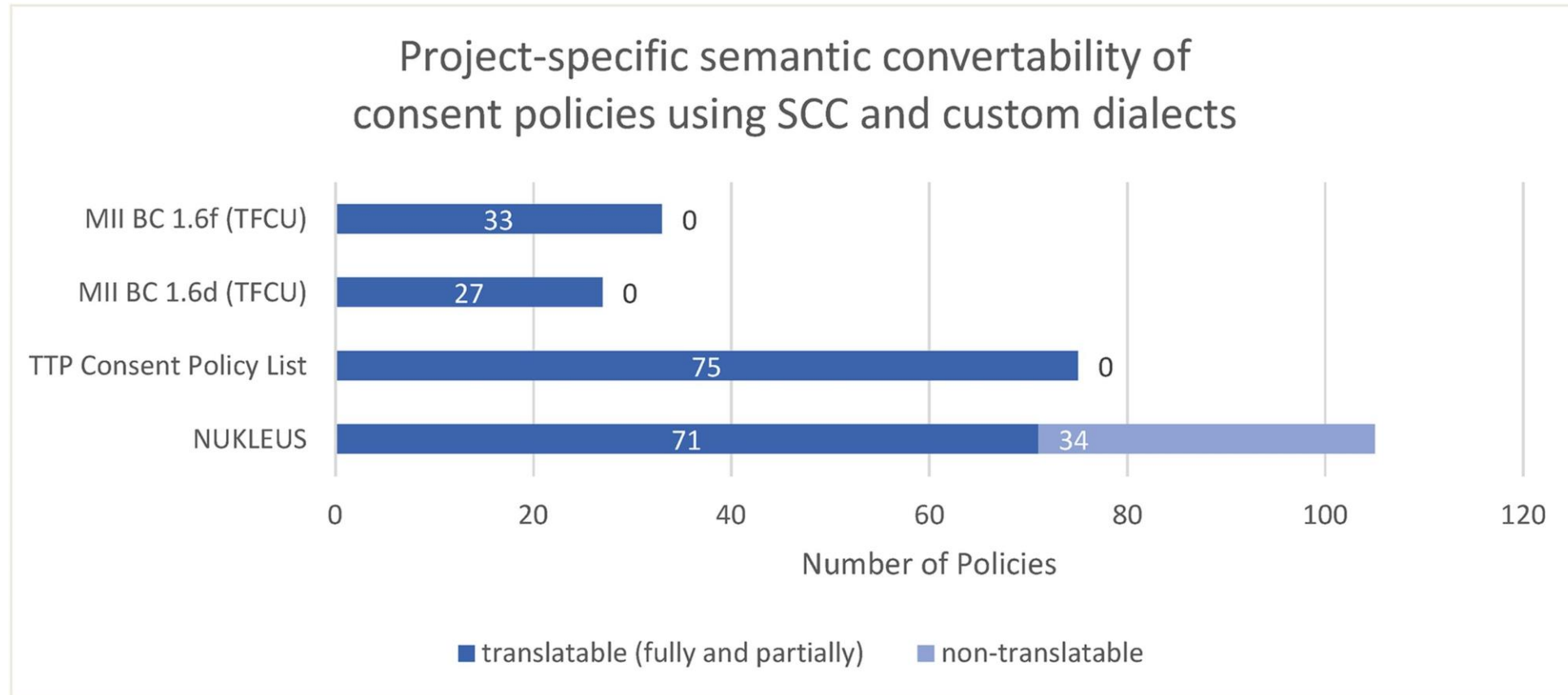
Output generated with Java and Junit

- source: `2022-01-27-MII-BroadConsent-1.6.d-TFCU-v1.0.json`
- dialect: `mii`
- success: `27/27/27`
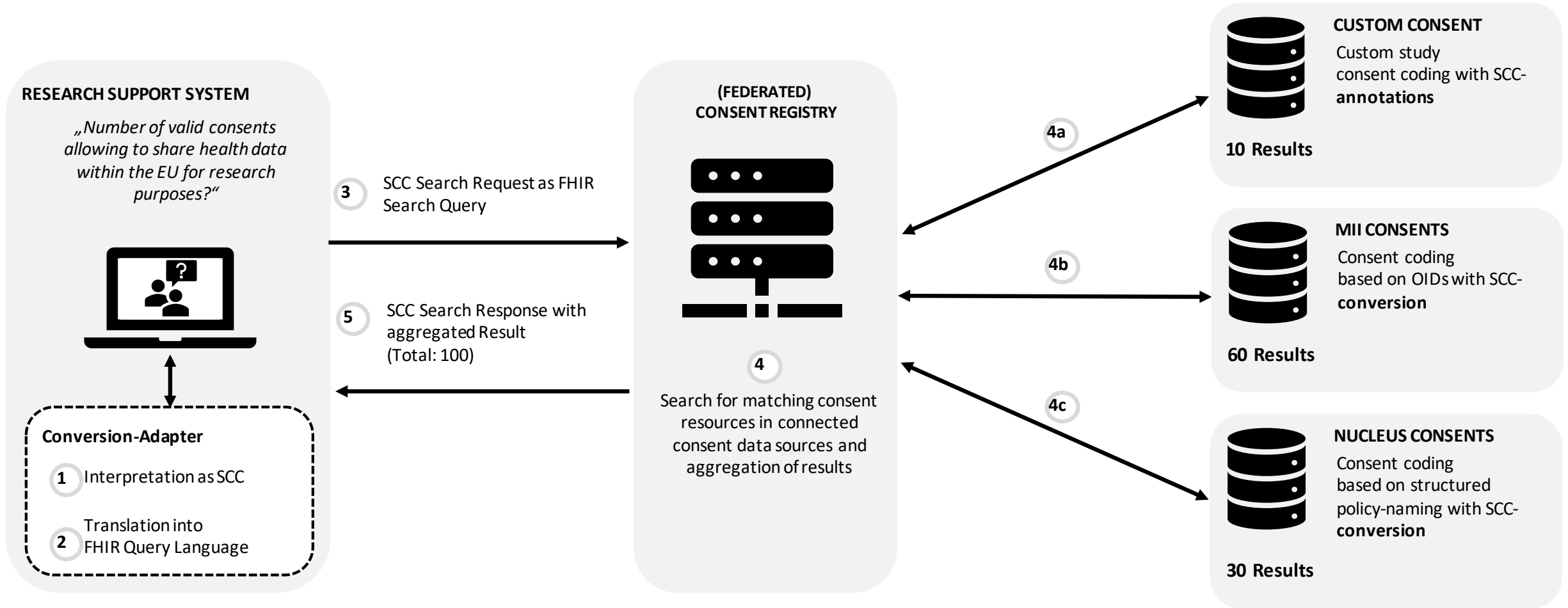- errors: `0/27`

Translated policies (27/27)

Semantic Consent Code (SCC)

- besteht aus **semantischen Achsen**: Class, Action, Purpose, Actor.

- ermöglicht die Beschreibung von Einwilligungsdokumenten **unabhängig von ihrer Struktur und Form**

- schafft eine flexible und **einheitliche Voraussetzung** für die Verarbeitung von Einwilligungsdaten.

- **unterstützt** die praktische Anwendung des Patientenwillens auf Forschungsdaten.

- **Konvertierbarkeit** bestehender Einwilligungskodierungen in/aus SCC **erfolgreich evaluiert**

User Manual (DE, EN)

Publikation

Planung eines gemeinsamen Kooperationsvorhabens mit **eTIC**

Vorhaben 1

Vorhaben 2

eTIC

Annotierter
Vorlagenexport

gICS®

Einheitliche Abfragen per
SEMANTIC CONSENT CODE

Neuer gICS-Embedded-Mode:
Einfache Integration von **Smartphone**
oder **Tablet-PC** zur Dokumentation von
Einwilligungen

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