Federal Office for Radiation Protection

Umwelt Bundesamt | KI-Lab Anwendungslabor für Künstliche Intelligenz und Big Data

EFOMP EUROPEAN FEDERATION OF ORGANISATIONS FOR MEDICAL PHYSICS

FAIR use of training data in medical radiation protection
… with or without AI

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***KI-Lab**: Viola Rädle, Imke Voss, Raphael Franke*

Federal Office for Radiation Protection (BfS)

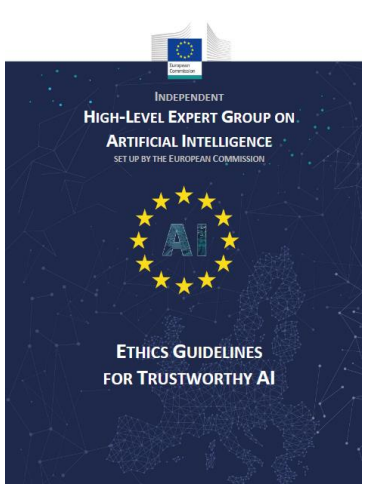
EUTERP „Train-the-trainer“ event, Milano, 25.06.2025

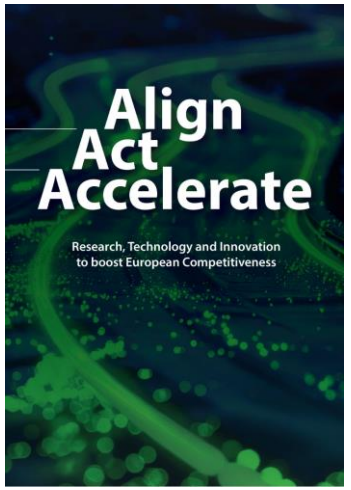
A FAIR use of data in medical radiation protection…

1. **What are we talking about?** – Illustrative example from medical imaging

2. Theory: The need for a FAIR approach

- Ethical Foundations (**ICRP 138**, 2018) – TG 109
- “Ethics guidelines for trustworthy AI” (EU, 2019)
- “Align Act Accelerate”. (EU, 2024)
- “AI Act” (EU, 2024)



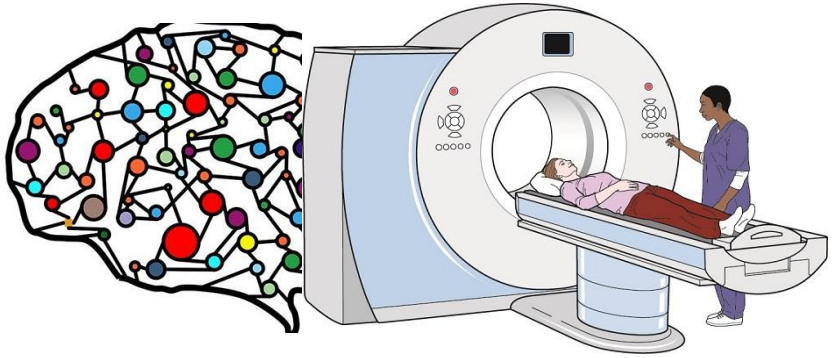


EU Artificial Intelligence Act

3. Practice: Setting an example with our own work

- Quality assurance of new technology (including AI)
- Tools to help regulators and researchers

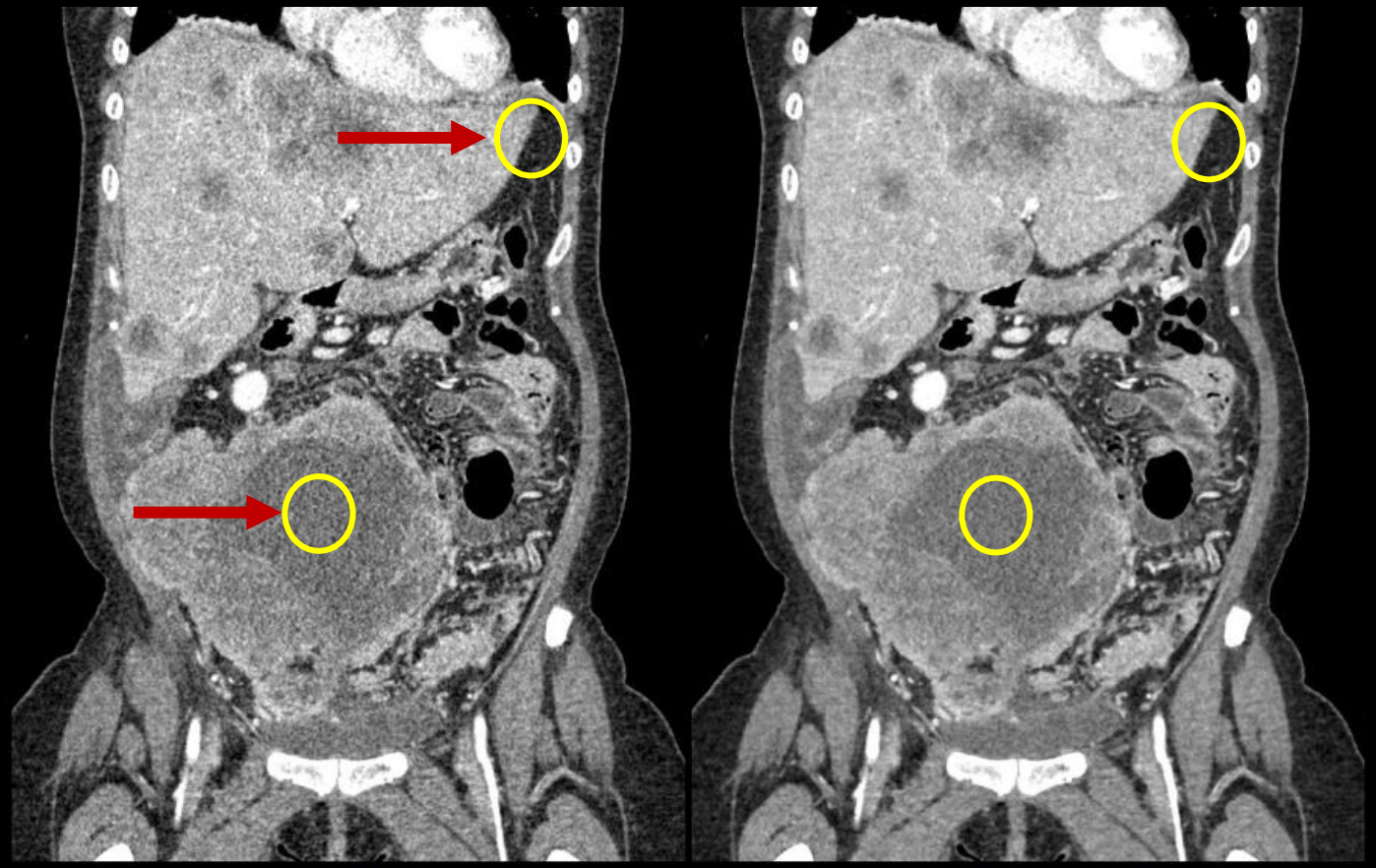
-> Special case of diagnostic reference levels



An **example** from **medical imaging**: AI-assisted imaging in CT

Reduction of noise (blurring)…

…and preservation of edges (without blurring!)



Filtered backprojection (since ca. 1980)

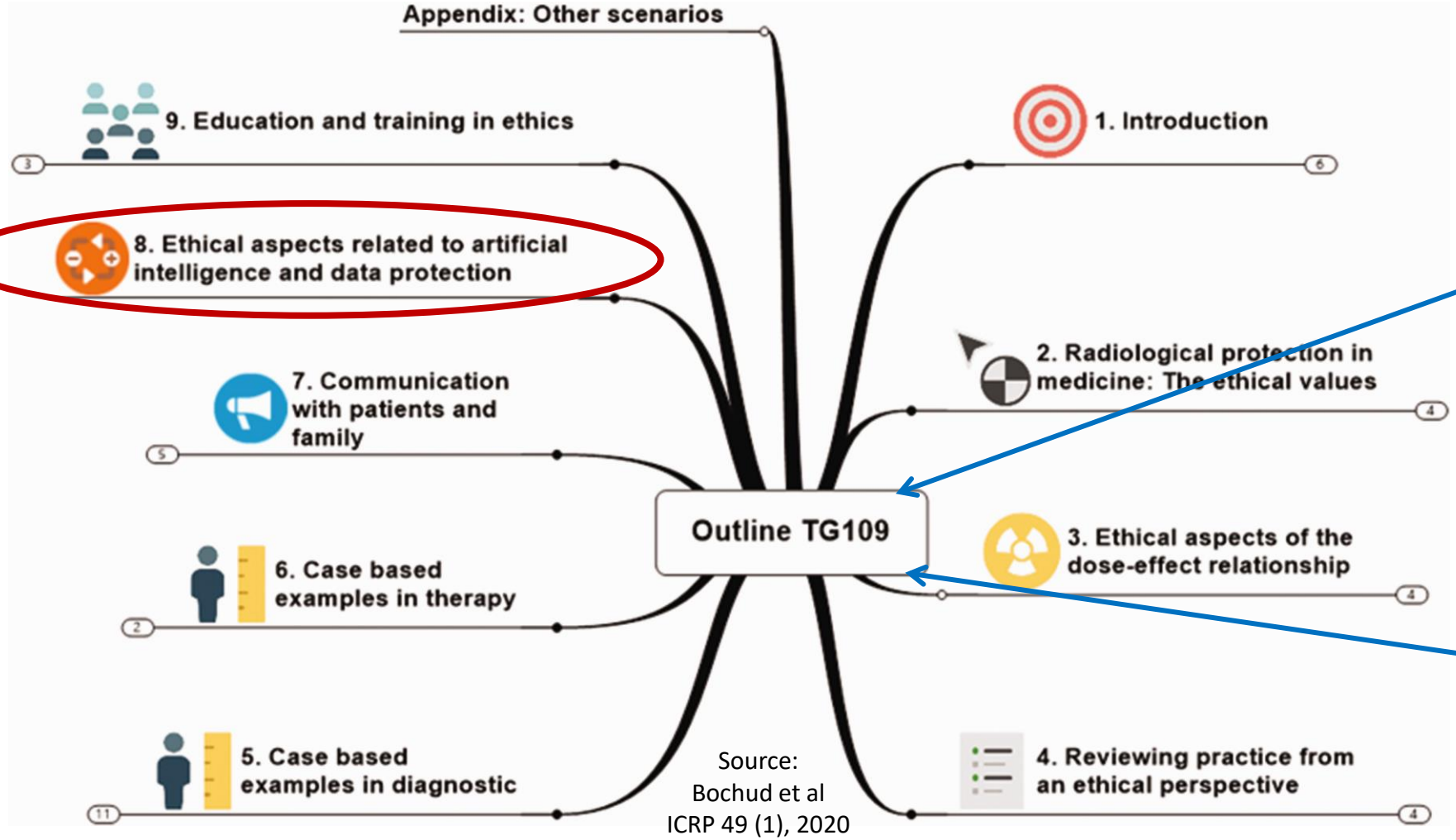
Iterative reconstruction (since ca. 2012)

Proprietary software (and data) -> No guarantee of fidelity to anatomy

Source: Marc Kachelrieß, DKFZ

Theory:
The need for a FAIR approach

From the aspects of ethics considered by **ICRP** we are focusing on **AI in medical applications**



Source:
Bochud et al
ICRP 49 (1), 2020

Core values:

Beneficence / non-maleficence

Prudence

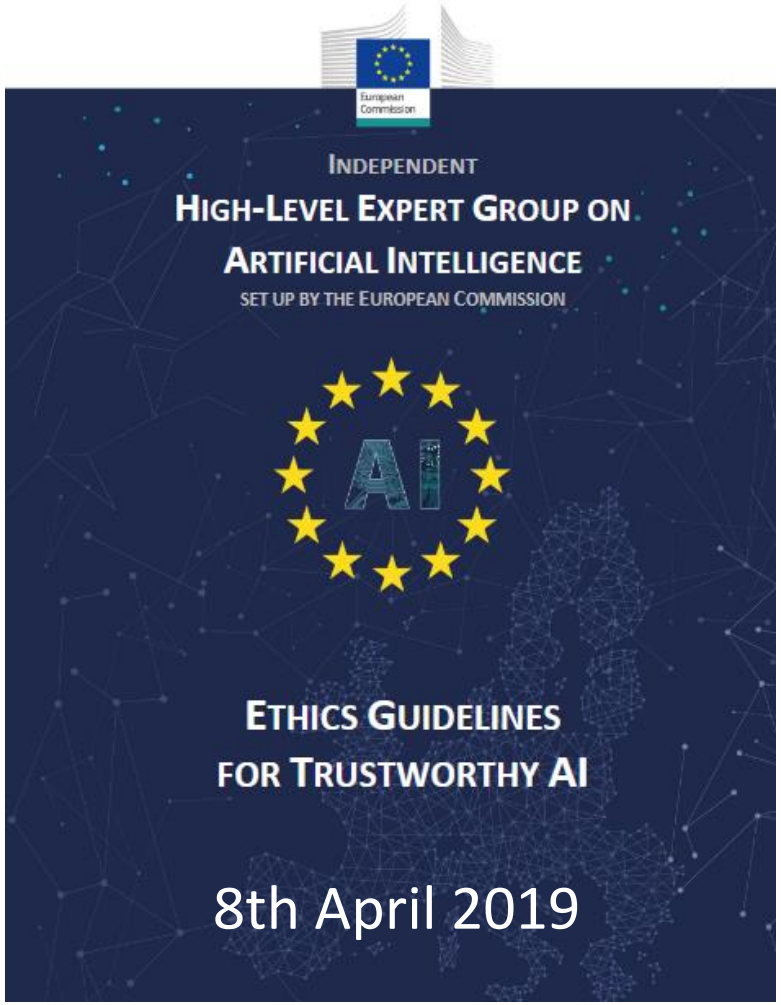
Justice

Dignity

Procedural values:

Accountability
Transparency
Inclusiveness
(empathy)

The ethics **guidelines for trustworthy AI** contain **requirements that are not met** at all in current applications that are **already in the market**… and in the **hospitals**!



Requirements of Trustworthy AI:

…

Transparency
Including traceability, explainability and communication

Diversity, non-discrimination and fairness
Including the avoidance of unfair bias,
accessibility and universal design, and stakeholder participation

Societal and environmental wellbeing
“[…] Ideally, AI systems
should be used to benefit all human beings, including future generations”

…

[…], so it is important at this stage of its development to put in place the **necessary safeguards**

"We are **at the very beginning** of the use of **AI in the sciences**, and at the same time this use is **spreading very rapidly**, so it is important at this stage of its development to put in place the **necessary infrastructure to monitor practices and experiment to rapidly capitalise on the potential benefits and establish the necessary safeguards**. "

From "**Align Act Accelerate. Research, Technology and Innovation to boost European Competitiveness " –**
- EC, Sept. 2024 -

-> **FAIR (findable, accessible, interoperable and reusable)** data sharing and management
(Initiated by ministries of Science of France, Germany and the Netherlands)

… only in **public sector**? Can we enforce this in the **private sector**? … How?

Federal Office for Radiation Protection

The recent **AI Act** gives practical steps towards an **AI governance framework**

EU Artificial Intelligence Act

The AI Act (*Regulation (EU) **2024**/1689 laying down **harmonised rules on artificial intelligence***) provides AI developers and deployers with clear requirements and obligations regarding specific uses of AI.

These principles, informed by ethical considerations, legal compliance, and a commitment to transparency and accountability, will guide organizations in harnessing AI's benefits while mitigating its risks, **ultimately fostering trust and success in the AI-driven future**.

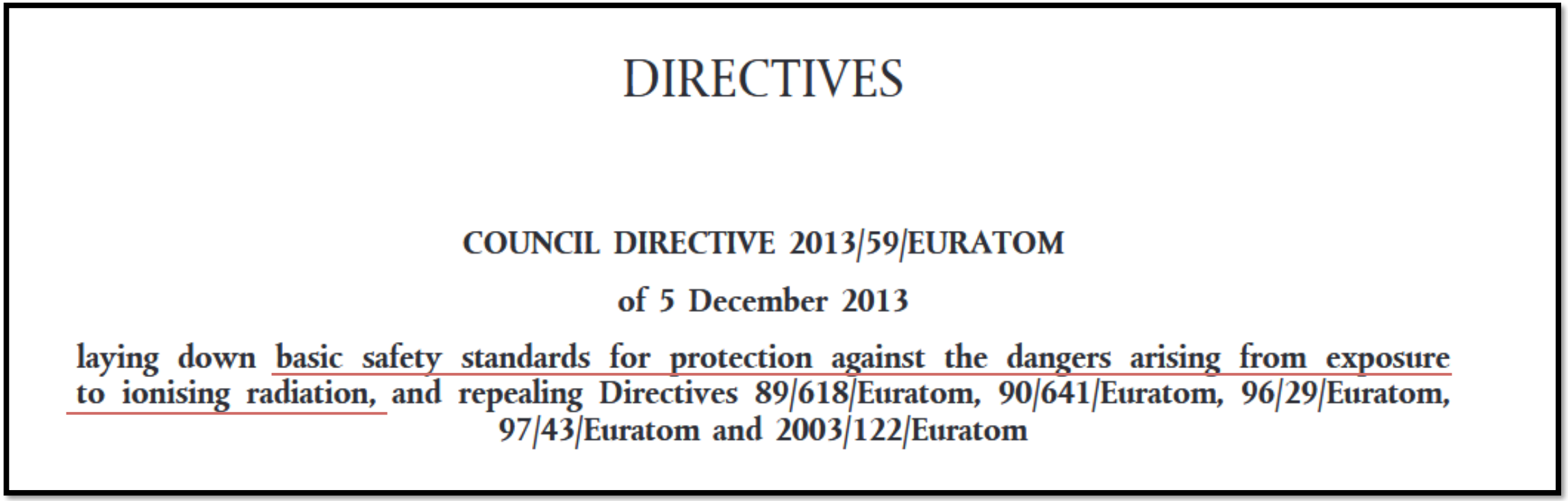
Core AI governance programs

- Governance and Accountability
- Human Oversight
- Fairness and Ethics Alignment
- Data Management
- Transparency Enhancement
- Privacy and Cybersecurity

↔ F A I R

Practice:
setting an example with our work

European countries adopted the **basic safety standards (BSS)** by 2018



DIRECTIVES

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

-> Italy: **DECRETO LEGISLATIVO 31 luglio 2020, n. 101 (2018)**

-> Germany: **StrlSchG (2017) and StrlSchV (2018)**

FAIR?

…or not FAIR?

For **regulators** there are hard **challenges** but also promising **opportunities**

Challenges

Quality assurance of AI-assisted (reconstruction) algorithms

Opportunities

Tools that may facilitate inspections and surveillance

Challenge and opportunity

Diagnostic reference levels

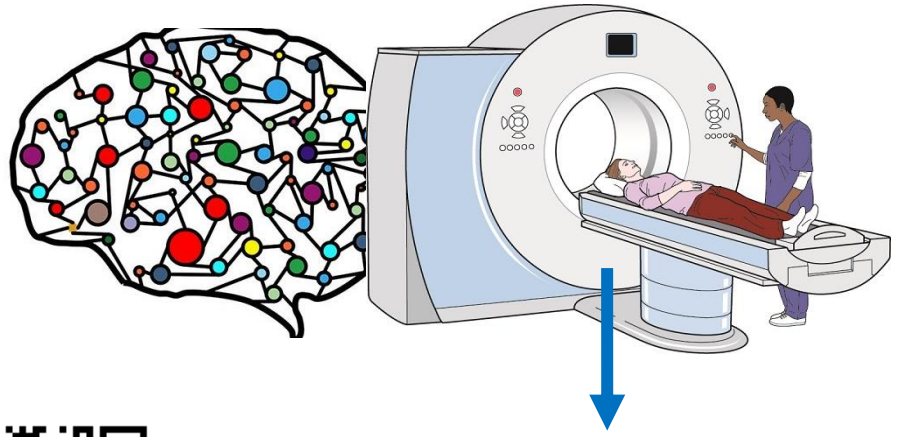
…and if possible optimised and harmonised, at least within Europe!

Great challenge: (harmonized) **Quality assurance of AI-assisted algorithms**

Guarantee „*strict surveillance*“ (BSS Article 60)

- E. g. Deep-learning “reconstruction” algorithms

  → Evaluations of **patient images**



Define „*maintenance procedure liable to affect the performance*” (BSS Article 60)

- E. g. Acceptance and constancy tests for algorithms improving themselves

  -> Is FAIR training data a solution?

  -> How can we implement it?

  -> Cooperation with authorities, researchers and vendors in EU

Anton et al. (2024)
Phys Med Biol 69(15)
doi: 10.1088/1361-6560/ad6119

Opportunities: Tools that may **facilitate** (harmonised) **inspections and surveillance**

Initiate corrective action (BSS Article 104)

- Find **patterns** within **European dosimetric data (AI?)**
- Identify **remarkable practices** or **trigger alerts**

⇒ Goal: **Predict (and avoid) potential incidents**!

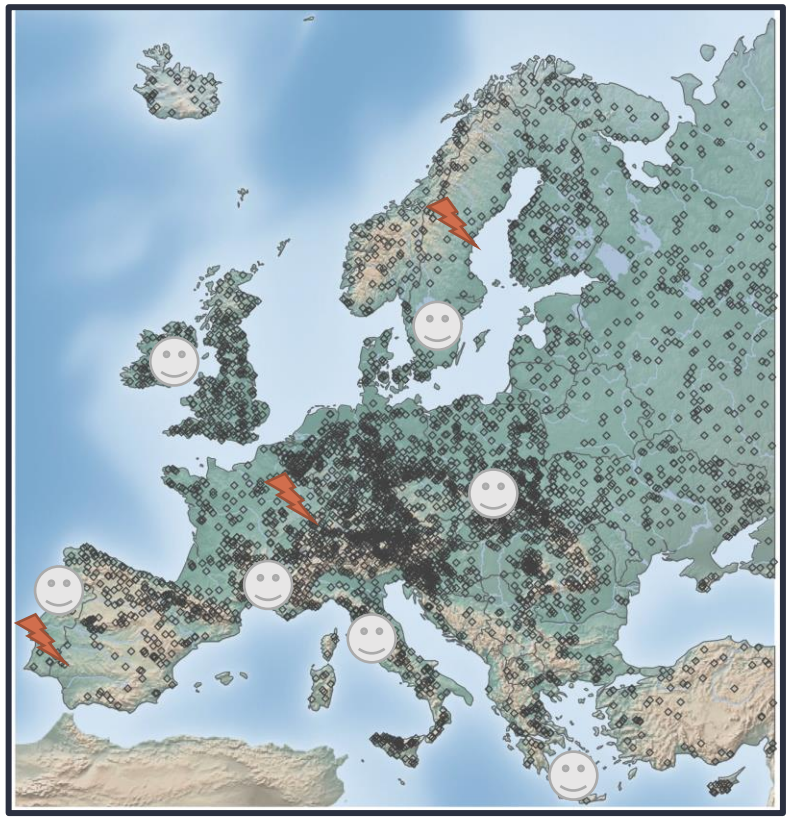
Availability and dissemination of information (Art. 104)

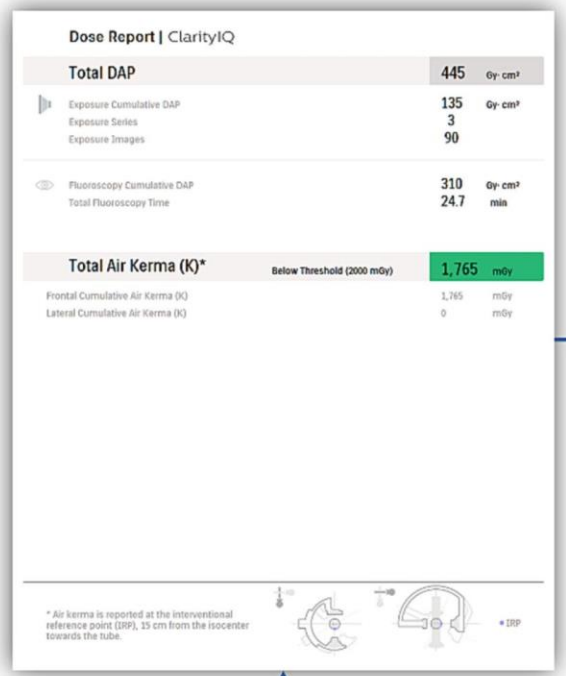
- **Check image quality parameters** and compare to dose
- **Alert** facilities and/or authorities in case of deviation

⇒ Goal: Guarantee inspections under **fair conditions**

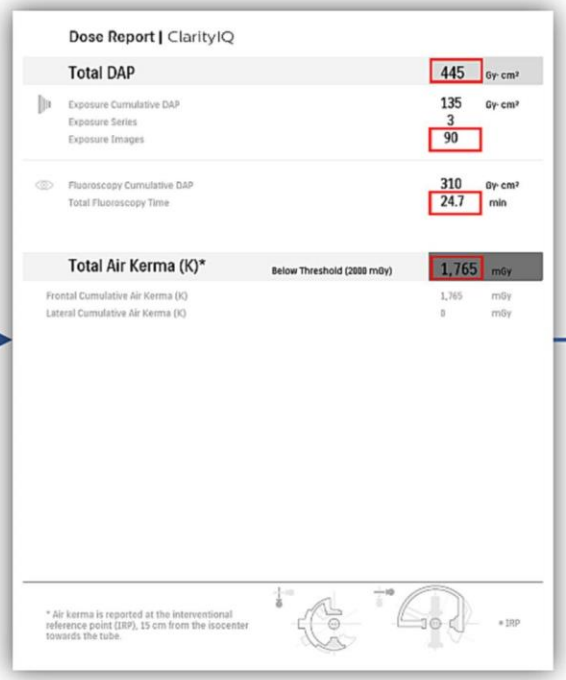
For Discussion:

How can AI help to harmonise and analyse the international dosimetric ("big") data?



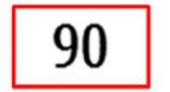


convert to 8-bit



crop

DAP sub-image



Exposure images sub-image

Fluoroscopy time sub-image

Air Kerma sub-image

Denoising and resizing

OCR with Tesseract

Store values to python lists

Was the last imported image?

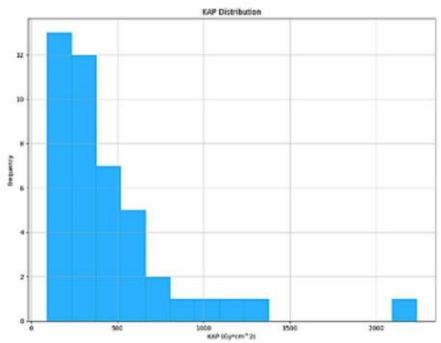
No

Next dose report

Yes

Calculate quartiles, create histograms and export

Excel file with analyzed data



Tzanis and Damilakis, 2023

The FAIR part of it…

7. Data and code

The data used for the current study and the developed code are available in the supplementary material. Moreover, readers can execute the developed code and reproduce the reported results through the following google colab notebook: https://colab.research.google.com/drive/1kodOqNIp6LYdFjh4jgJsm4iKgzaWam6t?usp=sharing.

Tzanis and Damilakis, 2023

Practice:
setting an example with our work

The case of
diagnostic reference levels (DRLs)

DRLs…
Check your knowledge!

DRLs help in optimisation

They are „investigational“ based on **survey data**

Dose repositories are rare

Data collection is prone to mistakes

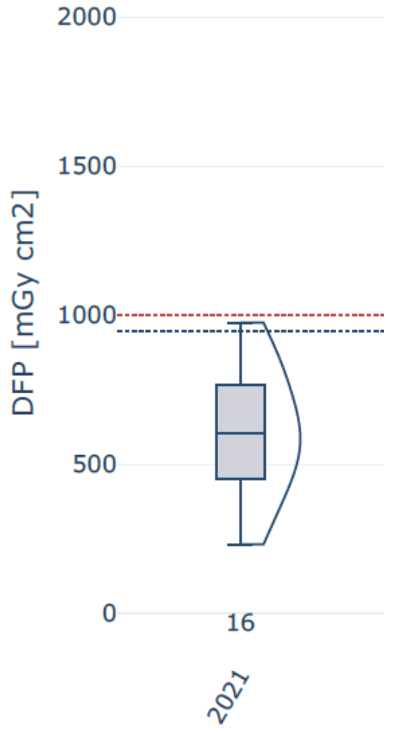
Typically set at **75th percentile**

… at **national (or European) level**

They are **updated on regular basis** (ca. each 5 years)

If a facility **exceeds the DRL**,

-> **optimisation** is usually necessary

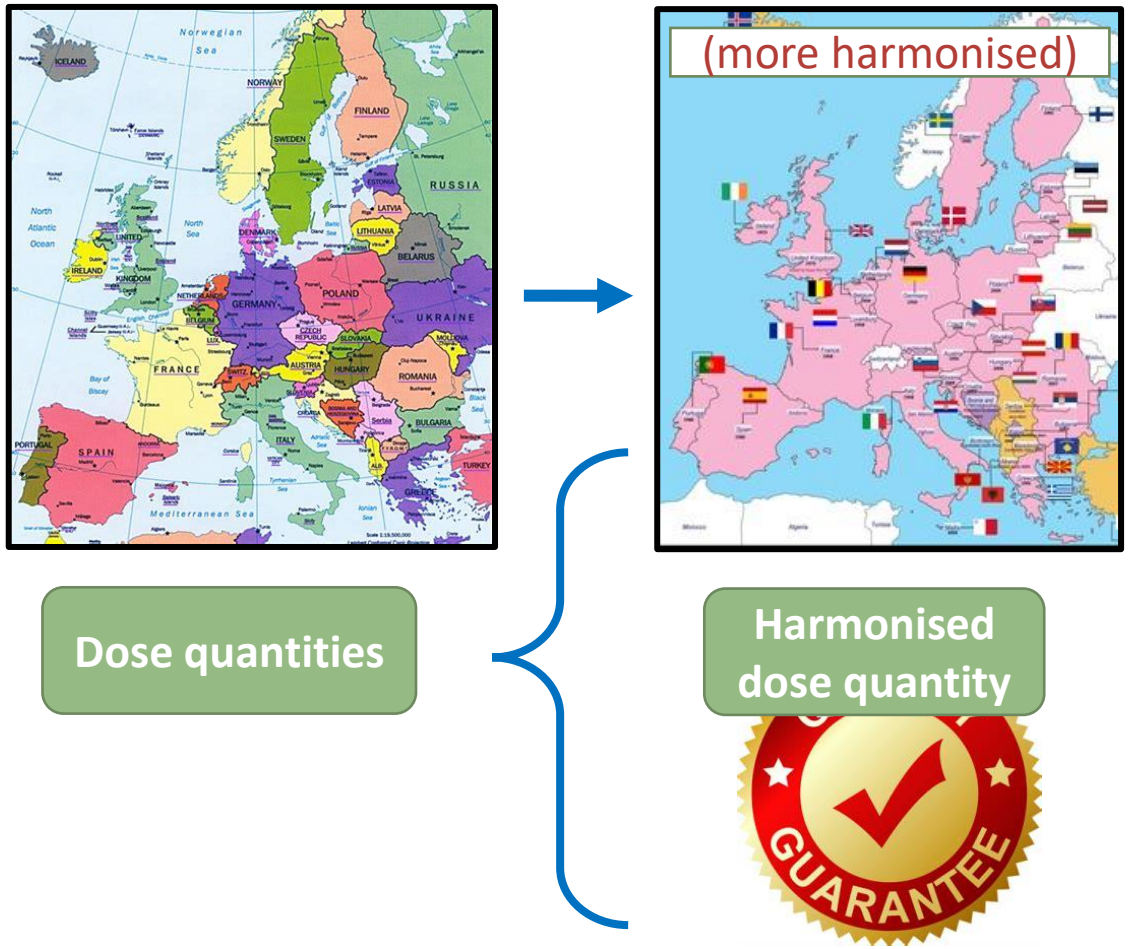


Both a **challenge** and an **opportunity**: (harmonised) **improvement of the concept of DRLs**

"*Establishment, regular review and use of diagnostic reference levels*" (BSS Article 56)

- Find **common approach to data collection and Interoperability** among Europe
- Include **image quality** indicators **(patient images)**
- Investigate why not all recommendations are followed

-> Example for EU technology cooperation



For discussion:

(how) can we construct a platform for (AI-) assisted QA of data and update of DRLs?

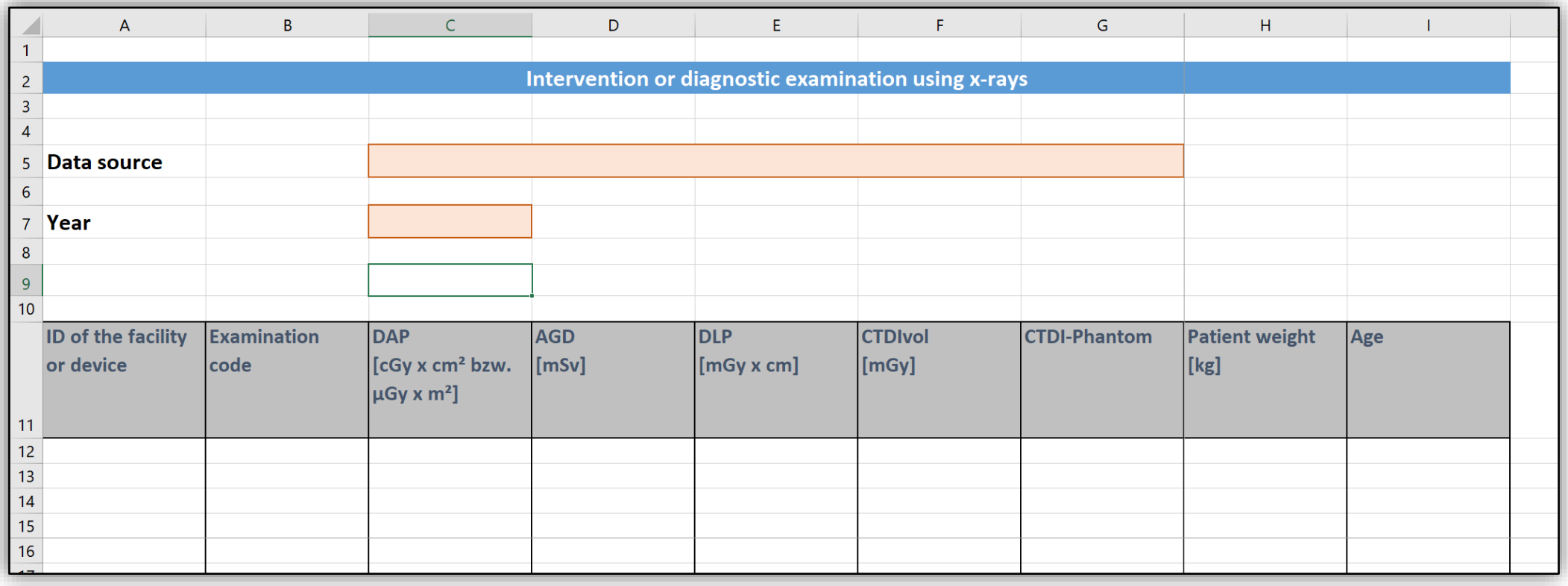
What have we done?

- Templates (data collection and structure)
- Software tool (data repair and analysis)

…and tried to make it FAIR!

FAIR (findable, accessible, interoperable and reusable)

An easy template, that everyone can use



	A	B	C	D	E	F	G	H	I
1									
2	Intervention or diagnostic examination using x-rays								
3									
4									
5	**Data source**								
6									
7	**Year**								
8									
9									
10									
11	ID of the facility or device	Examination code	DAP [cGy x cm² bzw. µGy x m²]	AGD [mSv]	DLP [mGy x cm]	CTDIvol [mGy]	CTDI-Phantom	Patient weight [kg]	Age
12									
13									
14									
15									
16									

IDs of facilities

Exposure data

Optional fields

Examination codes

Required repairs: change of names, change/addition of columns…

Federal Office for Radiation Protection

A file with the explanation of all codes (harmonised structure of data)

	A	B	F
1	Exam Code	Exam name	DRL2016
2	1010	Cranium	60
3	1020	Facial bones (diagnosis of tumor, trauma)	20
4	1021	Paranasal sinuses (Sinusitis, OP-Plan)	8
5	1022	Neck	15
6	1100	CT angiography of the brain-supplying vessels	20
7	1025	Intervertebral disc spaces of the cervical spine	25
8	1026	Bones of the cervical spine	20
9	1033	Intervertebral disc spaces of the thoracical spine	
10	1034	Bones of the thoracical spine	
11	1040	Intervertebral disc spaces of the lumbar spine	25
12	1041	Bones of the lumbar spine	10
13	1030	Thorax (soft tissue)	10
14	1031	High-contrast lung	3
15	1120	Total aorta	13
16	1110	EKG-synchronised coronary angiography d	20
17	1050	Abdomen (e. g. liver, pancreas)	15
18	1060	Abdomen and pelvis	15
19	1065	Torso (Thorax+Abdomen+Pelvis)	13
20	1070	Pelvis soft tissue	15
21	1071	Bones of the pelvis	10

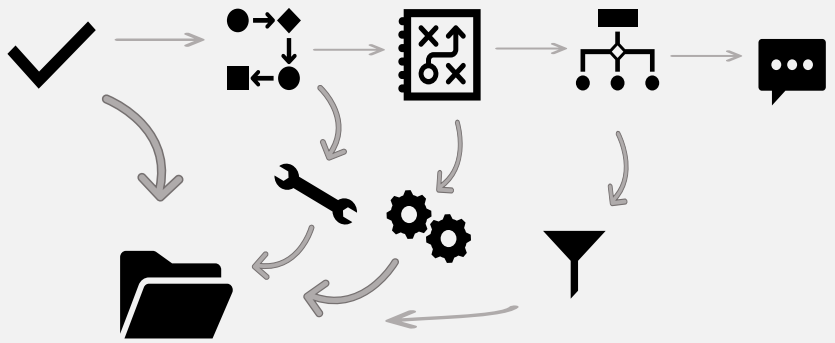
Examination codes

Examination names

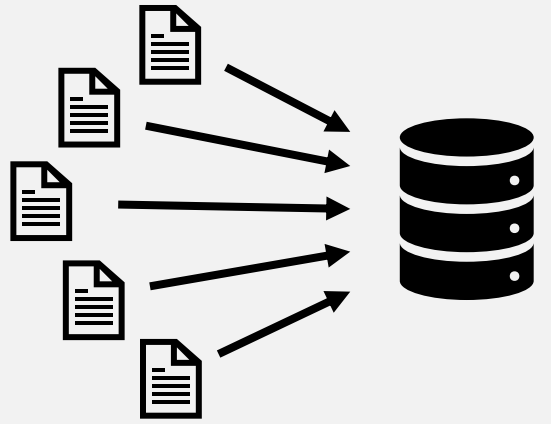
Other data of the examinations (e.g. DRLs)

…and a „user-friendly“ application

Application for supervision of medical exposures

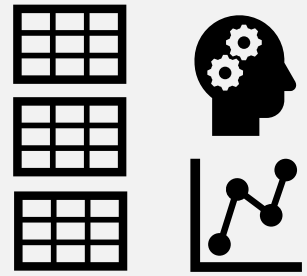


Automatic data repair



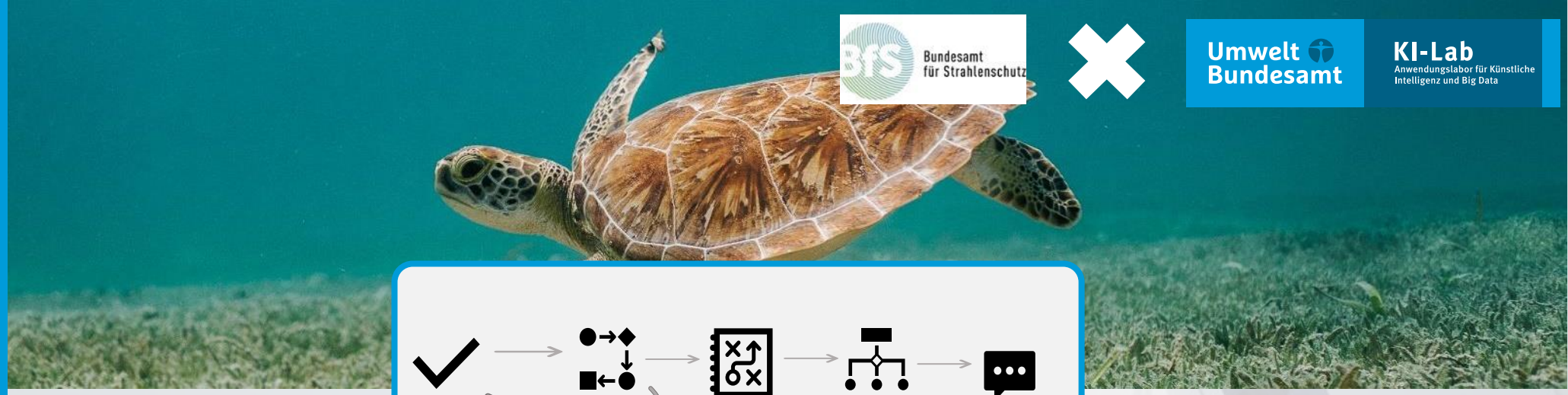
Storage in data base

Report and visualisation



Scientific data analysis (incl. AI)

© Quelle: https://medizinio.de/blog/ct-thorax

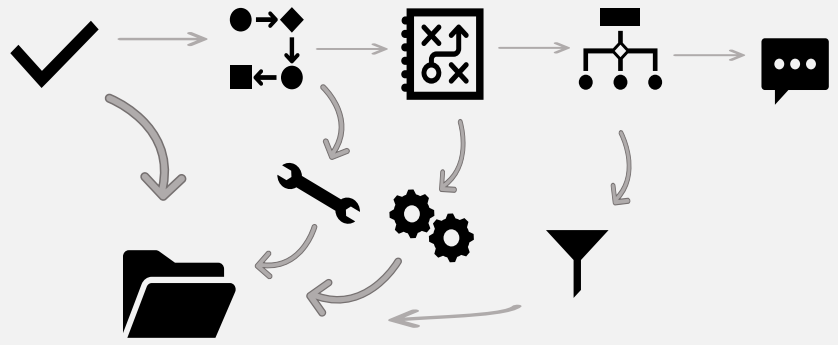


Bundesamt für Strahlenschutz

Umwelt Bundesamt

KI-Lab
Anwendungslabor für Künstliche Intelligenz und Big Data

Application for supervision of medical exposures



Automatic error-cleaning

Time of pipeline:
ca. 2min

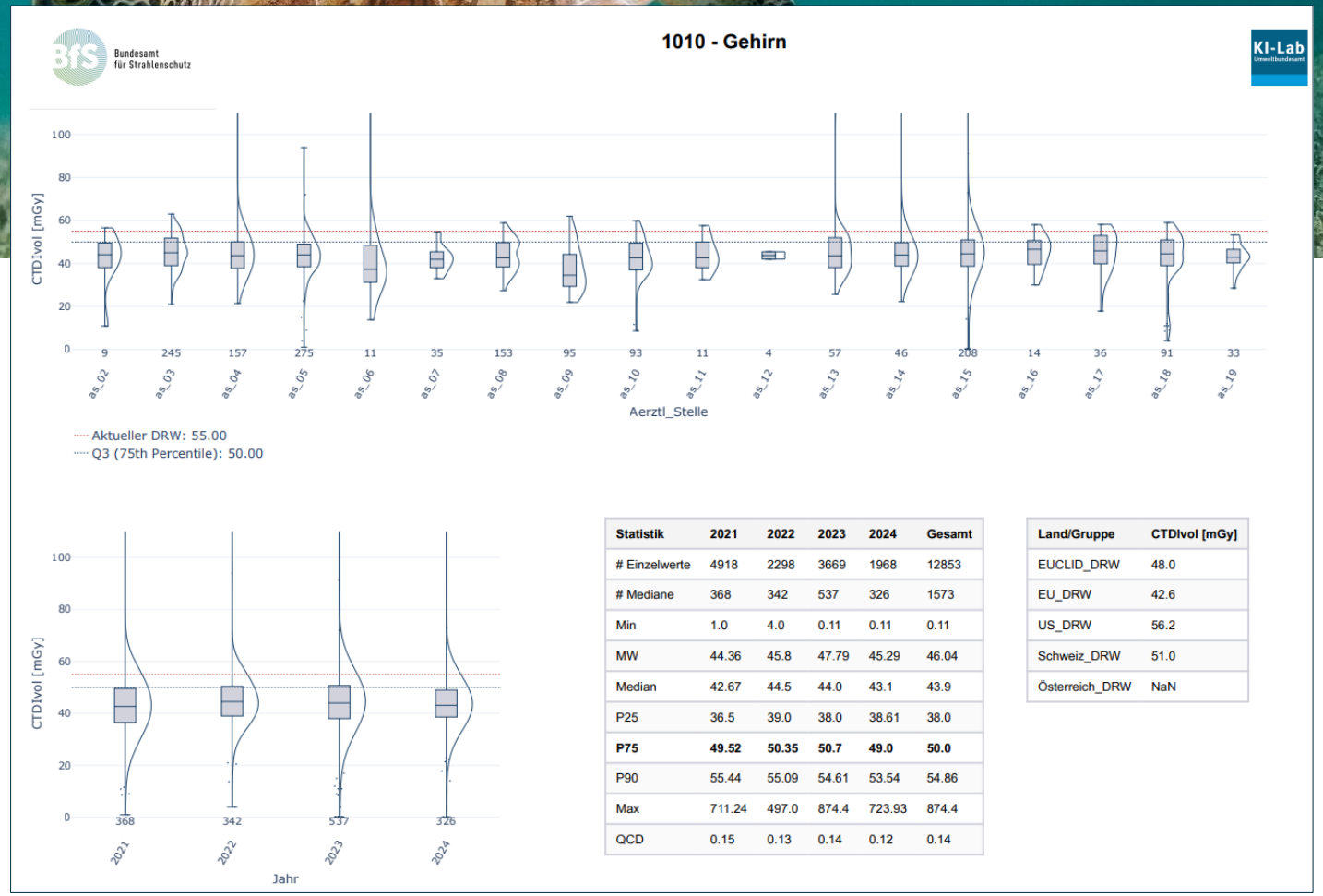
Data successfully read:
>96%

Quantity of data:
+20%*

*in comparison to past

Generation of pdf-reports

Including a version with pseudomised sources of data („Medical bodies“)

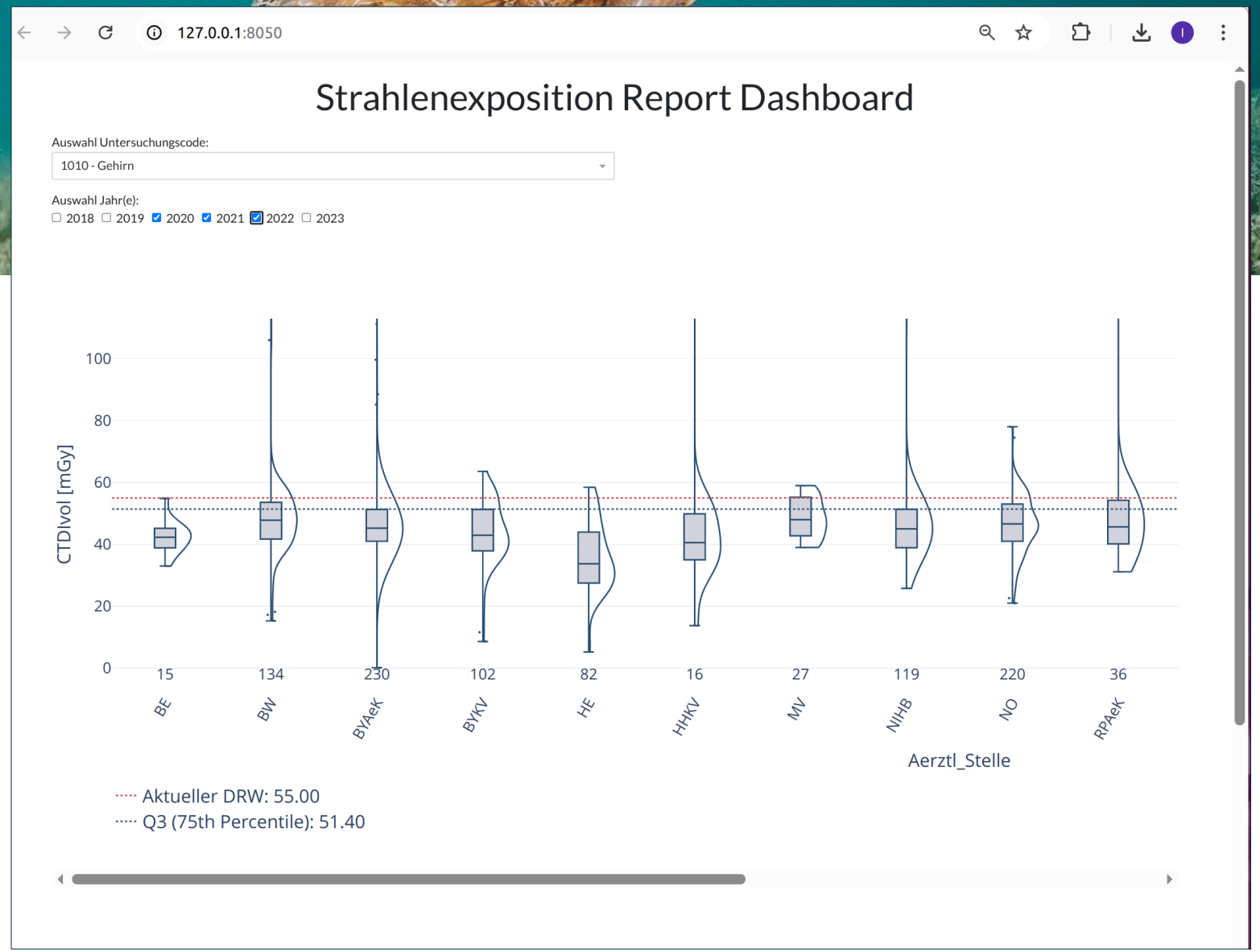


Statistik	2021	2022	2023	2024	Gesamt
# Einzelwerte	4918	2298	3669	1968	12853
# Mediane	368	342	537	326	1573
Min	1.0	4.0	0.11	0.11	0.11
MW	44.36	45.8	47.79	45.29	46.04
Median	42.67	44.5	44.0	43.1	43.9
P25	36.5	39.0	38.0	38.61	38.0
P75	**49.52**	**50.35**	**50.7**	**49.0**	**50.0**
P90	55.44	55.09	54.61	53.54	54.86
Max	711.24	497.0	874.4	723.93	874.4
QCD	0.15	0.13	0.14	0.12	0.14

Land/Gruppe	CTDIvol [mGy]
EUCLID_DRW	48.0
EU_DRW	42.6
US_DRW	56.2
Schweiz_DRW	51.0
Österreich_DRW	NaN

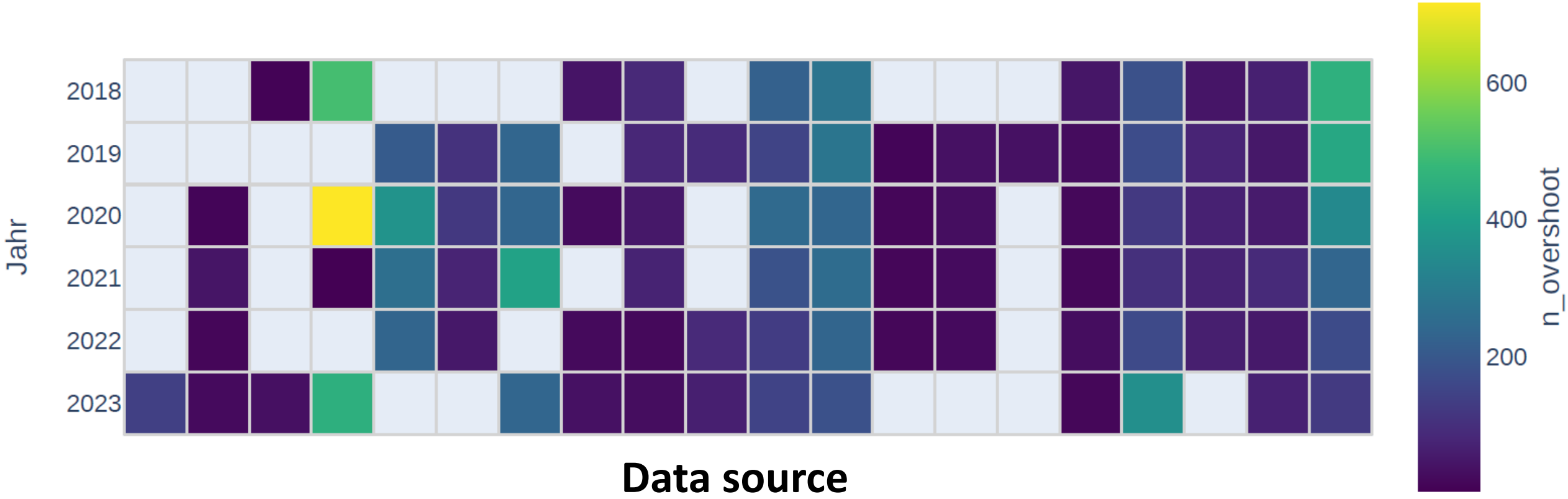
(Includes data from 2024)

Interactive visualisation of data

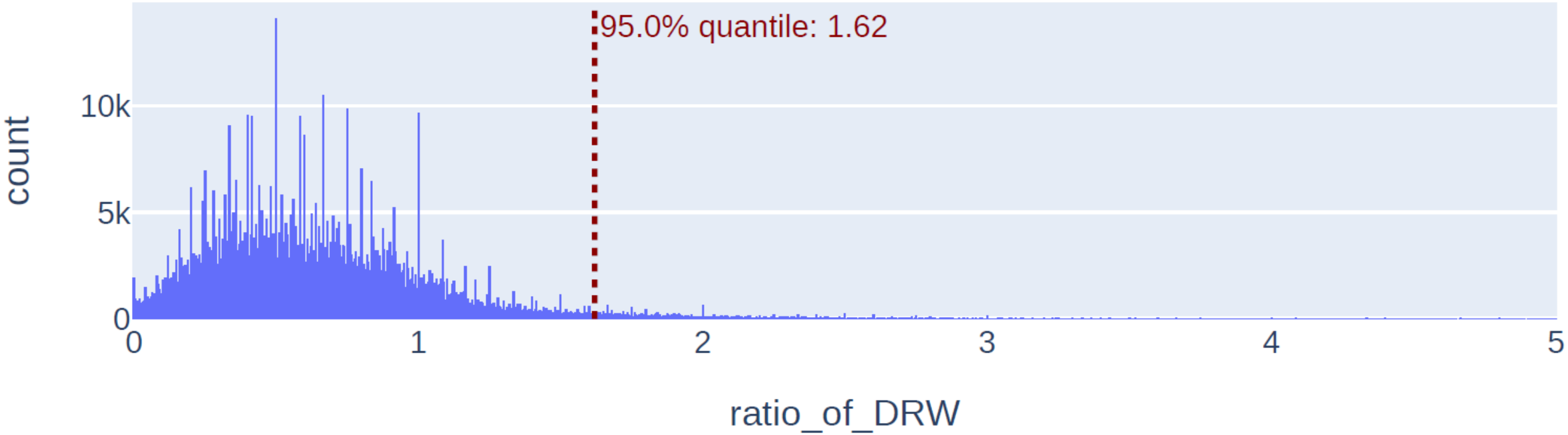


eatmaps

.g. Amount of data points above DRL in all years)

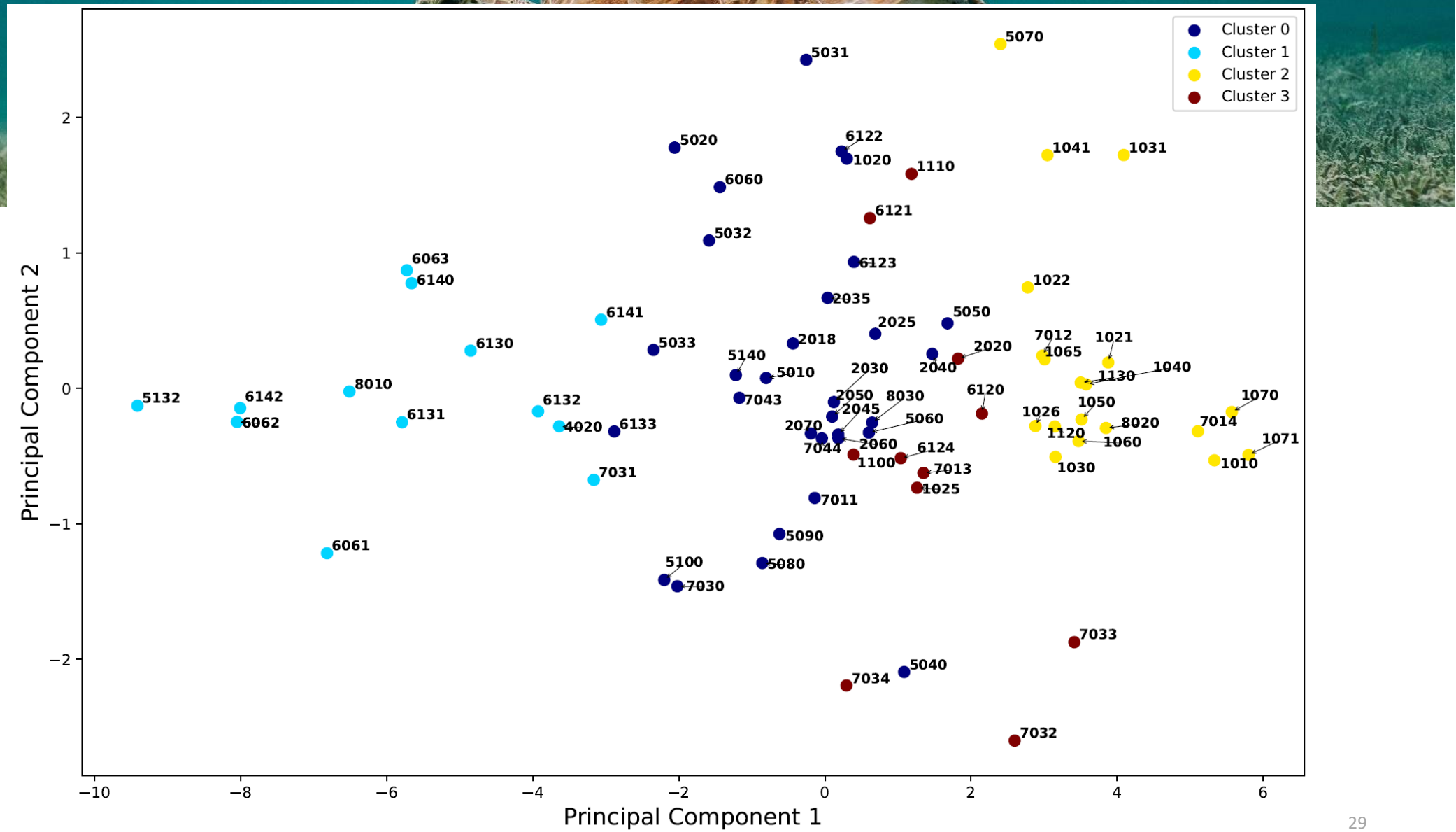


Outlier Analysis



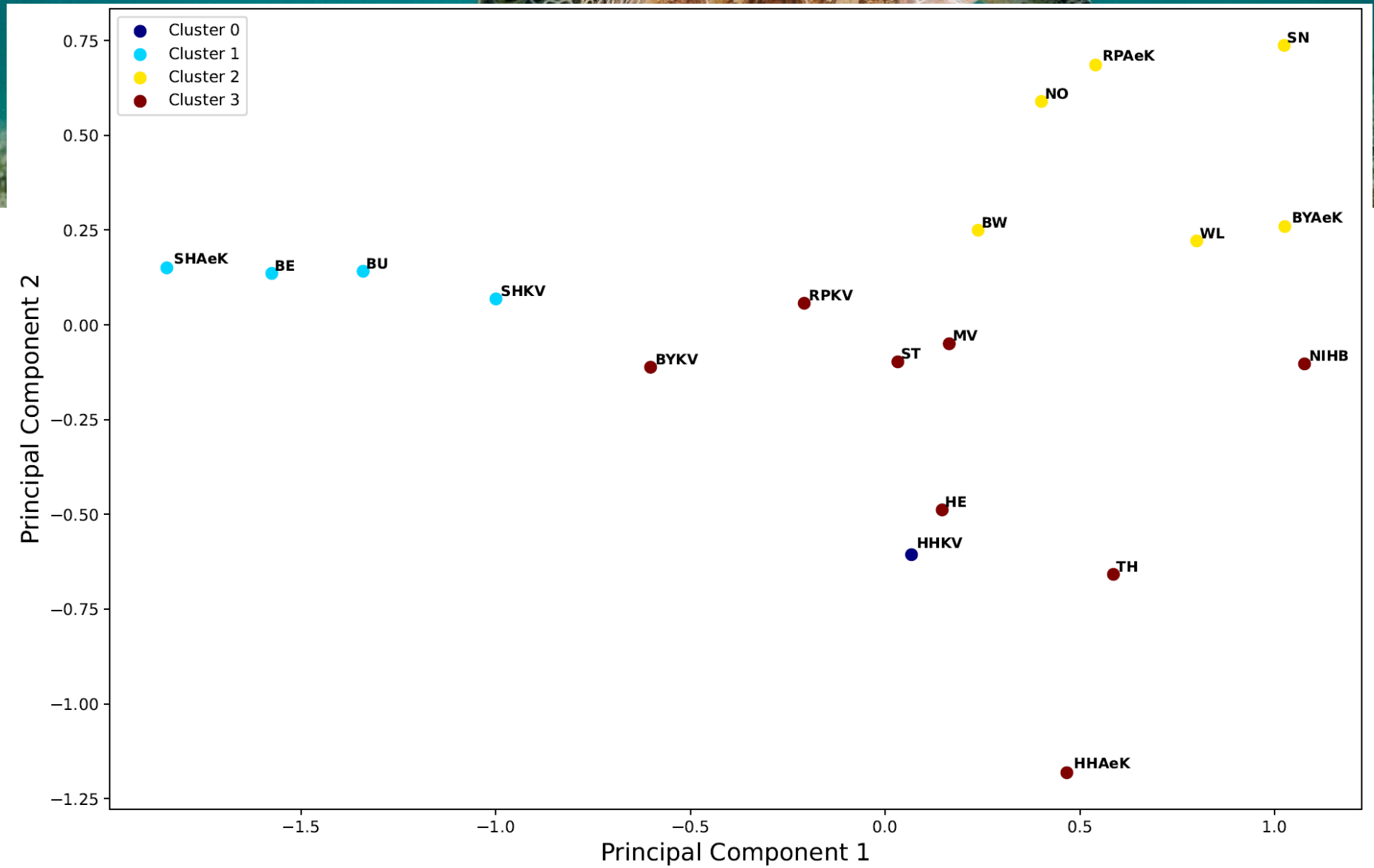
Clustering of Codes

With respect to **Median of dose value/DRL (2018-2020)**



Clustering of data sources

With respect to „QCD“ (dispersion) of dose value/DRL



We created findable, accessible, interoperable and reusable tools

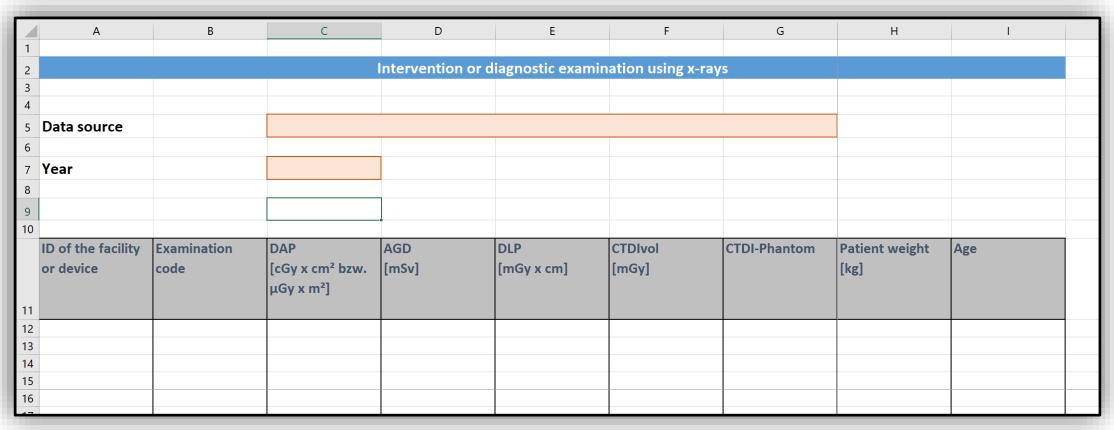
Data collection **(BfS):**

1. Templates that everyone can download and modify
2. Offered in our website: www.bfs.de

Data processing and reporting **(KI-Lab with BfS):**

1. A user-friendly application (open source code)
2. Open-source in a repository with corresponding license

https://gitlab.opencode.de/uba-ki-lab/strahlenexposition



Intervention or diagnostic examination using x-rays								
Data source								
Year								
ID of the facility or device	Examination code	DAP [cGy x cm² bzw. µGy x m²]	AGD [mSv]	DLP [mGy x cm]	CTDIvol [mGy]	CTDI-Phantom	Patient weight [kg]	Age

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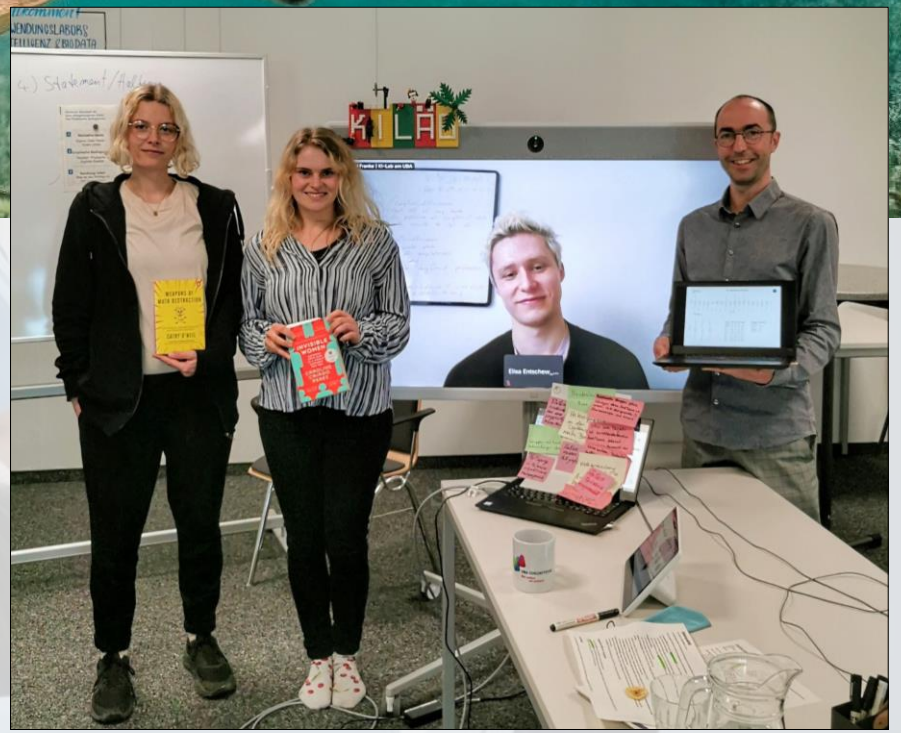
Data processing and reporting

Application for supervision of medical exposures



Thank you Viola, Imke and Raphael from KI-Lab
and Omid from BfS

…and thank ***you*** for your attention**!**

© Quelle: https://medizinio.de/blog/ct-thorax

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Federal Office for
Radiation Protection

- BACKUP slides -

KI in der Überwachung medizinischer Strahlung

Bundesamt für Strahlenschutz

Umwelt Bundesamt

KI-Lab
Anwendungslabor für Künstliche Intelligenz und Big Data

Create a „user-friendly“ application

Sprint 1
Zeitraum: 5 Wochen

- ✓ Einlesen der Originaldaten (alte Excelvorlage)
- ✓ Festlegung der Datenbankstruktur
- ✓ Ein- und Auslesen aus Datenbank
- ✓ Visualisierung als Violin-Plots
- ✓ Deskriptive Statistik (Median, P25, …)

Sprint 2
Zeitraum: 4 Wochen

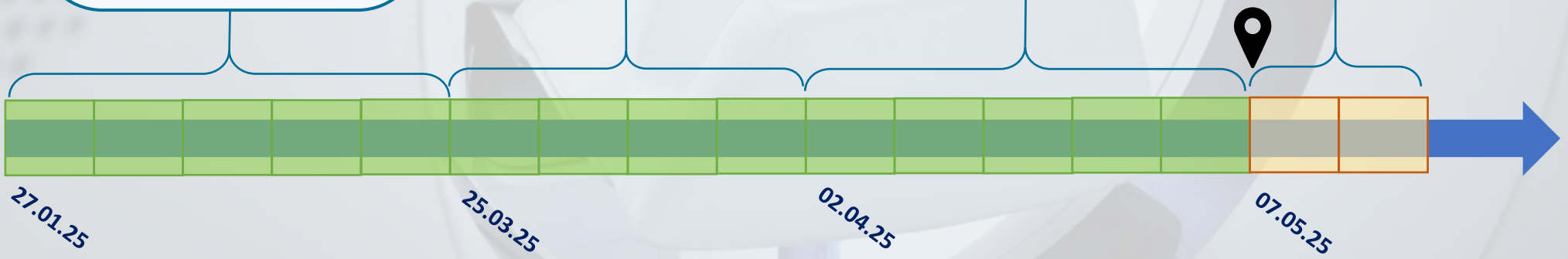
- ✓ Einlesen neue Excelvorlage
- ✓ Automatisierte Fehlerbereinigung
- ✓ Qualitätsprüfung Datenbank
- ✓ PDF-Bericht
- ✓ Ethikworkshop
- ✓ Anwendung auf Daten von 2024

Sprint 3
Zeitraum: 5 Wochen

- ✓ Kompatibilitätsprüfung
- ✓ User Testing
- ✓ Outlier analysis
- ✓ Clustering
- ✓ Heatmaps als Visualisierung
- ✓ Dokumentation
- ✓ Paketierung
- ✓ Übergabe an BfS

nach 07.05.25
Zeitraum: ?

- ✓ Lizenz
- ✓ Statement zu Datenqualität
- ✓ Software veröffentlichen
- ✓ ggf. Publikation?



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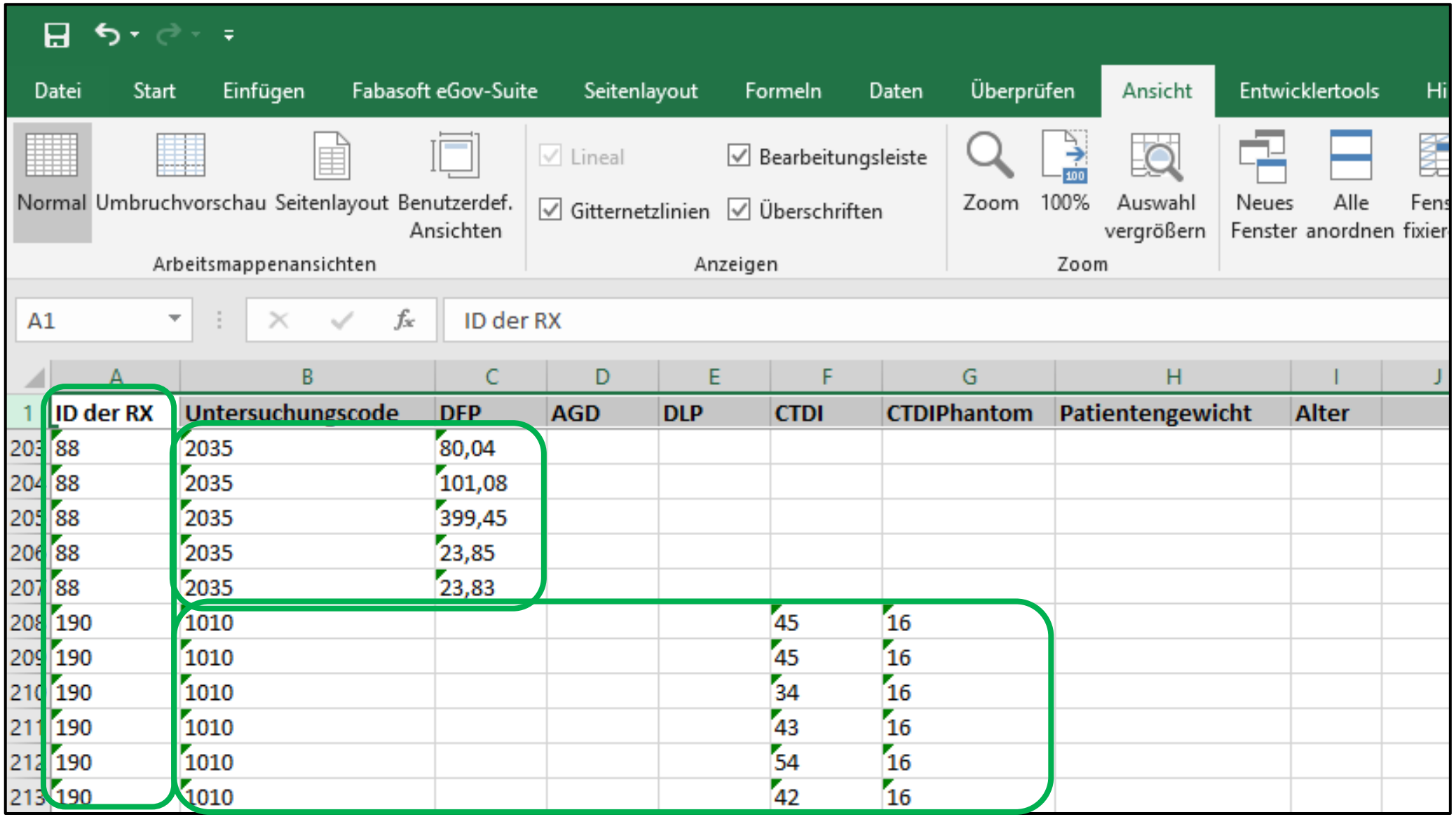
An easy template, that everyone can use



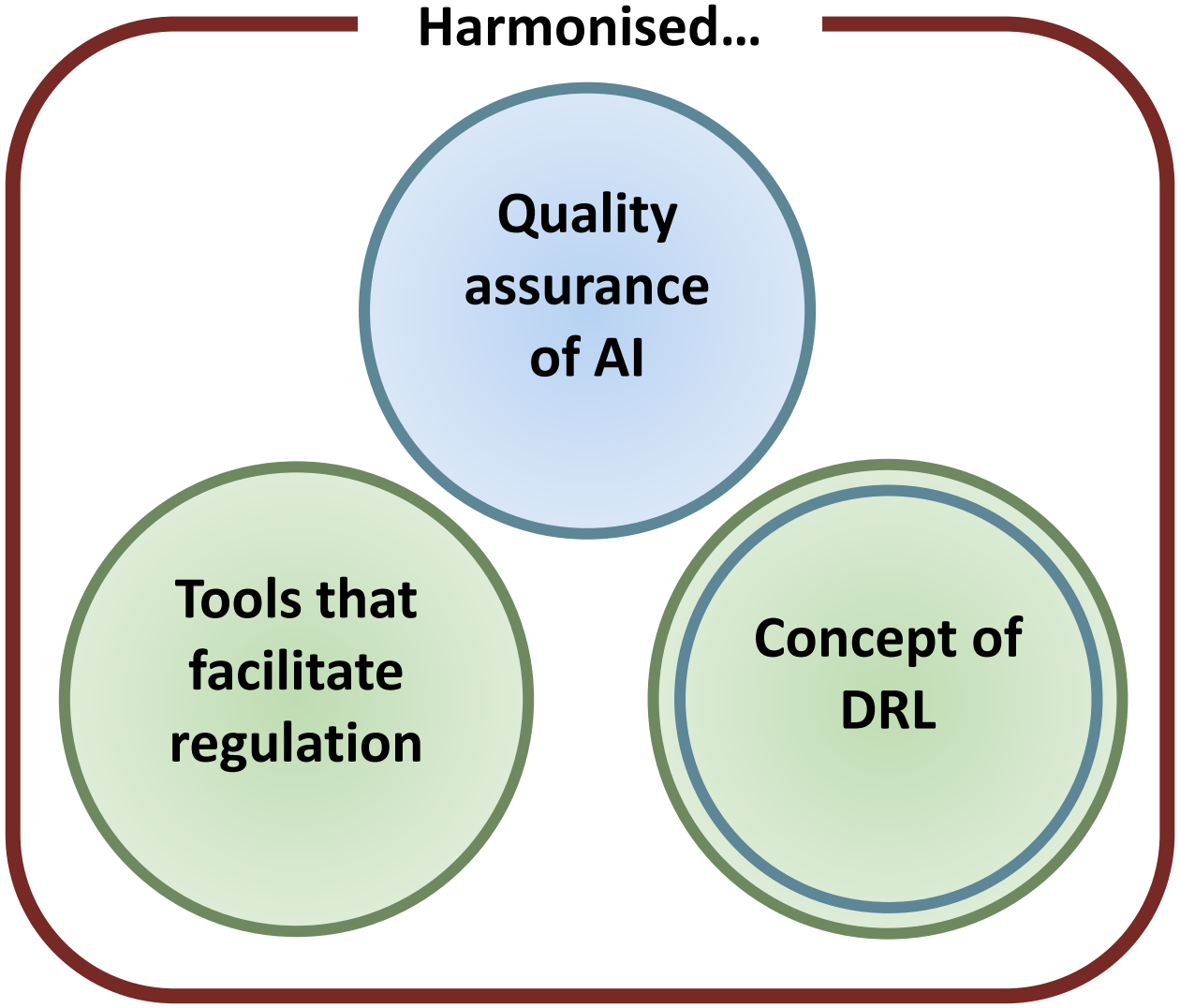
	A	B	C	D	E	F	G	H	I	J
1	ID der RX	Untersuchungscode	DFP	AGD	DLP	CTDI	CTDIPhantom	Patientengewicht	Alter	
203	88	2035	80,04							
204	88	2035	101,08							
205	88	2035	399,45							
206	88	2035	23,85							
207	88	2035	23,83							
208	190	1010				45	16			
209	190	1010				45	16			
210	190	1010				34	16			
211	190	1010				43	16			
212	190	1010				54	16			
213	190	1010				42	16			

IDs

Examination codes

Exposure data

Discussion



Can we enforce European principles on public and private initiatives?

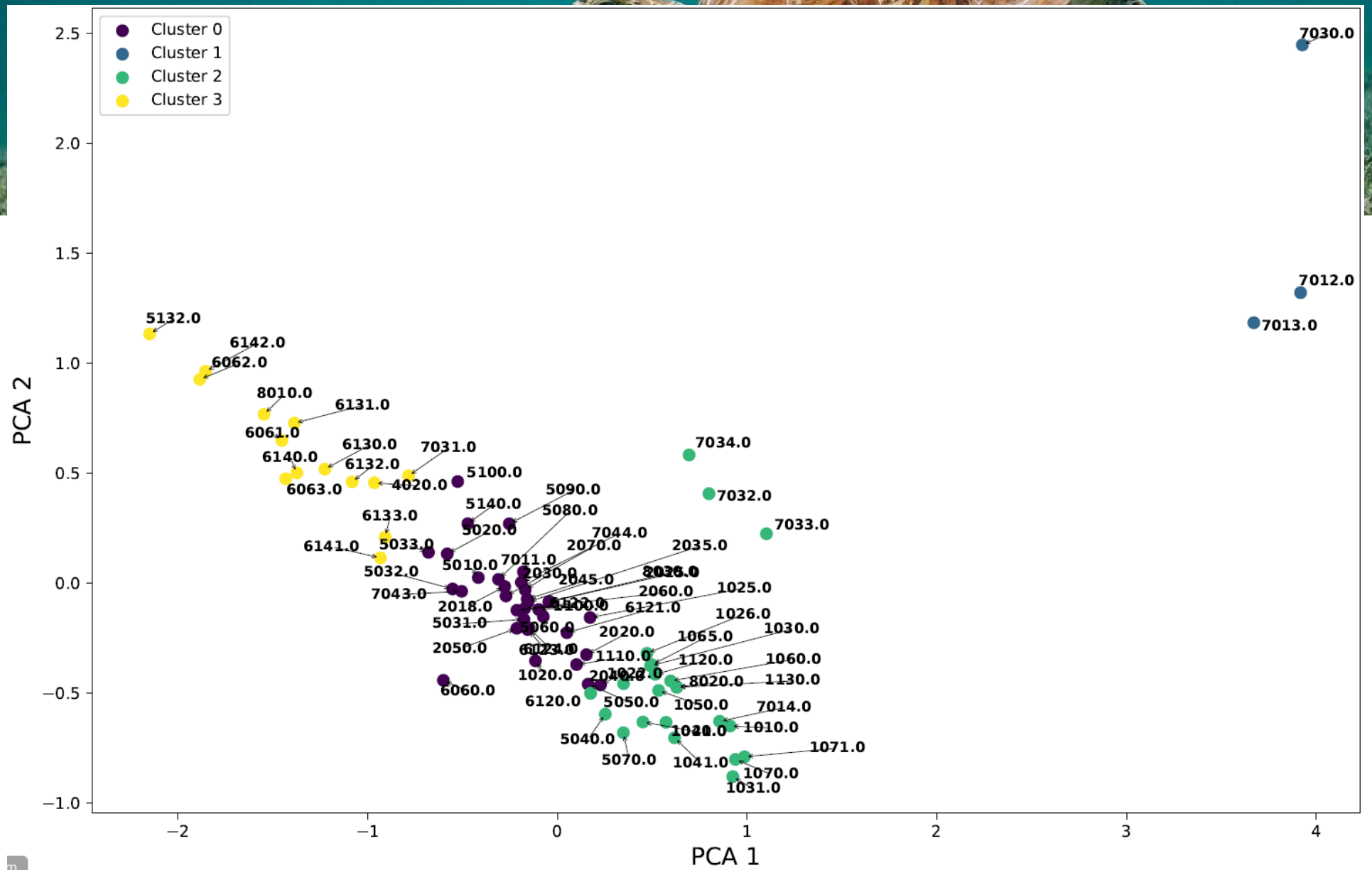
How to improve the cooperation among authorities, researchers and vendors?

How can AI help to harmonise and analyse the international (“big”) data?

Can we construct a platform for (AI-)assisted update of DRLs?

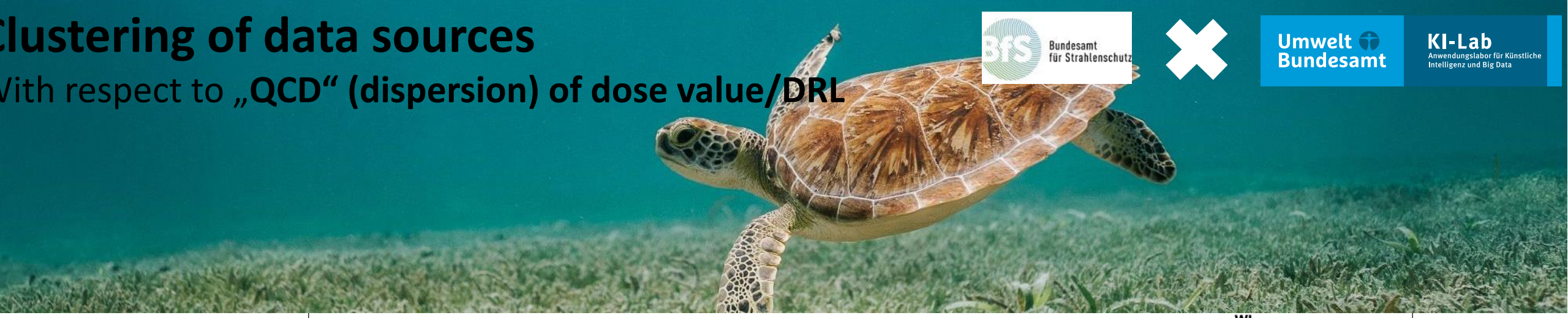
Clustering of Codes

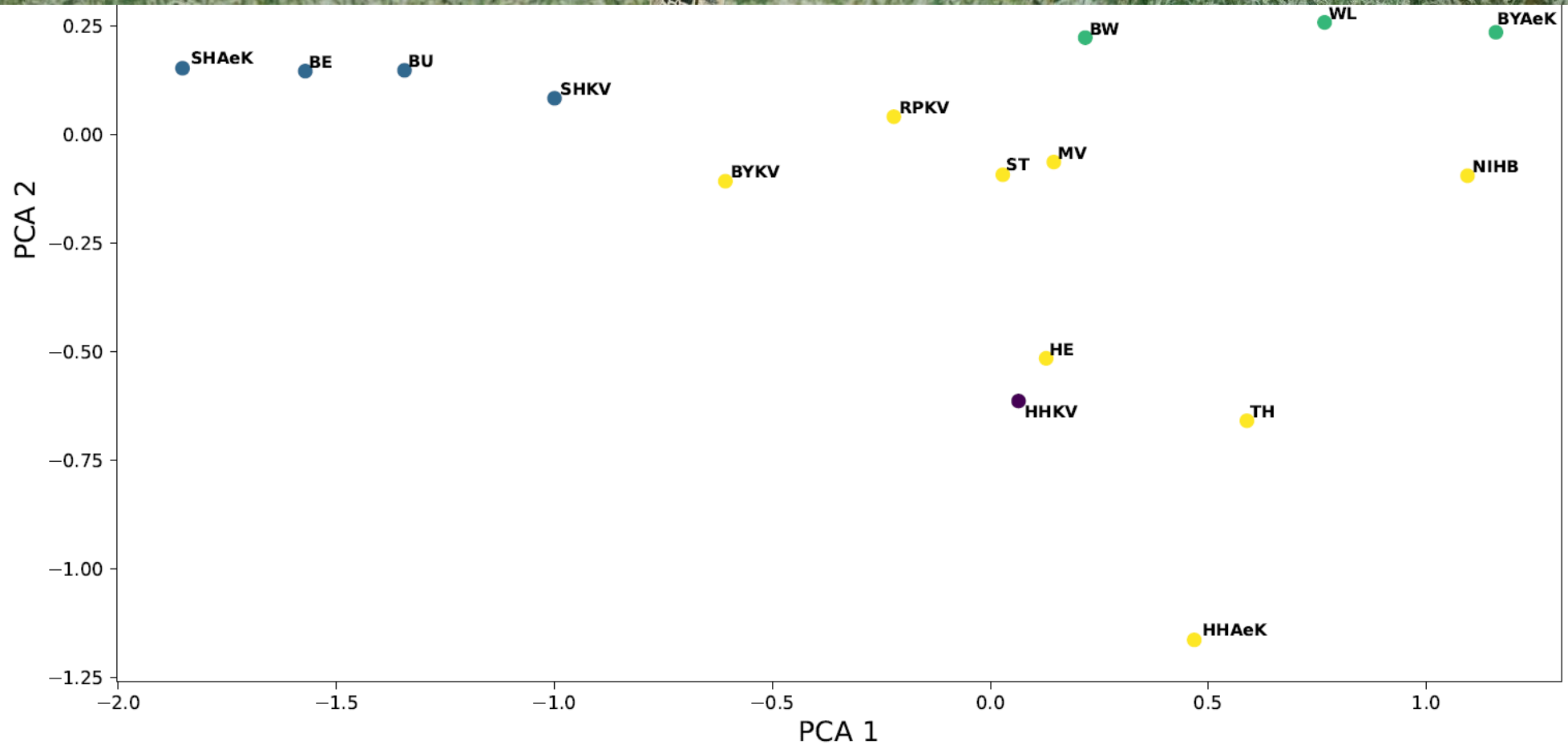
With respect to **Median of dose value/DRL**



Clustering of data sources

With respect to „QCD“ (dispersion) of dose value/DRL





PIANOFORTE WP5 objectives

EUROPEAN PARTNERSHIP FOR
RADIATION PROTECTION RESEARCH

- Oversight committee for infrastructures
- Access cross-national infrastructures
- Harmonization of quality standards, practices and protocols
- Utilisation, novel uses and inter-operability
- FAIR (findable, accessible, interoperable and reusable) data management

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WE NEED RESEARCH FOR…

1. Quality assurance of other new technologies (Not necessarily with AI) (BSS Article 60.1 and MDR Article 16.1.b)

Develop quality assurance in diagnostics

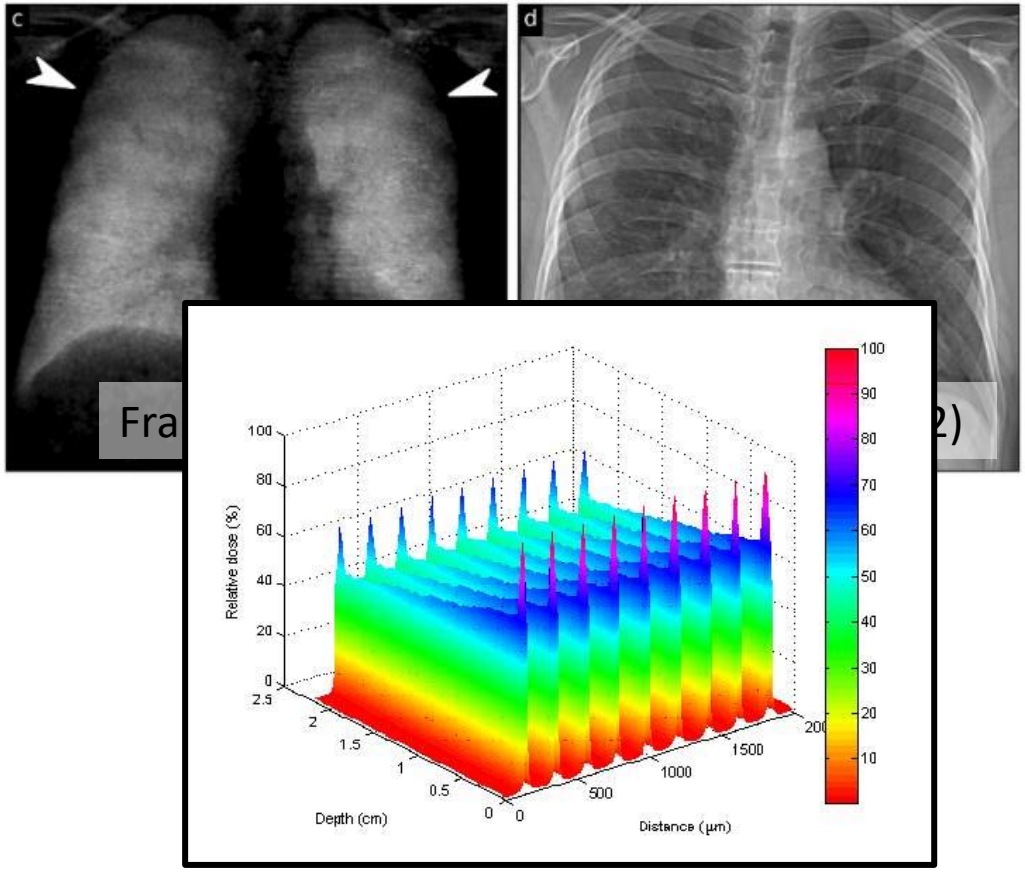
- Ex: Monochromatic x-rays, x-ray fluorescence
- Ex.: Dark-field, phase-contrast imaging

Develop quality assurance in therapy

- Ex.: FLASH therapy (proton, electron)
- Ex.: Heavy ions, micro and nanobeam therapy

Question:

Must/Can we define QA procedures tailored to all new technologies?



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WE NEED RESEARCH FOR…

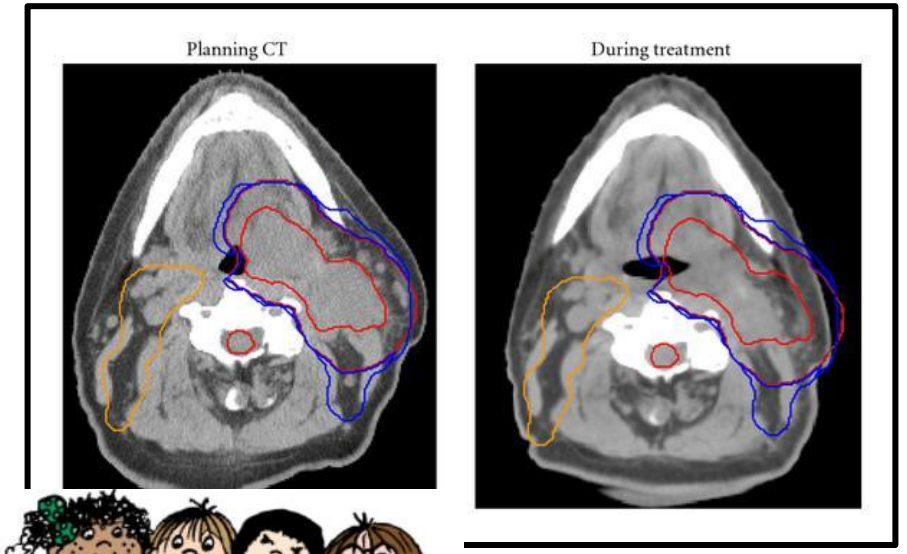
2. quality assurance of new AI for radiotherapy

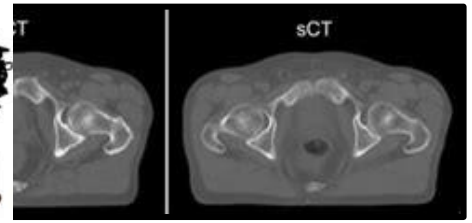
Optimisation including QA (BSS Article 56)

- Ex: Automatic segmentation and adaptive EBRT
- Ex: Synthetic computed tomography (sCT)

Accidental, unintended exposures (BSS Article 63)

- Automated quality assurance models





Studies are required to develop standards for QA of these new technologies