# Software for Dose Registry – practical aspects

## Seminar of the Federal Commission on Radiation Protection (KSR) – Radiation Protection in Medicine

**Thiago V. M. Lima PhD**
Medical Physics Expert
Institute for Radiology and Nuclear Medicine
Luzerner Kantonsspital

29.01.2021

luzerner kantonsspital
LUZERN SURSEE WOLHUSEN

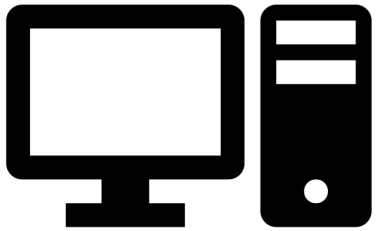
# Content

- Introduction and Legislation
- Dose registry software (Dose Management Systems) requirements
  - Common Features
  - Vendor Specific Features
- National Registries
  - Success stories
    - American College of Radiology (ACR) - NRDR
  - Swiss National CT Dose Registry Project
- Conclusion

# Introduction

Typical questions about software for dose registry are:

- Am I legaly oblighted to have one?
- What does it actually do?

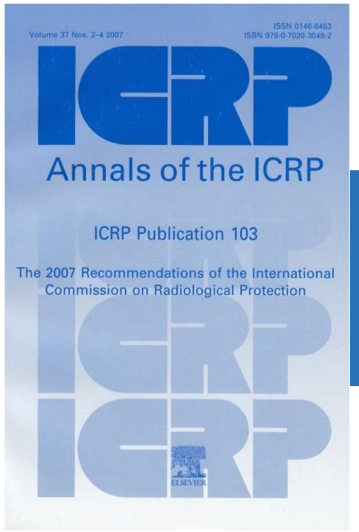


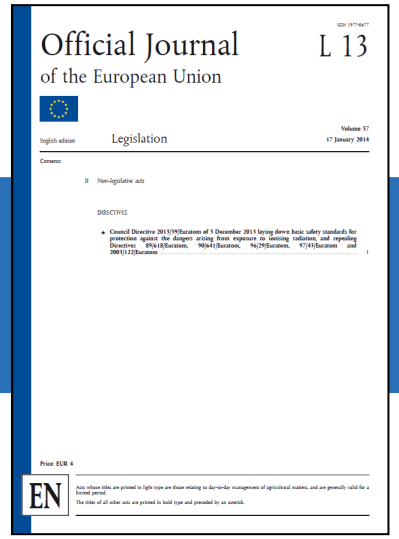
**What is not included in my talk:**

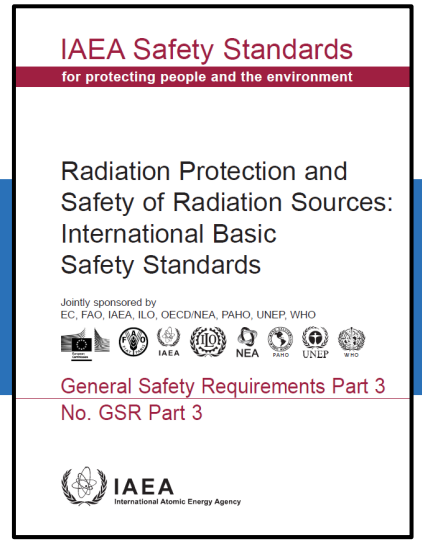
- The answer if you should or not buy a software (there are free options)
- Or even which software to get

# Swiss Legislation

## Radiation Protection Ordinance (StSV/ORaP)




**Strahlenschutzverordnung**
**(StSV)**

**814.501**

vom 26. April 2017 (Stand am 1. Januar 2021)

*Der Schweizerische Bundesrat,*
gestützt auf das Strahlenschutzgesetz vom 22. März 1991[1] (StSG)
und auf Artikel 83 des Bundesgesetzes vom 20. März 1981[2] über die Unfallversicherung,
*verordnet:*

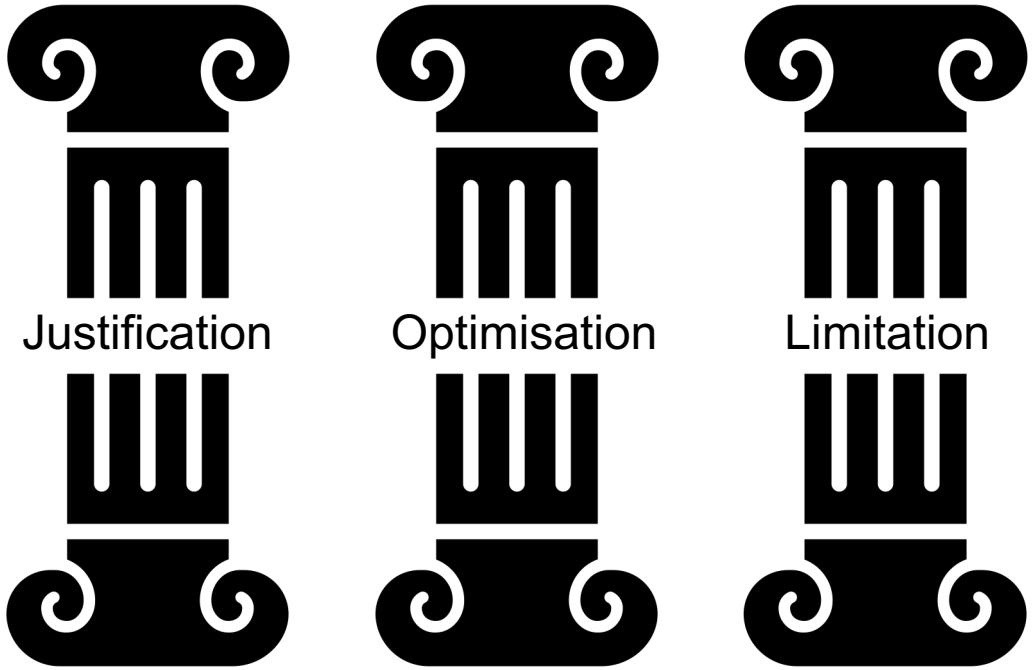
**1. Titel: Allgemeine Bestimmungen**
**1. Kapitel: Gegenstand, Geltungsbereich und Begriffe**

**Art. 1** Gegenstand und Geltungsbereich

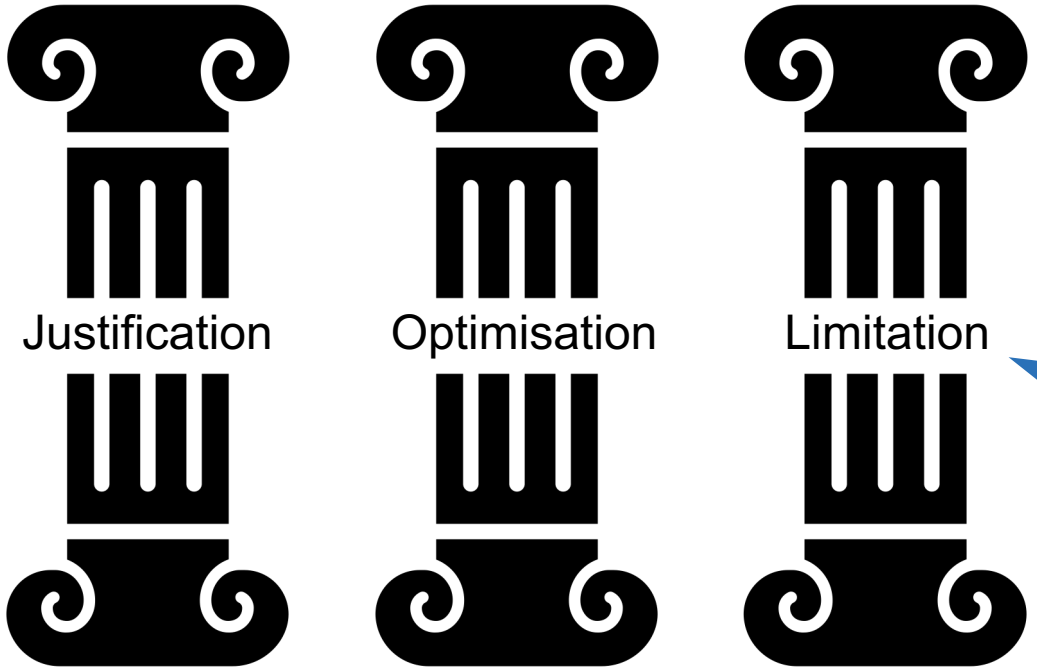
[1] Diese Verordnung regelt zum Schutz des Menschen und der Umwelt vor ionisierender Strahlung:

a. für geplante Expositionssituationen:
   1. die Bewilligungen,
   2. die Exposition der Bevölkerung,
   3. nicht gerechtfertigte Tätigkeiten,
   4. die medizinische Exposition,
   5. die berufliche Exposition

# Bases of Radiation Protection



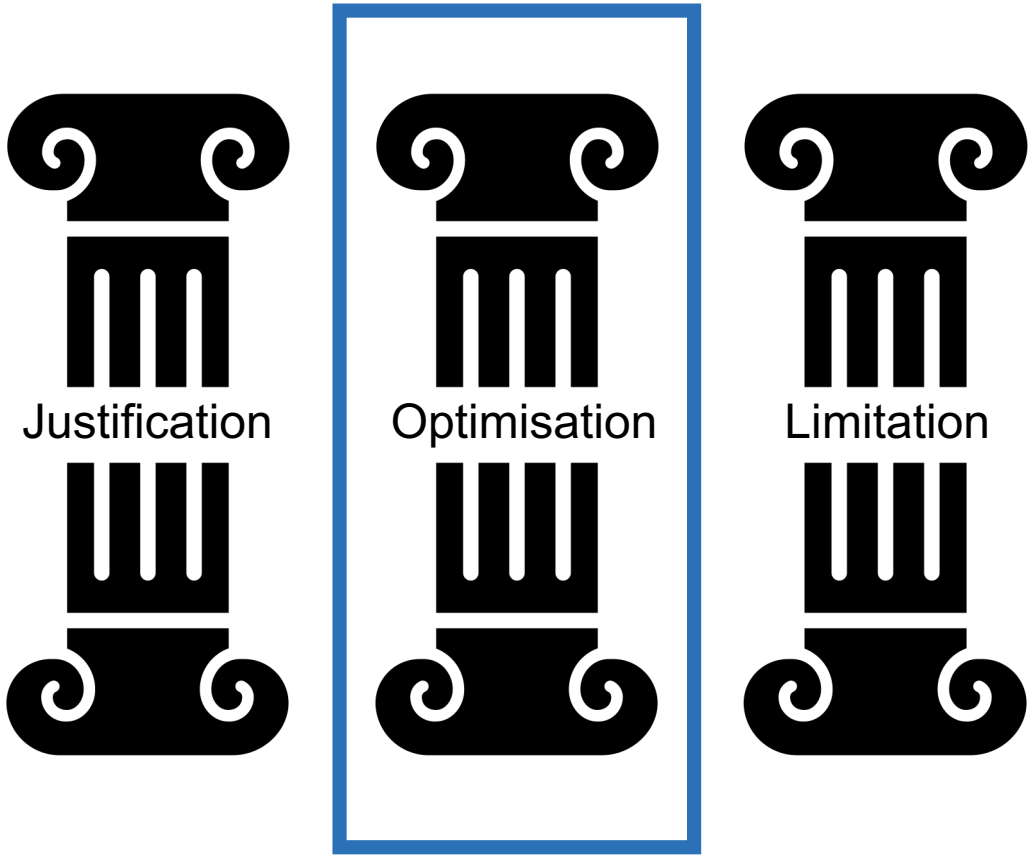
# Bases of Radiation Protection



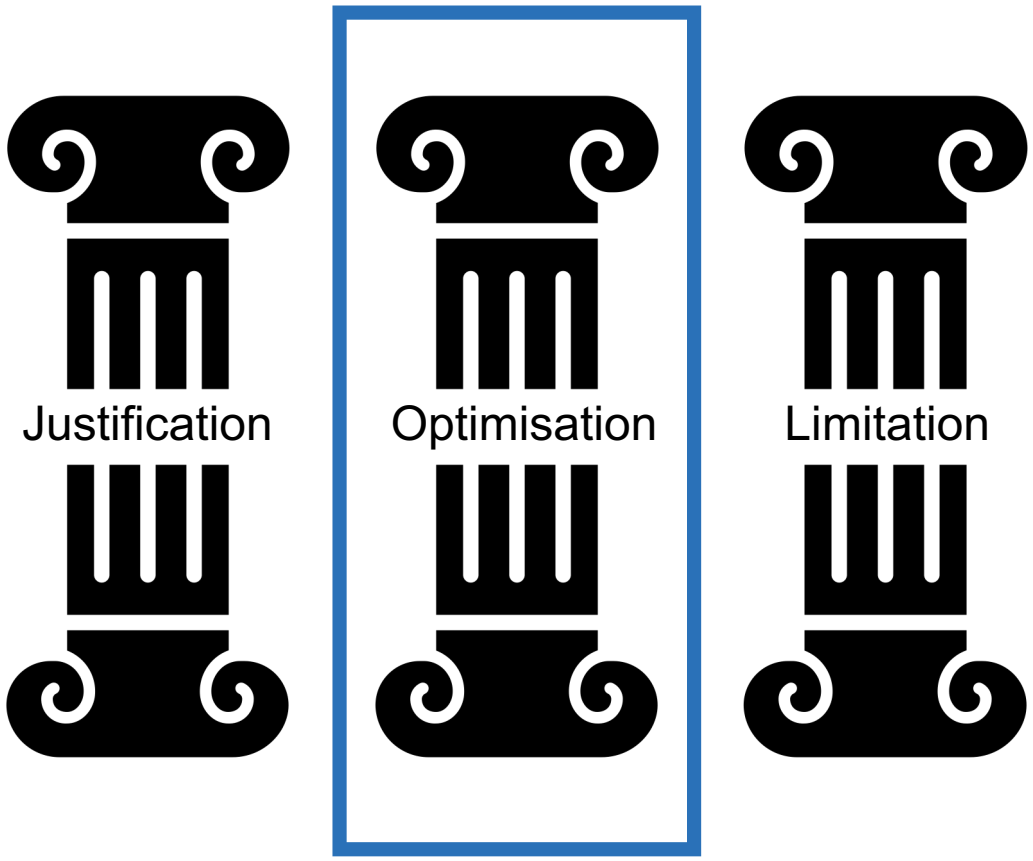

**RPO Art 5 Dose limits:**

For planned exposure situations, limits shall be specified which must not be exceeded by the sum of all radiation doses accumulated by a person in a calendar year (dose limit). **For medical exposures, no such limits shall be specified.**

# Bases of Radiation Protection



# Bases of Radiation Protection

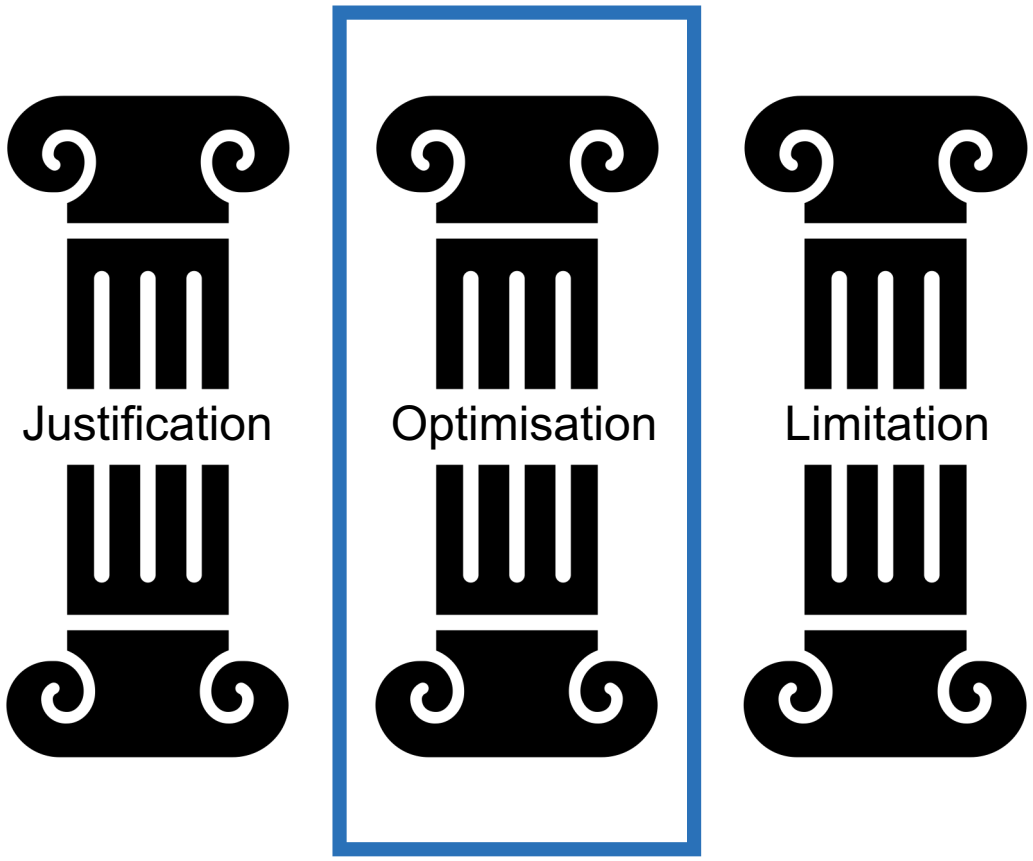



**Section 3 Medical Optimisation**
**Art. 32 Optimisation of medical exposures**

1 In diagnostic, interventional radiology and nuclear medicine examinations, **the licence holder must keep all radiation doses as low as achievable consistent with obtaining the required imaging information.**

2 For all therapeutic exposures, the licence holder must carry out individual dosimetric planning. The doses for risk organs must be kept as low as is achievable and consistent with the intended radiotherapeutic purpose.

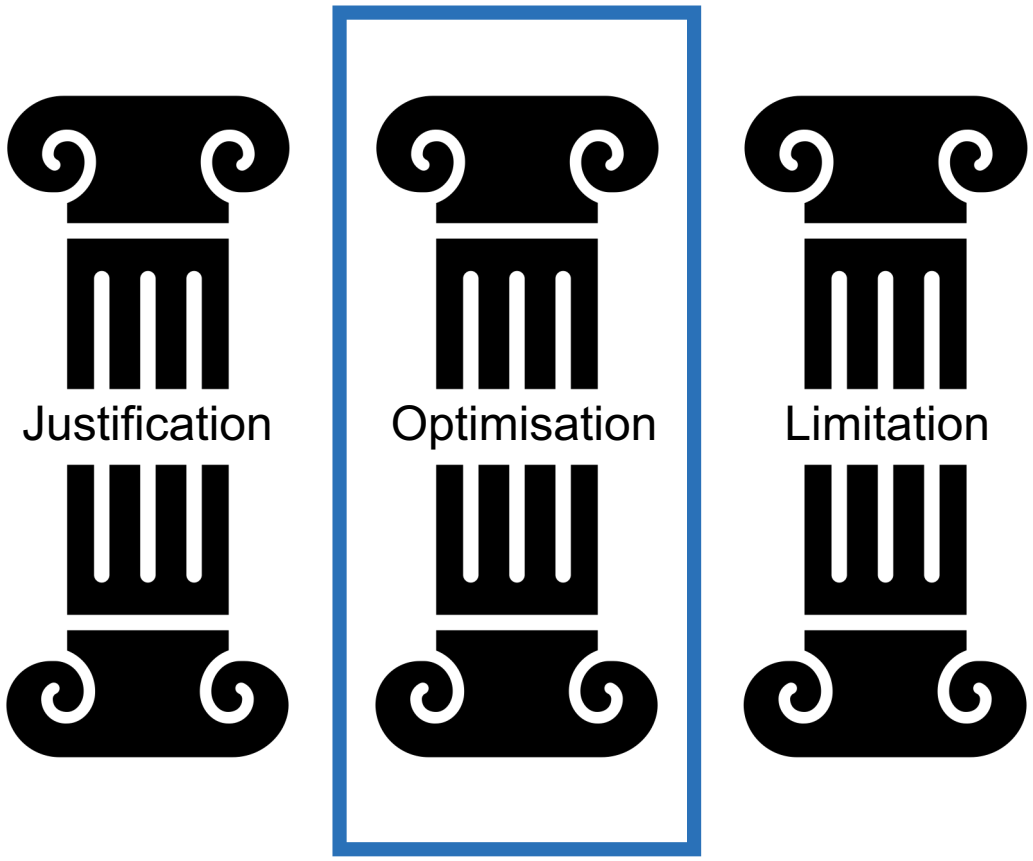
# Bases of Radiation Protection




[3] For the **protection of patients, the optimisation process involves in particular**:
a.selection of suitable equipment, including software;
b.consistent production of adequate diagnostic information or therapeutic outcomes;
c.the practical aspects of procedures;
d.quality assurance;
e.**assessment and evaluation of the patient dose or the administered activity**;
f.use of appropriate set-up parameters or appropriate radionuclides;
g.use of sensitive detectors;
h.for every medical installation, use of the elements required for the protection of patients.

[4] **The dose received by personnel must be taken into account in the optimisation process.**
[5] The FDHA may issue technical optimisation provisions for the protection of patients.

# Bases of Radiation Protection




**Art. 33 Documentation obligation**

**The licence holder must document** all therapeutic and diagnostic exposures in the medium-dose or high-dose range and in mammography in such a way that the **radiation dose received by the patient can be determined at a later date**.

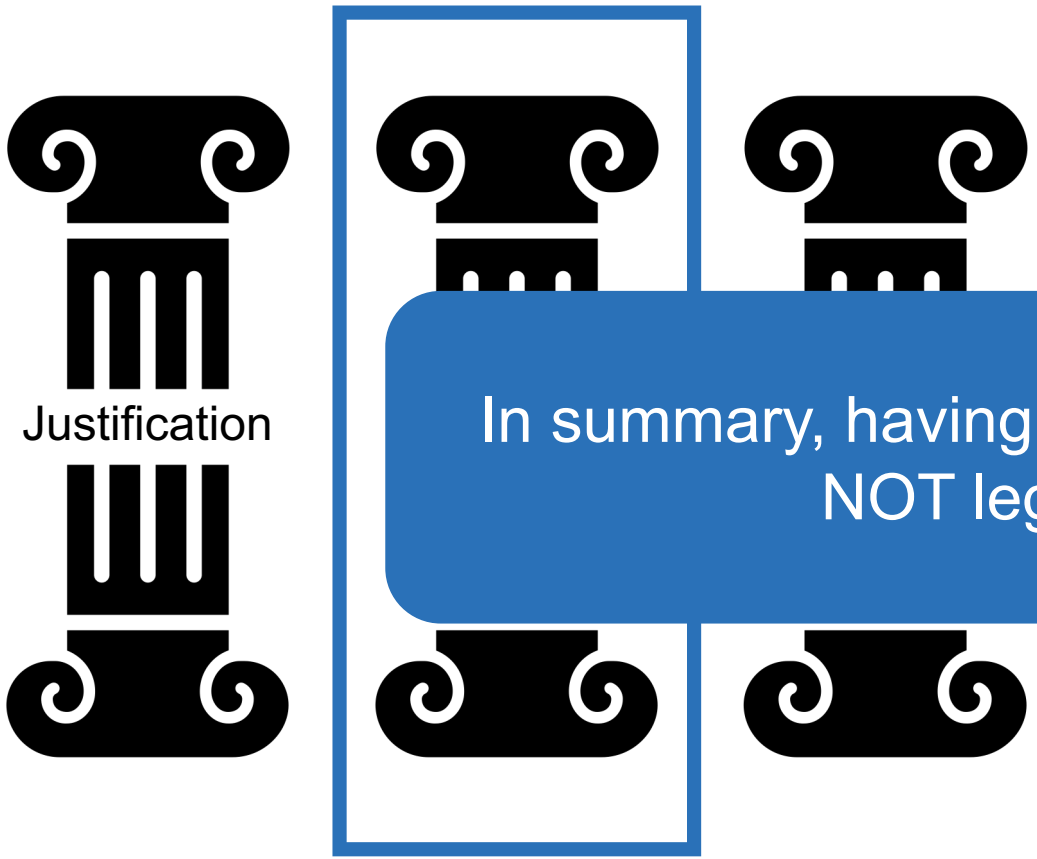
**Art. 35 Diagnostic reference levels**

[1] The FOPH shall publish recommendations on radiation doses for diagnostic, interventional or nuclear medicine examinations in the form of diagnostic reference levels.

[2] To this end, it shall conduct national surveys based on the data specified in Article 34 paragraph 2, take international recommendations into account and publish the results.

[3] **License holders must regularly review their own practices and account for any deviations from diagnostic reference levels.**

# Bases of Radiation Protection




**Art. 33 Documentation obligation**

**The licence holder must document** all therapeutic and diagnostic exposures in the medium-dose or high-dose range and in mammography in such a way that the **radiation dose received by the patient can be determined at a later date**.

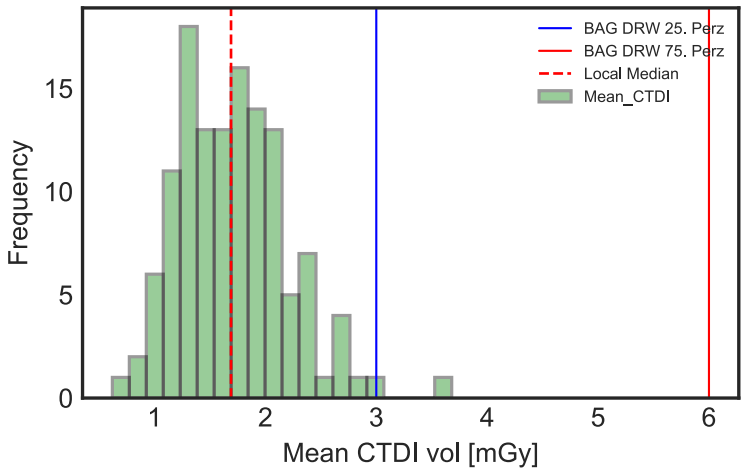
**…vels**

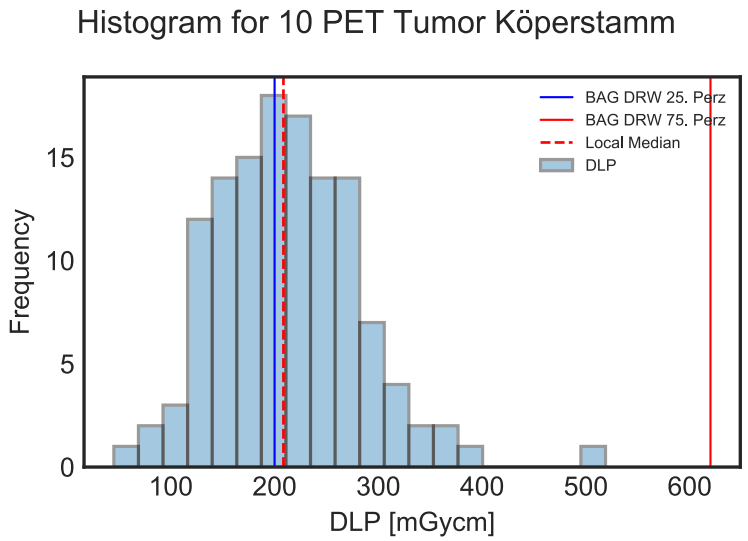
…mendations on radiation …al or nuclear medicine …ostic reference levels. …onal surveys based on the data specified in Article 34 paragraph 2, take international recommendations into account and publish the results.

3 **Licence holders must regularly review their own practices and account for any deviations from diagnostic reference levels.**

In summary, having such registry software IS NOT legaly required.

# Dose Evaluation and Optimisation



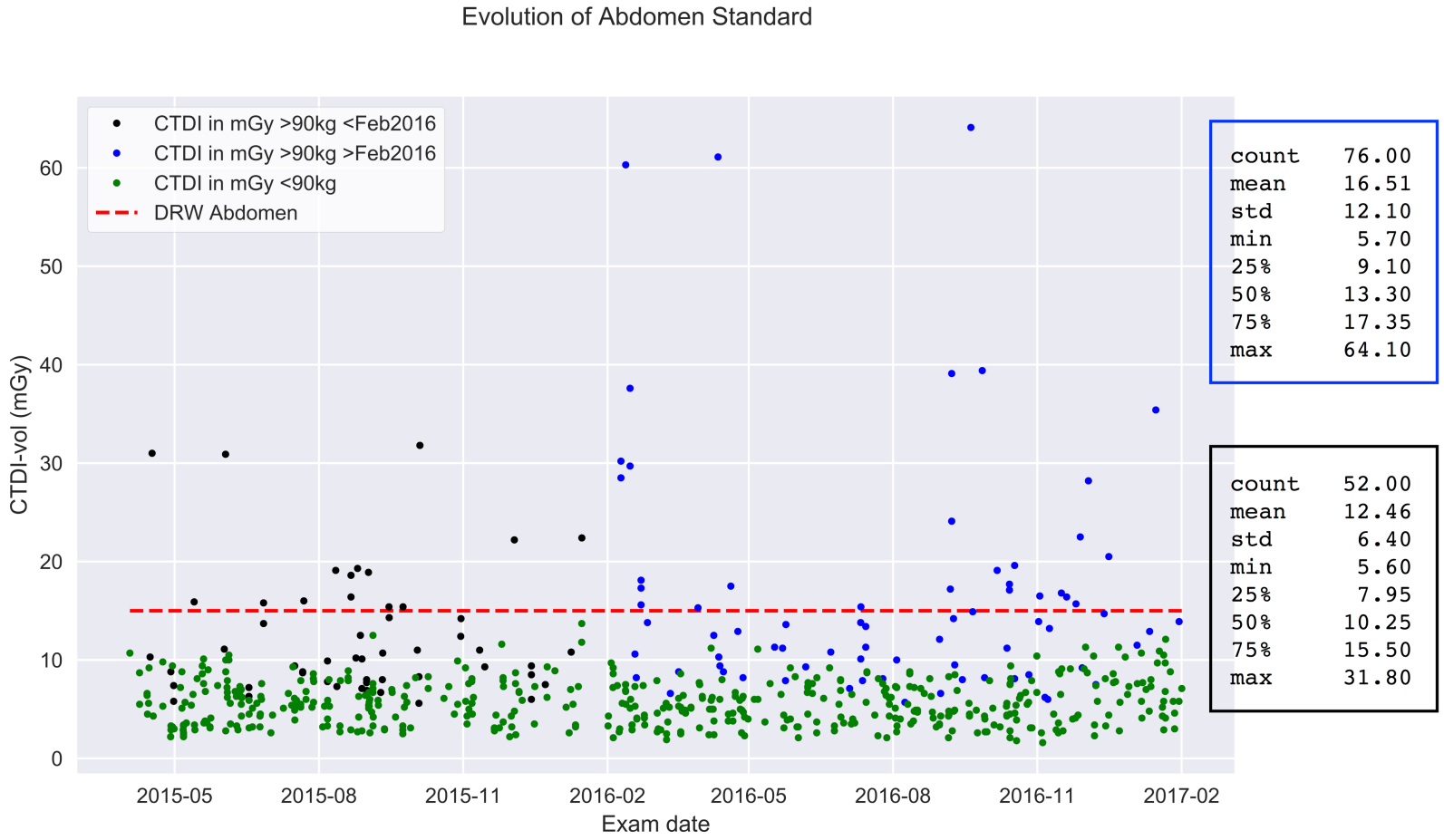

| | |
|---|---|
| Interne Protokoll | CT TK |
| BAG ref. Protokoll | 10 PET Tumor Köperstamm |
| Untersuchungen von | 20201001 |
| bis | 20201120 |
| Anzahl Studien | 127 |

| | Mean CTDIvol [mGy] | DLP [mGycm] |
|---|---|---|
| Minimum | 0.62 | 45.1 |
| 25. Perz | 1.32 | 163.6 |
| Median | 1.69 | 208.5 |
| 75. Perz | 2.02 | 253.2 |
| Maximum | 3.68 | 518.9 |

| | | |
|---|---|---|
| Zielgroesse BAG | 3 | 200 |
| DRW BAG | 6 | 620 |

Can you do it without the software? Yes!

# You can even do very fancy stuff

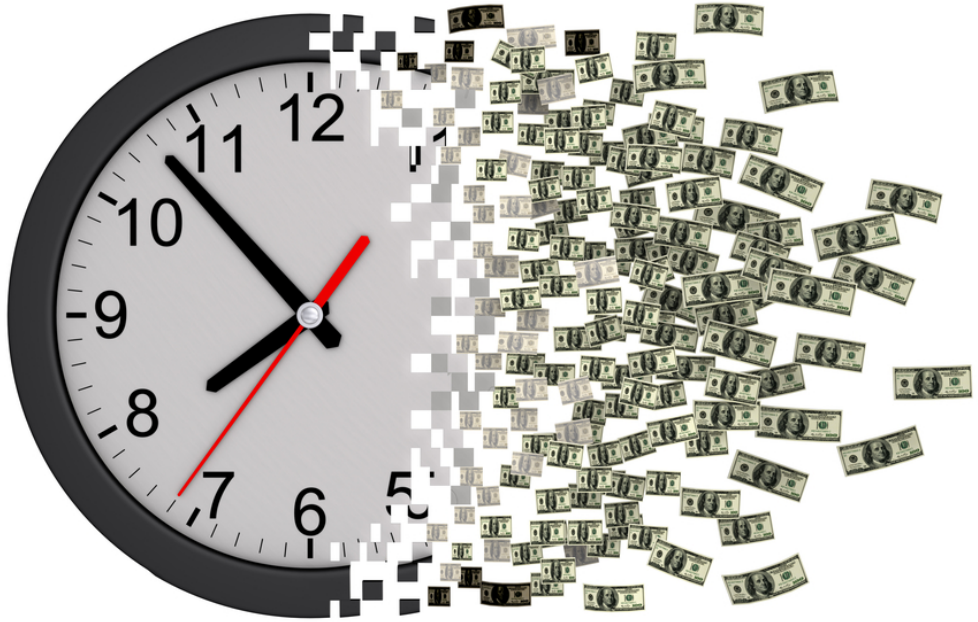



Lima, Thiago; Schindera, Sebastian; Scheidegger, Stephan ; Lutters, Gerd, 2018. *Connecting the missing piece: a retrospective evaluation of image quality and dose in respect to the parameters variability for a clinical CT protocol* ECR 2018, EuroSafe Imaging, Vienna, 28 February - 4 March 2018.

# …but…,

Individual dose information is stored in a PACS, systematic and comprehensive analysis usually requires high manual effort. But such an analysis of ionising radiation is inevitable for **improvements in radiological processes**.

- Medical Physicist, Radiologist/Nuclear Medicine Physician and Radiographer (MTRA/TRM) resources are limited
- And by using software registries, the local teams are able to streamline/ optimise their workflow



Disclaimer: There are different dose registry software, some are comercial tools others are freely available. During this presentation I will mention the name and features of different solutions, but neither myself nor my employer is finantially supported by these solutions.

# Radiation Dose Management System – requirements and recommendation

- Dose management systems (DMS) are **recommended but not mandatory** for X-ray equipment users, to comply with new radiation protection requirements like the EU-BSS.
- DMS are designed for medical practitioners, radiographers, medical physics experts (MPE) and other health professionals involved in imaging to **support their tasks and duties of radiation protection** in accordance with local and national requirements.
- In particular, the requirement according to the ALARA principle is to perform X-ray examinations with the aim to achieve a minimum dose level but maintaining a sufficient image quality or diagnostic accuracy, for the clinical indication.

European Radiology
https://doi.org/10.1007/s00330-020-07290-x

RADIOLOGICAL EDUCATION

## Radiation dose management systems—requirements and recommendations for users from the ESR EuroSafe Imaging initiative

Reinhard W. Loose[1,2] · Eliseo Vano[3] · Peter Mildenberger[4] · Virginia Tsapaki[5] · Davide Caramella[6] · Johan Sjöberg[7] · Graciano Paulo[8] · Alberto Torresin[9] · Sebastian Schindera[10] · Guy Frija[11] · John Damilakis[12] · on behalf of the European Society of Radiology (ESR)[13]

Received: 21 August 2020 / Revised: 7 September 2020 / Accepted: 11 September 2020

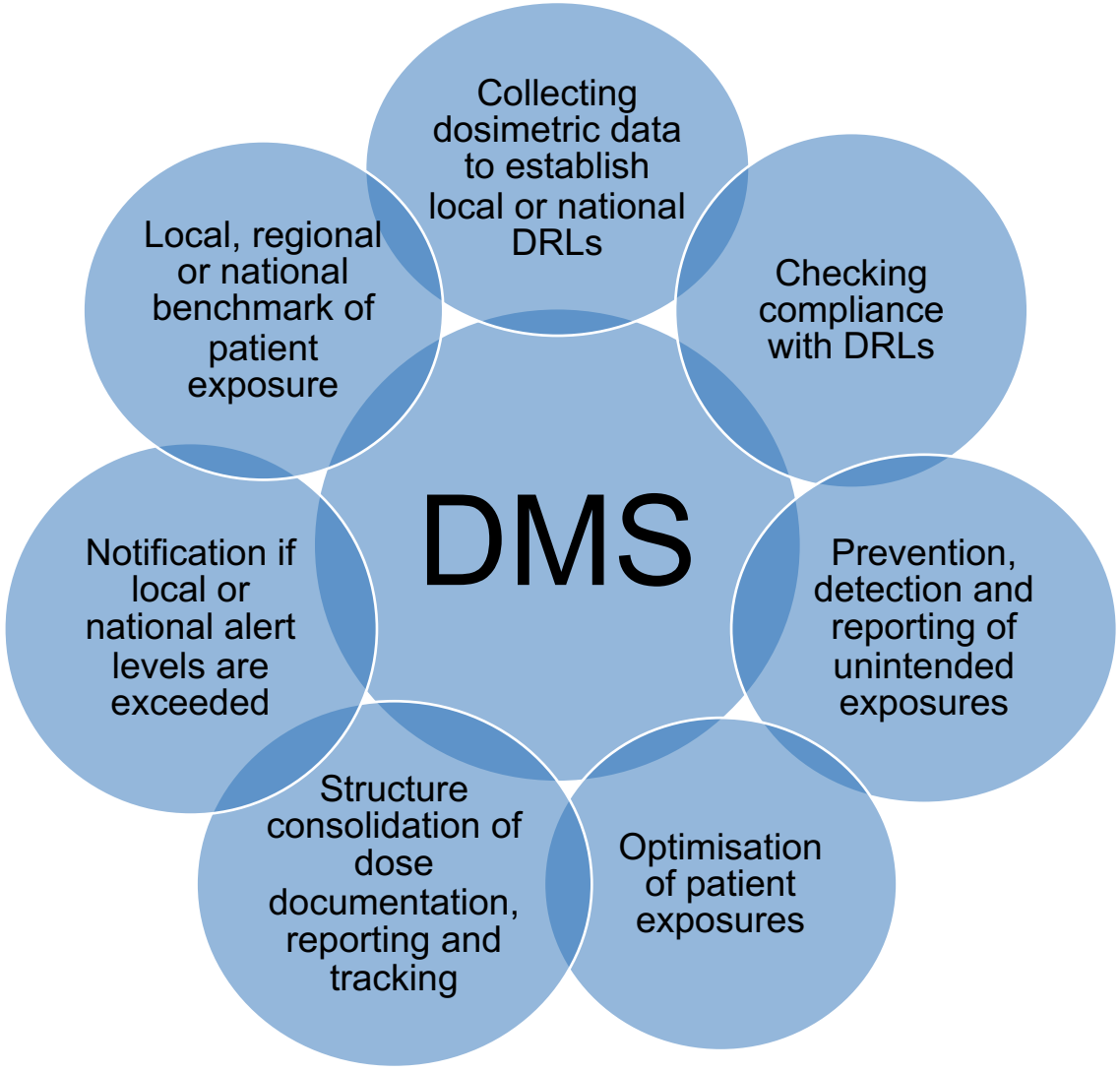

**Abstract**
The European Directive 2013/ ion to ensure justification and optimisation of radiological procedures and quality assurance. The EuroSafe Imaging campaign of the European Soc ose Management" with the aim to provide European recommendations o MS) in clinical practice. The WG follows Action 4: "Promote dose mana ean diagnostic reference levels (DRL)" of the EuroSafe Imaging Call for rs, radiographers, medical physics experts (MPE) and other health profes uties of radiation protection in accordance with local and national require s when installing a DMS and classified the individual functions at differe

+ my personal findings

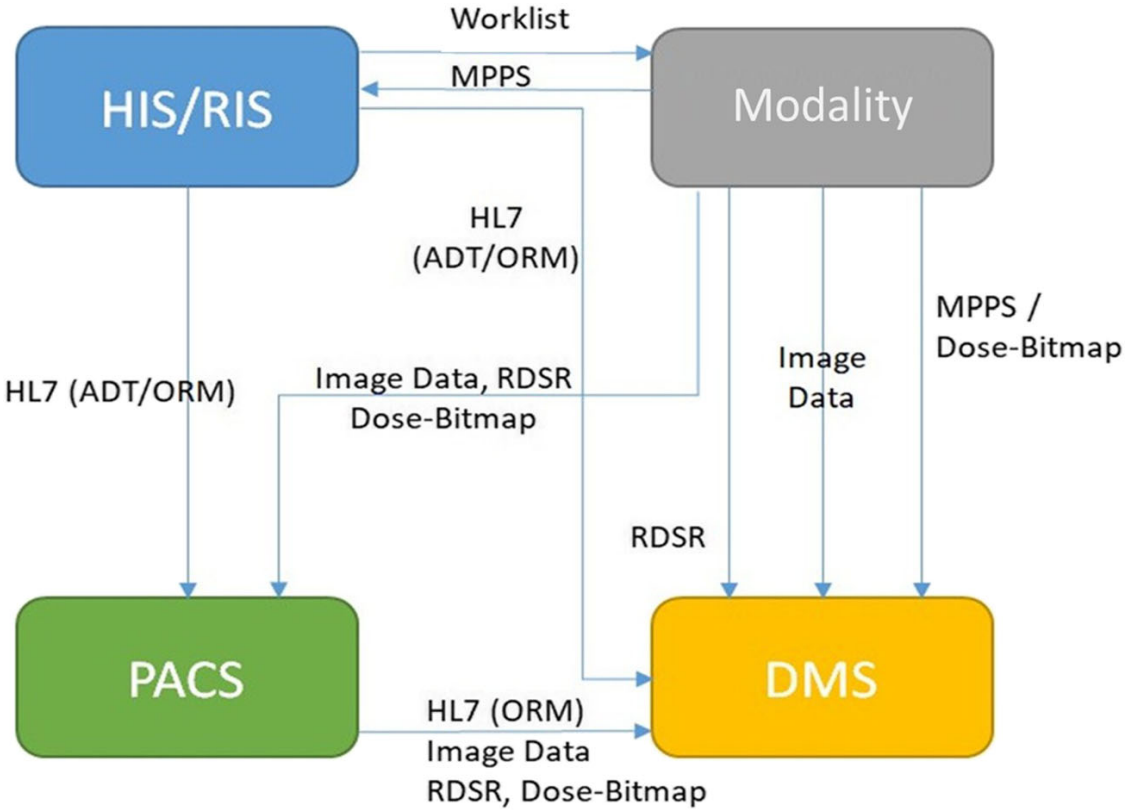
**Key Points**
- *DMS are very helpful software tools for [illegible] optimisation, compliance with DRLs and quality assurance.*
- *DMS can help to fulfil dosimetric aspects of the European Directive 2013/59/Euratom.*
- *The EuroSafe WG analyses DMS requirements and gives recommendations for users.*

**Keywords** Dose management systems · Radiation protection · Optimisation · Quality assurance

# Clinical Radiation Protection tasks supported by the DMS

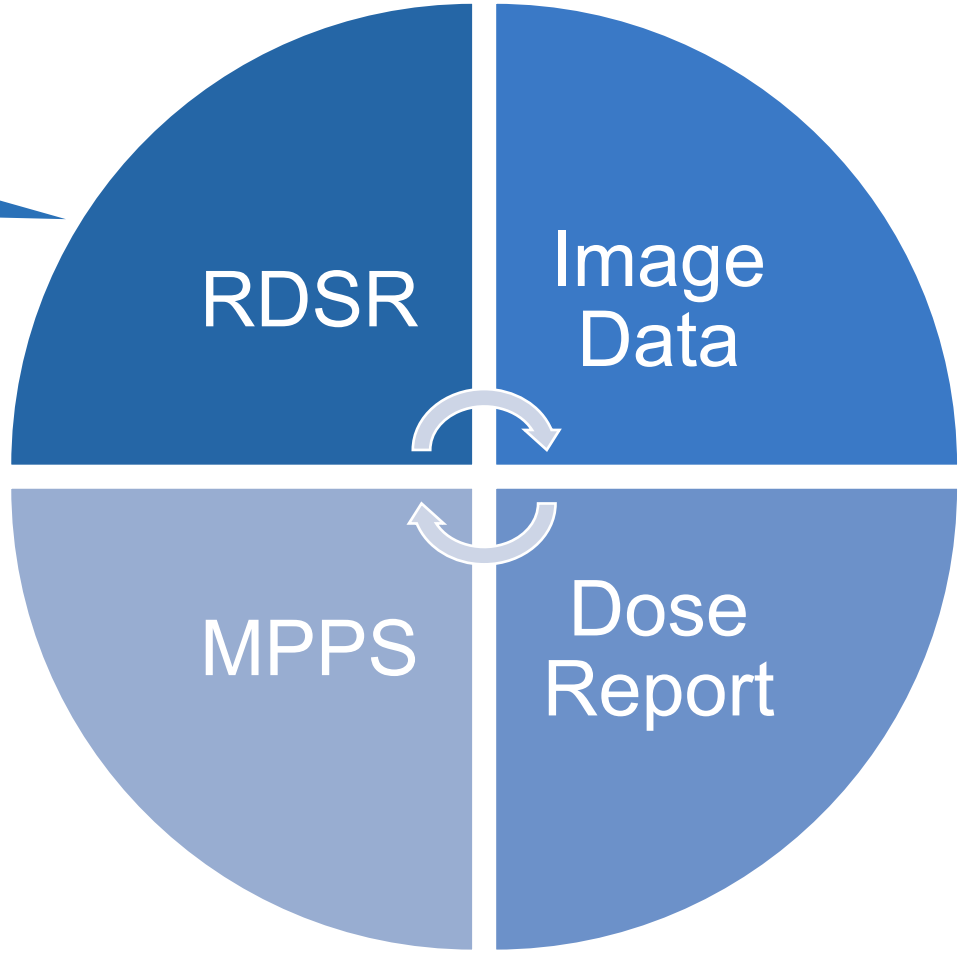


# Typical set-up of the DMS within IT infrastructure



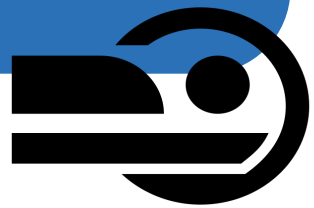
# Data Requirements

Prefered method as it contains most information that is needed for a full analysis



# Basic Requirements

These systems should use physical device–related DICOM dose parameters



Store dose data in a database

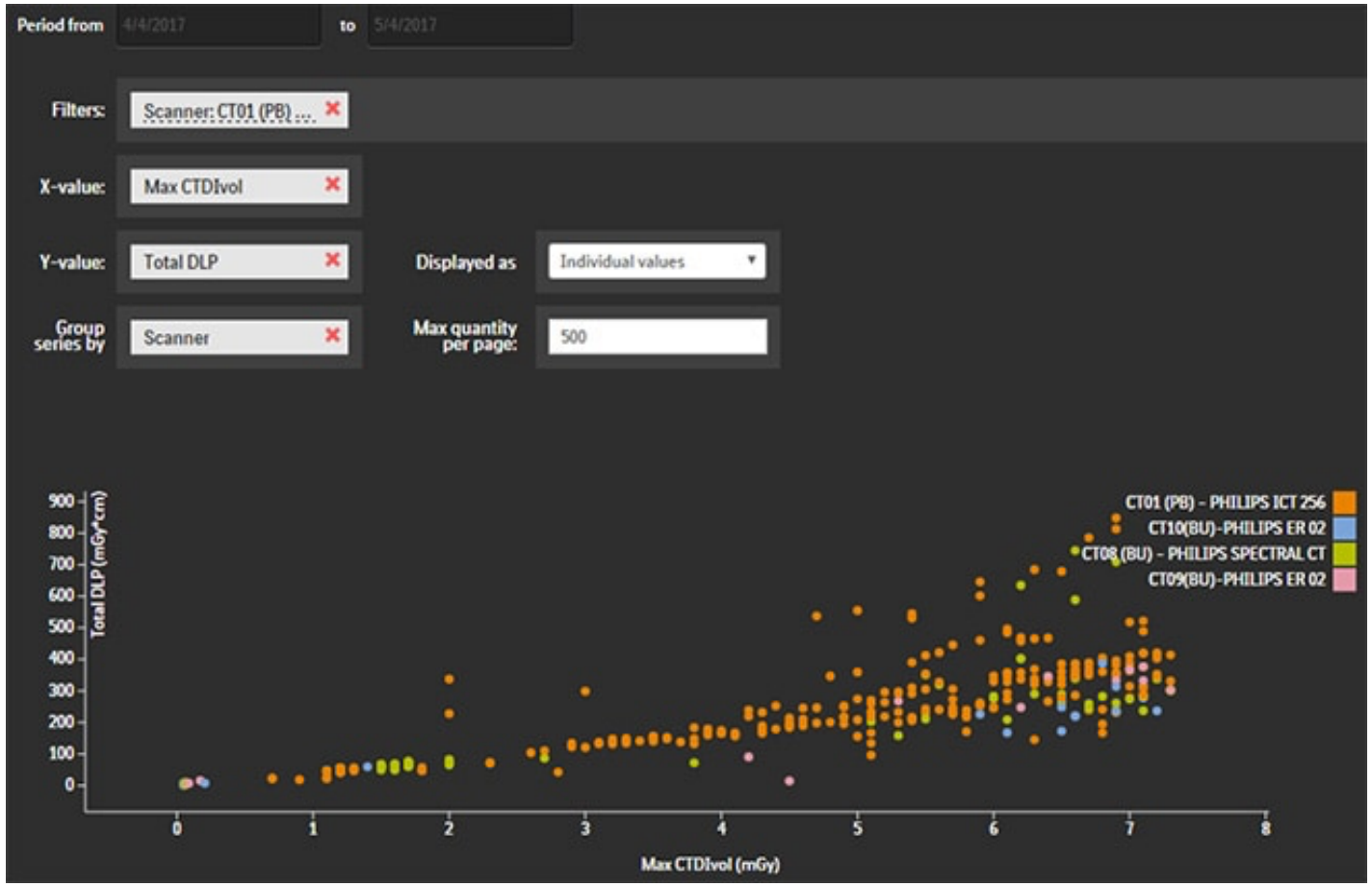
Local procedure names should be translated into standardised procedure names

Set alert trigger levels (local and national).

Export dose data for optimisation, QA, reporting (e.g. to national authority) and post processing

# Typical features

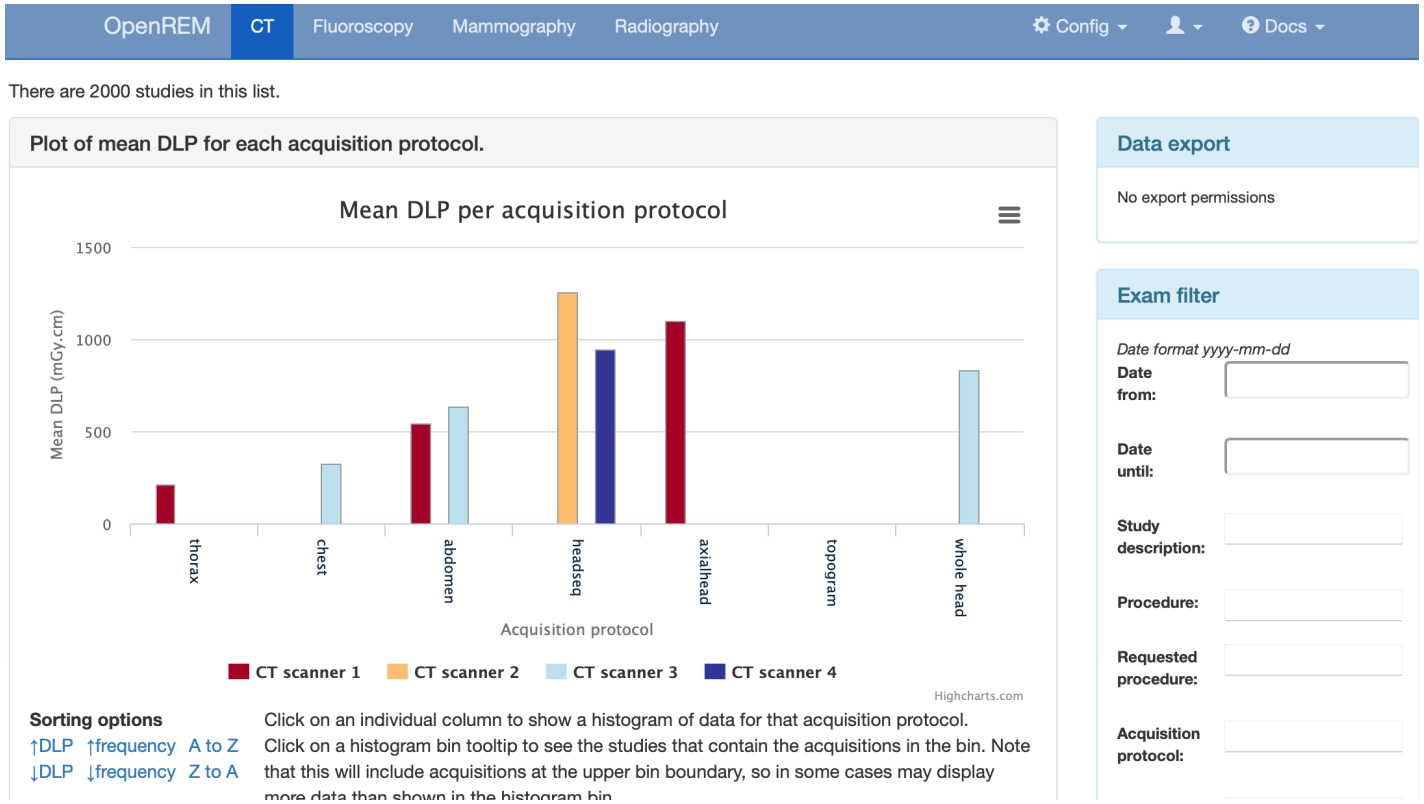
- Analysis of different dosimetric parameters (CTDIvol, DLP, DAP, …) and/versus device.




Philips - DoseWise

# Typical features

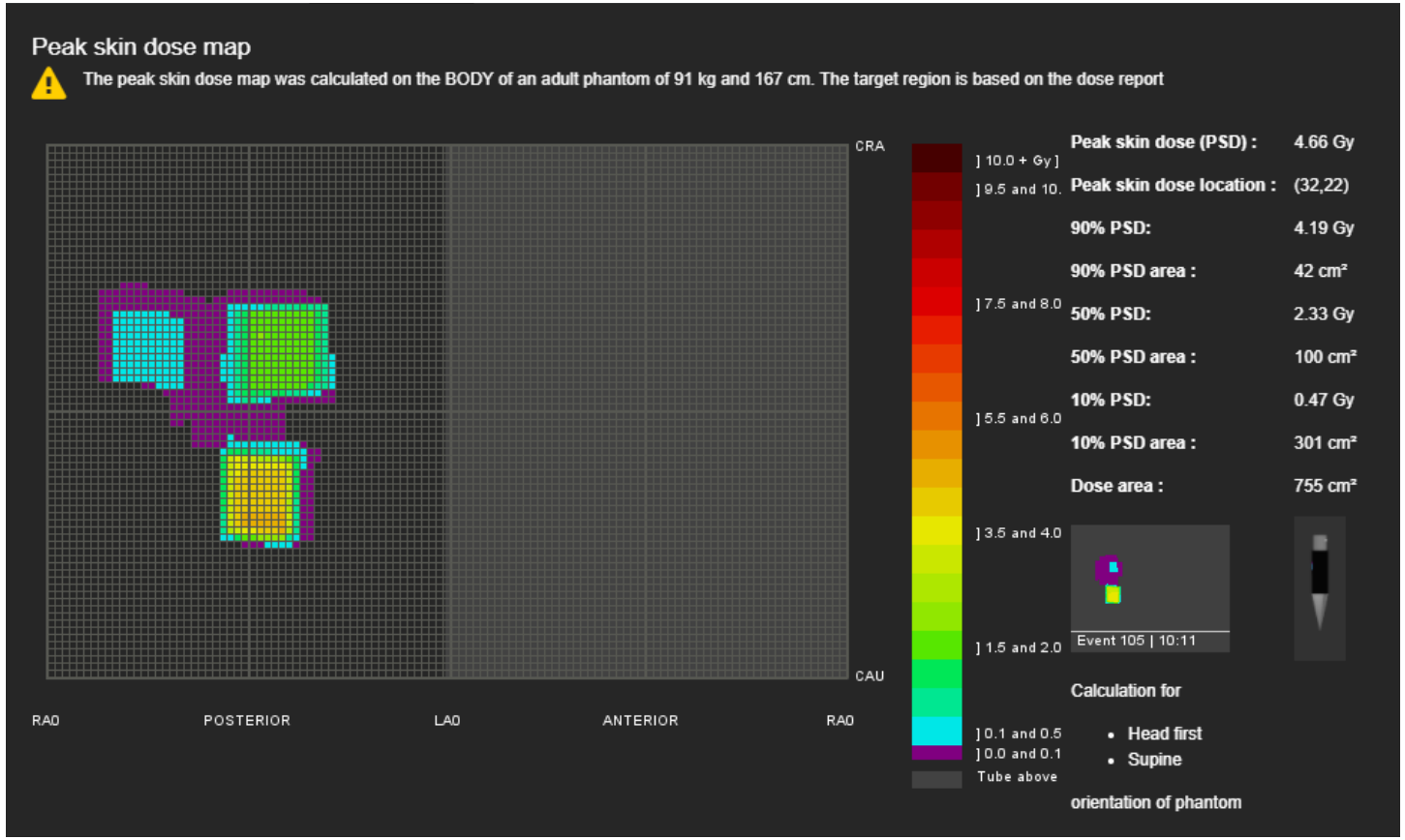
- Analysis of different dosimetric parameters (CTDIvol, DLP, DAP, …) and/versus protocol.




OpenREM

# Typical features

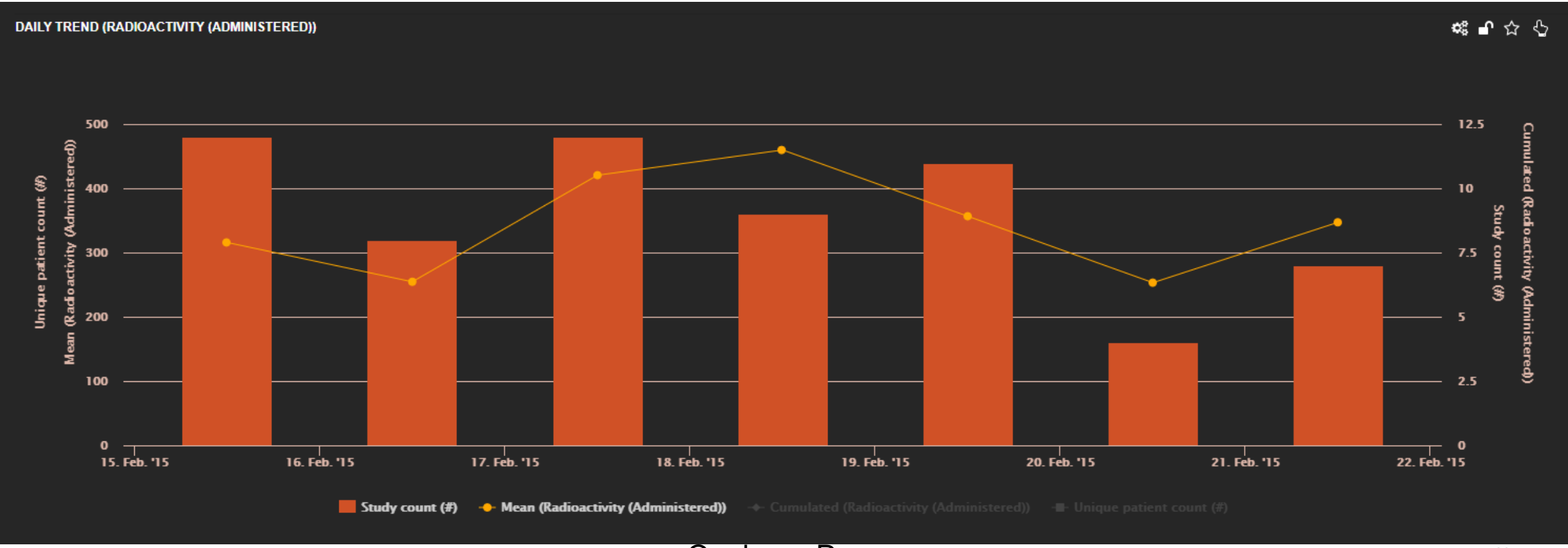
- Peak skin-dose map




Qaelum - Dose

# Typical features

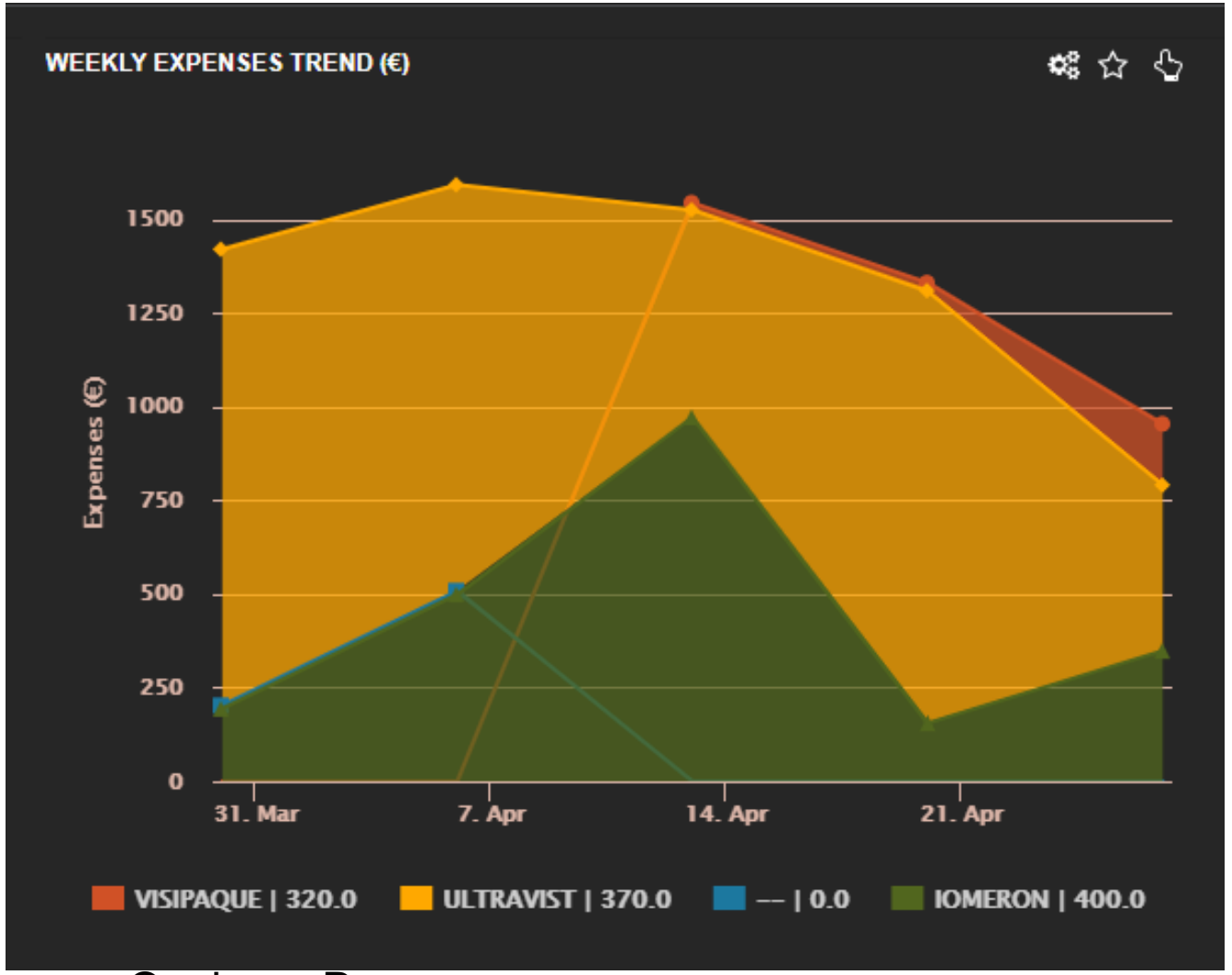
- Trend analysis




Qaelum - Dose

# Typical features

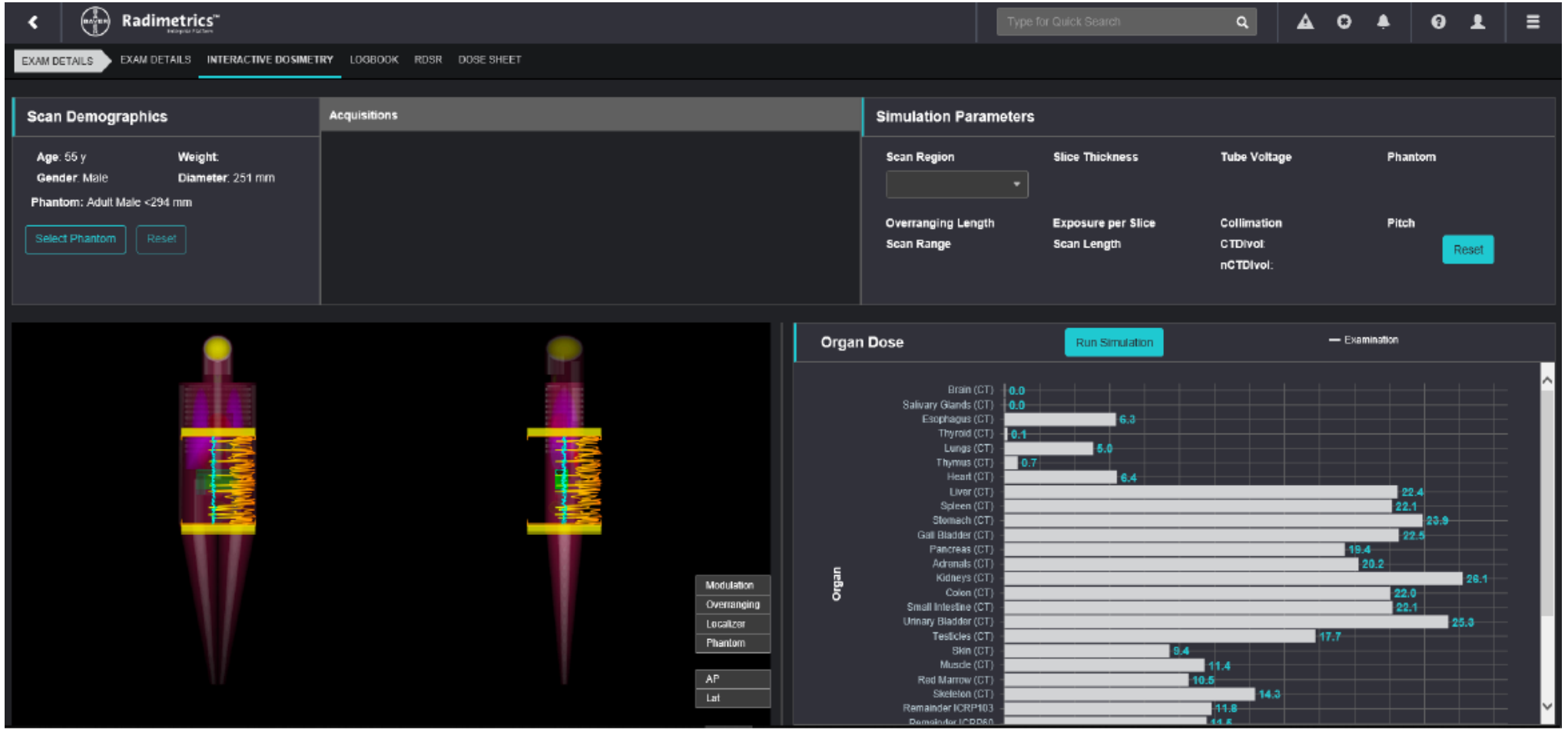
- Contrast media




Qaelum - Dose

# Typical features

- CT Organ dosimetry (including uterus doses RPO, art 40)




Bayer - Radimetrics

# Vendor specific features

- GE Dosewatch

Patient dosimetry based on phantom alignmend by scout/topo analysis.

**M85101DEED Dosewatch Duke Organ Dose (Organdosis)**

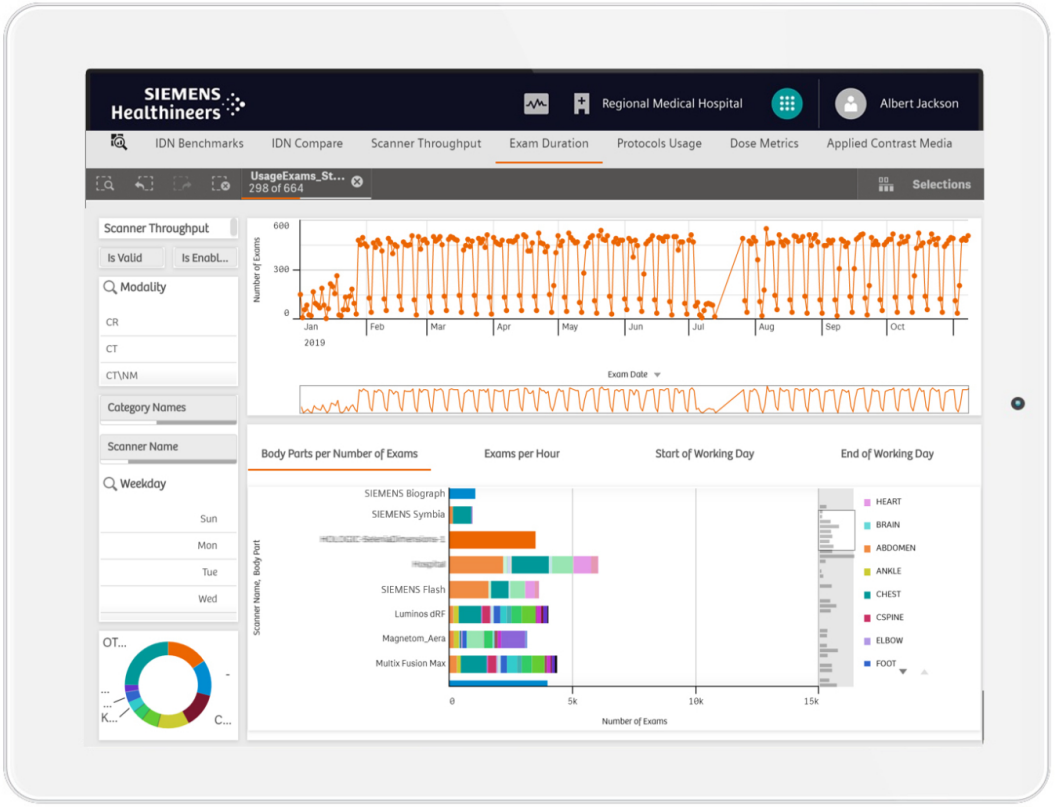
**Überblick:**

Aktiviert das Organ-Dosis-Modul für CT unter Verwendung der lizenzierten Dosimertrietechnologie der Duke University.
Unter Verwendung der XCAT-Phantombibliothek der Duke University, auf die in über 100 von Experten geprüften Artikeln verwiesen wird, verwendet das Modul einen einzigartigen auf Faltungen basierenden Ansatz für die Organdosis, einschliesslich der Anzeige von Konfidenzintervallen.
Dieses Modul verwendet mehr als 160 XCAT-Phantome, berücksichtigt die Röhrenstrommodulation und bietet eine Schätzung der Dosis für Gewebe ausserhalb des Sichtfelds.
Das Modul bietet auch eine Schätzung der fetalen Dosis basierend auf der Schwangerschaftswoche und der Verwendung von 50 XCAT-Phantomen für schwangere Patientinnen.
Verfügbar für DoseWatch 3.x-Systeme.

# Vendor specific features

- Siemens Teamplay

No local server instalation and protocol mapping tool




SIEMENS Healthineers

# Vendor specific features

- Qaelum Dose

Quantitative image quality scoring (Global Noise Level)

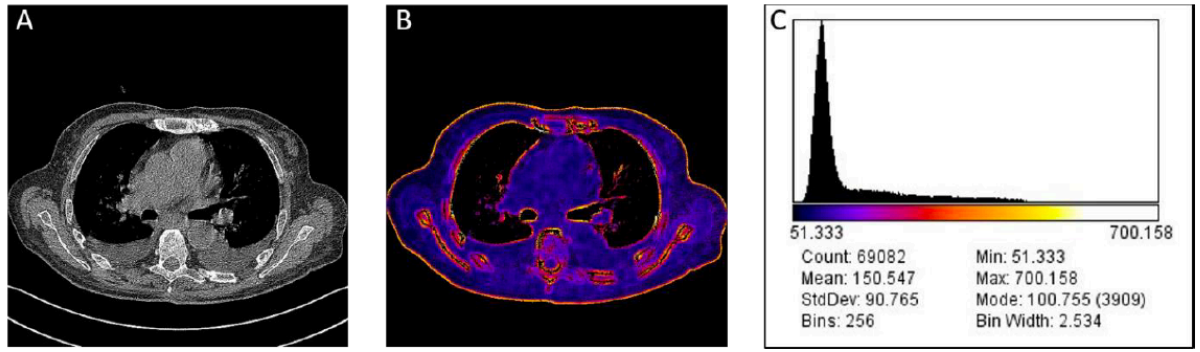



*Figure 1: Schematic overview of the noise detection algorithm from Christianson et al. (2015). A) Original Image, B) Noise map of soft tissue, C) Histogram of soft tissue noise map.*

Qaelum

# Vendor specific features

- Philips DoseWise (plus DoseAware)

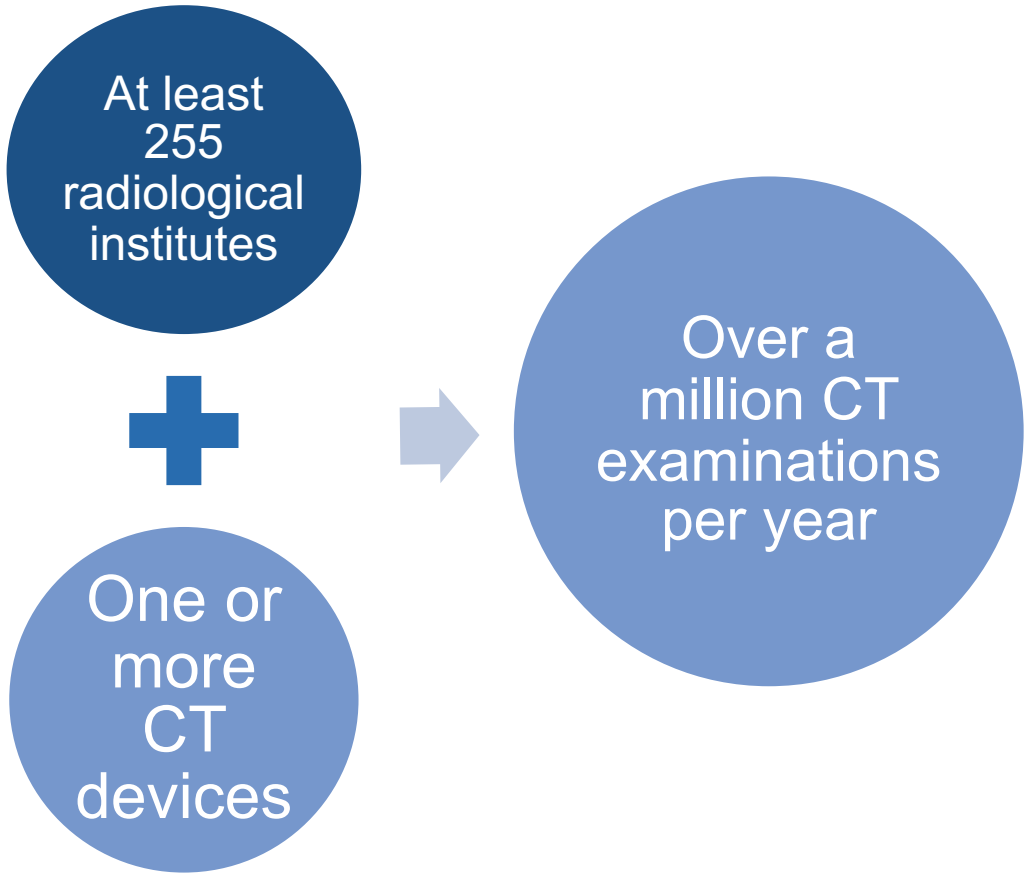
Integration with staff doses


PHILIPS

luzerner kantonsspital
LUZERN SURSEE WOLHUSEN

# This was just at the local level

# National Dose Registry

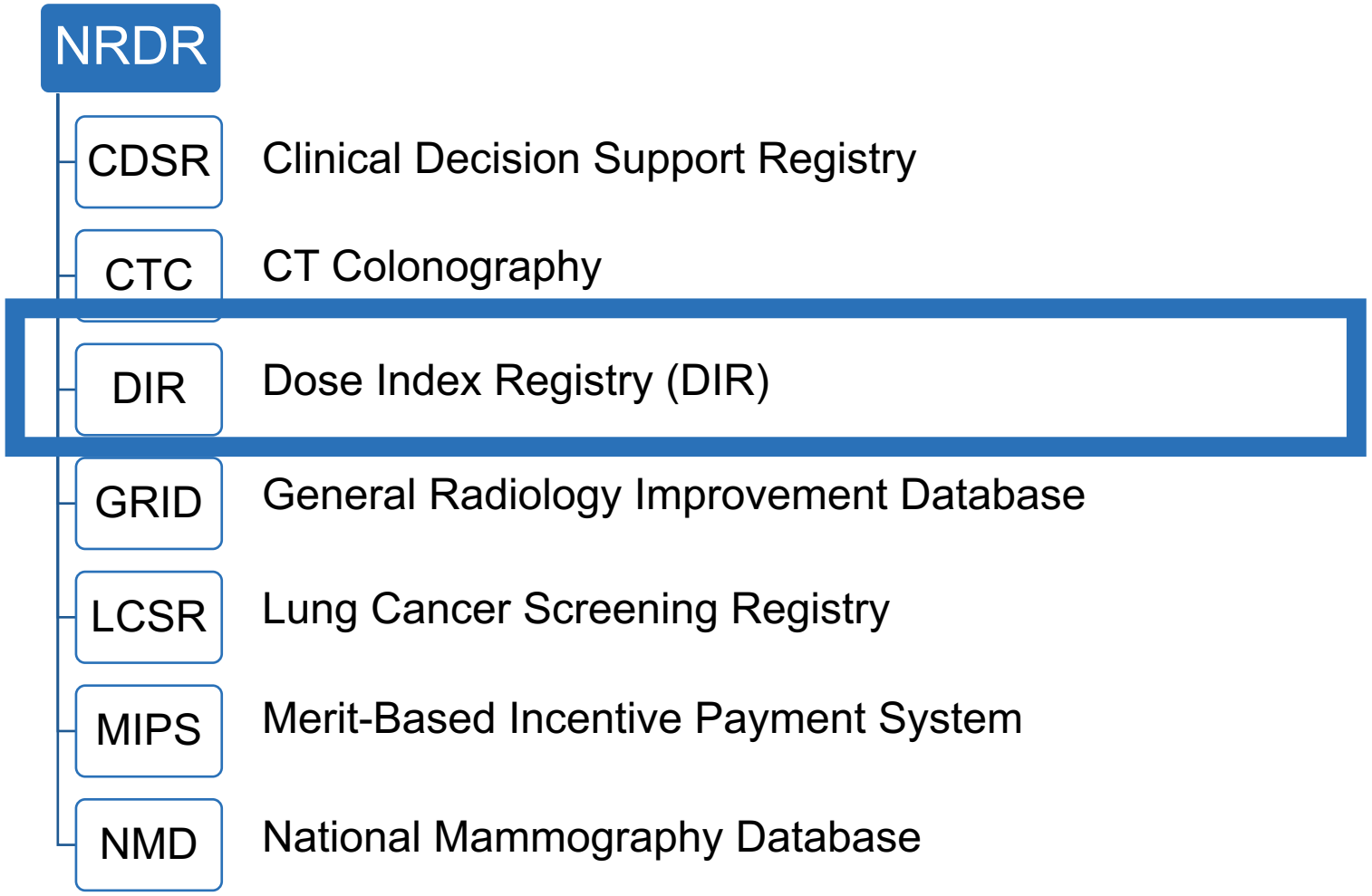



The **purpose** of the National Dose Registry **is to serve as a central platform to collect, analyse and publish dose information** from different radiology institutes. Its main goals are:

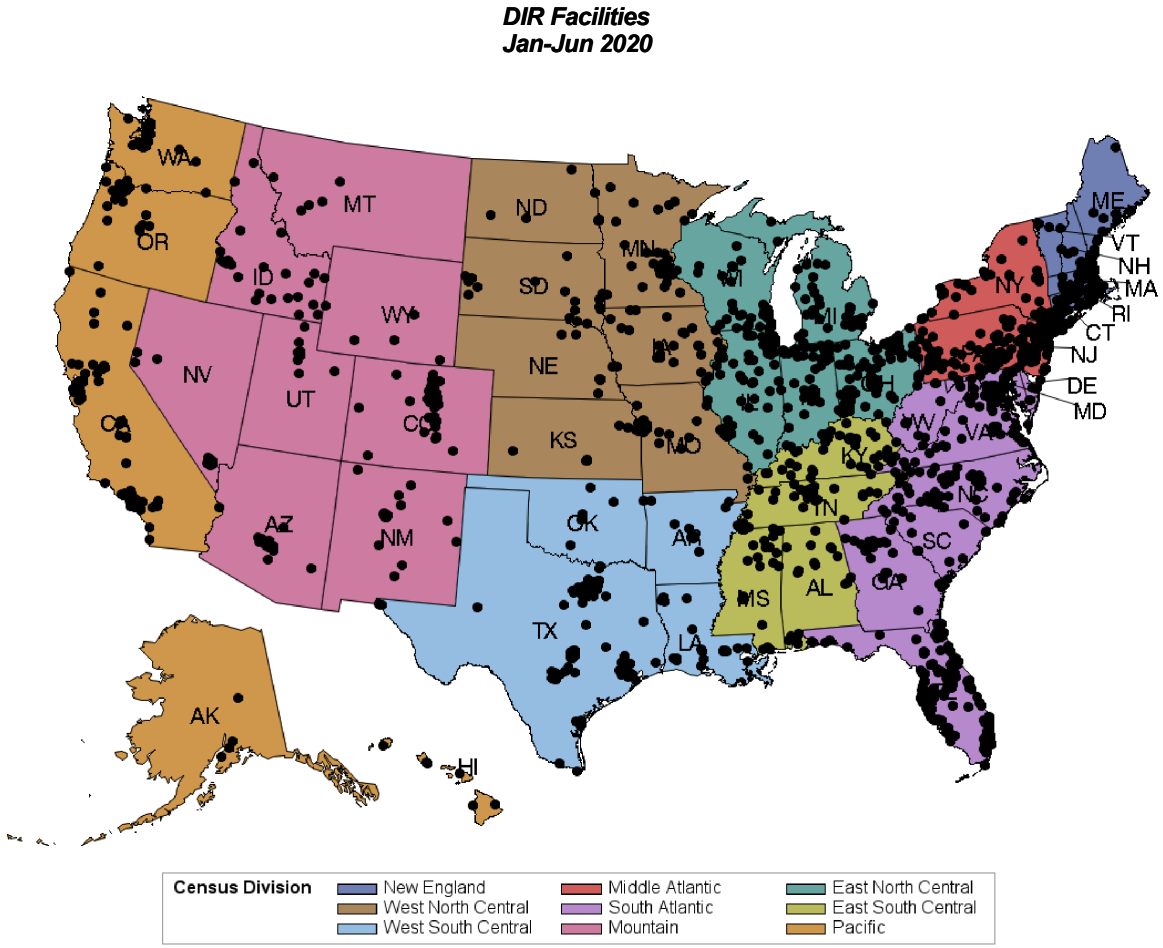
- **Reduce the effort** of participating institutes by offering a semi-automatic process.
- Build a larger and more up-to-date dataset to **improve the quality** of the evaluation results.
- Allow institute benchmarks, leading to **harmonisation of radiation doses**.
- More **frequent publication** of diagnostic reference levels.

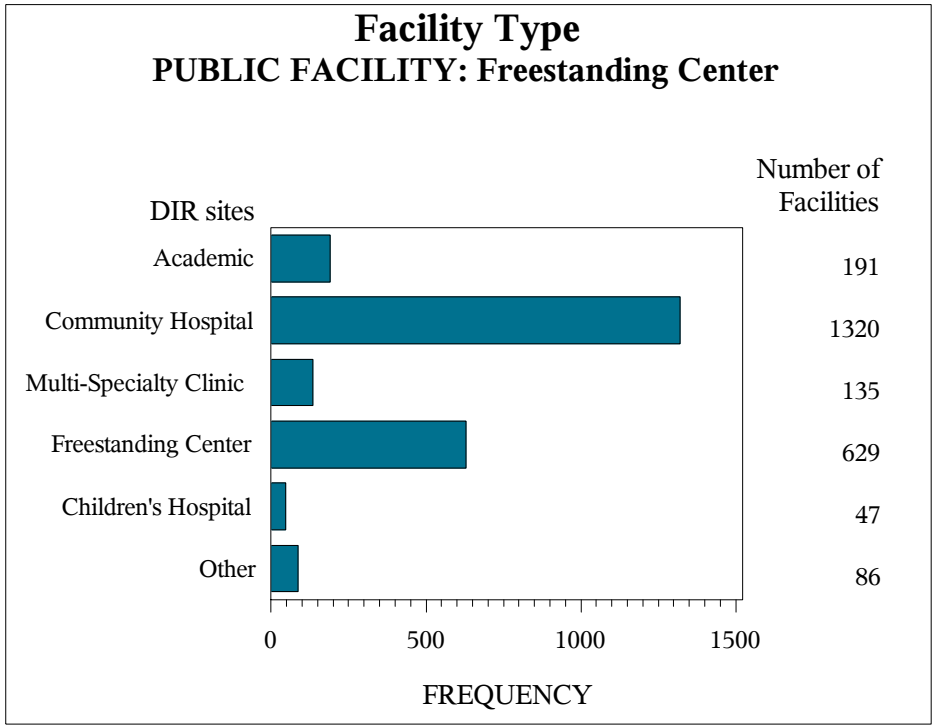
# ACR – National Radiology Data Registry

- The primary purpose of NRDR is to **aid facilities with their quality improvement programs and efforts to improve patient care by comparing facility data to that of their region and the nation**. A practice or facility may choose to participate in any or all registries as appropriate for their practice.



# A success history – DIR (Dose Index Registry) from ACR




2433 Facilities connected!!!

Total 2433 facilities submitted data for 2020Q1Q2 (indicated by black dots)

# Outcomes – DRL based on 10 most used procedures

| Exam Name | Median Patient Size | CTDIvol (mGy) | | SSDE (mGy) | | DLP (mGy-cm) | |
|---|---|---|---|---|---|---|---|
| | | DRL | AD | DRL | AD | DRL | AD |
| Head and brain without contrast | 14-16 | 56 | 49 | . | . | 962 | 811 |
| Neck with contrast | 18-22 | 19 | 15 | . | . | 563 | 429 |
| Cervical spine without contrast | 18-22 | 28 | 20 | . | . | 562 | 421 |
| Chest without contrast | 29-33 | 12 | 9 | 15 | 11 | 443 | 334 |
| Chest with contrast | 29-33 | 13 | 10 | 15 | 11 | 469 | 353 |
| Chest pulmonary arteries with contrast | 29-33 | 14 | 11 | 17 | 13 | 445 | 357 |
| Abdomen and pelvis without contrast | 29-33 | 16 | 13 | 19 | 15 | 781 | 639 |
| Abdomen and pelvis with contrast | 29-33 | 15 | 12 | 18 | 15 | 755 | 608 |
| Abdomen, pelvis and kidney without contrast | 29-33 | 15 | 12 | 19 | 14 | 705 | 576 |
| Chest, abdomen and pelvis with contrast | 29-33 | 15 | 12 | 18 | 14 | 947 | 779 |

**Radiation Units in Computed Tomography**

| Term | Description | Unit |
|---|---|---|
| CT Dose Index (CTDIvol) | Radiation energy absorbed per unit mass; for CT, determined for a standard phantom and not a patient | gray (Gy) or milligray (mGy) |
| Dose Length Product (DLP) | Absorbed dose multiplied by the length of exposure; for CT, determined for a standard phantom and not a patient | milligray-cm (mGy-cm) |
| Size Specific Dose Estimate | A patient dose estimate which takes into consideration corrections based on the size of the patient | milligray (mGy) |

1. Kanal KM, Butler PF, Sengupta D, et al. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations, Radiology 2017, ahead of print. (http://pubs.rsna.org/doi/abs/10.1148/radiol.2017161911?journalCode=radiology)

# CT and other modalities

- Current efforts to expand DIR to other modalities



CLINICAL STUDY

**The American College of Radiology Fluoroscopy Dose Index Registry Pilot: Technical Considerations and Dosimetric Performance of the Interventional Fluoroscopes**

Kevin A. Wunderle, PhD, A. Kyle Jones, PhD, Shalmali Dharmadhikari, PhD, Xinhui Duan, PhD, Don-Soo Kim, PhD, Usman Mahmood, MS, Steve D. Mann, PhD, Jeffery M. Moirano, MS, Rebecca A. Neill, MS, and Alan H. Schoenfeld, MS

# Research capabilities of DIR

## CT Volumes from 2,398 Radiology Practices in the United States: A Real-Time Indicator of the Effect of COVID-19 on Routine Care, January to September 2020

*Matthew S. Davenport, MD[a], Tom Fruscello, MBA[b], Mythreyi Chatfield, PhD[b], Stefanie Weinstein, MD[c], William F. Sensakovic, PhD[d], David B. Larson, MD, MBA[e]*

**Abstract**

**Purpose:** To determine the effect of coronavirus disease 2019 (COVID-19) on CT volumes in the United States during and after the first wave of the pandemic.

**Methods:** CT volumes from 2,398 US radiology practices participating in the ACR Dose Index Registry from January 1, 2020, to September 30, 2020, were analyzed. Data were compared to projected CT volumes using 2019 normative data and analyzed with respect to time since government orders, population-normalized positive COVID-19 tests, and attributed deaths. Data were stratified by state population density, unemployment status, and race.

**Results:** There were 16,198,830 CT examinations (2,398 practices). Volume nadir occurred an average of 32 days after each state-of-emergency declaration and 12 days after each stay-at-home order. At nadir, the projected volume loss was 38,043 CTs per day (of 71,626 CTs per day; 53% reduction). Over the entire study period, there were 3,689,874 fewer CT examinations performed than

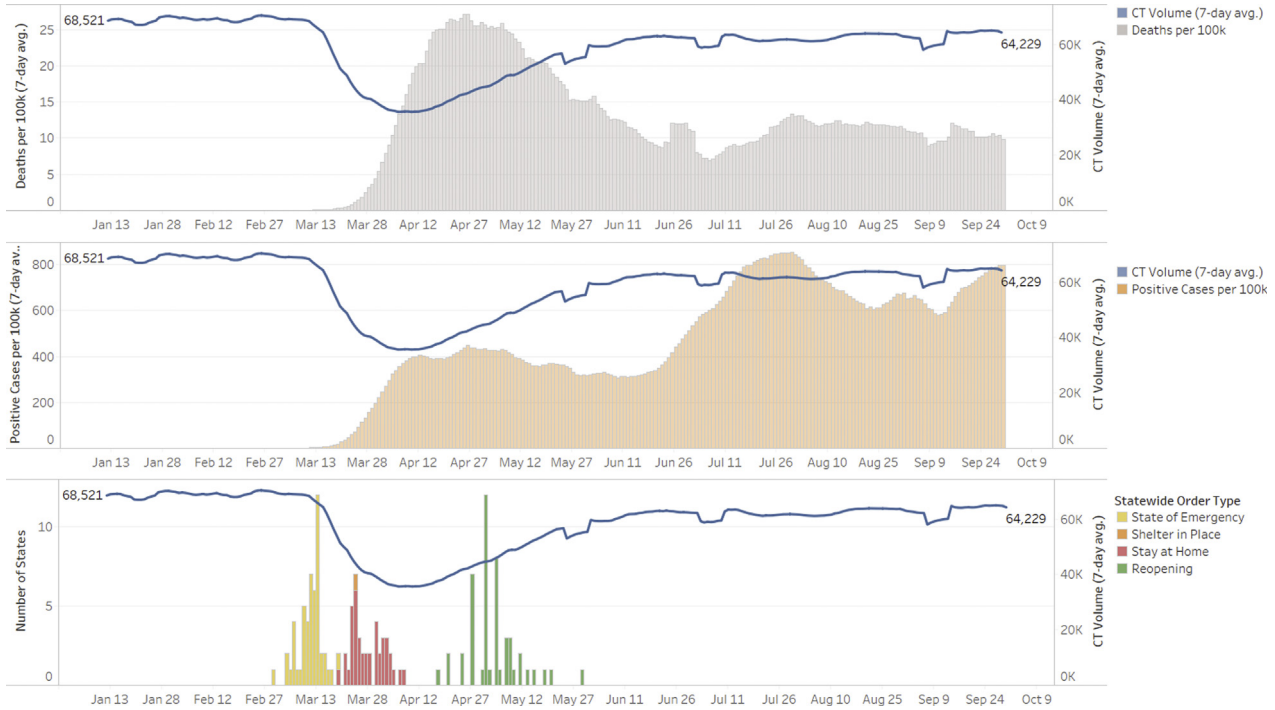
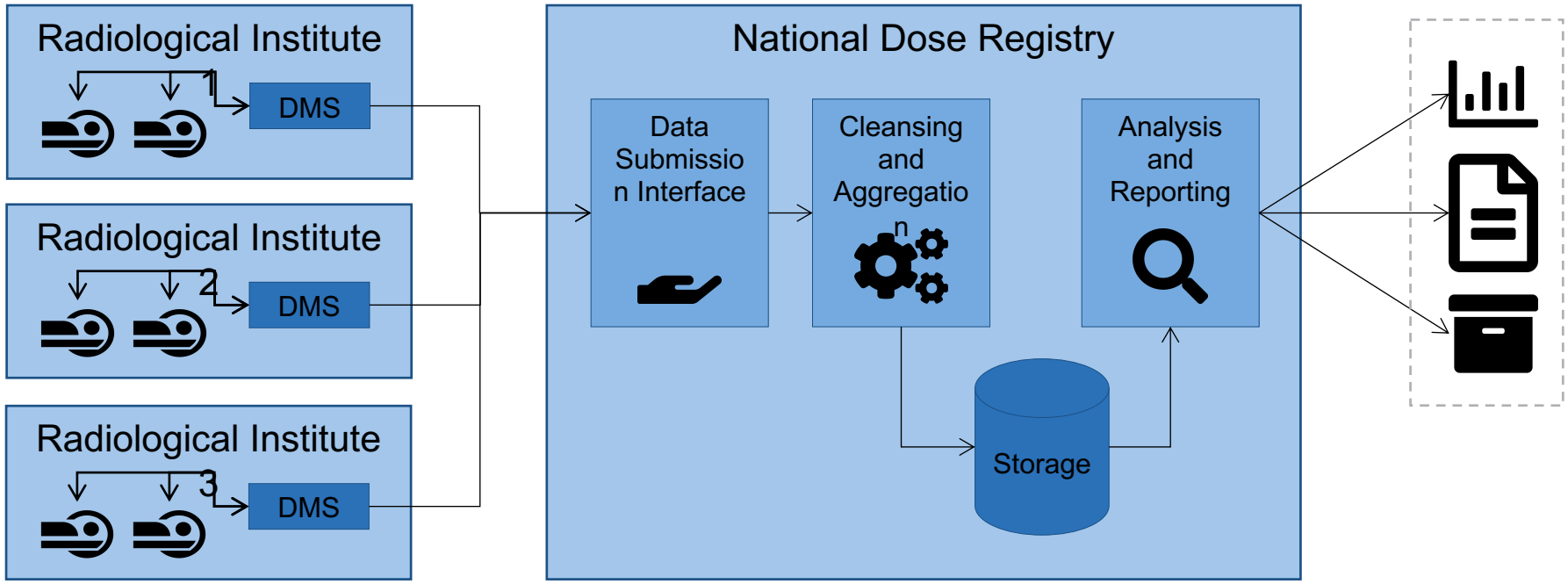



Fig 1. Nationwide relationship between CT imaging volume (blue lines; 7-day moving averages) and coronavirus disease 2019 (COVID-19)-attributed deaths (top, gray bars, normalized per 100,000 people), COVID-19 positive tests (middle, orange bars, normalized per 100,000 people), and state government executive orders (bottom). Data are from January 1, 2020, to September 30, 2020. The "notches" in CT volume during the months of May, July, and September correspond to 3-day Memorial Day, July 4th, and Labor Day weekends, and also occurred in 2019 (Fig. 2).

# The Swiss National CT Dose Registry – proof of concept project

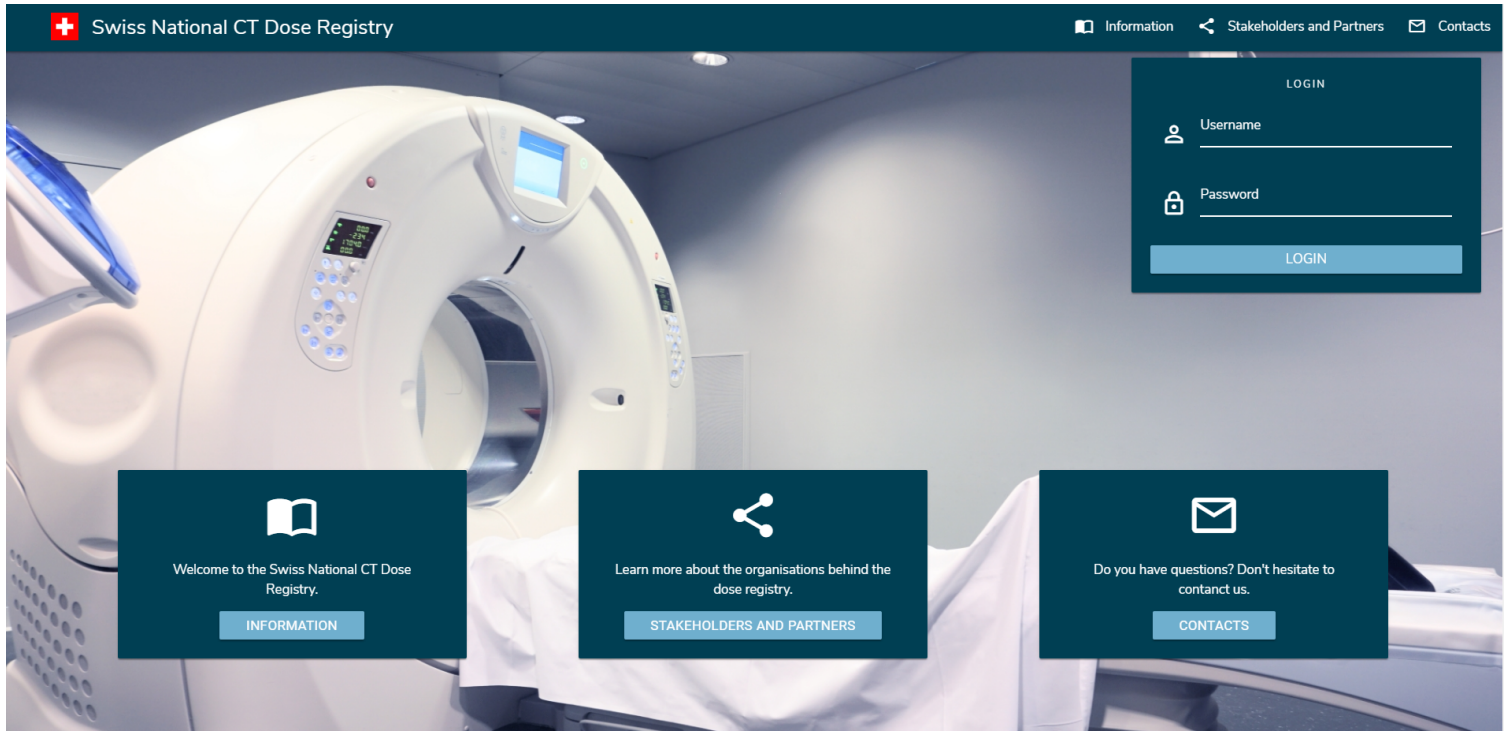
- Proof-of-concept project run by Kantonsspital Aarau (Prof Schindera, Dr. Lima and Mr Sigrist) and funded by Federal Office of Public Health

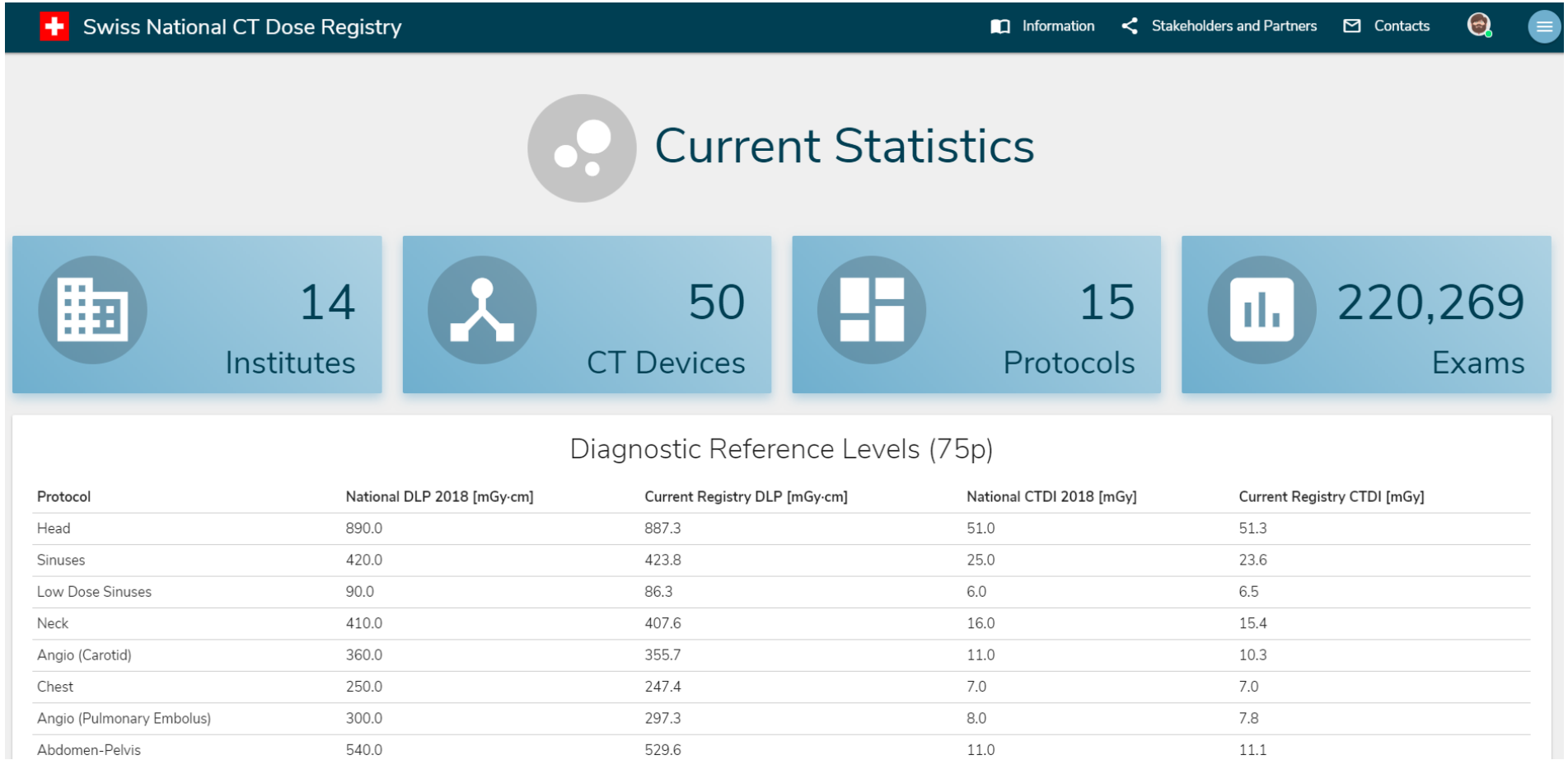



- Aimed to evaluate the viability of such project including implementation and running cost, technical aspects and development of a prototype.

# Proof of Concept Stage - Platform

- Implementation of core functionalities
  - Data submission (Interface for connecting institutes) and DMS
  - Providing tailored reports
  - Data cleansing process
  - Basis for data protection (Discussions, procedure mechanisms)
- Focus on view
  - Data analysis for participating institutes: Radiologists/Technologist/Med. Phy.
- Incorporating state-of-the-art web technologies
  - Goal: Using the PoC as foundation for the realisation





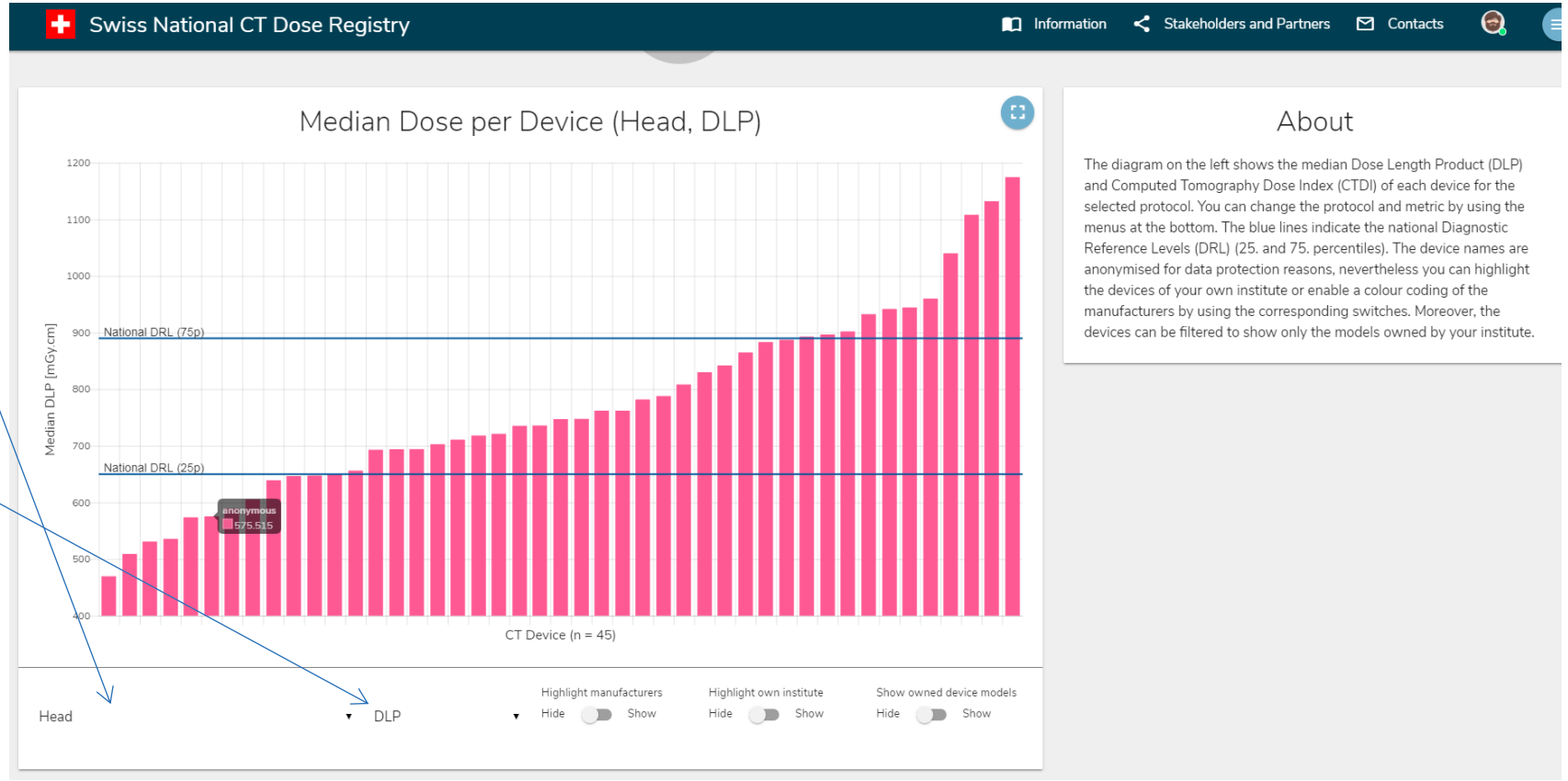

Diagnostic Reference Levels (75p)

| Protocol | National DLP 2018 [mGy·cm] | Current Registry DLP [mGy·cm] | National CTDI 2018 [mGy] | Current Registry CTDI [mGy] |
|---|---|---|---|---|
| Head | 890.0 | 887.3 | 51.0 | 51.3 |
| Sinuses | 420.0 | 423.8 | 25.0 | 23.6 |
| Low Dose Sinuses | 90.0 | 86.3 | 6.0 | 6.5 |
| Neck | 410.0 | 407.6 | 16.0 | 15.4 |
| Angio (Carotid) | 360.0 | 355.7 | 11.0 | 10.3 |
| Chest | 250.0 | 247.4 | 7.0 | 7.0 |
| Angio (Pulmonary Embolus) | 300.0 | 297.3 | 8.0 | 7.8 |
| Abdomen-Pelvis | 540.0 | 529.6 | 11.0 | 11.1 |

# Data analysis

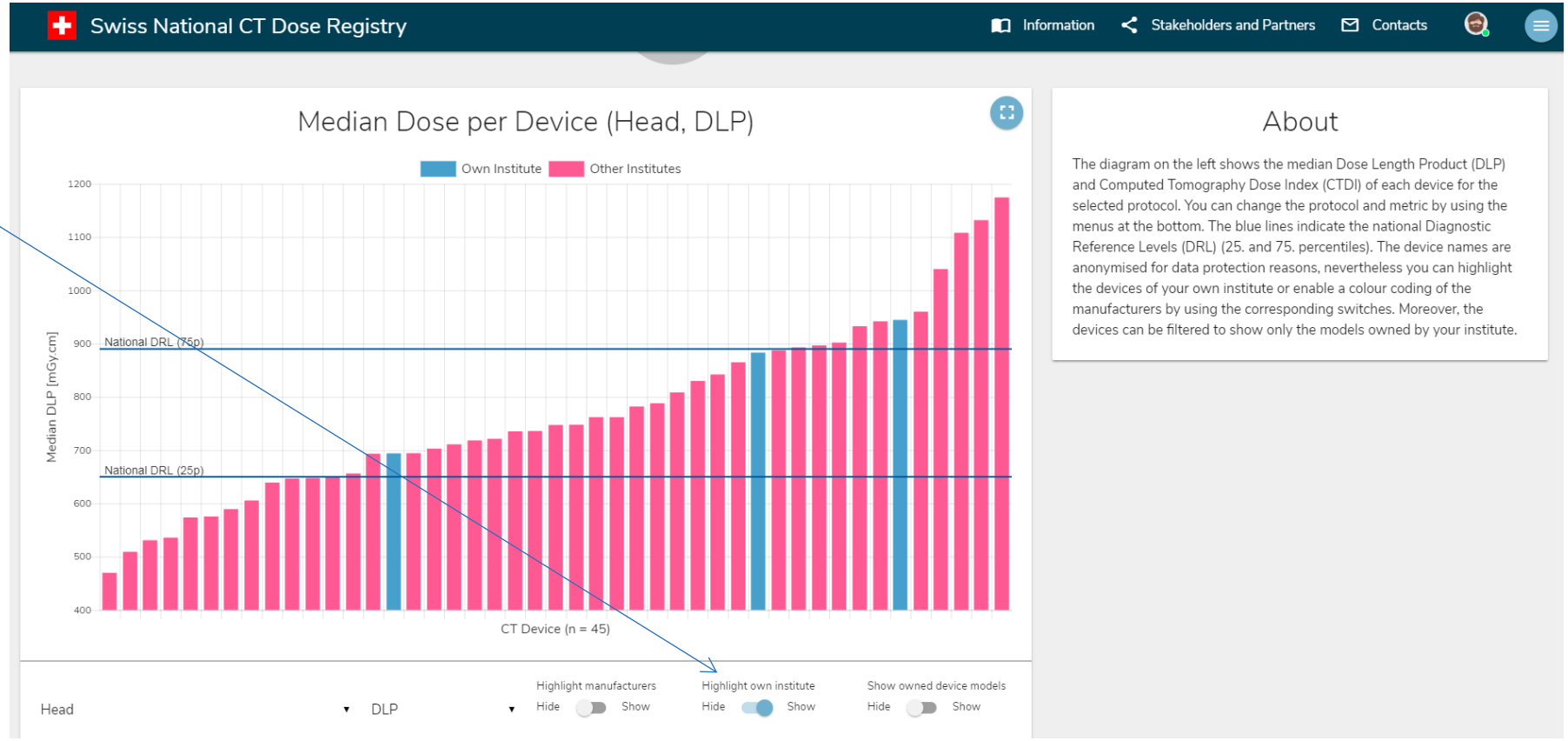
15 Protocols (as per DRLs)

DLP and $CTDi_{vol}$



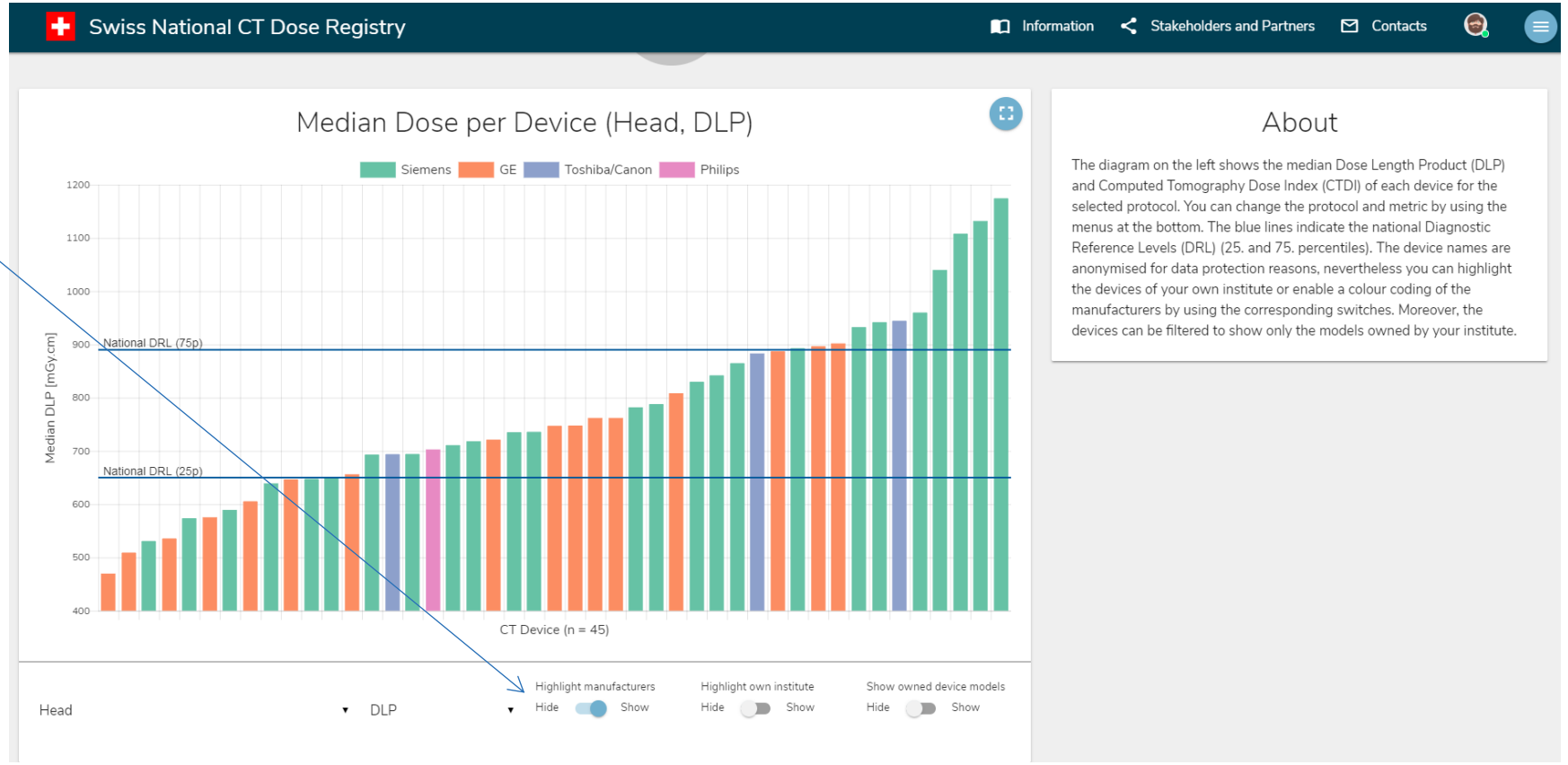
# Highlight own data

Own data



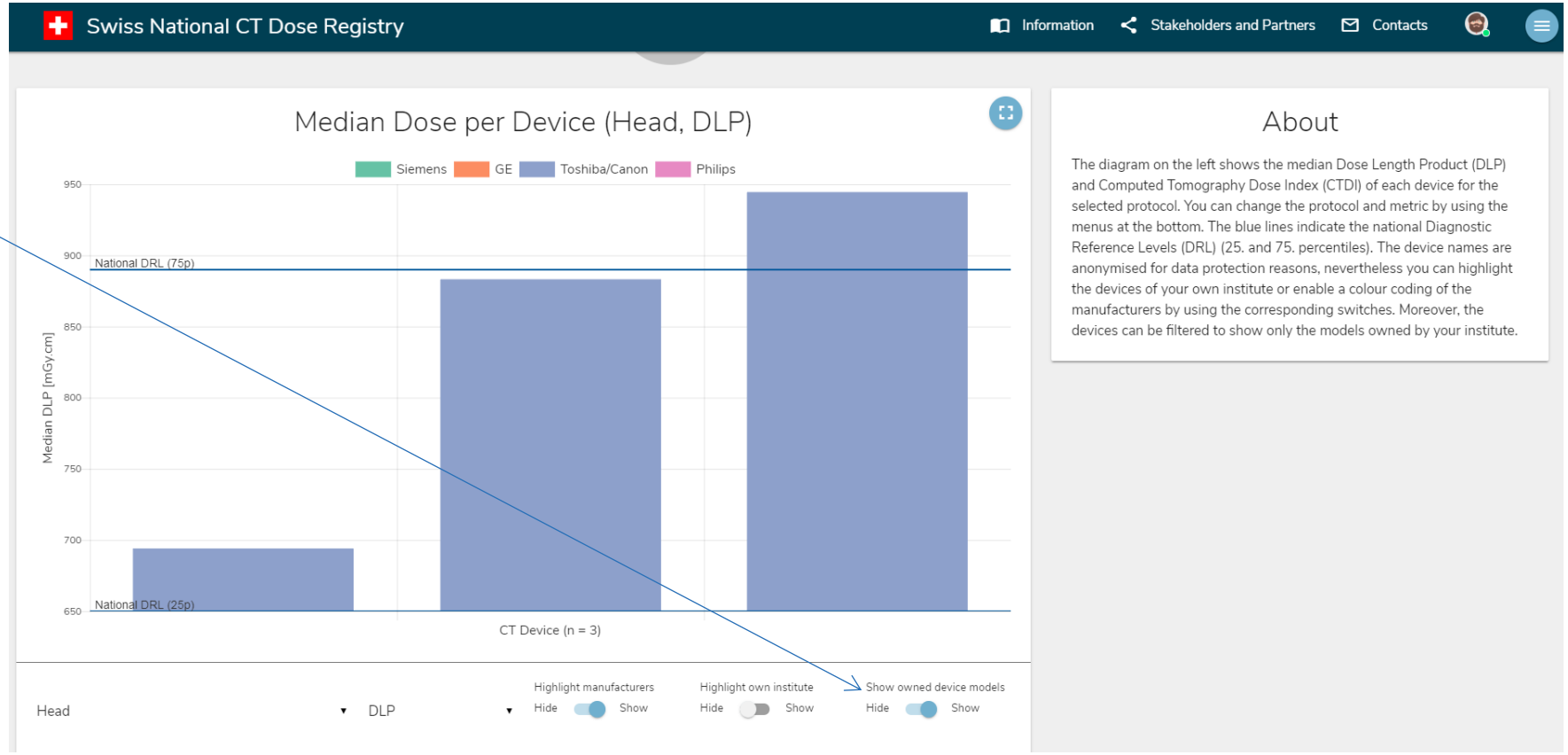
# By Vendors

Different Vendors



# Filtering just same vendors

Same Vendors as local devices



# Conclusion

- There is a legal requirement to optimise patient exposures.
- Dose Management Systems, or Software Registries, are one of the possible tools to help teams to implement optimisation strategies in their workflow.
- Most solutions present similar features (connectivity, analysis, reporting) but other features are specific to some vendors.
- Hospitals are not required to have a commercial software but normally in-house or opensource option require extra (human) resources.
- **Lastly, but not least, the analysis of these dose registry software will be/is as good as the data it has inside – having such solutions is only the begging of the work**

luzerner kantonsspital
LUZERN SURSEE WOLHUSEN

# Thank you for listening.