

The Aigora logo is displayed in a white rounded rectangle on a blue background with a network pattern of dots and lines. The word "aigora" is written in a lowercase, sans-serif font.

aigora

CONNECTING SILOED DATA  
TO ACCELERATE MEDICAL AI

## MIDI Workshop

Session 3: International Approaches  
to De-Identification

22 May 2023

Legal framework and best  
practices for medical image  
de-identification in the EU

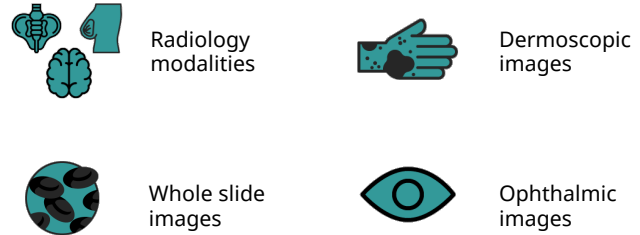
# Aigora at a glance

We provide real-world medical imaging data at scale to leading medtech and pharma companies for AI and RWE purposes

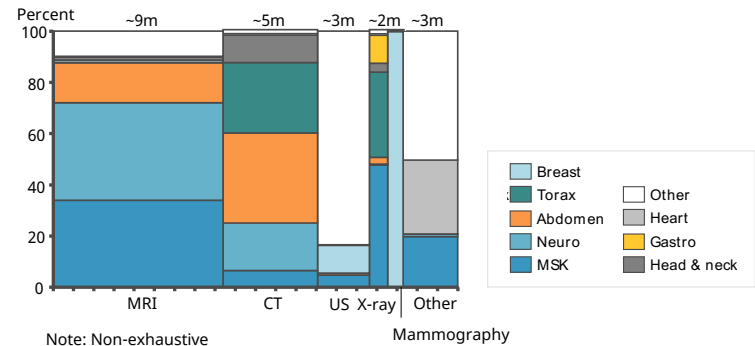
200+ clinical provider sites across four regions



All major medical imaging modalities



20+ million medical imaging studies



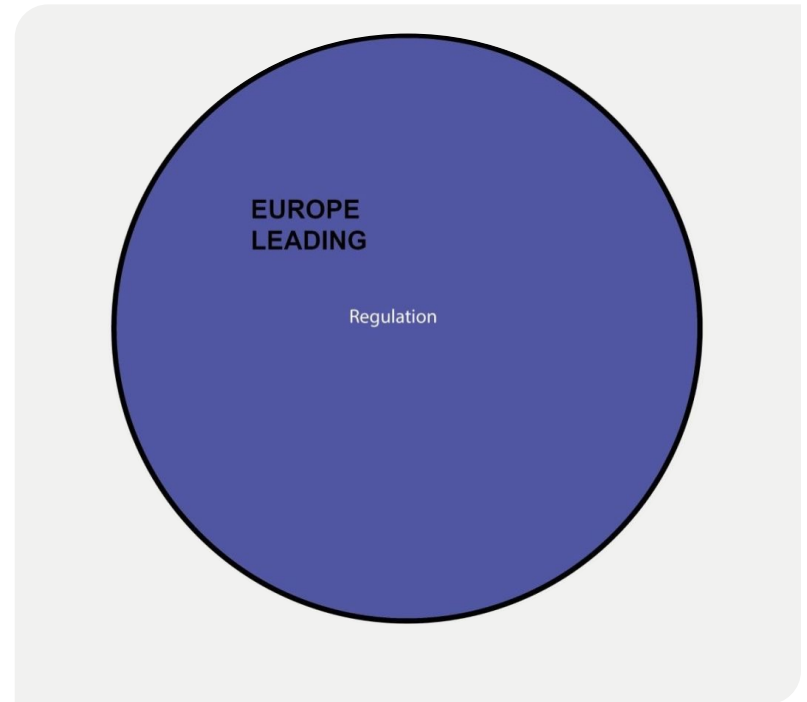
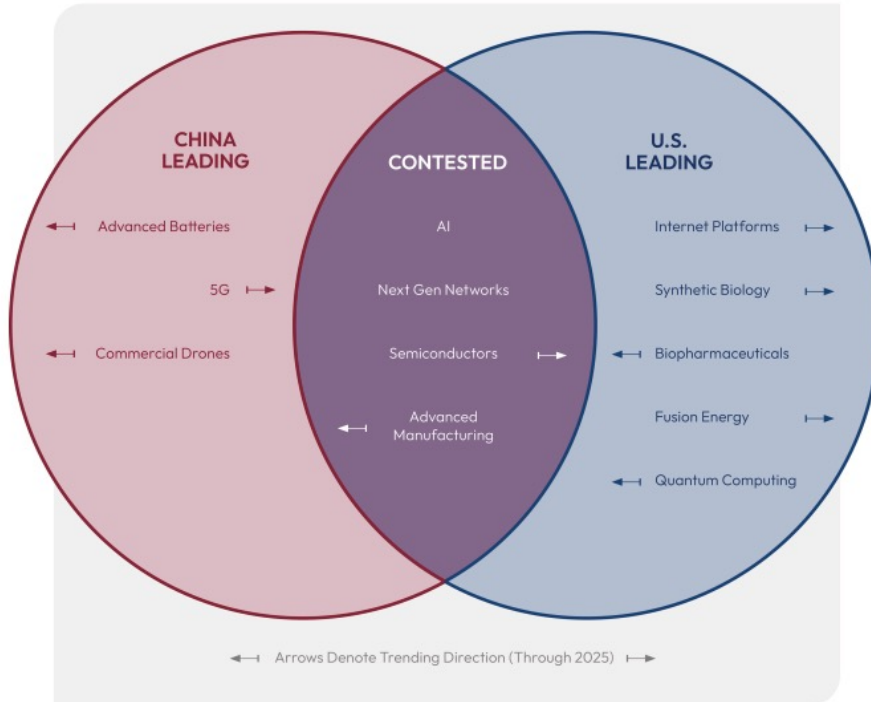
# Goals of this presentation

**Disclaimer:**  
Don't mistake this for legal advice.  
Consult with qualified  
professionals!

- 1 Provide a brief overview of the EU regulatory framework
- 2 Point out differences between GDPR and HIPAA with respect to de-identification
- 3 Share at a high level practices we employ to achieve and preserve medical image de-id

# Europe is the uncontested leader in regulation – it's tough!



## LEADERSHIP IN "KEY TECHNOLOGIES"



# Multiple layers of regulation help maintain that leadership position

## APPLICABLE REGULATION FOR MEDICAL IMAGE DE-ID

### NON-EXHAUSTIVE

Level	Regulation	Applicability
European Union	 General Data Protection Regulation (GDPR)	Processing of personal data and special categories of personal data incl. anonymization thereof
Country	 Translation of GDPR into national legislation, e.g., BDSG	Same as above (country specifics apply)
State / institutional	State hospital laws (and state data protection acts), e.g., LKHG, BayKrG, LDSG	Secondary uses (internal and external) of medical data from hospitals
Physician	Professional code of conduct for medical practitioners, e.g., BOÄ Bayern	Research with medical data

### Implications for medical image de-id

- GDPR is always applicable, with anonymization itself being a processing of personal data to which the data protection regulation applies
- Peculiarities of national data protection legislation need to be considered
- Further restrictions may apply, varying by state and setting

# There is no prescriptive standard for de-identification in EU legislation

## DE-IDENTIFICATION / ANONYMIZATION UNDER HIPAA VERSUS GDPR

### HIPAA

#### Definition

"... information that does not identify an individual and with respect to which there is **no reasonable basis to believe that the information can be used to identify an individual** is not individually identifiable health information." (45 CFR § 164.514 (a))

#### Guidance

Two approaches:

- (1) Expert determination method:** "A person with appropriate knowledge and experience ... determines that the risk is very small that the information could be used ... to identify an individual ..." (45 CFR § 164.514 (b) (1))
- (2) Safe harbor method:** Lists 18 identifiers to be removed (45 CFR § 164.514 (b) (2))

### GDPR

"... information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous **in such a manner that the data subject is not or no longer identifiable.**" (GDPR Recital 26 (5))

No prescriptive standard:

"To ascertain whether **means are reasonably likely to be used** to identify the natural person, account should be taken of all objective factors, such as the **costs of and the amount of time required for identification**, taking into consideration the **available technology at the time of the processing** and technological developments." GDPR Recital 26 (4))

#### Implications for medical image de-id

- Under GDPR, de-identification must be irreversible for everyone, even at clinic level
- Similar to HIPAA, GDPR recognizes residual risk inherent to de-id
- Unlike HIPAA, GDPR does not clarify the approach; focus is on outcome
- Several anonymization techniques may be envisaged; not limited to technology

# Technical and non-technical measures need to be considered for medical image de-id, while weighing re-identification risk against data utility

## HOW TO DE-ID MEDICAL IMAGING DATA?

### Guidance by European advisory body on data protection

---

- “The **optimal solution should be decided on a case-by-case basis**, possibly by using a combination of different techniques ...” evaluated based on the possibility to
  - still **single out** an individual
  - **link** records relating to an individual
  - **infer** information concerning an individual
- Severity and likelihood of **residual risk of re-identification** linked to any anonymization technique **needs to be assessed**

### Best practices at Aigora

---

#### Measures to achieve de-id\*

- Rule and statistically based de-id
  - removal or replacement of DICOM headers
  - hashing techniques (e.g., longitudinal datasets)
  - aggregation and k-anonymity wrt metadata
- Removal of burned-in text, unstructured text
- De-facing (if applicable and possible)
- Manual quality control

#### Add'l measures to preserve de-id

- Technical and organisational measures
- Non-technical measures
  - contractual agreements
  - structural layers

## Key takeaways and recommendations

- Anonymization itself constitutes a processing of personal data for which GDPR is applicable, even though anonymization removes applicability of data protection regulation (legal basis for de-id)
- Peculiarities in national legislation, state laws and potential restrictions by clinical setting may apply
- Some residual risk of re-identification will always remain
- There is no prescriptive standard for de-id; decide on a case-by-case basis and focus on outcome
- Employ a combination of technical and non-technical measures to achieve and preserve de-id
- Balance data minimization and data utility
- Consider alternatives to anonymization, e.g. pseudonymization requiring patient consent and ethics committee approval



The logo for Aigora, consisting of the word "aigora" in a white, lowercase, sans-serif font, positioned inside a white rounded rectangular shape. The background of the slide is a dark blue network of interconnected nodes and lines, with a large, light blue abstract shape on the left side.

aigora

# CONNECTING SILOED DATA TO ACCELERATE MEDICAL AI

## THANKS!

**Contact:**

Christian Ludwigs  
+49 151 5677 1197  
[christian@aigora.de](mailto:christian@aigora.de)

Aigora GmbH  
Franz-Joseph-Str. 39  
80801 Munich, Germany  
[www.aigora.de](http://www.aigora.de) | [info@aigora.de](mailto:info@aigora.de)