Leibniz ScienceCampus
Digital Transformation of Research

Research Data Management in Medical Data Science:

Integrating Multi-Source Data for Cardiological Simulations and Machine Learning: Challenges in Security, Privacy, and Legal Frameworks

FIZ Karlsruhe
Leibniz Institute for Information Infrastructure

Karlsruhe Institute of Technology

funded by Leibniz Competition

Who are we?

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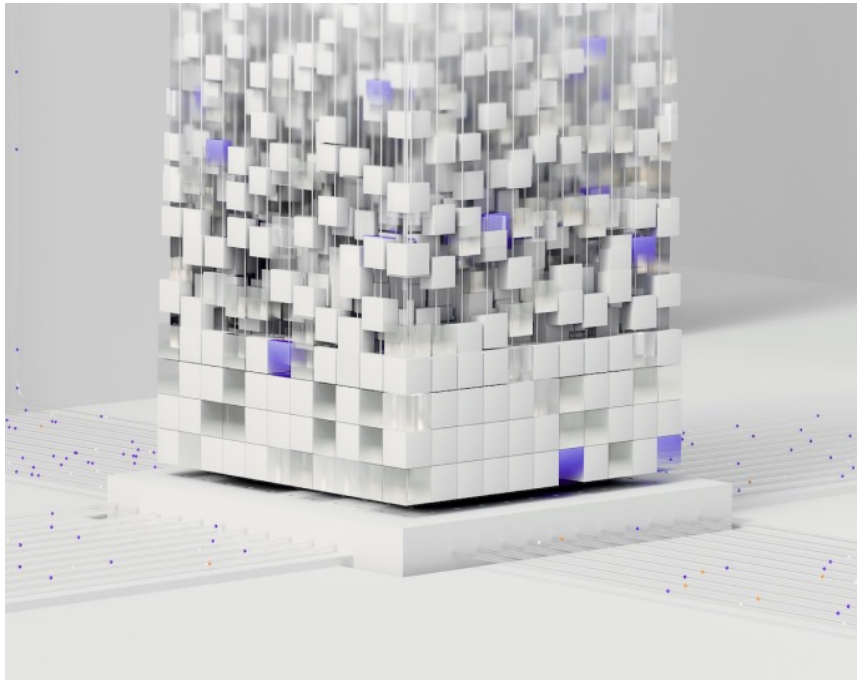

Graphic © FIZ Karlsruhe und Karlsruher Institut für Technologie (KIT)

Scient. Researcher for intellectual property rights at FIZ Karlsruhe

- legal and ethical support of the project and the Use Cases

Scient. Researcher at the Institute for Biomedical Engineering

- Part of the Use Case "Artificial Intelligence in Biomedical Engineering"

Example

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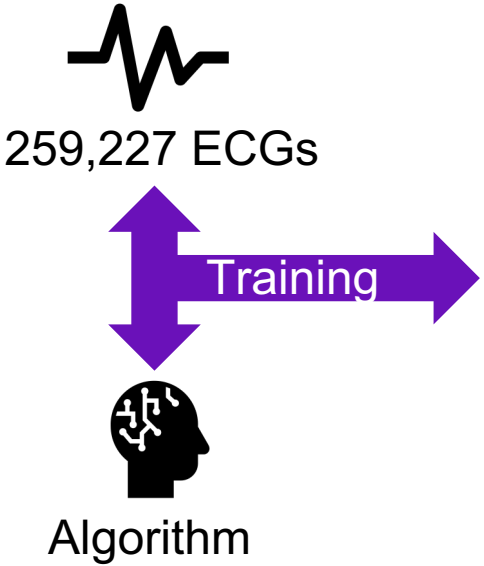
259,227 ECGs

Algorithm

DuBrock et al., 2024, Eur. Respir. J.

Example



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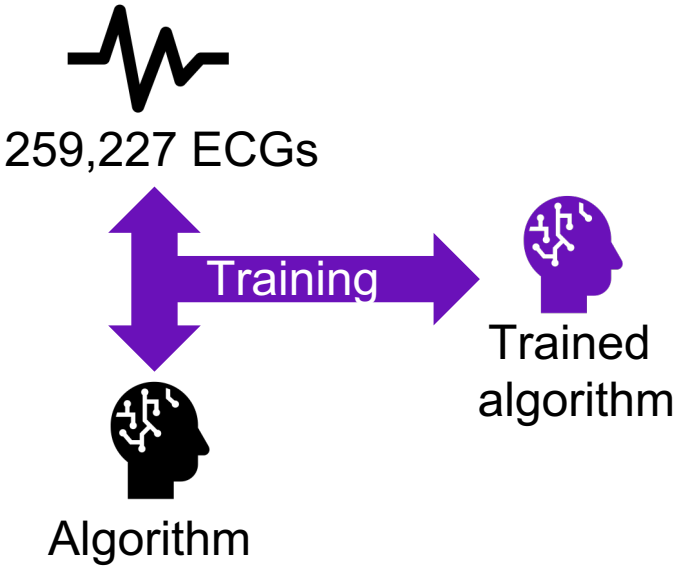
DuBrock et al., 2024, Eur. Respir. J.

Example



DuBrock et al., 2024, Eur. Respir. J.

Example

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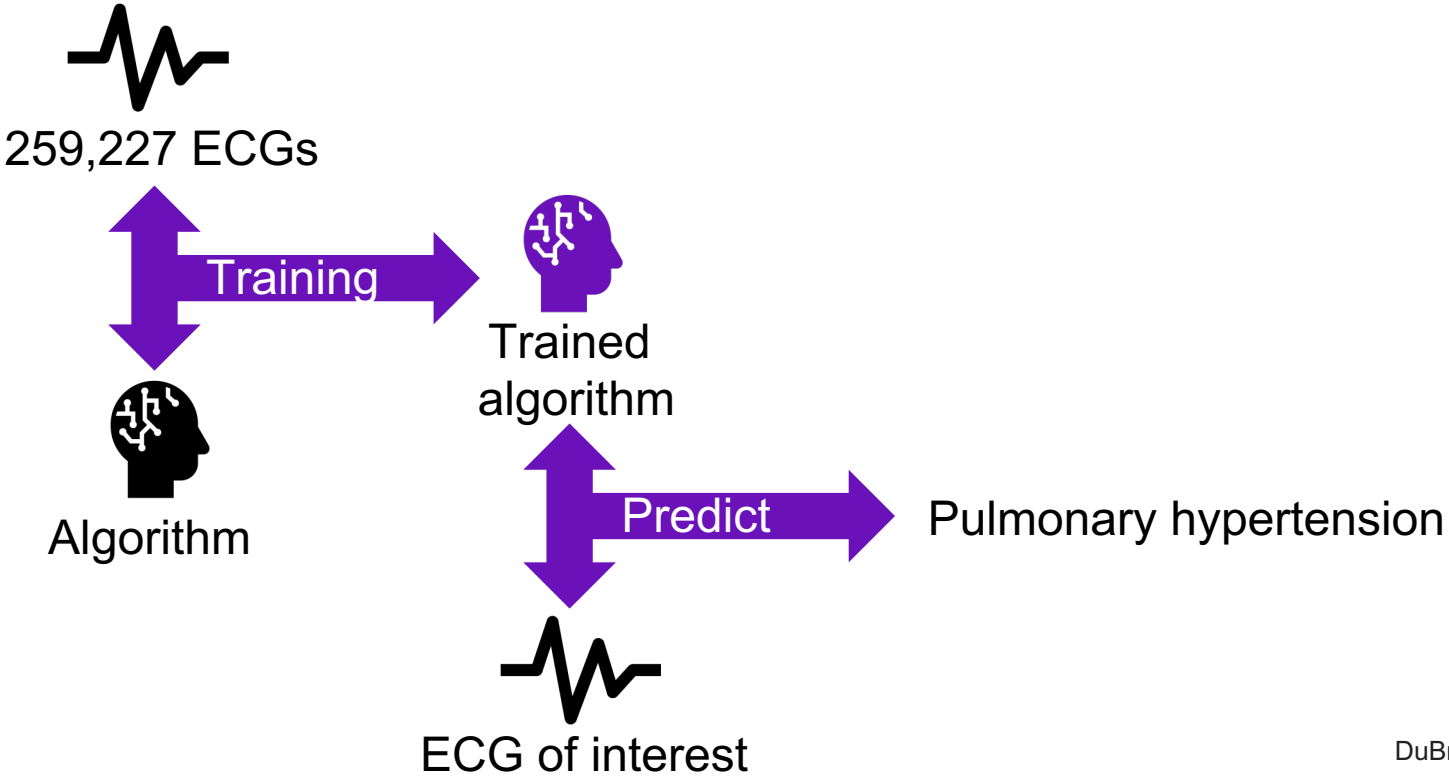

DuBrock et al., 2024, Eur. Respir. J.

Example

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DuBrock et al., 2024, Eur. Respir. J.

Digital twins

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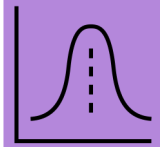
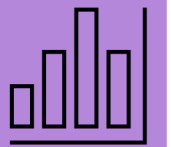
A: Inputs

MRI/CT

Electroanatomical mapping





Statistical/mathematical models

Graphic: Zhang et al., 2023, Journal of Cardiothoracic Surgery

Digital twins

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A: Inputs

MRI/CT

Electroanatomical mapping

Statistical/mathematical models

B: Model

Anatomical model

Functional model

Simulations

Graphic: Zhang et al., 2023, Journal of Cardiothoracic Surgery

Digital twins

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C: Outputs

Electrical propagation on the heart

Heart activity on body surface (ECG)

Graphic: Zhang et al., 2023, Journal of Cardiothoracic Surgery

Digital twins

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Legal background

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- EU: GDPR
- Nationally: BDSG/data protection laws of the states
- If data is used to train AI: AI-Act

Affected laws

- Medical data = sensitive -> Art. 9 Para 1 GDPR: Generally processing prohibited

What Articles apply

- Each phase of the model -> potential legal, ethical and practical challenges -> analysis of the different stages and phases

Approach

Phase A: collection of data sources

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Technical aspects:

Data access and availability

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Cooperations or open-source data

Data quality
Unbalanced datasets

↓

Careful selection of data

Legal aspects:

Adherence to the GDPR, e.g basis of data processing, information of data subject

↓

Anonymization
Circumvention of obligation

↓

Data accuracy regarding data quality

Phase B: creating synthetic data model

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Technical aspects:

- Controllable
  Explainable
  Scalable
  Simplifiable

- Generation of geometrical/functional model
  Data authenticity

↓

Segmentation methods
Handling of artefacts

Legal aspects:

- Synthetic data as anonymization technique

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- Definition of anonymization
  Risk of Re-Identification

↓

- Benefit in comparison to AI
  Higher protection of subject rights

Phase C: sharing model outputs

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Technical aspects:

Usable as training data for AI algorithms
Open science/FAIR principle

Possible bias when training AI

Be aware of limitations and biases

Legal aspects:

Metadata dilemma
GDPR through the “back door”

Issues with AI-Act when output is used to train AI

Outlook

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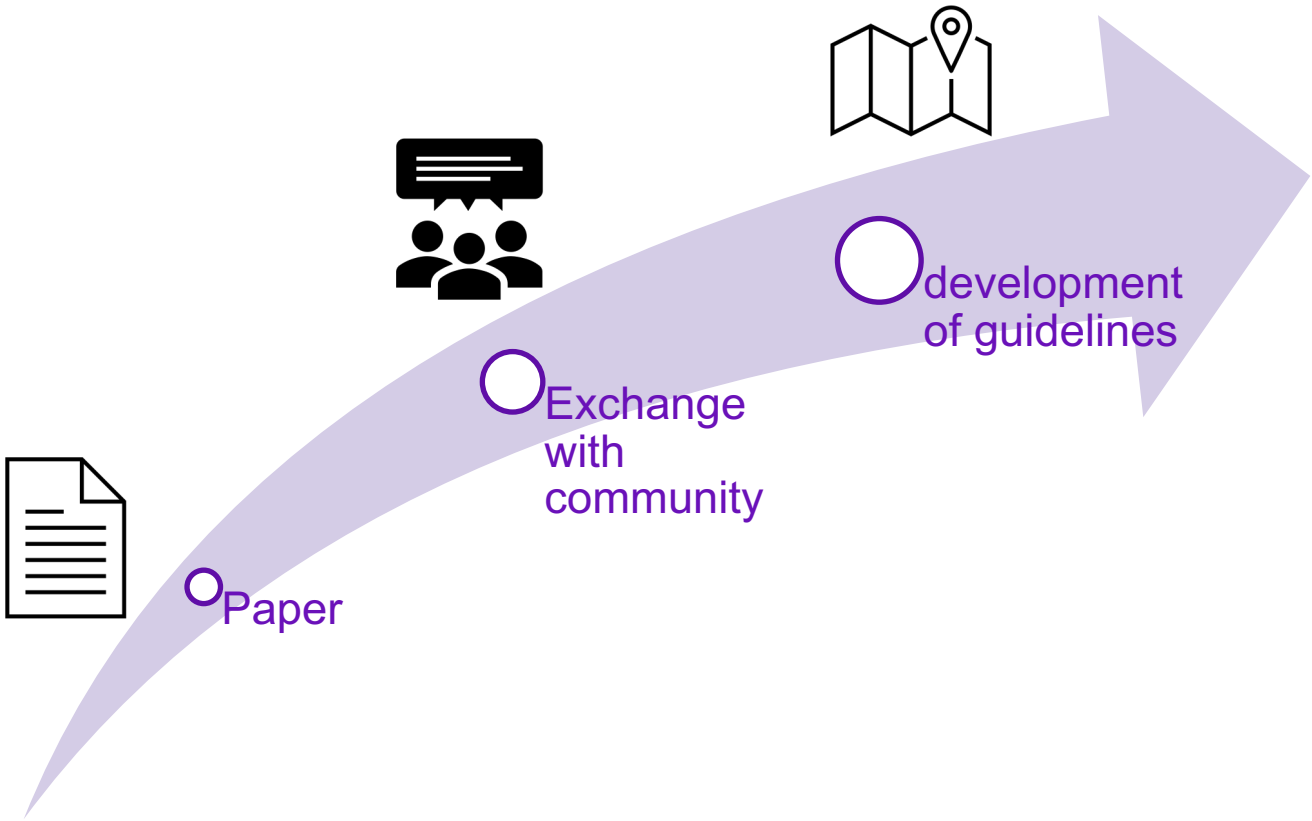

DiTraRe

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Thank you!

Visit us on

https://www.ditrare.de/en

Or write us:

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