# AI and digital technologies transforming cardiovascular device innovation.

*Opportunities and challenges on the path towards successful implementation of algorithmic innovation at scale.*

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***EMA Workshop: Supporting innovation in cardiovascular medicines and medical devices in the EU – Foster innovation in cardiovascular diseases with digitalisation and AI, Amsterdam, July 2nd, 2026***

# Disclaimer

- I am currently employed by the University Hospital Bonn and the University of Bonn.
- I have performed work under contract for the European Commission/the European Medicines Agency and the German Federal Ministry of Health, and some commercial entitities over the years.
- I have received and continue to receive grants from various national and international research funding institutions.

**The thoughts presented here reflect my personal perspective and opinion only.**

# Convergence of potentially transformative forces to enable algorithmic innovation as a translational game changer in cardiovascular medicine

### Hardware & Modeling Capabilities

Exponentially growing amounts of compute and storage capacity support ever larger and more powerful data driven (and mechanistic) models.

### Digital Documentation

Electronic health records are becoming ubiquitous across medical practice – providing an increasing flood of clinically relevant data.

### Infrastructure Readiness

National and international infrastructures for systematic secondary use of patient data have been established - e.g., Medical Informatics Initiative (MII) in Germany - or are under construction (EHDS)

### Standards

Deeper standardization (e.g., HL7 FHIR, ISO 11073 SDC) at the syntactic, semantic and procedural level.

# Where do we stand?

## Opportunities/Potential for… (a selection)

### Hardware & Modeling Capabilities

Exponentially growing amounts of compute and storage capacity support ever larger and more powerful data driven (and mechanistic) models.

- better decisions based on increasing amounts of established and novel data types
- improved efficiency in times of staff shortage
- system level optimization, e.g. via risk adjusted quality comparison & incentivization

### Digital Documentation

Electronic health records are becoming ubiquitous across medical practice – providing an increasing flood of clinically relevant data.

- clinical process improvement
- availability of data for secondary use (quality assurance, surveillance, research)

### Infrastructure Readiness

National and international infrastructures for systematic secondary use of patient data have been established - e.g., Medical Informatics Initiative (MII) in Germany - or are under

- accessibility of larger and more representative datasets
- reduced effort and time to implement data usage

### Standards

Deeper standardization (e.g., HL7 FHIR, ISO 11073 SDC) at the syntactic, semantic and procedural level.

- deeper system integration in production environments
- improved cross-institutional data usage

# Where do we stand?

## Challenges/Risk of… (a selection)

### Hardware & Modeling Capabilities

Exponentially growing amounts of compute and storage capacity support ever larger and more powerful data driven (and mechanistic) models.

- unsafe system behaviour, e.g. biased, wrong decisions
- limited cross-institutional transferability
- lack of robust and affordable performance evaluation

### Digital Documentation

Electronic health records are becoming ubiquitous across medical practice – providing an increasing flood of clinically relevant data.

- increased administrative/ documentation burden
- uncontrolled impact on clinical processes

### Infrastructure Readiness

National and international infrastructures for systematic secondary use of patient data have been established - e.g., Medical Informatics Initiative (MII) in Germany - or are under

- information security incidents/privacy leaks
- lack of end-user usability of infrastructure and usefulness of data
- cost & complexity explosion

### Standards

Deeper standardization (e.g., HL7 FHIR, ISO 11073 SDC) at the syntactic, semantic and procedural level.

Insufficient standardization depth or incorrect implementation leading to

- fragile system integration obstructing risk management
- misinterpretation of data

# Where do we stand?

## Challenges/Risk of… (a selection)

| Hardware & Modeling Capabilities | Digital Documentation | Infrastructure Readiness | Standards |
|---|---|---|---|
| **My hypothesis:** These challenges in implementing impactful and safe sociotechnical systems that support ***algorithmic innovations at scale*** are ***interlinked*** and ***interdependent***.<br><br>Mitigation requires a concerted systemic evolution that needs ***careful planning and guidance by the regulators***, but also ***a lot of hard construction work by medical domain experts and industry*** to<br>• achieve ***input data and implementation ecosystem harmonization*** and<br>• enable ***continuous, deep online surveillance/monitoring of safety and performance***. | | | |
| • unsafe system behaviour, e.g. biased, wrong decisions<br>• limited cross-institutional transferability<br>• lack of robust and affordable performance evaluation | • increased administrative/ documentation burden<br>• uncontrolled impact on clinical processes | • information security incidents/privacy leaks<br>• lack of end-user usabiltity of infrastructure and usefulness of data<br>• cost & complexity explosion | Insufficient standardization depth or incorrect implementation leading to<br>• fragile system integration obstructing risk management<br>• misinterpretation of data |

# Where do we stand?

## Challenges/Risk of… (a selection)

### Hardware & Modeling Capabilities

biased, wrong decisions
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### Digital Documentation

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### Infrastructure Readiness

incidents/privacy leaks
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depth or incorrect implementation leading to
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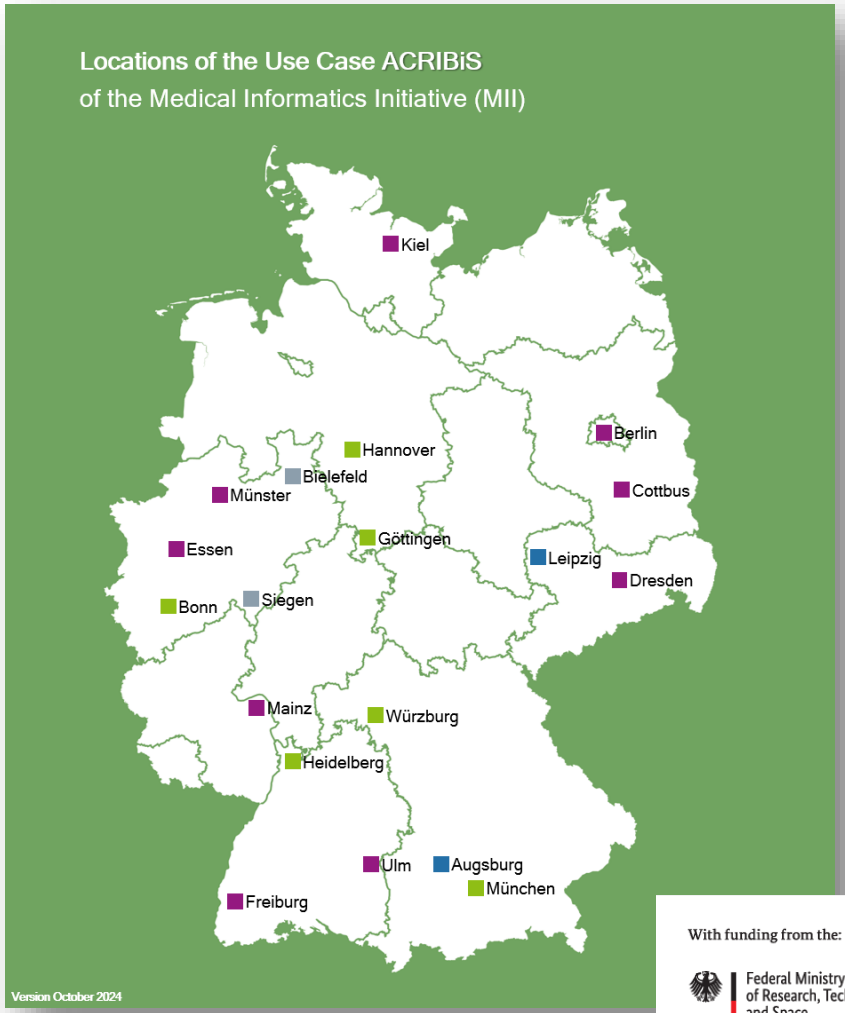
Mitigation requires a concerted systemic evolution that needs ***careful planning and guidance by the regulators***, but also ***a lot of hard construction work by medical domain experts and industry*** to

- achieve ***input data and implementation ecosystem harmonization*** and
- enable ***continuous, deep online surveillance/monitoring of safety and performance***.

**Up next: a few examples of what we‘re trying to do about it…**

# We‘re currently giving it a serious try - prototypically addressing *all components* in an academic consortium for cardiovascular medicine: ACRIBiS

(**A**dvancing **C**ardiovascular **R**isk **I**dentification with Structured Clinical Documentation and **Bi**osignal Derived Phenotypes **S**ynthesis)




**6 ACRIBiS core sites**

**9 ACRIBiS implementation sites**

**2 NUM DIZ- sites**

**Examples of associated Partners**

**Scientific Coordination:** Sven Zenker, University Hospital Bonn
**Co-Coordination:** Udo Bavendiek, University Hospital Hannover

Peter Heuschmann, University Hospital Würzburg

**Funding (Federal Ministry of Research, Technology and Space – BMFTR):**

- approx. 9.3 MEuros for original ACRIBiS MII project till 2027
- additional NUM DIZ upgrade: approx. 1.5 additional PY till 06/2025 for each of 14 DIZ sites for non-ACRIBiS dashboarding & centralizing ACRIBiS data usage across 8 sites (2 new partners) – first ACRIBiS milestone successfully completed 12/2023

# ACRIBiS aims in a nutshell

- Development of structured and standardized routine documentation in cardiology
- Development of an interoperable infrastructure for the integration and modular processing of ECG biosignals
- Evaluation of the predictive performance of existing risk quantification tools and innovative ML-driven hybrid models, *including online performance monitoring using state-of-the-art infrastructure*
- Increasing patients' risk awareness through interactive risk visualization

# Cardiovascular Risk Stratification *before ACRIBiS*

- Anamnestic info
- Physical exam
- ...

Labs/Biomarkers

Image data

Biosignals

Mobile data/sensors

"manual"

Separate, non-interoperable tools

**SCORES**

- Heart-Score (MI/Stroke)
- CHADS-Vasc-Score (cardiac embolism/VHF)
- MAGGIC/BCN-HF-Score (heart failure)
- Wells-Score (thromboembolism)
- PESI (pulmonary embolism)
- GRACE-Score (coronary syndrome)
- ...

# Cardiovascular Risk Stratification *after* ACRIBiS

- Anamn
- Physic
- ...

Labs/Bior

Image

Biosignals

Mobile data/sensors

Cross-site standardization, structured representation, and data quality assessment/an-notation

Integration

## Data integration center (DIZ)

**Interoperable representation**

**Modular analytics**

## SCORES

- Heart-Score (MI/Stroke)
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- GRACE-Score (coronary syndrome)
- **New Hybrid ML based Risk Metrics**

interventional CDS not primary goal (MDR!)

# ACRIBiS – *cross site* infrastructure – high level architecture

ESC European Society of Cardiology

ACRIBiS App (COMPASS Derivative)

- Anamnese
- Körperliche Untersuchung
- …

Labor/Biomarker

Bilddaten

Biosignale

Mobile Sensordaten, PROMs

Interventioneller CDS erst im weiteren Verlauf (MDR!)

DIZ

Interoperable Repräsentation

Modulare Analytik

SCORES

Heart-Score (MI/Stroke)

CHADS-Vasc-Score (Kardioembolie/VHF)

MAGGIC/BCN-HF-Score (Herzinsuffizienz)

Wells-Score (Thrombose)

PESI (Lungenembolie)

GRACE-Score (Koronarsyndrom)

…

Dash-board Data Proces-sor (DDP)

Site 1

PROMS & sensor data

Site n

Aggregated Results

&

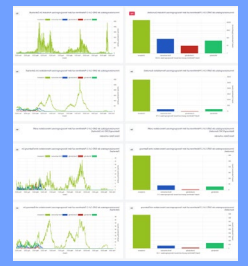
Calibration Data

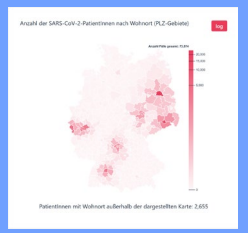
## NUM Dashboard

(Project specific restricted access area)

- ACRIBiS cohort enrollment tracking
- Data availability monitoring and reporting
- Online tracking of differential predictive performance of scores*
- Distributed recalibration of scores/risk models*

*Final project phase





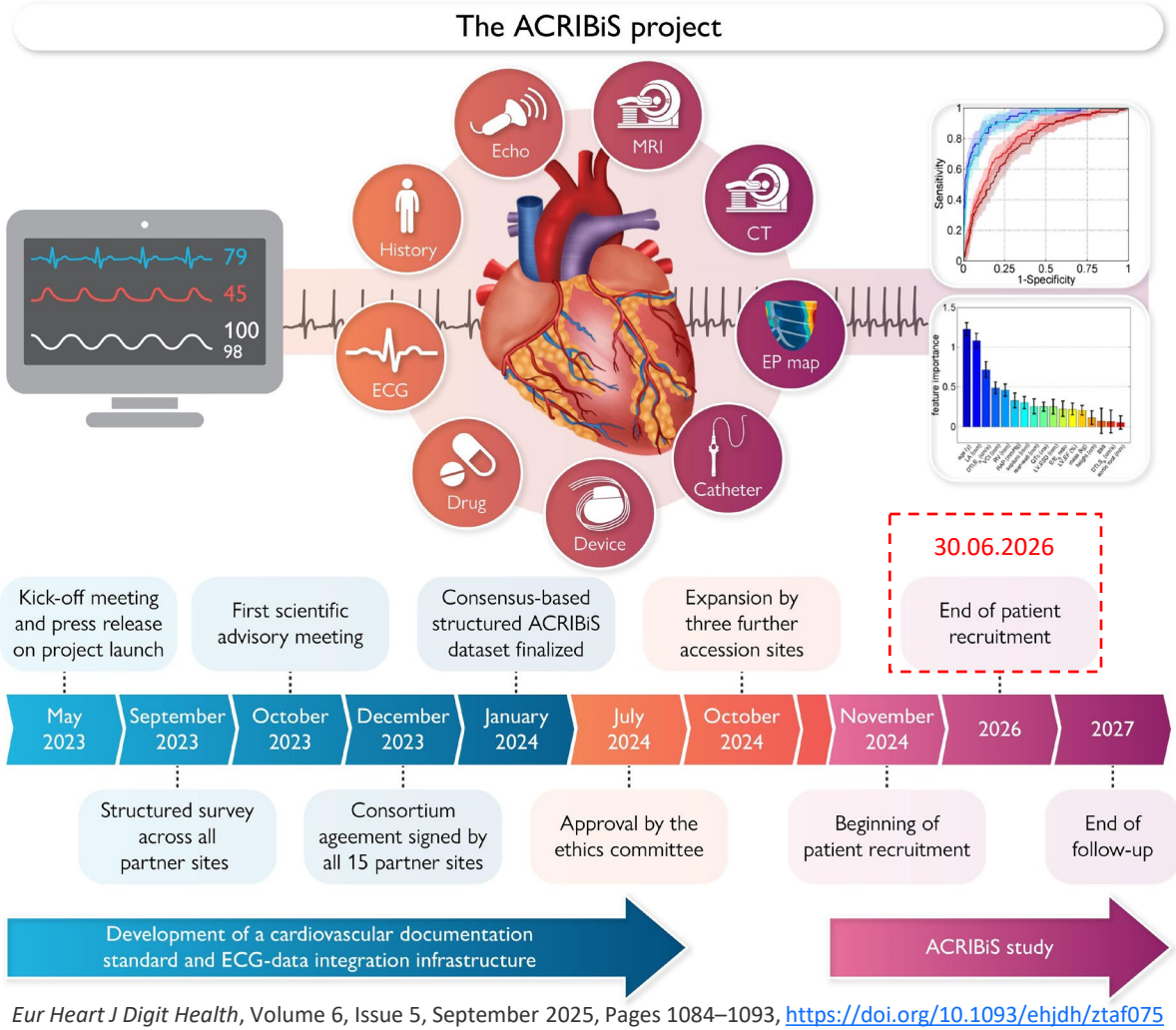
# ACRIBiS cohort

- The **ACRIBiS cohort study** is registered
  - Deutschen Register Klinischer Studien (DRKS)
    https://www.drks.de/DRKS00034792
  - WHO-Portal
    https://trialsearch.who.inte
- **Legal basis**: standard-compliant modular extension of the MII Broad Consent (ACRIBiS Z module)
  - ACRIBiS contributes to establishing nationally standardized approach
  - Data can be reused in other contexts
- **Recruitment status beginning of March 2026: 3.863/ 5.500** patients
- **12 month follow-up for patient-centered outcomes now ramping up**

International Clinical Trials Registry Platform Search Portal

Deutsches Register Klinischer Studien

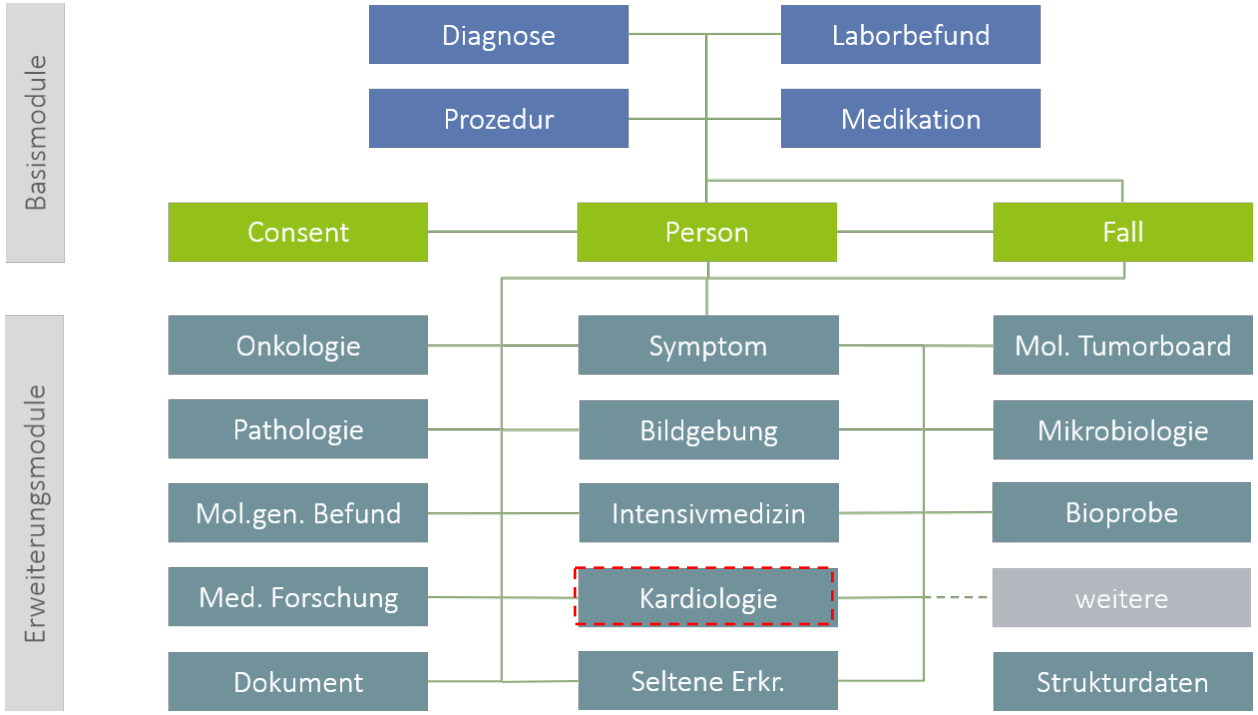
German Clinical Trials Register




*Eur Heart J Digit Health*, Volume 6, Issue 5, September 2025, Pages 1084–1093, https://doi.org/10.1093/ehjdh/ztaf075

# ACRIBiS Standardized Clinical Dataset

**Modular Core Dataset/National Level FHIR Standards**




https://www.medizininformatik-initiative.de/de/der-kerndatensatz-der-medizininformatik-initiative

- Dataset with various clinically relevant elements
- **ACRIBiS consensus datasets**:

| | Anzahl Standorte |
|---|---|
| **_Basic_ ACRIBiS Core Dataset**<br>**62 Items (BCN, CHA2DS2-VAs, SMART)** | **9** |
| **_Full_ cardiological dataset ACRIBiS**<br>**(290 Items) including all ACRIBiS scores plus additional clinically relevant data items.** | **7** |

- **MII KDS FHIR profiling:**
  - **„_Basic_“ fully profiled, _agile pilot implementation ongoing_**
  - **„_Full_“ work in progress**
- Intensive interdisciplinary collaboration
  - Clinicians & tech experts

# Input Data Standardization - Levels of Difficulty

„Deep“ standardization of clinical data, i.e., standardization that is specific enough to allow plug-and-play application in both clinical and secondary use scenarios, lives on a spectrum:

**„Simple“:**

- Primarily technical standardization  task that should use international terminologies/ontologies (LOINC, SNOMED CT, etc…)
- „plug-and-play“ interoperability still requires decisions to be made to eliminate ambiguities
- Interaction with international standardization organizations needed to fix gaps and errors
- Examples: vital signs, lab results, …

**„Hard“:**

- Before technical standardization, a consensus process for clinical documentation and/or process standardization is required
- Only after that, technical standardization can proceed
- Examples: cardiovascular anamnesis, physical exams, intensive care documenation practices

# Input Data Standardization – A Selection of Current Activities in Germany

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DIZ MEDIZIN INFORMATIK INITIATIVE – DATENINTEGRATIONSZENTRUM

NUM – Netzwerk Universitätsmedizin

- Standardized representation and provisioning of routine data for German university medicine BEFORE binding national level prescriptions
- Interoperability specifications and prototyping

AKTIN – Eine Infrastruktur im NUM

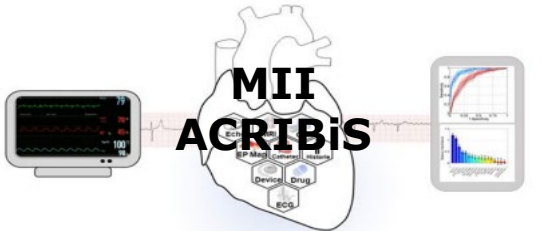
- ER documentation standardization
- Virtual registry

RAPID – A project within NUM

- ICU documentation standardization
- Virtual registry

**„Hard“:**

- Before technical stan… proc… docu… proc… requ… Only… stan… Exar… anar… inter… ractices




- Cardiological documentation standardization & standardized biosignal analysis pipeline
- Prospective evaluation of risk prediction performance

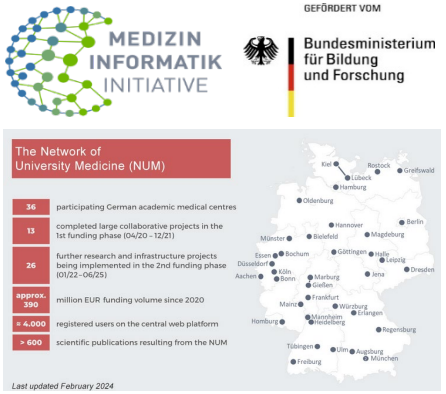
With funding from the:
Federal Ministry of Research, Technology and Space

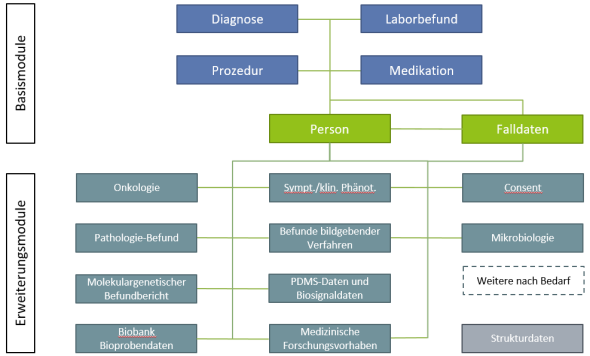
# Impact beyond Academia

Safe and scalabe deployment of complex AI systems will require an increasing level of standardization of the deployment environment, including, in particular, the input data streams. In Germany, recent developments appear promising wrt. improving the extremely heterogeneous clinical documentation landscape…

## Research

National working group interoperability develops modular, redundancy free „deep“ FHIR profiles to represent clinical data




Informs, advises & contributes to (based on practical implementation experience in university medicine)

## Production – Regular delivery of care

Directly controlled by Federal Ministry of Health - covers inpatient settings - defines FHIR profiles – implementation can be made obligatory for all EHR vendors

Covers outpatient settings - primarily controlled by National Association of Statutory Health Insurance Physicians

# *So we're making some inroads on the issues…*

…and are learning a lot along the way…

…are achieving real impact…

…but this does not really scale.

# Regulatory “Vision“

An **integrated technical and organizational, publically controlled and transparent infrastructure** that organizes healthcare data streams for

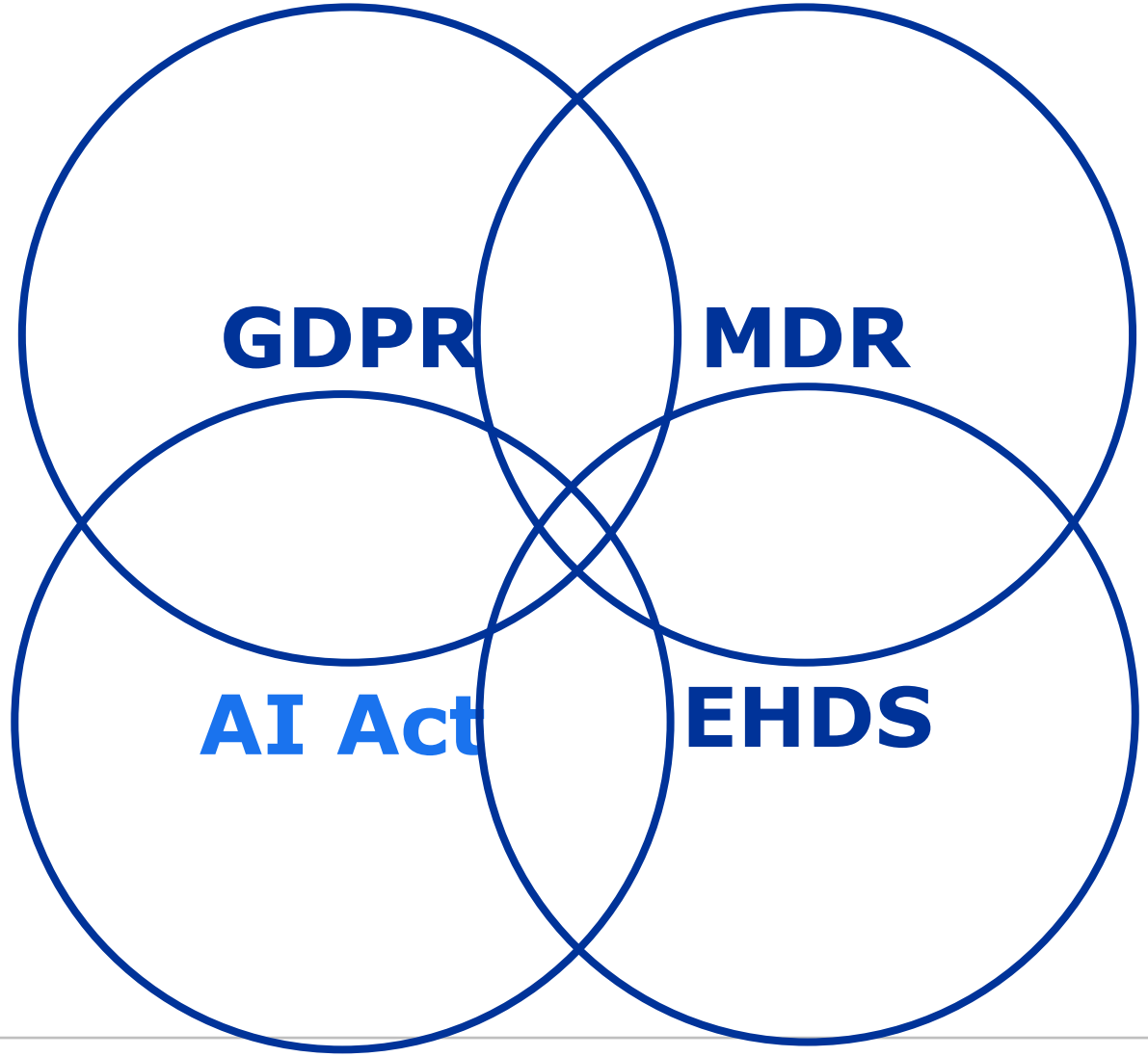
- research,
- development,
- validation and monitoring/surceillance

of **interoperable, transportable and composable algorithmic innovations** into a well-orchestrated, international architecture that

- facilitates agile development
- respects citizen privacy
- ascertains close-to-realtime transparency both of data use and algorithm performance (also for post-market surveillance/continuous validation)
- fosters commercial innovation but makes activity and outcome effects publically transparent.

***The EU may be uniquely positioned to achieve this.***

# Regulatory Architecture in the EU: Key Pieces of the Puzzle



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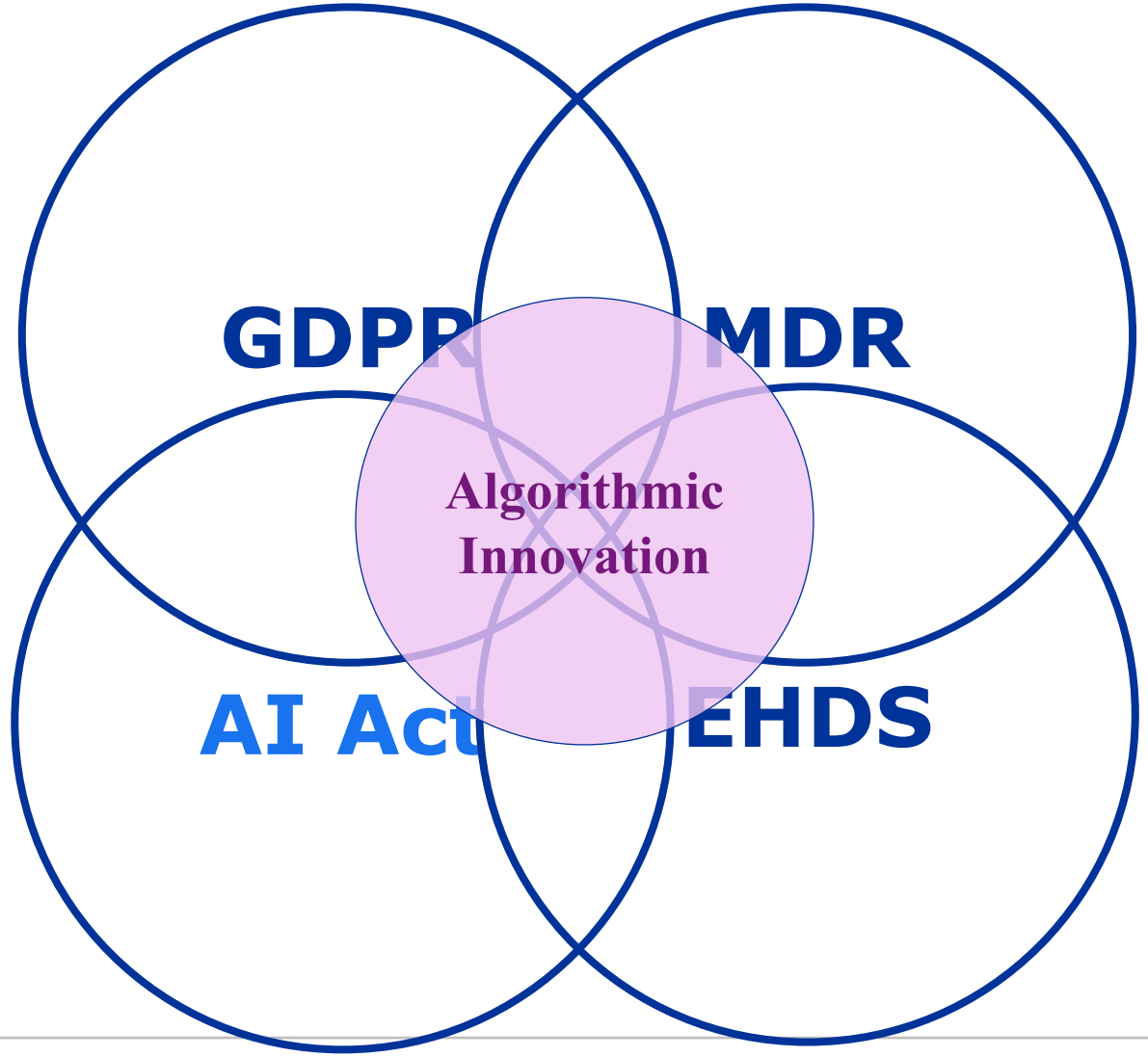
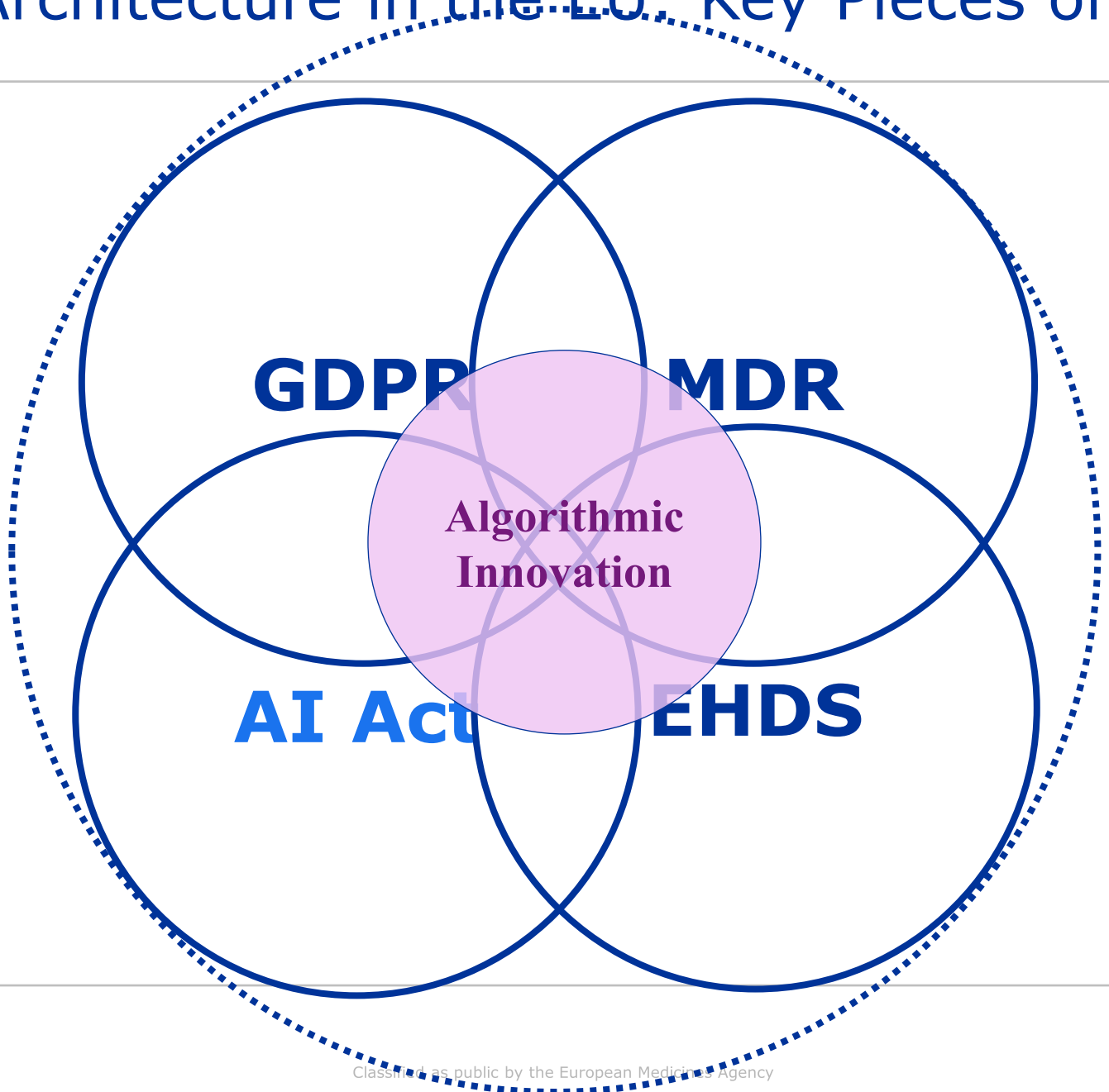


# Regulatory Architecture in the EU: Key Pieces of the Puzzle

**Potential for Integrative/ Cross-cutting Regulatory Adaptations**

Incentivization or binding provisions for convergent and practical data and implementation ecosystem standardization building on existant initiatives (MDR, AI Act, EHDS 1 /2 )




Publically controlled, privacy preserving infrastructure for scalable model development, validation, and *deep, continuous surveillance datastreams to enable scalable, representative verification and continuous safety and efficacy monitoring* evolved from existing infrastructure prototypes (GDPR, EHDS 1 / 2, MDR, AI Act)

# Thank you…

**…for your attention!**

**Questions? Comments?**