The EU approach to AI in healthcare

AI Implications on European Union Civil Society: Perspectives from Denmark – Conference

Session: Harnessing AI and Big Data for Advancements in Rare Diseases

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European Commission

AI and Rare diseases

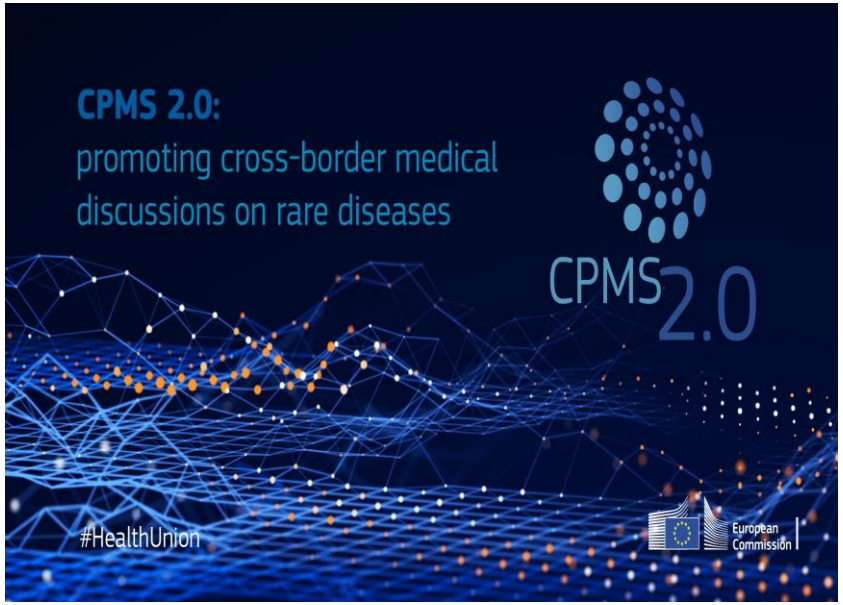
Challenges

- Small patient population
- Scarcity and fragmentation of data
- Expertise fragmented across Member States

  ⇨ Clear added value of EU-level collaboration

Opportunities

- **European Reference Networks (including ERN registries)**
- **EHDS:**
  - Access to representative data
  - Provides the ecosystem for AI to be developed and deployed to better treat patients with **rare diseases**
- **AI & Big Data:**
  - Analysis of vast datasets
  - Multimodal AI algorithms
  - Streamlining of drug discovery process



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AI can already…

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Analyse medical images and assist doctors in handling **high volumes of patients**

Repurpose existing and identify new **medicines** for addressing unmet medical needs

Enhance the **delivery** of care and patient consultation with speech-to-text tools

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Support care pathways and hospital **workflows** via data integration

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Help researchers **generate** synthetic **data** and explore knowledge spaces at higher speeds

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Enable faster & more accurate genetic analysis, **advancing gene editing** and gene **therapy**

→ these assist and support, but do not wholly replace, healthcare professionals

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The EU pillars towards AI in healthcare

Access to Data

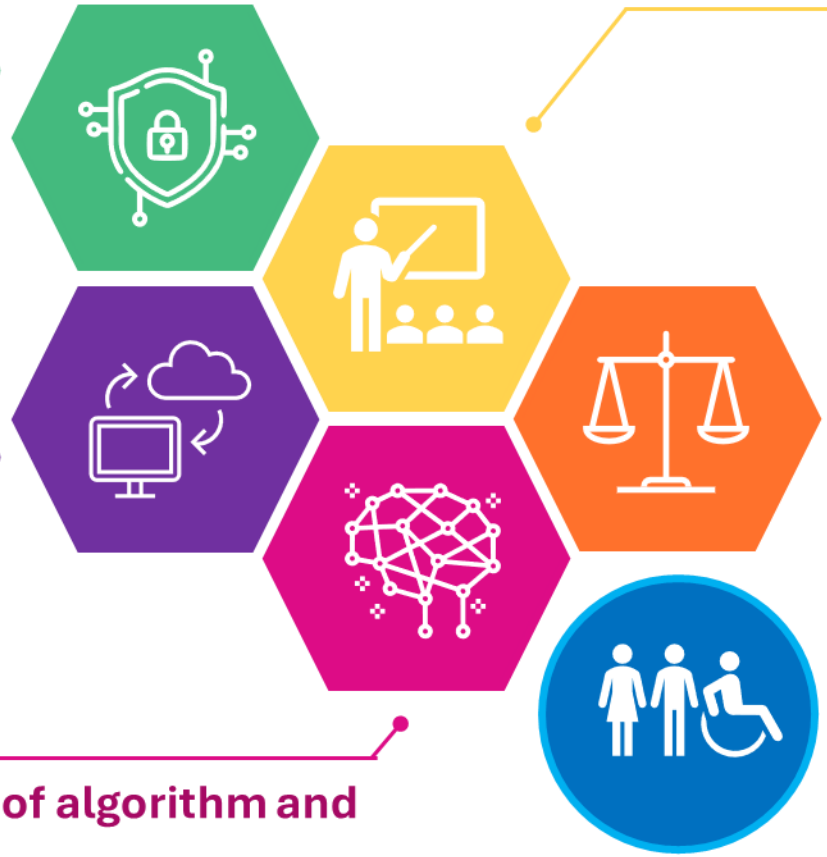
- **EHDS** : cross-border access to high quantity of diverse and high-quality health data.

Computing infrastructures

- **TEFs, AI Factories, AI Gigafactories**
- Pilot projects like SHAIPED for real-world testing of health AI

Development of algorithm and adoption

- **Apply AI Strategy**: supports innovation with public value — from start-ups to hospitals and patients, with ethical-by-design tools.



Skills

- **EU4Health & Pact for Skills**: training clinicians to understand, use, and challenge AI tools.

Regulatory guidance

- **AI Act, MDR, IVDR**: clear, risk-based and clinically aligned rules for safe AI in healthcare.

Patients, ethics, trust

People first, patients at the centre : AI for better health outcomes.

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