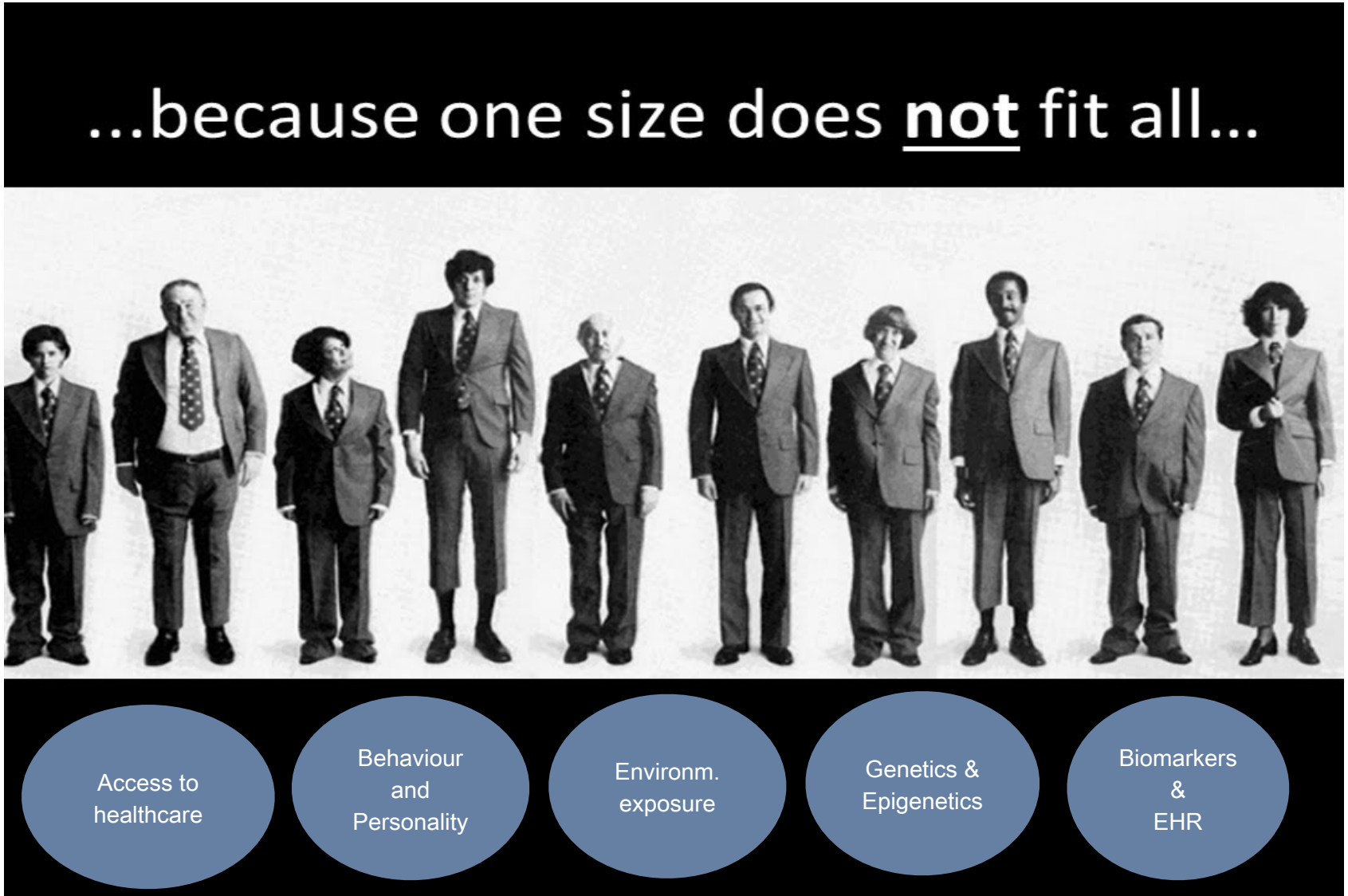
// Trends in Medical Care

- Chronic Disease Management

// Trends in Medical Care

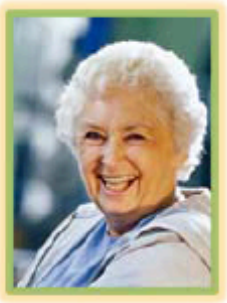
- Personalised / persision Medicine



// Trends in Medical Care

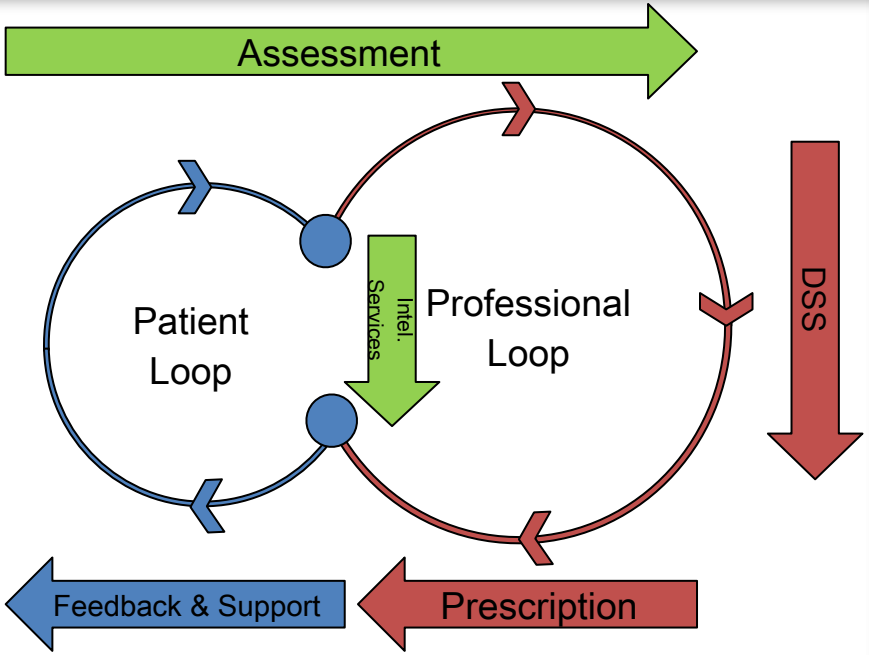
- Personalised / persision Medicine

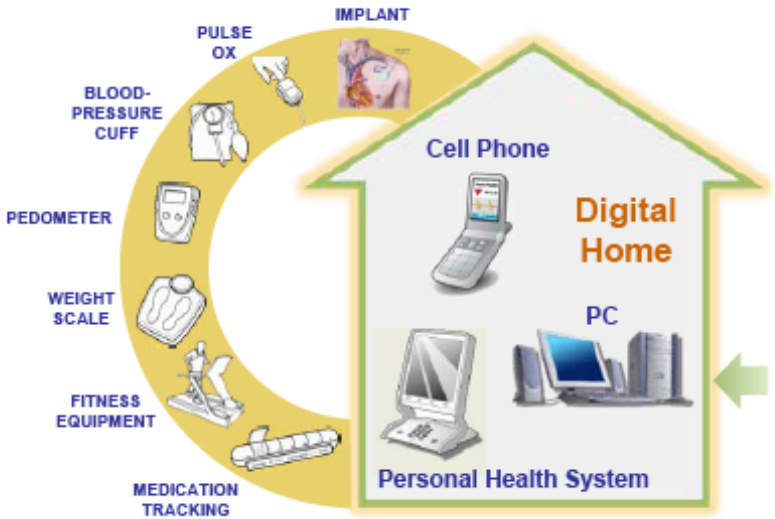
// Trends in pHealth



- Chronic disease
- Post trauma
- Pre-op

Continua HEALTH ALLIANCE





Internet

Continua member companies help people with chronic conditions live healthier lives by connecting them to their care team through a more efficient exchange of personal health information.

// Dependability Challenges: Assessment

- Invisibility – unawareness of what, how and where data is tracked
  - Heterogeneous domains: Health data is obtained from multiple (unregulated) contexts
  - Complex ecosystem (health providers, commercial vendors …) with different business models, privacy policies, **heterogeneous jurisdictions**
  - Unclear ownership: regulated healthcare data, self-reported health data, business relationships, hidden behavioural data
  - Regulations do not effectively protect patients
- Marketability of data
  - You are the business
- Identifiability
  - Crosss-correlation among different datasets
- Mortality – data never expires

The New York Times

GoodRx Leaked User Health Data to Facebook and Google, F.T.C. Says

The popular drug discount app deceptively shared details on users' illnesses and medicines with ad firms, regulators said in a legal complaint.

Give this article

Two screenshots of the GoodRx app, one showing how you can search for a prescription and the other showing the search results comparing prices of a particular prescription.

Millions of people have used GoodRx, a drug discount app, to search for lower prices on prescriptions. GoodRx

By Natasha Singer

Natasha Singer, a tech reporter, has covered health privacy since 2010.

Feb. 1, 2023

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Relevant impact on adherence to technology

Need new “standards” for deidentification, use and protection of information


The New York Times

GoodRx Leaked User Health Data to

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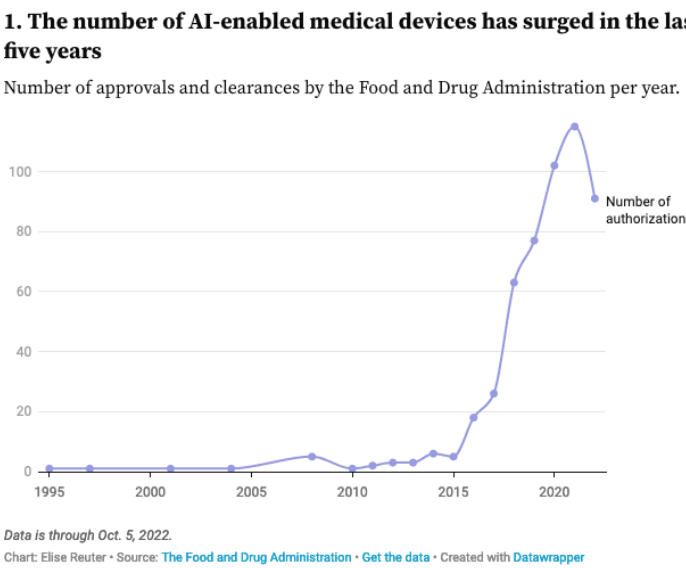
// Dependability Challenges: Certification

- **Certification of AI-based SaMD (e.g. CE-MDR, FDA)**

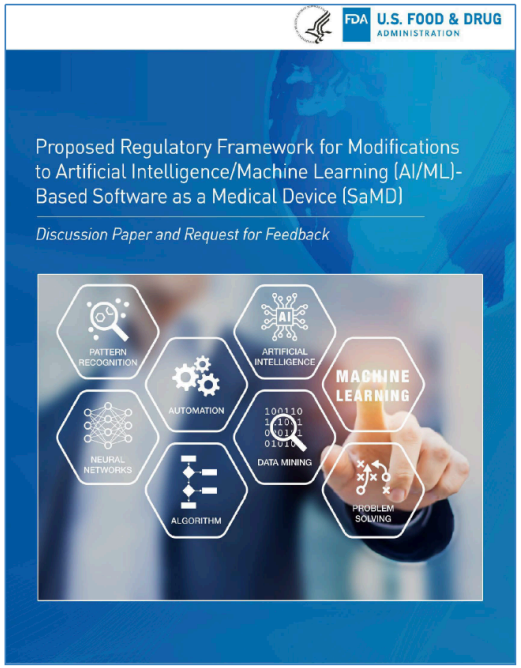
- **Knowledge-based**
  - Conceptually straightforward
  - Usually low-risk due to high degree of transparency and interpretability

- **Data-based: locked models**
  - Band aid: current marked AI-based solutions
  - Updates: must undergo regulatory review
  - Performance may degrade over time if not updated

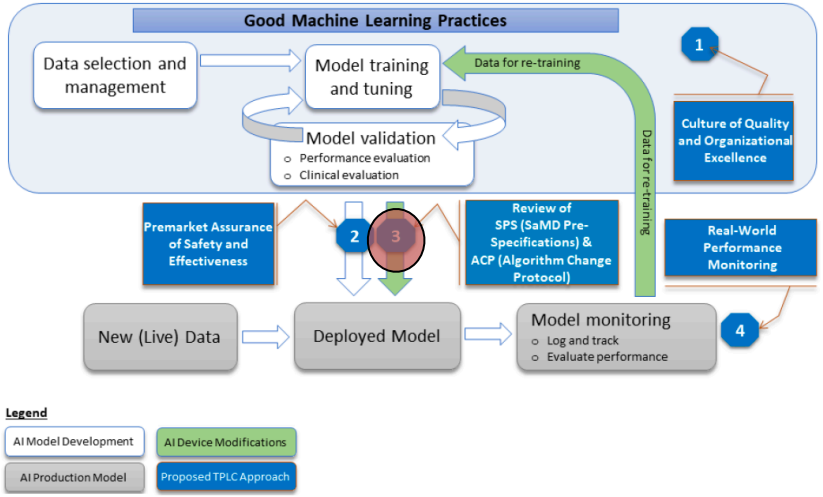
- **Data-based: continuous learning models**
  - Automatically change over time: potential impact on safety and effectiveness
  - Regulatory framework: under discussion



Proposed Regulatory Framework for AI/ML-Enabled Device Software



Overlay of FDA's TPLC Approach on AI/ML Workflow



www.fda.gov/digitalhealth

- New approval: whenever there is a major risk (new/change/control)
  - FDA: New intended use or function change
  - Other: Statistically relevant performance changes of updating learning

FDA: Good Machine Learning Practice Principles

1. Multi-disciplinary expertise throughout the total product life cycle
2. Good S/W Eng. and Security practices are implemented
3. Clinical Study participants and data sets are representative of the intended use
4. Training data sets are independent of test data sets
5. Selected reference data sets are based upon best available methods
6. Model design is tailored to the available data and reflects the intended use of the device
7. Focus is placed on the performance of the human-AI team
8. Testing demonstrates device performance during clinically relevant conditions
9. Users are provided clear, essential information
10. Deployed models are monitored for performance and re-training risks are managed

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Interpretability / explainability
Reliability / performance for different groups / known limitations

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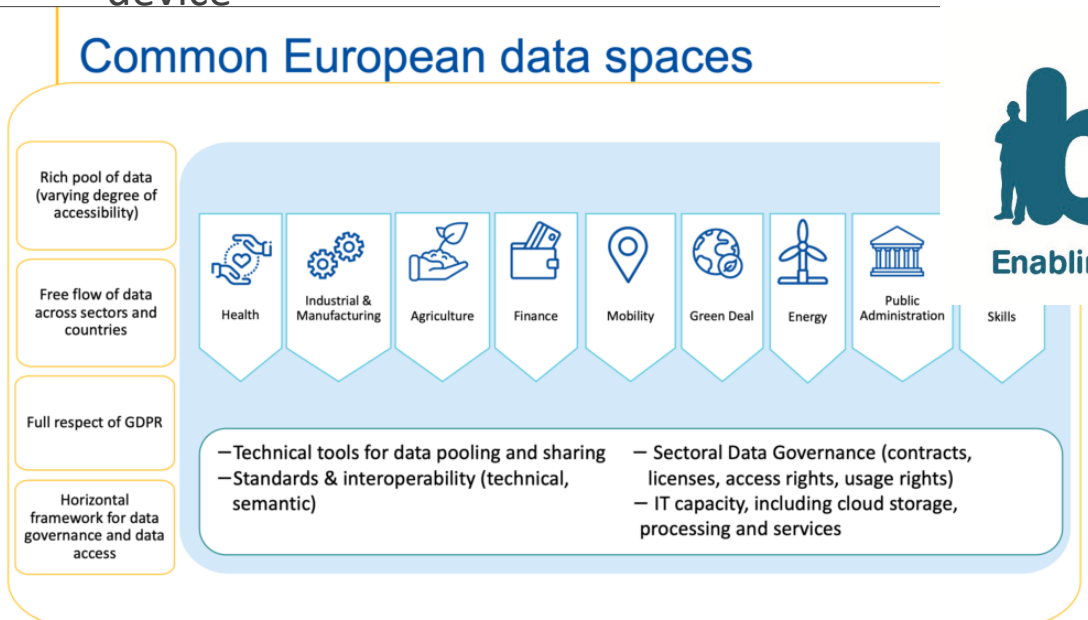

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