Future Clinical Trials

Transforming Clinical Trials with Data Science and Patient Centricity

Health Tuesday
6th of April

Challenges Facing Clinical Research Today

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While average time to bring a drug through clinical trial has decreased, the rate of success has reduced.

Cost to get a new prescription medicine to market is on average $2.6 billion.

productivity

R&D productivity is declining.

Bottlenecks in data processing.

Lot of manual steps.

Recruiting patients and keeping them engaged is a costly endeavour.

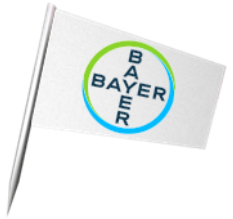
A burden to doctors and patients alike.

Strict regulatory framework.

Data privacy issues are a bottleneck.

Future Clinical Trials Project

Expected duration: 2020 - 2023



BUSINESS FINLAND

- We develop unique
  - patient centric and
  - data driven solutions
    - to challenges in clinical trials today
- With a potential to become global innovations

- Our core project team members work in global roles of Bayer's
  - Data Science & Analytics
  - Clinical Development Operations
  - Oncology Development Operations
  - R&D IT
  - Integrated Evidence Generation in Medical Affairs

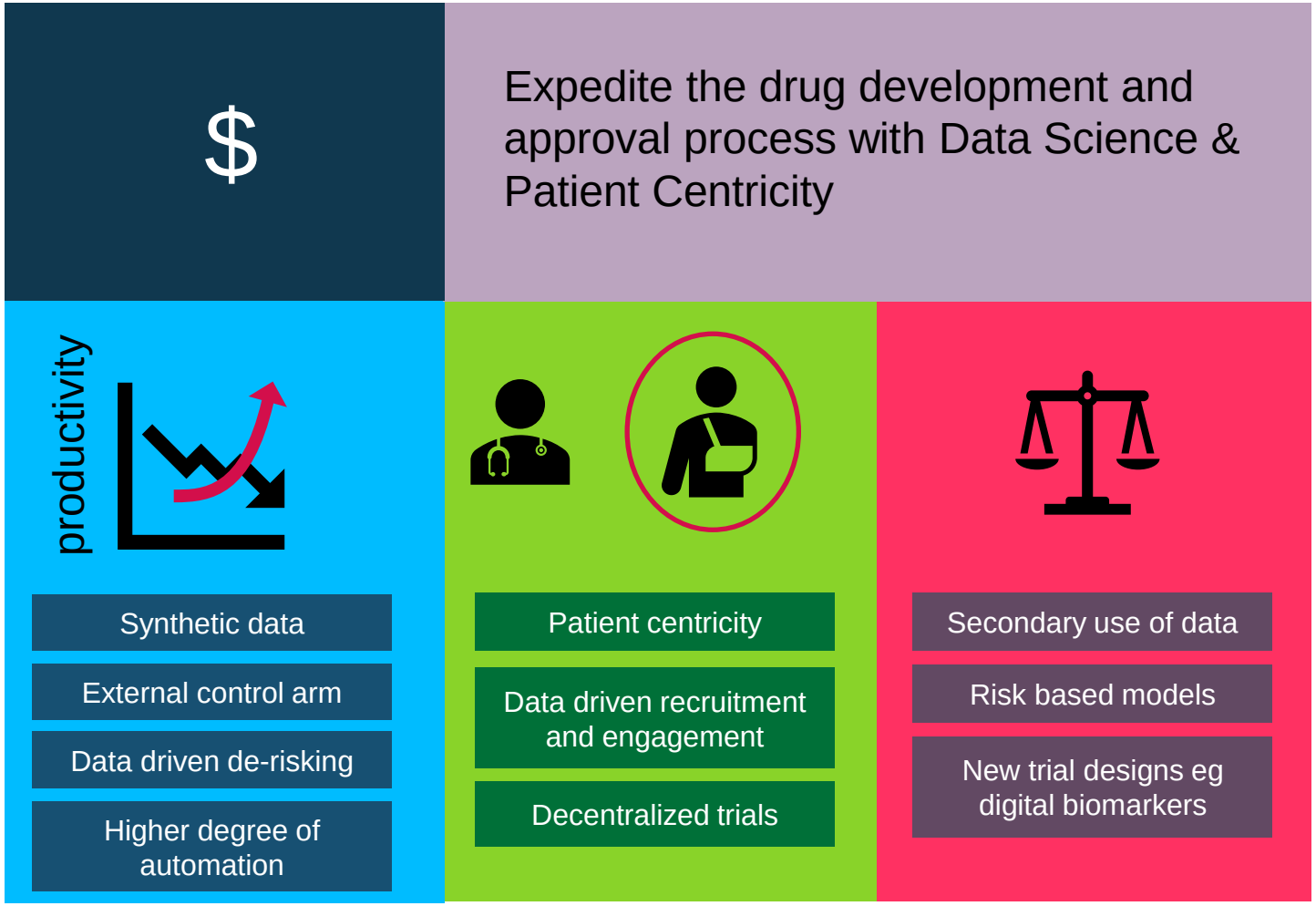
Our Vision

What We are on a **journey to transform** the way we **plan and conduct clinical trials** in the future.

Why To **improve the health outcomes** and **reduce the burden** on **patients, doctors and overall costs**.

How The **health eco-system** in Finland offers an excellent environment to **co-design and test data-driven solutions** that have the potential to become **global innovations**.

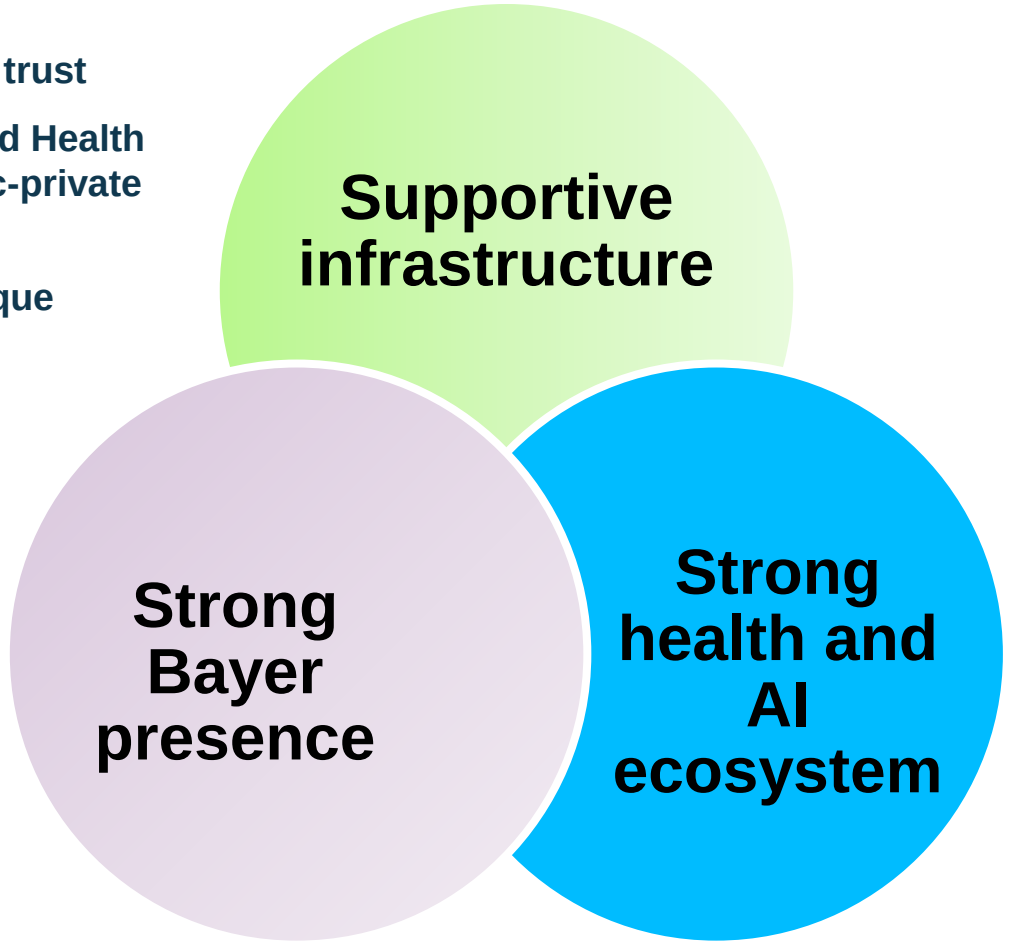
Our Solution: Leveraging Digital Technologies and Data



Why Finland?

An excellent environment to co-design and test data-driven solutions that have the potential to become global innovations

- **Engaged citizens and a culture of trust**
- **Up to date research legislation and Health Growth Strategy promoting public-private partnerships**
- **100% digital health records & unique national registries**



- **Sizeable research unit in Finland, currently investing heavily in growing the data science capabilities.**

- **Strong medical technology ecosystem, with many innovative start-ups and growth companies in the digital health cluster**
- **World class research on AI, growing number of companies active in the area**

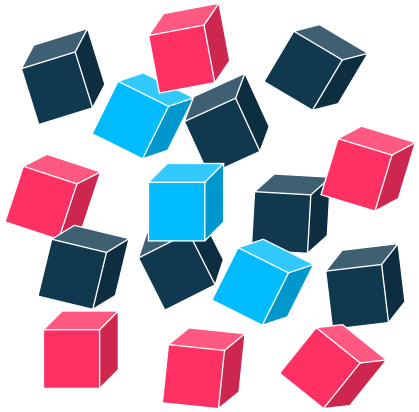
Permissive Legislation to Tap into High-Quality Real-World Data

2019: Act on the secondary use of health and social data. Internationally unique!

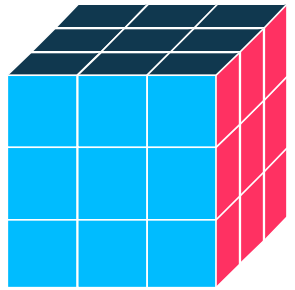
2020: Data permit and analysis processes in place, Findata started, first data permit applications submitted in May.

What data is available?

- Health and social data from all social and healthcare providers and national registers
- Detailed, patient level pseudonymous data available for scientific purposes
- Aggregated data (statistics) for development and innovation purposes
- Business friendly interpretation: properly anonymized, patient level data can be extracted and used in variety of use-cases



Single health data sources



Secondary use of health & social data legislation

Collaborations in the Project So Far

Tapping into the Finnish expertise on healthcare data and service design

Medical data science
Real World Data expertise

SW solutions for biomedical data
Data model expertise

Health data de-identification services
Anonymization strategies

Data and AI consultancy
Project coordination
AI development support

Contracted

Artificial intelligence
Research collaboration

Service design
Clinical trial process

Under preparation

Expedite the drug development & approval process with ***Patient Centricity***

Patient Centricity

Simplifying patient and site journey in decentralized elements implementation

Data Science

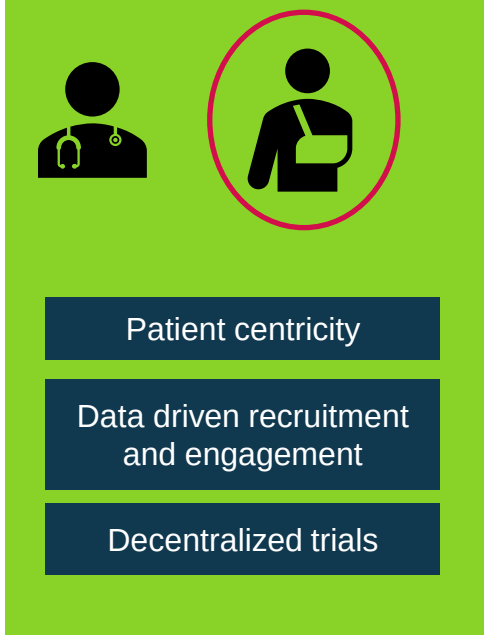
Integrating data sets

Pattern recognition & process optimization

Virtual control arm

Data Platform & Architecture

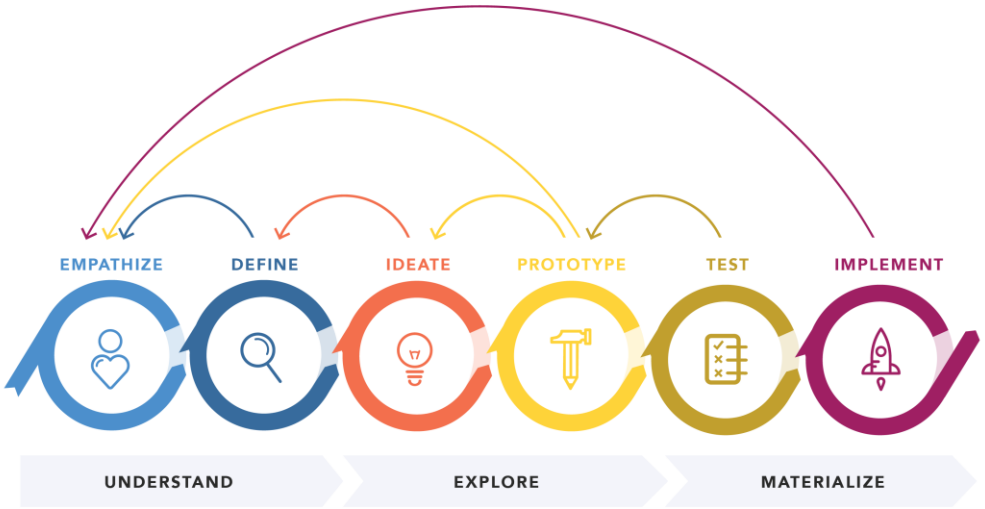
Hospitals Data Lakes Biobanks EHR Bayer data



Approach to Service Design for Clinical Trials

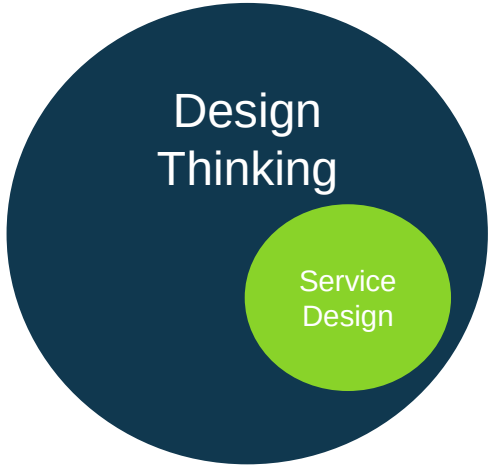
What is Service Design?

- Service Design is an extension of **design thinking** such that behind any innovation, product or solution, is a service. The planning of resources to improve the quality of that service is service design.
- The **service design** focuses on the whole customer (clinical trial E2E) journey – from awareness to how it meets the goals, including post engagement and support.



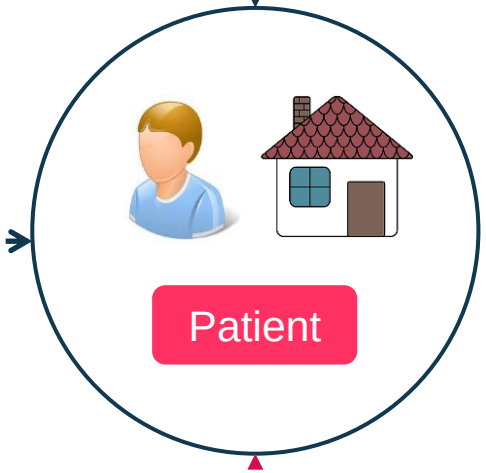
How is service design beneficial?

- Identifying critical opportunities to improve overall clinical trial experience
- Is the current clinical trial process handling new technology easily and pleasant for patients and sites?
- With more digital solutions available, can we improve the quality and quantity of the data within the clinical trial process?
- How can we apply the service design results globally within the clinical trial process?



Decentralized Clinical Trials

DCT - Technology



DCT - Services

Current

Expedite the drug development & approval process with ***Data Science***

Patient Centricity

Simplifying patient and site journey in decentralized elements implementation

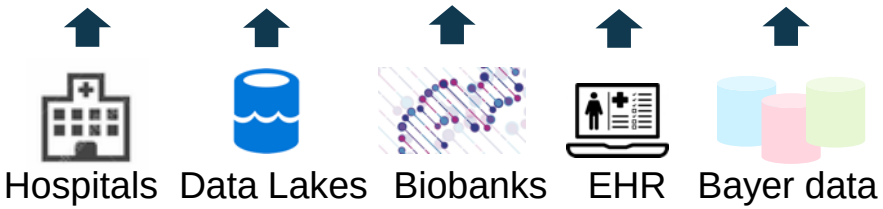
Data Science

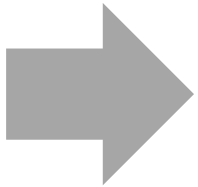
Integrated data sets

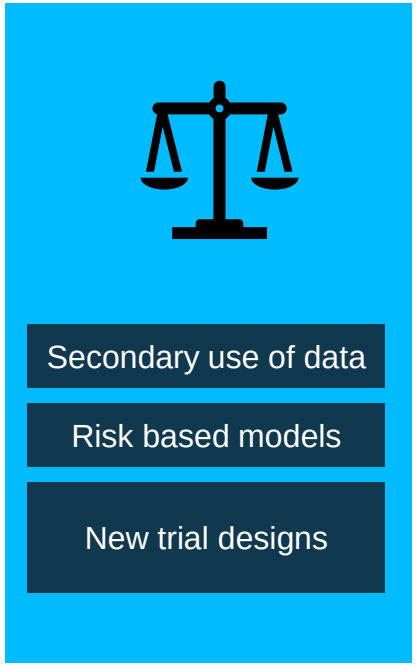
Pattern recognition & process optimization

External control arm

Data Platform & Architecture



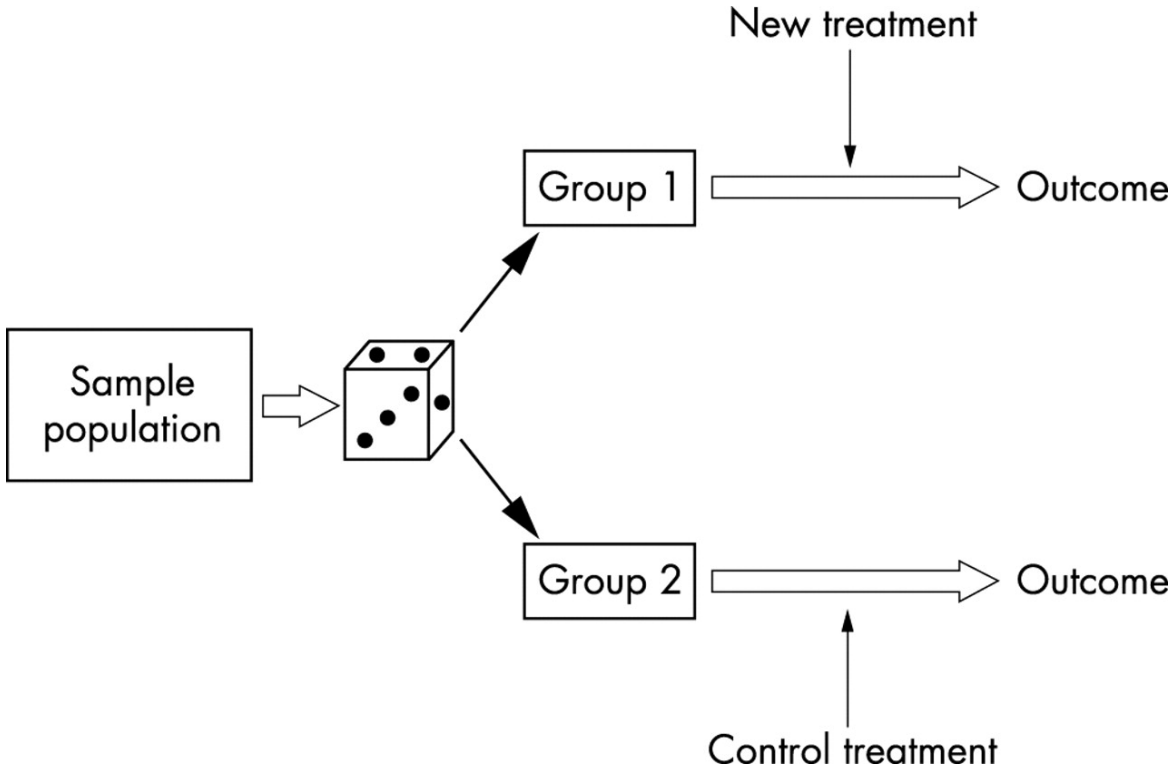




Project Goals in Data Science

Integrated datasets	• Building the capabilities of embedding of real-world data into clinical development programs
Pattern recognition	• New data sciences methods to plan, predict and manage the risks in clinical trials based on both RCT & RWD
Virtual and synthetic controls	• Create methodology for providing virtual or synthetic controls to clinical trials based on RWD and legacy clinical trial data

Why to Use External Control Arm in a Clinical Trial?



Number of patients: Especially with rare diseases, difficult to find enough subjects

Ethical concerns: If you know that the new drug is most likely better, you want everyone in the trial to benefit

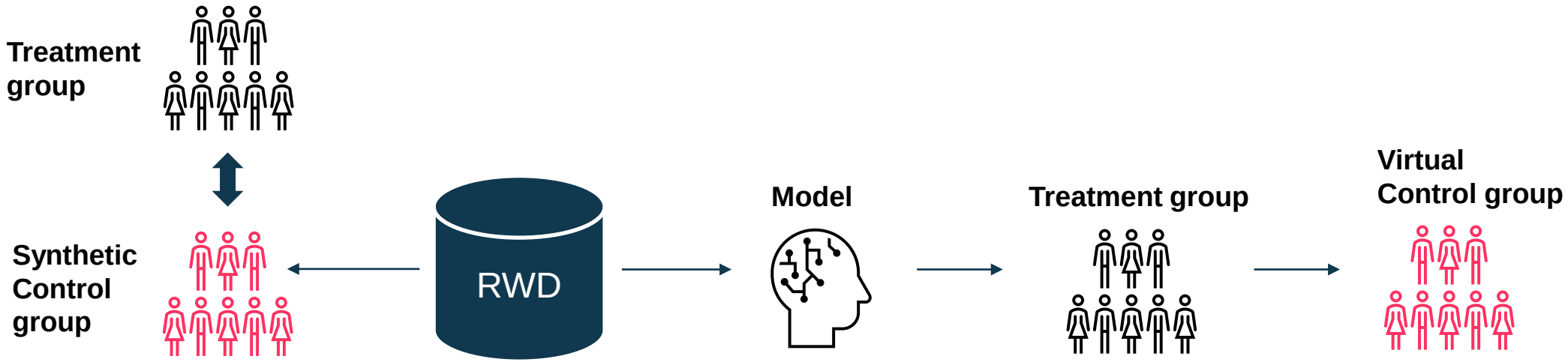
Costs, time to market: recruiting subjects to traditional clinical trials is slow and expensive

Designing a research project: randomised controlled trials and their principles
Emergency Medicine Journal 2003;**20:**164-168.

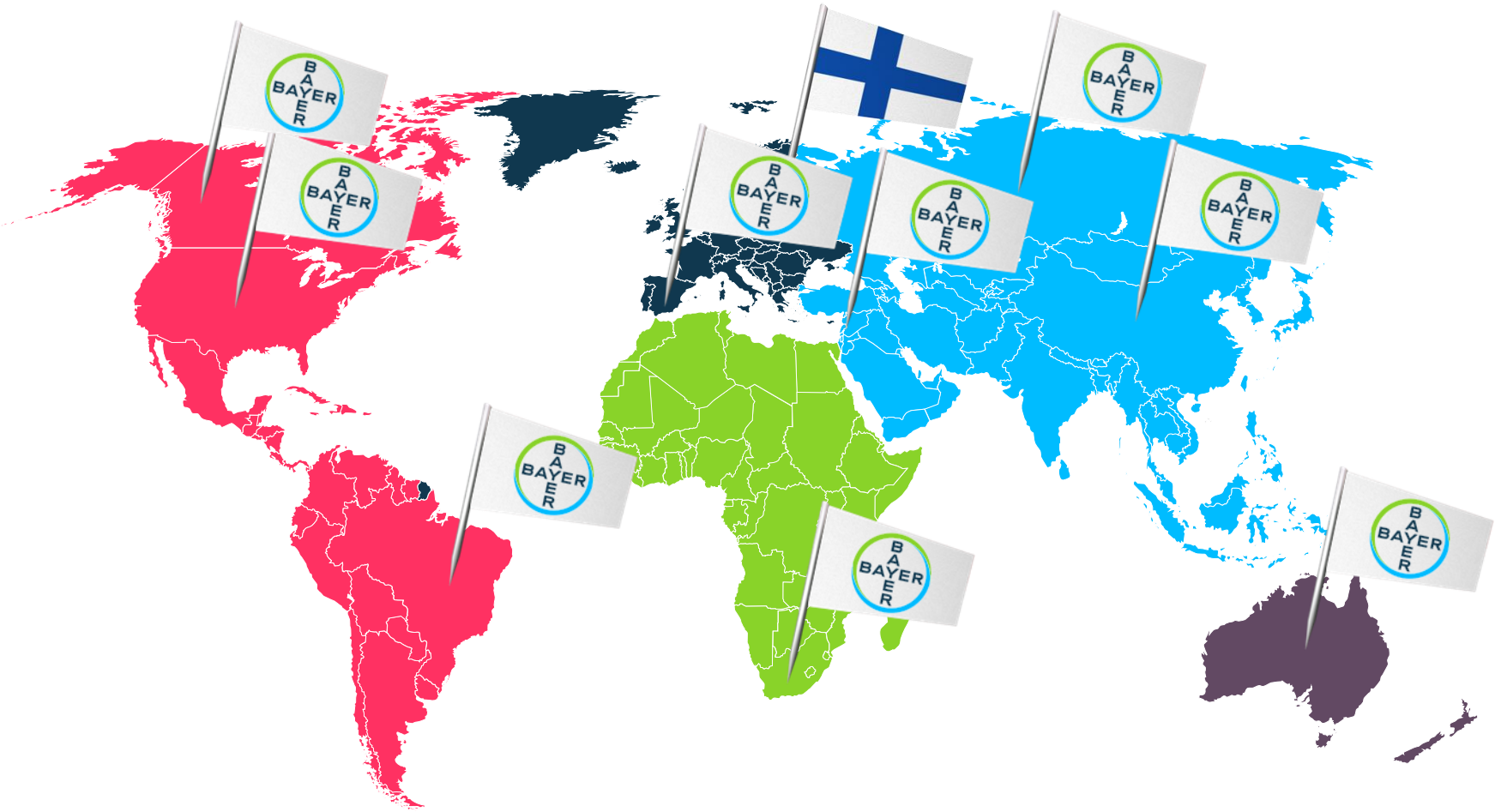
External Control Arm Development in Future Clinical Trials

We will create methodologies and processes to work on two types of external controls

- **Synthetic controls** = patients from an external data source, selected with statistical methods so that the baseline characteristics are balanced and comparable with the experimentally treated patients
- **Virtual controls** = predictive models based on actual patient data, predicting how the participants in the experimental treatment group would have reacted to standard of care



Clinical Trials Are Global – So Should The External Controls



Thank You!