Future Clinical Trials

Transforming Clinical Trials with Data Science and Patient Centricity

Health Tuesday
6th of April
Challenges Facing Clinical Research Today

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.

- **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

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, and 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

Expedite the drug development and approval process with Data Science & Patient Centricity

- Synthetic data
- External control arm
- Data driven de-risking
- Higher degree of automation
- Patient centricity
- Data driven recruitment and engagement
- Decentralized trials
- Secondary use of data
- Risk based models
- New trial designs eg digital biomarkers
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.

Supportive infrastructure

- 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

Strong Bayer presence

Strong health and AI ecosystem
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
Collaborations in the Project So Far
Tapping into the Finnish expertise on healthcare data and service design

<table>
<thead>
<tr>
<th>Medical data science</th>
<th>Artificial intelligence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real World Data expertise</td>
<td>Research collaboration</td>
</tr>
<tr>
<td>SW solutions for biomedical data</td>
<td></td>
</tr>
<tr>
<td>Data model expertise</td>
<td></td>
</tr>
<tr>
<td>Health data de-identification services</td>
<td></td>
</tr>
<tr>
<td>Anonymization strategies</td>
<td></td>
</tr>
<tr>
<td>Data and AI consultancy</td>
<td></td>
</tr>
<tr>
<td>Project coordination</td>
<td></td>
</tr>
<tr>
<td>AI development support</td>
<td></td>
</tr>
<tr>
<td>Contracted</td>
<td></td>
</tr>
<tr>
<td>Under preparation</td>
<td></td>
</tr>
</tbody>
</table>

Artificial intelligence
- Research collaboration

Service design
- Clinical trial process

MedENGINE
- Medical data science
- Real World Data expertise

MediSapiens
- SW solutions for biomedical data
- Data model expertise

VEIL.AI
- Health data de-identification services
- Anonymization strategies

DAIN STUDIOS
- Data and AI consultancy
- Project coordination
- AI development support
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

**Patient centricity**
- Data driven recruitment and engagement
- Decentralized 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
- eConsent
- eCOA
- Telehealth
- Drug Adherence
- Devices/Wearables
- Sensors
- Future Apps
- Patient insights/engagement
- Engagement Content

DCT - Services
- Local Lab
- Home Nurse
- Direct to Patient
- Remote Metasite

Current
- Phone visits
- eCOA
- Devices/Wearables
- Sensors
Expedite the drug development & approval process with **Data Science**

**Data Platform & Architecture**

- Hospitals
- Data Lakes
- Biobanks
- EHR
- Bayer data

**Data Science**

- Integrated data sets
- Pattern recognition & process optimization
- External control arm

**Patient Centricity**

- Simplifying patient and site journey in decentralized elements implementation

**Productivity**

- Synthetic data
- External controls
- Data driven de-risking
- Higher degree of automation

**Risk based models**

- Secondary use of data
- New trial designs
Project Goals in Data Science

**Integrated datasets**
- Building the capabilities of embedding 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
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!