

Managing Clinical Data under the MDR

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Elon Musk's Neuralink implants brain chip in first human

Reuters

January 30, 2024 8:20 AM GMT+1 · Updated 7 days ago



 **Elon Musk**  
@elonmusk **Subscribe** ...

The first human received an implant from [@Neuralink](#) yesterday and is recovering well.

Initial results show promising neuron spike detection.

4:37 PM · Jan 29, 2024 · **6.1M** Views

 9.1K  13K  61K  2.8K 

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Jan 29 (Reuters) - The first human patient has received an implant from brain-chip startup Neuralink on Sunday and is recovering well, the company's billionaire founder Elon Musk said.

About me & my work

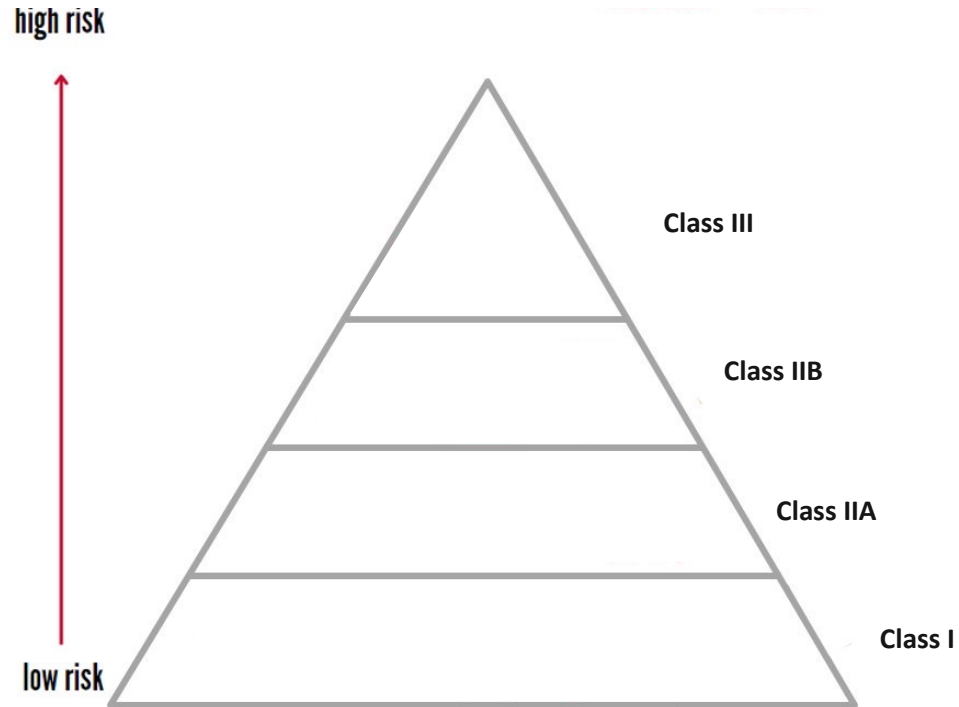
- Background in Biotechnology, Management & Data Science
- Data Manager/Data scientist for 6 years
- Family-owned medical device company
- Cochlear implants and other hearing implants
- Dedicated clinical research department
- Two full-time data managers
- Located in Innsbruck, Austria



What is a medical device?

Any device ... or software... for **diagnosis, ..., treatment** and which **does not achieve** its principal intended action by **pharmacological, immunological or metabolic means**, in or on the human body...

Types of medical devices



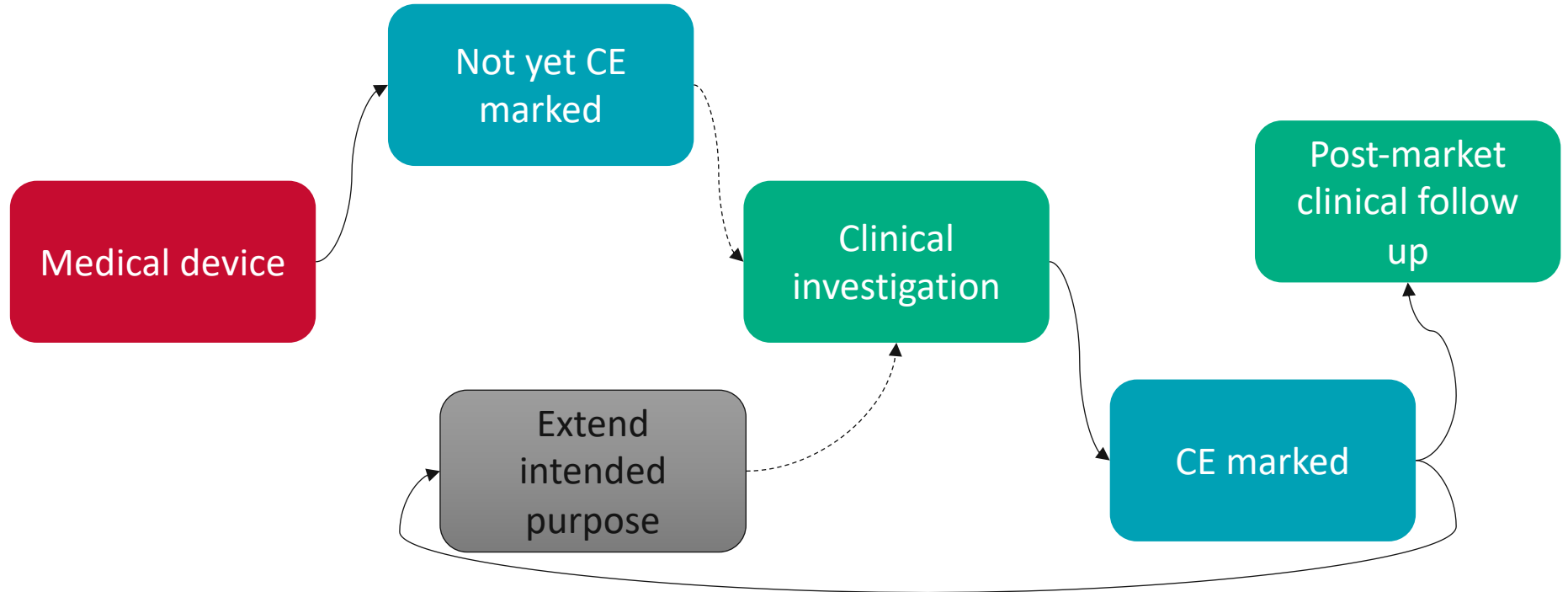


manufacturers express that their product meets the requirements of a European directive or an EU regulation

MDR

- Concerns all medical devices sold in EU
- Goal: harmonize clinical trials in EU member states
- Manufacturers have to demonstrate patient safety, device safety & effectiveness
- Establish, implement, document and maintain a risk management system

MDR - Roadmap



Clinical Investigations

Medical Devices

First-in-human

Pilot

Pivotal

Post-market

Pharma

Phase I

Phase II

Phase III

Phase IV

MDR – Post-market surveillance



What?

- Performance
- Safety
- Risks
- Off-label use



How long?

- Entire lifetime of the device

Ways to satisfy PMCF



Literature review



PRO



Device data

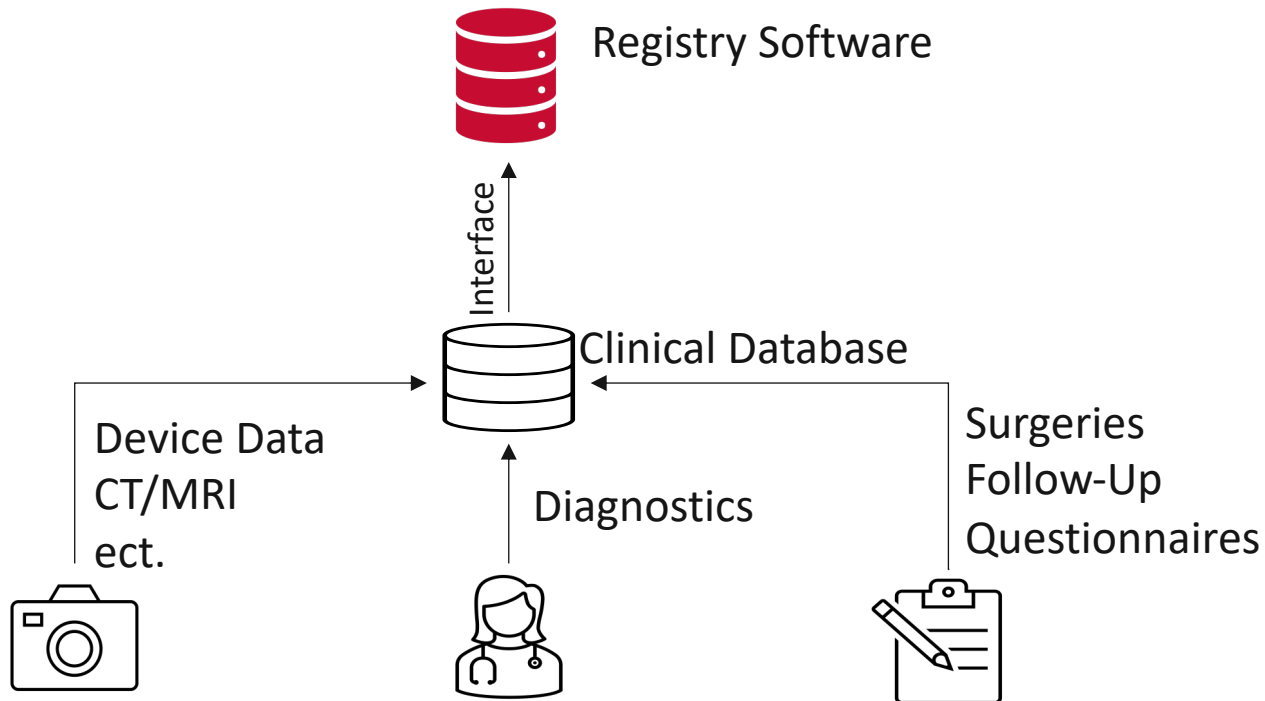


Registries

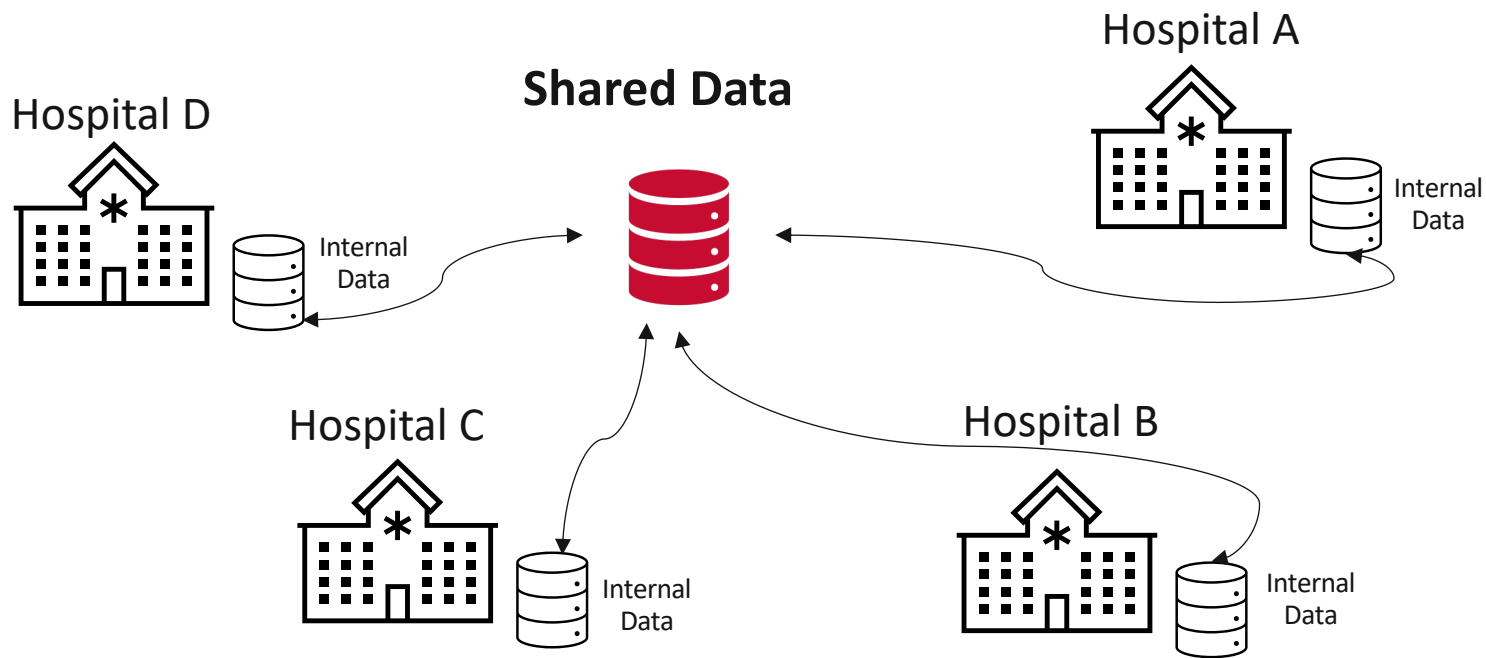


Post-market
studies

Registries



Registries



Risk Management – Risk control measures

- Regular analysis intervals
- Processes to share safety data
- Risk-based monitoring
- Potential for automation

Learnings



Diverse Data
Sources



Data Quality
and Integrity



Regulatory
Compliance



Monitoring &
Surveillance

Summary

- MDR in effect since May 2021
- Demand for real-world data and post-market clinical surveillance
- Regular reporting intervals for recertification
- Increased complexity and diverse data sources