Harvard-MIT Center for Regulatory Science

Johner Institut

“Boosting Medical Device Approval Times”

A joint research project of the Harvard-MIT Center for Regulatory Science and the Johner Institute

Why we need your help

Situation
The new EU regulations (MDR and IVDR) raise the bar for medical device manufacturers. Different stakeholders see important objectives of regulations at stake: Patient safety, competitiveness, innovation, and the supply of healthcare systems with effective and affordable medical devices.

For some products, the FDA works on a more modular, agile, effective and efficient approval processes.

Complication
Regulatory systems may begin to diverge, increasing burdens for medical device manufacturers. There is currently no evidence allowing researchers and policymakers to compare the effectiveness and efficiency of regulatory systems. E.g., it is unclear which parameters (approval process, product type) determine the time from application to approval.

Research Questions
The joint research team aims to understand: What determines the duration of approval processes? When and how can these be safely accelerated?

A novel research initiative

Research method
The research includes quantitative and qualitative data:

- Quantitative data: Structured data provided by manufactures, FDA and notified bodies on
  - Companies (few core characteristics, e.g., size),
  - products (e.g., type, active/non-active) and
  - approval processes (type (e.g., 510(k), MDR annex IX), start / end date etc.).
- Qualitative data: Structured interview with manufacturers and notified bodies.

Time-line
The research project was initiated in mid 2021. Most structured data shall be collected by end of Q1 2022 and of qualitative data by end of Q2 2022.

A research paper shall be submitted by end of 2022.

Research team
The research team consists of regulatory scientists (post-docs) from Harvard University and Johner Institute and is led by Professor Ariel Stern and Professor Christian Johner.

What we wish from you

Data
The research team highly appreciates your support in contributing structured data. You can submit this data as a MS Excel spreadsheet. The data fields are described on the next page.

Our scientists can provide diverse support, including transferring data from existing sources (databases, unstructured files and implicit expert knowledge).

Your team’s workload should be limited to about one day, in most cases even only a few hours.

Answers (optional interviews)
A lot of knowledge is hidden in experts’ brains. Our scientists want to extract and highlight your insights via structured interviews inquiring e.g., about insights on factors determining the duration of medical device approvals.

Confidentiality
We do not collect personal data. Only anonymized information will be published and will not permit any conclusion to be drawn about individual organizations.