Improving Medical Device Evaluation

CulturalCare Tech

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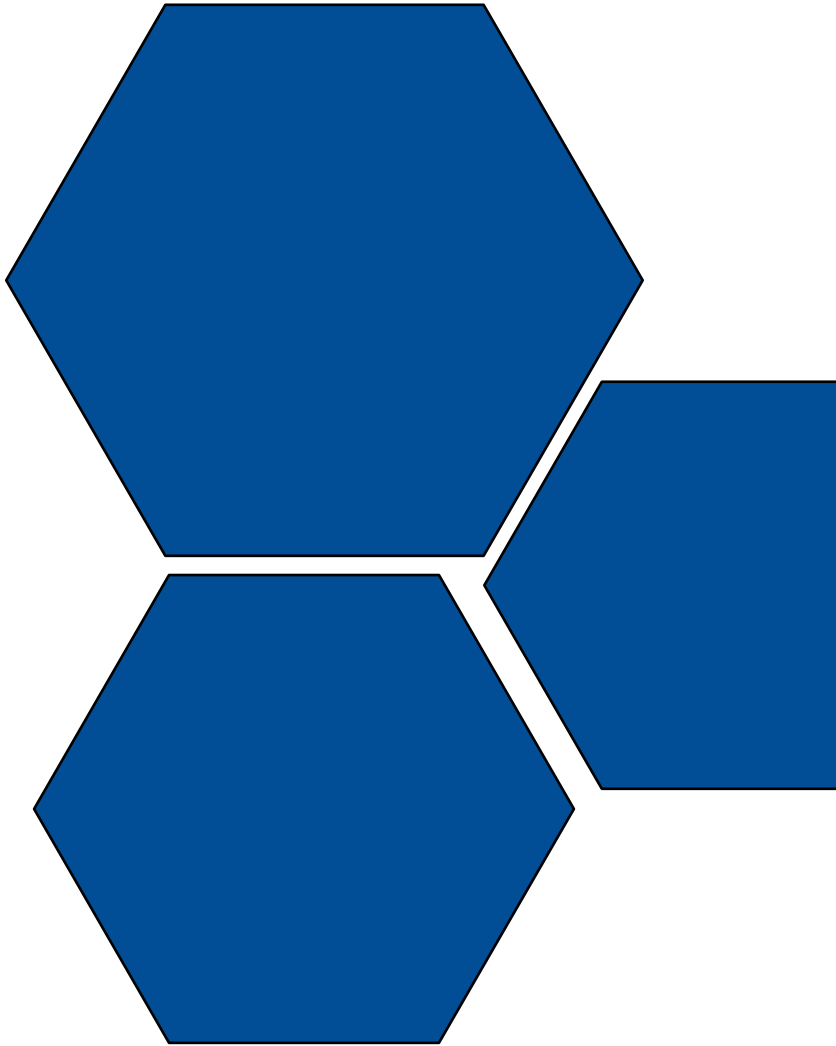
Agenda

- Introduction
- Problem statement
- Current evaluation method
- Proposed solutions
- Architecture & Interface
- Discussion/Conclusion

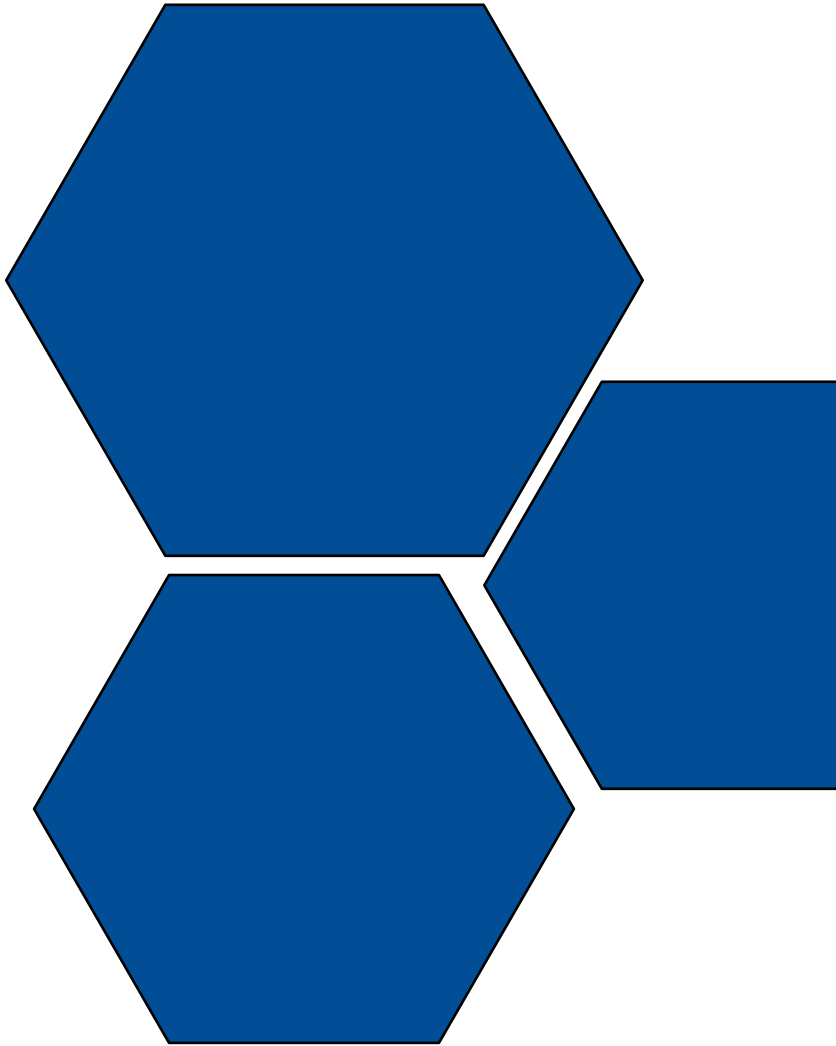
Problem Statement

There have been **many device failures** in the U.S. **due to lax regulation of industry**. Recent well-known examples include respiratory carcinogens from CPAP machines, metallosis from hip implants, pulse oximeters that do not perform well in people-of-color, complications from pelvic surgical mesh, cancers from silicone breast implants, and failed defibrillators. In addition, there are many "low-risk" medical devices on the market that are not proven effective. There is no good system in place for preventing, detecting, and correcting medical device failures. **The cost has been lives, wasted expenditures, and a system that is not self-correcting.**



Vision

The platform should take a systems-engineering approach to the evaluation of medical devices. The approach should be simple, and include testing rather than reliance on perceptions of technological equivalence, meeting haphazard industry standards, and reliant on the views of expert panels. The scope of this work would be large. A systematic approach with simplified testing has been needed for 50 years.



Introduction

Definition:

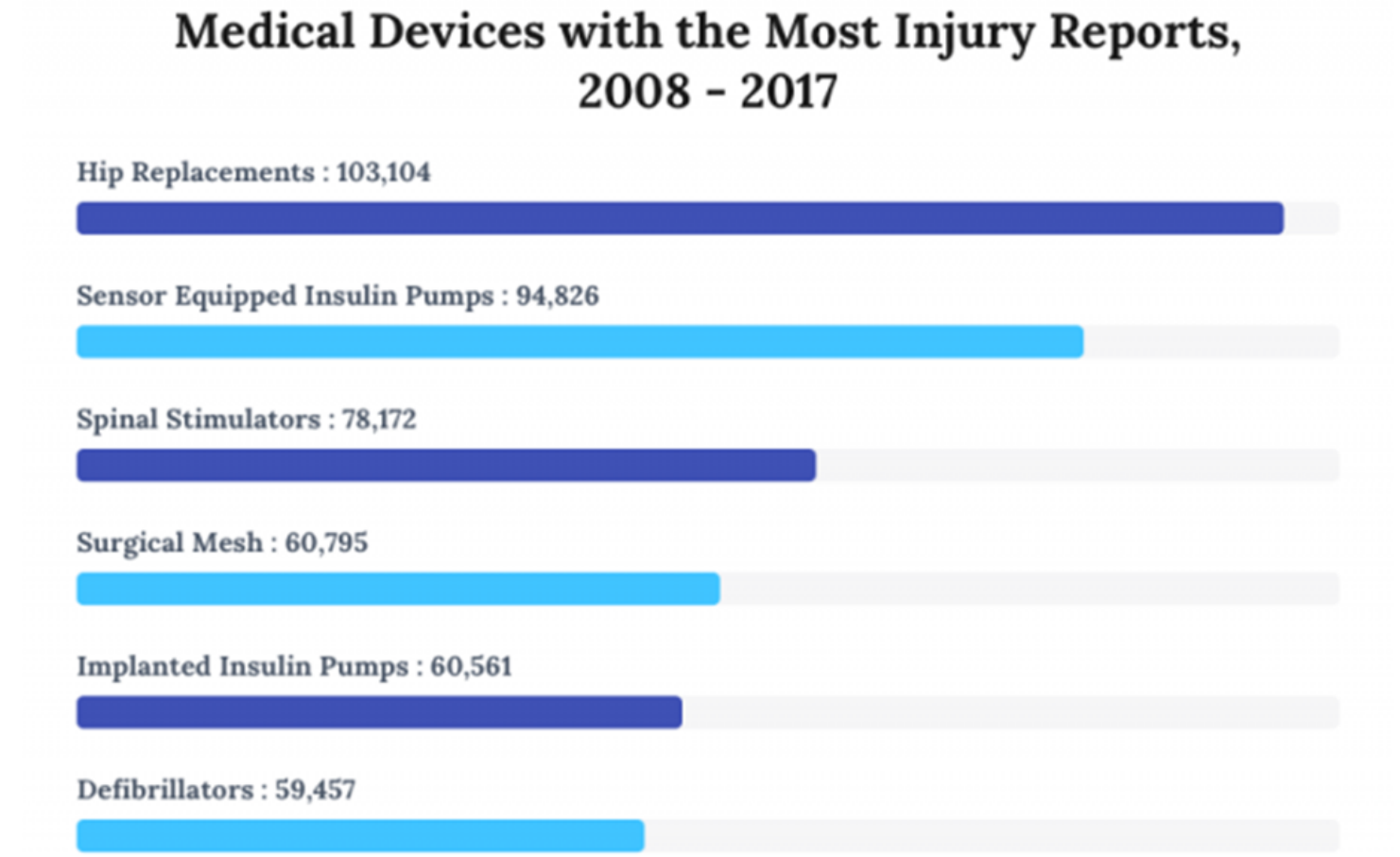
- Introduce medical devices as instruments, machines, implants, or software intended to diagnose, treat, or prevent diseases.

Types of Medical Device

- CPAP Machines for sleep apnea treatment.
- Hip Implants for joint replacement.
- Pulse Oximeters for monitoring oxygen saturation.
- Pelvic Surgical Mesh for supporting weakened or damaged tissue.
- Silicone Breast Implants for reconstruction or augmentation.
- Defibrillators for treating life-threatening cardiac dysrhythmias

103,104

Injury report in hip replacement



https://www.consumernotice.org/wp-content/uploads/top-medical-device-injuries-640x0-c-default.png

Failure status

Acknowledge that despite their crucial role in healthcare, medical devices can sometimes fail, leading to significant health risks, underscoring the critical need for rigorous evaluation processes to ensure their safety and efficacy.

CPAP Machines: Respiratory Carcinogens

- Recalled due to the potential carcinogen release from foam degradation, risking respiratory issues and cancer

Failed Defibrillators

Malfunction can result in failure to deliver necessary heart rhythm correction, risking fatal outcomes.

Metallosis from Hip Implants

Wear of metal components releases particles, causing local tissue damage, pain, and systemic toxicity.

Silicone Breast Implants and Cancer:

Rarely, they're associated with a specific cancer type (BIA-ALCL), leading to implant removal or further treatment.

Pelvic Surgical Mesh

Cause pain, organ damage, and infection due to mesh erosion or movement, necessitating additional surgeries.

Current evaluation

Pre-market evaluation

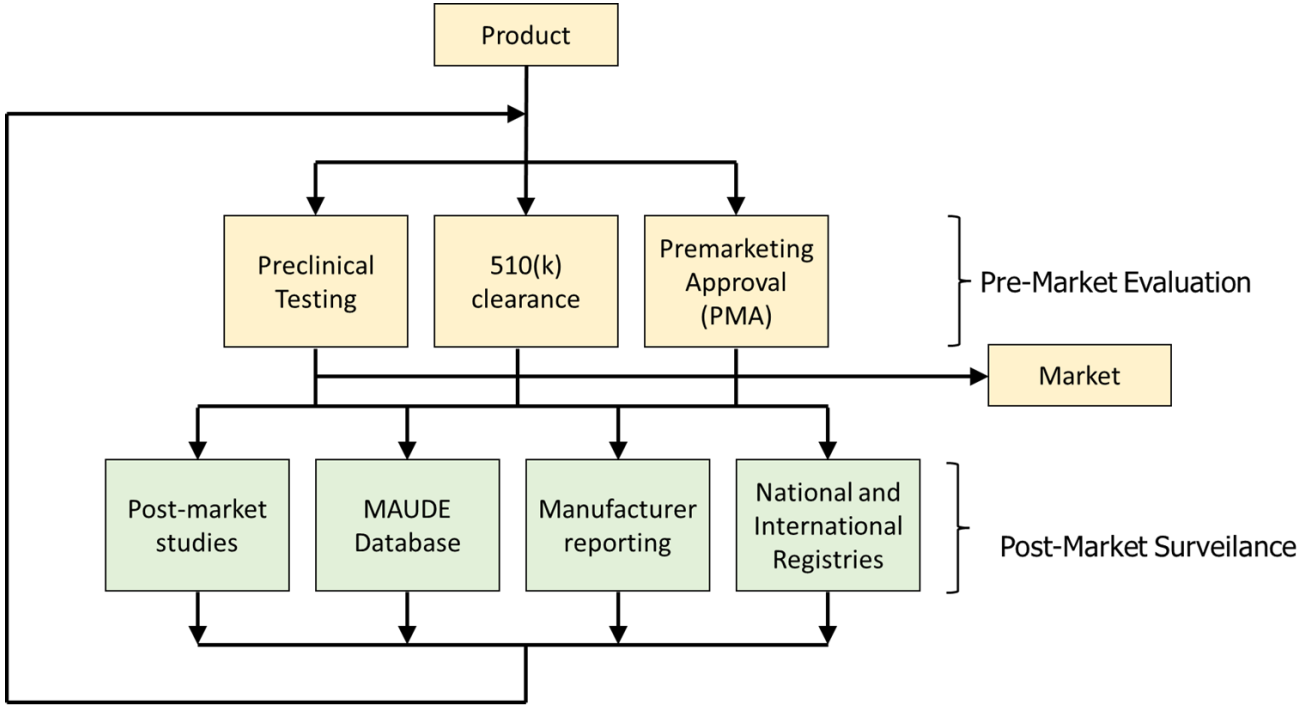
Preclinical Testing	Manufacturers must conduct extensive laboratory testing, including mechanical testing and biocompability assessments, to demonstrate that the device is safe and performs as intended.
510(k) clearance	many hip implants are reviewed through the 510(k) process, where the manufacturer must show that their device is substantially equivalent to another new clinical data if the device is similar enough to an existing product.
Premarketing Approval (PMA)	This is a more stringent review process that requires manufacturers to provide evidence of the device's safety and effectiveness, usually including data from clinical trials

Current evaluation

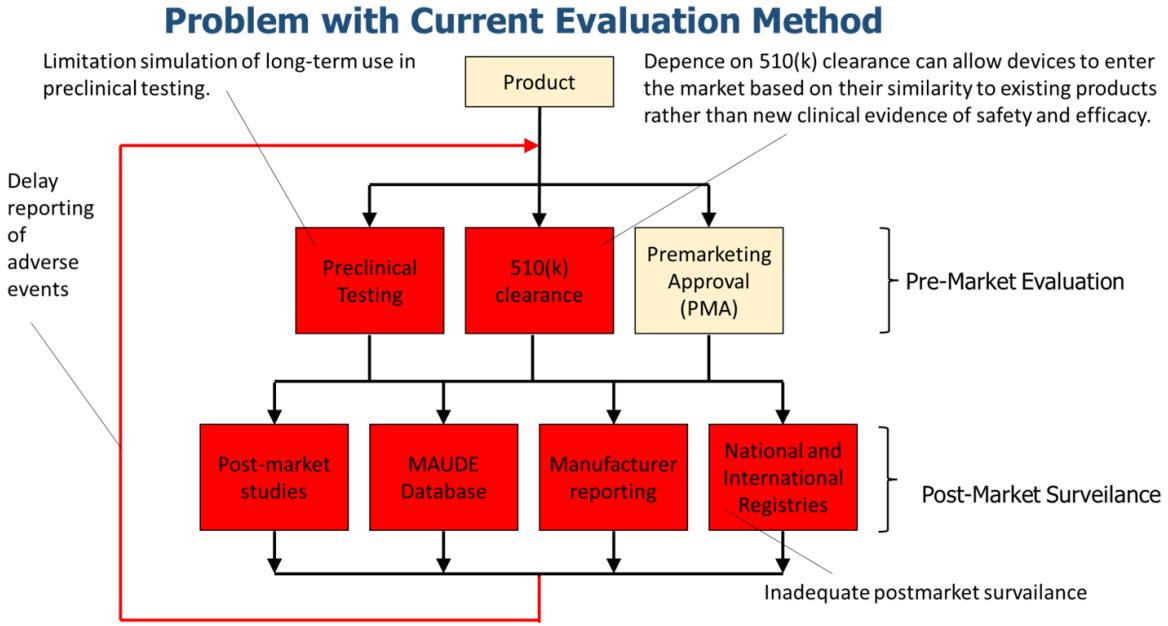
Post-market survalaince

Manufacturer reporting	Manufacturers are required to report any adverse events they learn of that could be related to their devices, including complications such as metallosis.
MAUDE Database	The manufacturer and user facility device experience (MAUDE) database collects reports of adverse events involving medical devices.
Post-market studies	FDA may require manufacturers to conduct post market surveillance studies to monitor the device's performance and safety in a real-world setting
National and International Registries	Hip implant registries in various countries collect data on the outcomes of surgeries to help identify trends in device performance overtime.

Current Evaluation Method

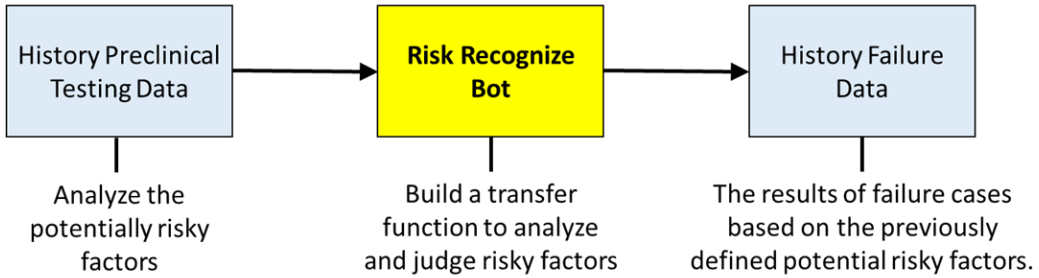


Problem with Current Evaluation Method



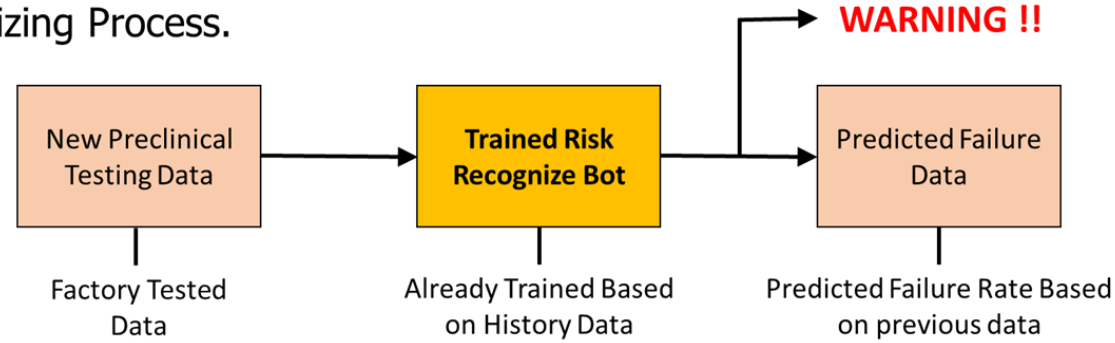
Proposed Solution

- Create an initial warning system for the FDA to precaution the potentially risky product.
  - Training Process.



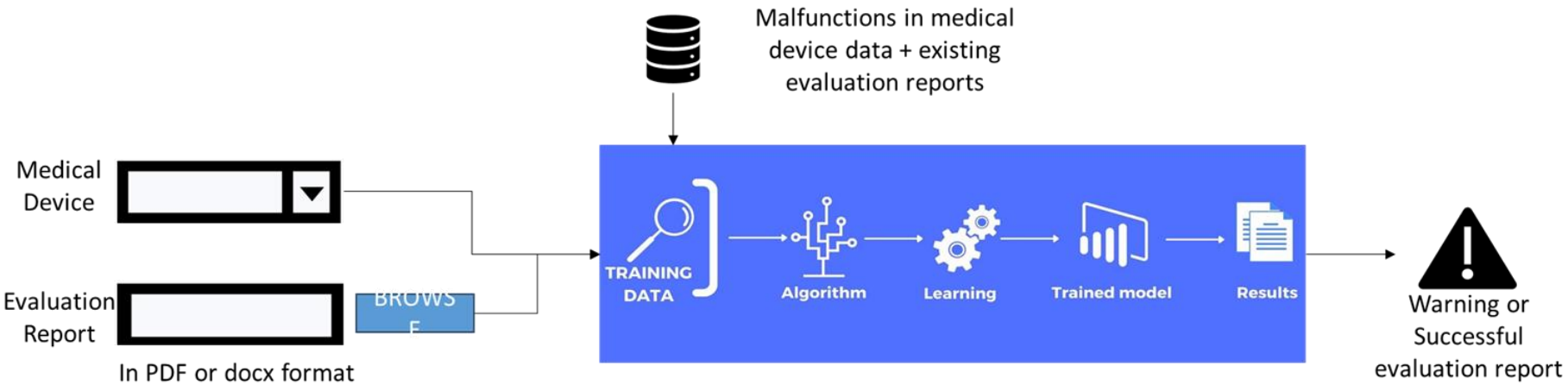
Proposed Solution

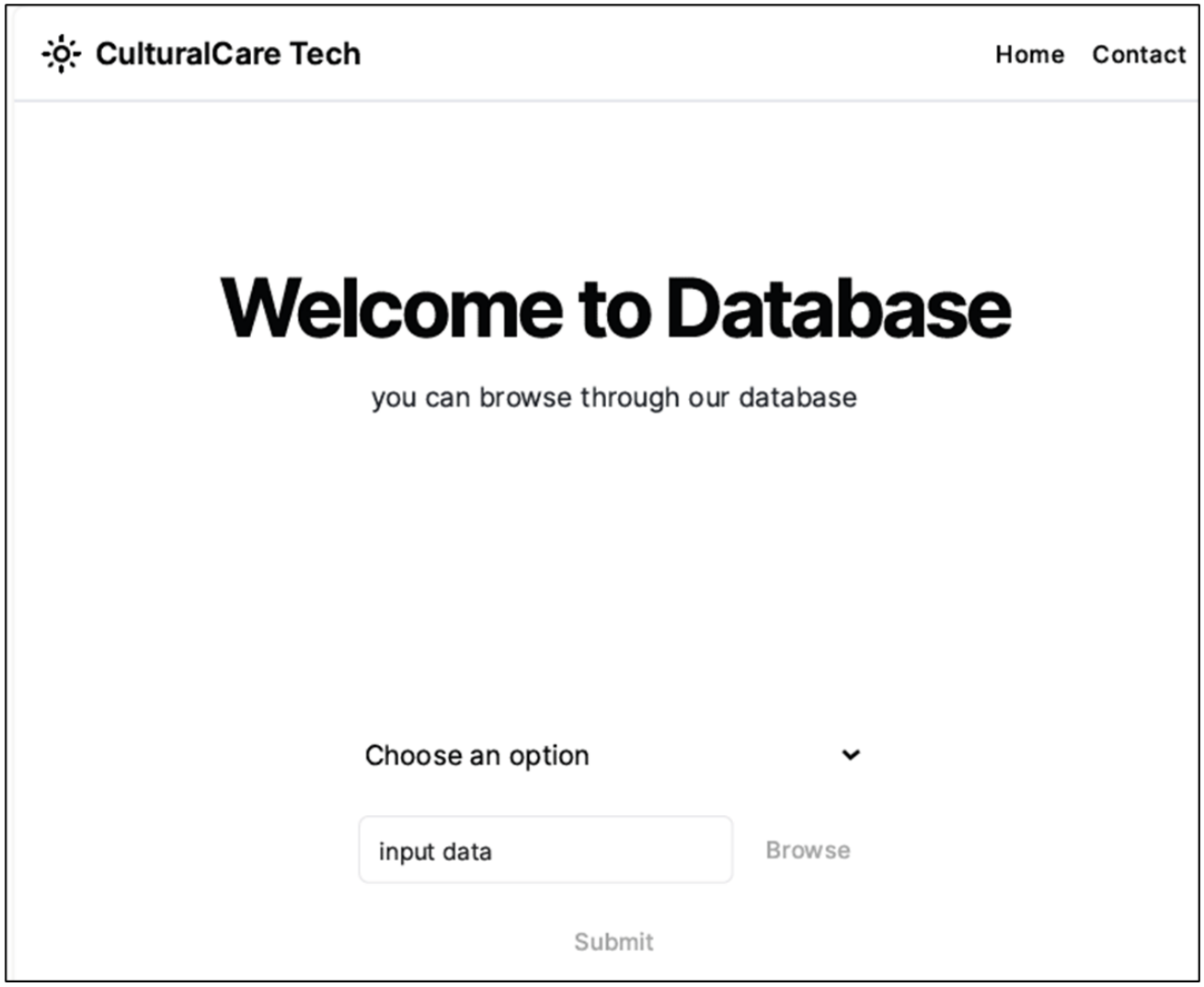
- Create an initial warning system for the FDA to precaution the potentially risky product.
  - Recognizing Process.



  - Give a warning to FDA on doubtful signs so that intime action can be committed.

Proposed Solution

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Home
Contact
Welcome to Database
you can browse through our database
Choose an option
input data
Browse
Submit

Discussion/Conclusion

- **Advantages**
  - Take charge of a warning system the FDA before the risky product flow into the market uses with moderately increase reliability overtime. With intime caution, deaths can be avoided.
- **Disadvantages**
  - Need a lot of time and data to build up the reliability of the method.
- **Futuristic Plan:**
  - Collect more data samples to increase the reliability of the solution.
  - Perform the experiment with a larger data size.
  - Come up with website or official functional application.

Discussion/Conclusion

Societal Impact:

- Improved patient safety and trust
- Enable healthcare providers to take timely action
- Enhanced Public Awareness
- Empower people with the attention of the risk associated medical device

Economic Impact:

- Reduce Healthcare costs: Avoid additional costs - additional surgeries treatments, hospital stays and significantly increasing healthcare costs

Environmental Impact:

- Reduction in Medical Waste: Contribute to the reduction in medical waste produced
- Sustainable production: High main duty on producing safe and durable devices

Thank you!