Smart Event Evaluation & Reporting (SEER)

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Current adverse event reporting initiatives

• FDA Adverse Event Reporting Systems (FAERS)
  • Database of adverse event reports brought to FDA by manufacturers and consumers directly
• MedWatch
  • Reporting program for health professionals, patients, and consumers
  • MedWatch safety alert subscription
• Safety Reporting Portal
  • Report product safety issues to FDA and NIH
• Vaccine Adverse Event Reporting System (VAERS)
  • Early detection of safety problems with US-licensed vaccines
• Center for Food and Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System
• Manufacturer and User Facility Device Experience Database (MAUDE)
  • Medical devices

Key conclusion: many streams for adverse event reports to be submitted and reviewed
Key problem: more data than can be interpreted

2,334,353 adverse event reports into FAERS in 2021

- FAERS Public Dashboard, 2022
FDA 2021 Focus Area of Regulatory Science

FDA Strategic Initiative 3: Unleashing the Power of Data
Artificial Intelligence

How does AI fit into FDA?

"...obtain more and higher-quality data, be more proactive in gathering data, and be more creative and thorough in analysis and interpretation."

"...harnessing this power to improve regulatory decision-making and more effectively connect today’s groundbreaking scientific discoveries with the rapid development and approval of new FDA-regulated products. FDA can also increase the knowledge of patients and consumers who must make informed decisions about FDA-regulated products."

Our Solution: Leverage AI to make more sense of the data

Manufacturers -> Clinicians -> Adverse event report database -> SEER System

Highlights
Trends
Outbreaks
Connections
SEER is applicable to all stages of the regulated product lifecycle.

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SEER can be used as a preventative and reactive strategy

Potential insights provided by SEER:
- Where/why did things go wrong?
- Which evaluation tools were (not) effective predictors?
- What metrics (un)succcessfully predicted the effectiveness of the solution?
SEER can be used as a preventative and reactive strategy

Product characterization, manufacturing, and quality $\rightarrow$ Non-clinical pre-market evaluation $\rightarrow$ Clinical pre-market evaluation $\rightarrow$ Post-market activities

Potential insights provided by SEER:
- Where did things go wrong?
- For whom did things go wrong and why?
- What events lead up to/followed the adverse event(s)?
- What can be done better or differently based on learnings from previous solutions?
Proven effectiveness in many areas

- Flood Warning (https://www.eurekalert.org/news-releases/607634)
Thank you! Questions?

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