# 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**

*2021: Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science*. U.S. Food and Drug Administration. (2021). Retrieved 10 January 2022, from https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science.

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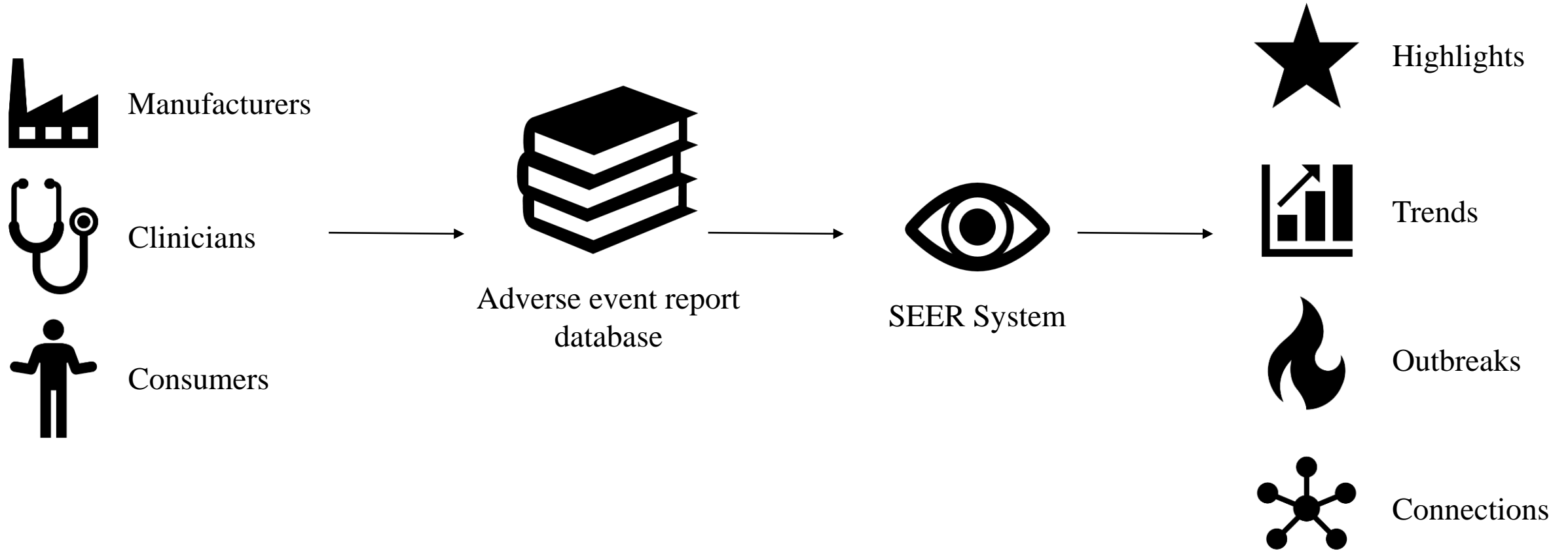
# How does AI fit into FDA?

"...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."

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



Manufacturers

Clinicians

Consumers

Adverse event report database

SEER System

Highlights

Trends

Outbreaks

Connections

# SEER is applicable to all stages of the regulated product lifecycle

| FDA Strategic Initiative | Focus Area of Regulatory Science | Regulated Product Lifecycle | | | |
|---|---|---|---|---|---|
| | | Product Characterization, Manufacturing, and Quality | Non-Clinical Pre-market Evaluation | Clinical Pre-market Evaluation | Post-market Activities |
| Unleashing the Power of Data | Product Safety Surveillance | | | | ✓ |
| | Artificial Intelligence | ✓ | ✓ | ✓ | ✓ |
| | Digital Health | ✓ | ✓ | ✓ | ✓ |
| | Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making | | | ✓ | ✓ |

*2021: Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science*. U.S. Food and Drug Administration. (2021). Retrieved 10 January 2022, from https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science.

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# SEER can be used as a preventative and reactive strategy

Product characterization, manufacturing, and quality → Non-clinical pre-market evaluation → Clinical pre-market evaluation → Post-market activities

Potential insights provided by SEER:
- Where/why did things go wrong?
- Which evaluation tools were (not) effective predictors?
- What metrics (un)successfully predicted the effectiveness of the solution?

# SEER can be used as a preventative and reactive strategy

Product characterization, manufacturing, and quality → Non-clinical pre-market evaluation → Clinical pre-market evaluation → 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

- Earthquakes (https://www.livescience.com/deep-learning-network-earthquake-shaking.html)
- Air Quality Warning (Mo, Zhang, L., Li, H., & Qu, Z. (2019). A Novel Air Quality Early-Warning System Based on Artificial Intelligence. International Journal of Environmental Research and Public Health, 16(19), 3505–. https://doi.org/10.3390/ijerph16193505)
- Flood Warning (https://www.eurekalert.org/news-releases/607634)
- New COVID-19 Variants (https://fortune.com/2022/01/12/biontech-instadeep-ai-early-warning-covid-19-variants-of-concern-omicron-delta/)
- Online Misinformation (Michael Yankoski, Tim Weninger & Walter Scheirer (2020) An AI early warning system to monitor online disinformation, stop violence, and protect elections, Bulletin of the Atomic Scientists, 76:2, 85-90, DOI: 10.1080/00963402.2020.1728976)
- Violent Escalation in Police Interactions (https://data.berkeley.edu/fall-2020-discovery-project/public-safety-warning-system)

# Thank you! Questions?

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