

OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event
Reports

Table of Contents

1. Executive Summary	2
2. Methodology	2
2.1. Data Source	2
2.2. Data Standardization	2
2.3. Problem Classification	2
3. Temporal Trend Analysis	3
3.1. Overall Reporting Trends	3
3.2. Cumulative Reports Over Time	5
4. Product Problem Analysis	6
4.1. Product Problems Analysis	6
5. Patient Problem Analysis	8
5.1. Patient Problems Analysis	8
6. Manufacturer Analysis	10
6.1. Top Manufacturers	10
7. Device Brand Analysis	11
7.1. Top Device Brands	11
7.2. Brand Temporal Trends	12
8. Technical Appendix	12
8.1. Data Source	12
8.2. Analysis Tools	12
8.3. Exclusion Criteria	13
8.4. Report Metadata	13

1. Executive Summary

This report analyzes **12,814** FDA medical device adverse event reports submitted between **June 04, 2009** and **October 31, 2025** (a period of **196.9** months). The dataset includes **6** unique manufacturers and **10** unique device brands. The average reporting rate was **65** reports per month, with peak reporting of **206** reports in **May 2015**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	12,814
Date Range	June 04, 2009 to October 31, 2025
Reporting Duration	5993 days (196.9 months)
Unique Manufacturers	6
Unique Device Brands	10
Average Monthly Reports	65 reports/month
Maximum Monthly Reports	206 reports in May 2015

2. Methodology

2.1. Data Source

The search of the FDA Manufacturer and User Facility Device Experience (MAUDE) database was conducted using the openFDA Device Event API. Retrieved JSON-formatted data were downloaded directly from the API and subsequently processed and cleaned for analysis.

2.2. Data Standardization

The analysis employs fuzzy matching algorithms to standardize manufacturer and brand names, addressing inconsistencies in naming conventions across reports. This standardization process uses the **RapidFuzz** library with partial ratio matching to group similar names under a canonical representation.

2.3. Problem Classification

Patient and product problems are extracted and categorized, excluding non-informative categories to focus on meaningful data patterns.

3. Temporal Trend Analysis

3.1. Overall Reporting Trends

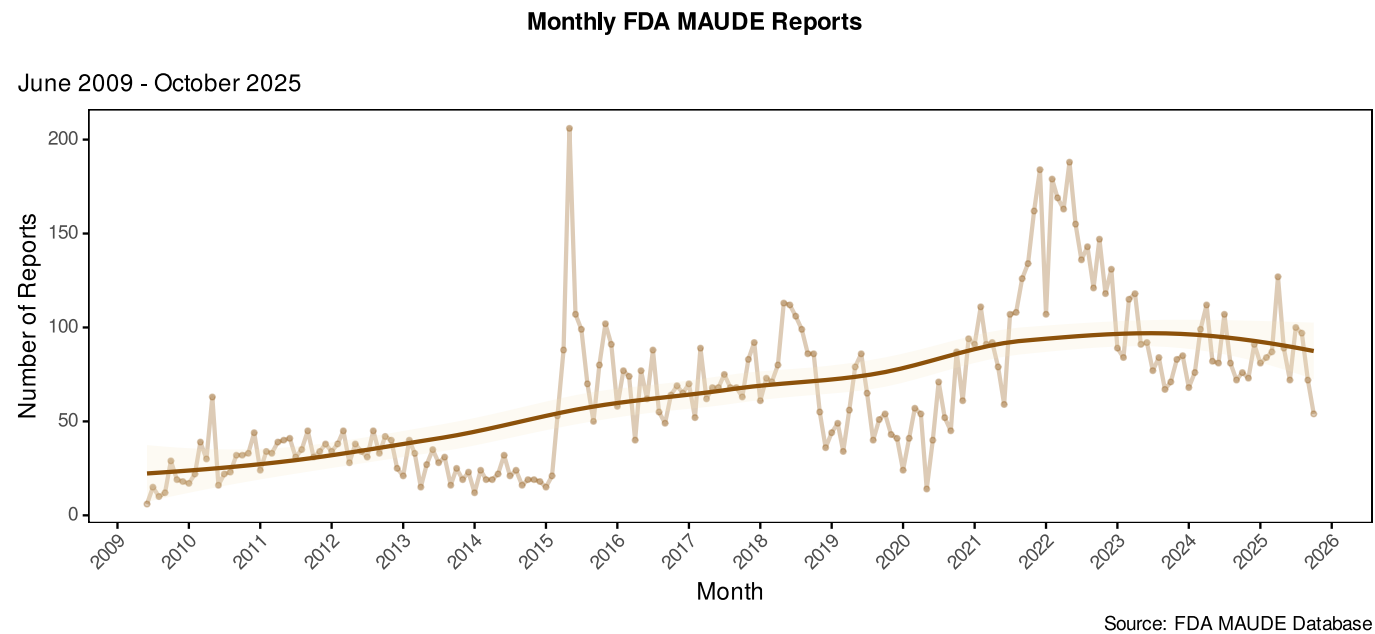


Figure 1: Monthly trend of FDA MAUDE reports

i Statistical Trend Analysis

Reporting Variability: The average monthly reporting rate is **65** reports (SD = **39.4**, CV = **60.5%**).

Statistically Significant Peaks (≥ 2 SD above mean, $p < 0.05$):

9 month(s) identified: May 2015 (206 reports, $z=3.58$, +216.7%); May 2022 (188 reports, $z=3.12$, +189%); December 2021 (184 reports, $z=3.02$, +182.9%); February 2022 (179 reports, $z=2.89$, +175.2%); March 2022 (169 reports, $z=2.64$, +159.8%); April 2022 (163 reports, $z=2.49$, +150.6%); November 2021 (162 reports, $z=2.46$, +149.1%); June 2022 (155 reports, $z=2.28$, +138.3%); October 2022 (147 reports, $z=2.08$, +126%)

Statistically Significant Valleys (≥ 2 SD below mean, $p < 0.05$):

No statistically significant valleys detected at 95% confidence level.

Note: Months are considered statistically significant outliers when they deviate by ≥ 2 standard deviations from the mean ($z\text{-score} \geq |2|$), corresponding to approximately 95% confidence level.

3.2. Cumulative Reports Over Time

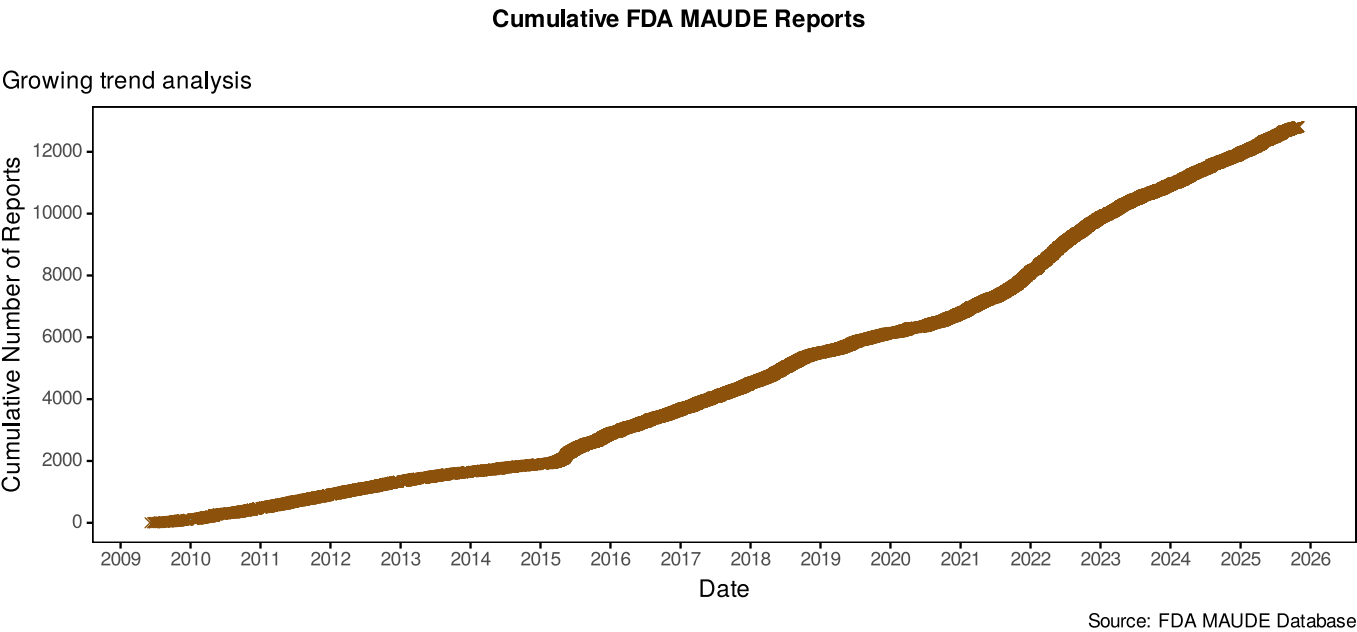


Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Product Problems Analysis

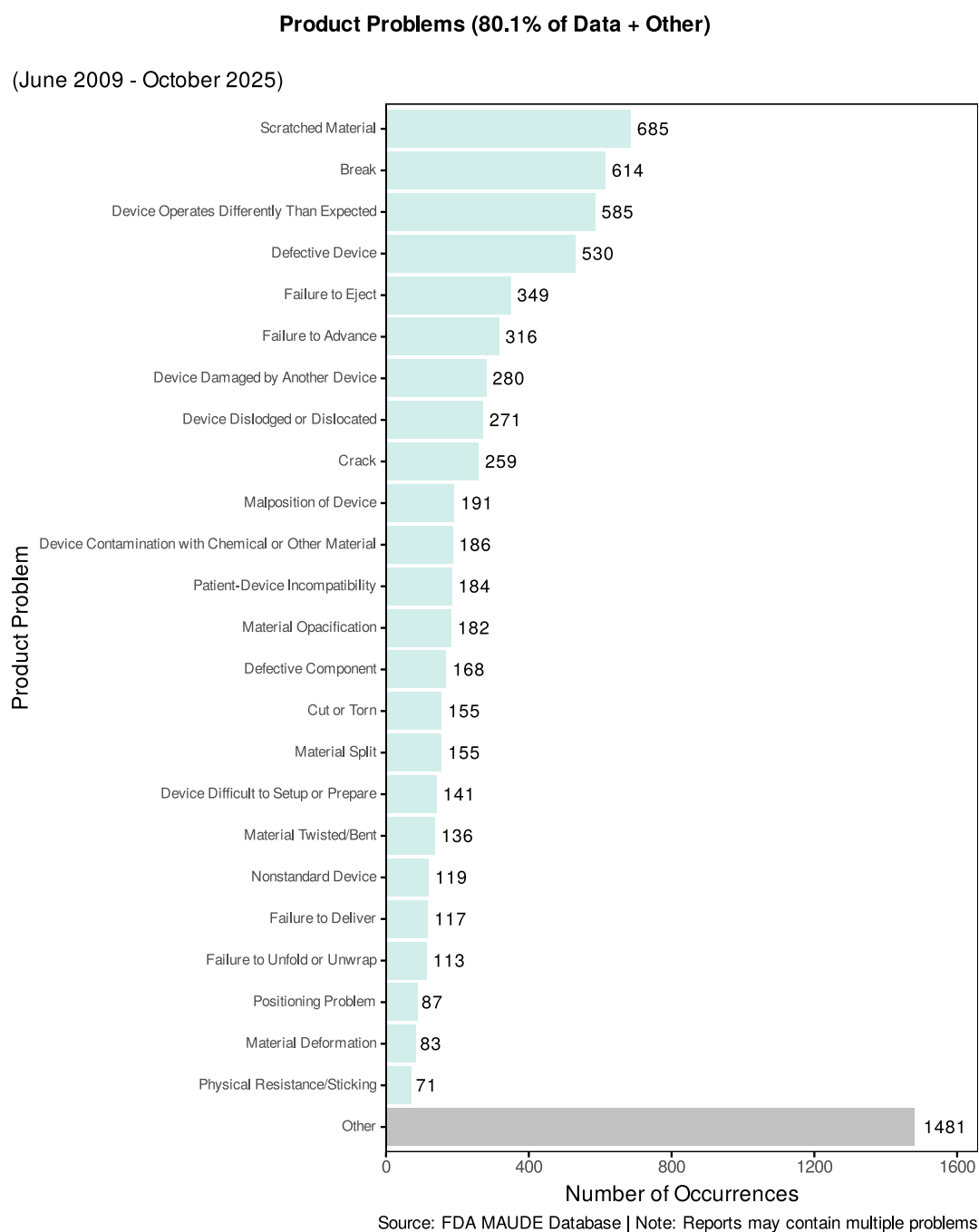


Figure 3: Product problems representing approximately 80% of problem occurrences (80.1%), plus 'Other' category

Product Issues Analysis

A total of **24** product problem types account for **80.1%** of all reported problem occurrences (**5,977** occurrences).

The remaining **1,481** problem occurrences (**19.9%**) are categorized as “Other”.

Note: Individual reports may list multiple problems, so total occurrences may exceed the number of reports.

All Product Problems Representing 80.1% of Data:

1. **Scratched Material** - 685 occurrences (9.2%)
2. **Break** - 614 occurrences (8.2%)
3. **Device Operates Differently Than Expected** - 585 occurrences (7.8%)
4. **Defective Device** - 530 occurrences (7.1%)
5. **Failure to Eject** - 349 occurrences (4.7%)
6. **Failure to Advance** - 316 occurrences (4.2%)
7. **Device Damaged by Another Device** - 280 occurrences (3.8%)
8. **Device Dislodged or Dislocated** - 271 occurrences (3.6%)
9. **Crack** - 259 occurrences (3.5%)
10. **Malposition of Device** - 191 occurrences (2.6%)
11. **Device Contamination with Chemical or Other Material** - 186 occurrences (2.5%)
12. **Patient-Device Incompatibility** - 184 occurrences (2.5%)
13. **Material Opacification** - 182 occurrences (2.4%)
14. **Defective Component** - 168 occurrences (2.3%)
15. **Cut or Torn** - 155 occurrences (2.1%)
16. **Material Split** - 155 occurrences (2.1%)
17. **Device Difficult to Setup or Prepare** - 141 occurrences (1.9%)
18. **Material Twisted/Bent** - 136 occurrences (1.8%)
19. **Nonstandard Device** - 119 occurrences (1.6%)
20. **Failure to Deliver** - 117 occurrences (1.6%)
21. **Failure to Unfold or Unwrap** - 113 occurrences (1.5%)
22. **Positioning Problem** - 87 occurrences (1.2%)
23. **Material Deformation** - 83 occurrences (1.1%)
24. **Physical Resistance/Sticking** - 71 occurrences (1.0%)

5. Patient Problem Analysis

5.1. Patient Problems Analysis

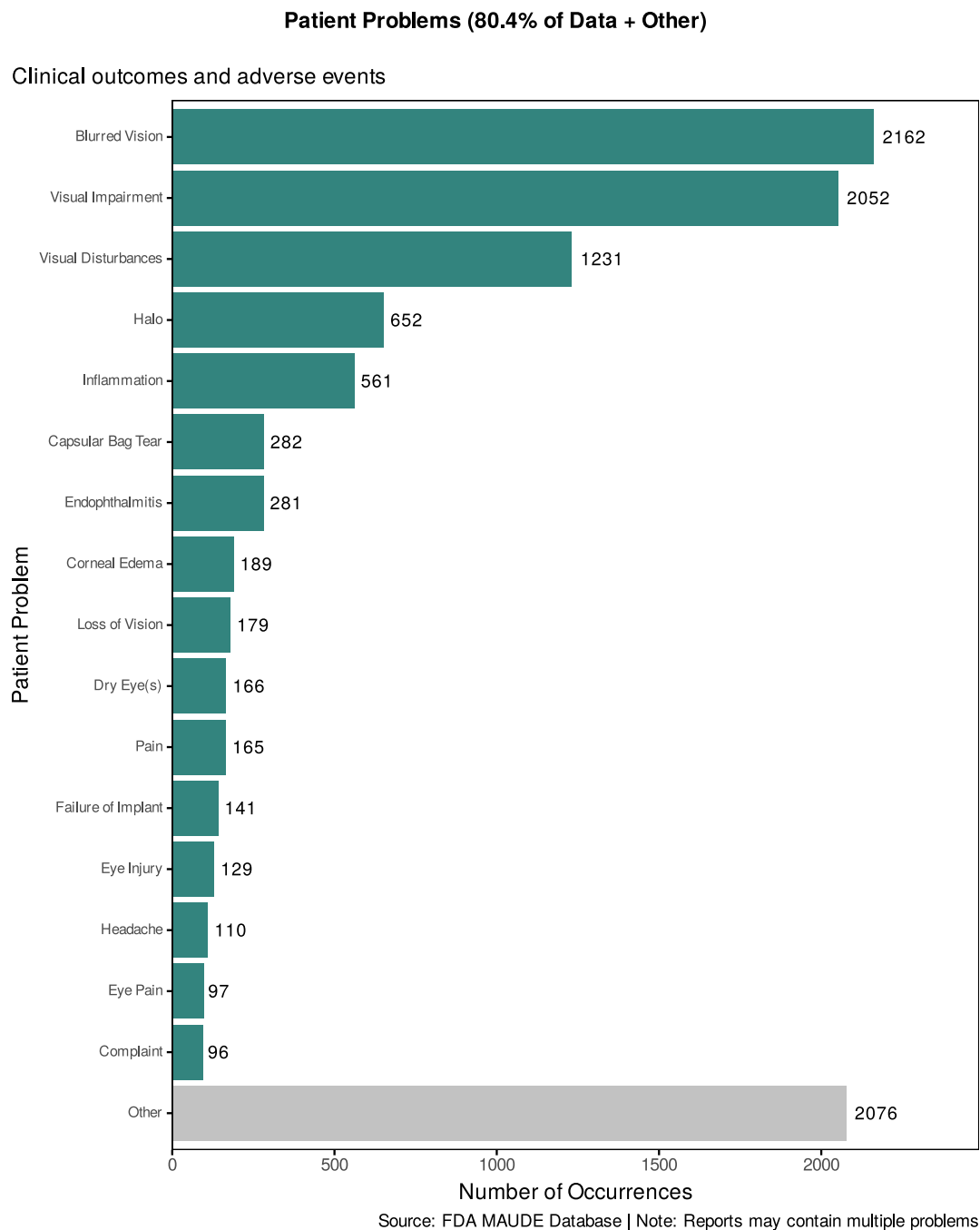


Figure 4: Patient problems representing approximately 80% of problem occurrences (80.4%), plus 'Other' category

i Patient Problems Analysis

A total of **16** patient problem types account for **80.4%** of all reported patient problem occurrences (**8,493** occurrences).

The remaining **2,076** problem occurrences (**19.6%**) are categorized as “Other”.

Note: Individual reports may list multiple patient problems, so total occurrences may exceed the number of reports.

All Patient Problems Representing 80.4% of Data:

1. **Blurred Vision** - 2,162 occurrences (20.5%)
2. **Visual Impairment** - 2,052 occurrences (19.4%)
3. **Visual Disturbances** - 1,231 occurrences (11.6%)
4. **Halo** - 652 occurrences (6.2%)
5. **Inflammation** - 561 occurrences (5.3%)
6. **Capsular Bag Tear** - 282 occurrences (2.7%)
7. **Endophthalmitis** - 281 occurrences (2.7%)
8. **Corneal Edema** - 189 occurrences (1.8%)
9. **Loss of Vision** - 179 occurrences (1.7%)
10. **Dry Eye(s)** - 166 occurrences (1.6%)
11. **Pain** - 165 occurrences (1.6%)
12. **Failure of Implant** - 141 occurrences (1.3%)
13. **Eye Injury** - 129 occurrences (1.2%)
14. **Headache** - 110 occurrences (1.0%)
15. **Eye Pain** - 97 occurrences (0.9%)
16. **Complaint** - 96 occurrences (0.9%)

6. Manufacturer Analysis

6.1. Top Manufacturers

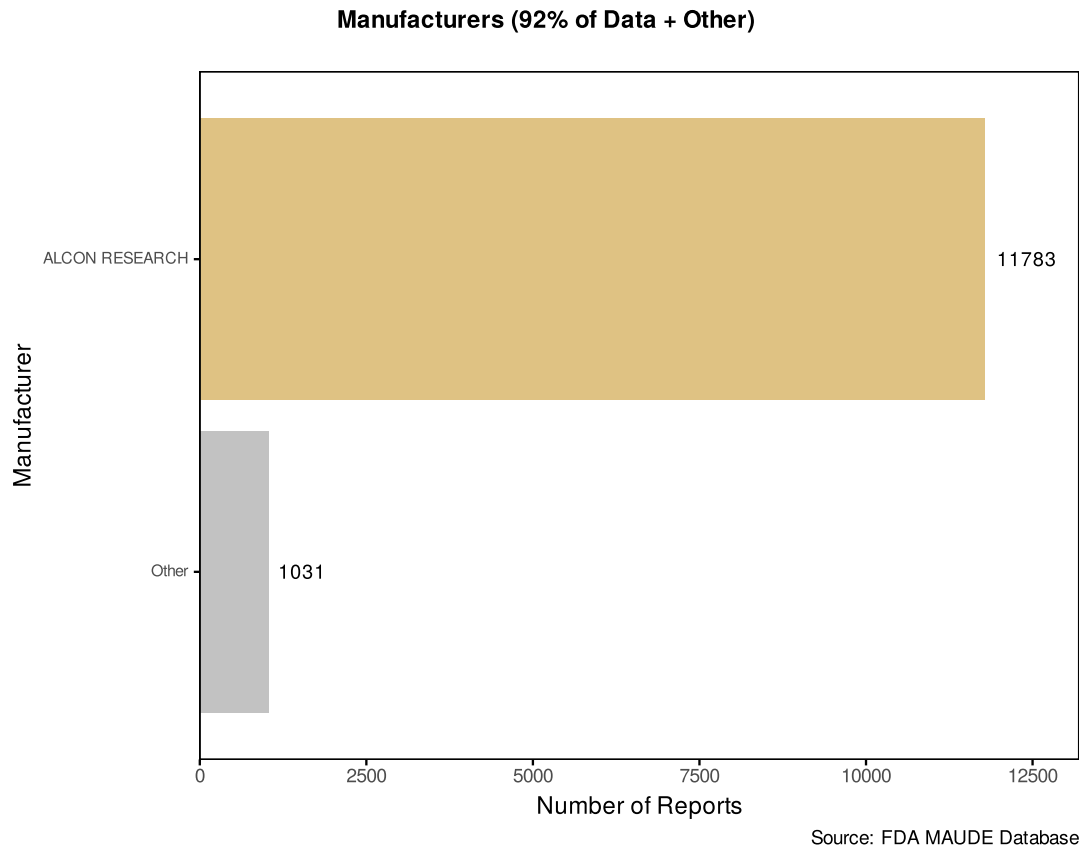


Figure 5: Manufacturers representing approximately 80% of reports (92%), plus 'Other' category

A total of **1** manufacturers account for **92%** of all reports (**11,783** reports).

The remaining **1,031** reports (**8%**) are from other manufacturers.

The top manufacturer, **ALCON RESEARCH**, accounts for **11,783** reports (**92%** of total).

Table 2: Manufacturers representing 92% of reports

Rank	Manufacturer	Reports	% of Total
1	ALCON RESEARCH	11,783	91.95%

7. Device Brand Analysis

7.1. Top Device Brands

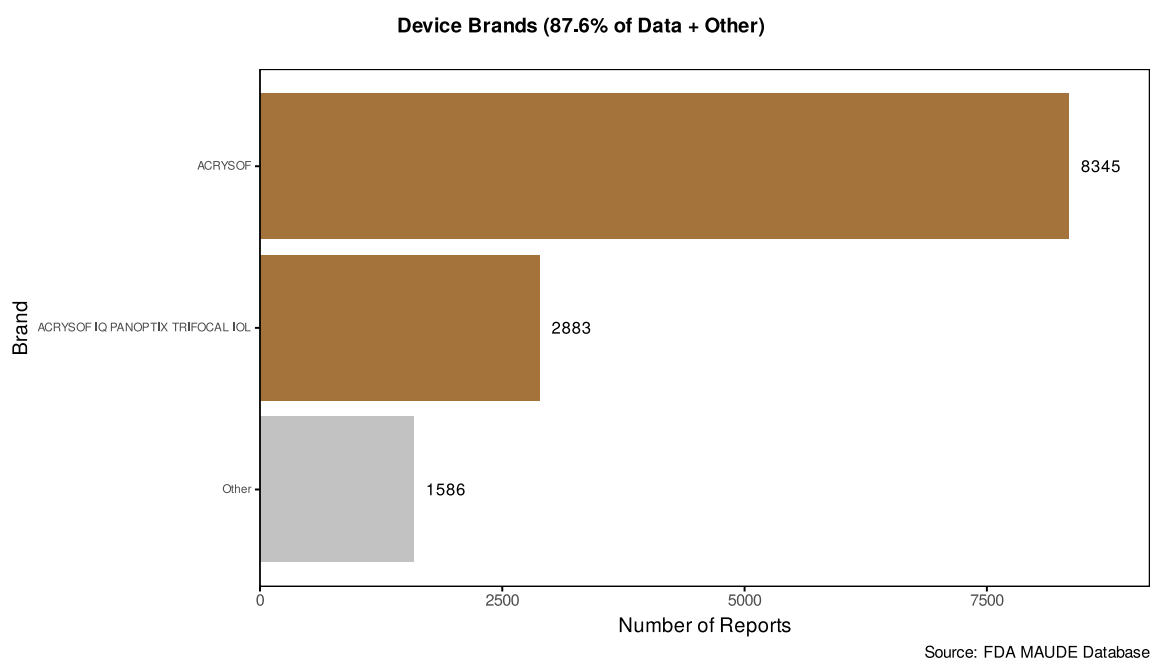


Figure 6: Device brands representing approximately 80% of reports (87.6%), plus 'Other' category

A total of **2** device brands account for **87.6%** of all reports (**11,228** reports).

The remaining **1,586** reports (**12.4%**) are from other brands.

The top device brand, **ACRYSON**, accounts for **8,345** reports (**65.1%** of total).

Table 3: Device brands representing 87.6% of reports

Rank	Brand	Reports	% of Total
1	ACRYSOF	8,345	65.12%
2	ACRYSOF IQ PANOPTIX TRIFOCAL IOL	2,883	22.50%

7.2. Brand Temporal Trends

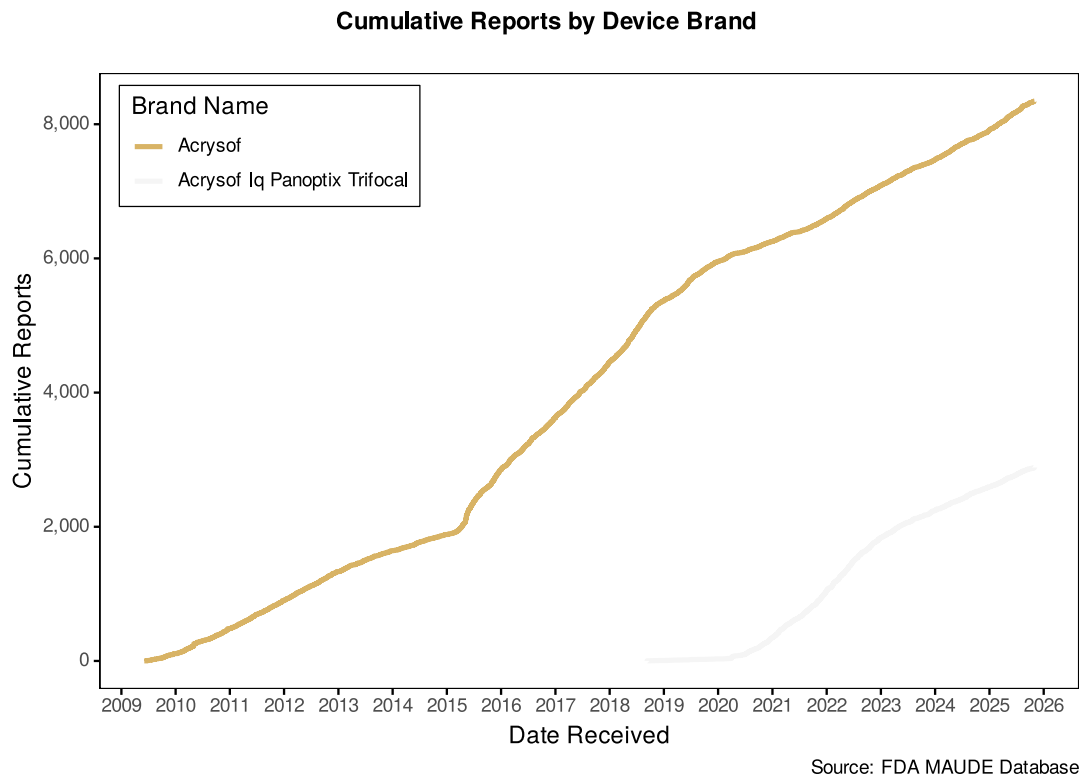


Figure 7: Cumulative adverse event reports by top 5 brands

8. Technical Appendix

8.1. Data Source

- **Database:** OpenFDA Medical Device Adverse Events
- **API Access:** <https://open.fda.gov/apis/device/event/>

8.2. Analysis Tools

- **Python 3.x** with pandas and rapidfuzz for data processing
- **R** with tidyverse, ggplot2, and lubridate for visualization

- **Fuzzy Matching:** RapidFuzz library for text standardization
- **Visualization:** ggplot2 with custom base R theme
- **Report Generation:** Quarto for reproducible analytics

8.3. Exclusion Criteria

Patient Problems Excluded:

No Code Available, No Known Impact, Symptoms or Conditions,
No Information, No Consequences, Insufficient Information

Product Problems Excluded:

Adverse Event Without Identified Device, No Apparent Adverse Event,
Appropriate Term/Code Not Available, Unknown, Insufficient Information

8.4. Report Metadata

- **Generated:** 2025-11-19 20:24:19
- **Dataset Version:** 2025-10-31
- **Total Records Analyzed:** 12,814
- **Analysis Pipeline:** OpenFDA Medical Device Adverse Event Analysis v2.1

List of Figures

Figure 1	Monthly trend of FDA MAUDE reports	3
Figure 2	Cumulative FDA MAUDE reports over time	5
Figure 3	Product problems representing approximately 80% of problem occurrences (80.1%), plus 'Other' category	6
Figure 4	Patient problems representing approximately 80% of problem occurrences (80.4%), plus 'Other' category	8
Figure 5	Manufacturers representing approximately 80% of reports (92%), plus 'Other' category	10
Figure 6	Device brands representing approximately 80% of reports (87.6%), plus 'Other' category . . .	11
Figure 7	Cumulative adverse event reports by top 5 brands	12

List of Tables

Table 1	Summary statistics of FDA MAUDE reports	2
Table 2	Manufacturers representing 92% of reports	10
Table 3	Device brands representing 87.6% of reports	12