# OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

# Table of Contents

# 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 and Fuzzy Matching

The analysis employs fuzzy matching algorithms to standardize manufacturer and brand names, addressing inconsistencies in naming conventions across reports. FDA MAUDE reports often contain variations in manufacturer and brand name spelling, capitalization, and formatting (e.g., "MEDTRONIC INC", "Medtronic Inc.", "MEDTRONIC").

**Fuzzy String Matching Approach**: Textually similar names are identified and grouped using the Levenshtein distance algorithm, which calculates the minimum number of single-character edits needed to transform one string into another. This standardization process uses the **RapidFuzz** library with partial ratio matching.

**Matching Thresholds**: Manufacturer names with ≥65% similarity and brand names with ≥75% similarity are consolidated under a canonical representation (typically the shortest variant). This reduces artificial fragmentation in the data and provides more accurate reporting volume estimates per manufacturer and brand.

## 2.3. Problem Classification and Data Quality Filters

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

**Key Considerations:**

- Individual reports may list multiple product problems per incident
- Individual reports may list multiple patient problems per incident
- Total problem occurrences can exceed the total number of reports
- Each problem occurrence is counted separately to identify the most frequent failure modes and issues

Non-informative categories are excluded from both patient and product problem analyses. For the complete list of excluded categories, see Section 8.3 in the Technical Appendix.

## 2.4. 80% Concentration Analysis

This analysis employs a concentration-based approach to identify the critical few problems, manufacturers, and brands that account for the majority of occurrences. Rather than arbitrarily selecting a fixed number (e.g., "top 10"), we dynamically identify categories that collectively represent approximately 80% of all reported occurrences.

**Implementation**: For each category (problems, manufacturers, brands), items are ranked by frequency and cumulative percentages calculated. Items are included in the main analysis if the previous item's cumulative percentage was below 80%. This ensures complete categories are included—no category is split between the main analysis and "Other".

**Key Features**: The exact percentage may exceed 80% to maintain category integrity. All categories meeting the threshold are listed, not just a predetermined number. The "Other" category provides perspective on the long-tail distribution of remaining items.

## 2.5. Statistical Analysis of Temporal Trends

**Variability Metrics**: Standard Deviation (SD) measures the typical spread of monthly reports around the average. Coefficient of Variation (CV) expresses SD as a percentage of the mean (CV = SD/Mean × 100), enabling relative comparison. CV < 15% indicates low variability, 15-30% moderate, and >30% high variability in reporting patterns.

**Outlier Detection**: Z-scores measure how many standard deviations each month's report count deviates from the mean. Months with z-scores ≥ |2| are flagged as statistically significant outliers ($p < 0.05$), indicating unusually high (peaks) or low (valleys) reporting activity beyond approximately 95% of normal distribution.

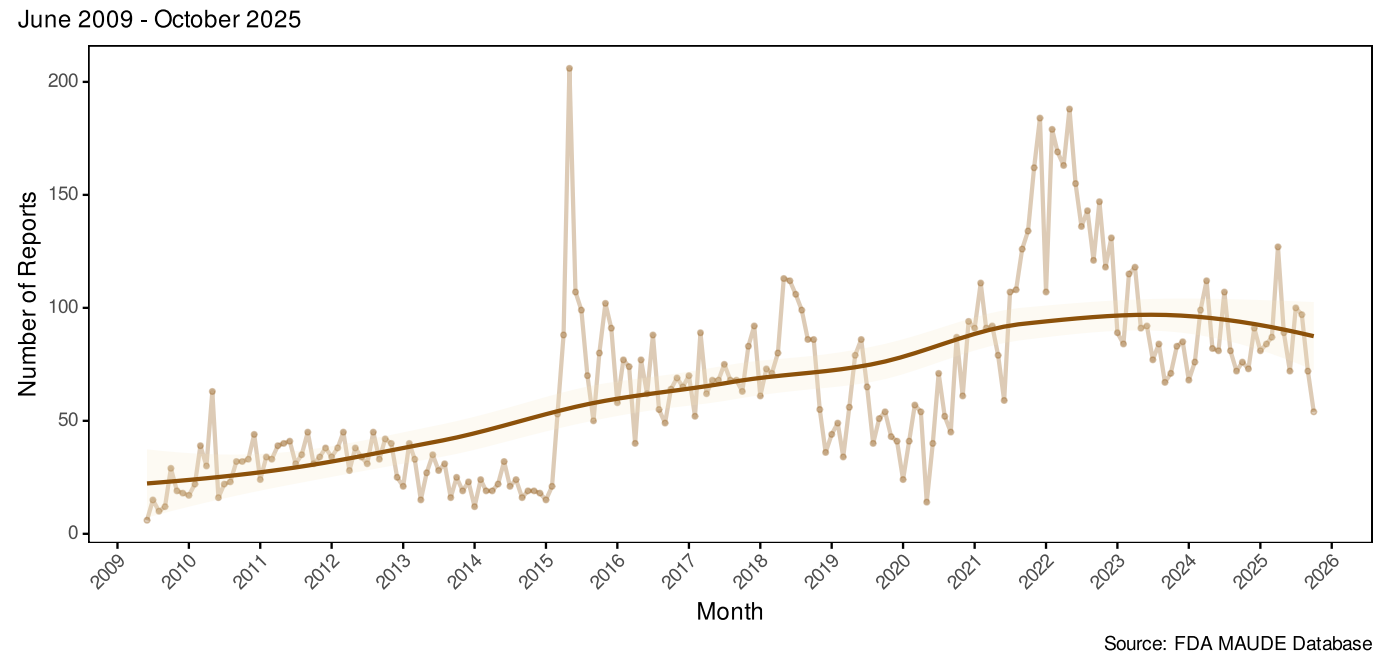# 3. Temporal Trend Analysis

## 3.1. Overall Reporting Trends



Figure 1: Monthly trend of FDA MAUDE reports

## 3.2. 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.
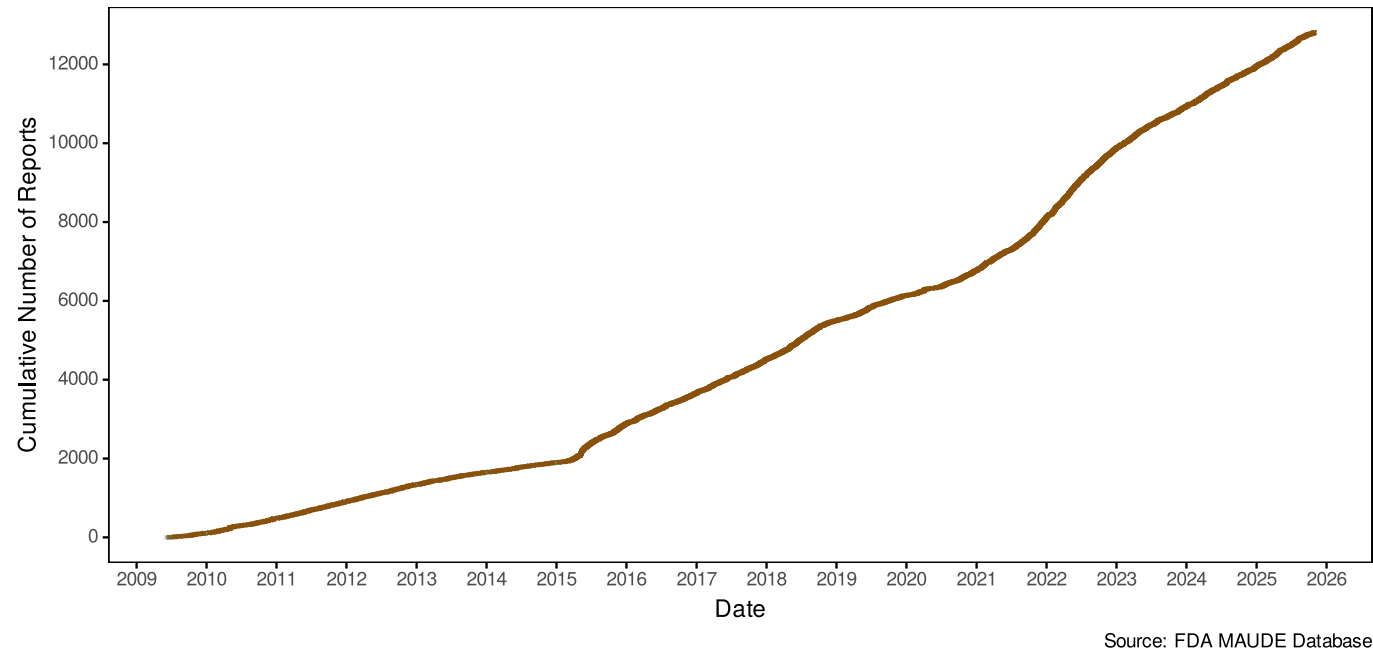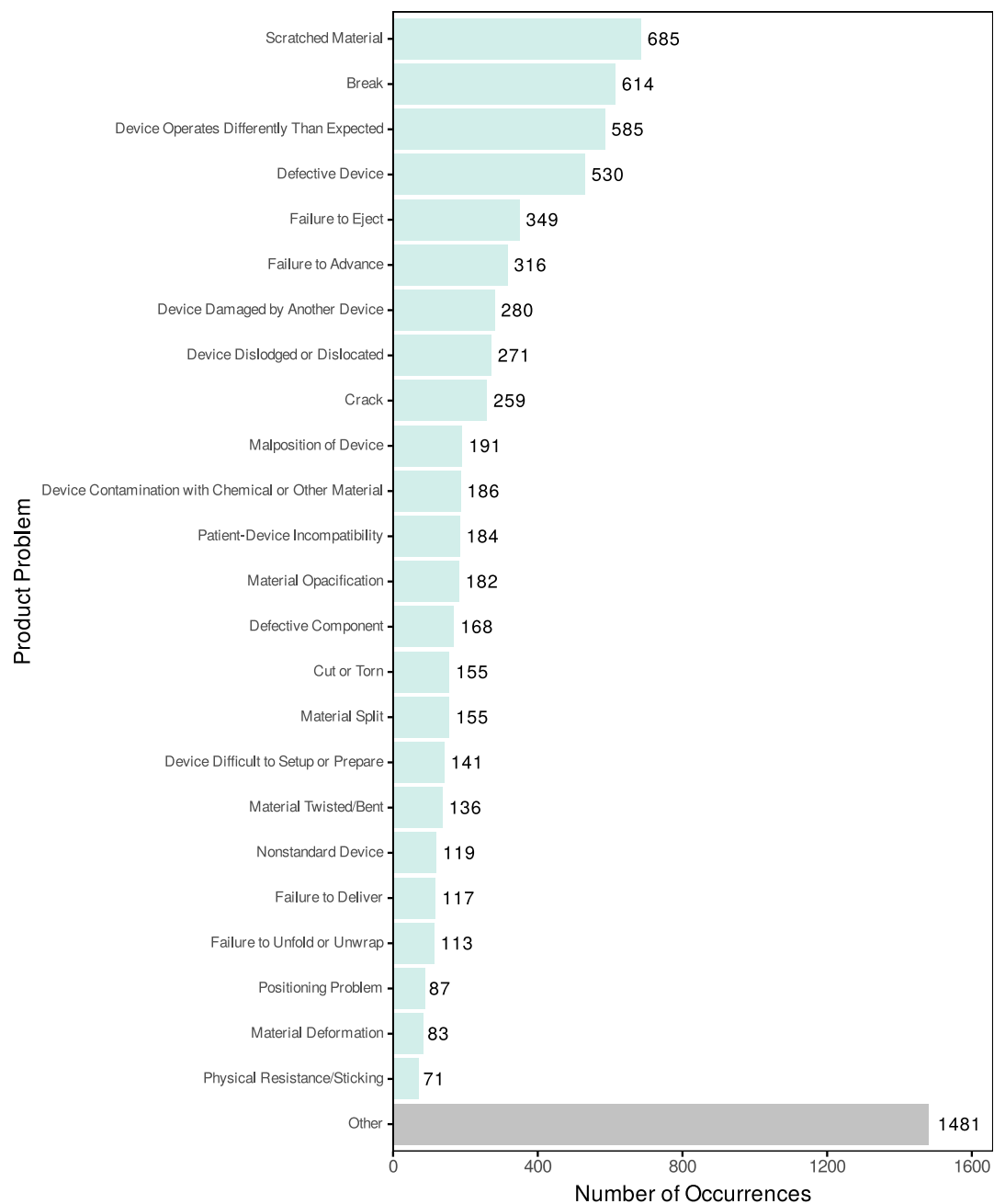
## 3.3. Cumulative Reports Over Time



Figure 2: Cumulative FDA MAUDE reports over time

# 4. Product Problem Analysis

## 4.1. Product Problems Analysis

(June 2009 - October 2025)



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

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

The remaining **1,481** problem occurrences (**19.9%**) are categorized as "Other".
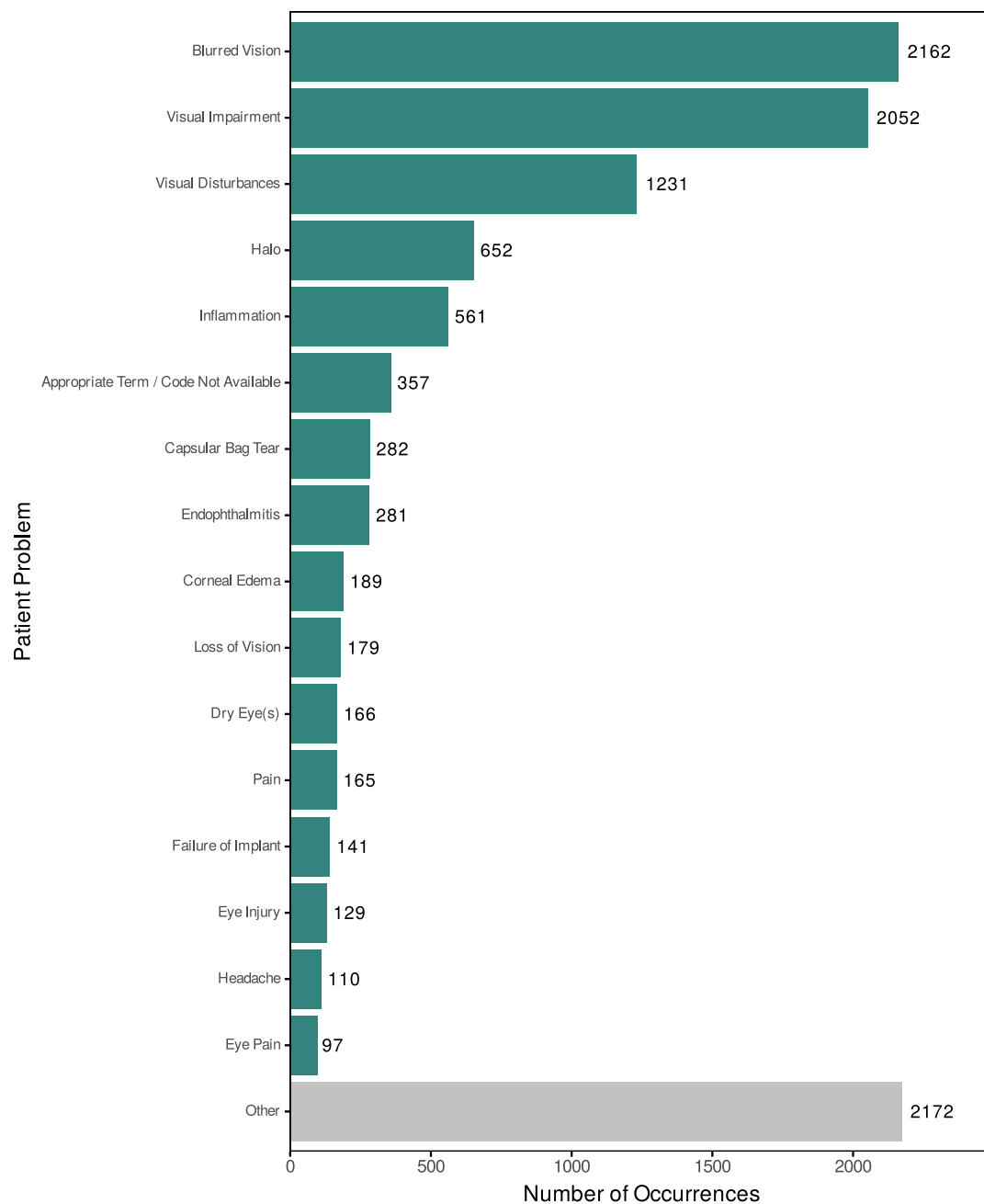
**All Product Problems Representing 80.1% of Data:**

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

Clinical outcomes and adverse events



Figure 4: Patient problems representing approximately 80% of problem occurrences (80.1%), plus 'Other' category

A total of **16** patient problem type(s) account for **80.1%** of all reported patient problem occurrences (**8,754** occurrences).

The remaining **2,172** problem occurrences (**19.9%**) are categorized as "Other".

**All Patient Problems Representing 80.1% of Data:**

1. **Blurred Vision** - 2,162 occurrences (19.8%)
2. **Visual Impairment** - 2,052 occurrences (18.8%)
3. **Visual Disturbances** - 1,231 occurrences (11.3%)
4. **Halo** - 652 occurrences (6.0%)
5. **Inflammation** - 561 occurrences (5.1%)
6. **Appropriate Term / Code Not Available** - 357 occurrences (3.3%)
7. **Capsular Bag Tear** - 282 occurrences (2.6%)
8. **Endophthalmitis** - 281 occurrences (2.6%)
9. **Corneal Edema** - 189 occurrences (1.7%)
10. **Loss of Vision** - 179 occurrences (1.6%)
11. **Dry Eye(s)** - 166 occurrences (1.5%)
12. **Pain** - 165 occurrences (1.5%)
13. **Failure of Implant** - 141 occurrences (1.3%)
14. **Eye Injury** - 129 occurrences (1.2%)
15. **Headache** - 110 occurrences (1.0%)
16. **Eye Pain** - 97 occurrences (0.9%)

# 6. Manufacturer Analysis

## 6.1. Top Manufacturers
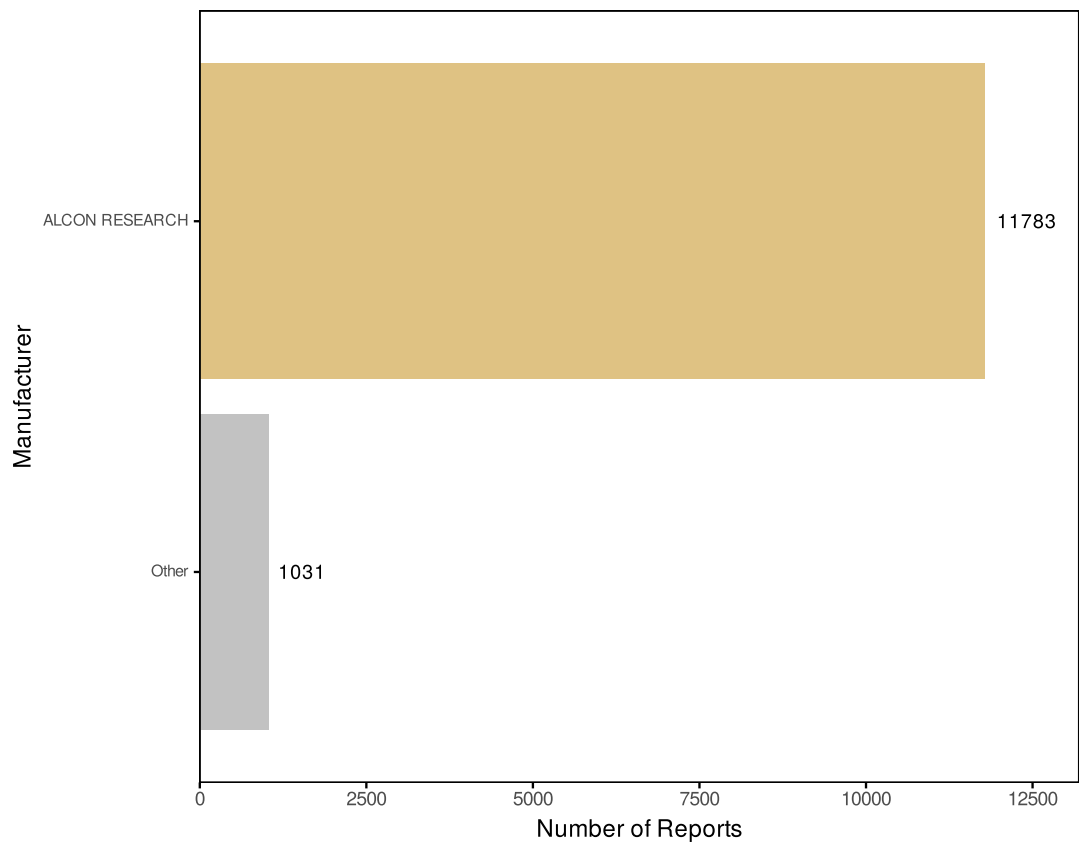


Source: FDA MAUDE Database

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

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

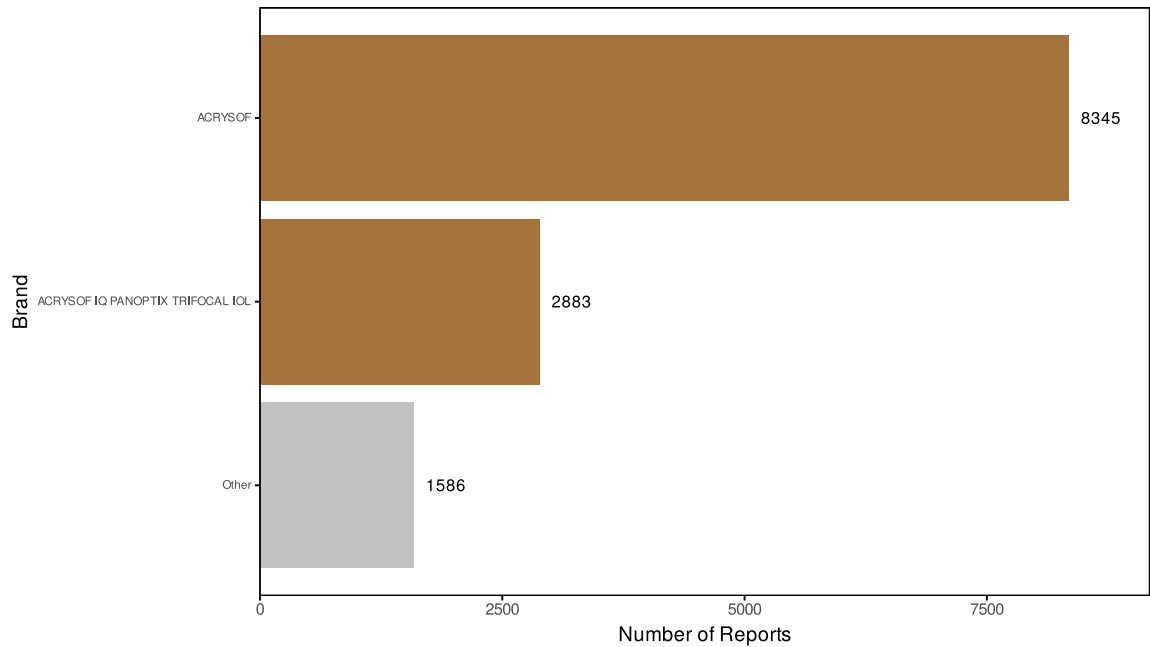The remaining **1,031** reports (**8%**) are from other manufacturers.

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

Table 2: Manufacturer(s) 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



Source: FDA MAUDE Database

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

A total of **2** device brand(s) 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, **ACRYSOF**, accounts for **8,345** reports (**65.1%** of total).

Table 3: Device brand(s) representing 87.6% of reports

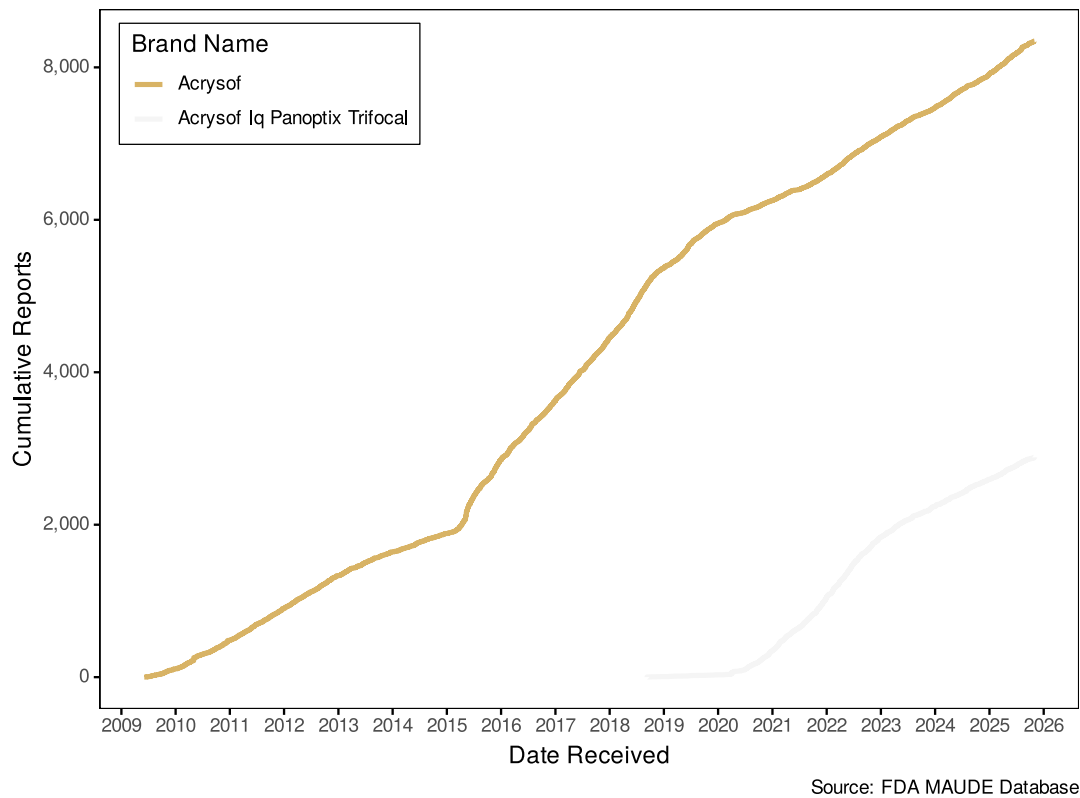| Rank | Brand | Reports | % of Total |
|------|-------|---------|------------|
| 1 | ACRYSOF | 8,345 | 65.12% |
| 2 | ACRYSOF IQ PANOPTIX TRIFOCAL IOL | 2,883 | 22.50% |

## 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 Or Consequence To Patient
- Symptoms or Conditions
- No Information
- No Consequences Or Impact To Patient
- Appropriate Clinical Signs
- No Clinical Signs
- Conditions Term / Code Not Available
- Appropriate Term / Code Not Available
- Insufficient Information
- No Patient Involvement
- Reaction
- Patient Problem/Medical Problem

**Product Problems Excluded:**

- Adverse Event Without Identified Device or Use Problem
- Appropriate Term/Code Not Available
- Appropriate Term / Code Not Available
- Unknown (for use when the device problem is not known)
- Insufficient Information
- No Apparent Adverse Event

## 8.4. Report Metadata

- **Generated**: 2025-11-19 21:05:07
- **Dataset Version**: 2025-10-31
- **Total Records Analyzed**: 12,814
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

# List of Figures

# List of Tables