# OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

BVI Medical

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# 1. Executive Summary

This report analyzes **858** FDA medical device adverse event reports submitted between **January 02, 2025** and **October 29, 2025** (a period of **9.9** months). The dataset includes **2** unique manufacturers and **3** unique device brands. The average reporting rate was **85.8** reports per month, with peak reporting of **127** reports in **April 2025**.

Table 1: Summary statistics of FDA MAUDE reports

| Metric | Value |
|---|---|
| Total Reports | 858 |
| Date Range | January 02, 2025 to October 29, 2025 |
| Reporting Duration | 300 days (9.9 months) |
| Unique Manufacturers | 2 |
| Unique Device Brands | 3 |
| Average Monthly Reports | 85.8 reports/month |
| Maximum Monthly Reports | 127 reports in April 2025 |

# 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 uses automated text matching to standardize manufacturer and brand names across reports. FDA MAUDE reports often contain variations in spelling, capitalization, and formatting (e.g., “INC”, “Inc.”, or “LLC”).

Names with ≥75% similarity are grouped together under a single standardized name. This reduces data fragmentation and provides more accurate counts.

> **i** Note
>
> For technical details on the fuzzy matching algorithm, see Section 8.3.2 in the Technical Appendix.

## 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

> **i** Note
>
> For the complete list of excluded categories, see Section 8.4 in the Technical Appendix.

## 2.4. Concentration-Based Analysis Methodology

This analysis identifies the critical few problems, manufacturers, and brands that account for the majority of occurrences. Rather than selecting an arbitrary "top 10", we dynamically identify categories that collectively represent approximately 80% of all reported occurrences.

Categories are ranked by frequency, and those accounting for approximately 80% of the data are analyzed in detail. The remaining items are grouped as "Other(s)". This approach ensures no category is artificially split.

> **i** Note
>
> For implementation details, see Section 8.3.3 in the Technical Appendix.

## 2.5. Statistical Analysis of Temporal Trends

Monthly reporting patterns are analyzed using standard statistical methods to identify unusual increases or decreases in reporting activity.

**Variability Metrics**: Standard deviation and coefficient of variation measure how much monthly reports fluctuate around the average.

**Peak and Valley Detection**: Months with unusually high or low reporting (more than 2 standard deviations from average) are flagged as statistically significant.

> **i** Note
>
> For detailed statistical methodology, see Section 8.3.4 in the Technical Appendix.

# 3. Manufacturer Analysis

## 3.1. Top Manufacturers

A total of **1** manufacturer(s) account for **93.5%** of all reports (**802** reports), as shown in Table 2 .

The remaining **56** reports (**6.5%**) are from other manufacturers.

The top manufacturer, **ALCON RESEARCH LLC HUNTINGTON**, accounts for **802** reports (**93.5%** of total).

The following table presents the detailed breakdown of manufacturers and their report volumes.

Table 2: Manufacturer(s) representing 93.5% of reports

| Rank | Manufacturer | Reports | % of Total |
|---|---|---|---|
| 1 | ALCON RESEARCH LLC HUNTINGTON | 802 | 93.47% |
| NA | Other(s) | 56 | 6.50% |

# 4. Device Brand Analysis

## 4.1. Top Device Brands

A total of **2** device brand(s) account for **87.1%** of all reports (**747** reports), as shown in Table 3 .

The remaining **111** reports (**12.9%**) are from other brands.

The top device brand, **ACRYSOF IQ TORIC SINGLEPIECE IOL**, accounts for **607** reports (**70.7%** of total).

The following table presents the detailed breakdown of device brands and their report volumes.

Table 3: Device brand(s) representing 87.1% of reports

| Rank | Brand | Reports | % of Total |
|---|---|---|---|
| 1 | ACRYSOF IQ TORIC SINGLEPIECE IOL | 607 | 70.75% |
| 2 | ACRYSOF IQ VIVITY EXTENDED VISION IOL | 140 | 16.32% |
| NA | Other(s) | 111 | 12.90% |

## 4.2. Brand Temporal Trends

The following figure illustrates the cumulative growth of adverse event reports for the top 5 device brands over time.

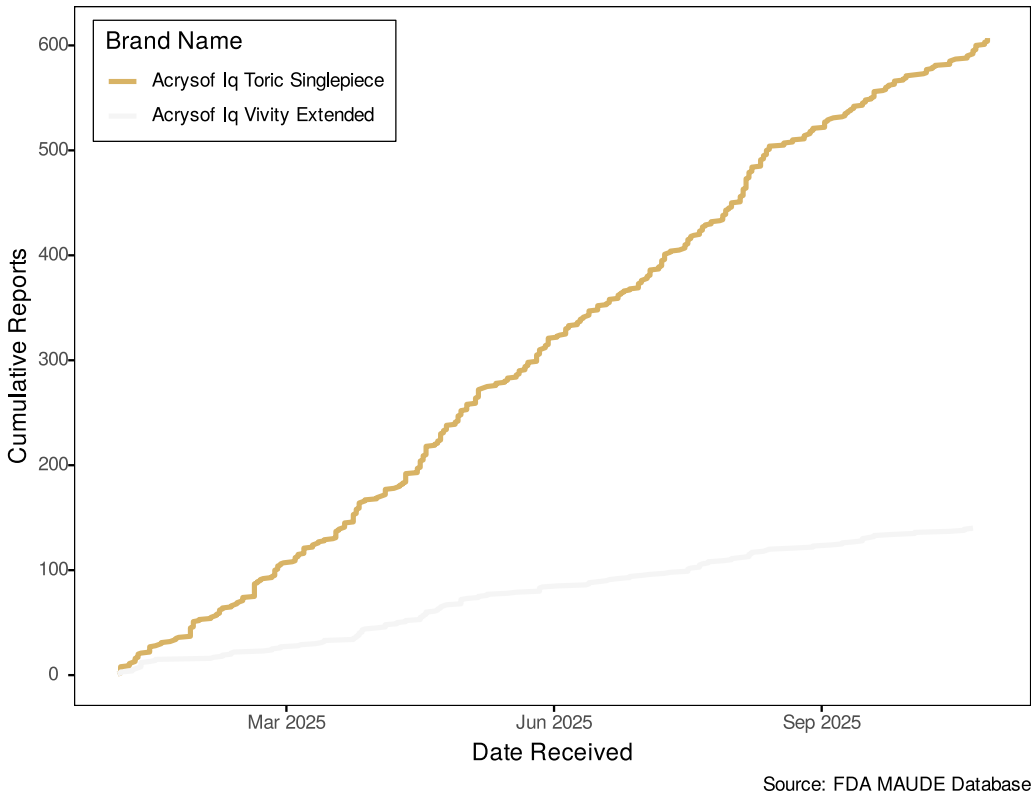


Figure 1: Cumulative adverse event reports by top 5 brands

# 5. Temporal Trend Analysis

## 5.1. Overall Reporting Trends

The following figure presents the monthly trend of adverse event reports over the analysis period.

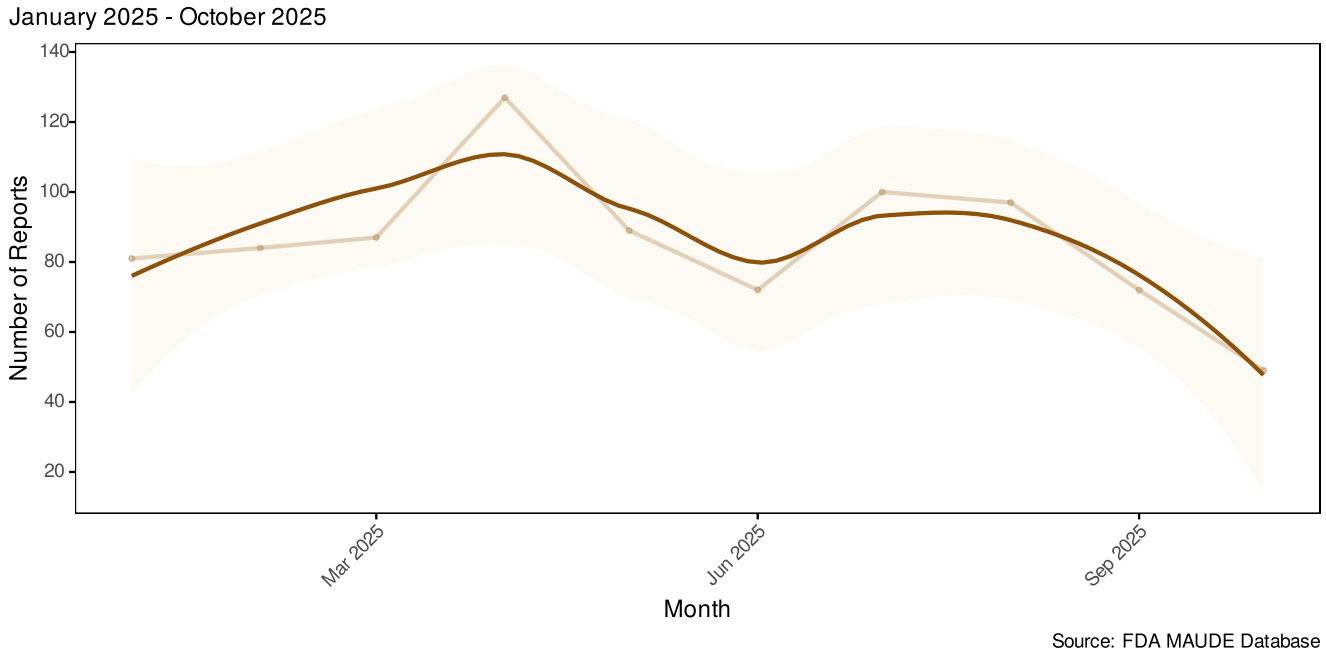


Figure 2: Monthly trend of FDA MAUDE reports

## 5.2. Statistical Trend Analysis

**Reporting Variability:** The average monthly reporting rate is **85.8** reports (SD = **20.5**, CV = **23.9%**).

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

1 month(s) identified:

- **April 2025**: 127 reports (z=2.01, +48%)

## 5.3. Cumulative Reports Over Time

The following figure shows the cumulative accumulation of adverse event reports throughout the study period.

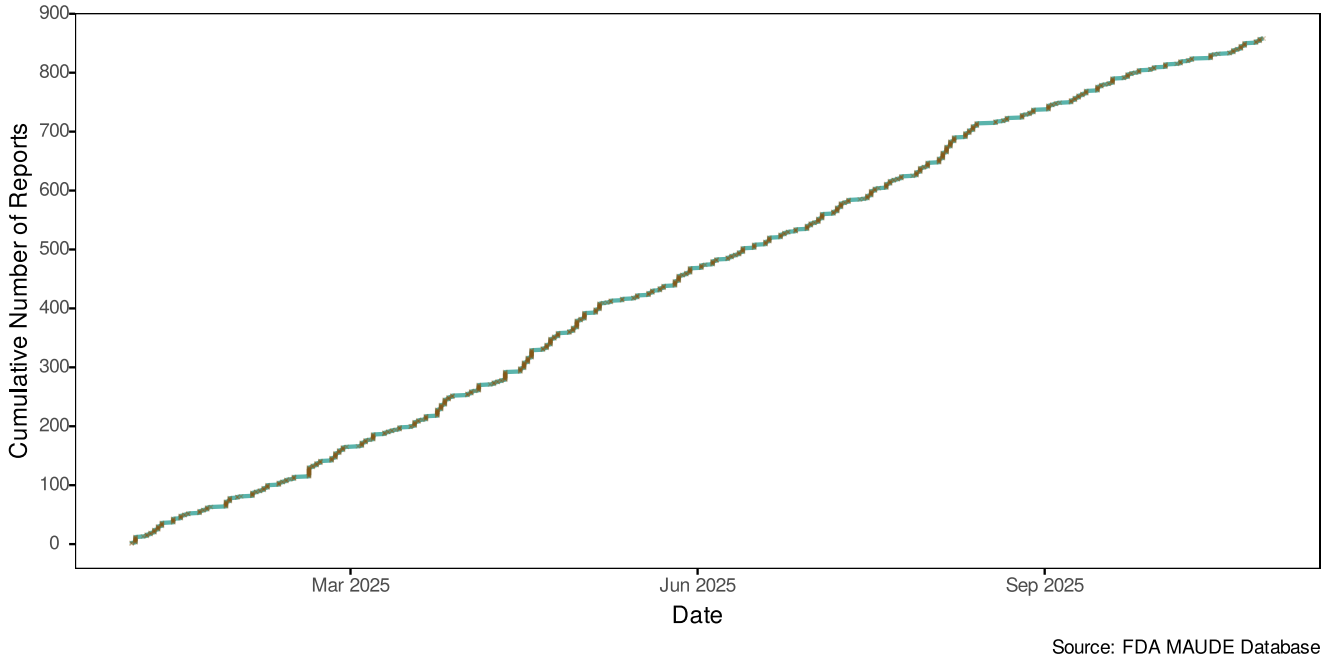


Figure 3: Cumulative FDA MAUDE reports over time

# 6. Product Problem Analysis

## 6.1. Product Problems Analysis

A total of **10** product problem type(s) account for **81.4%** of all reported problem occurrences (**803** occurrences).

The remaining **184** problem occurrences (**18.6%**) are categorized as "Other(s)".

The following figure displays the most frequently reported product problems, accounting for the majority of problem occurrences.

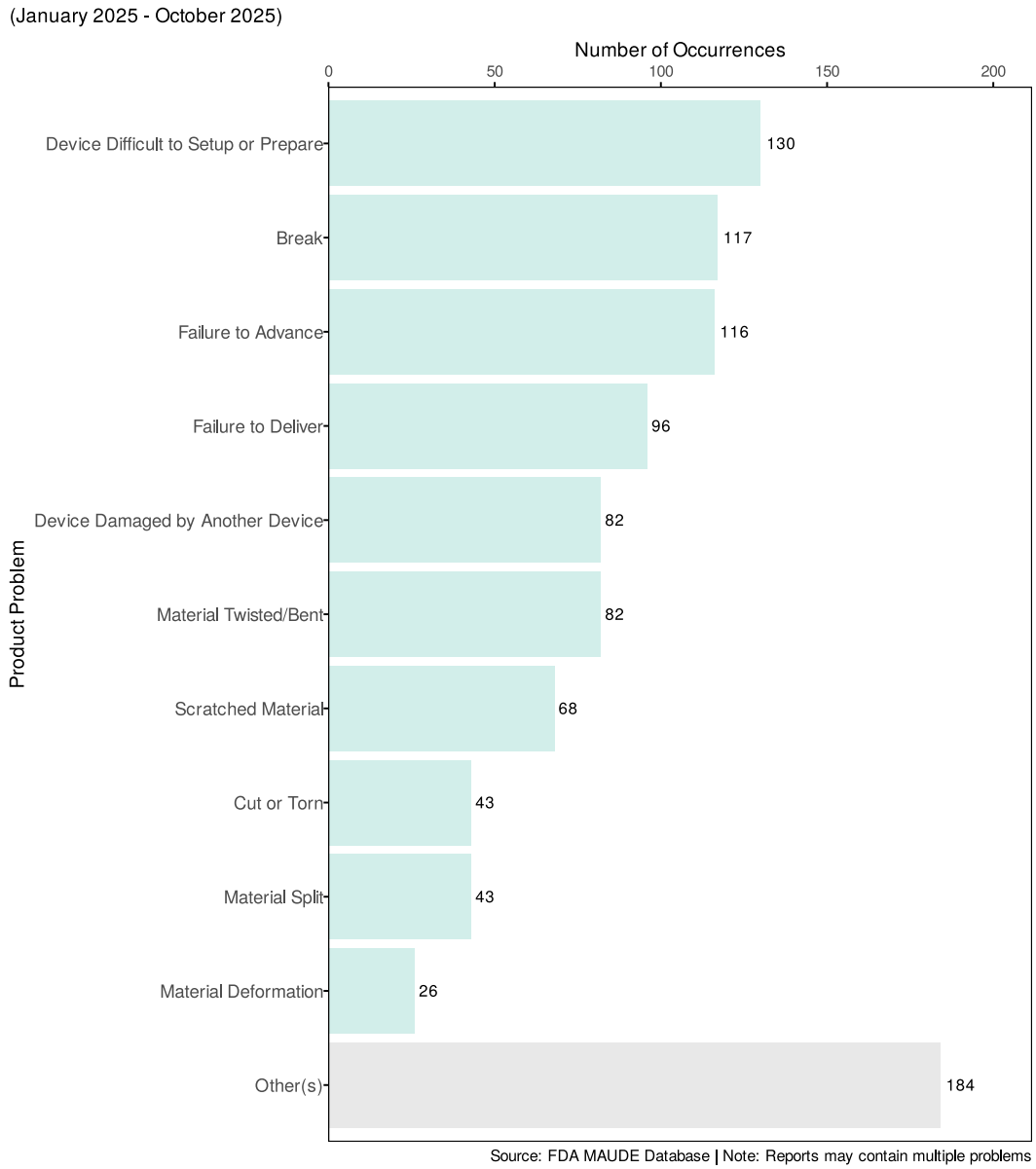


Figure 4: Product problems representing 81.4% of problem occurrences, plus Other(s) category

**All Product Problems Representing 81.4% of Data:**

1. **Device Difficult to Setup or Prepare** - 130 occurrences (13.2%)
2. **Break** - 117 occurrences (11.9%)
3. **Failure to Advance** - 116 occurrences (11.8%)
4. **Failure to Deliver** - 96 occurrences (9.7%)
5. **Device Damaged by Another Device** - 82 occurrences (8.3%)
6. **Material Twisted/Bent** - 82 occurrences (8.3%)
7. **Scratched Material** - 68 occurrences (6.9%)
8. **Cut or Torn** - 43 occurrences (4.4%)
9. **Material Split** - 43 occurrences (4.4%)
10. **Material Deformation** - 26 occurrences (2.6%)

# 7. Patient Problem Analysis

## 7.1. Patient Problems Analysis

A total of **9** patient problem type(s) account for **80.8%** of all reported patient problem occurrences (**252** occurrences).

The remaining **60** problem occurrences (**19.2%**) are categorized as “Other(s)”.

The following figure presents the most frequently reported patient problems associated with these adverse events.

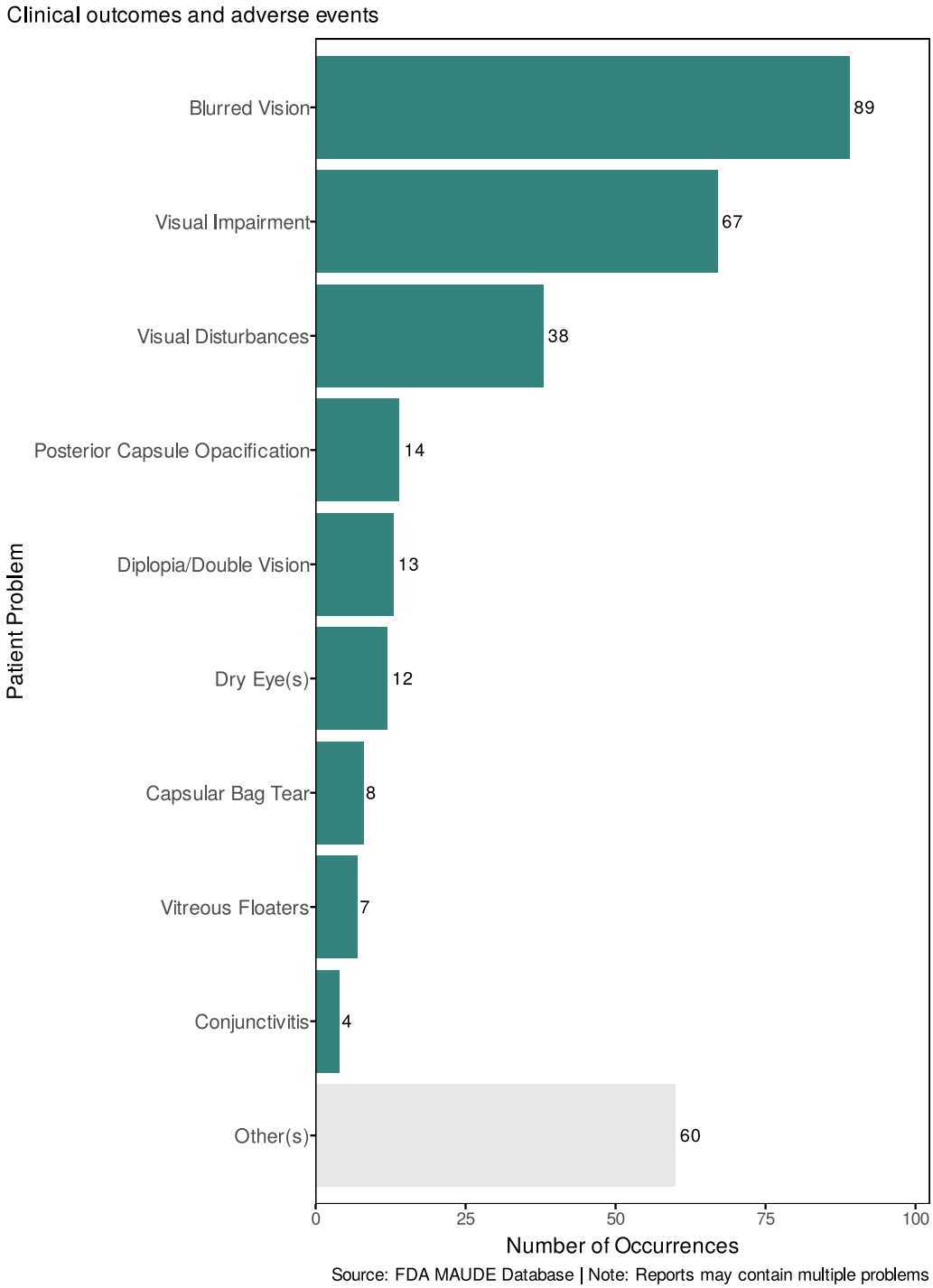


Figure 5: Patient problems representing 80.8% of problem occurrences, plus Other(s) category

**All Patient Problems Representing 80.8% of Data:**

1. **Blurred Vision** - 89 occurrences (28.5%)
2. **Visual Impairment** - 67 occurrences (21.5%)
3. **Visual Disturbances** - 38 occurrences (12.2%)
4. **Posterior Capsule Opacification** - 14 occurrences (4.5%)

5. **Diplopia/Double Vision** - 13 occurrences (4.2%)
6. **Dry Eye(s)** - 12 occurrences (3.8%)
7. **Capsular Bag Tear** - 8 occurrences (2.6%)
8. **Vitreous Floaters** - 7 occurrences (2.2%)
9. **Conjunctivitis** - 4 occurrences (1.3%)

# 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. Detailed Methodology

### 8.3.1. Data Query Information

**Search Query**: Acrysof IQ date_received:[2025-01-01+TO+2025-10-30]

**OpenFDA Database**: event

**API Endpoint**: https://api.fda.gov/device/event.json

**Search Executed**: 2025-11-20 13:37:34

**Data Last Updated**: 2025-11-11

**Total Results**: 864 records found in OpenFDA database

**Records Retrieved**: 864 records

**Records Analyzed**: 858 records (after data cleaning)

### 8.3.2. Fuzzy Matching Algorithm

**Algorithm**: The analysis uses the Levenshtein distance algorithm, which calculates the minimum number of single-character edits (insertions, deletions, or substitutions) needed to transform one string into another.

**Implementation**: The RapidFuzz library implements partial ratio matching, which finds the best matching substring and calculates similarity as a percentage (0-100%).

**Matching Process**: 1. Text is normalized: converted to uppercase, special characters removed, whitespace standardized 2. Similarity scores are calculated between all name pairs 3. Names with ≥75% similarity are grouped together 4. The shortest variant in each group becomes the canonical name

**Example**: “MEDTRONIC INC”, “Medtronic Inc.”, and “MEDTRONIC” would all be grouped under “MEDTRONIC” (shortest variant).

#### 8.3.3. Concentration-Based Analysis

**Implementation Details**: 1. Items are sorted by frequency (descending order) 2. Cumulative percentages are calculated for each item 3. Items are included if the *previous* item’s cumulative percentage was below 80% 4. This ensures complete categories—no category is split between main analysis and “Other(s)”

**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(s)” category provides perspective on the long-tail distribution

#### 8.3.4. Statistical Methods

**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 $\times$ 100) - **Interpretation**: CV $<$ 15% = low variability, 15-30% = moderate, $>$30% = high variability

**Outlier Detection**: - **Z-scores**: Measure how many standard deviations each month’s report count deviates from the mean - **Threshold**: Months with |z-score| $\geq$ 2 are flagged as statistically significant ($p < 0.05$) - **Interpretation**: Indicates unusually high (peaks) or low (valleys) reporting activity beyond ~95% of normal distribution

## 8.4. 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

## 8.5. Report Metadata

- **Generated**: 2025-11-20 13:56:04
- **Dataset Version**: 2025-10-29
- **Total Records Analyzed**: 858
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

# List of Figures

# List of Tables