OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

BVI Medical

2025-11-19

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1. Executive Summary

This report analyzes **147** FDA medical device adverse event reports submitted between **July 09, 1998** and **October 24, 2025** (a period of **327.5** months). The dataset includes **19** unique manufacturers and **41** unique device brands. The average reporting rate was **1.5** reports per month, with peak reporting of **5** reports in **January 2025**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	147
Date Range	July 09, 1998 to October 24, 2025
Reporting Duration	9969 days (327.5 months)
Unique Manufacturers	19
Unique Device Brands	41
Average Monthly Reports	1.5 reports/month
Maximum Monthly Reports	5 reports in January 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 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 $\times$ 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 $\geq |2|$ 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

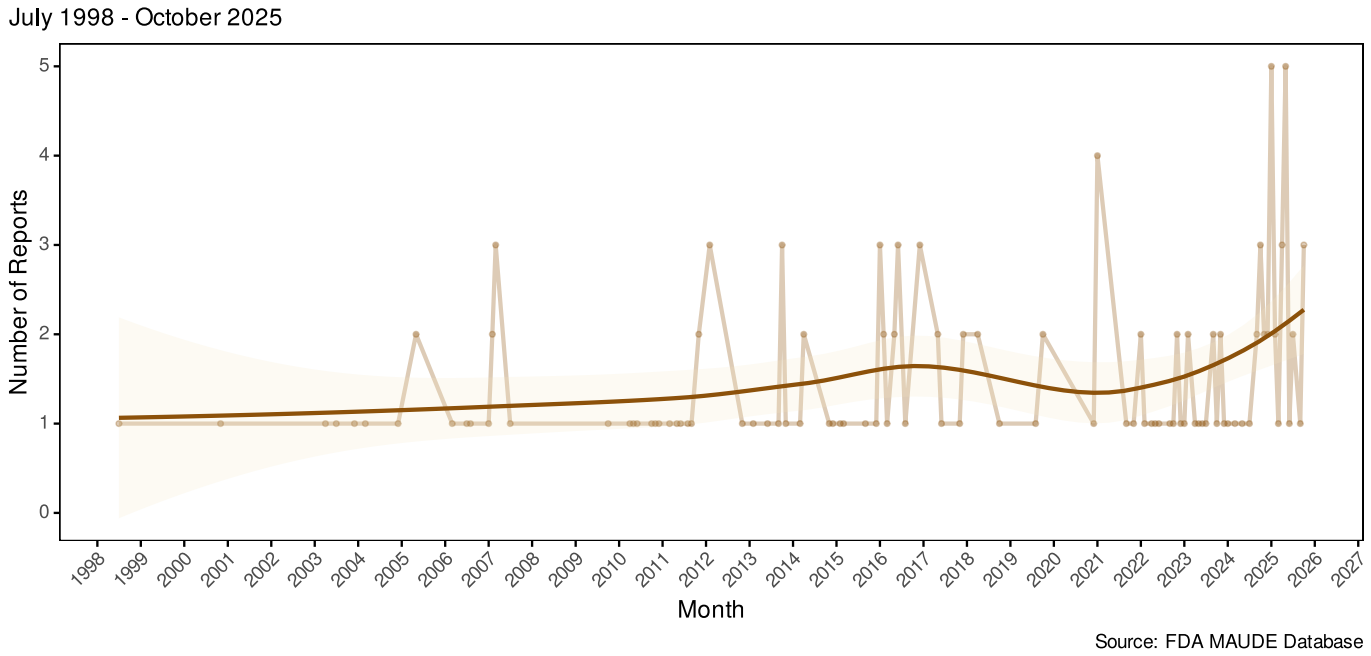

Figure 1: Monthly trend of FDA MAUDE reports

3.2. Statistical Trend Analysis

Reporting Variability: The average monthly reporting rate is **1.5** reports (SD = **0.9**, CV = **57.6%**).

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

3 month(s) identified:

- **January 2025**: 5 reports (z=4.05, +233.3%)
- **May 2025**: 5 reports (z=4.05, +233.3%)
- **January 2021**: 4 reports (z=2.89, +166.7%)

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

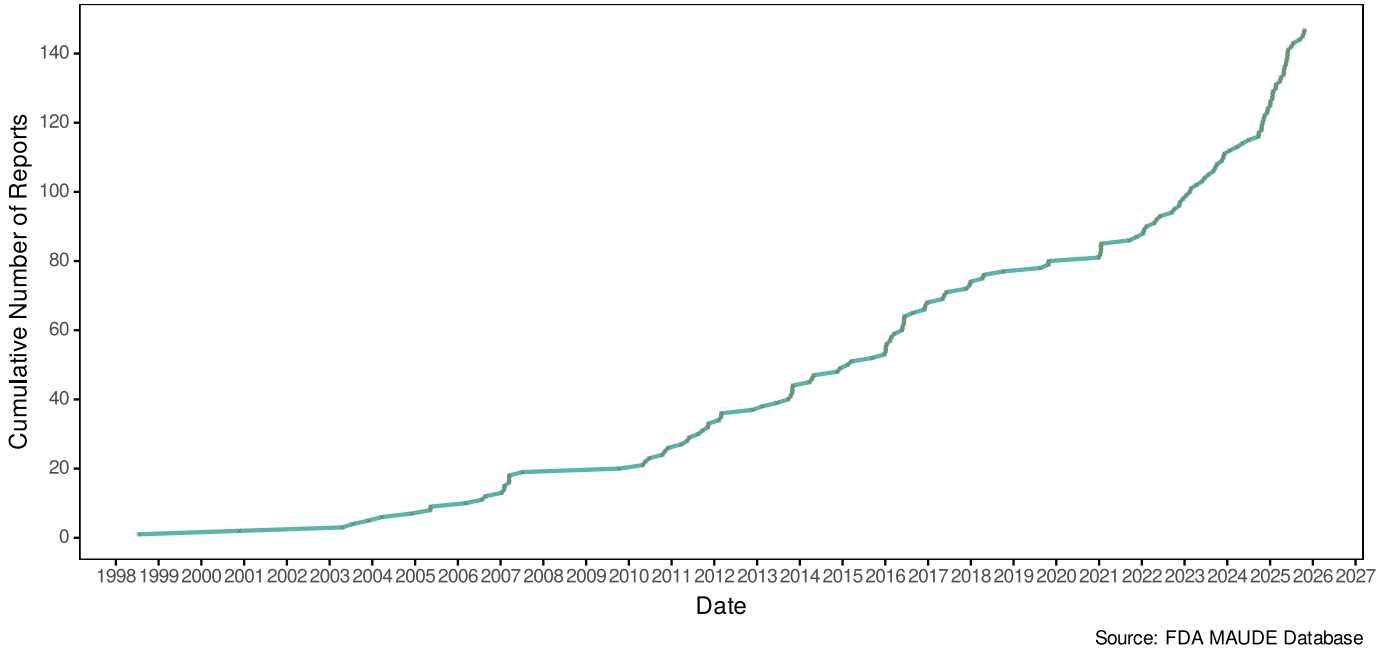

Figure 2: Cumulative FDA MAUDE reports over time

4. Product Problem Analysis

4.1. Product Problems Analysis

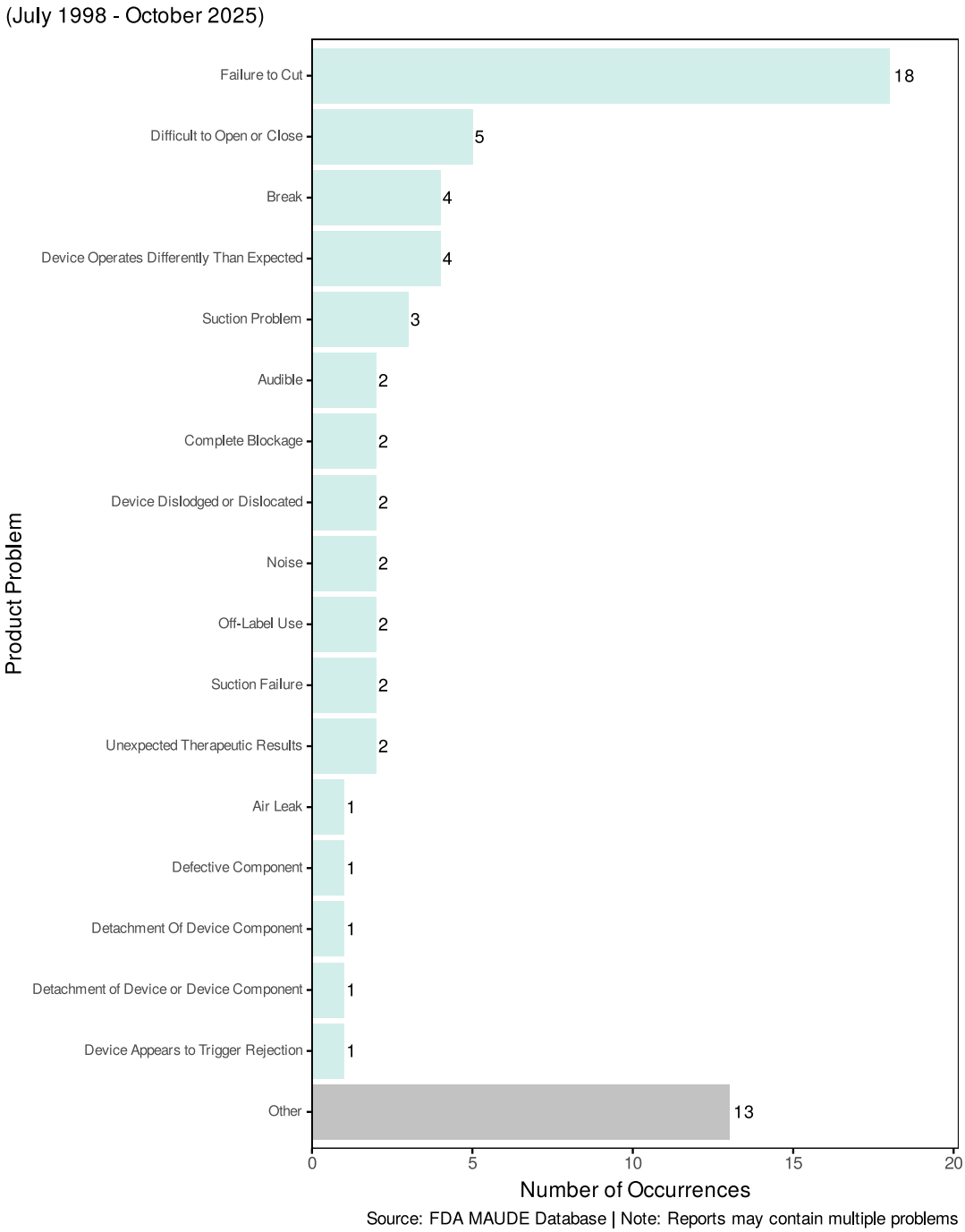

Figure 3: Product problems representing approximately 80% of problem occurrences (80.3%), plus 'Other' category

A total of **17** product problem type(s) account for **80.3%** of all reported problem occurrences (**53** occurrences).

The remaining **13** problem occurrences (**19.7%**) are categorized as "Other".

All Product Problems Representing 80.3% of Data:

1. **Failure to Cut** - 18 occurrences (27.3%)
2. **Difficult to Open or Close** - 5 occurrences (7.6%)
3. **Break** - 4 occurrences (6.1%)
4. **Device Operates Differently Than Expected** - 4 occurrences (6.1%)
5. **Suction Problem** - 3 occurrences (4.5%)
6. **Audible** - 2 occurrences (3.0%)
7. **Complete Blockage** - 2 occurrences (3.0%)
8. **Device Dislodged or Dislocated** - 2 occurrences (3.0%)
9. **Noise** - 2 occurrences (3.0%)
10. **Off-Label Use** - 2 occurrences (3.0%)
11. **Suction Failure** - 2 occurrences (3.0%)
12. **Unexpected Therapeutic Results** - 2 occurrences (3.0%)
13. **Air Leak** - 1 occurrences (1.5%)
14. **Defective Component** - 1 occurrences (1.5%)
15. **Detachment Of Device Component** - 1 occurrences (1.5%)
16. **Detachment of Device or Device Component** - 1 occurrences (1.5%)
17. **Device Appears to Trigger Rejection** - 1 occurrences (1.5%)

5. Patient Problem Analysis

5.1. Patient Problems Analysis

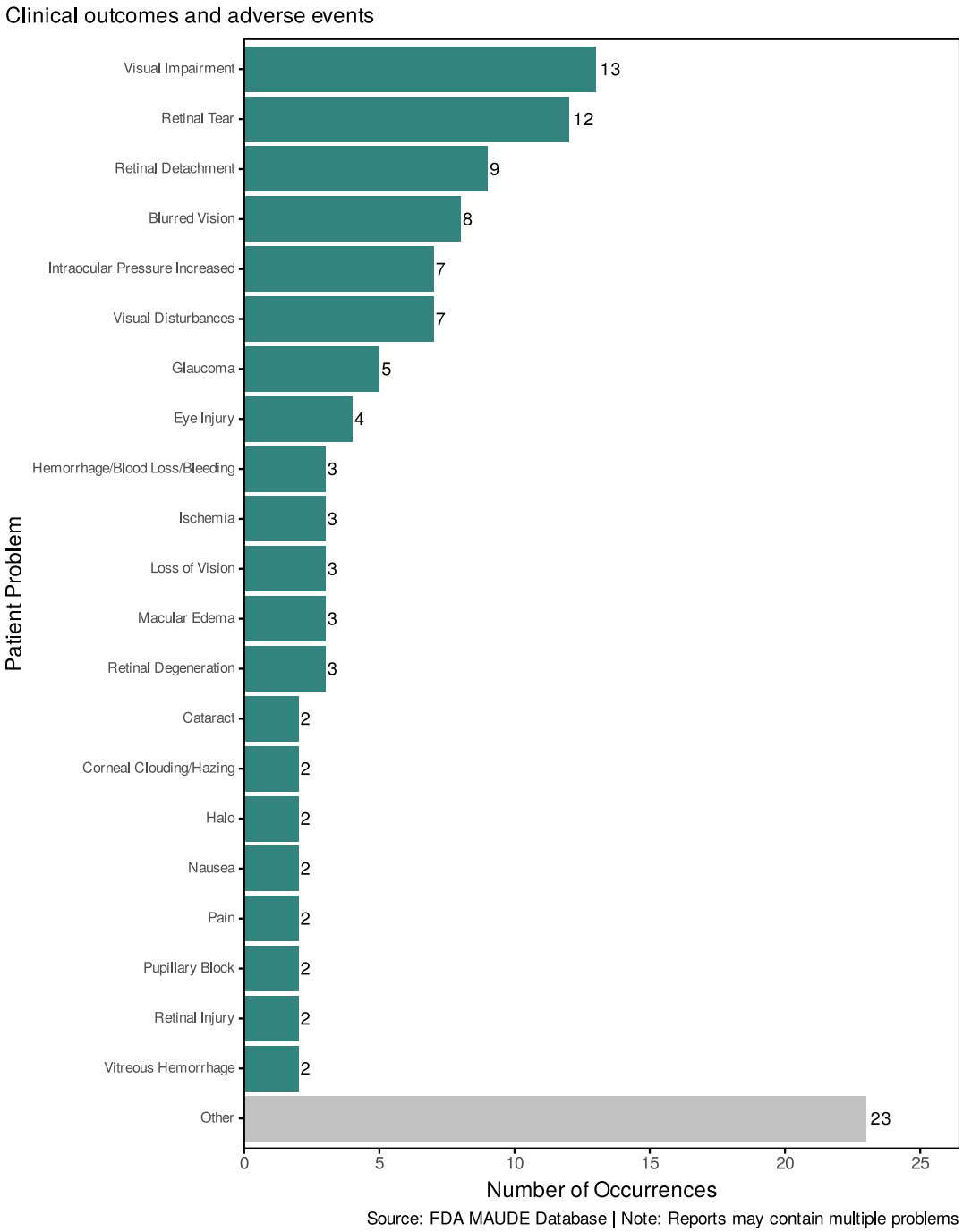

Figure 4: Patient problems representing approximately 80% of problem occurrences (80.7%), plus 'Other' category

A total of **21** patient problem type(s) account for **80.7%** of all reported patient problem occurrences (**96** occurrences).

The remaining **23** problem occurrences (**19.3%**) are categorized as "Other".

All Patient Problems Representing 80.7% of Data:

1. **Visual Impairment** - 13 occurrences (10.9%)
2. **Retinal Tear** - 12 occurrences (10.1%)
3. **Retinal Detachment** - 9 occurrences (7.6%)
4. **Blurred Vision** - 8 occurrences (6.7%)
5. **Intraocular Pressure Increased** - 7 occurrences (5.9%)
6. **Visual Disturbances** - 7 occurrences (5.9%)
7. **Glaucoma** - 5 occurrences (4.2%)
8. **Eye Injury** - 4 occurrences (3.4%)
9. **Hemorrhage/Blood Loss/Bleeding** - 3 occurrences (2.5%)
10. **Ischemia** - 3 occurrences (2.5%)
11. **Loss of Vision** - 3 occurrences (2.5%)
12. **Macular Edema** - 3 occurrences (2.5%)
13. **Retinal Degeneration** - 3 occurrences (2.5%)
14. **Cataract** - 2 occurrences (1.7%)
15. **Corneal Clouding/Hazing** - 2 occurrences (1.7%)
16. **Halo** - 2 occurrences (1.7%)
17. **Nausea** - 2 occurrences (1.7%)
18. **Pain** - 2 occurrences (1.7%)
19. **Pupillary Block** - 2 occurrences (1.7%)
20. **Retinal Injury** - 2 occurrences (1.7%)
21. **Vitreous Hemorrhage** - 2 occurrences (1.7%)

6. Manufacturer Analysis

6.1. Top Manufacturers

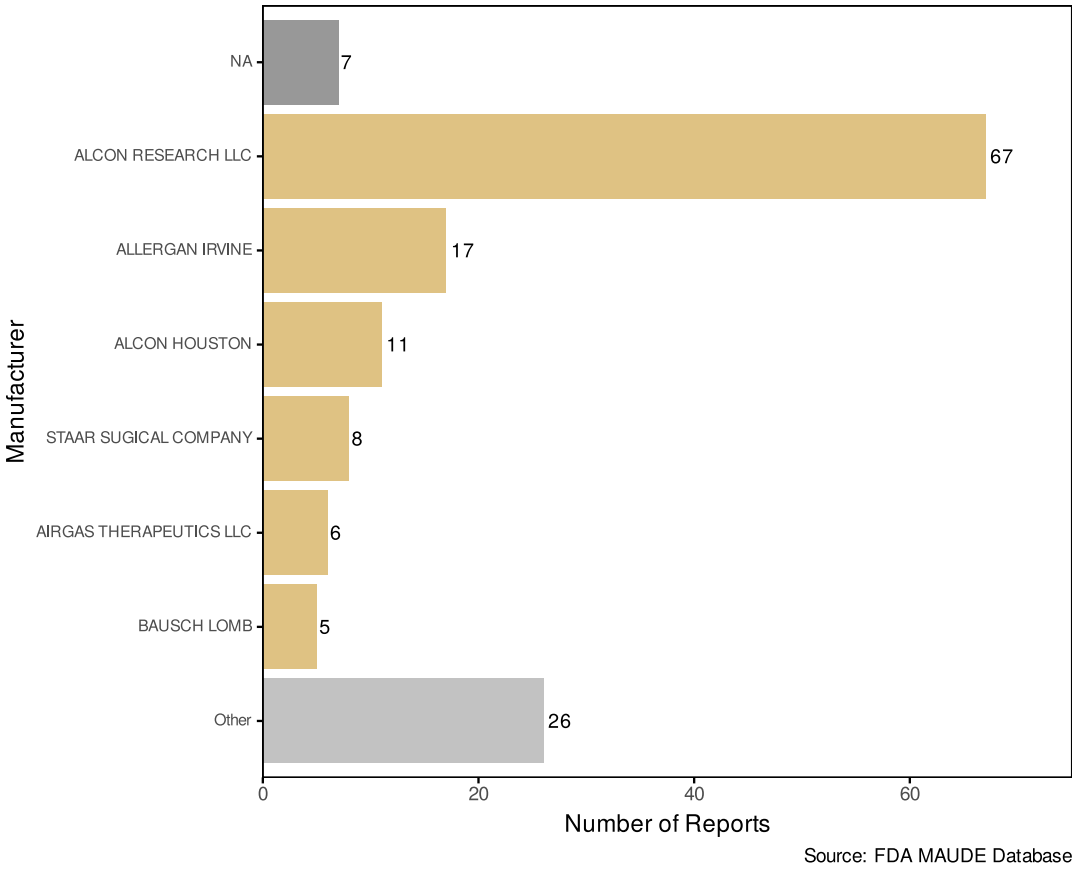

Figure 5: Manufacturers representing approximately 80% of reports (82.3%), plus 'Other' category

A total of **7** manufacturer(s) account for **82.3%** of all reports (**121** reports).

The remaining **26** reports (**17.7%**) are from other manufacturers.

The top manufacturer, **ALCON RESEARCH LLC**, accounts for **67** reports (**45.6%** of total).

Table 2: Manufacturer(s) representing 82.3% of reports

Rank	Manufacturer	Reports	% of Total
1	ALCON RESEARCH LLC	67	45.58%
2	ALLERGAN IRVINE	17	11.56%
3	ALCON HOUSTON	11	7.48%
4	STAAR SUGICAL COMPANY	8	5.44%
5	NA	7	4.76%

Rank	Manufacturer	Reports	% of Total
6	AIRGAS THERAPEUTICS LLC	6	4.08%
7	BAUSCH LOMB	5	3.40%

7. Device Brand Analysis

7.1. Top Device Brands

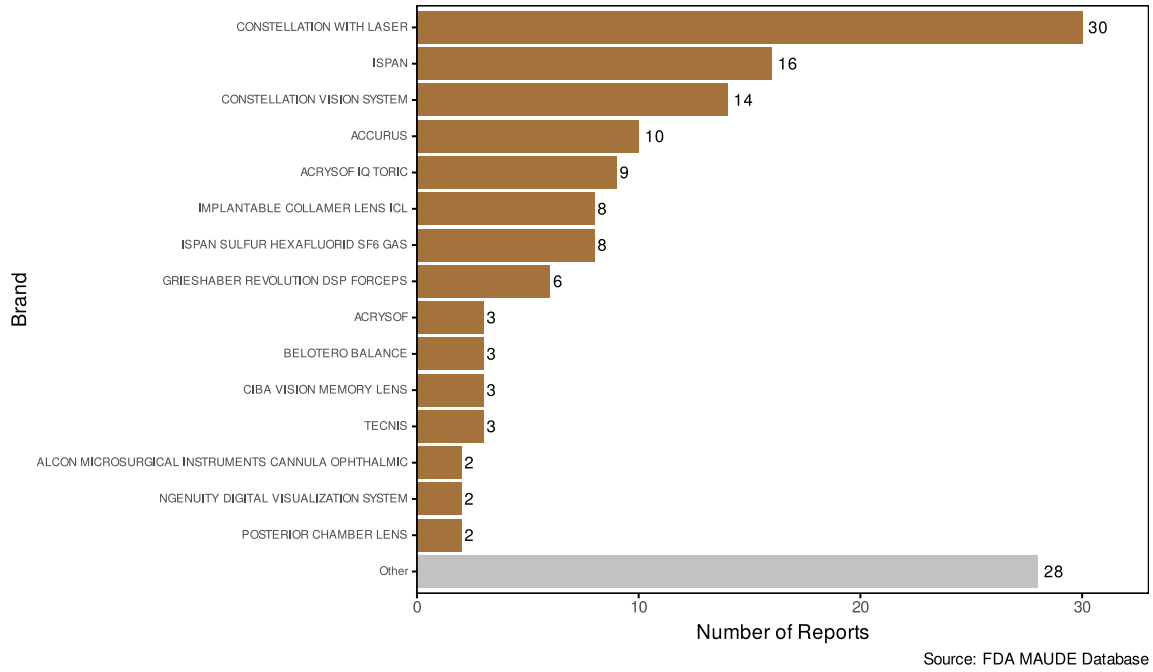

Figure 6: Device brands representing approximately 80% of reports (81%), plus 'Other' category

A total of **15** device brand(s) account for **81%** of all reports (**119** reports).

The remaining **28** reports (**19%**) are from other brands.

The top device brand, **CONSTELLATION WITH LASER**, accounts for **30** reports (**20.4%** of total).

Table 3: Device brand(s) representing 81% of reports

Rank	Brand	Reports	% of Total
1	CONSTELLATION WITH LASER	30	20.41%
2	ISPAN	16	10.88%
3	CONSTELLATION VISION SYSTEM	14	9.52%
4	ACCURUS	10	6.80%
5	ACRYSOF IQ TORIC	9	6.12%
6	IMPLANTABLE COLLAMER LENS ICL	8	5.44%
7	ISPAN SULFUR HEXAFLUORID SF6 GAS	8	5.44%
8	GRIESHABER REVOLUTION DSP FORCEPS	6	4.08%
9	ACRYSOF	3	2.04%
10	BELOTERO BALANCE	3	2.04%
11	CIBA VISION MEMORY LENS	3	2.04%
12	TECNIS	3	2.04%
13	ALCON MICROSURGICAL INSTRUMENTS CANNULA OPHTHALMIC	2	1.36%
14	NGENUITY DIGITAL VISUALIZATION SYSTEM	2	1.36%
15	POSTERIOR CHAMBER LENS	2	1.36%

7.2. Brand Temporal Trends

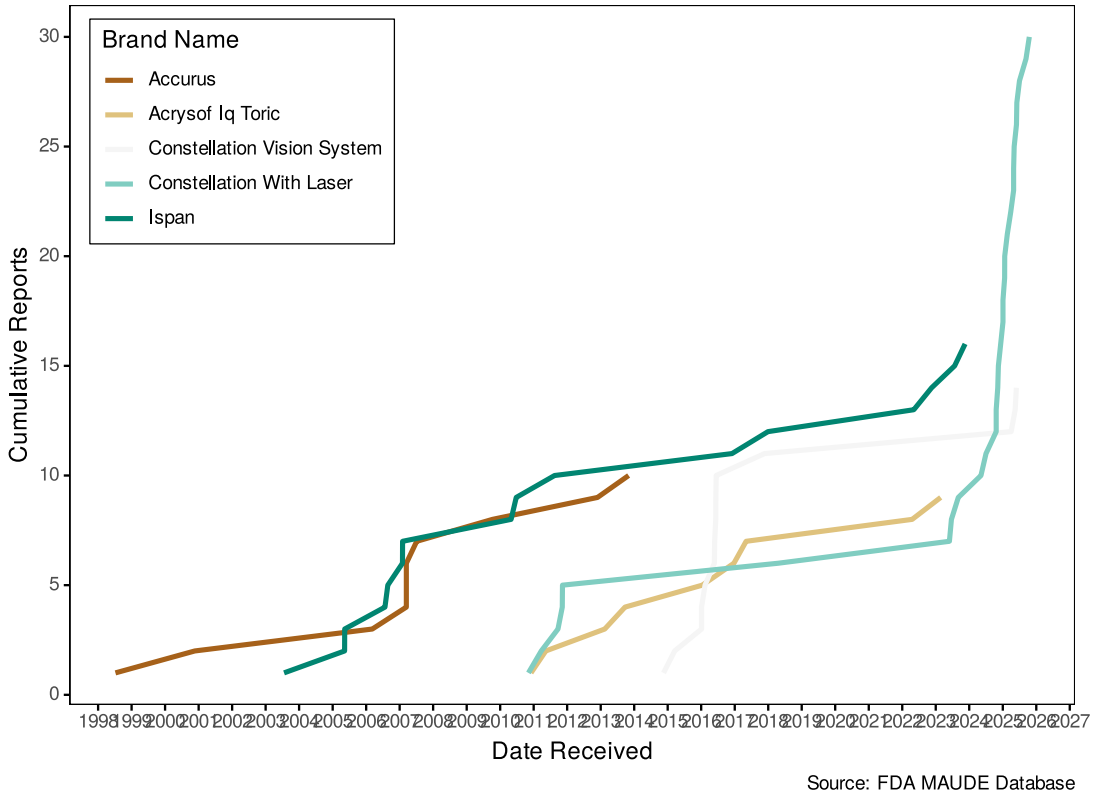

Figure 7: Cumulative adverse event reports by top 5 brands

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 21:39:02
- **Dataset Version**: 2025-10-24
- **Total Records Analyzed**: 147
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

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