# Suffix Use for Biosimilar Product Identification in Postmarketing Adverse Event Reporting

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The opinions expressed are those of the presenter, and do not necessarily represent the views of the US Food and Drug Administration, US Public Health Service, or the US Government

No conflicts of interest to disclose

# CDER's Postmarket Safety Surveillance

- FDA's Center for Drug Evaluation and Research (CDER) conducts surveillance of all marketed drug and therapeutic biologics
- Surveillance is multi-disciplinary and life-cycle based, beginning early in a product's development
- Signal identification and evaluation draw on multiple data sources (e.g., spontaneous reports, medical literature, observational studies, periodic safety reports, premarketing data)

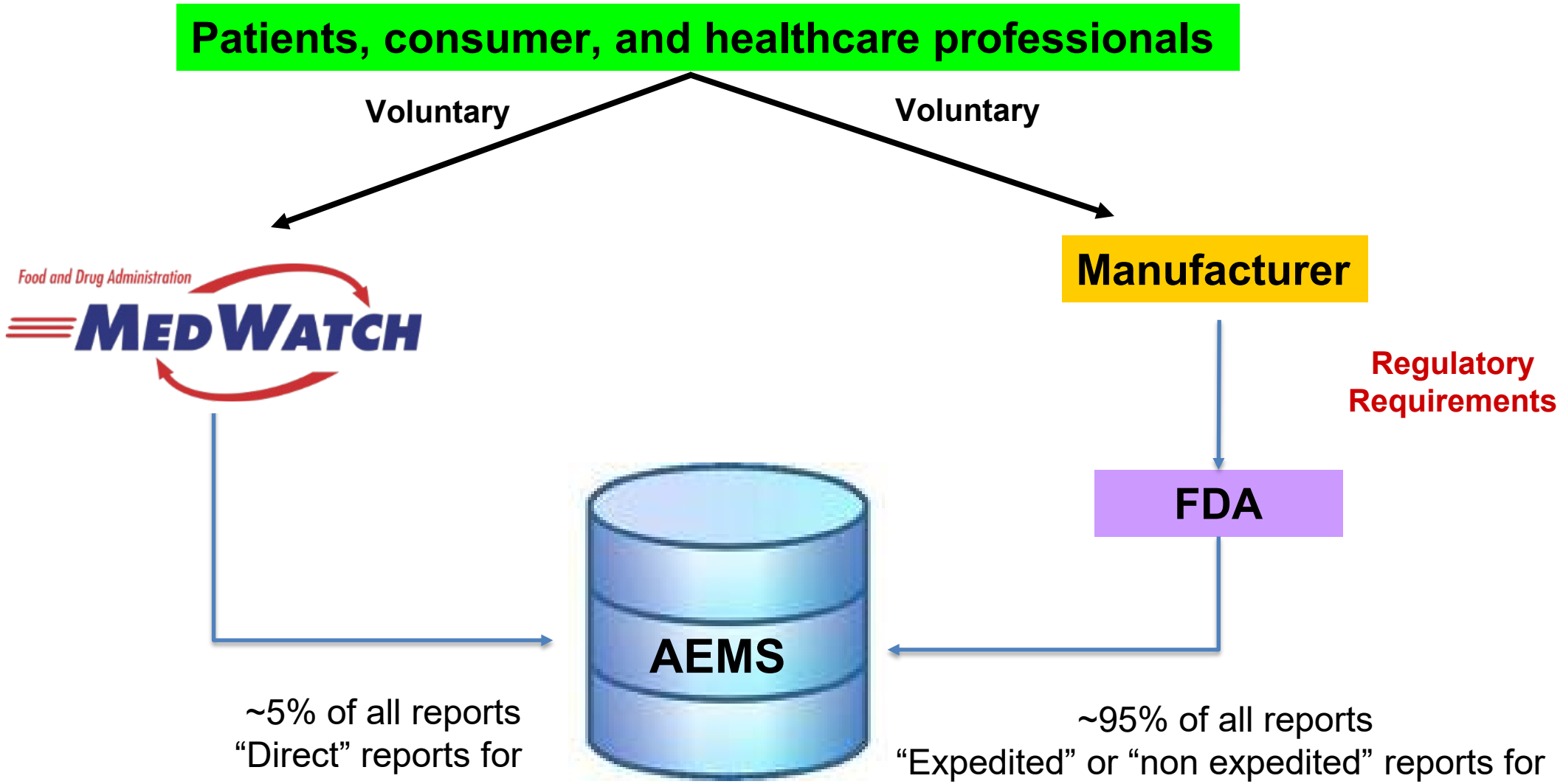
Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff. January 2024. Available: https://www.fda.gov/media/130216//download
FDA CDER MAPP: Collaborative Identification, Evaluation, and Resolution of a Newly Identified Safety Signal. April 2020. Available: https://www.fda.gov/media/137475/download

# FDA Adverse Event Monitoring System (AEMS)

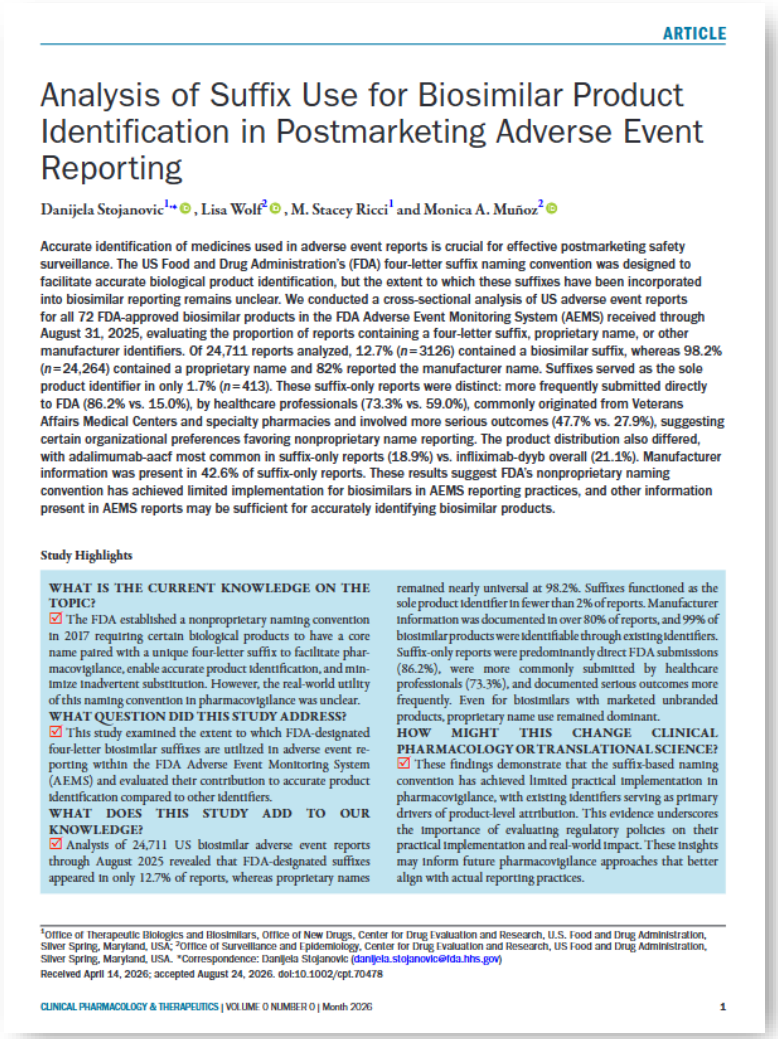
- Launched March 2026, AEMS is FDA's primary system for intake, processing, analysis, and reporting of safety-related events across all marketed FDA-regulated product categories
- Includes reports previously contained in FAERS (FDA Adverse Event Reporting System)
- For drugs and therapeutic biologics, AEMS captures adverse events, medication errors, and product quality issues from healthcare professionals, consumers, manufacturers, and other sources
- Suspect products are coded to FDA's internal product dictionary
- Adverse events are coded using MedDRA terminology

FDA Adverse Event Monitoring System (AEMS). October 17, 2026. Available at: https://www.fda.gov/safety/fda-adverse-event-monitoring-system-aems

# How Postmarketing Reports Get to FDA



# Suffix Reporting Patterns in AEMS



ARTICLE

## Analysis of Suffix Use for Biosimilar Product Identification in Postmarketing Adverse Event Reporting

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Accurate identification of medicines used in adverse event reports is crucial for effective postmarketing safety surveillance. The US Food and Drug Administration's (FDA) four-letter suffix naming convention was designed to facilitate accurate biological product identification, but the extent to which these suffixes have been incorporated into biosimilar reporting remains unclear. We conducted a cross-sectional analysis of US adverse event reports for all 72 FDA-approved biosimilar products in the FDA Adverse Event Monitoring System (AEMS) received through August 31, 2025, evaluating the proportion of reports containing a four-letter suffix, proprietary name, or other manufacturer identifiers. Of 24,711 reports analyzed, 12.7% ($n$ = 3126) contained a biosimilar suffix, whereas 98.2% ($n$ = 24,264) contained a proprietary name and 82% reported the manufacturer name. Suffixes served as the sole product identifier in only 1.7% ($n$ = 413). These suffix-only reports were distinct: more frequently submitted directly to FDA (86.2% vs. 15.0%), by healthcare professionals (73.3% vs. 59.0%), commonly originated from Veterans Affairs Medical Centers and specialty pharmacies and involved more serious outcomes (47.7% vs. 27.9%), suggesting certain organizational preferences favoring nonproprietary name reporting. The product distribution also differed, with adalimumab-aacf most common in suffix-only reports (18.9%) vs. infliximab-dyyb overall (21.1%). Manufacturer information was present in 42.6% of suffix-only reports. These results suggest FDA's nonproprietary naming convention has achieved limited implementation for biosimilars in AEMS reporting practices, and other information present in AEMS reports may be sufficient for accurately identifying biosimilar products.

**Study Highlights**

**WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?**
☑ The FDA established a nonproprietary naming convention in 2017 requiring certain biological products to have a core name paired with a unique four-letter suffix to facilitate pharmacovigilance, enable accurate product identification, and minimize inadvertent substitution. However, the real-world utility of this naming convention in pharmacovigilance was unclear.

**WHAT QUESTION DID THIS STUDY ADDRESS?**
☑ This study examined the extent to which FDA-designated four-letter biosimilar suffixes are utilized in adverse event reporting within the FDA Adverse Event Monitoring System (AEMS) and evaluated their contribution to accurate product identification compared to other identifiers.

**WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?**
☑ Analysis of 24,711 US biosimilar adverse event reports through August 2025 revealed that FDA-designated suffixes appeared in only 12.7% of reports, whereas proprietary names remained nearly universal at 98.2%. Suffixes functioned as the sole product identifier in fewer than 2% of reports. Manufacturer information was documented in over 80% of reports, and 99% of biosimilar products were identifiable through existing identifiers. Suffix-only reports were predominantly direct FDA submissions (86.2%), were more commonly submitted by healthcare professionals (73.3%), and documented serious outcomes more frequently. Even for biosimilars with marketed unbranded products, proprietary name use remained dominant.

**HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?**
☑ These findings demonstrate that the suffix-based naming convention has achieved limited practical implementation in pharmacovigilance, with existing identifiers serving as primary drivers of product-level attribution. This evidence underscores the importance of evaluating regulatory policies on their practical implementation and real-world impact. These insights may inform future pharmacovigilance approaches that better align with actual reporting practices.

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We evaluated the real-world implementation of biosimilar suffix reporting in AEMS and its contribution to accurate product identification.

Stojanovic D, Wolf L, Ricci MS, Muñoz MA. *Clin Pharmacol Ther*. 2026 Sep 6:10.1002/cpt.70478.

# Methods: AEMS Search Strategy

| | |
|---|---|
| **Date of Search** | September 5, 2025 |
| **Time Period** | Data as of August 31, 2025 |
| **Product Active Ingredients*** | All 72 FDA-approved biosimilars as of August 31, 2025 (e.g., adalimumab-aacf, adalimumab-aaty, adalimumab-adaz) |
| **Country Derived** | United States |

* The presence of suffixes in structured AEMS fields (e.g., product active ingredient, product name) does not necessarily reflect reporter usage. For example, if a reporter provides "Inflectra" as the verbatim suspect product, the report is automatically coded to infliximab-dyyb in the structured product active ingredient field, because "-dyyb" is the suffix for infliximab marketed under the trade name Inflectra.

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# Reported and Coded Product Identifiers

- Verbatim suspect product: Reported product exactly as it appears on the MedWatch or E2B submission
- Product Name: Coded field (proprietary name if provided)
- Product Active Ingredient: Coded field

| Verbatim Suspect Product | Product Name | Product Active Ingredient |
|---|---|---|
| Inflectra | INFLECTRA | INFLIXIMAB-DYYB |
| Inflectra (infliximab-dyyb) | INFLECTRA | INFLIXIMAB-DYYB |
| Inflectra-DYYB | INFLECTRA | INFLIXIMAB-DYYB |
| Infliximab-DYYB | INFLIXIMAB-DYYB | INFLIXIMAB-DYYB |
| CT-P13 | INFLIXIMAB-DYYB | INFLIXIMAB-DYYB |

# Methods: Product Identifiers in AEMS

- We examined the presence of key identifiers in all biosimilar reports:
  - Biosimilar suffixes
  - Proprietary names
  - 351(k) product codes
- All three identifiers assessed in two data fields:
  - Verbatim suspect product field
  - Free-text narrative describing the adverse experience

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# Methods: Categorization of Reports

- Reports grouped based on available identification information:
  - **Proprietary name/product code**: Proprietary name or 351(k) product code present, with or without a suffix
  - **Suffix-reported**: Suffix present, with or without other identifiers
  - **Suffix-only**: Suffix present without a proprietary name or product code
- We manually reviewed additional fields in suffix-only reports for manufacturer information, including manufacturer name, NDCs, and BLA numbers.

Stojanovic D, Wolf L, Ricci MS, Muñoz MA. *Clin Pharmacol Ther*. 2026 Sep 6:10.1002/cpt.70478.

# Results: Product Identifier Use (N = 24,711)

| Product Identifier[a] | Reports no. (%) | Information Location, no. (%) | | Sole Identifier no. (%) |
|---|---|---|---|---|
| | | *Verbatim Product* | *Narrative* | |
| **Proprietary Name**[b] | 24,264 (98.2%) | 24,125 (99.4%) | 22,110 (91.1%) | 21,138 (85.5%) |
| **Suffix** | 3,126 (12.7%) | 1,979 (63.3%) | 2,649 (84.7%) | 413 (1.7%) |
| **351(k) Product Code** | 88 (0.4%) | 76 (86.4%) | 75 (85.2%) | 28 (0.1%) |

[a] More than one identifier could be provided for each report.
[b] Includes 14 reports with misspelt proprietary names.

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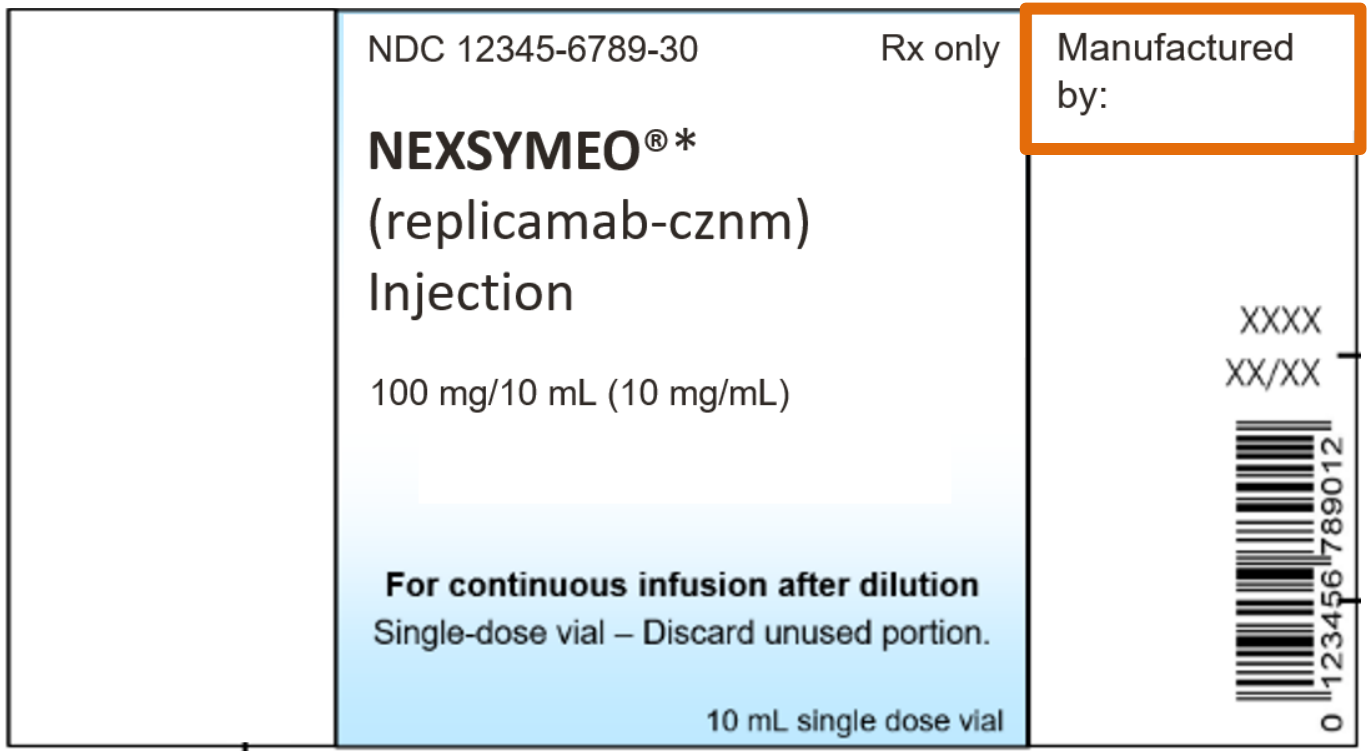
# Results: Suffix-Only Reports (n=413)

- Manufacturer information was available in 176 of 413 suffix-only reports (42.6%)




*FICTIONAL PRODUCT

**Any MFR Information**
176 (42.6%)**

**Product MFR**
173 (41.9%)

**NDC**
80 (19.4%)

**MFR in Verbatim Product**
41 (9.9%)

**Application Number**
64 (15.5%)

**MFR in Narrative**
4 (1%)

** Each report may include biosimilar manufacturer information in multiple data fields.

# Key Takeaways

- Suffixes have achieved limited real-world implementation in adverse event reporting
  - Suffixes appeared in only 12.7% of identifiable biosimilar reports and were the sole identifier in fewer than 2%
  - Proprietary names were the dominant identifier (98%)
  - Most biosimilar reports also included a product manufacturer name (82%)
- Pharmacovigilance may be better served by improving capture of existing product information (e.g., NDCs) than by adding to reporting expectations