



# Post-marketing surveillance of adalimumab-adaz in psoriasis patients: A comparative analysis of adverse events in FDA drug-labeling and FDA Adverse Event Reporting System

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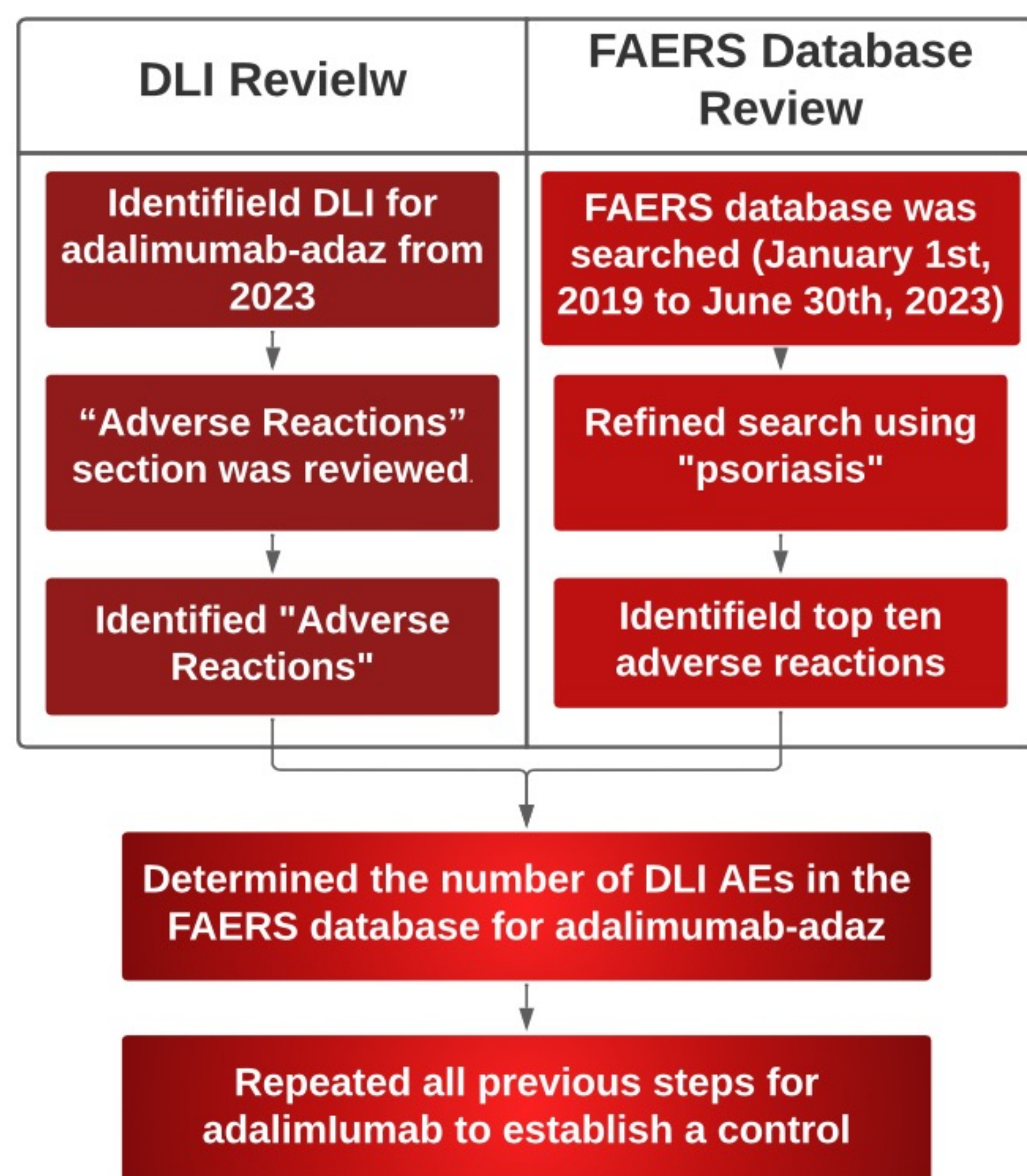
## Introduction

- Biosimilars play a crucial role in dermatologic care by offering cost-effective therapeutic alternatives to biologics, thereby improving patient access and healthcare affordability.<sup>1</sup>
- Adalimumab-adaz, a biosimilar of adalimumab, has only been FDA-approved within the last year.<sup>2,3</sup>
- Continued post-marketing surveillance of outcomes & adverse events (AEs) is highly important.

## Purpose

To compare the FDA Adverse Event Reporting System (FAERS) with drug-labeling information (DLI) for adalimumab-adaz to assess real-world adverse effects among psoriasis patients.

## Methods



## Results

### SUMMARY OF FINDINGS:

- Four AEs were identified in the DLIs (Table I).<sup>2,3</sup>
- For adalimumab, all four AEs in the DLI were also in the top ten AEs in the FAERS database (Table II).<sup>2,4</sup>
- For adalimumab-adaz, only rash and pain were listed in the top ten AEs in FAERS (Table III).<sup>3,4</sup>
- Notably, rash (psoriasis), arthralgias, elevated CRP, and hypertension emerged as the four most common AEs for adalimumab-adaz (Table III).

Table I: DLI Adverse Events

Drug-Labeling Information	
Infections	Injection Site Reactions
Headache	Rash

The most common DLI-reported AEs listed in both adalimumab-adaz & adalimumab were infections, injection site reactions, headache, and rash.<sup>2,3</sup>

Table II: Adalimumab FAERS AE's

ADALIMUMAB	
Adverse Event	Cases
1.) Psoriasis	4,175 (16.3%)
2.) Arthralgia	1,805 (7.0%)
3.) Pain	1,771 (6.9%)
4.) Fatigue	1,287 (5.0%)
5.) Headache	1,099 (4.3%)
6.) Rash	1,079 (4.2%)
7.) Injection Site Pain	1,029 (4.0%)
8.) Covid-19	956 (3.7%)
9.) Condition Aggravated	915 (3.6%)
10.) Pain In Extremity	911 (3.6%)

A review of the FAERS database for adalimumab (n=25,659) showed all four AEs ranking within the top ten.<sup>2,4</sup>

Table III: Adalimumab-adaz FAERS AE's

ADALIMUMAB-ADAZ	
Adverse Event	Cases
1.) Psoriasis	28 (14.3%)
2.) Arthralgia	21 (10.7%)
3.) CRP Increase	17 (8.7%)
4.) Hypertension	13 (6.6%)
5.) Fall	12 (6.1%)
6.) Pruritus	11 (5.6%)
7.) Pain	11 (5.6%)
8.) Glucose Increased	11 (5.6%)
9.) Hemoglobin Decreased	11 (5.6%)
10.) Dyspnea	10 (5.1%)

A review of the FAERS database for adalimumab-adaz (n=196) showed only rash and pain to be listed in the top ten AEs.<sup>3,4</sup>

## Discussion

- In early post-marketing surveillance data, differences in AEs between DLI and FAERS were noted in psoriasis patients treated with adalimumab-adaz.
- Arthralgias, elevated CRP, and hypertension emerged as common AEs in FAERS for adalimumab-adaz that were not in the DLI.
- This underscores the importance of continued post-marketing surveillance to capture the full spectrum of potential adverse reactions in psoriasis patients using biosimilars.



## References

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