

Data set for

“Safety of Biologics for the treatment of Asthma in children and adolescents: a systematic review”

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1 General Information

Dataset title	Safety of Biologics for the treatment of Asthma in children and adolescents: a systematic review
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Keywords	Asthma, Pediatrics, Biologics, Adverse events
Language	English
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2 Description

This document provides tables (S3, S4, S5) of the extracted data, which served as the basis for the systematic review of the range of reported adverse events (AES) of biological treatments approved for pediatric asthma (Xolair®, Fasenra®, Dupixent®, Nucala®, Tezpire®). Each table includes a separate sheet on each examined biologic.

3 Data Acquisition

The primary data was extracted in Tables S3 and S4. Table S3 contains the study title, NCT number (if available), primary purpose, allocation, interventional model, masking, age group, asthma specification, sponsor/ investigator, duration of treatment, study type, treatment groups, number of participants, all-cause-mortality (total number, frequency), SAE (total number, frequency) and information on the reporting of AEs. Table S4 presents specific observations of adverse events (AEs) for each investigated drug, along with the frequency of observations categorised into five groups: very common, common, uncommon, rare, and cannot be estimated. Data are reported as outlined in the publication. If applicable, statistical tests (conducted by the authors of the included studies) between different groups, e.g., drug vs. placebo, were mentioned in the data extraction table S4. Based on the data in Table S4, it was then possible to determine in how many studies a specific AE was described with which frequency (very common, common, uncommon, rare) occurred. The AEs were also analyzed by study duration. If reports included data from registered studies (ClinicalTrials.gov), the published results were compared to the register entry and supplemented if additional information was available. The identified studies listed on ClinicalTrials.gov are presented in Table S5. The results arising from the extracted primary data are included in the main manuscript and the supplementary material.

4 File Format

The data is provided in an Excel format.

5 Archive Structure

S3.xlsx	Information Summary of all included studies after a systematic literature search (one data sheet for each biologic, in total 5 table sheets)
S4.xlsx	Extraction of specific Adverse events mentioned in each publication and/or clinical study and clustering by frequency (one data sheet for each biologic, in total 5 table sheets)
S5.xlsx	The identified studies listed on ClinicalTrials.gov (one data sheet for each biologic, in total five table sheets)

6 References

Wirthgen E, Quickert S, Weitzel J, et al. Safety of biologics for the treatment of asthma in children and adolescents: a systematic review. *Eur Respir Rev* 2025; 0: 240269 [DOI: 10.1183/16000617.0269-2024].