



## Toward Precision Immunology in Severe Asthma: Bridging the Gap Between Biologics and Real-World Evidence

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Despite the undeniable enthusiasm surrounding biologic therapies, a critical question remains: are we truly treating severe asthma, or merely targeting a fragment of its underlying immunology?

Biologic therapies have redefined the management of severe asthma, representing one of the most significant advances in modern respiratory medicine. However, despite their proven efficacy, important limitations persist in their application in real-world clinical practice. Severe asthma, although affecting a minority of patients, disproportionately contributes to morbidity, systemic corticosteroid use, and healthcare costs. Biologics targeting type 2 (T2) inflammatory pathways (anti-IgE, anti-IL-5/IL-5R, anti-IL-4/13) have demonstrated significant reductions in exacerbations and improvements in disease control [1]. Nevertheless, recent evidence highlights a heterogeneous response, with a non-negligible proportion of patients classified as non-responders or partial responders [2].

Real-world data from the Italian Severe Asthma Network Italy (SANI) registry provide crucial insights into these dynamics. Recent studies report that after 12 months of biologic treatment, only approximately 45% of patients achieve complete clinical remission,

while a substantial proportion exhibit partial or no response [3]. Furthermore, commonly used biomarkers (blood eosinophils, serum IgE, FeNO) are not consistently predictive of treatment response, underscoring the limitations of current stratification strategies [3]. The SANI registry has also highlighted the significant impact of comorbidities and chronic oral corticosteroid use on both clinical burden and healthcare resource utilization [4].

These findings suggest that the current therapeutic paradigm, although effective, remains incomplete. There is a pressing need to move toward a precision medicine approach based on deeper immunological endotyping and the identification of more reliable predictive biomarkers. In parallel, dynamic strategies, including biologic switching and sequential approaches, should be systematically investigated.

In conclusion, biologic therapies represent a paradigm shift in the treatment of severe asthma; however, bridging the gap between clinical trial efficacy and real-world effectiveness remains the key challenge. Without a true integration of precision immunology into clinical practice, we risk having highly effective therapies that are not yet fully effective for the right patient.

## Bibliography

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