

# Recognizing Unmet Needs in Anaphylaxis Care: Insights from Clinician and Caregiver Surveys

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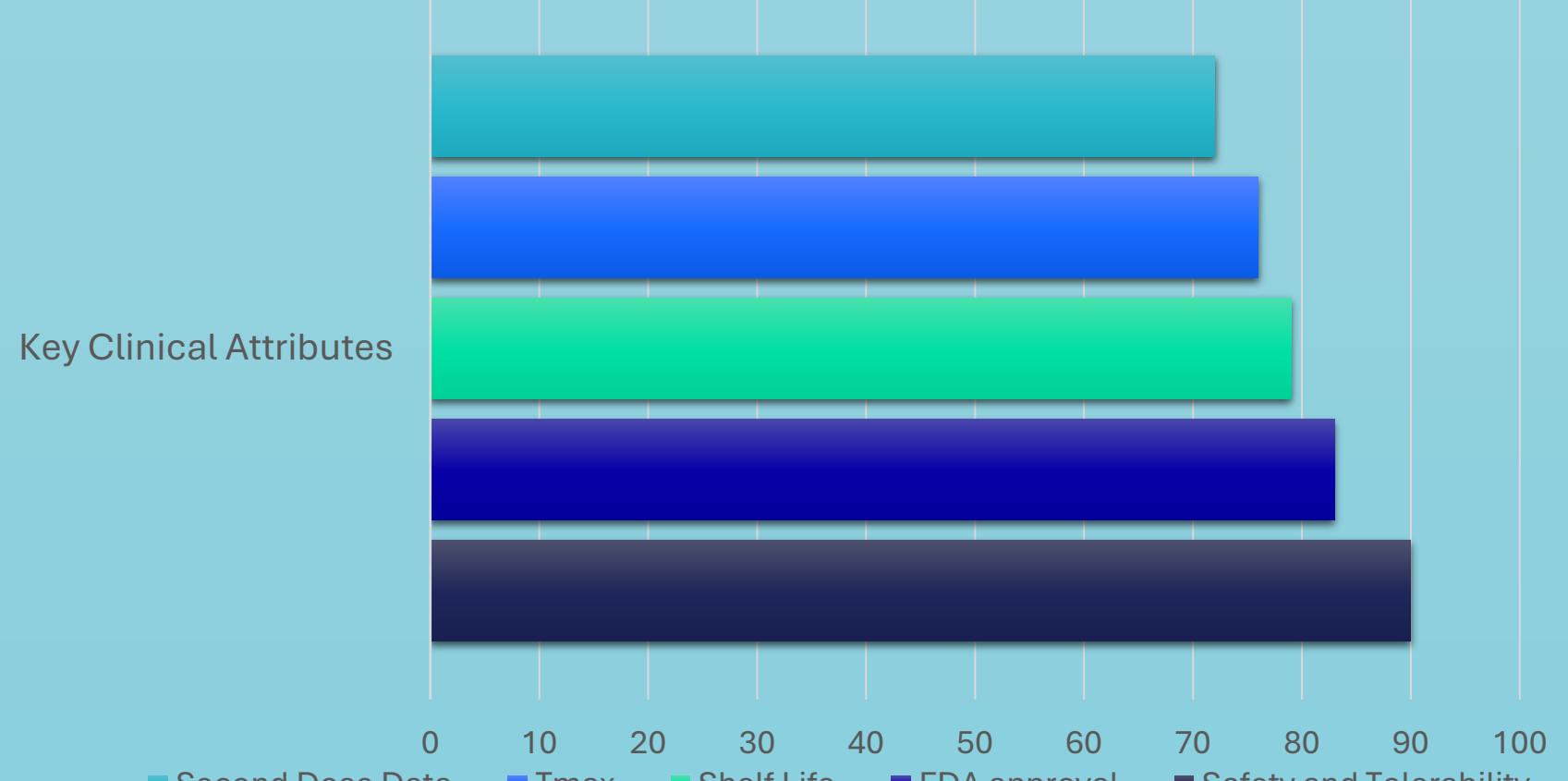
After nearly four decades of epinephrine availability in the US, clinicians and caregivers indicate continued unmet needs with room for improvement in terms of emergent epinephrine delivery. Additional clinician education is needed for evaluation of emerging epinephrine products. Feedback from providers and caregivers indicates that novel delivery platforms hold promise for improving both portability and time to epinephrine administration.

## INTRODUCTION

- Since 1987 epinephrine autoinjectors have served as the primary intervention for acute, life-threatening allergic reactions, including anaphylaxis.<sup>1,2</sup>
- Decades of clinical use and broad patient adoption have shaped perceptions and behaviors regarding device portability, safety and usability.
- Rapid administration is critical, yet barriers to injection (i.e., poor carriage, needle phobia) put patients at risk.<sup>1,2</sup>
- To inform product development of epinephrine sublingual film and uncover insights into understanding of approved and emerging epinephrine products, we conducted comprehensive surveys of providers and patients/caregivers with key findings reported here.

## OBJECTIVE

- To evaluate Healthcare Providers (HCPs) perceptions regarding the clinical performance of existing epinephrine auto-injectors (EAIs), understand key pharmacokinetic and pharmacodynamic data when evaluating new products, and interest in non-injectable alternatives.
- To identify patient and caregiver barriers to device carriage and use, current behavioral attributes and preferences for non-injectable alternatives

KEY TAKEAWAYS	HCP Awareness Trial and Usage (ATU) Survey:	HCP Quantitative Survey:	Patient/Caregiver Quantitative Survey:												
RESULTS	<p>A survey of HCPs found that when evaluating a new form of epinephrine, safety, FDA approval, shelf-life and time to maximum concentration (<math>T_{max}</math>) were important data to consider.</p>	<p>The results of this survey found that HCPs are concerned that their patients do not have their epinephrine when away from home and believe they often carry antihistamines as first line treatment. Most HCPs would be interested in a non-injectable epinephrine alternative.</p>	<p>Patients and caregivers underscored that device size and needle dependence impede carry rates and timely use of epinephrine. Respondents were also concerned about their EAI in various temperature ranges (hot and cold) and expressed preference for a non-needle dosing alternative.</p>												
METHODS	<p>Graph 1: Important Clinical Data for new drug evaluation</p>  <table border="1"><caption>Estimated data for Graph 1: Important Clinical Data for new drug evaluation</caption><thead><tr><th>Attribute</th><th>Importance (approx. %)</th></tr></thead><tbody><tr><td>Second Dose Data</td><td>75</td></tr><tr><td>Tmax</td><td>78</td></tr><tr><td>Shelf Life</td><td>80</td></tr><tr><td>FDA approval</td><td>85</td></tr><tr><td>Safety and Tolerability</td><td>90</td></tr></tbody></table>	Attribute	Importance (approx. %)	Second Dose Data	75	Tmax	78	Shelf Life	80	FDA approval	85	Safety and Tolerability	90	<ul style="list-style-type: none"><li>~90% of respondents were at least somewhat concerned that patients don't consistently have their EAI with them when away from home.</li><li>~80% of respondents believe at-risk patients too often carry OTC products instead of epi when away from home.</li><li>&gt;95% of HCPs expressed interest in a non-EAI administration alternative.</li><li>Nearly 100% of respondents indicated that head-to-head data with EAIs and <math>T_{max}</math> were highly important data when deciding to prescribe a new product.</li></ul>	<ul style="list-style-type: none"><li>&lt;50% were highly satisfied with the size and carry convenience of their EAI.</li><li>Post symptom onset, respondents estimated a delay time of 5 minutes before administering an EAI.</li><li>Close to 90% were concerned about EAI hot temperature exposures.</li><li>Close to 80% were concerned about EAI exposure to cold temperatures.</li><li>~80% would prefer a non-injectable dosing option.</li></ul>
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REFERENCES	<p>N=125 HCPs, including allergists, NPs and PAs, participated in Awareness, Trial and Usage (ATU) market research.</p>	<p>N=300 Physicians, including allergists, pediatricians and primary care physicians participated in a quantitative research survey.</p>	<p>N=200 patients and caregivers participated in an online quantitative survey (100 adult patients at risk of anaphylaxis, 75 caregivers of children at risk of anaphylaxis and 25 teenagers at risk of anaphylaxis).</p>												

### REFERENCES

1. Data on file.

### ACKNOWLEDGMENTS

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### DISCLOSURES

Drs. Kraus and Confer are employees of Aquestive Therapeutic, Inc.

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