

Development of a Novel Questionnaire to Capture Caregiver-Reported Outcomes in a Phase 2 Trial of Epicutaneous Immunotherapy for Peanut Allergy

Douglas P. Mack,^{1,2} Philippe Bégin,^{3,4} Gideon Lack,⁵ Michael O'Sullivan,^{6,7} Kirsten P. Perrett,^{8,9,10} Julia Upton,^{11,12} Dianne E. Campbell,¹³ Todd Green,¹³ Audrey Dunn Galvin¹⁴

¹Department of Pediatrics, McMaster University, Hamilton, Ontario, Canada; ²Halton Pediatric Allergy, Burlington, Ontario, Canada; ³Department of Pediatrics, Division of Allergy and Clinical Immunology, Centre Hospitalier Universitaire Sainte-Justine, Montreal, Quebec, Canada;

⁴Department of Medicine, Section of Allergy and Clinical Immunology, Centre Hospitalier de l'Université de Montréal, Montreal, Quebec, Canada; ⁵Department of Women and Children's Health, School of Life Course and Population Sciences, King's College London, London, UK;

⁶Immunology Department, Perth Children's Hospital, Nedlands, Western Australia, Australia; ⁷Paediatrics Division, Medical School, University of Western Australia, Perth, Western Australia, Australia; ⁸National Allergy Centre of Excellence, Population Allergy Group, Murdoch Children's Research Institute, Melbourne, Victoria, Australia;

⁹Department of Paediatrics, University of Melbourne, Melbourne, Victoria, Australia; ¹⁰Department of Allergy and Immunology, Royal Children's Hospital, Parkville, Victoria, Australia; ¹¹Division of Immunology and Allergy, Food Allergy and Anaphylaxis Program, The Hospital for Sick Children, Toronto, Ontario, Canada;

¹²Department of Pediatrics, University of Toronto, Toronto, Ontario, Canada; ¹³DBV Technologies SA, Châtillon, France; ¹⁴Department of Applied Psychology, University College Cork, Cork, Ireland

RATIONALE

- Although validated instruments for assessing psychosocial and quality-of-life (QoL) outcomes exist, these instruments were not designed to evaluate research outcomes in pediatric food allergy clinical trials, highlighting the need for patient-reported outcome (PRO) tools specifically designed for use in evaluating potential food allergy treatments¹⁻³
- Epicutaneous immunotherapy (EPIT) is an innovative treatment approach for peanut allergy that uses the skin's immune properties to promote desensitization over time, while limiting systemic allergen exposure⁴
- The VIASKIN® Peanut Patch is a novel approach to treating peanut allergy that utilizes EPIT by applying a patch containing 250 µg of peanut protein (1/1000th of 1 peanut kernel) to intact skin to induce allergen desensitization⁵⁻⁹
- The ongoing Phase 2 trial, THRIVE (ISRCTN63504081), will assess the efficacy and safety of EPIT with VIASKIN® Peanut Patch to achieve ad libitum (ad lib) peanut consumption in infants with peanut allergy aged 6-12 months at treatment initiation; efficacy is being evaluated based on peanut consumption (following 3 years of treatment) and caregiver-reported outcomes¹⁰

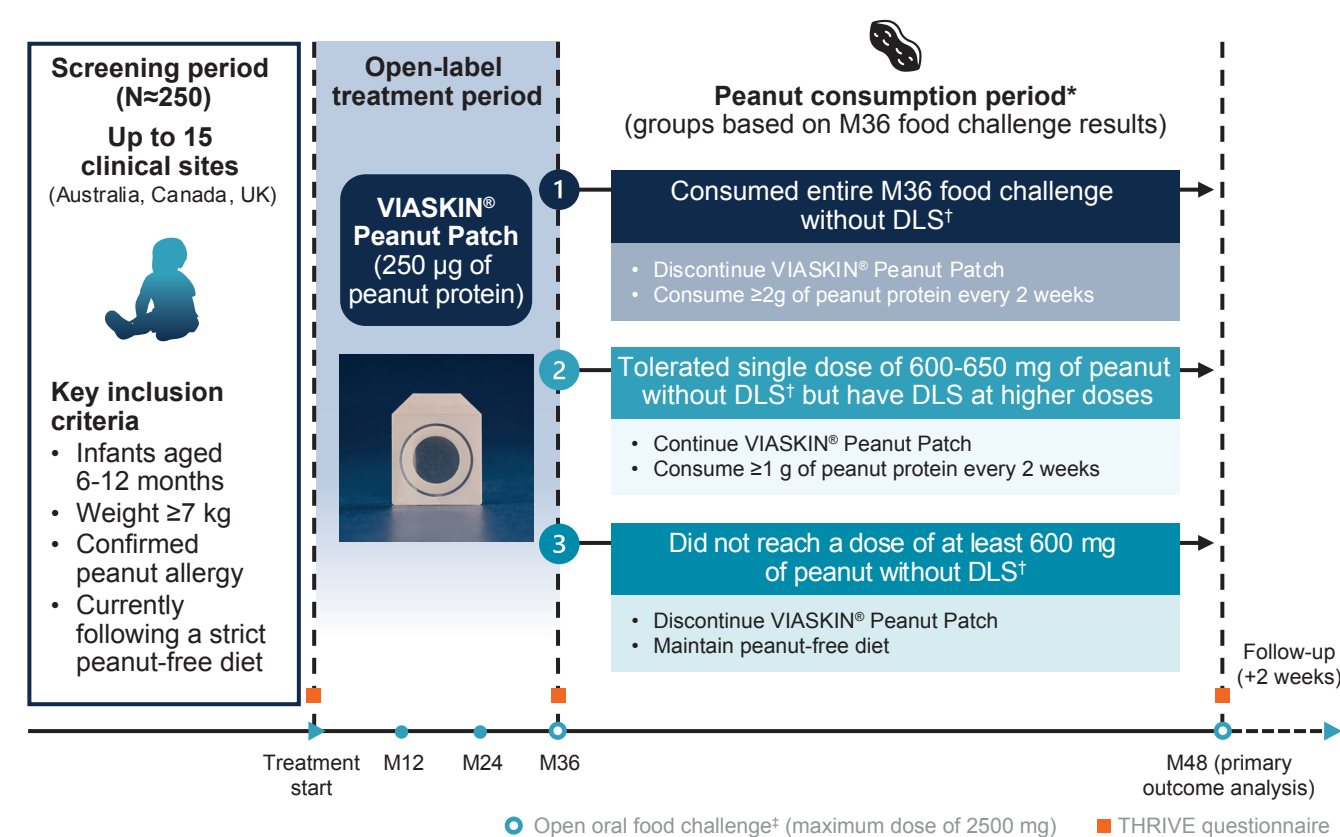
OBJECTIVE

- To describe the novel design of the THRIVE Phase 2 trial, which will assess the efficacy, safety, and parent and caregiver-reported outcomes of VIASKIN® Peanut Patch treatment in achieving ad lib peanut consumption in infants with peanut allergy

METHODS

- THRIVE is an ongoing, 48-month, single-arm, open-label, Phase 2 trial that began enrollment in May 2026 and is estimated to complete in 2031. The study design is outlined in **Figure 1**
 - Participants from clinical trial sites in Australia, Canada, and the UK will receive VIASKIN® Peanut Patch daily for 36 months, followed by an open oral food challenge (FC) at month 36 to determine ad lib peanut consumption regimens during months 37-48
 - Peanut allergy was assessed via clinical history and confirmation by an investigator (**Figure 2**)

Figure 1. THRIVE Study Design



*Caregivers will determine the peanut protein consumption regimen and type of peanut-containing food based on family lifestyle/convenience and discussions with the investigator; a list of potential foods and approximate peanut protein amounts will be provided to caregivers. Group 3 will not take part in the peanut consumption period but will continue to be followed. †Consortium for Food Allergy Research DLS as defined in protocol. ‡At month 48, a group 2 subset undergoes the open oral food challenge, as defined in the protocol. DLS, dose-limiting symptoms; M, month.

REFERENCES:

1. Dantzer JA, et al. *J Allergy Clin Immunol Pract.* 2024;13(4):763-772.
2. Ezhuthachan ID, et al. *Ann Allergy Asthma Immunol.* 2026;136:630-638.
3. Nowak-Węgrzyn A, et al. *Ann Allergy Asthma Immunol.* 2026;136(6):619-620.
4. Herve PL, et al. *Front Allergy.* 2023;4:1290003.
5. Ravindran M, et al. *Allergy.* 2025;80(1):63-76.
6. Fleischer DM, et al. *JAMA.* 2019;321(10):946-955.

7. Fleischer DM, et al. *J Allergy Clin Immunol.* 2020;146(4):863-874.
8. Greenhawt M, et al. *J Allergy Clin Immunol Pract.* 2025; 13(5):1176-1187.e7.
9. Greenhawt M, et al. *N Engl J Med.* 2023;388(19):1755-1766.
10. ISRCTN Registry. ISRCTN63504081. Updated July 3, 2026. Accessed October 10, 2026. <https://www.isrctn.com/ISRCTN63504081>

FUNDING SOURCE/ACKNOWLEDGMENTS: The THRIVE trial is sponsored by DBV Technologies. Medical writing and editorial support for the preparation of this poster were provided by Roxanna Munir, PhD, of LiNK Health Group and funded by DBV Technologies.

VIASKIN® Peanut Patch is an investigational agent and has not yet been approved by the US Food and Drug Administration or any other regulatory authority. © 2026, DBV Technologies. All rights reserved.

Presented at the 81st Annual Canadian Society of Allergy and Clinical Immunology (CSACI) Scientific Meeting; October 15-18, 2026; Toronto, ON, Canada

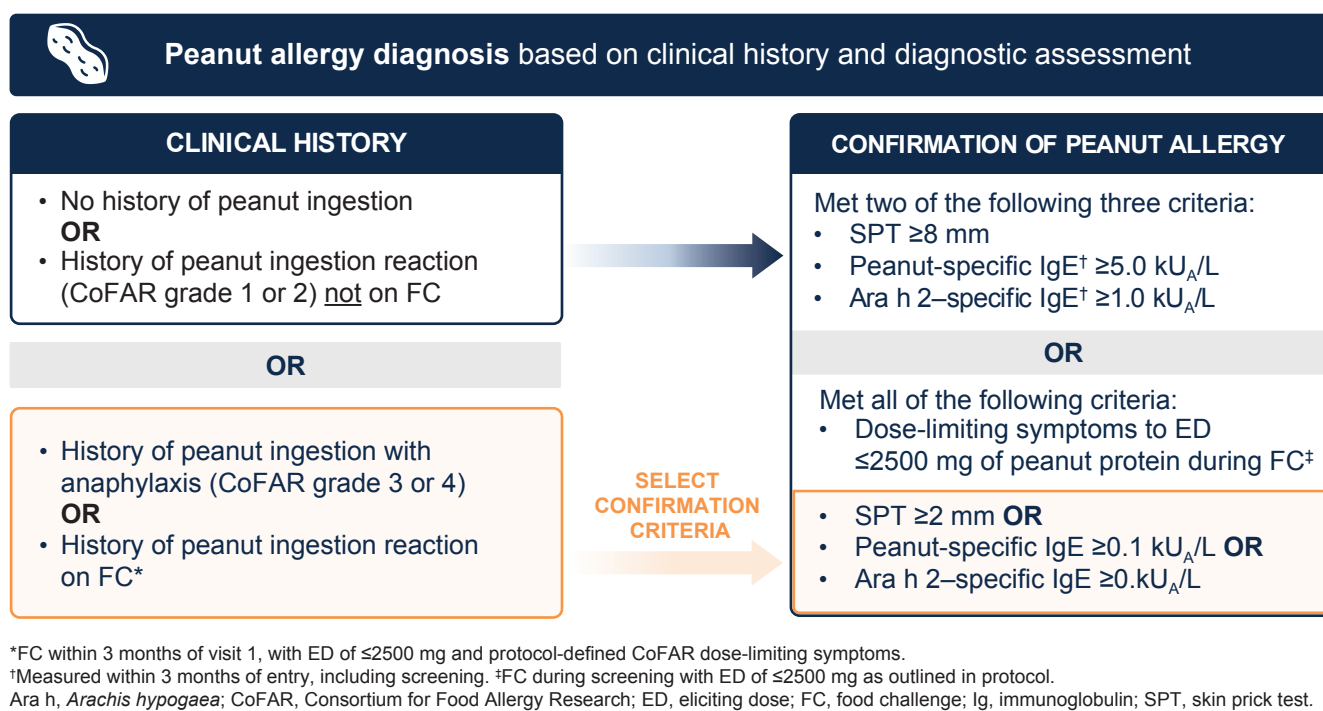
KEY POINTS

- THRIVE is an ongoing Phase 2 trial investigating the efficacy and safety of daily EPIT via VIASKIN® Peanut Patch to achieve ad lib consumption of peanuts in infants with peanut allergy
- Results are expected to inform future immunotherapy protocols and, using a patient-centered approach, improve understanding of whether EPIT with VIASKIN® Peanut Patch can support meaningful dietary incorporation of peanut alongside clinically relevant patient-and caregiver-centered outcomes in young children with peanut allergy
- By capturing caregivers' assessments of treatment experience, THRIVE seeks to evaluate treatment goals beyond the clinical trial setting for oral FCs. This is one of the first food allergy immunotherapy trials to prospectively incorporate a study-specific caregiver-reported measure, and the first time that this form of tool has been developed specifically for EPIT

METHODS

- The primary endpoint is the proportion of participants achieving ad lib peanut consumption at month 48, defined using oral FC tolerated dosing, consumption patterns, and caregiver-reported treatment satisfaction (**Figure 3**)
- A novel THRIVE-specific caregiver-reported questionnaire was developed through an iterative process involving multidisciplinary food allergy experts, and was reviewed by two independent patient advocacy groups to ensure clinical relevance and caregiver acceptability
- The questionnaire will be provided before treatment initiation and at months 36 and 48 to evaluate caregiver expectations and treatment experience with VIASKIN® Peanut Patch over time

Figure 2. THRIVE Peanut Allergy Diagnosis

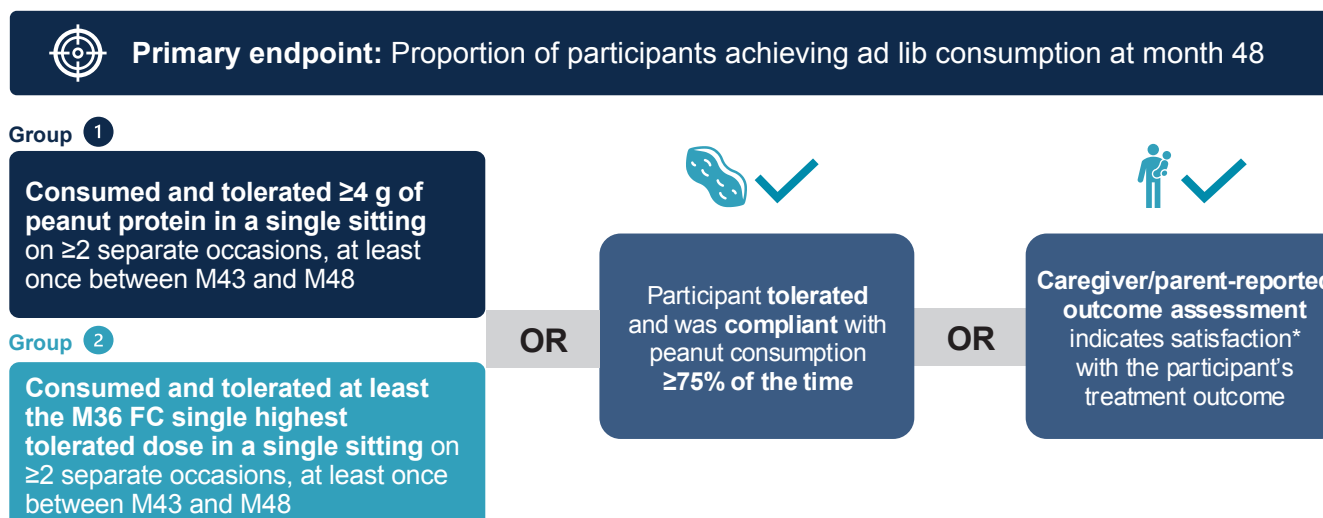


*FC within 3 months of visit 1, with ED of ≤2500 mg and protocol-defined CoFAR dose-limiting symptoms.

†Measured within 3 months of entry, including screening. ‡FC during screening with ED of ≤2500 mg as outlined in protocol.

Ara h, *Arachis hypogaea*; CoFAR, Consortium for Food Allergy Research; ED, eliciting dose; FC, food challenge; Ig, immunoglobulin; SPT, skin prick test.

Figure 3. THRIVE Primary Endpoint



*Treatment satisfaction, independent of criteria 1 or 2, was rated on a VAS from strongly disagree to strongly agree, in response to:

Overall, I am satisfied with the treatment experience taking into consideration the following (1) amount of peanut consumed during the study, including food challenge(s), (2) ease of use of the patch, (3) side effects associated with the patch; (4) impact on our family's life.

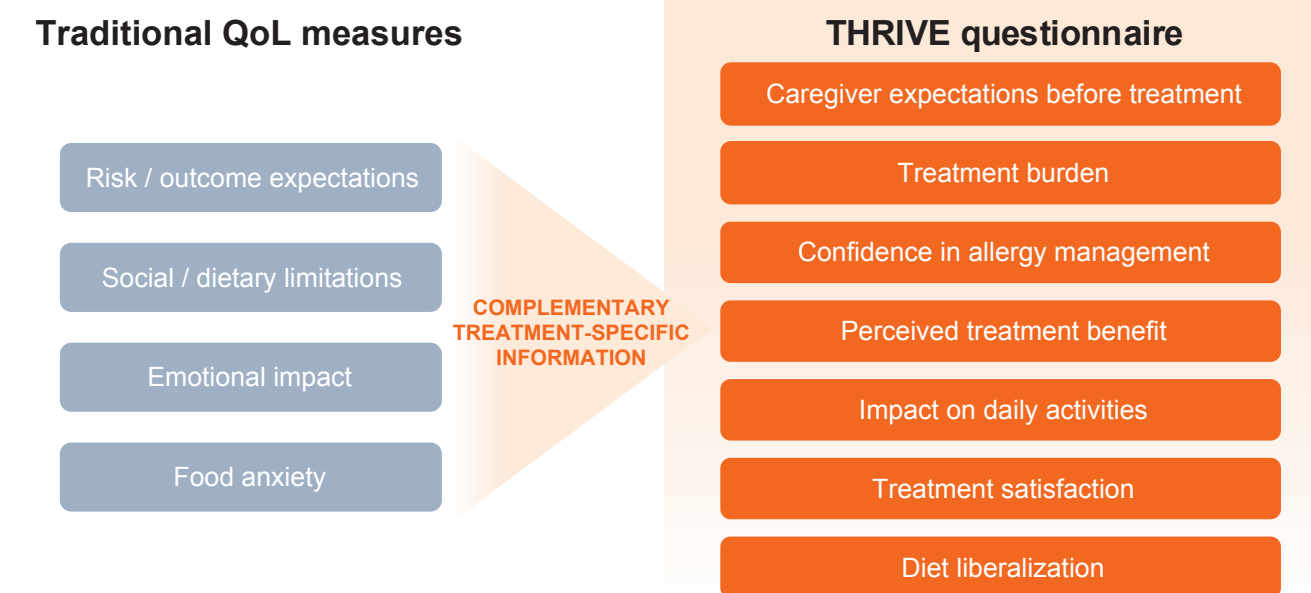
ad lib, ad libitum; FC, food challenge; M, month; VAS, visual analog scale.

PLANNED CAREGIVER-REPORTED ASSESSMENT

The THRIVE Caregiver-Reported Outcome Questionnaire

- The THRIVE caregiver-reported outcome questionnaire captures domains extending beyond traditional QoL measures, including caregiver expectations before treatment, treatment burden, confidence in allergy management, perceived treatment benefit, impact on daily activities, and treatment satisfaction (**Figure 4**)
 - Sample statements are shown in **Figure 5A**
 - Each statement is given a response using a visual analog scale, rating from "strongly disagree" to "strongly agree" (**Figure 5B**)
- Caregiver-reported treatment satisfaction has been incorporated as a clinically meaningful component of the primary endpoint, recognizing that successful food allergy treatment should be evaluated not only by oral FC outcomes but also by meaningful improvements in the everyday experiences of patients and families

Figure 4. THRIVE Caregiver-Reported Outcome Questionnaire Domains

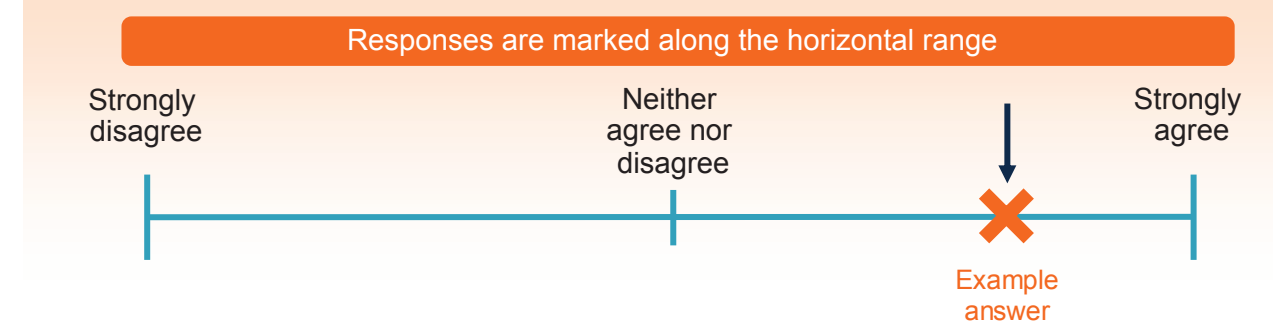


QoL, quality of life.

Figure 5. THRIVE Caregiver-Reported Outcome Questionnaire Sample Statements and VAS

- A.
- Disruption to my child's routine and day-to-day life was minimal
 - My child's ability to be included in social activities has improved
 - The risk of my child experiencing any allergic reaction to a food containing peanut has decreased
 - There are fewer restrictions on the type and variety of foods my child may eat
 - My child's quality of life has improved

B. Assessed using VAS



VAS, visual analog scale.