The majority of adverse events reported in phase 2 and 3 clinical trials were allergic and mild/moderate. The prevalence of food allergy among children in the United States was estimated to be 7.6% in 2016. Inclusion criteria varied between the studies, with more stringent peanut sensitization and allergy history required in RAMSES compared with PALISADE. The difference observed in systemic allergic reaction risk rates between European and North American children may reflect regional differences in the definition of anaphylaxis, as it may also be due to differences in practice standards for epinephrine use between European and North America, with higher rates reported in North America.

Several factors were identified that may increase the risk of a systemic allergic reaction while on PT treatment, including a history of peanut-related anaphylactic reaction, older age (≥12.5–17.0 years), psIgE level ≥70 IU/mL, residing in a European vs North American region.

The observed differences in systemic allergic reaction risk rates between European and North American children may reflect regional differences in the definition of anaphylaxis, as it may also be due to differences in practice standards for epinephrine use between European and North America, with higher rates reported in North America. None of the identified risk factors predict preclinical or potential treatment outcomes; however, awareness of these potential risk factors can contribute to shared decision-making discussions when considering PT treatment.