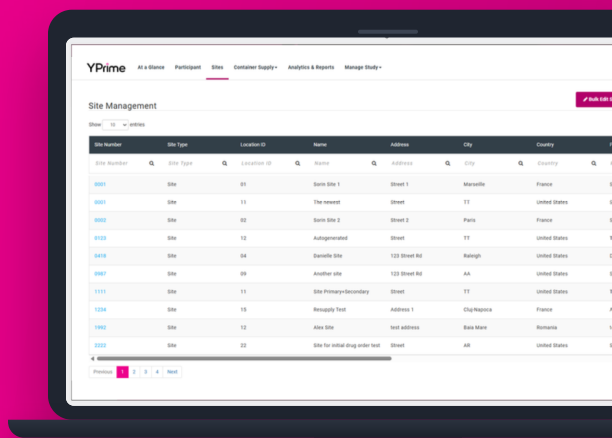


When Subjects Stop Treatment, but Randomization Must Continue: YPrime IRT Engineered a Multi-Phase Randomization with Unbiased Food Challenge Sequencing

THERAPEUTIC AREA: FOOD ALLERGY / IMMUNOTHERAPY



THE CHALLENGE

A combination biologic and oral immunotherapy trial for peanut allergy required more than a single randomization event. In an initial double-blind treatment phase, more than 150 subjects were randomized, stratified by screening peanut allergy levels and body weight, with minimum enrollment requirements built in for each weight category.

At a pre-defined milestone, subjects were re-randomized into new treatment arms based on whether they reached a maintenance threshold. Subjects who missed that threshold, or who discontinued early, still went through a randomization call to generate a hypothetical assignment, preserving the blind and supporting intent-to-treat analysis. Subjects on placebo followed the same rule in reverse.

A nuanced factor for the IRT to support, subjects were re-randomized into sequenced food challenges requiring an independent re-randomization process.

Three randomizations while maintaining the blind.

A complex trial carrying three independent randomization layers, each with its own logic and its own risk to the blind.

01

Initial treatment assignment.

Double-blind randomization of more than 150 subjects, stratified by screening peanut allergy levels and body weight, with minimum enrollment requirements per weight category.

02

Conditional re-randomization at the maintenance milestone.

New treatment arms assigned on whether a subject reached the maintenance threshold, with hypothetical assignments generated for those who missed it or discontinued early.

03

Independent challenge-day sequencing.

A separate randomization into sequencing groups at every scheduled food challenge visit, run independently of both treatment assignments.

THE YPRIME SOLUTION

YPrime designed and validated an integrated randomization system supporting three independent layers within a single blinded trial: the initial double-blind treatment assignment, a conditional re-randomization at the maintenance milestone, and randomized challenge-day sequencing at every food challenge visit.

The maintenance-phase logic did more than determine the real treatment assignment. It also generated a hypothetical assignment for subjects who discontinued or did not meet the dosing milestone, preserving the blind and ensuring intent-to-treat analysis could proceed without revealing a subject's actual study status. For food challenges, the system independently randomized participants into different sequencing groups.

"A trial like this doesn't have one randomization. It has three, and the blind has to hold across every one of them, even for subjects who never make it to the next phase."

CARLY NEWHARDT

Executive Director, IRT Delivery, YPrime

YPRIME DELIVERED



A validated multi-phase randomization design spanning initial treatment assignment, conditional maintenance-phase re-randomization, and independent food challenge sequencing



Hypothetical treatment assignment logic that preserved blinding and supported intent-to-treat analysis for subjects who discontinued or did not meet protocol-defined milestones



Stratified randomization based on screening allergen-specific antibody levels and body weight, with built-in minimum enrollment safeguards



Independently randomized challenge-day sequencing across multiple study visits

RESULTS

Maintained blinding across independent randomization layers throughout a multi-phase treatment and maintenance design

Delivered randomized, unbiased food challenge sequencing across every scheduled challenge visit

Supported study launch on time, across multiple countries and sites

From FPI to last-patient-last-visit, YPrime gives you the flexibility, speed, and quality to keep your trials moving forward.

Contact us at
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YPrime
Solve with Certainty