Adaptive Designs in nQuery

Effective and Efficient Drug Development

The Challenge: Increased Cost, Risk, and Competition in Drug Development Processes

Dr. Luis Rojas, the Executive Director Head of Biostatistics at Target Health, is a subject matter expert in study design and sample size calculations with more than 30 years of industry experience. He has worked in the leading CROs in the industry and has assisted pharmaceutical companies with the drug development process with clinical trials, programs, and portfolio designs. His experience extends from preclinical, phases I through IV, biosimilar, and bioequivalent using fixed, adaptive designs, stand-alone, and master protocols in multiple therapeutic areas.

Today this work presents new challenges. Drug pipelines are larger than ever before, while the cost of bringing new drugs to market has nearly doubled in the past decade. This trend has compressed drug development ROIs and increased competition.

KEY CHALLENGES FOR CLINICAL TRIAL DESIGN

- Increasing trial complexity
- Changing regulations
- Spiraling costs
- Patient access

"nQuery is the complete trial design platform to make clinical trials faster, less costly, and more successful."

DR LUIS ROJAS, EXECUTIVE DIRECTOR HEAD OF BIOSTATISTICS AT TARGET HEALTH

"nQuery is a one-stop. It is 100% reliable," said Dr Rojas. "If the user knows the study design that needs to be implemented, then sample size calculation is a question of just minutes. Trying to programmatically do the same calculations in SAS or R usually takes more than 20 times longer. nQuery's documentation is very helpful and provides very clear guidance to understand and implement the calculations that you need to perform. Side tables in most sample size modules make the process even easier."

The Solution: nQuery is a complete solution for Adaptive Trial Design

With increasing costs, competition, and risk, adaptive clinical trials have made rapid headway as a method to alleviate these challenges. Adaptive trials enable continual modification to the trial design based on interim data. This means that with adaptive trials, you have the opportunity to make changes to your trial, while it is still ongoing.

Within nQuery, the world's most trusted clinical trial design platform, there is a dedicated module for adaptive clinical trials that provides biostatisticians with a range of tools across various adaptive disciplines for sample size calculation.

nQUERY: THE WORLD'S MOST TRUSTED CLINICAL TRIAL DESIGN PLATFORM

- Achieve regulatory approval
- Reduce costs & improve rates of success
- Increase flexibility for better and earlier decision-making
- Design ethical and efficient clinical trials by reducing the risk to patients

THE ADVANTAGES INCLUDE:

The ability to make earlier decisions

Optimize financial resources and reduce costs

Better statistical efficiency, which provides higher potential success

Reduce the risk to patients

That's why Dr. Rojas is a proponent of nQuery to serve as a reliable digital tool for sample size calculations in adaptive and fixed trials. Leveraging nQuery, Dr. Rojas has developed hundreds of clinical trials and programs.

nQuery

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