



Advancing patient care for Japan's most common cancer

Using nQuery to optimize clinical trials

The Challenge: Calculating the appropriate sample size for a first of its kind stage-II colon cancer trial

As Chairman of the Department of Biostatistics, Professor Satoshi Teramukai leads a variety of investigator-initiated clinical trials at the Kyoto Prefectural University.

With over 35 years experience, hundreds of published papers and thousands of citations, Professor Satoshi Teramukai's innovative work ranges from a Bayesian predictive sample size design for a single-arm exploratory clinical trial, to designing and implementing SACURA, the only randomized-controlled trial focused on adjuvant therapy for stage II colon cancer.

Colorectal cancer has been the most common cancer in Japan since 2015. While adjuvant chemotherapy is the internationally accepted standard of care with established efficacy for stage III colon cancer, its usefulness for stage II disease remains controversial.

To ensure patients are receiving the best treatment following stage II colon cancer surgery, Professor Satoshi Teramukai and his team set out to verify the benefit of adjuvant chemotherapy for stage II colon cancer compared with observation without any adjuvant treatment and to investigate which subgroups benefit from adjuvant chemotherapy.

The challenge they faced was a large sample size would be necessary to confirm any benefit of adjuvant chemotherapy over surgery alone because the recurrence rate is generally low.

KEY CHALLENGES FOR CLINICAL TRIAL DESIGN

- Increasing trial complexity
- Changing regulations
- Software accuracy
- Time efficiency

"nQuery is one of the most reliable tools for sample size in clinical trial design. It is accurate, easy to use and saves us time."

PROFESSOR SATOSHI TERAMUKAI, CHAIRMAN OF THE DEPARTMENT OF BIostatISTICS AT KYOTO PREFECTURAL UNIVERSITY OF MEDICINE & GRADUATE SCHOOL OF MEDICAL SCIENCE



"I have used nQuery for around 20 years. Reliability is so important in statistical software when implementing complex calculations."

"nQuery is one of the most reliable tools for sample size calculation in clinical trial design. It is easy to use and very useful for calculating the critical values for group sequential designs such as alpha spending function."

The Solution: nQuery is the complete solution for optimizing clinical trial design

At the study planning and protocol development phase, Professor Satoshi Teramukai and his team objectively assessed all ethical and scientific appropriateness of the study.

Should the sample size be too small it may produce inconclusive results, whereas if the sample size was too large it would waste scarce resources and could expose more participants than necessary to any related risk.

nQuery was used to calculate the appropriate target sample size of 2000 patients, determined with one-sided alpha of 0.05, power of 0.9 and assumed hazard ratio (HR) 0.729.

Professor Satoshi Teramuka knew that he could trust nQuery for optimizing his trial design with the appropriate sample size. Using nQuery for reliable and accurate results, he could further save time on study protocols for both this and future SAPs by also using the various nQuery outputs such as the sample size statement.

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

Leveraging nQuery, as a reliable digital tool for clinical trial design and sample size calculations in adaptive, Bayesian and fixed-term trials, Professor Satoshi Teramukai has developed hundreds of clinical trials and programs that complete the essential role of evaluating and developing new treatments for all diseases.



2365 Northside Dr., Suite 560
San Diego, CA 92108