

With Medidata Patient Cloud[®], Danone Captures the Best Quality Patient-reported Outcome Data Possible for Key Gastrointestinal Study

Gastrointestinal functional disorders and especially constipation are common morbidity factors in otherwise healthy persons. There has been growing popularity in using probiotics for the management of constipation, and Danone is a global leader in this research.

Bringing Health Through Food With Research and Innovation

About Danone Nutricia Research

Danone is an international company present on all five continents. The group holds top positions in healthy categories: Fresh Dairy Products, Early Life Nutrition, Waters, and Medical Nutrition.

Research and development is at the very heart of Danone's mission: "bringing health through food to as many people as possible".

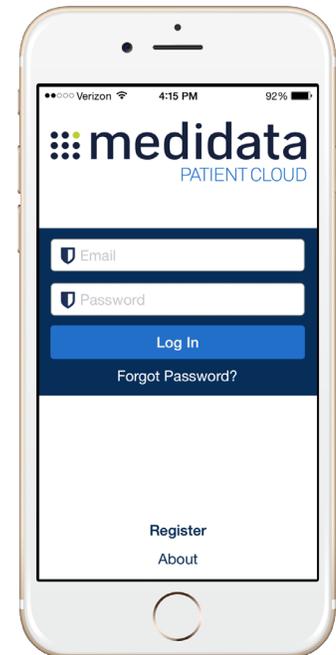
Danone Nutricia Research combines the research and innovation of Danone, through 1500 researchers and developers all around the world gathered in six research centers and 55 R&D branches. Danone Nutricia Research delivers safe, healthy and enjoyable food products firmly rooted in scientific and technological knowledge and understanding.

Danone Nutricia Research has developed scientific expertise in selecting and characterizing lactic acid bacteria as well as in understanding the ways these bacteria, known as probiotics, can benefit human health including anti-infective defenses, nutritional and metabolic balance and digestive comfort.

Danone believes so strongly that some of its products have health benefits that it would like to market them with health claims—and for this, they need to follow clinical development guidelines.

“We want the best quality data possible by reducing missing data and error rates with an ePRO that could fit seamlessly into our existing end-to-end data flow, so we choose Patient Cloud”

Gerald Neveu, Data Manager,
Danone Nutricia Research



Study Design

Danone Nutricia Research decided to evaluate the effect of three fermented milk products against a control arm to deepen associated health claims. They initiated this study as a key part of a larger program in support of their scientific strategy.

This study, designed to evaluate the effects of fermented milk products on bowel functions, is a randomized, double-blind, controlled adaptive study.

Some of the study objectives were heavily dependent on patient-reported outcomes:

- To assess (via questionnaires) changes on objective and subjective markers of bowel functions over several weeks of consumption.
- To assess study product satisfaction after consumption.

The study called for 150 patients who were selected based on specific questionnaires and randomized to one of four balanced arms.

Patient self-assessments include a validated instrument of assessment of bowel functions marker based on a referential picture and two other primary validated instruments on Symptoms and Quality of Life.

Other questionnaires were used to track the study product intake, assess the compliance of subject habits (e.g., diet, physical activity) with study protocol and follow safety parameters (e.g., adverse event, medication) during the study.

Integrating Medidata Rave® EDC & Medidata Patient Cloud® ePRO™

Because Danone Nutricia Research planned to use the study results to validate a health claim, they realized that data quality was critical: they wanted to ensure the study collected the data cleanly and at the high quality required by health regulators.

This is one of the key reasons that Danone Nutricia Research decided to use the Medidata unified EDC/ePRO solution. They viewed Rave as the most appropriate platform, and it had the extension to collect patient self-assessments via Patient Cloud, making it a natural choice that fit flawlessly with the data strategy envisioned for this study by the Danone Nutricia Research's data management team.

Mobility was another key reason for choosing Patient Cloud ePRO. With many assessments capturing large volumes of subjective data, Danone Nutricia Research wanted subjects to report as accurately as possible at the precise moment prescribed, so the ePRO mobile app was judged the best option possible.

“We wanted the best quality data possible by reducing missing data and error rates

About Patient Cloud® ePRO™

Patient Cloud ePRO is the mobile app that takes ePRO to new places. Patients report information directly from their mobile devices directly into the Medidata Clinical Cloud.

Patient Cloud ePRO:

- Reduces study risk. Capturing better and more current patient data on devices patients already use mitigates a broad range of study risks — including regulatory risk, patient compliance and adverse events.
- Accelerates study timeline. It speeds database lock by eliminating the time-consuming transcription of paper-based PROs.
- Lowers development costs. It eliminates the many costs incurred from paper-based PROs, and informs earlier go/no-go and adaptive trial decisions. And without custom programming or devices, Patient Cloud ePRO offers a more compelling return on investment than traditional ePRO.

with an ePRO that could fit seamlessly into our existing end-to-end data flow, so we choose Patient Cloud,” said Gerald Neveu, Data Manager, Danone Nutricia Research. “Adopting a sophisticated design emphasizing the patient experience and using Patient Cloud’s intuitive interface ensured the highest data consistency.”

The Danone Nutricia Research study build team was led by its senior data manager who has experience with some of the largest and most complex clinical development programs at the world’s largest pharmaceutical companies. Medidata was an obvious choice given the study timelines, objectives and functional requirements.

A key benefit of the Medidata solution is that it easily adapted to Danone Nutricia Research’s existing data management workflow, which included the use of external design tools based on CDISC ODM (XML). A first ODM file, which includes Medidata’s custom attributes, facilitates almost 95 percent of study design in Rave for both eCRF and ePRO forms. Data output from Rave (in ODM format, including the clinical study data and metadata) is passed through an extract, transform and load (ETL) tool to perform the SDTM data mapping. “Medidata’s choice to implement the Patient Cloud ePRO solution in a unified environment with Rave allows the user to extend their study design knowledge and ease the ePRO design, especially for beginners”, said Neveu.

Leveraging Medidata Enablement Services, Danone Nutricia Research was able to set up their first study on their own, thereby reducing start-up costs even further. “The Enablement program provided us with valuable best practices in the setup and use of Patient Cloud that we leveraged immediately,” said Neveu. “Together we worked with Medidata to meet our business objectives while taking full advantage of the product functionality.”

Danone Nutricia Research is now beginning to prepare a second study using, once again, the Medidata EDC/ePRO solution.

Choosing the Right Device & Questionnaire

Danone Nutricia Research decided to provide subjects with Apple iPad Minis as compensation for participation while also serving as a platform for the ePRO app. The Ethics Committees allowed Danone Nutricia Research to offer either full monetary compensation or an iPad with a partial compensation, but Danone Nutricia Research adopted the second option. Patients would be able to keep the iPad only if they remained on the study for the entire duration so it serves as motivation for both recruitment and retention. Patient Cloud ePRO allows a BYOD (Bring Your Own Device) strategy providing multiple ways to complete each questionnaire.

Danone Nutricia Research included these devices in the study budget and viewed it as a cost-effective method. They provided patients with an electronic support document in PDF format as well as a paper booklet which gave, among other things, examples of questionnaires and login instructions.

Mapi Research Trust, copyright owner of some of the questionnaires used in this

study, conducted a survey over several weeks at Danone Nutricia Research's request. The goal was to perform cognitive and linguistic validation of the validated questionnaires in the local languages to ensure accordance with FDA and ISPOR Guidance for PRO use in Clinical Research. Some additional time was invested to validate the electronic adaptation of these questionnaires on the device. These steps provided an adequate methodology to optimize the understanding from the patients while ensuring compliance.

Impact of Patient Cloud® ePRO™

The Danone Nutricia Research study team has instant visibility to patient self-assessments which enables the adaptive aspect of the study. The electronic, real-time PRO data collection allows an immediate data quality check due to the unified Rave/Patient Cloud solution. Edit checks and custom functions are used to cross-reference data between eCRF and ePRO forms and to automate CRF item completion based on the data from the ePRO app, which reduces the data entry error rate from sites.

Calendar functionality in the ePRO app encourages subjects to complete questionnaires on a timely basis, minimizing recall bias and ensuring the highest quality data. The Bristol Stool Scale image integration, the one-to-one question environment and dynamic navigation enhances the subject experience and increase the data quality.

With Patient Cloud's design based on Rave's Architect module, little effort was required to adapt Danone Nutricia Research's design workflow to meet the most rigorous industry standards. The study design was completely manageable by Danone Nutricia Research's team avoiding the management of different systems and different teams.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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