A Cytel Case Study: The Use of CDISC Standards in Unilever's Cosmetics and Food Products Trials

By Meghana Bhagwat, Senior Project Manager, Cytel India
Edited by Andrea Vadakin, CDISC Manager of Public Relations

Introduction: Cytel's Experience with CDISC Standards Implementation

Cytel is a technology services provider that develops statistical software, clinical trial programming and analytic services. The company has extensive experience in clinical development and expertise in biostatistics, operations research, SAS programming, medical writing, data management and software development, and is a leader in the design and implementation of adaptive clinical trials.

With experience migrating over 150 studies as part of 20 U.S. Food and Drug Administration (FDA) submissions, Cytel's CDISC Implementation Team efficiently develops CDISC SDTM and ADaM data sets that are compliant with required guidelines. The CDISC Implementation Team is comprised of expert programmers and statisticians that understand the analytical requirements of complex trials and have extensive experience preparing data for submissions to regulatory authorities. All studies in which Cytel has led migration and submission to the FDA have been accepted.

Background: Unilever's Need for Data Standardization

Unilever is a consumer products company with over 400 health and skincare products currently on the market. For the past 10 years, Unilever has worked closely with Cytel on statistical analysis assignments on a regular basis. Recently, their skincare product team approached Cytel with a new request: to convert data from their cosmetics trials to CDISC SDTM standards.

An ongoing project, the long-term goal of the Unilever Data Sciences Team has been to combine data from all human trials into a single database using an industry standard format. Their rationale for this is that cosmetics trials are very similar to the clinical trials that they perform for their food products. In the future, Unilever anticipates expanding use of the CDISC standards to their food product trials as well as cosmetics trials.

Decision to Use CDISC SDTM in Unilever Pilot Study

During initial discussions, the Cytel programming team studied the sample data provided by Unilever and determined that the cosmetic trial data showed great similarity to drug trial data. The study documentation was consistent and the protocol and CRF designs were similar as well. The difference lied in the variety of data. Cosmetics trials are mainly for topical application of products and hence the data collected is limited as compared to drug trials.

As Cytel has the greatest depth of experience migrating legacy data into CDISC SDTM format for their many clients, SDTM seemed the natural choice for the standard to be used. Cytel already has a team of experienced programmers working in this area, and this, along with Cytel's in-house tool, MapGenie, built to help in the faster migration of data to SDTM, ensured that this was the best choice for Unilever.

The pilot was first run on a single study. The purpose of the study was to test the efficacy of a skin fairness cream in comparison to another similar cream. Both products were applied to opposite sides of each subject's face and efficacy assessments were completed over a period of 8 weeks. Demography data, product application information, adverse event information and assessment data was provided. The raw data was provided to Cytel in multiple file formats such as Microsoft Excel and Word. With their extensive knowledge in SDTM version 3.1.2, Cytel decided to use this version for the implementation. Standard domains DM, EX and Trial Design were created using information mainly from the protocol. The assessment data fit perfectly in the findings domain, and although there were a couple of non-standard variables, these fit very well in supplementary qualifier datasets. Specifications were generated for reference and provided to Unilever along with SAS datasets. It was unnecessary to provide data in the XPT format, as this was not planned to be a regulatory submission.

Unilever's Reaction and Next Steps

After review, the Unilever team expressed satisfaction at the fact that their data could now be stored in a standard format that is widely accepted by the industry. They confirmed that the formatted data was easy to use for further required analysis. Michiel Gribnau, Data Sciences Team Leader at Unilever R&D, noted the success of the pilot, stating, *"We are still piloting this approach, but the first reactions are very positive as many people are absolutely tired of getting data in all kinds of different formats."*

Looking forward, Unilever hopes to see all data, both cosmetics and food products data, in one place to ensure easy processing. This will obviously permit faster decision-making and allow Unilever the ability to more easily and efficiently combine data from different trials.

The success of this pilot is further illustrated through Unilever's request that Cytel now convert data from another five skincare product trials to SDTM version 3.1.3. Cytel and Unilver are also working to develop SDTM with specifications, which would allow them to use a structure more suited to their data. The Cytel team is currently working on the migration of these trials. Even more impressive, as an additional future objective, Unilever has plans to ensure that all of their data, from multiple CROs, will be delivered in the CDISC SDTM format.