

Prototype Testing Informs FDA Preparation and Commercial Strategy

Collecting Critical Local Market Feedback
on Device Usability and Packaging Prior to
the Required FDA UX Testing



Company Background

Company X is a South Korean healthcare startup with cutting-edge diabetes diagnostics and management technology that makes A1c monitoring and testing more accessible, affordable, and accurate: anytime, anywhere. They are currently preparing for FDA clearance and U.S. commercialization.

The Challenge

Entering the U.S. Healthcare Sector

Breaking into the U.S. healthcare industry brings unique challenges, especially as a foreign company. Company X has developed an easy-to-use A1c self-testing device to diagnose and monitor A1c levels more conveniently and accurately than existing pocket-size devices. As Company X prepared to launch its product, the BDMT team conducted small-scale UX testing interviews to prepare for required UX testing, optimize the product and the user experience, and ensure FDA-required testing goes smoothly.

Other portable A1c tests on the market can be inaccurate, difficult to understand, faulty, and unreliable. Instructions can also be too complex, confusing, or not specific enough. Getting real-time feedback from users is critical to ensure their A1c test will perform as expected. First impressions can make or break a product launch: If the product does not work the way it should, it will be hard for buyers to change their opinions, even if the product improves.

Before testing their device in a full-length human study with blood samples, Company X was seeking to finalize the prototype design and needed feedback on the device's usability to ensure the device was set up for success with US users before FDA clearance and commercialization.

Because the device targets all age groups, the device, packaging and instructions needed to be tested to ensure alignment across all of the age and gender demographics.



To position the device for PoC (Point of Care) in addition to B2C (Business to Consumer) use cases, we also collected intelligence from providers to analyze their needs for face-to-face patient care, telehealth, as well as at-home providers.

BDMT Strategies and Approach

UX Testing Preparation and Scheduling

The goal of this research was to ensure laypersons can use the device at home with minimal supervision and health providers can test their patients at the point of care.

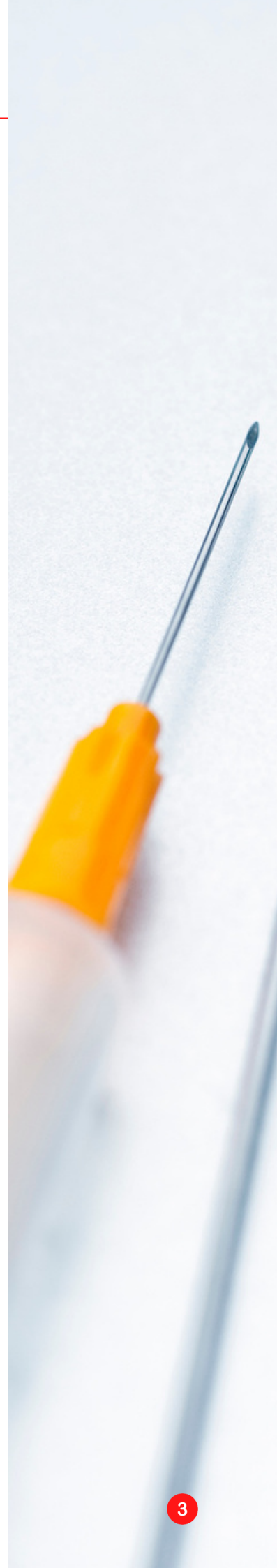
The BDMT testing team included very senior experts: a medical device testing expert, a UX expert, and a product launch strategist.

Diversity of skills and staff seniority on the testing team ensured that multiple tests could be packed into one small-scale testing project and all insights would be properly captured, cataloged, and actioned to the Client X.

Over the course of eight weeks, BDMT planned, secured, organized, and then conducted testing sessions with eight respondents to gather information from potential users of the device.

Testing sessions took place over Zoom for the respondents' convenience as well as due to the ability to record the session and review the process to capture all insights. BDMT carefully selected and scheduled qualified participants.

After accepting the invitation, BDMT provided respondents with instructions to review and collect signatures on all the necessary legal documents provided by Company X.



Testing included two meetings: one pre-meeting to ensure they had read and understood the documents, to review their cameras, and space requirements, and to confirm that they received the box of test materials. The second meeting was the actual interview session, where they would complete the test and answer the research questions.

During the interview session, the moderator provided advice to help respondents complete the test while noting issues and challenges that occurred during the process. If the respondent had questions, the moderator referred them to the Instructions for Use (IFU) or lid instructions (based on their preference) to determine their next steps and then advised when required.

Participants included lay patients (male and female), and HCPs: the Director of Diagnostics at a Laboratory & Imaging Center, an Inpatient Nurse, and an In-Home Clinical Services Nurse.

Testing Results & Critical Insights

Respondents Were Excited About the Future of This At-Home A1c Test Device

Overall, the participants liked the idea of an at-home option for A1c testing. During the testing sessions, BDMT gathered that the participants were very enthusiastic about this type of testing device option due to its ease of use and small size. They commented on the high quality of the device, while pointing to issues with some aspects of the device, the box design, and instructions.

The respondents found that the IFU, lid Instructions, and step-by-step instructions on the device were not clear and made it difficult to complete the test without professional assistance. Some of the device instructions included too much information that confused the participants, while other instructions were oversimplified. The UX testing proved that the instructions had to be redone to cater to the audience that will be using the device, to avoid any confusion and misinterpretation.

Packaging is also a crucial part of ensuring a product's commercial and clinical success. Multiple respondents found the packing of the test kit to be unclear, and some participants could not easily tell what the product was for.



The key product differentiators such as fast, accurate, easy, etc., on the box were too small, while less relevant information took more space. The respondents also noticed that the packaging was short on branding in terms of colors and logos and that the product would not stand out sufficiently when placed on a typical pharmacy shelf.

Highest Priority BDMT Recommendations

Insights Spanned Multiple Aspects of Product and User Experience

One of the test's most attractive features was that it only took five minutes, yet it was missing from the front of the box. To attract customers, this should be placed on the front cover.

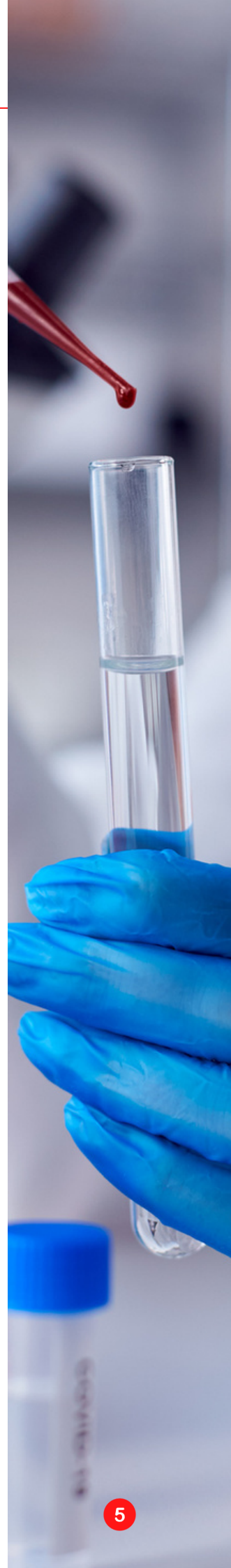
Users were optimistic about the future with this device. However, the instructions require revision for product adoption and user satisfaction.

The BDMT team recommended that the instructions be rewritten and significantly simplified to improve clarity to accommodate a wide range of literacy and cognitive abilities. This is especially important for A1c testing devices because diabetes affects people of all ages.

Additional improvement recommendations included:

- Clear markings on all test kit items
- Photography-based instructions
- Step-by-step outcomes and expected results
- Box redesign for better brand and product differentiation
- Clear identification of test purpose
- QR code with built-in instructional video
- Bolder use of colors and logos for better brand recognition

Based on our research, BDMT recommended Company X include a “physician recommendation” label to make the device more desirable, as well as a warning to the user to talk to their physician regarding results.



Key UX Test Benefits to Client X

Multiple Objectives Reached with a Small Initial Investment

This UX testing is necessary before the product is launched in the U.S. Hearing feedback from the people using the device before FDA-required UX testing allowed BDMT to draw insights and provide recommendations to Company X in order to ensure a successful streamlined FDA application and market launch.

As seen with competitor A1C Now, a product's reputation can be damaged if it launches while still needing improvements. Dissatisfied users will likely complain, providing negative feedback and influencing other buyers, thus significantly reducing market acceptance.

Working with BDMT Global helped Client X fit multiple tests into a small-scale project. Provided feedback, including input into IFUs to properly prepare for the mandatory FDA test, as well as U.S. buyer and user input to help with differentiation, package attractiveness, and appeal to the target audience, which will help with switching current competitive product users at the store and online.

About BDMT Global

Headquartered in Boston, BDMT Global is an outsourced business growth and marketing execution team offering strategic go-to-market, business development, and marketing services for international companies trying to break into the U.S. market and other parts of the world.

The company is led by Suzy Im, the Managing Partner of BDMT Global, and Dr. Jake Lee, who has more than 20 years of experience in the US biotechnology and pharmaceutical industries. Suzy is a widely-known name in global business development and an award-winning marketing transformation leader featured in publications such as Fortune Magazine. Dr. Lee's experience spans R&D, process development, product development, manufacturing support, operations, and business development fields at multinational companies in biotech and biopharmaceuticals, such as Pfizer, Lonza, Shire, Amgen, and Takeda. For more information, visit www.bdmtglobal.com



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