CASE STUDY

Partnering in assay development and optimization

Background

OncoMark is a startup in Dublin, Ireland, that was developing a qPCR-based kit for breast cancer. OncoMark wanted the test to receive Conformité Européene *in vitro* diagnostic (CE-IVD) clearance.

Challenges

OncoMark was a spinoff from the University College of Dublin, and the proof of principle studies were conducted at the university's research laboratory. Coming from the academic setting, OncoMark had limited laboratory resources and product development experience, which posed a challenge for them to move the project beyond the discovery phase. In order to kick start the product development lifecycle, they needed help optimizing the test and selecting an instrument on which their test would be run.

Partnership

We began our partnership with OncoMark by discussing with them their project, goals, challenges, and expectations. Once we agreed on what needed to be done, we developed a statement of work (SOW) to outline the specific work, timeline, and cost associated with the project. OncoMark had working assays, but they needed assistance in bridging the technology and optimizing the assays for performance, ease of use, and commercial suitability. We recommended that OncoMark develop their assays for the 96-well Applied Biosystems™ 7500 Fast Dx Real-Time PCR System, because it has the largest install base in their target market.

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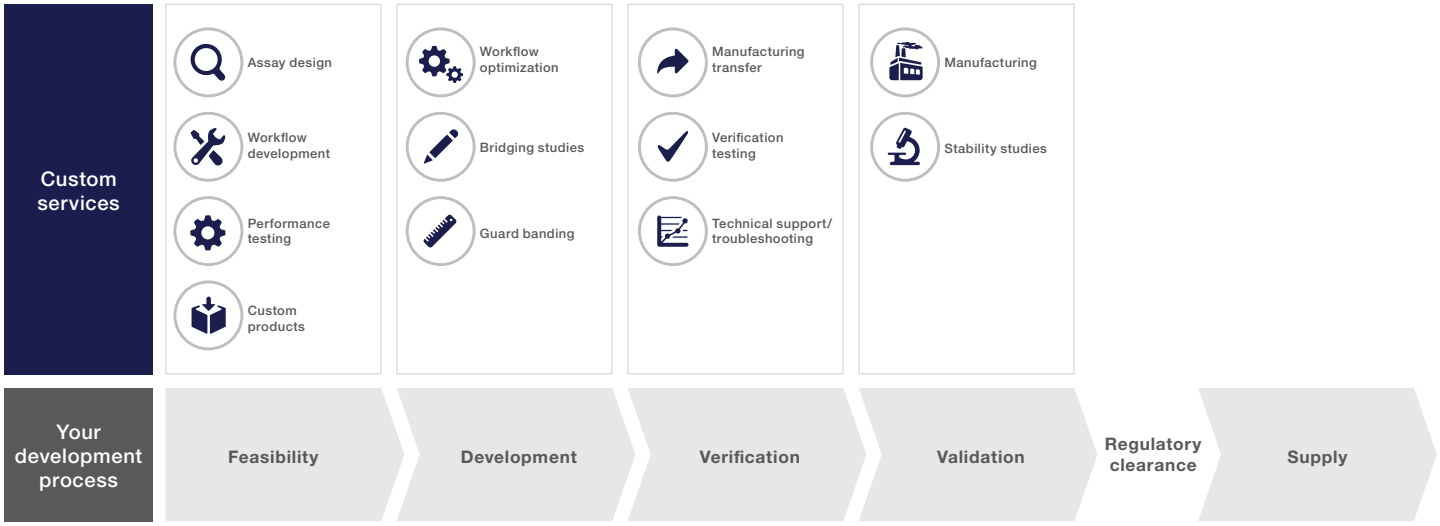

Results

Bioinformatics and assay screening

Our team evaluated key performance characteristics of the 15-target custom assay training panel from OncoMark. They decided to transition some of their custom assays to predesigned assays to leverage their performance and reproducibility advantages. Assay screening studies were performed on the 96-well 7500 Fast Dx instrument.

Baseline performance study on the 7500 Fast Dx instrument

Each assay was evaluated across a linear dynamic range with a statistically relevant selection of customer-provided samples. Performance between liquid and dried-down assays (pre-spotted) was compared. Desired performance was demonstrated on the 7500 Fast Dx instrument, with no statistical difference between liquid and dried-down assays. OncoMark chose to proceed with dried-down assays on a 96-well plate in order to reduce pipetting steps for optimal ease of use for the end user.

Bridging studies

Multifactor evaluation of critical workflow components was performed to compare one-step vs. two-step master mixes, and fast vs. standard thermal cycling conditions. Thermal cycling protocols, assay primer and probe concentrations, and sample input volume and concentration were also evaluated. Optimal performance was achieved with specific cycling conditions and reagent concentrations.

Summary

By partnering with our commercial supply team, OncoMark was able to simplify their workflow and more rapidly optimize their assays on the 7500 Fast Dx instrument. By outsourcing some of their assay development at earlier stages, they were able to reduce their development timeline by six months, and received CE-IVD approval on the *OncoMasTR*™ RT-qPCR test in August of 2018.

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