GODDARD
PRODUCT DEVELOPMENT

CASE STUDY

FDA Approval in Under Two Months for a Life-Sustaining Device

Goddard's human factors team validated a post-market design change with actual implanted patients and aligned with FDA reviewers, getting a remediated life-sustaining device to patients far sooner than a traditional timeline would allow.

Overview

Client

A global medical device manufacturer

Industry

Class III medical devices

Services

Human factors engineering, usability validation, FDA regulatory support

Product

A Class III implantable device providing life-sustaining support for compromised cardiac output

Outcome

FDA approval in under two months with no additional human factors questions; patients received the updated device within a year of study completion

The Challenge

A Class III implantable device provides life-sustaining support for individuals with compromised cardiac output. The version in the field exposed patients to a high-severity risk of harm, and the manufacturer developed a remediated device with updated user interface and labeling to address it.

The core tension was speed against rigor. The remediated device had to be validated to international and FDA human factors expectations, but every week spent in validation was another week patients remained exposed to the original device. The client needed a validation program that satisfied regulators and reached patients as quickly as possible, with no room for schedule slips or rework.

The Solution: Goddard's Approach

Targeted UI design support

Goddard ran a design workshop to develop visual differentiator concepts for the updated device, then conducted an expert review to surface usability issues in the user interface. These findings guided focused improvements that met regulatory needs without triggering a broader, slower redesign.

Validation with actual implanted patients

Rather than relying on representative users, the human factors engineering (HFE) team recruited actual patients implanted with the life-sustaining device, along with their caregivers and clinicians, and ran the human factors validation study (HFVS) across five cities. The study focused on whether users could identify the updated device and distinguish it from the existing model, adhering to international regulatory standards throughout.

Proactive planning that protected the schedule

Three planning decisions kept an aggressive timeline on track:

- To save time, sessions began before FDA feedback arrived through the optional pre-submission process. When FDA's feedback came in on the second morning of study conduct, the team updated the protocol before Day 2 sessions began. No completed sessions had to be replaced, saving roughly a week of schedule and budget.
- The team built in a one-week decision point in case usability issues surfaced early. When the first week revealed issues that matched the expert review findings, that buffer let the team and client work through them without losing momentum.
- At the decision point, Goddard guided the client through a risk-based determination on whether to proceed without further device changes. Together they presented interim results to FDA and aligned on a benefit-risk framework that justified completing the study with the device as-is. Because of the planned buffer, this alignment did not delay sessions.

Comprehensive regulatory support

Goddard developed the HFVS protocol and moderator's guide and shared them early so the client could give FDA reviewers visibility into the validation approach ahead of the pre-submission. Throughout the program, the team supported multiple FDA meetings covering the protocol, interim findings, and the residual benefit-risk framework, keeping everyone aligned and preventing schedule and budget losses from regulatory misalignment.

Within days of completing sessions, the team prepared an FDA presentation: rapid data analysis, a structured script, and rehearsal both independently and with the client's human factors manager. Because the study lead had conducted the sessions herself, the client trusted her to present findings directly to FDA. The team then integrated pre-submission feedback into the HFVS report, justifying user group selection and clearly identifying critical tasks, and contributed to a benefit-risk analysis showing that residual risks did not outweigh the significant benefit of patient access to the updated device.

The Results

Fast approval

FDA approved the submission in under two months, with no additional human factors questions after submission.

Earlier patient access

Patients received the remediated device within a year of study completion, far sooner than a traditional timeline would allow.

Protected timeline and budget

Proactive planning meant no replacement sessions, no schedule slip, and no budget overrun from regulatory misalignment.

Reduced patient harm and burden

Many patients knew about issues with the original device. Earlier access to the updated version reduced their exposure to harm and eased the psychological burden, improving their sense of safety and well-being.

The program shows what focused human factors support can do in a complex regulatory environment: a strong validation approach, responsive collaboration with FDA, and clear documentation that together accelerated access to critical life-sustaining therapy.

Let’s Build Something Great. Talk to Our Team.

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