

## **The Challenge**

A large biopharmaceutical company approached TLS to partner on the design and execution of a pilot study to test the feasibility of administering a remotely measured clinical study endpoint for patients with a chronic GI disease. The sponsor team was most interested in whether a patient's personal physician, rather than the specially designated study physicians typically used for clinical trials, could act as a primary collector of patient data for the clinical study. This is an important issue, because if patients' regular physicians can serve in this role, conducting trials without centralized clinical study sites becomes far more feasible.

## **TLS Solution**

The study sponsor came to TLS with a nearly complete protocol document, so TLS's crowdsourcing efforts were largely limited to confirming the sponsor's draft. TLS worked with the sponsor and a team of technology providers to assemble a digitized monitoring system that made it possible to obtain patients' informed consent, perform blood draws, and assess the study's primary endpoint without visiting a clinical study site. TLS also served as the regulatory sponsor of this study.

This study was a small proof-of-concept effort to demonstrate whether patients with a chronic condition – in this case, a type of gastrointestinal disease – could be monitored and assessed from home. The data that patients transmitted via video and Bluetooth links was clean and ready for analysis. Participants indicated satisfaction with the technology and the home-based assessments.

## **The Benefit**

The sponsor and TLS concluded that the study successfully demonstrated that patients are willing and able to use the latest mobile health technology to participate in clinical trials, and that personal physicians can have an active role in the clinical trial process, replacing some or all of the physician monitoring typically done at distant centralized sites. Patients were given a satisfaction survey at the end of the study, and the responses were overwhelmingly positive. Additionally, the study coordinators reported that the use of digital technology made the study more efficient, and they also provided many examples of how the system of digital components can be better integrated into future studies.