# Case Studies

Clinical Research Insight (CSI)



A research team with limited resources received funding to run a couple-based behavior study but faced several challenges. The study involved a nationwide pool of potential participants, which meant that communication and clinician consultations would be a challenge to overcome.

Study protocols mandated that couples enrolled in the study have coordinated clinician consultations, where all other activities could take place independent of one another for the duration of the study. Thus, presenting a unique management challenge.

## **The Solution**

Our team provided the PI and the study team with:

• An automated recruiting tool that determined eligibility, automatically registering eligible participants.

Couples were created based on their registration, then consultations were linked for coordination.

- A mobile iOS and Android app for participants to take surveys and communicate with research members.
- Coordinated telemedicine sessions with a clinician host through a HIPAA compliant video conference.
- Notification and reminders to alert the research team and participants of upcoming due dates and scheduled sessions.
- Real-time metrics on a dashboard for the study team to track participation, manage the risk of incomplete activities and view communications.

A leading research university had an isolated database collection that ran on individual computers. This led to an issue of visibility into protocol compliance, data collection and study resource management. They needed a role-based administrative application that minimized their compliance risk, could be used by multiple study teams and support electronic data capture from participants.

### **The Solution**

Softura built a cloud hosted application for study management which included:

- Configurable study setup to allow for multi-site, cross team and protocol specific management
- Real-time alerts & notifications on upcoming milestones and activities
- Dashboard driven metrics at both the study and participant level to mitigate compliance risks
- Study team resource calendars for managing participants online and in-person visits
- Text message module for messaging participants directly from the study dashboard
- Lab results module for importing key lab data for all participant
- Export of study data to a password protected file
- iOS and Android mobile apps for electronic data capture from participants

A cost effective platform to provide digital transformation of study management

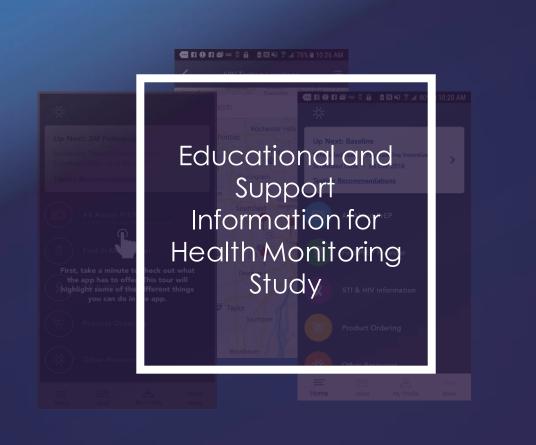


A team at Emory University needed a way to track clinical providers and their services. Including a critical annual survey to update contacts and services of existing providers as well as adding new providers. Budget constraints led the team to request that Softura help provide a solution within the existing clinical research management software platform being used at the University.

# The Solution

The team provided an innovative solution by configuring the existing CRMS platform to include milestones and activities to support the provider update timeline

- Automatic notifications and reminders were set up for the clinics to update their information annually
- The Emory team had permissions to add/modify the contact information provided in the annual surveys
- The study admin dashboard provided the metrics for the team regarding late surveys from the clinical sites
- Custom data fields were used to capture specialized data for this contact management business application
- An import of an existing set of contacts was completed to establish almost 1,500 clinical sites with contacts



A study with the charter to monitor the health of young adults through behavior surveys and lab results was in need of a way to offer support information to its participants. This information was in the form of disease profiles, clinical locations, free products and questions to ask the doctor. The data was to be delivered to the participants in a mobile app along with milestone activity reminders and notifications.

### **The Solution**

- The existing clinical research management software was used as the foundation of the solution
- A content management portal was integrated into the platform to give the study team a mechanism to author the content
- A mobile app capable of displaying the new content and study protocol timeline was delivered to the study team
- Participants download the apps from the app store and can follow their study timeline, view the supporting content and self-report lab results
- Prior to seeing a doctor, the participant can search for a convenient location and save questions to ask the doctor right to the gallery on their mobile device