

CLINICAL TRIALS DATA MANAGEMENT SYSTEM: CONTINUOUS GLUCOSE MONITORING

Client Profile:

A medical device company focused in diabetes who markets an implantable sensor for long-term Continuous Glucose Monitoring (CGM). The company was seeking to develop a web-based application that includes an interface to the device and can track/trend glucose data.

Technologies Used:

Use Case Analysis, Wireframes, Human Factors Engineering, Requirements Engineering, .NET framework, ASP.NET, Microsoft Visual Studio, Bluetooth interface technology, knowledge of Medical Device functionality and interfaces, FDA Application Development / V & V Guidelines and HP Mercury Quality Center for requirements, test protocols, bug tracking.

Project Summary:

The project consisted of the development of a Data Management System (DMS) which organizes, displays and manages blood glucose data and other relevant health-related information. Data is stored on the web. Users may choose to share information with a designated healthcare provider. A user may also, with appropriate permission, access information belonging to another user (such as an elderly parent or a child). The system is composed of an implantable glucose sensor, a wearable wireless receiver/transmitter, and data management software (the DMS). The user uploads information from the wireless receiver/transmitter to the DMS application. The system allows patients and healthcare providers to share information – to monitor, track, compare, and evaluate glucose monitoring data. Detailed reports provide in-depth analysis of health status. The application is available in English and German.