



Flaskdata.io Reports on Customer OrthoSpace's Success in Using Its System for Protocol Compliance Automation in Clinical Trials

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Flaskdata.io, a technology company based in Israel, has announced the success of its customer, OrthoSpace in using its system for protocol compliance automation for clinical trials. OrthoSpace is a company that develops and commercializes biodegradable balloon systems for the orthopedic market. These biodegradable balloon spacers are simple to implant and therefore only require minimally invasive surgery. OrthoSpace's first product is the InSpace?, which is indicated for patients with severely torn rotator cuffs, for improving range of motion and decreasing shoulder pain. It should be noted that OrthoSpace was recently acquired by Stryker in a \$220 million deal. The company is currently conducting post-marketing studies to monitor patient safety compliance in the EU and the UK. More about this and similar Flaskdata.io customer case studies can be found on their website.

Elana Markovitz, VP for Clinical and Regulatory Affairs at OrthoSpace, says, "Flask Data is a fascinating and novel tool for reinforcing patient adherence. We look forward to seeing FlaskData.io continue to develop and disseminate the technology in the EU. The ability of a smart mobile agent to increase patient's compliance to a clinical protocol can have a significant impact on obtaining statistically-meaningful results in clinical trials

and are of immense importance for medical practice.?

Flaskdata.io makes use of a cloud platform to allow clients, like OrthoSpace, to perform real-time data gathering during clinical trials and benefit from automated protocol compliance monitoring. One of the components of system is the Flask Data API, which allows clients that are using connected medical devices for their clinical trials to gather data directly from those medical devices. Meanwhile, patients who are participating in the clinical trials would be able to report their outcomes through the Flask Forms and all of these data can be monitored in real time using the Flask Data remote monitoring platform. The open Flask Data API can also be used to monitor compliance for wearable devices and non-compliance can be easily detected through the patient's vital signs.

Automation of patient compliance monitoring is essential because patients following the protocol have an impact on the ultimate success of site-less trials, patient-centric studies, home use devices, digital therapeutics, and decentralized trials. Meanwhile, AI and playbook response are used to ensure high patient compliance reporting and provide high quality risks signals from patients. Through the Flaskdata.io system, clients and other people who have a stake in the success of the clinical trials can readily get an immediate overall picture of the state of patient compliance at any given time.

It should be noted that an important benefit of the Flask Data system that automates the detection of protocol deviation is the minimization of costs and the presence of alerts on deviations, which is over 100 times faster when compared to the usual manual approaches of centralizing monitoring and risk-based monitoring services.

Another important component of the Flaskdata.io platform is the Flask Forms ePRO and eSource. Customers can create eCRFs (case report forms) using a drag and drop user interface and deploy to desktop, tablet and mobile devices for direct data collection in real-time.

The Flask API enables life science companies and digital therapeutics developers to collect data from connected mobile devices and mobile medical devices that are either at home or worn by the patient. The Flask API exposes the capabilities of the Flaskdata.io platform for managing studies, subjects, case report forms. In addition Flask API can be used to provide scalable infrastructure to facilitate automation of data collection from hospital electronic health record systems into the Flaskdata.io clinical trials digital platform,

Companies interested in exploring capabilities of the Flaskdata.io platform should contact Flaskdata.io for more information.

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