



SUMMARY

PAREXEL International

Industry

Pharmaceuticals

Business Value

- Business Intelligence
- Operational Insight
- Performance Optimization
- Process Controls
- Quality Management

PI System™ Components

- PI Server™
 - Data Archive
 - Asset Framework (AF)
- Developer Technologies
 - PI Web API
- PI Vision™1
- PI Integrator for Business Analytics (BA)

Adherence in Clinical Trials: PAREXEL Uses the PI System and Wearables to Increase Patient Participation

PAREXEL International is a global consulting company specializing in pharmaceuticals and medical devices. From strategy to condition of clinical trials to post-release marketing, for over 30 years, PAREXEL has helped pharmaceutical companies get critical drugs into the hands of consumers as quickly, safely, and cost-effectively as possible. Typically, it takes a drug manufacturer an average of 10 years from the time of discovery to bring a drug to market. One of the most complex and expensive aspects of this 10-year process is clinical trials, a period when patient participation and adherence is imperative to success. To increase the success rates of clinical trials, PAREXEL turned to the combination of wearable devices and the OSIsoft PI System.

A Race Against the Patent Clock

When researchers discover a new molecule, a drug company applies for a patent, and those patents are good for a 20-year period. Given the fact that it often takes a manufacturer 10 years to bring the drug to market, “Out of those 10 years in average... the clinical trial part is taking a very relevant part, something like six, seven years,” said Jean-Marc LeBideau, Director of the PAREXEL Engineering Solution Incubator, during the 2017 OSIsoft EMEA Users Conference in London.

“The longer the therapy is in the market, and the longer our clients are able to make profit with it,” noted LeBideau. “After that, it becomes generic and it’s open to different companies.” For PAREXEL, shortening the clinical trial process would not only decrease drug development costs, it would give manufacturers a longer period in which to maximize profits before the patent expired.

A Sensor-Based Approach

For every drug product, several clinical trials are conducted, and all clinical trial activities are pre-defined by a study protocol. That protocol consists of various activities, observations, and events surrounding the participating patients. Previously, that information was collected on site. Patient participation and dropout rates were some of the biggest challenges companies faced.

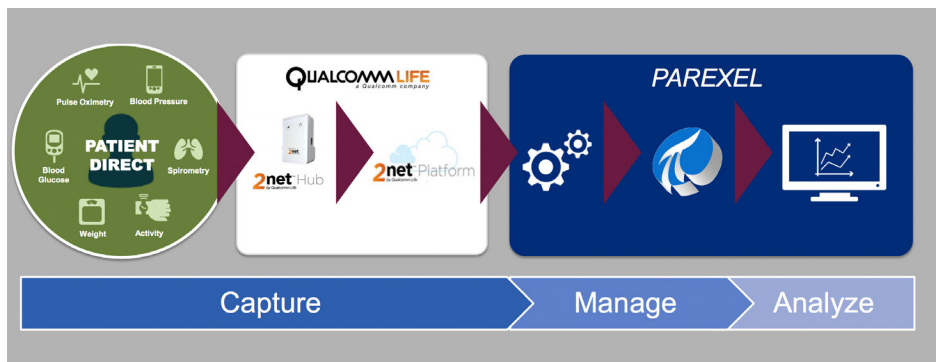
To collect necessary patient data and increase participation rates and clinical trial accuracy, PAREXEL created the Patient Sensor Platform centered on wearable sensors and the PI System. Now, human body data, such as blood pressure, glucose levels, and respiratory rates can be collected remotely, painting a faster and more accurate picture of a drug’s effectiveness.

Defining the Methodology

Clinical trial participants already receive drug and lab kits that contain sensors, but with the Patient Sensor Platform, patients can connect to the data hub via Bluetooth, which helps facilitate the remote collection of sensor data. An initial exploratory study was performed to align clinical standards and assess whether results provided by wearables were concurrent with clinical standard methodology. Part of the study was performed in-house, while the other was performed with patients at home and, to the delight of PAREXEL, the results were very similar between the two groups.

Capture, Manage, Analyze

PAREXEL then implemented the “Capture, Manage, Analyze” process where the team created how-to guides, found sensors that were fit for the trials and integrated those devices into the hub. Using AF SDK and PI Web API, each patient was assigned a PI tag, and incoming patient data was stored on the PI Server. Asset Framework organized and structured that data on the server, and PI Vision gave immediate access to the sensor readings. Using PI Integrators, PAREXEL extracted information into a separate database, allowing users to visualize expected versus actual readings in context with other data, such as demographic information, within the trial.



Capture, Manage, Analyze: With the help of the PI System, PAREXEL can now extract insights from patient data streaming from a network of wearable sensors.

Future Implications of Clinical Trials

Given the initial success, PAREXEL plans to expand its wearables platform to the cloud and offer a companion app. Thanks to wearables, PAREXEL can help increase patient participation in clinical trials, making them more cost-effective, faster, and accurate. As clinical trials become shorter and more successful, companies can get important drugs to market faster than ever before. For more information about PAREXEL and the PI System, watch the [full presentation here](#).

¹PI Coresight was renamed to PI Vision in 2017.

LaBideau, Jean-Marc. What are the Components of Ensuring Sensors and Wearables are Applied Correctly in Clinical Trials? OSISOFT.COM. 18 October. 2017. Web. 24 November 2017. <<https://www.osisoft.com/Presentations/What-are-the-Components-of-Ensuring-Sensors-and-Wearables-are-Applied-Correctly-in-Clinical-Trials-/>>

“Here we did observe very good transmission time... it takes a certain time for readings to be taken from the device and transmitted to the hub. But after that... we had the data finding the home in the PI System within seconds. This is, for our industry... quite impressive.”

— Jean-Marc LaBideau,
Director of Engineering
Solution Incubator