

## Late Phase Research and Managing Post-Market Risk: A Conversation with Scott Dixon



### Overview

In continued efforts to focus on bringing effective drugs to market without causing harm to patients, the pharmaceutical industry has invested heavily into improving safety profiles of drugs and therapies. New technologies and analytical methods have been employed to evaluate risks of drugs and potential adverse events, which has led to more systematic approaches to identifying and analyzing post-market risks.

As Senior Director of Health Sciences solutions, Scott Dixon focuses on late phase research and ePRO for Oracle. Mr. Dixon has more than 18 years of experience in the health care, life sciences, and pharmaceutical industries and has translated his talents into opening new markets and developing strategy for emerging service providers. Here, Mr. Dixon discusses how to streamline data collection—specifically for late phase research—and how to reduce post market risk.

### Frequently Asked Questions

#### How does late phase research improve drug safety?

Late phase (or post-marketing) research is conducted on drugs after they have passed regulatory review to confirm the appropriate use of the drugs and to collect data on their safety in real-life settings. These studies can reveal unexpected adverse events and drug interactions that did not appear during the drug approval process, which can improve a drug's overall safety profile. While not universally required, regulatory agencies are increasingly mandating these studies on new drugs sold in the United States and Europe. In Japan they are already required on every new drug sold in the country.

#### What makes late phase studies so challenging to conduct?

Late phase studies intrinsically deal with a large number of patients and are often quite lengthy and geographically dispersed—significant challenges in their own right. But late phase research also mainly takes place outside the controlled

clinical environment and is typically performed by general practitioners with limited experience in running clinical trials. These challenges are compounded by the overall scope and size of these projects. Maintaining patient enrollment and getting quality data are often difficult tasks, especially if the data collection process is not straightforward and easy to use.

There is also a growing need for collection of patient reported outcomes (PRO) directly from patients themselves in late phase studies, exacerbating the casual user issue. It is important then to have a single and simple method that combines and integrates both site and patient entered data. Fundamentally, the increasing regulatory focus on these studies necessitates that sponsors regularly report safety and analysis results, which highlights the need for real-time access to quality data.

#### What is the benefit of collecting data directly from patients?

Self-reported measurements provide valuable information on the trial experience, including hard to quantify data such as the physical and emotional impact of both symptoms, and the toxicity of therapies. Patients don't describe how they are feeling in terms of elevated white blood cell count. Instead, they report, for example, that they are "feeling sluggish" or "have a lot of energy." When this type of data is combined with the clinical data collected from the healthcare provider it can create a complete picture—or a 360-degree view—of the patient outcome at baseline, during therapy, and after therapy. An understanding of overall treatment satisfaction and effectiveness, as well as the impact of a drug on patients' day-to-day lives is highly useful for safety measures.

#### How have companies traditionally collected data in late phase studies?

Distributing paper forms to patients has been a primary collection method. While these studies are quick to deploy, they are resource intensive and arduous to manage, especially because of the large number of patients, sites, and physicians

involved. The paper data can often take months to process and send to central hubs— sometimes getting lost in the process. Once it is received it is too late to reconcile inaccurate and incomplete data because manual follow-ups are ineffective. This makes it difficult to draw meaningful conclusions from data, track the data, track the safety profile, and quickly and regularly meet regulatory reporting requirements.

### **Can you provide some details on the solution that Oracle offers in the late phase space?**

Oracle Health Sciences OutcomeLogix On Demand solution is a Web-based data collection tool designed specifically for late phase research. Both site and patient entered data is combined in a single system to provide the 360-degree view of therapy required for late phase research.

The solution easily scales to a large number of sites and patients, and its multilingual capabilities make it ideal for global studies. The flexibility of Oracle Health Sciences OutcomeLogix On Demand also allows sponsors to brand studies with their own logos and colors and to quickly implement customized configurations. With Oracle Health Sciences OutcomeLogix On Demand, sponsors can streamline the overall processes of data collection, patient recruitment and reporting. Patients can self enroll in post-marketing studies through Web screening, helping better manage patient recruitment, and sponsors can efficiently validate data and report to regulatory agencies. Its Web-based architecture was designed for the casual user and allows patients and physicians to enter data through the Internet on computers they use in their everyday life, this also helps encourage patients to remain involved in studies. The user friendly interface walks patients step-by-step and form-by-form through the data collection process to help them accomplish their focused tasks.

### **Is Oracle working on other projects for the late phase space?**

Oracle—in conjunction with two top ten pharma companies— has developed the integrated post marketing surveillance (iPMS)

solution for use in Japan. The iPMS solution leverages Oracle Health Sciences OutcomeLogix On Demand and the clinical data repository from Oracle Health Sciences Clinical Development Center to collect data and generate submission reports across multiple studies. Because it is Web-based and uses a standard library of highly intuitive forms, the iPMS solution can be quickly deployed and requires minimal training of the general practitioners who enter the data. The results thus far have been striking. In the first implementation of the solution, a study was deployed in just five weeks and enrolled 100% of its target enrollment within 10 days after it went live. Help desk calls from physicians were minimal. In the first two months of the study, only four incoming calls related to application support. This greatly reduced the number of physicians generally required to conduct such a study. This success has spurred a larger rollout of the iPMS solution in the Japanese marketplace.

### **What are the implications of Oracle's late phase technology for the industry?**

We believe the technology we have developed is truly transformational to the existing late phase research business processes. The conventional paper-based method of conducting these increasingly mandated studies has not been effective, and traditional EDC does not meet all the requirements of late phase research.

With Oracle's technology, sponsors and sites will have more immediate data access, more effective tracking of safety and reporting to regulators, and likely greatly reduced operational costs. The availability of clean data much earlier in the process should help accelerate the acceptance of drugs in the market while giving patients greater confidence in the safety of the products they are using. As late phase studies become increasingly required, the need to more efficiently conduct these massive studies will become more acute.

## **Contact Us**

For more information about Oracle Health Sciences OutcomeLogix On Demand, visit [oracle.com/healthsciences](http://oracle.com/healthsciences) or call +1.800.ORACLE1 to speak to an Oracle representative.



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