

PHILIPS

PHILIPS ORAL HEALTHCARE

The Promise of Electronic Data Capture (EDC):

How Phase Forward's InForm™ Solution Helped Philips Oral Healthcare Deliver on the Benefits of Automation and Standardization

- In late 2004, a small team of biostatisticians at Philips Oral Healthcare (POHC) embarked on the challenge of converting their internally-developed, paper-based clinical trial system to electronic data capture (EDC). While the home-grown Microsoft® Access and Microsoft Excel-based systems were easy to use, they lacked validation and compliance with major regulations, leading the group to consider other alternatives and take on standardization and automation. As Sonia Souza, Director of the Clinical and Scientific Affairs Support Core at POHC comments, "We felt we needed a common and secure platform with audit trails and e-signatures that could be used anywhere in the world. We also wanted a system that could be standardized according to our company needs."

CASE STUDY

So began a rigorous process of evaluating and selecting an EDC vendor. Selection criteria were established that included:

- **The financial stability of the vendor**
- **Customer references**
- **The ease of interacting with the vendor**
- **Broad-based training options**
- **The ability to be independent once fully trained**
- **Price**

At the outset, POHC knew they were going to select a system that they could bring in-house. Yet with a small team of three, POHC had to be extremely careful to make the right choice. In the words of Ms. Souza, "We were looking for a vendor we could trust. We knew we would be working with them as a partner for a long time. Responsiveness was particularly important." The solution had to be relatively intuitive and provide ample support to train a team that was used to a paper-based system.

POHC began the process by reviewing 10 vendors and then reduced the short list to 6 with each vendor visiting POHC for a demonstration. Finally, the team narrowed the choice between 2 vendors with Phase Forward's InForm™ solution ultimately selected. Among the reasons, Phase Forward was considered the best long-term fit, with a quality product from a leader in the industry. As Ms. Souza recalls, "It also seemed like a very straightforward implementation that would enable us to present the case to Philips about the value of automation and standardization."

The Implementation Experience

POHC began the InForm implementation by carefully reviewing the steps required to create a database. This initial focus allowed the team to determine how to best use their limited resources to develop a process that resulted in the shortest time between final protocol and first patient visit. Their answer was to develop a set of standard libraries that represented the most common types of studies conducted by POHC. As Matt Johnson, POHC Senior Statistician and Lead Database Developer, puts it, "This use of libraries helped everyone quickly appreciate the value of standardization."

The next implementation challenge was to accept Phase Forward's naming conventions for the database components. While the new nomenclature required some adapting, its value was quickly realized as it became easier to track data all the way through the system. Coupled with CDISC standards, the end product became a sound and robust foundation for all the trial datasets.

In the 6 months that POHC has implemented the Phase Forward solution, 8 trials covering almost 1000 subjects have been conducted. While in the beginning some awkwardness was experienced due to the more restrictive environment associated with conforming to standards and greater compliance, once POHC adjusted to the new system, efficiencies were immediately experienced. As Mr. Johnson describes it, "We had to adjust how we made changes in our processes and perform validation but the final process is very solid, easy to use and efficient." The other challenge POHC experienced was managing the increased number of queries due to the ability to more easily visualize data and detect mistakes. POHC views this change as positive because as Ms. Souza comments, "While the queries have increased, so have the accuracy and quality of the data."

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For POHC, the benefits experienced by the adoption of the InForm solution have been far-reaching and significant. Some of the most positive aspects cited by the team include:

■ **Improved Compliance**

The POHC team likes being able to see a record of changes. The new system's security automates the audit trail for any change made.

■ **Closer Communications with CROs**

Under the old system, team members sent emails to CROs to get updates. Not anymore. Because of vastly improved data visibility through InForm reporting, "I can know what is going on in a trial every second of every day. I can see enrollments by day. If they are slow, I can act early and find out why," says Sonia Souza. Database lock is also improved as both CROs and POHC can be working on an issue simultaneously.

■ **Study Go-Live Accelerated**

The time between final protocol and starting the study can now take as little as 3 days because of the pre-validated libraries. Today there are 8 libraries fully validated. Ms. Souza says that the new approach is very efficient, noting "When we begin a new study, the library that most closely matches the study is selected and the level of changes required to meet the protocol is defined. Based on the changes and validation required, we can take from 1 day to 2 weeks to have the new study up and running. Most studies take 2 to 3 days."

■ **Improved Data Quality**

Today, POHC has written SAS programs that pull data directly from the InForm product to perform global edit checks and also standardize all outputs for the final report. This automation has aided the database lock process, dramatically decreasing the amount of time between the last subject visit and database lock. Put that together with the ability to monitor the progress and quality of the data in real-time and **what once took 1-3 months can now take 1-3 days.** It also allows for final tables for the Clinical Study Report (CSR) within 24 hours post database lock.

Based on the implementation experience to date, does the Philips team believe that the InForm solution has met their high expectations? The original business drivers spurring change were compliance, standardization, globalization and improved quality. While the team sees even more potential ahead, there is an overall feeling of accomplishment. As Ms. Souza sees it, "Our goals were to establish a common and secure platform, develop the best-in-class robust processes, be compliant with all regulations and by doing that, improve the overall quality of our studies. We have done that and more."

Top-Notch Support and Unique Tools Make the Difference

The question often asked is how POHC achieved such impressive results in such a short period of time. For example, valuing their independence, POHC wanted to bring the InForm solution in-house, with all the expertise that entails. True to their goal, after the second trial, POHC was largely self-sufficient.

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Director of
Clinical and
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Support Core,
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The team points to a few key areas that made the difference. One is Phase Forward's continued support. As Mr. Johnson notes, "We used Phase Forward support quite a bit during the first database design and implementation. Support is extremely valuable. We are not programmers, we are statisticians and for a group like us that wants to retain as much control as we do, we need effective support." Flexible training, timely validation of the system, and even a product manager coming to visit when CRF submit was being installed were all examples of Phase Forward being responsive and a true partner.

The second difference was the presence of some key tools within the InForm solution. For example, CRF Submit has been an extremely useful addition to their system. CRF Submit software enables sponsors and CROs to prepare CRFs for electronic submission by creating PDFs. As Ms. Souza explains, "Every note, every change of data is all there. It makes it very easy for the FDA submission. The output is organized, easy to use and fulfills our requirements, as well as those of our CROs."

Looking Ahead

While Philips Oral Healthcare is clearly satisfied with how the implementation has proceeded, plans are already shaping up as to their next steps. "We know we have better quality data and faster turnaround of our trials. We believe that our CROs being fully trained on Phase Forward's products will eventually lead to lower costs as they become more efficient," projects Mr. Johnson. Ms. Souza concludes, "The common platform has allowed us to leverage work for our next trials. Incorporating CDISC has also been important as a 'standardization within standardization' and will yield major benefits. What is next for us is the building of new efficiencies by extending what we have already begun."

True to their own efficient nature, the team has already drawn up their list of where systems can be tightened and information can be streamlined. For example, POHC plans to use the InForm Architect product to build forms that will be used in their process for screening subjects. The data collected will be used for inclusion in a recruiting database. This and more lie ahead. For now, though, the team gets to relish in the accomplishment of setting some high goals and beating them in record time.

PHASE•FORWARD™

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Phase Forward is a leading provider of integrated data management solutions for clinical trials and drug safety. The company offers proven solutions for electronic data capture (InForm™), clinical data management (Clintrial™), clinical trials signal detection (CTSD™), strategic pharmacovigilance (WebVDME™ and Signal Management), adverse event reporting (Clintrace™) and applied data standards (WebSDM).