Most industries recognize that data integration is critical for optimal supply chain and financial management. In the pharmaceutical industry, data integration of clinical trials information is finally getting the scrutiny it deserves. Clinical trials are the starting point of the pharma new product commercialization process. Yet for many CRO and pharma firms, data integration of clinical trials is an ideal, not a reality. Many companies are still mired in an incomplete stage of clinical systems development and integration. They are bogged down in implementation problems and misconceived notions of how to aggregate and prepare clinical data for analysis.

To find out why there is a gap between the need for data integration and fully integrated systems, SAS and Pharmaceutical Executive conducted confidential TDIs (Telephone Depth Interviews) with senior pharmaceutical executives and CROs. Based on those interviews, we arrived at some recommendations about how to achieve optimal clinical data integration.
More Pressure for Clinical Trials Data Integration

Clinical trials are becoming increasingly more complex and competitive for both CROs and pharmaceutical companies. There were several trends mentioned by interviewees:

**Expense of global clinical trials is increasing.** The number of clinical trials is increasing steadily as more drugs are being tested in a global marketplace. The number of patients in each trial is also growing and trials are often for longer periods of time. Companies would like to think in terms of economies of scale. But in a marketplace that is also increasingly regionalized, companies also have to fit trials to the regulatory needs of each country. And products have to match the economics of each patient population.

“Health Economics Outcomes Research (HEOR) is going to get bigger in the next five to ten years. We are getting requests after approval or during approval from different countries requesting different analysis for their country. It’s a cost savings if we already have that data at our fingertips,” said the head of statistical programming for North America for a major pharmaceutical firm.

**More personalized medicine.** At the same time as drug studies are becoming more expensive, there are fewer blockbuster drugs. Companies need to pinpoint patient populations and make more effective compounds—new indications for existing agents that rely on legacy data. “Understanding what was done in the past, right or wrong, can give us the best historical information to predict how a specific design may react,” said the vice president of primary care for a major pharmaceutical company.

**Risk management of product life cycle is more important.** Companies need to improve the risk management of the product life cycle for all stakeholders including patients, investigators and regulators. They need to speed up clinical trials and make

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**FIG. 1**

**ADVANTAGES OF DATA INTEGRATION**

**Advantages to CROs**
- Transfers senior programmer responsibilities to lower cost resources
- Speeds submissions
- Reduces errors
- Eliminates data delivery errors through pre-built, customizable, easy-to-use standards adherence checking
- Provides transparency by producing code-level documentation
- Creates new revenue opportunities around legacy data conversions through pre-built CDISC data models and processes to standardize data.

**Advantages to Sponsors**
- Automates cross-study integration effort, reducing cost and increasing quality to derive value from existing data assets
  - Identifies potential new indications
  - Improves safety monitoring
  - Enhances trial design
  - Reduces number of trials conducted
- Supports and automates the aggregation and standardization of ongoing clinical trials
- Standardizes data to internal analysis and submission standards at lower cost and higher quality
- Provides pre-built data models and processes to standardize data to CDISC SDTM
- Speeds data preparation for medical publications
- Automates migration of acquired data assets through data standards

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sure that data is accurate and consistent. Often companies conduct post-marketing trials and revisit existing data. “Our product has already been FDA approved, but we’ll take additional trials or testing to communicate clearly what we want through messaging,” notes the CEO of one pharmaceutical company. A VP for medical affairs at another firm concurs: “It’s important for us to have access to secondary outcomes for publication purposes. In the US, we cannot promote those, but if it’s truly credible clinical research in highly regarded peer reviews, we have an opportunity to show the value of our products in a different light.”

While the benefits of clinical trials data integration are apparent to both CROs and pharma companies, many firms are finding it difficult to achieve a truly integrated clinical trials system.

### Impediments to Data Integration of Clinical Trials

Interviewees mentioned several reasons for the lack of progress in achieving true data integration, including concerns about budgets, organizational roadblocks and poor strategic direction:

**Focus has been on data storage but not analysis.** Many companies have concentrated on the front end of data integration—processing patient information—without thinking about how to generate reports for analysts and regulators.

“It’s a crude method,” admitted a director of clinical affairs at a mid-sized pharmaceutical company. “We really just use electronic data capture (EDC) for clinical trials. We really don’t have a process where we’re integrating data in a way that different staff can reach.” Many companies are warehousing data, but they are not providing access to generate reports more easily. Data warehouses become dead ends—data gets in but it never comes out.

**Upfront time and costs often seem burdensome.** To some firms contemplating more

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**Fig. 2**

**Old Model of Clinical Trials Data Integration**

The old method of clinical trials data integration was linear. The process made cross-trial analysis difficult to achieve. IT intervention was continually needed to map, clean, aggregate, and validate data.
extensive data integration, the costs and timeframe for systems implementation seem overwhelming. Interviewees estimated an implementation timeframe of three to six months with a $400-500K investment, amounting to about 5-10% of a total research budget. Additional programming to create reports adds time and money and drains resources.

**Cross-functional signoff required.** The final decision on data integration systems requires director-level approval or higher, often a CEO or CMO. Some companies may require approval by the board and investor representatives. For CROs, an additional level of approval by their sponsor clients may be required.

While the medical and technical staff are usually easily convinced that data integration is important, its value to other functions and levels of management is often less apparent.

**How to Achieve the Best Data Integration**

Despite the impediments mentioned previously, some of the interviewees reported that their companies are moving toward better integration of clinical data. Their experience suggests some pointers:

- **Think in terms of evolution—not a Big Bang.** One of the reasons that data integration seems so daunting is that many companies think it requires a one-shot, Big Bang approach. Instead, if data integration is approached incrementally, it’s more likely to succeed. EDC is estimated to be used by 50% of the pharmaceutical industry. While there are many upfront costs, once the investment is made, keep in mind that there are many cost savings through eliminating data re-working and fixing errors, and speeding regulatory submission through data standardization.

- **Pitch the system to a cross-functional team.** True systems integration of clinical trials means that the system is useful to a variety of organizational functions and levels. For example, the pitch...
to medical and scientific staffs is that they could benefit from improved safety monitoring and easier identification of new indications. For the IT staff, the argument is that less coding and error correction would free up their staff for other tasks. And for the finance and operations staffs, access to the system would make reporting on clinical trials easier. Approaching each of these constituencies will help break down the silos that made integration difficult.

Choose a platform that addresses your needs. After figuring out the needs of different stakeholders who might use the system, companies need to decide which platform works best for them. They should consider outsourcing to a host. They should also look at whether the system should be web-based where data is shared via an XML open standard or through a CTIP portal (Clinical Trial Interchange Platform), which can enable integration between trials through multiple databases.

“We take a high-level look at what efficiencies can be created and determine if we have the resources to create those efficiencies or do we need to buy or outsource? Then we evaluate the different provider and their capabilities, pros and con to determine the most cost-effective models. Finally we enter into negotiations with three or four different providers,” said a director of clinical research.

Test for a user-friendly interface. It is important to select a system with a user-friendly interface. “We need to manipulate the reports without having to have the programmers assist us in order to look at the data differently. This would save time and make things work more efficiently,” said an associate director for global R&D.

“It should be graphically oriented where I don’t need programming knowledge or relational data bases,” said a senior director of clinical development.

Data should be customizable. Data should be available with customizable views across a range of departments. “Different departments and different functions should be able to get limited access to data as required by regulations,” said one respondent, the head of statistical programming for North America. While clinical investigators need to remain blinded, the data can still be customized to fit their needs. Other functions should be able to pull data on demand without calling upon programmers.

With these guidelines in mind, CROs and pharma firms can achieve a new model for a fully integrated, seamless and cost-effective clinical trials system and give their firms a competitive advantage in an increasingly challenging marketplace.