

# Foresight

An  
INC Research  
publication

## Q&A with Executive Leadership: How INC Research is harnessing key clinical development trends to better meet customer needs

As we begin 2012, CEO James Ogle, COO Jamie Macdonald, and Chief Business Officer Neil MacAllister preview the company's plans to help transform clinical development programs for our customers through innovation and strategic growth. They provide insightful perspectives on how risk-based monitoring will impact trials, what Trusted Process® 2.0 means, the role of CROs in academic industry collaborations, reflections from 2011 and more.

### James T. Ogle



*James T. Ogle  
Chief Executive Officer*

*James T. Ogle has served as president or CEO of global corporations for two decades, after completing a distinguished military career where he achieved the rank of Lieutenant Colonel, United States Army.*

#### **Q: What are the most important business objectives for the life sciences industry in 2012?**

**A:** Innovation – on many levels – will be the focus for us in 2012. The cost-cutting trend of recent years will be replaced by more innovative and out-of-the box approaches to bring drugs to market while still growing shareholder value. For instance, instead of focusing solely on reducing margins for suppliers and outsourcers, biopharms will be forming more alliances with CROs where both parties can work toward taking costs out of the business.

As biopharms and CROs further establish mutually beneficial incentives and risk-sharing paradigms, we will see increasing innovation not only with new drug development techniques, but also with new ways to reduce overall costs. We are seeing the FDA promote ways to cut costs without sacrificing quality, such as its recent guidance on risk-based monitoring.

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## Q: How is INC Research better positioning itself to deliver on customer needs?

A: We are focused on continuing our growth by executing projects well and closely collaborating with our customers to best meet their evolving needs. To accomplish this, we will continue to build capabilities in three key areas:

### **Operational excellence through the Trusted Process®.**

By significantly reducing variability in clinical trials, our customers benefit from a reduced number of change orders, for example. This also provides a higher level of predictability and enables our customers to better control costs. We are finding our proprietary methodology very valuable when developing successful long-term strategic alliances. In 2012, we will see the development of “Trusted Process® 2.0,” which will raise the standard of quality clinical development. Through our collaboration with SAS, we will be introducing a new set of tools designed to increase decision-making speed, efficiency and flexibility. With new simulation models, we will be able to provide a level of analysis that is beyond anything available in the CRO industry by leveraging our vast amount of historical clinical research data for more accurate analyses and forecasts. Customers will benefit from reduced failure rates and overall costs in both traditional and emerging drug development methodologies, such as accelerated proof-of-concept (APoC).

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### **Increased depth and breadth of therapeutic expertise.**

To better meet the needs of our customers in areas of increasing therapeutic need, we will strengthen our expertise in niche areas, such as vaccines. Likewise, we are actively focused on expanding our service offerings in areas such as post-approval. We remain committed to achieving sustained, organic growth and making key acquisitions in strategic areas to better meet the needs of our customers.

### **Broadened global scale and experience.**

To manage large-scale global trials and focused regional trials, we will be strengthening our global presence in key markets such as Japan, and reinforcing our existing high-quality teams with experienced project and data managers.

## Q: What are you most proud of from 2011?

A: I am very pleased with our successful integrations of Kendle and Trident, along with our customers’ overwhelmingly positive response to the new INC Research. The integration process reinforced a strong sense of accountability at every level and our teams have done a phenomenal job of joining forces to deliver on our customers’ needs. I look forward to leveraging our combined resources and continuing our growth to better meet the needs of our customers in 2012.

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## Jamie Macdonald

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### Q: What are the top trends that will most impact global operations?

A: There will be more focused effort on quality and quality management of global deliverables, such as more thorough due diligence around sites and suitability related to a specific protocol, as well as closer monitoring and scrutiny of data flow.

Another area is cost management around global operations. Questions are being asked regarding the relative costs of conducting trials in different regions and in different countries. Rising fees, entry costs and regulatory timelines in emerging regions may drive overall cost per patient up at a country level.

In response, our customers are asking us to take greater responsibility for overseeing third-party vendor and pass-through costs not directly in our control. We can provide better resources to manage and track the total cost of development, such as clinical supplies, central lab and cold chain management logistics costs. We are well positioned to be good custodians of total drug development spend on our customer's behalf – especially when analyzing costs on a regional or country basis.

Another steadfast trend is better use of data, particularly in a global setting. We have reached a point where there is a good flow of data with IVR/IWR and EDC systems. Now the focus will be on integrating that data into business analytics and intelligence to help our customers make better and earlier decisions around execution. At the back end of a five-year timeframe, we will begin to see how this data integration will support further adoption of adaptive trials.

### Q: What are the new key strategies that INC Research will be implementing in 2012?

A: One of our highest priorities is developing new approaches for risk-based monitoring. We will see a migration away from traditional monitoring, which has been 100 percent focused on source data verification, toward a focus on key areas within the case report form such as study design, patient consent and adverse events – in a more centralized manner. This is a better measure of trial data that accurately and fairly represents the conduct of the trial and the progress of those patients.



**Jamie Macdonald**  
**Chief Operating Officer**

*Jamie Macdonald leads INC Research's operations, as well as its global therapeutic business units, and has more than 15 years' of senior management experience in operational and financial roles in the CRO and biopharmaceutical industries.*

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A targeted effort related to key variables and parameters is designed to yield better results. We will look at how to adopt best practices from GLP, GMP and Lean Six Sigma processes in a collaborative manner. We are developing plans to incorporate the best thinking from key stakeholders – internally and at the customer, site and regulatory levels – and introduce new approaches that improve monitoring through an emphasis on risk and activity.

## Q: What has been most surprising to you in this last year?

A: Maybe not so surprising is the wave of industry-wide consolidation. This has further reinforced the fact that our acquisitions of Kendle and Trident were vital to remain competitive. We've expanded our global reach, therapeutic depth and resources to continually improve our operational excellence via our Trusted Process®, and therefore, provide best-in-class services to our customers. Our focus is on more than winning business and gaining market share. It is about demonstrating that we have high-quality, value-added services and are the right choice as your outsourcing partner.

## Neil MacAllister

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### Q: How have open innovation models changed for drug developers?

A: There is a dynamic happening at the basic research level that is, frankly, complicating open innovation. Traditional drug developers are moving away from discovery in a big way – through reductions in headcount and R&D budgets. At the same time, an increasing number of federal grants for academic research are requiring commercial endpoints. Academic institutions are under pressure to convert grants to patents with commercial propositions before handing them over to the drug industry. In response, “academic industry collaboration” is becoming more pronounced than ever before. Large biopharms are now investing in basic research with universities that have a solid commercialization track record. Institutions are learning how to best leverage these funding sources as they recognize bigger opportunities for return on investment for their research and risk.

### Q: What is the role of CROs in academic industry collaborations?

A: CROs create a bridge between academic science and drug developers. We are well positioned to partner directly with academic institutions to help take compounds beyond the proof-of-concept stage to a more proven entity that drug companies find valuable. Not only can we provide therapeutic and clinical trial expertise, but also the ability to translate between academia and corporations. There is a cultural divide between



*Neil MacAllister  
Chief Business Officer, INC Research  
and President, AVOS Consulting  
Neil MacAllister, founder and President of  
AVOS Life Sciences, has 30 years' experience  
in life sciences with more than half being  
in executive management positions within  
both consulting and pharmaceutical  
service companies.*

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academia's thirst for knowledge and a drug company's thirst for commercial products. They do not speak the same language when discussing preclinical and clinical processes. We understand and can articulate both the science and operational know-how; something they do as normal course of business.

**Q: What are you most looking forward to in 2012?**

**A:** We are really excited to take advantage of what we've created this past year – in a very proactive and strategic manner. Our acquisitions have transformed the position and perception of INC Research in the market. With our enhanced scope and size, we are having very different conversations with drug developers across the board, and have already started discussing co-development opportunities with several major drug development and R&D players.

We look forward to delivering on the needs of our customers and helping them achieve their clinical development goals in 2012.

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For more information about INC Research, as well as insights that can prepare you for 2012's key development challenges, contact us at [info@incresearch.com](mailto:info@incresearch.com).

