Cognizant's Clinical Transformation: More than a Solution, It's a New Way to Work

Introduction
The pharmaceuticals industry is at a turning point. Many prescription drugs are leaving patent protection; getting new patents takes longer than ever before and can cost tens or hundreds of millions of dollars. New federal guidelines are now adding to the complexity by mandating companies proactively review clinical drug trial data to reduce patient risks and improve overall trial performance.

Trial data is at the heart of clinical operations: reviewing it, analyzing it and delivering it to regulatory bodies for approval is essential. But the data is often difficult to access in real time and not readily available in convenient formats. Worse, personnel and processes are often siloed in separate departments. Managing handoffs is challenging.

Our Clinical Transformation solution revamps the clinical trial process with a vision for the Future of Work. It enables teams to view data in real time, optimizing the way they work, while letting them take proactive and adaptive approaches to decision-making while studies are under way. Our solution also transforms communication. It lets teams collaborate virtually and globally, staying connected and informed with social media and mobile communications features.

Clinical Transformation Benefits
Our Clinical Transformation solution delivers an integrated approach that enables operational changes life sciences companies require.

For starters, it can shorten clinical trial cycle times more than 20% due to improved process optimization and utilization of technology. In addition, field monitors spend 60% less time on administrative tasks per visit through built-in remote monitoring processes and technology workflows. What’s more, e-document management eliminates 75% of manual effort in Trial Master File (TMF) management and cuts the time spent on document collection and filing.

Our Clinical Transformation solution also reduces costs. Companies can expect significant cost savings compared with traditional CRO outsourcing models. A company that outsources large numbers of new studies annually can expect to save 40% to 50% on trial costs, according to our benchmarking studies.

Cognizant's Clinical Transformation Solution in Action
To thrive in today’s global market, drug companies need to leverage more innovative ways of conducting clinical trials including remote monitoring and risk-based targeted monitoring, while leveraging proactive decision-making tools and better team collaboration. Moreover, most companies are seeking more cost-effective ways of conducting clinical trials.

We have developed an array of clinical operations services which will transform existing clinical monitoring methods by creating the most efficient processes,
leverage the right people in the right roles, and using technology to enable scale and productivity.

To execute on this vision, our Clinical Transformation solution optimizes operational roles, processes and technology, to deliver remote monitoring and risk-based targeted monitoring that leverages a proprietary cloud-based platform to deliver improved operational efficiency.

**Remote Monitoring**

Centralized and remote clinical trials monitoring is clearly an emerging trend. Initially, these activities were focused primarily on large-scale late phase studies. Today, with increasing opportunity to apply technology and enhance visibility to data, clinical trials are shifting to hybrid monitoring models and risk-based triggered monitoring across earlier phase studies. In our solution, remote monitors collaborate with their field monitor counterparts to shift the burden of administrative support, site support, and data/document management.

However, this model can only be effective and highly efficient with the application of robust technology that creates complete transparency of information and data.

**Key Benefits**

- Enhanced safety quality
- Proactive decision-making
- Better data visibility
- Reduced cost
- Faster time to market
- Improved productivity
Critical Capabilities

and eliminates as many manual processes as possible. We propose that the optimal and most efficient solution is to synergize the end-to-end processes across data management and clinical monitoring processes by ultimately collapsing key roles and to include a robust collaboration technology platform to enable a full and productive partnership between remote monitoring and field monitoring personnel.

Fundamentally, remote monitoring moves many of the tasks associated with site visit preparation and follow-up, as well as routine site management currently conducted by field monitors to regional hubs where remote monitors are responsible for the following:

- Manage critical risk analysis during the clinical trial, monitor metrics, and track performance indicators and trends within and between programs to ensure proactive decision making and reduced operational risk.
- Monitor quality indicators and alert teams to proactively address and ensure compliance.
- Leverage improved processes to reduce cycle time for query resolution and database lock.
- Shift administrative field monitor tasks from field monitors to remote monitors in our global hubs. This leaves field monitors with more time to spend on source data verification and site relationship management.

Risk-based targeted monitoring and reduced source data verification monitoring offers the following benefits:

- Addresses regulatory guidance on risk-based monitoring plans.
- Leverages proactive analytics, industry benchmarking, proprietary algorithms, key risk indicators and leading metrics to highlight risk factors to mitigate risk, drive higher quality monitoring and reduce operational cost.

Cloud-based Hosted Process

Our Clinical Transformation solution leverages cloud-based hosted process and technology platform to enable remote and risk-based monitoring. This includes:

- Portals with integrated role-based data visibility and leading indicator dashboards that improve real-time data visibility of global virtual teams.
- Key risk indicators and data insights for real-time decision making.
- Workflows, alerts and automation to deliver actionable resolution of risk issues to support risk-based monitoring and adaptive operations.
- Mobility solutions for field monitors.
- Electronic trial master file and electronic site files; integration with document management.
About Cognizant

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world’s leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work.

With over 50 delivery centers worldwide and approximately 150,400 employees as of September 30, 2012, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at www.cognizant.com or follow us on Twitter: Cognizant.

Contact Us

The answer to your company’s challenges is transformation, not incremental solutions. Our clinical solution transforms clinical trials by bringing together people, processes and products. It leverages data to create a smart, decision-making environment.

Real transformation requires real change. Contact us at inquiry@cognizant.com and let us show you how your company can achieve both.

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