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Deploying Best Practice Functional Teams to Improve and Sustain Productivity in the Clinical Development Process

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Biotechnology and pharmaceutical companies continue to face increasing pressure to improve and sustain productivity—reducing the cost and effort of bringing a drug or device through development. Improved productivity is needed to counter the pricing, patent and a relative lack of process innovation within the clinical development organization. Many downstream research and development (R&D) functions, such as manufacturing and inventory management, have matured into lean processes and can attribute “outsourcing [as] the final frontier of operational improvement;” (APQC Consortium Benchmarking Study-Best-Practice Report, 2005) however, when applied to all clinical R&D functions across an organization, traditional productivity drivers fail to provide the necessary momentum to improve and maintain high levels of productivity. To achieve sustainable productivity gains, processes and functions must be separated into core, clinical functions versus non-core, non-clinical functions and clear practices must be established to increase R&D productivity. Alternatively, “fundamental discovery” functions and “continuous improvement” functions

need to be separately identified and addressed because the former are not scalable functions. (Garnier, 2008) Contract management, regulatory document processing, document management and site payment administration are key non-core, non-clinical functions that can be industrialized in the clinical development organization.

The challenge of sustained productivity has organizations doing everything they can to create a more innovative environment that is commonly seen in smaller, biotech organizations. Mergers are used to create energy that can be used to make larger organizational changes. (Owens, 2007) Moves toward focused business units and/or therapeutic areas allow another level of specialized expertise. It is argued that, “The way to solve the productivity problem is not to break up the pharmaceutical giants into smaller companies. It is to return power to the scientists by reorganizing R&D into small, highly focused groups.... It is to fix broken processes and promote a strong culture of innovation marked by a passion for excellence and an awareness that results matter.” (Garnier, 2008) Each of these attempts to force innovation, typically, is driven by an executive mandate to refocus or reset corporate, departmental or therapeutic unit goals. (Cohen, 2003) Even with strong executive backing, most of these organizational changes, alone, achieve only fleeting operational (and hence, short-term financial) (Rippy, 2007) gains which do not lead to sustained productivity. Because the clinical development organization has not been a place that spurs process innovation, the focus should be on scrutinizing the functional, non-core processes where a true culture of continuous improvement can be built in an industrialized fashion through well defined practices that promote sustained productivity.

Functional, non-core processes are the only true processes within a clinical development organization that are scalable. This is due to the fact that (1) tasks within a function can be specialized, (2) processes can be standardized regardless of therapeutic area, and (3) a centralized, shared services approach opens allows for better resource utilization. In most non-core functions, a biopharmaceutical can leverage the best available expertise, technology and delivery model to lead to year-on-year productivity gains. Investments made in improving non-core functions, are presumed to lead to smaller cost reductions; however, non-core functions performed by subject matter experts in a shared services delivery model can lead to 30-40% direct cost savings (e.g., labor associated with the functional tasks) and even larger indirect cost savings (e.g., improvement in quality to the point that secondary reviews are unnecessary and staff can be reassigned to other projects), depending on the size of the organization. When applied to a portfolio or pipeline of work, this cost savings has a tremendous impact.

The best-practice R&D organizations have clear policies and practices aimed at increasing productivity. In short, they (1) “adopt long-range visions”, (2) “structure the product development process”, (3) “have uniform, periodic reports of metrics”, (4) engage in “competitive analysis”, (5) develop a “future-oriented focus”, and (6) dedicate staff to own the service development process”. (APQC Consortium Benchmarking

Study-Best-Practice Report, 2005) A business process outsourcing (BPO) approach provides a solid delivery model for each of these practices aimed at increasing R&D productivity. For each of the best-practices, BPO offers a solution:

- Engagements are long-term allowing for incremental productivity improvements to build upon each other over the course of time.
- Each function runs the same structured process across all studies, allowing for standardized training and management that results in efficiencies captured by reduced cycle times.
- Due to a higher volume running the standardized process, metrics are aggregated and support trend analysis and targeted training initiatives that improve quality.
- Companies initially evaluate the best-in-class functional provider and can easily compare functional results with competing firms.
- A proactive, continuous improvement mindset is created within the team and innovation is a function of all team members, as they know their improvements will be applied to the next study.
- Functional teams become an extension of the biopharmaceutical customer where they are accountable for all aspects of a particular function.

Because “productivity is a lagging indicator” (Owens, 2007) in clinical development organizations, it is helpful to employ a BPO-style model that delivers non-core functions in long-term, high volume shared services in order to build a process that operates with improved and sustained productivity. The functional operations of the process are second nature to the dedicated team; therefore optimizing the process becomes the primary objective in this type of delivery model. Applying Six Sigma or other improvement methodologies such as “Plan-Do-Study-Act (PDSA)” (Institute for Healthcare Improvement) can create both large and small wins that are magnified across the portfolio. The results are the creation of innovative and nimble functional units that offer best-in-class service to all study teams across the entire company’s portfolio. The development of these functional teams with a focus on continuous improvement will be the backbone that supports improved and sustained operational productivity for the long term within the biopharmaceutical industry.

INC Research has established process-driven and industrialized FSP teams that operate across all therapeutic areas. These dedicated teams are hubs of continuous improvement that not only provide delivery of the particular industrialized function, but also consultative advice on our customer’s process, key performance indicators and subsequent analytics that drive on-going efficiencies. INC Research has a global team of contract and investigator site relationship professionals, supporting company-wide operations of contract management functions and Functional Service Provider (FSP)/Business Process Outsourcing (BPO) shared site start-up services in North America, Europe and Asia.

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