

The Clinical Development Practice at Campbell Alliance

Success in clinical development is key to the long-term success of pharmaceutical and biotech companies. Today, however, the size and complexity of clinical programs are increasing disproportionately faster than available resources. To succeed, clinical organizations must find new, more efficient ways of operating.

That requires reviewing (and often revamping) current work processes, organizational structures, and technologies. Our clients are clinical development leaders that are seeking a partner to help improve the efficiency and effectiveness of their operations. They need experts to help drive change initiatives so that their key staff can remain focused on producing clinical results.

Our Clinical Development Practice is composed of operations improvement specialists who are also experts in clinical development. We have the expertise to serve as an extension of our clients' clinical development leadership teams and the focus to drive major change initiatives to completion as quickly as possible.

For example, our clients retain us to help lead their electronic data capture (EDC) initiatives because they

- Understand that for EDC to bring real benefits, the organization must fundamentally alter the way it works from a paper-based, serial approach to an on-line, parallel approach
- Know that redefining their working processes will require significant effort, but the internal staff who are most qualified to lead that effort are also the ones who are most pivotal to ensuring the success of ongoing studies and can't spare the time or resources
- Take advantage of our expertise to support their EDC initiatives, allowing their key internal staff to be involved only when their guidance is essential

Clients cite similar reasons for partnering with Campbell in many of their most important change initiatives, including

- Re-engineering the protocol design and development process
- Creating more effective outsourcing, project management, and vendor management processes
- Leveraging new technology and processes in data collection and management
- Revising the organizational structure to take advantage of improvements in technology, enhancements of roles, or better geographic distribution

Our clinical development experts have seen numerous tools, processes, and methods for improving clinical efficiency through their work as consultants, as well as their previous experiences working in leading pharmaceutical companies, CROs, and other related organizations. As a result, they have developed a keen awareness of what actually works and what doesn't.

The following outlines our Clinical Development Practice's service offerings:

Electronic Data Capture

- Develop EDC business cases and strategies
- Assist with EDC system selection
- Redesign clinical processes to maximize the benefits of EDC solutions
- Design EDC implementation plans
- Develop and help execute EDC training and rollout plans

Improved Operational Efficiency

- Assess operational processes to identify opportunities for improvement
- Re-engineer operational processes to improve efficiency
 - Data flow management
 - Patient enrollment
 - Protocol design and development
 - Site initiation and activation
 - Site performance
 - Site relationship management
 - Training initiatives and program management
 - Publication planning and implementation
- Develop metrics to help measure, track, and manage key processes

Strategic Change

- Assess corporate strategies, anticipate the demands that will be placed on the clinical organization, and determine how the organization should plan to meet those demands
- Design new clinical development functions from the ground up
 - Organizational size and structure
 - Roles and responsibilities
 - Tools and technologies
 - Processes
- Strategically improve, expand, or refine existing clinical organizations
- Develop or improve outsourcing strategies and approaches

About Campbell Alliance

Campbell Alliance is the leading management consulting firm specializing in the pharmaceutical and biotechnology industries. The firm's clients include most of the world's "top 20" pharmaceutical companies, as well as numerous emerging and midsize firms. Campbell Alliance is organized into practice areas, each specializing in a critical industry function, including Brand Management, Business Development, Clinical Development, Managed Markets, and Sales. From its locations in Raleigh, N.C., Parsippany, N.J., Woodland Hills, Calif., South San Francisco., Chicago, and New York City, the firm serves clients throughout North America, Europe, and Japan.

For more information please contact:

James Forte

Public & Media Relations Manager
Campbell Alliance
Office: 919-844-7100 x7195
Fax: 919-844-7560
Mobile: 919-961-4066
jforte@campbellalliance.com
<http://www.campbellalliance.com>