



## Ascendant Technology Solution for Clinical Trial Disclosure

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### Partner Solution

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■ **Target Industries**

*Industrial Products  
Life Sciences*

■ **Business Application**

*Clinical Trial Registry*

■ **Products**

*IBM FileNet Business Process  
Manager  
IBM FileNet Content Manager*

### Business Challenge

Due to new legislation and in response to public and regulatory concerns raised in recent years, pharmaceutical and biotechnology organizations, as well as medical equipment companies, must disseminate information on clinical trials. This information must be made available to the general public on registries such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org)

As a result, the top 15 biopharmaceutical companies have spent an estimated \$50-70M on Web-based initiatives to publicize active and completed trials since April 2004. Not only is this effort costly, it is also time- and labor-intensive. To maintain compliance, organizations need to acquire historical information on past trials as well as maintain information related to ongoing trials. They must comply with strict Food and Drug Administration (FDA) guidelines in conjunction with the International Committee of Medical Journal Editors (ICMJE) and the Pharmaceutical Research Manufacturers Association (PhRMA), as well as international and U.S. state mandated requirements.

Aside from the need for support of these legally mandated activities,

there is a need to support similar requirements supporting different yet equally important objectives. Innovative companies have begun realizing the importance of facilitating and managing additional business outcomes by creating their own clinical trial registries. In particular, the recruitment of subjects and doctors for clinical trials and post marketing studies is critical and requires pharmaceutical, biotechnology and medical equipment companies to use and create any competitive advantage that may be available. Additionally, given the recent increase in post marketing studies being conducted following FDA approval, pharmaceutical companies, clinics and hospitals need solutions to assist in the management of data collection and reporting processes.

### Solution

Ascendant Technology's Solution for Clinical Trial Disclosure is a Web-based, secure, password accessible content management system designed to provide life sciences companies with their own clinical trial registry portal and support submission of required clinical trial results to third-party sites. Leveraging IBM Enterprise Content Management (ECM) suite of products, the solution features an easy



to use and friendly interface which captures clinical trial results and helps manage overall data flows across inter-departmental organizations of the pharmaceutical and biotechnology industries.



The solution is designed to support:

- Late Phase Clinical Trial Registries (i.e., Phase III – IV)
- Outcome Registries/Post Marketing Studies
- Clinical Trial Portals (e.g., publicly accessible clinical trial portals)

The solution offers multi-level authentication for access control. Sponsors can remotely manage their own trial results and protocol summaries. Full reporting functionality allows users to view activity and status per summary listing. Additionally, the solution allows for backup and storage on sponsor-operated servers.

### Value Proposition

The solution enables organizations to:

- Improve document management processes across disparate geographical regions;
- Eliminate the need for data quality and collection efforts across global trial sites;
- Improve overall communication efforts from study sites and integrate with marketing initiatives;
- Improve compliance with the International Committee of Medical Journal Editors (ICMJE) and the Pharmaceutical Research and Manufacturers of America (PhRMA) by streamlining data compilation and submission efforts; and,
- Support global protocol registry and results data bases.

As a result, organizations leveraging Ascendant Technology's solution can achieve greater transparency in the clinical trial process and improved accessibility to the general public. The solution promotes more effective recruitment of both patients and doctors to clinical trials and post marketing studies.

### Company Description

Ascendant Technology, an IBM Software ValueNet Partner, helps organizations both large and small achieve the flexibility and responsiveness business demands from technology investments. Our combination of business acumen and deep technical expertise provides insight for our customers to solve business problems and drive business innovation. To learn more, please visit us at [www.atech.com](http://www.atech.com)

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