INDUSTRY SOLUTION

An Agile Aggregate Spend Compliance Solution
for the Biopharmaceutical, Medical Device, and Medical Supply Industries

CAMBRIDGE SEMANTICS

SEARCHLIGHT COMPLIANCE ADVISORS

Introducing an Agile Aggregate Spend Compliance Solution

As a result of the February 2013 release of the Center for Medicare & Medicaid Services' Final Rule, many biopharmaceutical, medical device and medical supply companies are implementing aggregate spend solutions to capture and report on direct or indirect payments and transfers of value to physicians for promotional, medical research or investment reasons.

Stakeholders at affected companies are scrambling to quickly put into place a system that meets the bare minimum data aggregation and reporting requirements. But the bare minimum is not enough. Instead, affected organizations should look for a solution that allows them to mine, analyze, and reuse compliance data, in order to transform this cost center into a value-add solution for staying ahead of the competition. Moreover, basing a compliance solution on an agile data management platform that can easily adapt to new data requirements allows organizations to future-proof their solution to the ever-changing regulatory environment.

For these reasons, Cambridge Semantics has joined forces with Searchlight Compliance Advisors to jointly design and deliver a solution that not only allows companies to rapidly comply with current federal and state compliance reporting requirements, but also to do so in a way that allows flexibility and adaptability over time to the ever-changing expectations of policy makers and other internal and external industry stakeholders. By leveraging Cambridge Semantics' award-winning Anzo software suite with the compliance design and deployment operational insights of Searchlight Compliance Advisors, participating companies will be able to:

The Value of an Aggregate Spend Solution

- ♦ **Future-proof against regulatory changes**
- ♦ **Automate tedious data gathering**
- ♦ **Incorporate and investigate new data sources as needed**
- ♦ **Reuse data and findings to improve sales spend ROI**

- Reduce the time and effort required to gather, curate, analyze, and report on aggregate spend data so that more attention can be focused on ensuring data quality and meeting reporting deadlines for federal and state reporting requirements;

- Leverage compliance data from a variety of structured and unstructured sources, enabling:
  - ◊ analysis of rich and robust data sets that can be used to answer both fixed and ad-hoc spend questions for internal and external audiences
  - ◊ identification of compliance outliers requiring company action, and
  - ◊ highlighting spend trends that require attention at either the brand management or sales management level

- Rapidly anticipate and respond to changes in the regulatory environment and to new data requirements without additional costly investments in infrastructure or new systems;

- Deploy always up-to-date analytics, dashboards, alerts, and workflows tailored to the needs of policy makers, regulators, physicians, patients and internal stakeholders; and

- Accommodate additional categories of spend above and beyond those required for legal or regulatory reporting purposes, enabling an even more comprehensive examination of total spend practices to identify those investments that make the most sense from a cost or ongoing return-on-investment perspective.

About Cambridge Semantics' Anzo Software Suite

Cambridge Semantics' award-winning Anzo software suite allows companies to aggregate, analyze and report on compliance data either behind their firewalls or in a secure, private cloud. Anzo is a Unified Information Access platform that lets companies combine data residing in their own databases, documents and spreadsheets with external sources of data (either public or proprietary 3rd party sources). Anzo aggregates and harmonizes diverse data to produce curated and customized dashboards, analytics, alerts and operational applications to solve business needs.

About Searchlight Compliance Advisors' Approach to Compliance

Searchlight Compliance Advisors specializes in providing a full-range of life sciences compliance consulting services to monitor, support and assess our clients' compliance programs and activities. We have extensive knowledge of the biopharmaceutical and medical device industries and the associated legal, regulatory and voluntary industry compliance requirements. Our experience has shown that while the rules and regulations may be consistent across organizations, there are no "cookie cutter" solutions that work for every client. A robust compliance program is about more than just a rules-based system focused on specific laws and regulations. It is a foundation of solid business practices and self-regulatory processes that can make your organization stronger. We are committed to working with our clients to provide compliance services that are:

♦ Aligned with the corporate vision and objectives of the organization;

♦ Structured appropriately to fit the size and activities of the organization; and

♦ Capable of rapidly adapting to change due to internal and external forces.

The Compliance Data Challenge

Biopharmaceutical, medical device and medical supply companies are facing pressure from a variety of stakeholders regarding disclosure and transparency of financial payment information:

♦ *Company management, employees and investors* who want their companies to grow and provide a sustainable return on investment while ensuring appropriate internal financial controls are in place to safeguard earned profits and guarantee compliance with appropriate state and federal laws and accepted industry practices;

♦ *Federal and state lawmakers and regulators* who want to ensure industry promotional, medical education and clinical research expenditures are not unduly influencing physician prescribing behavior;

♦ *University and teaching hospitals and physician purchasing organizations* who want to ensure that their employee physicians are maintaining their professional obligations with their employers while receiving appropriate, above board and necessary industry support for research and educational programs;

♦ *Physicians* who want to have a clearer picture of how transparency requirements impact their individual and group practice of medicine. Physicians also must ensure continued financial support for important clinical research and medical society activities, as well as for providing physician, patient and community education that helps them stay current with evolving treatment guidelines and therapeutic options; and

♦ *Patients and caregivers* who want to know that their attending physicians are making appropriate treatment decisions based on relevant data and prevailing clinical experience and not just on personal financial considerations.

Key Compliance Data Stakeholders

♦ *Investors*—seeking risk-protected revenues

♦ *Regulators*—enforcing compliance

♦ *Physicians*—continuing education in current therapeutic best practices

♦ *Patients*—demanding data-driven care without undue influence

Is it any wonder that these industries are struggling to identify solutions that meet the competing information demands from so many interested parties? As a result, many companies have taken the practical approach of implementing solutions that do nothing but satisfy the minimum current state and federal reporting requirements. While this is necessary for legal compliance and is a laudable goal in and of itself, some leading companies are realizing that the compliance landscape will continue to evolve over time and that current solutions cannot be easily reconfigured in the future without significant additional investment of time and money. They recognize that it would be prudent to invest now in a compliance aggregate spend management solution that can scale easily over time with increases in scope and complexity as regulatory requirements change or become more rigorous.

“*Is it any wonder that these industries are struggling to identify solutions that meet the competing information demands from so many interested parties?*

Designing a Flexible and Adaptable Compliance Solution

An effective compliance management solution must take into consideration a wide variety of structured and unstructured data elements that reside across many different data sources. These sources differ in data structure, data format, and in the presence or absence of any robust data management procedures. Consider the extraordinary diversity of data elements that companies capture for internal and external use and reporting:
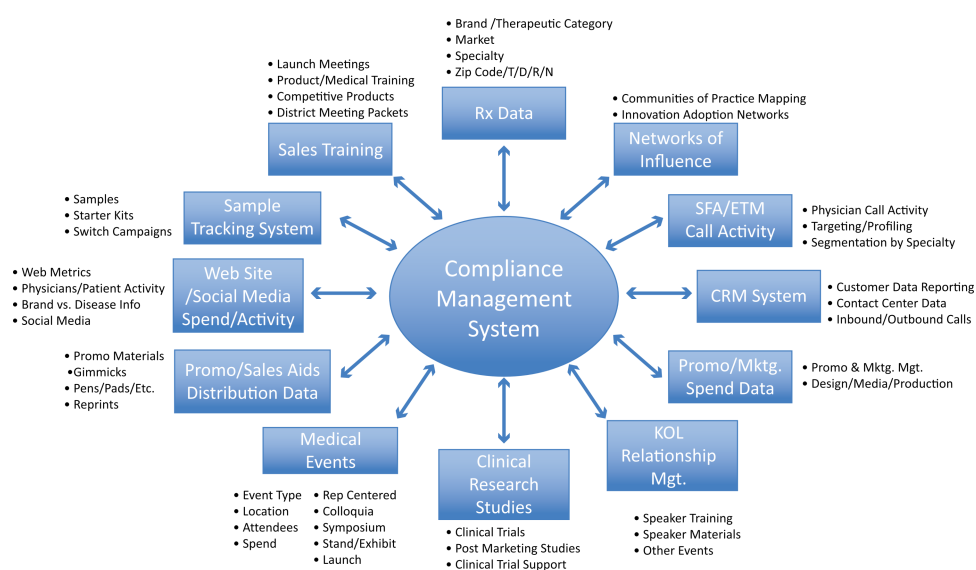
While federal and state disclosure and transparency rules do not require companies to report on all these elements, leading companies recognize that many of these elements will need to be utilized in full or in part in order to create complete and accurate reporting on the physician payment sunshine provisions. A strategic compliance solution must therefore be able to aggregate all these elements into one easy-to-use interface that facilitates the analysis and reporting of spend transparency data.

> " *Leading companies recognize the strategic need to aggregate diverse data elements into one easy-to-use interface that facilitates analysis and reporting of spend transparency data.*

This flexibility and adaptability are the key benefits of compliance solutions from Searchlight Compliance Advisors and Cambridge Semantics. Together, we can identify the necessary data elements and then use the Anzo software suite to aggregate, analyze and report on the necessary compliance data. The next section briefly details how we can accomplish this in concert with your organization.

Implementing a Tailored Aggregate Spend Solution for Your Compliance Organization

Developing a tailored compliance aggregate spend solution begins by identifying the scale and scope required of your compliance reporting effort. Design and implementation of the solution proceeds in four stages:

1. *Needs/Gap Analysis:* Searchlight Compliance Advisors conducts a comprehensive needs and gap assessment in conjunction with different areas of your organization (Regulatory/Compliance, Sales/Marketing, Medical Affairs, Clinical Research, Finance, IT, etc.) to determine your current and future state of compliance policies and procedures, the locations, formats, quality and extent of your compliance data holdings and the extent of data analysis and reporting required to meet Federal and State Disclosure and Transparency requirements.

2. *Customer Solution Design:* Searchlight Compliance Advisors develops detailed business requirements for your compliance data management solution and shares these with Cambridge Semantics so that we can jointly work with your IT organization in an iterative fashion to create your solution using the Anzo software suite. The solution is driven by an ontology, a comprehensive semantic model of all compliance concepts and relationships of interest. Anzo allows your company to map any source of information – internal spend compliance databases,

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4 Steps to an Agile Aggregate Spend Solution

1. **Identify compliance needs & gaps**

2. **Map _any_ source of information to a common conceptual model**

3. **Search, query, & analyze the data as needed**

4. **Easily adapt the solution as regulations and strategies evolve**

customer relationship management systems, sales force automation solutions, ad-hoc spreadsheets, presentations, web pages, literature and more – to this ontology. Given our extensive compliance experience, Searchlight works with your organization to provide the compliance taxonomy and subject-matter expertise used within Anzo to harmonize the data as it comes from diverse sources.

3. *Solution Implementation:* Once the data has been combined from various sources, the Anzo software suite provides tools to search the data, manage and curate the data, define the necessary analytics and spending thresholds that can identify emerging trends and insights, answer ad-hoc queries from internal and external stakeholders, generate reports with the desired frequency (daily, weekly, monthly, annually), and to create interactive executive dashboards that showcase the most relevant and necessary data for decision-making and strategy formulation.

4. *Manage & Adapt:* The ease of use and flexibility of Anzo compliance solutions allows you to easily adapt the solution for compliance policies and procedures in response to changes in the legal and regulatory landscape. Meanwhile, Searchlight Compliance Advisors provides audit, process enhancement and benchmark support while Cambridge Semantics provides ongoing technical support and upgrades for the Anzo software suite.

Consider a practical example of such an aggregate spend solution in action. Suppose you want to improve your organization's ability to track and respond to spending limits set for a series of speaker programs sponsored by your brand teams. These speaker programs are administratively executed by your field sales organization, are led by specific key opinion leader speakers who are paid honoraria, and require you to enforce per-attendee spending limits.

> **"** *Harmonize data from internal spend databases, CRM systems, sales force automation apps, spreadsheets, presentations, web pages, literature, and more.*

> **"** *Interactive executive dashboards showcase the most relevant and necessary data for decision-making and strategy formulation.*

A compliance solution from Cambridge Semantics and Searchlight would connect together spend data from a variety of accounting, customer relationship management and expense reporting systems at both the corporate and field sales management levels. Compliance officers would then set compliance spending thresholds that could be proactively tracked by territory, speaker program, KOL speaker and individual physician attendee. The solution would also support setting up both proactive alerts and periodic standard reports that will enable rapid response by your compliance organization to emerging trends or issues needing immediate attention.

Realize Immediate Value & Benefits

Simplified Compliance with Federal and State Requirements

Rather than spending a lot of time manually gathering, inputting and combining disparate pieces of data in order to satisfy compliance requirements, you can let the Anzo platform do the heavy lifting of data aggregation so you can focus your energies on ensuring proper spend data quality and meeting the federal and state compliance reporting deadlines.

Ability to Identify Compliance Outliers and Trends

Since the Anzo solution presents the data in quick and easy-to-read visual summaries, you can quickly identify physicians who are approaching preset thresholds, territories or districts that may require increased or decreased investment, and spend trends for certain brand teams within your company that may need to be addressed.

On-the-fly Adjustments to New Compliance Requirements

As regulatory bodies gain more familiarity with transparency data disclosure, it is likely that they will continue to ask for additional analyses and reports on areas of interest, and some additional regulatory requirements may also be imposed. The Anzo compliance solution allows your company to rapidly adapt to new requirements and ad-hoc requests for information without having to make additional costly investments in new systems or infrastructure.

Key Value & Benefits

- **Reduce manual compliance effort and costs**
- **Proactively identify potential compliance issues**
- **Quickly ensure compliance with changing regulations**
- **Distribute customized spend reports to various stakeholders**
- **Combine spend compliance data with other data to improve marketing & sales performance**

Streamlined and Automated Information Distribution

The Anzo solution allows you to set up workflow and automated reports at predetermined frequencies so that all interested parties can receive their required information exactly when they want or need it and in the format they require.

Measure and Analyze Marketing and Sales Effectiveness

The solution also accommodates the aggregation of additional internal spend and market performance data to help companies readily identify if marketing and sales programs are cost-effective.

A Broader Perspective

No matter how biopharmaceutical, medical device and medical supply companies view the physician spend transparency requirements, the fact remains that data transparency promotes fairness and ethical business practices. In the mid-to-long term this emphasis should benefit companies by helping improve public perception, even if in the near term they may create the potential for public-relations challenges. Since all companies have to report this spend information, it is likely that they will all pay more attention to marketing and sales practices that in the past have given some companies an unfair advantage in the marketplace.

In addition, as companies become more familiar with analyzing and reporting their levels of promotional and marketing spending, they may begin to question whether or not these investments are having the desired effect. Use of the solution described in this paper to aggregate spend data will enable companies to analyze whether or not massive investment in sales force visits, samples, promotional materials, speaker events, and other programs are having the desired impact on the market. This analysis may lead to changes in promotional and marketing budget allocations and perhaps even the development of predictive models that can anticipate changes in spending and their resultant impact on product usage.

To Learn More

Contact Cambridge Semantics:

information@cambridgesemantics.com
http://www.cambridgesemantics.com

Contact Searchlight:

info@searchlightcompliance.com
http://searchlightcompliance.com

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ABOUT CAMBRIDGE SEMANTICS

Cambridge Semantics provides the award-winning Anzo software suite, an open platform for building interactive Unified Information Access (UIA) solutions.

Enterprises face an increasing need to rapidly discover, understand, combine, and act on data from diverse sources both from within and across organizational boundaries. Anzo makes it easy for both IT and end users to deal with this need by rapidly creating solutions that leverage unified access to structured and unstructured data from varied sources in the context of specific business problems.

ABOUT SEARCHLIGHT COMPLIANCE ADVISORS

We are experienced healthcare compliance professionals who help our global pharmaceutical, vaccine, medical device, diagnostics, nutraceutical and biotechnology clients better understand and take action on the federal and state compliance requirements (legal/regulatory/voluntary industry) and technologies impacting their commercial and R&D business operations. We focus on providing practical and comprehensive compliance solutions and programs for the challenges our clients face every day.