LEGAL & REGULATORY EXPERTISE FOR THE HEALTHCARE & PHARMACEUTICAL INDUSTRY

INFORMATION GOVERNANCE, DATA PRIVACY & E-DISCOVERY

EXPERTS WITH IMPACT™
AN INDUSTRY IN TRANSFORMATION

Increasing data privacy regulation, compliance monitoring requirements, M&A activity and the use of modern technology have transformed the Life Sciences industry - exposing great potential and even greater information management risk.
$1,204.8 billion
Revenue of the global pharmaceutical market in 2018

Up to 4% of global annual revenue
Potential fine for a data breach under the GDPR

$3.86 million
The average cost per data breach in 2018

36%
The annual growth rate in healthcare data through 2025

69%
The percentage of corporate information with no legal or business value

200+
The number of regulatory authorities overseeing healthcare and life sciences companies worldwide

400+
The number of healthcare and pharma companies with Corporate Integrity Agreements with the Department of Health and Human Services

$200 billion
The amount of life sciences and pharmaceutical M&A activity in 2018

Source: Statista article: “Global Pharmaceutical Industry - Statistics & Facts” by Matej Mikulic, August 27, 2018

Source: Article 83 of GDPR: “General conditions for imposing administrative fines”

Source: IBM and Ponemon Institute Research study: 2014 Cost of Data Breach Study: United States, 2018

Source: Health IT Analytics article: “Big Data to See Explosive Growth, Challenging Healthcare Organizations” by Jessica Kent, December 03, 2018


Source: Parenteral Drug Association Regulatory Resources: Global Regulatory Authority Websites

Source: U.S. Department of Health and Human Services OIG: Corporate Integrity Agreement Documents, July 10, 2019
Typical Client Concerns We Address

Legal, compliance, data privacy and IT personnel are increasingly challenged with complex questions.

“We need to develop, implement and/or refresh data privacy programs like CCPA and GDPR.”

“We are going through M&A activity and need project management support for legal, IT and Integration Management Office (IMO) teams.”

“We have a Corporate Integrity Agreement and need support to coordinate data collection from business systems and review for compliance monitoring.”

“We have back-up tapes and email archives that may not need to be kept for legal, regulatory and business reasons.”

“We have been thinking of replacing our legal hold system for the last two years but it keeps getting pushed due to a shortage of in-house resources.”

“We need a smart Information Governance framework for a unified approach to data privacy, e-discovery and compliance.”

Table of Contents:

- Information Governance Page 6-7
- E-Discovery Services Page 8-9
- IG/Legal Integration (M&A) Page 10-11
- Data Privacy Page 12
- Corporate Integrity Agreements Page 13
Why FTI Consulting

As an award-winning global consultancy firm, FTI has extensive experience supporting challenging engagements with large data volumes, complex workflows and short timelines. Our team is adept at building solutions around diverse health industry regulations in the United States and internationally. As a result of our years of experience in supporting large-scale projects for healthcare and pharmaceuticals, we have developed defensible methodologies for managing projects and meeting critical deadlines.

FTI has a wide range of flexible production capabilities. From small engagements around specific regulations to ongoing managed services, we work closely with in-house legal, IT and compliance teams to meet the production requirements and specifications of the various agencies.

- **Founded in 1982** and $2.9B equity market capitalization
- **With 4,600+ employees and offices in 27 countries** on six continents, our breadth and depth extends across every major social, political and economic hub around the globe
- **Expertise across a range of industries**: Real Estate, Energy, Power & Products, Financial Institutions, Healthcare & Pharmaceutical, Retail & Consumer and Telecom, Media & Technology
- **53 of the Global 100 corporations are clients**

---

8 Number of total shares outstanding as of July 2018, times the closing share price as of July 27, 2018.
Reducing Cost and Risk with Information Governance

As data grows in size and complexity, we help organizations better govern, secure, find, analyze and rapidly make sense of information.

**DATA PRIVACY ADVISORY**
Data privacy assessments, program implementation, Data Subject Access Request (DSAR) solutions

**LEGAL INTEGRATION MANAGEMENT OFFICE (IMO) FOR M&A AND DIVESTITURES**
Expert project management, identification of data systems and custodians for ongoing preservation, integration and segregation of business systems and data

**INFORMATION GOVERNANCE CENTER OF EXCELLENCE (COE)**
Data mapping, IG policy and frameworks, HIPAA compliance

**CORPORATE INTEGRITY AGREEMENT SUPPORT**
Collection, review and monitoring of email, audio and video files, text messages, IMs, and data from business systems

**LEGAL HOLDS**
System selection, implementation, hold migration, change management

**SECONDMENTS & EXPERT STAFF AUGMENTATION**
IG, privacy and discovery specialists for stop-gap, overflow work and long-term needs

**OPTIMIZATION OF MICROSOFT OFFICE 365 APPLICATIONS**
Data migration and preservation, collection workflows for Microsoft O365 email, One Drive for Business, Teams, SharePoint, Yammer and more

**DATA REMEDIATION & DEFENSIBLE DISPOSITION OF DATA DEBRIS**
Backup tapes, legacy email and systems, business apps, file shares

**RECORDS RETENTION TECHNOLOGY AND POLICIES**
Defensibly refresh records management policies and implement new technologies
Reduce Data Footprint and Future Risk at BCBSNC

The Information Governance team at Blue Cross Blue Shield North Carolina (BCBSNC) sought to provide greater visibility into corporate data stored on its various networks, as well as on the numerous SharePoint websites within its environment.

**SOLUTION**
FTI’s team created a custom content management solution leveraging best-of-breed technology. This new tool allowed FTI Technology to:

- Systematically split up the client’s data into smaller, more manageable case files;
- Conduct parallel processing on multiple servers simultaneously, assigning different jobs to each one for faster data output;
- Perform security scans to identify hidden and secure folders.

**IMPACT**
Forty-three terabytes of data was indexed, allowing BCBSNC to assign security protocols and ready the healthcare network for any future legal challenges.

As the data footprint grows larger, sophisticated tools and methods are required to manage information. The partnership between FTI Technology and BCBSNC continues to mature with tools and methodologies to provide further analysis, identify useless data, and keep indices up to date. FTI Technology’s experience and custom solutions play a key role in supporting BCBSNC’s efforts to efficiently manage their data.

Defensible Disposal of One Billion Emails

A global corporation sought to create an email classification system that would remediate more than one billion legacy emails and automate ongoing and defensible disposal – while maintaining legal hold requirements.

**SOLUTION**
The FTI Technology team created a step-by-step playbook to address the problem including:

- A robust classification model across 140 record categories;
- A file plan that defined records categories with retention periods and risk levels;
- Advanced analytics and e-discovery software.

**IMPACT**
The company achieved successful data remediation and defensible disposal across a set of more than one billion emails. Additionally, they identified a cost savings of up to $10 million by disposing of 750 million emails. Finally, automatic retention and deletion rules were enabled across the entire email population, achieving ongoing regulatory compliance.
FTI Technology has extensive experience collecting and analyzing data within the health industry. One of FTI Technology’s specialties is working with corporate clients to create e-discovery playbooks that meet the client’s needs. These playbooks can cover anything from standard processing and exception handling specifications to standard workflows leveraging analytics early to reduce document populations and the total cost of discovery. FTI Technology’s global experts are deeply familiar with healthcare and pharmaceutical data types and are well versed in the production requirements in this highly litigious industry.

DATA COLLECTION & FORENSIC INVESTIGATIONS
Global forensic collection and investigative services including EMEA and APAC

E-DISCOVERY CONSULTING
Best-of-breed technology, workflow, data re-use, review of process efficiencies and training

E-DISCOVERY MANAGED SERVICES
Project management, overflow staff and services, software management and maintenance

MANAGED REVIEW, INCLUDING FOREIGN LANGUAGE
Advanced software & analytics, expert attorney review teams, innovative workflows, deposition preparation and case theme development

CROSS-BORDER / DATA PRIVACY
International e-discovery services, foreign language review, Data Subject Access Request (DSAR) support for corporate clients and law firms in US and EMEA

ADVANCED ANALYTICS
Powerful visual analytics, analysis of enterprise data from disparate sources

CONTRACT INTELLIGENCE
Pre and post-merger contract diligence, aligning contract terms with emerging regulations, highlighting trends and risks

SECOND REQUEST EXPERTISE
Expert consultations, advanced analytics & predictive coding to meet tight deadlines
Results in Action:

Healthcare Merger Aided in Second Request and Litigation

Two healthcare companies faced two challenges complying with the Second Request investigation and preparing for the impending litigation. When the actual Second Request was issued by the FTC, the company had just 60 days to respond.

**SOLUTION**

FTI Technology provided a deep bench of experienced analytics review lawyers to research the data for the post-Second Request litigation. This enabled counsel to find key documents faster and the legal team to prepare deposition and white paper documents earlier.

**IMPACT**

After starting with over 8 million documents, through culling, predictive coding, analytics and privilege review, the healthcare companies produced less than 700,000 documents in total. FTI Technology’s managed review team helped in-house counsel and the law firm achieve substantive compliance as requested, on time, and within budget.

Forensic Data Collection from Mobile Devices

A global client needed to quickly investigate a suspected security breach, which required the collection and review of data from over two hundred of its employees’ mobile phones.

**SOLUTION**

The FTI Technology team’s immediate priority was to design a forensic process which would enable a timely collection and return of all the devices, and the extraction of all the relevant data, with minimal business disturbance. The team supported this with a fully documented, defensible and proportionate process which included clear chain of custody records.

Having collected the data, FTI Technology then converted it for review using software to deconstruct each mobile phone data source into individual messages, call entries, and contacts – a granular level of data which enabled the client to quickly refine review to specific points-in-time and identify where specific phrases, numbers and events were used.

**IMPACT**

As a result, the client discovered all of the information needed to pursue its internal investigation.

Our experts trained the client’s own IT, security and legal teams to be able to quickly and cost effectively undertake further reviews themselves, in full adherence with relevant data privacy laws.
M&A and Divestitures With Legal Integration Expertise

FTI Technology provides Integration Management Office (IMO) support for cross-functional workstreams including legal, IT, HR, compliance, data privacy and other business units. Many of these workstreams, such as merging legal hold systems, separating sensitive document repositories, reviewing contractual obligations and realigning data governance policies, involve a heavy lift. FTI Technology can reduce the burden on in-house teams, improve data governance framework and strengthen the risk posture for the new organization.

- **EXPERT PROJECT MANAGEMENT SUPPORT**
  - IMO support including detailed project plan, coordination with records management, IT, legal, privacy and global stakeholders

- **CONSOLIDATING BUSINESS DATA AND APPLICATIONS**
  - IMO support including detailed project plan, coordination with records management, IT, legal, privacy and global stakeholders, defining Transition Services Agreement (TSA) obligations

- **MERGING AND MAINTAINING LEGAL HOLDS**
  - Migrate and consolidate existing legal holds, evaluate technology and update legal hold system

- **DIVESTITURE DATA SEGREGATION**
  - Segregate organizational information, email, intellectual property, personally identifiable information across servers and networks globally with FTI’s deep expertise

- **DATA PRESERVATION & COLLECTION**
  - Identify legal custodians, systems and data on legal hold on disparate systems, servers and locations globally for preservation and collection

- **CHANGE MANAGEMENT**
  - Create playbooks, update workflows and SOPs to reflect changes in systems and processes, train personnel
Results in Action:

Legal Integration Services for Mergers and Divestitures

A global entity, in the midst of a large merger and divestiture transaction, require support for its legal and records management departments. They quickly needed a project plan to identify and address the custodians, systems and data sources on legal hold that were being divested, along with integrating new legal holds and custodians from the acquired group.

They also needed to remove/remediate their IP from networks and workstations of the divesting company.

SOLUTION

Our experts put together a project plan for a cross-functional strategy to collaborate with legal, IT and records departments for actionable workstreams. These projects included:

• Legal hold assessments, including the scope and location of required data, completed for ongoing data collection and preservation. Structured and unstructured data sources were identified and experts assisted the IT team during email and data migration. The location and preservation of data on legal hold was documented to establish the process for future requests.

• Though the client had an in-house team for routine data remediation and governance, our forensics and e-discovery experts were brought in to develop a strategy for addressing the data sources that contained IP for segregation. Collaborating with the legal and IT stakeholders, we developed a customized workflow to facilitate a sampling review by the client’s team. This enabled the review team to develop IP-identifying keywords and a log of files targeted for remediation. Working closely with the client, our teams were able to defensibly remediate the data.

• An assessment was also completed on the legal hold vendor landscape, resulting in the selection and implementation of a new legal hold system. Change management and training for the legal department attorneys, paralegals and discovery team was provided.

• An organizational re-design was developed to meet the discovery needs of the new company, including RFP coordination, selection of preferred providers and updating the discovery program and SOP playbook.

IMPACT

Our client received ready-access to industry experts with experience in information governance, e-discovery and data preservation, which are at the heart of legal and information management issues throughout a merger and/or divestiture.

Processes and playbooks were developed to optimize and facilitate future legal hold requests with little disruption to the company. Most importantly, the improved data governance framework created an overall stronger risk posture for the new organization.
Comprehensive and Integrated Data Privacy Services

From small engagements around specific regulations to ongoing managed services, we help each organization better define, implement and operationalize data privacy programs.

- **PRIVACY PROGRAM DEVELOPMENT**
  Program strategy, design, development and implementation

- **REGULATORY ASSESSMENTS**
  Compliance gap assessments across global privacy and security regulations

- **PRIVACY MANAGED SERVICES**
  Privacy program management, on-call response services, Data Protection Officer (DPO) as a service

- **PRIVACY TECH ENABLEMENT**
  Vendor selection, requirements gathering, design and implementation

- **PRIVACY RISK MANAGEMENT**
  Risk assessments & quantitative analysis, risk treatment roadmaps & recommendations, control monitoring and reviewing

- **REGULATORY PROCESS IMPLEMENTATION**
  Regulatory affairs support, complaints & inquiries handling, data subject rights request response, consent tracking, etc.

- **M&A AND DEAL SUPPORT**
  New venture, M&A privacy due diligence and post-acquisition integration support

- **INDUSTRY-SPECIFIC SOLUTIONING**
  Technology, telecom, media, financial services, healthcare and life sciences

- **SUBJECT MATTER EXPERTISE IN GLOBAL DATA PRIVACY REGULATIONS**
  - GDPR, privacy regulation
  - The California Consumer Privacy Act of 2018 (CCPA), HIPAA, HiTECH, GLBA, 23 NYCRR 500
  - PIPEDA, various provincial requirements
Expertise for Corporate Integrity Agreements

Meeting the obligations of a Corporate Integrity Agreement (CIA), which typically runs for five years, can be burdensome on teams that are already stretched for capacity. FTI Technology’s experts work with legal and ethics and compliance teams to quickly and cost-effectively address these obligations.

**PROJECT MANAGEMENT SUPPORT**
Dedicated support for in-house team, including secondments and overflow staff

**DATA COLLECTION & PRESERVATION**
Establish workflows and expectations to coordinate collection and preservation of data from stewards across the company, and from a myriad of business systems

**MONITORING & REPORTING**
Support the day-to-day monitoring program and reporting to internal compliance committee

**ADVANCED ANALYTICS**
Search collected data and quickly identify data and documents for compliance review

**ONGOING DATA REVIEW**
Resources to conduct periodic reviews of data collected from business systems, email, text messages, audio/video files, etc.
Results in Action:

GDPR Program for Healthcare Tech Company

A global healthcare technology company wanted support to implement business-as-usual (BAU) privacy processes and procedures in order to ensure compliance with GDPR and deliver user privacy settings.

**SOLUTION**
Partnering with the legal and compliance teams, we to FTI Technology reviewed the GDPR program to date and were able to develop a prioritized roadmap to GDPR compliance and embed privacy and compliance within BAU processes.

**IMPACT**
FTI’s GDPR team of experts:
- Developed project and stakeholder alignment plans
- Developed training and awareness to improve understanding of Data Subject Rights and Privacy by Design
- Developed processes for completing data protection impact assessment (DPIA)
- Updated SDLC and change management processes to embed Privacy by Design
- Supported technical teams to develop privacy functionality and settings
- Developed processes for meeting data subject rights, including erasure and portability

Corporate Integrity Agreement Support

An in-house compliance team was stretched for capacity after signing a new CIA with the US Department of Health and Human Services’ Office of Inspector General, which resulted from a Department of Justice investigation. They were looking for outside expertise to assist in meeting the CIA obligations.

**SOLUTION**
Our team worked with the in-house ethics & compliance department to preserve and collect data from various systems, people and company policies. Our experts served in the project management role and facilitated quarterly data collection requests and sampling of laptop and mobile device data from field and sales personnel.

They established workflows to preserve and collect data from various business systems. A dedicated project manager facilitated quarterly data collection requests from systems. Data was then sent for review by a small team of experts, using certain keywords to flag potential issues. Any data flagged was sent for review to the in-house compliance team. Advanced visual analytics were applied to identify trends and patterns in marketing activities and behaviors.

**IMPACT**
To compile the annual CIA report, our experts collected data and policies from departments across the company in addition to the quarterly monitoring results. Obtaining timely extracts of data and establishing expectations with various departments hugely reduced the burden for the in-house compliance team.
Global Reach

With offices in every major financial center and every corner of the globe, we successfully serve our clients wherever challenges and opportunities arise.

**NORTH AMERICA**
Canada
Calgary
Toronto

United States
Annapolis
Atlanta
Austin
Baltimore
Boston
Brentwood
Charlotte
Chicago
Coral Gables
Dallas
Denver
Great Neck
Houston
Indianapolis
Lake Oswego
Los Angeles
McLean
Miami
Mountain View
New York

Vancouver
Oakland
Pasadena
Philadelphia
Phoenix
Pittsburgh
Princeton
Red Bank
Rockville
Roseland
Saddle Brook
San Francisco
Santa Barbara
Seattle
Tucson
Walnut Creek
Washington, D.C.
Wayne
West Palm Beach
Winston-Salem

**EUROPE, MIDDLE EAST, AFRICA**
Belgium
Brussels

Denmark
Copenhagen

France
Paris

Germany
Berlin
Frankfurt

Ireland
Dublin

Netherlands
Den Haag

Qatar
Doha

Russia
Moscow

South Africa
Cape Town
Johannesburg

Spain
Madrid

United Arab Emirates
Abu Dhabi
Dubai

United Kingdom
London
Stirling

**LATIN AMERICA**
Argentina
Buenos Aires

Brazil
Rio de Janeiro
São Paulo

Caribbean
British Virgin Islands
Cayman Islands

Colombia
Bogotá

Mexico
Mexico City

Panama
Panama City

**ASIA PACIFIC**
Australia
Brisbane
Melbourne
Perth
Sydney

China
Beijing
Guangzhou
Hong Kong
Shanghai

India
Mumbai
New Delhi

Indonesia
Jakarta

Japan
Tokyo

Korea
Seoul

Malaysia
Kuala Lumpur

Singapore
About FTI Consulting

FTI Consulting is an independent global business advisory firm dedicated to helping organizations manage change, mitigate risk and resolve disputes: financial, legal, operational, political & regulatory, reputational and transactional. FTI Consulting professionals, located in all major business centers throughout the world, work closely with clients to anticipate, illuminate and overcome complex business challenges and opportunities. For more information, visit www.fticonsulting.com and connect with us on Twitter (@FTIConsulting), Facebook and LinkedIn. FTI Consulting, Inc., including its subsidiaries and affiliates, is a consulting firm and is not a certified public accounting firm or a law firm.

www.fticonsulting.com