

INFORMATION PAPER

Drug and Medical Device Companies Face Big Challenges in eDiscovery

Overcoming the Complexities of Data Discovery in Healthcare

HAYSTACK[®]



Navigating the Unique Challenges of Discovery in Healthcare

Amid a challenging legal and technological landscape, pharmaceutical and medical device companies constantly grapple with government scrutiny, escalating whistleblower activities, and fluctuating regulations. Litigation involving patent infringement, medical device product liability, fraudulent drugs, unlawful promotion, off-label marketing, and contentious issues of opioid and physician kickbacks are frequent. Notably, the evidence from these drug and medical device cases can quickly expand into terabytes, especially in instances of multi-district litigation (MDL) or class action suits.

Understanding the gravity of these challenges, HaystackID, a specialized eDiscovery services firm with extensive experience in supporting the healthcare industry, has identified five top eDiscovery challenges faced by organizations and individuals in the healthcare ecosystem. These findings magnify the critical need for all drug and medical device companies to accurately comprehend what data they have, where it is stored, how to retrieve it, and, ultimately, how to correctly format it for production. Constructing data management workflows with eDiscovery at the forefront is no longer merely a convenient suggestion but an unequivocal imperative.

Five Top Healthcare-centric eDiscovery Challenges

1. Internet of Medical Things

The growing market of the Internet of Medical Things (IoMT) and BodyTech/wearable devices are starting to significantly impact product liability. Data from wearables are becoming a primary source of discovery because of the wealth of user data they provide both onboard and in the cloud.

New wearable devices, implants, telemedicine, cloud integration, and legacy technology present collection and production challenges. Cloud services like Office 365, DropBox, Github, AWS, and GSP compound the data retrieval process during eDiscovery. Data acquisition from these devices can be complex because of poor design, various data formats, language issues, and minimal logging.

Wearable device companies and IoMTs should have an eDiscovery action plan to determine evidence sources, how the evidence can be safely preserved and collected, and the acceptable production formats. Being proactive is necessary since eDiscovery technology may only be somewhat effective when analyzing the data from the new medical devices available.

2. Electronic Medical Records

Electronic Medical Records (EMR) unnecessarily complicate the discovery process. EMRs look very different on paper or PDF format than on a doctor's or a nurse's screen. The most challenging part of medical records discovery is producing the logs in a form that satisfies FRCP requirements and facilitates responsive discovery. Because EMRs are not static documents designed to be manipulated, it becomes challenging to safeguard them from alteration and prove that the records are true and accurate when collected.

3. Privacy

HIPAA, GDPR, and new state data privacy laws add a layer of discovery risk and compliance challenges. With the increase and complexity of privacy laws at the state, federal, and international levels, collecting the data is challenging since many of these laws require strict controls and procedures to follow, and the data sources may be spread among different states and countries. The differences in requirements for collecting, using, and protecting information subject to these laws require careful planning between legal, IT, and your data management partner to avoid the risk of non-compliance.

4. Big Data

The “digital footprint” of patient data is growing and changing significantly. The volume of data from new medical technology can easily reach into the terabytes for a single lawsuit. Managing big data can be challenging during identification, preservation, collection, processing, and remediation. Cutting-edge data management technology is required to deal with the volume and challenges it presents.

Unfortunately, no single technology can easily handle the collection, information governance, volume, and analysis of this data at such a scale. Big data drives the need for firm IG policy and skill in managing the eDiscovery process. A data-specific policy and a master data management (MDM) governance program should be adopted to address healthcare data.

5. The Cloud

Cloud solutions in the medical device industry are creating a network architecture that doesn't require moving the data to a user terminal or a mobile app to access it. Although the benefits are enormous, concerns remain regarding the data's dynamic nature, difficulty locating it, data destruction, security, privacy, ownership, and data extraction during discovery.

New technological advances using the cloud were not created with discovery in mind when trying to understand where and how data is stored. Additionally, since the data and infrastructure are often not considered owned by users, legal access to data can be limited by contract, policy, and national and international privacy regulations.

Cloud service providers (CSP) still need to catch up in addressing the process required to extract data from the CSP's servers for discovery. As they move to the cloud, medical device companies need a strategy to address eDiscovery requirements (identification, preservation, collection, processing, and production formats).

Be Litigation Ready*

- What discoverable data exists in medical devices?
- Where does the data exist (in the cloud, onboard, etc.)?
- What format(s) is the data in?
- How can the data be properly preserved and extracted for litigation?
- Is the data in a format that attorneys can easily review?

**Consult with a HIPAA-compliant discovery management vendor to help answer these questions before litigation arises.*

Harnessing the Data Surge

A recent study estimated that hundreds of thousands of mobile health apps are now available on the market. The pandemic crisis has only accelerated this growth. In fact, the global market value for medical device technology is projected to grow to \$52bn in 2024. Whether these apps help to track a weekly jog or verify life-saving dialysis treatment, they generate a tremendous amount of data that may be relevant to discovery.

With the advancement and proliferation in medical technology, extracting electronically stored information (ESI) from devices and databases is challenging because metadata, patient data, transaction logs, etc., may be hidden, embedded, and encoded in various proprietary and encrypted formats.

Additionally, medical terms (abbreviations and terminology) continue to cause difficulty during the processing, review, and analysis phase of eDiscovery. New medical technologies have brought new terms requiring subject matter experts to interpret and explain them in context during the discovery analysis and attorney review phase. HaystackID has an experienced pharmaceutical review team that can quickly navigate through nuanced medical terms.

Learn More. Today.

[Contact us today](#) to learn more about how legal, security, privacy, and compliance teams can partner with an experienced data management company like HaystackID to handle the challenging healthcare data management landscape.

About HaystackID®

HaystackID is a specialized eDiscovery services firm that supports law firms and corporate legal departments and has increased its offerings and expanded with five acquisitions since 2018. Its core offerings now include Global Advisory, Discovery Intelligence, HaystackID Core™, and artificial intelligence-enhanced Global Managed Review services powered by ReviewRight®. The company has achieved ISO 27001 compliance and completed a SOC 2 Type 2 audit for all five trust principles for the second year in a row. Repeatedly recognized as a trusted service provider by prestigious publishers such as Chambers, Gartner, IDC, and The National Law Journal, HaystackID implements innovative cyber discovery services, enterprise solutions, and legal discovery offerings to leading companies across North America and Europe, all while providing best-in-class customer service and prioritizing security, privacy, and integrity. For more information about its suite of services, including programs and solutions for unique legal enterprise needs, please visit HaystackID.com.