

Educational Presentation

# Hatch-Waxman and eDiscovery

## Turbo-Charging Pharma Collections and Reviews

HAYSTACK

September 2020

# Michael D. Sarlo, EnCE, CBE, RCA, CCLO, CCPA

## Partner and Senior EVP of eDiscovery and Digital Forensics

Michael is a Partner and Senior Executive Vice President of eDiscovery and Digital Forensics at HaystackID.

In this role, Michael facilitates all operations related to electronic discovery, digital forensics, and litigation strategy both in the US and abroad while working on highly complex forensic and e-Discovery projects.

Michael is fluent in a wide variety of digital forensic, ECA, e-Discovery processing and hosting technologies in addition to the IT infrastructure associated with deploying and administering such tools. He is also a frequent speaker on digital forensics best practices, GDPR issues, ESI treatment methodologies, and cost containment strategies for working with massive volumes of data.

Michael is an expert witness and holds certifications around several forensic tools including Cellebrite, EnCase, and BlackLight. He is also a Relativity Certified Administrator (RCA).

# John Wilson, ACE, AME, CBE

## CISO and President of Forensics, HaystackID

John provides expertise and expert witness services to help companies address various matters related to digital forensics and electronic discovery (eDiscovery), including leading investigations, ensuring proper preservation of evidence items and chain of custody. He develops processes, creates workflows, leads implementation projects as well as GDPR data mapping services for clients including major financial institutions, Fortune 100 companies, Am Law 100 law firms as well as many other organizations small and large. In addition, he provides expert witness services and consulting in matters of all sizes. His work spans some of the largest litigations and matters on record in the United States and many of the 39 countries where he has worked on cases.

John is a certified forensic examiner, licensed private investigator and information technology veteran. He has over two decades of experience working with the US Government and both public and private companies. He serves clients in a variety of industries and is an advisor to outside counsel, general counsel and in-house executives on best practices.

# Vazantha Meyers Esq.

## Vice President of eDiscovery Services, HaystackID

As VP of eDiscovery Services for HaystackID, Vazantha has extensive experience in advising and helping customers achieve their legal document review objectives.

Previously, she worked as a litigation associate at Mayer Brown LLP. While at Mayer Brown, Vazantha worked in the Electronic Discovery and Records Management Group, providing counsel to corporate clients on discovery and records management issues.

Vazantha contributed to the Practising Law Institute treatise Electronic Discovery Deskbook: Law and Practice (2009 and 2019) and has written many articles and presentations on various topics related to electronic discovery. Vazantha attended Valparaiso University School of Law, where she graduated as a Monsanto Honors Scholar.

# Albert Barsocchini, Esq.

## Director of Strategic Consulting, HaystackID (NightOwl Global)

Albert brings over 25 years of global legal and technology experience in discovery, digital investigations and compliance. He spent 15 years as a first chair trial attorney before going in house at Guidance Software. He joined NightOwl Global in 2011 as a strategic consultant for the client advisory group.

He has also served as past-chair of the California State Bar Law and Technology section, and occasionally acts as a special master for the State Bar of California and mediator in State Court.

Albert's extensive technology certifications include Exterro, EnCase, Relativity, Nuix, BigID and One Trust.



# Agenda

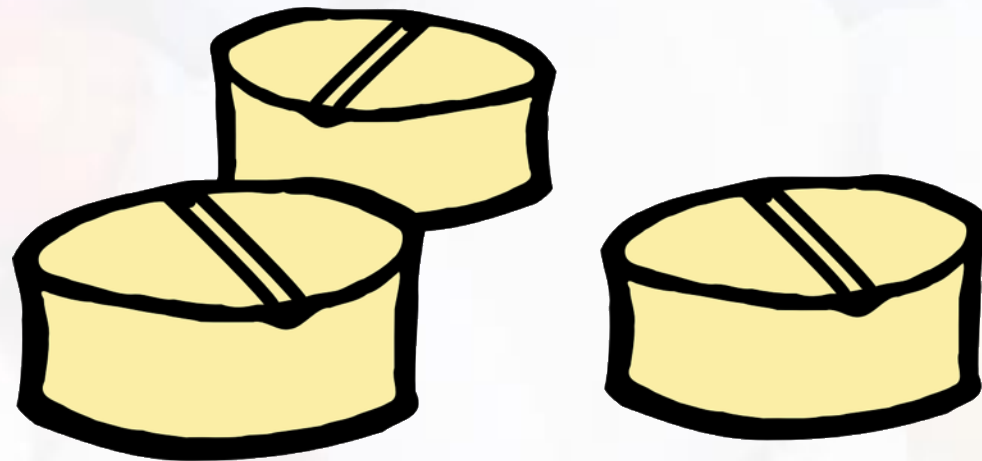
## Hatch-Waxman and eDiscovery

- **NDA and ANDA Processes**  
Through the Lens of Hatch-Waxman
- **ECTD Filing Format Overview**  
FDA (NDA/ANDA) Submissions
- **Information Governance and Collections**  
Hatch-Waxman Considerations
- **Enhancing Document Review**  
Medical Abbreviations and Terminology in Pharma Matters
- **Best Practices and Proprietary Technology**  
Document Review in Pharma Litigation



# Hatch-Waxman Act Overview

The research and development process of a new drug is a complex process and the regulatory controls and requirements around pharma data are challenging. This act helped the US become a leader in biopharmaceutical research and development.



# Roche Products, Inc. v. Bolar Pharmaceutical Co 733 F.2d 858 (1984)

- This case involved a Roche owned drug called flurazepam, the active ingredient in a sleeping pill "Dalmane." Bolar was seeking to sell a copy after Roche's patents expired. Bolar was hoping to time the approval with the expiration of the patents and began work on drug development activities while Roche's patents were still in force.
- The problem for Bolar was that by doing so before the patent expired, it was infringing on the patents. Roche sued for infringement and ultimately won.
- This in effect extended the term of the patent because another manufacturer can't work on a drug while the patent is still in force.



# In 1983 Hatch-Waxman is Passed

- Congress acted quickly in response to the *Roche* case and passed the Hatch-Waxman Act (formally known as the Drug Price Competition and Patent Term Restoration Act). The Act provides incentives for generic drug companies to challenge patents owned by innovators and gives generics a research exemption to develop generic drugs while patents are still in force without being liable for infringement.
- The Act strikes a balance between inducing pioneering development of pharmaceutical formulations / methods **vs.** facilitating efficient transition to low-cost, generic copies of pioneering inventions at the close of a patent term.

# The Orange Book

- Each new drug application (NDA) holder is required to identify, or "list," any patent that claims the drug or a method of using the drug for which an action of infringement can reasonably be asserted. Listing is required when the NDA is filed or when a patent is subsequently issued.
- All such patent information is compiled in a collection entitled Approved Drug Products with Therapeutic Equivalence Evaluations, known as the "Orange Book."
- Having a patent listed in the Orange Book provides significant benefits to the NDA holder.

# The ANDA

- The Act established an abbreviated new drug application (ANDA) process for generics before the original patent expires.
- By filing an ANDA, the generic challenger is proposing to market “bioequivalent” to the innovator product and certifying that an innovator patent covers the proposed product.
- The process of challenging patents is by a Paragraph IV Certification that must state: an application that contains data from a bioequivalence or bioavailability study has been submitted; seeking approval to engage in the commercial manufacture, use, or sale of the listed drug before the expiration of the listed patent(s); and a factual and legal basis why the patent is invalid or will not be infringed
- The Electronic Common Technical Document (eCTD) is the standard format for submitting applications, amendments, supplements, and reports to FDA’s Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER).

# The Patent Owner

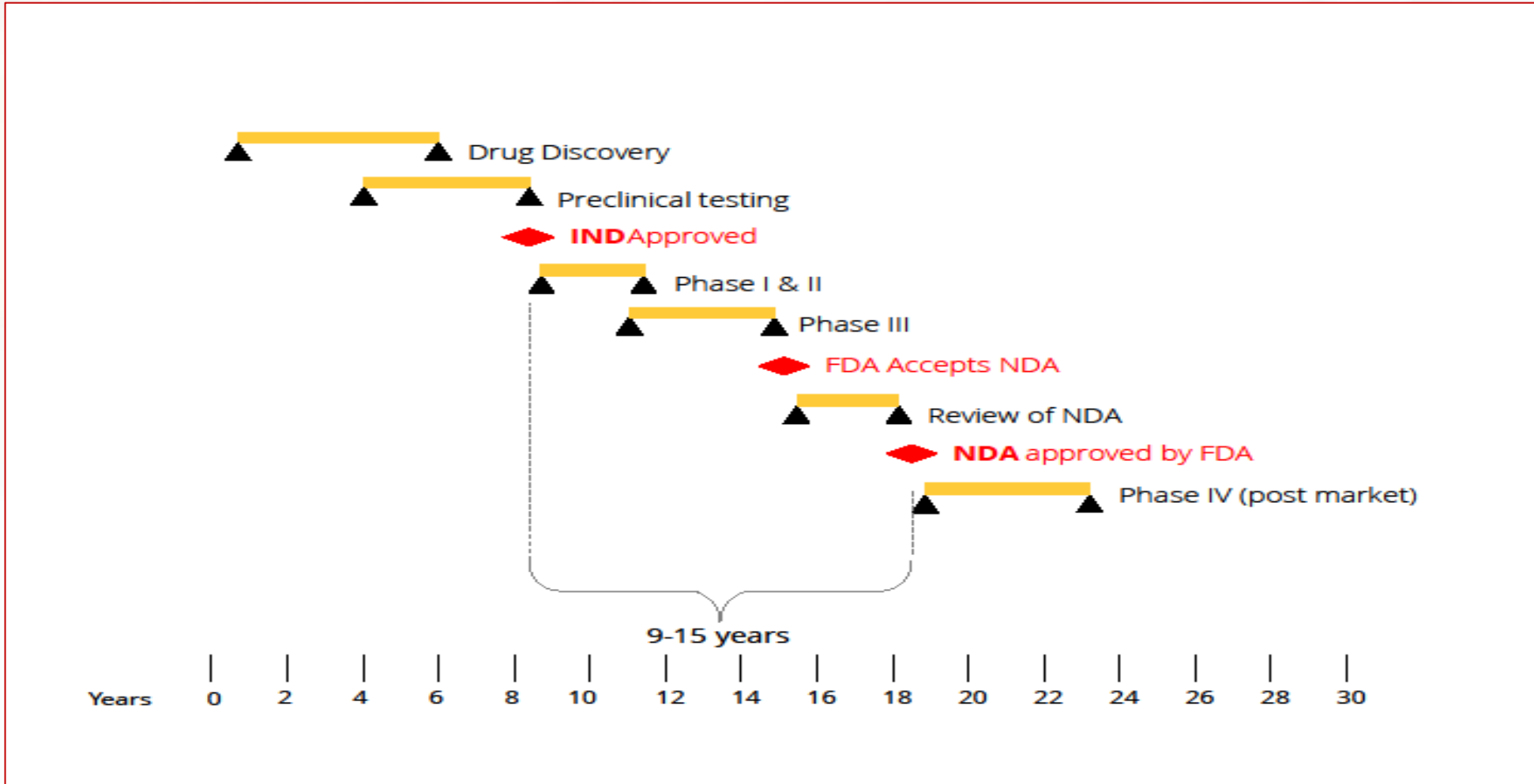
- Patent terms are set by statute. Currently, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States. Many other factors can affect the duration of a patent.
- Innovator drug companies are generally given a 5 year “data” exclusivity, during which the FDA will not approve a generic and a 3 Year “marketing” exclusivity. Exclusivity and patent protections are mutually distinct.
- If a patent owner files an action for infringement against an ANDA applicant within 45 days of receiving notice of a Paragraph IV certification, approval of the ANDA is stayed for 30 months (or such other period as the court may order). The 30-month stay protects the patent owner from the harm that could otherwise ensue from the FDA granting marketing approval to a potentially infringing product.

# The Hatch-Waxman Race to the Finish Line

- Under the act, the first filer or FTF (first to file) of an abbreviated new drug application (ANDA) with a Paragraph IV certification is entitled to a 180-day market exclusivity period for the first marketed generic.
- This encourages a race to market by competing generic manufacturers and can generate multiple lawsuits.
- The fast pace nature of this act requires a strong data management policy, effective compliance monitoring, robust data collection planning and a skilled legal review team using the latest technology.

# Lifecycle of a New Drug

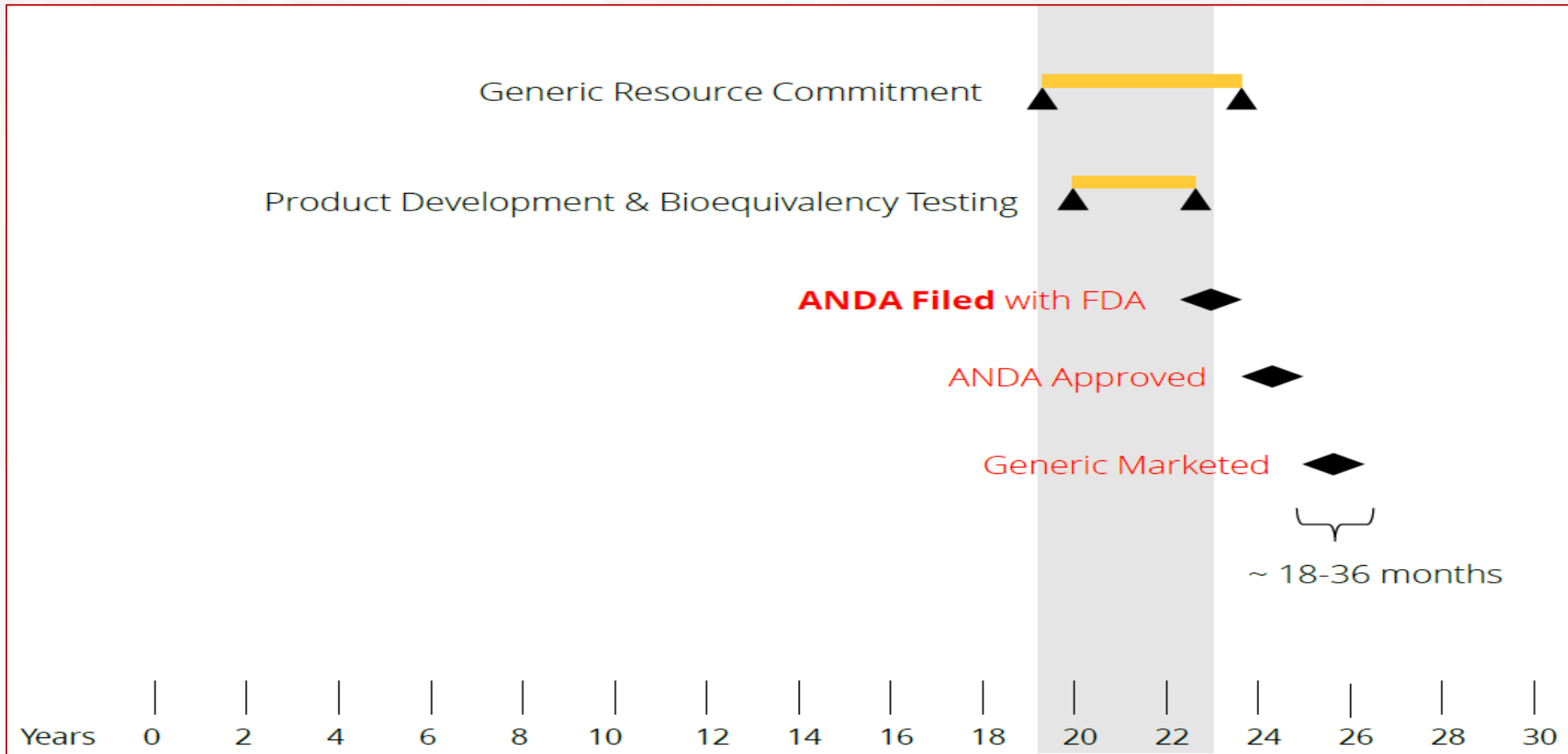
## From Invention to Market





# Lifecycle of a New Drug

## From Invention to Market





# eCTD Filing Format

Purpose, Structure and Proprietary eDiscovery Solutions

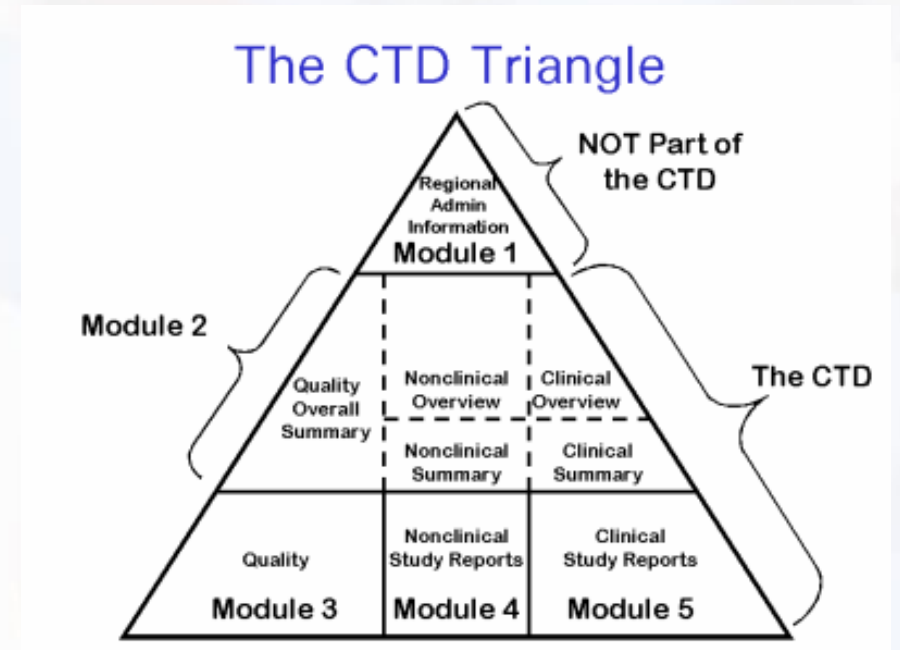
# CTD and eCTD Purpose and Evolution

## Common Technical Document Features

The **Common Technical Document (CTD)** is a set of specifications for an application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States in *paper* format.

It is an internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries.

On January 1, 2008, the Center for Drug Evaluation and Research (CDER - FDA) mandated that electronic submissions had to use the **Electronic Common Technical Document (eCTD)** format. That decision sparked a sharp jump in the cumulative number of eCTD submissions, which tripled in a single year, from nearly 15,000 (October 2007) to more than 43,000 by October 2008.



# CTD and eCTD Application Format Overview

## Types of Applications – Paper to Digital

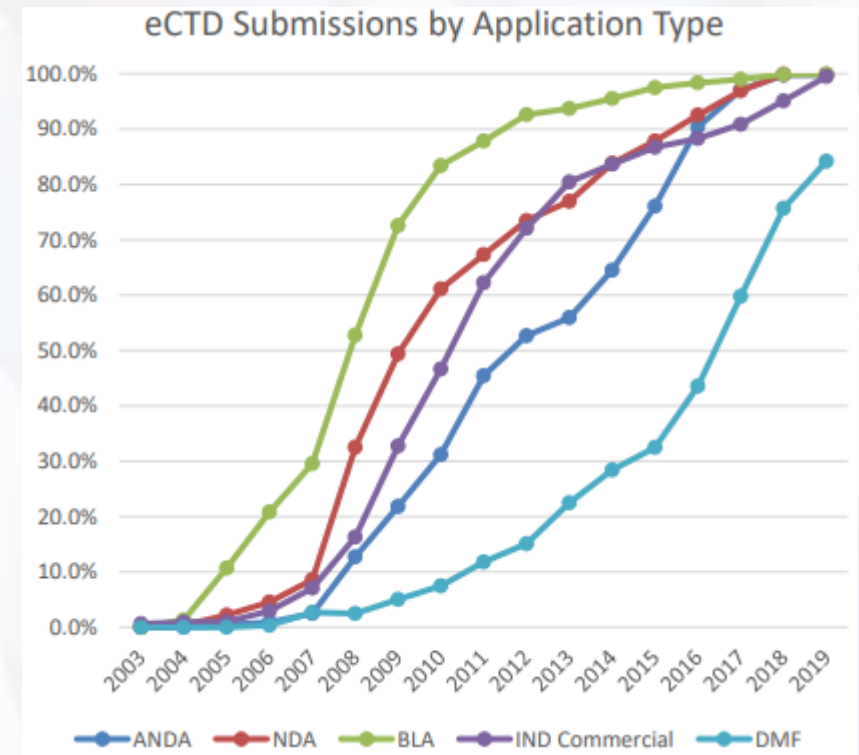
As of date, electronic submission requirements apply to the following types of submissions to CDER/CBER:

- NDAs (New Drug Applications) –2017
- ANDAs (Abbreviated New Drug Applications) –2017
- BLAs (Biologics License Applications) - 2017
- INDs (Investigational New Drug Applications) 0 May 5<sup>th</sup> 2018

All subsequent submissions to these types of applications, including amendments, supplements, and reports, even if the original submission was filed before the requirements went into effect

Master files, such as DMFs, which are considered to be submissions to an IND, an NDA, an ANDA, or a BLA.

TMF (Trial Master Files) are also a consideration, although the eTMF is becoming somewhat of its own format.





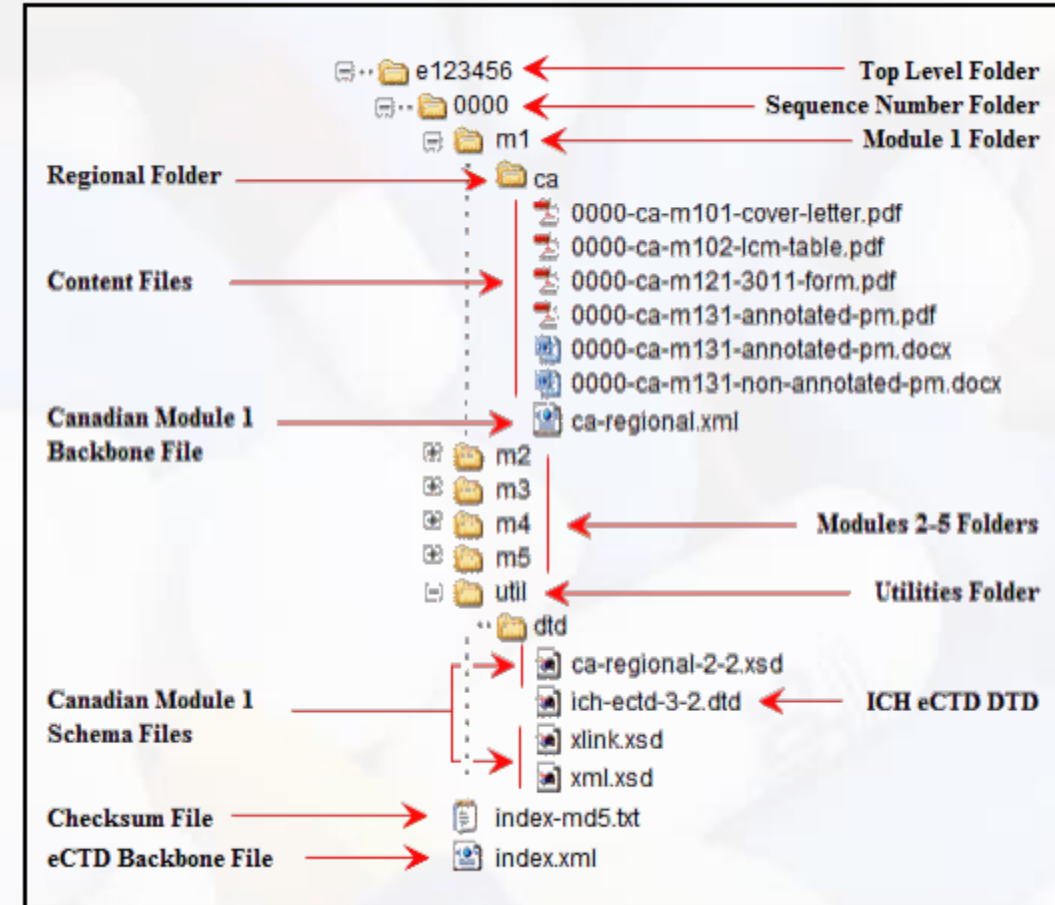
# eCTD Files and eDiscovery

## Common Technical Document Features

Submission files come in two parts from a top line perspective:

**XML Transport File:** that contains metadata about the eCTD itself, sections and modules in the eCTD, and metadata about supporting files *and* folders that are part of a complete eCTD submission. This metadata includes revision history regarding when pieces of the application was edited, modified or added (important for Hatch-Waxman matters).

**Files/Folders:** The XML transport file organizes and describes supplemental files, folders, and their relationships to specific modules within the eCTD. Files and folders are packaged with the complete eCTD submission, and XML files refer to those files and folders. Documents can also be linked, and a TOC allows for navigation across the entire eCTD



# HaystackID eCTD Compliance Review Module

## eCTD eDiscovery Parser and Review and Production (Proprietary)

### eCTD Compliance Review Module Features

**Direct integration with Relativity for dynamic review, search, culling, tagging, redaction, and production.**

**Viewing of historical sequence timelines of submission lifecycles.**

**Full preservation of complex folder structure, metadata, and revision history within Relativity.**

**Automated parsing and Relativity field mapping of embedded XML-based metadata content.**

**Push button review of family-level, linked document associations.**

**Customizable relational pane in Relativity for eCTD submission display.**

**Streamlined production process of all associated metadata and file content to industry-standard electronic discovery load-file formats.**



# HaystackID eCTD Compliance Review Module

## eCTD eDiscovery Parser and Review and Production (Proprietary)

The screenshot displays the HaystackID eCTD Compliance Review Module interface. The left sidebar shows a folder tree for 'HS - eCTD Demo' with subfolders like '045678', '0000', 'm1-administrative-information-and-prescribing-informatio', 'm2-common-technical-document-summaries', 'm2-2-introduction', 'm2-3-quality-overall-summary', 'm2-3-introduction', 'm2-3-p-drug-product', 'm2-3-s-drug-substance', 'm2-7-clinical-summary', 'm2-7-3-summary-of-clinical-efficacy', 'm3-quality', 'm4-nonclinical-study-reports', 'm5-clinical-study-reports', '0001', 'm1-administrative-information-and-prescribing-informatio', 'm2-common-technical-document-summaries', '0002', and 'm1-administrative-information-and-prescribing-informatio'. A callout box points to the folder path, stating: 'Folder Path populated from internal eCTD structure rather than file system location'. The main area shows a table of review items with columns: #, ReviewID, Title, eCTD ID, Operation, Modified-File, Version, and Keywords. A callout box points to the 'Operation' column, stating: 'Operation field tracks the version history of each document'. The table contains 10 rows of data, including items like 'US Module 1 XML File 0000 submission', 'Introduction to the Marketing Application', 'Introduction to the Quality Overall Summary', 'Drug Substance', 'Drug Product', 'Summary of Clinical Efficacy - Nausea', 'Summary of Clinical Efficacy - Pain', 'Structure (Floxacin, Danube)', 'General Properties (Floxacin, Danube)', and 'Manufacturer (Floxacin, Danube)'. The bottom of the interface shows a search bar, a 'Checked' dropdown, an 'Edit' dropdown, a 'Go' button, and a pagination control showing 'Viewing the First 70 of 70 items in sets of 25 per page'.

#	ReviewID	Title	eCTD ID	Operation	Modified-File	Version	Keywords
1	REV1111	US Module 1 XML File 0000 submission	a000003	new			
2	REV1112	Introduction to the Marketing Application	a000004	new			module2
3	REV1113	Introduction to the Quality Overall Summary	a000005	new	REV1113		
4	REV1114	Drug Substance	a000006	new	REV1114		
5	REV1115	Drug Product	a000007	new	REV1115		
6	REV1116	Summary of Clinical Efficacy - Nausea	a000021	new	REV1116		
7	REV1117	Summary of Clinical Efficacy - Pain	a000022	new	REV1117		
8	REV1118	Structure (Floxacin, Danube)		new	REV1118		
9	REV1119	General Properties (Floxacin, Danube)		new	REV1119		
10	REV1120	Manufacturer (Floxacin, Danube)		new	REV1120		



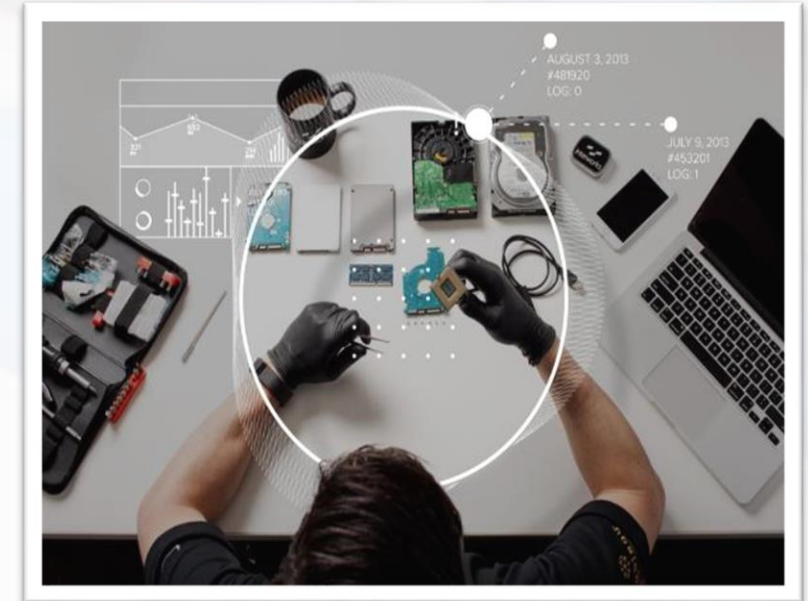
# Information Governance

Legal Hold and Data Collection in The Context of Hatch Waxman  
Preparing for Paragraph IV

# Preparing to Challenge a Paragraph IV

## Building an Actionable Fact Timeline and Data Map

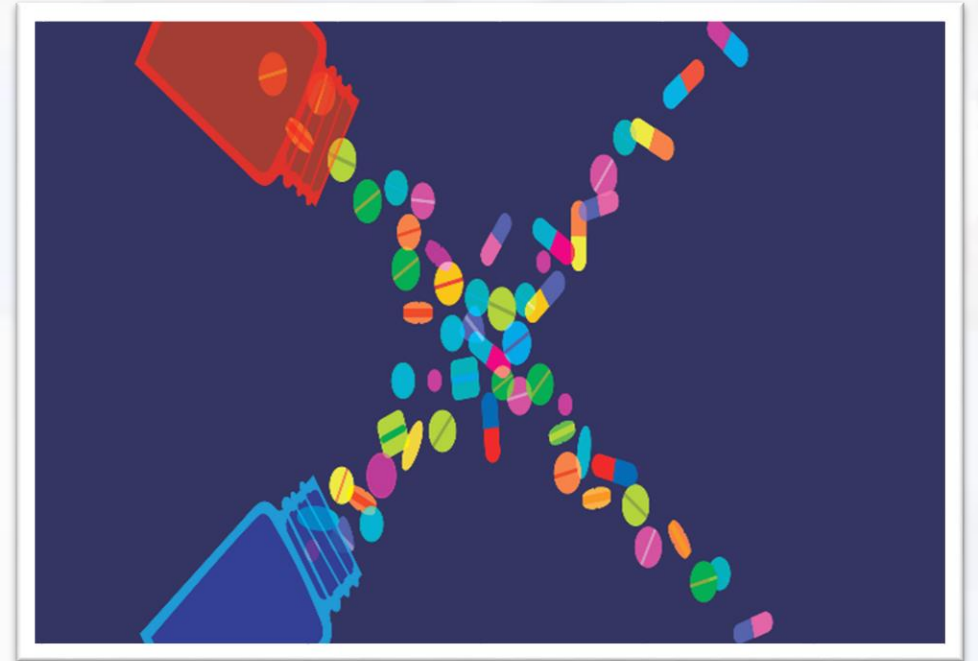
- **Receiving a Paragraph IV acknowledgement letter automatically should trigger a legal hold process.**
  - Generic must send notice letter within 20 days from ANDA “receipt” acknowledgement letter from FDA
  - NDA sponsor can sue when it receives notice, and if suit brought within 45 days of notice, ANDA approval is stayed for 30 months.
- **Pharmaceutical companies should be well prepared to challenge all generic manufactures ahead of a patent's expiration, if that is their prerogative.**
- **IND/NDA timelines can span more than 15 years from development to market.**
  - IND/NDAs will be a mix of AND digital filing formats and paper
  - It is important that they are parsed properly for review and production so they can be acted on appropriately during the litigation
- **Gain a strong understanding of backup systems, and company procedures for storing historical information**



# Data and Key Personnel Mapping

## Building a Fact Timeline and Data Map

- Assume that data points are going to be a mix of paper and digital information depending on the drug's overall invention and regulatory filing timeline
- Identify key players in the drugs development, and key milestones within the timeline relating to the drugs development.
- Understanding who was involved in what is an important exercise, and especially as it relates to the key original inventors.
  - Individuals may become key witnesses, and inventors may no longer be at the company, or even deceased.
  - Inventors may have their own personnel files that might need to be tracked down
  - Lab notebooks are typically incredibly important in these matters and need to be handled with care.
- Identify any document management systems, including industry specific document management systems that may.
  - These systems oftentimes require special collection procedures in so much as metadata is oftentimes stored separately from files. HAYSTACK has a specialized division to handle these non-typical data repositories.





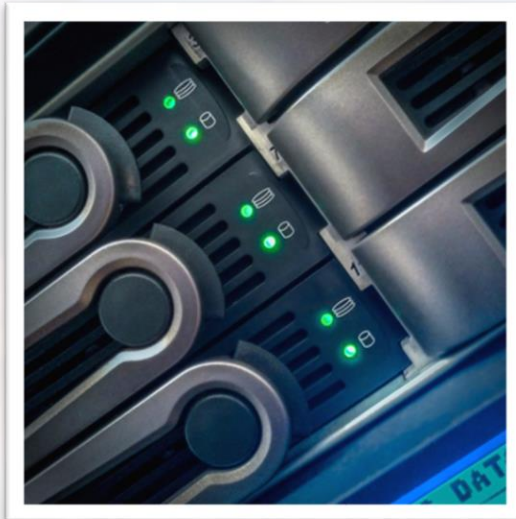
# Understand the Data Points

## Driving Legal Hold

### Collection Planning to Support Global Investigations

#### *Traditional Storage Locations*

- *Application/Email Service Providers*
- *Archived Data*
- *Audit Trails, Logs, and Registries*
- *Backup Computer Files*
- *Cache Data*
- *Firewalls*
- *Internet Service Providers*
- *Legacy and Disaster Data*
- *Random Access Memory (RAM)*
- *Removable Media*
- *Residual Data*
- *Voice Mail*
- ***PAPER / OFF-SITE STORAGE / BACKUP TAPES***



#### Storage and Communications Devices

- *Servers (Network)*
- *Personal (Desktop and Laptop) Computers*
- *Mobile Computing Devices*
- *Mobile Telephone Devices*
- *Faxes*
- *Scanners*
- *Printers*
- *Copiers*
- *Security Systems*



# Enhancing Document Review

Medical Abbreviations and Terminology



# Understanding the Data

## Medical Abbreviations and Terminology

In order for a document reviewer to accurately categorize a document during their analysis and coding process, they must understand the terminology being used.

The Hatch-Waxman process uses several abbreviations or process specific terms that are important for a reviewer to be familiar with before they start analyzing documents.

Drug names and treatment protocols are often complicated and will be abbreviated internally and publicly in order to make communication easier.



# Understanding the Data

## Streamlining Understanding and Information Library

**Shared Resources:** Generate and continually update shared lists of attorneys, project code names, acronyms/initialisms, and chronologies and custodian crib sheets during active projects.

**Information Library:** In addition to collecting project level background information, client level terminology, abbreviations, code names should be maintained in an information library and shared between project teams.

**Client Teams:** Client teams allow multiple project managers and review teams to share information about the clients' processes and data

**Public Sources:** There are also publicly available resources that have libraries of commonly abbreviated pharmaceutical and medical terminology. (See, e.g.,

<https://www.allacronyms.com/pharmaceutical/abbreviations>



# Communication

## Secure Chat Room and Issue Logs

**Secure Chat Room:** All reviewers must remain logged into the review workspace and monitor the secure chat simultaneously on dual screens. Separate threads are created in each room for separate topics and inquiries. Rooms are designated by workflow. RMs/Team Leads (“TLs”) are assigned monitoring hours to ensure full coverage to answer questions.

**Issue Logs:** Project questions that are substantive and impactful to the review should be documented and shared amongst all of the stakeholders in a project.



A blurred background image of two women in an office setting. One woman with long blonde hair is in the foreground, looking intently at a computer monitor. Another woman with dark hair is partially visible behind her, also looking at the screen. The overall scene is dimly lit, suggesting a professional or technical environment.

# Reviewer Selection

Qualification, Identification, Screens, Ratings and Certification

# Reviewer Selection

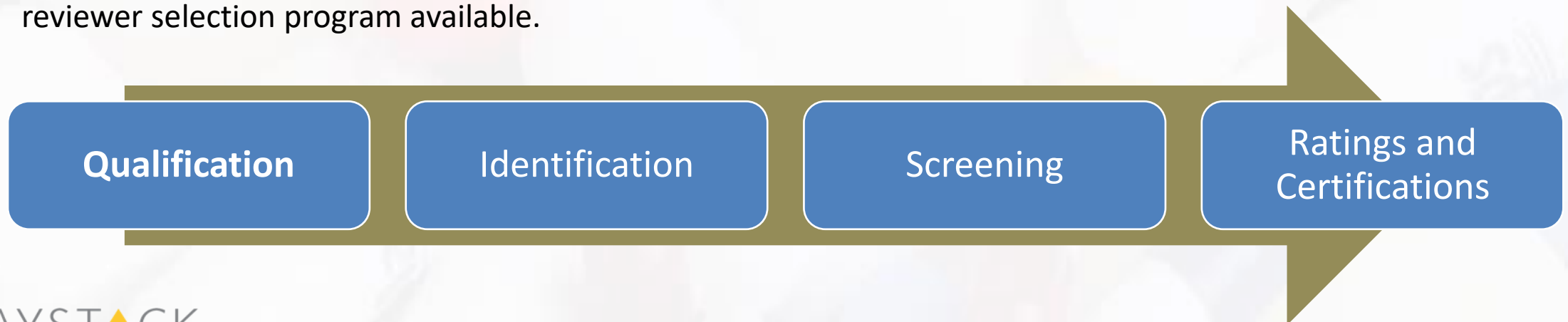
## Overview

### **Proprietary ReviewRight Software:**

- Evaluates contract attorneys through exclusive testing and artificial intelligence allowing HaystackID to structure the most efficient, accurate, tailored review teams for each and individual project regardless of project specifications.

### **ReviewRight Match**

The core of the ReviewRight Match process is the active and systematic recruitment of tested, qualified, identified, certified and continuously evaluated document review attorneys as part of the most comprehensive reviewer selection program available.

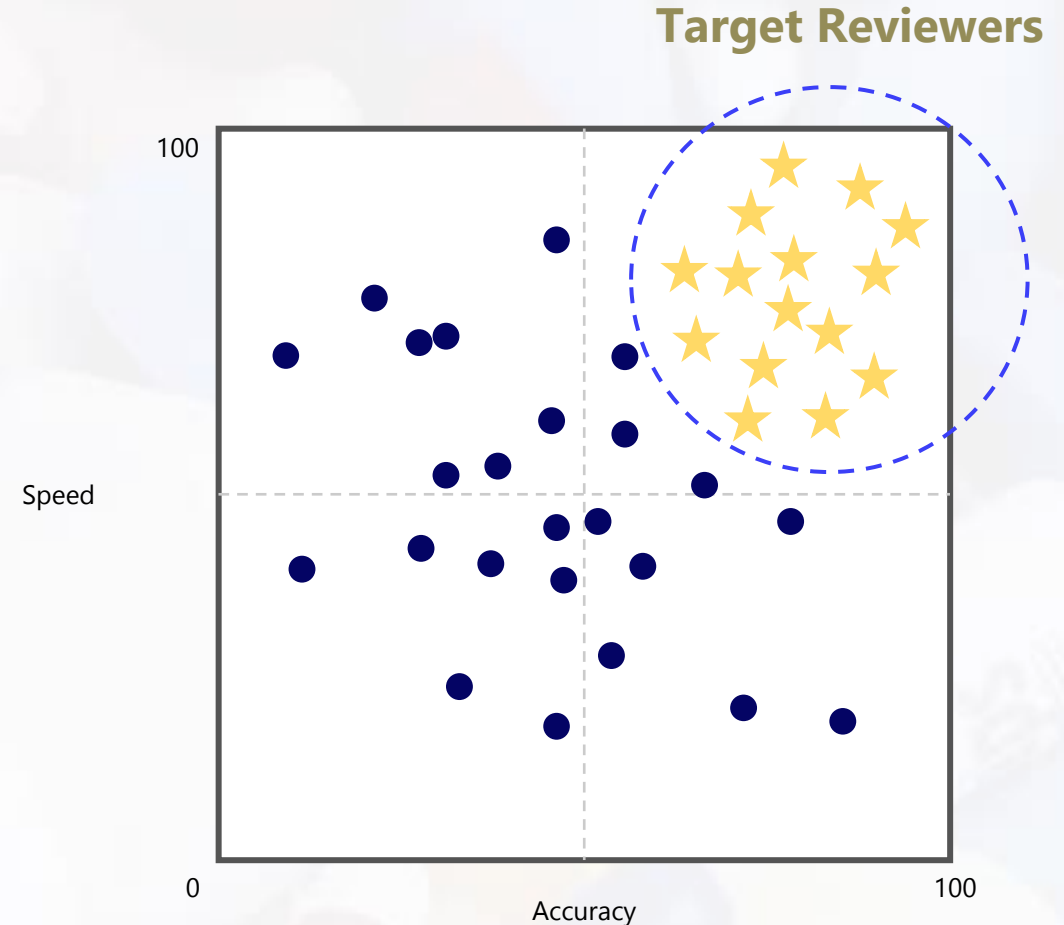


# Reviewer Selection

## Qualification

### ReviewRight Test Assessment

Reviewers who seek to be considered for document review opportunities must first take a skills assessment test. They are presented with a fact pattern (i.e. case background) and a review protocol. With this information, the reviewers are administered 15 documents and are asked four (4) questions related to relevance, issue spotting and privilege per document that provides HaystackID with immediate, quantifiable, objective insight into a reviewer's legal review capabilities, including projected accuracy per task and rate of review.





# Reviewer Selection

## Identification

**Comprehensive Classification for Remote Reviewers:** Reviewers are required to have completed a minimum of three (3) document review projects in addition to achieving a qualifying score on the skills assessment.

**Classifications:** Reviewers are further classified based on their expertise in 31 practice areas, 12 languages, and 13 review tasks/roles, totaling 4,836 unique combinations to allow for the assembling of a targeted review team with the highest level of expertise, knowledge, proficiency, and skills for each review project.

### **Experience Counts:**

- Hatch-Waxman experience
- Client specific experience
- Industry experience
- Patent experience
- Science and chemistry backgrounds

# Reviewer Selection

## Screens: Background Checks, License Verifications, and Conflict Checks

**Background Checks.** HaystackID conducts background checks on all document reviewers. All reviewers being considered for placement must have a clear background check on file at HaystackID within the last 365 days. Checks include but are not limited to:



**License Verifications.** Prior to each individual project placement, HaystackID verifies each candidate has an active bar license in good standing with no disciplinary actions.

**Conflicts of Interest Screens.** Contract attorneys are required to keep accurate records of both represented, adverse and third-parties, along with employers, law firms (if known), and a brief description of the matters worked on for their past seven (7) years. All self-identified parties for each candidate are screened against relevant parties for each potential project.



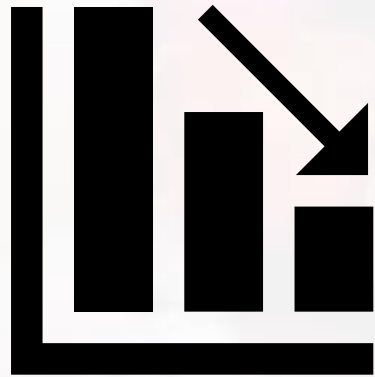
# Managed Attorney Review

## Best Practices for Managing Pharmaceutical Reviews

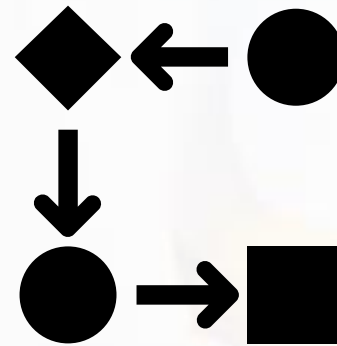
# Managed Review

## Review Philosophy

**Review Managers** work closely with counsel and clients from the early stages of litigation through final document production and analysis to devise document review strategies that limit review set populations, select review technologies, craft customized workflows that increase review speed and accuracy, and develop searches to target key documents to enable counsel to tailor legal strategies to the case facts.



**Reduced Review Counts**

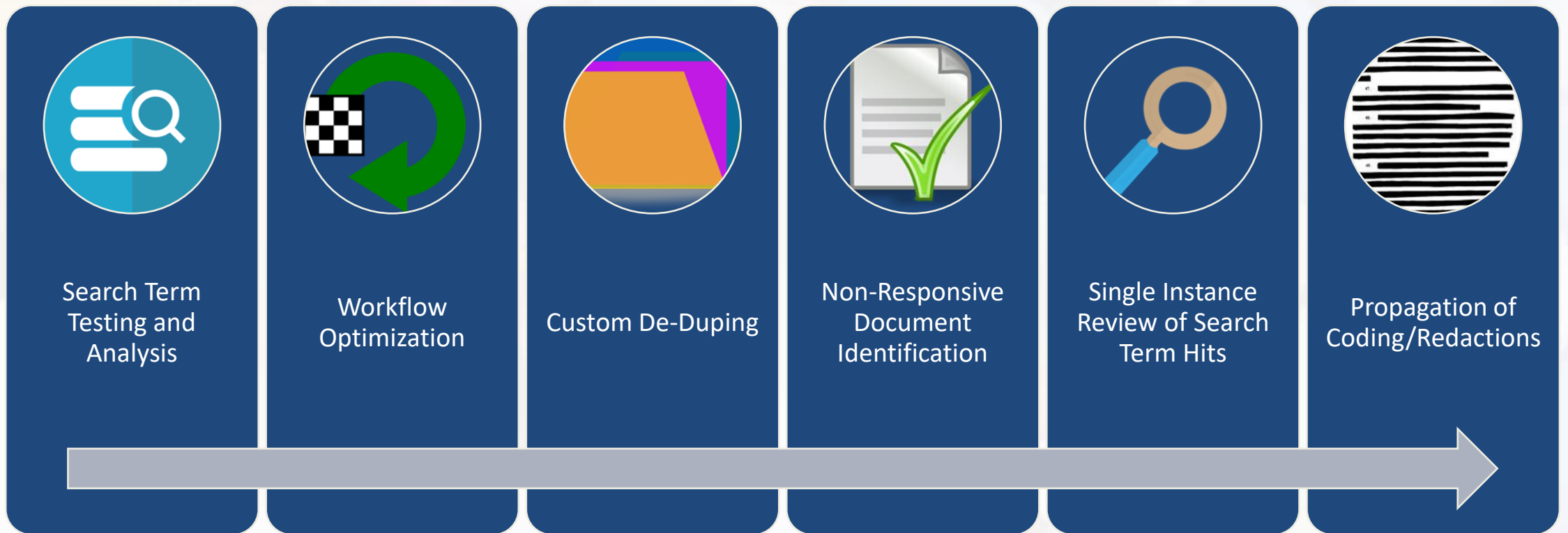


**Optimized Workflows**

# Managed Review

Reduced Review Counts and Optimized Workflows

## Example Tactics and Techniques





# Quality Control

## Proactive and Continuous

### Gauge Analysis:

Before releasing team members to pull general review batches, use a gauge analysis that **tests and scores each reviewer's coding on the same set of documents**. This allows an assessment of the reviewers understanding of the data, the instructions, and the subject matter. It also tests the instructions and protocols the reviewers have been given.

### Sampling and Targeted QC:

Throughout the course of a review, the coding should be sampled and tested on a regular basis to make sure that the documents are being coded correctly. If mistakes are found retraining should occur and problematic and systematic coding mistakes should be targeted and corrected.



# Quality Control

## Proactive and Continuous

### Event Handlers:

Most review tools are able to implement event handlers that prevent reviewers from coding documents inconsistent with some coding instructions.

- Presence of PII/PHI
- Presence of presumptively privileged terms
- Necessary coding on Responsive documents

### Conformity and Consistency Searches:

Prior to release for production certain consistency and conformity searches should be run to make sure that like documents receive similar coding where necessary.

- Hashtag
- Near dupe
- Similar text and file names





# Questions and Answers

# HaystackID Backgrounder

## Service Portfolio

# About HaystackID

## Why HaystackID Instead of Other Providers

HaystackID is a **specialized eDiscovery services firm** that helps corporations and law firms find, listen to, and learn from data when they face complex, data-intensive investigations and litigation.

Focus	Enablers	Markets	Workstreams	Models
Forensics	Experts	Law Firms	Audits	Pay for Use
Early Case Insight	Technology	Corporations	Investigations	Subscriptions
Legal Review	Integration	Governments	Litigation	MSA*

HaystackID serves more than 500 of the world's leading corporations and law firms from North American and European locations. HaystackID's combination of expertise and technical excellence coupled with a culture of white glove customer service make it the **alternative legal services provider** that is *big enough to matter but small enough to care*.



# Forensic First Services

## Why HaystackID Instead of Other Providers

**Forensics First Services** help you **find** your data during investigations and litigation.

- Computer Forensic Collections and Analysis
- Computer Forensic Expert Witness Testimony
- ESI Identification, Collection and Preservation
- ESI Triage Services
- Data Discovery Consulting and Management (Compliance, Information Governance, Computer Forensics)

These services can be employed in **data discovery** and legal discovery situations from the point of unstructured data creation and interrogation to data collection.

Data Discovery: The exploration of patterns and trends within unstructured data with the objective of positive outcomes through insight.



Interrogation



Indexing



Preservation



Collection

# Early Case Insight Services

## Why HaystackID Instead of Other Providers

**Early Case Insight Services** help you **listen** to your data to gain insight for legal discovery decisions.

- ESI Ingestion and Processing
- ESI Assessment and Analytics
- ESI Hosting
- Managed Services
- Legal Discovery Consulting and Management

These services can be employed in data discovery and **legal discovery** situations from the point of collection through the ingestion, processing, and review of data.

Legal Discovery: The process of identifying, preserving, collecting, processing, searching, reviewing, and producing ESI.



Ingestion



Processing



Review



Production



# ReviewRight Services

## Why HaystackID Instead of Other Providers

**ReviewRight Services** help you **learn** from your data to make the right decisions for positive and quality investigation and litigation outcomes.

- ReviewRight Match (Reviewer Selection/Sourcing)
- ReviewRight Translate (Foreign Language Review)
- ReviewRight Manage (Integrated Review/Metrics)
- ReviewRight Host (Review Platform Hosting)
- ReviewRight Automate (Predictive Coding)
- ReviewRight Virtual (Remote Review)



These services can be employed in **legal discovery** situations after processing for the review of data.

ReviewRight provides six services that can be used individually or integrated to optimize review impact on investigations and litigation.



Review



Match



Translate



Manage



Host



Automate



Virtual