



# Medical Record Data Abstraction... Simplified

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Keeping your sanity when integrating medical record  
data into large scale clinical research projects



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Research studies that incorporate medical record data face numerous complex challenges. While medical records provide researchers with objective, “real world” data, the process of abstracting those records is fraught with potential pitfalls that can lead to project delays, ineffective record procurement, added cost or even premature study termination.

Despite perceived obstacles, researchers can steer clear of anticipated hazards by following best practice methodologies to improve overall data quality, allowing organizations to differentiate themselves from competitors by adding a rich source of real world clinical data. Real world data merits serious consideration as part of any well-designed empirical research effort and to support evidence-based medicine initiatives.

This paper provides an overview of how the medical record data abstraction model can be enhanced, including:

- Avoiding research design flaws
- Streamlining the procurement process
- Building a quality abstraction team
- Ensuring data collection objectivity

This report also investigates the role of health information management (HIM) professionals as integral components of abstraction teams and provides examples of successful case studies.



## Best Practice Approach

*“The tactics of extracting data from medical records are performed according to the laws of laissez faire: the investigator usually chooses the records and removes the data in whatever manner he/she wishes, and he/she seldom reports specific details regarding methods”*

– AR Feinstein 1969

Although the quote is nearly 40 years old, there is a kernel of truth that illuminates reservations researchers may have about adding a medical record review component to a study protocol.

When a research study involving medical record abstraction falls short of its goals, a careful assessment will often reveal easily addressed pitfalls that could have made the difference between success and failure.

These pitfalls include a study design that neglected to consider commonly available medical record documentation, inappropriate specialty or facility focus for medical record requests, poorly designed and/or inadequately tested abstraction tools, and abstractor bias and/or inexperience.

Leading research organizations reduce these errors by adhering to industry best practices. Best practices offer a blueprint for effective and efficient studies that raise the standard of medical record abstraction data quality for clinical research. In addition, organizations and researchers following best practice methodologies differentiate themselves in the marketplace, thereby creating opportunities for new business.



## Why Medical Records?

Because the medical record provides real world data, it also offers added value compared to the coded patient information acquired from administrative or claims data. While claims data may present a convenient overview of the information in medical records, this source tends to be biased toward reimbursement and incomplete from a clinical standpoint. Being at least one step removed from the primary source (the patient’s medical record), administrative data is subject to more human error, including improper or incorrect coding.

When a research company sets out to study a specific medical condition or cause/effect relationships of particular drugs or other therapies to various clinical outcomes, the “gold standard” source for relevant and objective clinical data is the medical record.

Certain challenges do arise, however, when researchers incorporate medical record data into their studies.

Two hurdles facing research organizations that seek to abstract medical record data are procuring records and establishing a valid case rate to correspond with research goals. Each task depends on the success of the other.

#### Procurement (securing medical records for a selected study-specific sample)

When medical records are required and data collection criteria have been established, researchers may compile a list of potential records to send to the abstraction specialists.

These records may be maintained anywhere in the country, from large or small, rural or urban hospitals, to small provider practices or large inner city clinics – and in hard copy or electronic format. The abstraction team has the responsibility of obtaining as many of these records as possible, through appropriate and secure measures and in compliance with client (researcher) guidelines, HIPAA regulations and other government standards.

Experienced abstraction procurement teams use every available resource, including phone calls, e-mails, faxes and postal mail, to secure the medical records needed to access the essential data for a given study. Even with today's apparent preference for electronic communication, most medical records still arrive in paper format, either faxed or mailed.

Sifting through the sheer volume of these records alone can be intimidating. The process is further complicated by missing, illegible or incomplete data; records not relevant to the research; time constraints; and human error. Each hurdle successfully conquered can significantly impact the validity of medical record data for the purposes of a given study.

#### Valid case rate

Many studies with a medical record abstraction component aim to reach an anticipated valid case rate. The reason is simple: for a study to collect and report on valid data, a minimum number of records must be procured to meet the criteria established in the study design. Valid case rate, an estimated ratio that may be established during the design phase of a study, helps to predict how many records must be sampled and procured during the course of a study to reach a threshold of appropriate records for study-related review.

Skilled abstraction professionals rely on their wide-ranging experience and expert procurement knowledge to help researchers determine valid case parameters, either prior to or during early phases of the study.

Researchers consider a number of factors to ultimately predict what percentage of patient records will likely qualify for study inclusion. Experienced clinical data abstractors can assist in this process. Because valid case thresholds will vary widely from study to study, hundreds to potentially thousands of records may need to be procured to secure the required number of relevant records. Record procurement can be further challenged by tightly defined studies such as those focused on rare or unusual conditions.

Experienced medical record abstraction teams keep researchers informed of case validation rates and other abstraction issues during every step of the procurement and record review process, fully aware that even small variations can significantly impact a study's timeline and budgetary constraints. Clinical data abstractor skill and expertise mitigate the risk of reviewing records not relevant to research goals, and abstractor objectivity increases the quality of collected data.

#### Objectivity

High quality clinical data abstraction focused on study intent requires an objective, unbiased approach. All abstracted data must reflect actual entries in the medical record – nothing more or less. Objectivity is critical for research data validity, and experienced, credentialed data abstractors are trained to handle all abstraction projects from an objective perspective.

This ingrained objectivity distinguishes abstractors from clinicians when it comes to medical record data collection. Abstractors learn to search for precise information, recording it strictly as documented in a record. Clinicians, on the other hand, tend to look for medical trends or issues and apply professional opinions and interpretation of documentation when reviewing medical records, as they have been trained to do.

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### Objectivity *(continued)*

While such training is essential for delivering quality care, assumptions or inference of intent from medical record review may introduce inaccuracies or bias into the collected data and the study as a whole. This potential for flawed data is why researchers often seek experienced health information management (HIM) professionals to carry out their clinical data abstraction rather than assembling teams of clinicians (such as nurses or physicians) for record review.

By acknowledging and addressing these challenges during the study design process, researchers lay the groundwork required to successfully incorporate medical record data into a variety of study formats.

 **Common Approaches**

Medical research takes various forms, from early-phase safety and efficacy studies (Phases I-III), which include linear studies that span years, to post-approval or late-phase studies, which may range from several weeks to several years. Projects involving collection of clinical data from medical records may seek information on how treatments are being applied by practicing clinicians and may require tracking patient responses and/or reactions to drugs prescribed for specific medical conditions or other implications of treatment interventions on medical outcomes.

### From a question to a plan

All research begins with a question, but an effective and efficient plan to answer the question can separate a successful research study from one that fails to deliver.

Study design and planning should outline the purpose and goal of the research, define how the research will be conducted, document the timeframe, establish participant attributes, and include cost constraints.

To avoid study planning problems such as vague or unfocused research processes, inappropriate data targets, or overly cumbersome procedures, research teams should focus on the goals of the study first and work backwards.

This approach consistently creates strategic study or protocol designs, focused on answering the study's question by supporting or denying its hypothesis.

### Who's involved?

Medical research studies differ in scope and complexity, yet most follow a standard formula. For example, a pharmaceutical company with products being marketed for a specific condition may want to know how clinicians prescribe these products and the effect they have on patients.

Since medical record data offers the most comprehensive answers to these questions, researchers can tap unidentifiable, aggregate insurance-related claims data to identify a sample of patient profiles matching criteria for study inclusion. To validate a claims data-based sample, researchers can enlist the help of an organization or individuals practiced in medical record abstraction and skilled in coding validation to abstract relevant clinical data from corresponding medical records.

The medical record procurement phase of the process, like other important steps required for robust real world clinical data abstraction, presents unique challenges that can be overcome with the help of a skilled and experienced abstraction team.

### Building an abstraction team

With procured records in hand, skilled abstractors can sift through volumes of medical information and hone in on the specific data needed. Professional medical record data abstractors are highly-skilled experts with extensive backgrounds in medical coding and hands-on clinical data abstraction. They hold degrees in Medical Records/Health Information Management (HIM) or related fields. Their professional certifications include Registered Health Information Administrator (RHIA), Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS) and Certified Tumor Registrar (CTR). All credentials require ongoing education to maintain certification.

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### Building an abstraction team *(continued)*

The importance of a skilled and knowledgeable abstraction team cannot be overstated. These teams enhance the quality of data for clinical research because they:

- Identify potential study design pitfalls early in the process
- Know what to ask for in the medical record procurement process
- Maintain medical chart review objectivity
- Hone in on what's important in the medical record to satisfy study data requirements
- Preserve compliance with privacy and confidentiality, considering both patient and research concerns
- Assess the quality (consistency, reliability and validity) of data collected throughout the abstraction process

The ideal clinical data abstraction team includes the following professionals:

- Project Manager: oversees all elements of the medical record abstraction project, including budget and timeframes
- Research Manager: a highly-trained and experienced professional with clinical and technical expertise, including database management; oversees work scheduling and ensures the quality of abstracted data
- Lead Abstractor: manages the day-to-day details of the abstraction process and trains and supervises the abstractors
- Abstractors: experienced in both clinical data abstraction and medical coding; conduct the actual data abstraction



## The Health Information Management Advantage

Hiring health information management (HIM) professionals to conduct medical record data abstraction offers numerous advantages. Many credentialed HIM professionals possess years of experience as both coders and medical record abstractors, with in-depth knowledge of classification systems such as ICD-9, ICD-10, and ICD-O. Their experience allows them to assist in practical study design and mine medical record documentation more efficiently, saving time and improving data quality.

Researchers can secure the services of HIM professionals in several ways. Some privately funded foundations or academic-based research organizations build their own in-house teams of HIM professionals. Others, such as corporate clinical research organizations and pharmaceutical companies, may hire HIM professionals as independent contractors or hire an organization that specializes in HIM services, including comprehensive and highly-specialized medical record procurement and abstraction support.

The size, scope, timeline and budget of a study often dictate options for clinical data abstraction. Smaller projects may be served well by independent abstractors, but for large, complex projects, researchers will generally have more success working with a specialized third-party organization or building out their own in-house teams.

The proof lies in the results. Following are two recent examples of researchers turning to third-party data abstraction organizations to enhance clinical research. The first example examines the role of third party abstraction organizations in a late-phase real world clinical data analysis project; the second covers a large-scale clinical trial with a medical record abstraction component to assess patient outcomes during the trial.

### Late-phase research

A large clinical research organization leverages HIM professionals to gather and analyze health care data and provide clients with findings and expert perspectives to empower smart decisions. This clinical research organization has conducted studies for a variety of diseases and corresponding treatments, including such chronic illnesses as asthma, diabetes, glaucoma, congestive heart failure and HIV infection, as well as lung and breast cancer, stroke, and rheumatoid arthritis.

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#### Late-phase research *(continued)*

The organization's research studies require detailed data to be collected directly from patient medical records, as opposed to relying on coded data from administrative claims, though claims data is used initially to identify the sample of medical records to be procured and reviewed. This type of study design created several persistent challenges. Furthermore, this organization had relied on nurses and other clinicians to perform data abstraction but found this approach increasingly difficult due to the limited number of available clinicians and the need for the utmost objectivity.

In addition, they were faced with study design flaws that became apparent only after medical record review was underway and had difficulty navigating privacy issues related to medical record procurement. The reliability and validity of clinical data collected was questioned by some of their clients.

To rectify these issues, this organization hired Care Communications to develop more efficient, accurate and effective project solutions. Care Communications proposed and executed a multi-level approach that could be integrated into all of the organization's research projects involving medical record abstraction.

Care Communications developed guidelines for abstracting, provided an abstraction team of HIM professionals, and assisted with study and process design to assure the privacy and security of data collected. Once the new processes were in place, this organization saw research projects completed on time and within budget guidelines, data quality enhanced, and design shortcomings addressed and corrected.

#### Large-scale screening trial

A leading U.S. university also chose to work with a third party medical record abstraction company in a large-scale clinical trial that is still underway. The study design requires analyzing outcomes data collected from thousands of medical records across multiple time intervals over the study's eight-year timeframe.

The complexity of the trial's clinical data abstraction and coding process requires a highly specialized abstraction and nosology (a branch of medicine that deals with the classification of diseases) team.

The university's biostatistics center hired Care Communications to build the abstraction team, schedule and track outcomes, perform record review, and abstract clinical outcomes data for thousands of study participants.

Despite well-documented shortages of qualified medical coders and specialized abstractors with HIM credentials, Care Communications successfully assembled a team of HIM professionals that included:

- Project manager
- Research manager
- Clinical data abstractors
- Certified tumor registrars
- Nosologists

Working together with the university's biostatistics center, Care Communications refined clinical data collection guidelines and support materials and created policies and procedures for all abstraction and other trial-related outcomes data collection functions. Care Communications continues to provide their client with detailed productivity and progress reports for critical trial documentation and maintain detailed problem logs and record tracking reports, including tracking of all corrective actions.

The university's study is currently on pace to be completed on time and on budget.



## Conclusions

- The "real world" data contained in patient medical records provides researchers with "gold standard" quality but only when properly and objectively abstracted.
- Conducting high-quality medical record data abstraction requires the specialized skills of highly trained, experienced health information management (HIM) professionals.
- Recruiting professional clinical data abstractors can ensure that research projects will follow industry best practices, leading to better data objectivity, enhanced overall project quality, budget containment and adherence to project timelines.
- Hiring organizations specializing in medical record data abstraction can enhance the overall quality of medical research, especially for complex studies where real world medical data is either limited or difficult to obtain.

A small version of the Care Communications logo, consisting of a stylized circular icon.

## About the Author

Denise Moline, RHIA  
Clinical Research Manager

Denise Moline has more than 20 years of ICD-9-CM/ CPT-4 coding (nosology), clinical data abstraction, training, clinical research and project management experience. Before joining Care Communications, Denise worked for Lockheed Martin Information Technology as a Senior Medical Data Coordinator. Currently, Denise supervises Care Communications Research Coder/Abstractor Consultants, coordinates training and assignments, monitors clinical data integrity, performs quality checks, and serves as a key contact for researchers and study site/client research associates.

Contact her at [dmoline@care-communications.com](mailto:dmoline@care-communications.com).