

For decades, our Data Management group has met sponsor requirements and has provided the highest level of data integrity for Late Phase studies.

Data management activities include Case Report Form design, application of various data capture technologies, query management, medical coding, and ongoing quality control and assurance. Our Data Management team applies these core competencies to the unique demands of Late Phase data collection.



The following elements of Clinical Data Management service ensure the success of your project:

## Planning

A REGISTRAT-MAPI Data Management Plan is not just a collection of specifications; it's a genuine plan, progressively elaborated, that provides guidance for the collection and cleaning of the data. Because there can be diverse sources of data, we outline clear data flows (that still enable complex data to be captured, when necessary), reconciliation processes, and cleaning methods.

## Investigator and Patient Focus

Late Phase Investigators are often research naïve, and study participation is discretionary. Data Management can promote site and patient retention by providing clear, convenient data collection forms, patient visit reminders, and by linking grant payments to good performance. We often deploy several collection mechanisms in each study, including EDC, paper, and telephone interviews tailored to the convenience of the participants.

## Cleaning Methods

Because clinical monitoring in Late Phase studies is infrequent, if it occurs at all, we cannot rely on source document verification of clinical data. Instead, we develop sophisticated edit checks to trap errors, and we avoid burdening the sites with a high volume of queries. REGISTRAT-MAPI's electronic Case Report Forms (eCRFs) promote clean data entry, while online edits trap errors efficiently. Our paper forms are designed to be logical and unambiguous. Grant payments are linked to the delivery of clean information, promoting compliance.

## Flexibility

REGISTRAT-MAPI deploys a variety of data collection mechanisms to promote participation and compliance. When a study lasts for years, changes are likely; REGISTRAT-MAPI's Data Management staff, processes, and technology are prepared to collect additional or changed information. We have developed and deployed sub-study data collection mechanisms during an active study. For instance, REGISTRAT-MAPI also delivers special subsets of data to investigators who run their own studies. Working closely with our biostatisticians and programmers, REGISTRAT-MAPI frequently provides reports and data to support publications and presentations on short notice.

## Late Phase data collection is characterized by:

- Very large volumes of data
- Hundreds to thousands of patients and Investigators
- The inclusion of Patient-Reported Outcomes (PROs)
- Long study durations, often exceeding 10 years
- Limited, or no, clinical monitoring and source document verification