Key Data Management Strategies for SUCCESSFUL LATE-PHASE STUDIES

Late-phase studies present a set of unique goals and challenges unlike those in earlier phase clinical trials. Because this brand of research strives to reflect the real world, study designs are varied, data may be unavailable, and the uncontrolled environment may present unexpected results. At the same time, there already may be a large body of data available on a given product or disease. As a result, existing information may be leveraged to limit data required to be collected for later phase research. To assemble a reliable data source in a late-phase setting, a strategic data management approach is necessary — and must incorporate some critical factors.

No. 1: Question Common Data Management Assumptions

Within the regulated and expensive world of clinical development, data quality is paramount. But when the consumer of data is not a regulatory agency, there may be some latitude for relaxing certain commonly held data management principles while still meeting basic principles of GCP, quality, and 21 CFR part 11 compliance. As such, the rigor in which data management is conducted may not always be the same. For example:

If data are collected on paper, is double-data entry truly required? If questionnaires are commonly used, the risk of transcription error may be less. Furthermore, image recognition technology can potentially supplant the need for data entry altogether, particularly if questions are designed with discrete or simple responses.

Is medical coding necessary to categorize co-morbidities, adverse events, or concomitant medications, or would a pre-defined list of choices suffice? Perhaps only key medications are of interest, or treatment options are well-established. If so, only specific AEs may be of interest, perhaps simple tick-boxes for those pre-specified AEs can be used, rather than collecting free text and event details. This may make categorization of these events more efficient and less costly. Moreover, if the research question is to observe how a medication is administered, without specific regard to safety, medical coding may be avoided altogether.

No. 2: Flexible Data Management Systems

Given the varied nature of late-phase research, a correspondingly flexible set of data management tools are needed to support this area. However, this does not mean that late-phase data management systems are more expensive; in many cases, the opposite is true. Moreover, the effectiveness of any EDC system usually hinges on training and usability, which is especially crucial for late-phase research.

For example, a very ill population may need paper forms to complete at the bedside. Or, logistically, it may be easiest for the site to hand out paper forms for later entry into the system. In order to complete PROs/diaries between visits, ePRO (electronic data capture directly by the patient) offers a higher compliance rate and accuracy than paper in a population that has home internet access. Specialized features may allow self-reporting of special adverse events (AEs) of interest between site visits and automatically alert the investigator or project team.

Sites are often more research-naïve in late-phase scenarios. As a result, keep things simple for them: a plain EDC user interface, well-designed eCRFs may go a long way in minimizing their frustration. An EDC system must have effective, remote training and support, and run with minimal interference. This is especially important in long studies with infrequent visits.

EDC support costs and database changes can loom large in late-phase research. Prospective studies often span many years and research questions may evolve over time. Start-up and close-out timelines may be important to preserve, and having a system with responsive support is still important. However, users may not need help desk support 24/7/365, and sophisticated modules for reporting or data integration may not be necessary. Choosing a system that has the essentials for data management but lacks extraneous services can be an important way to manage cost while preserving quality of the data.

Contributed by

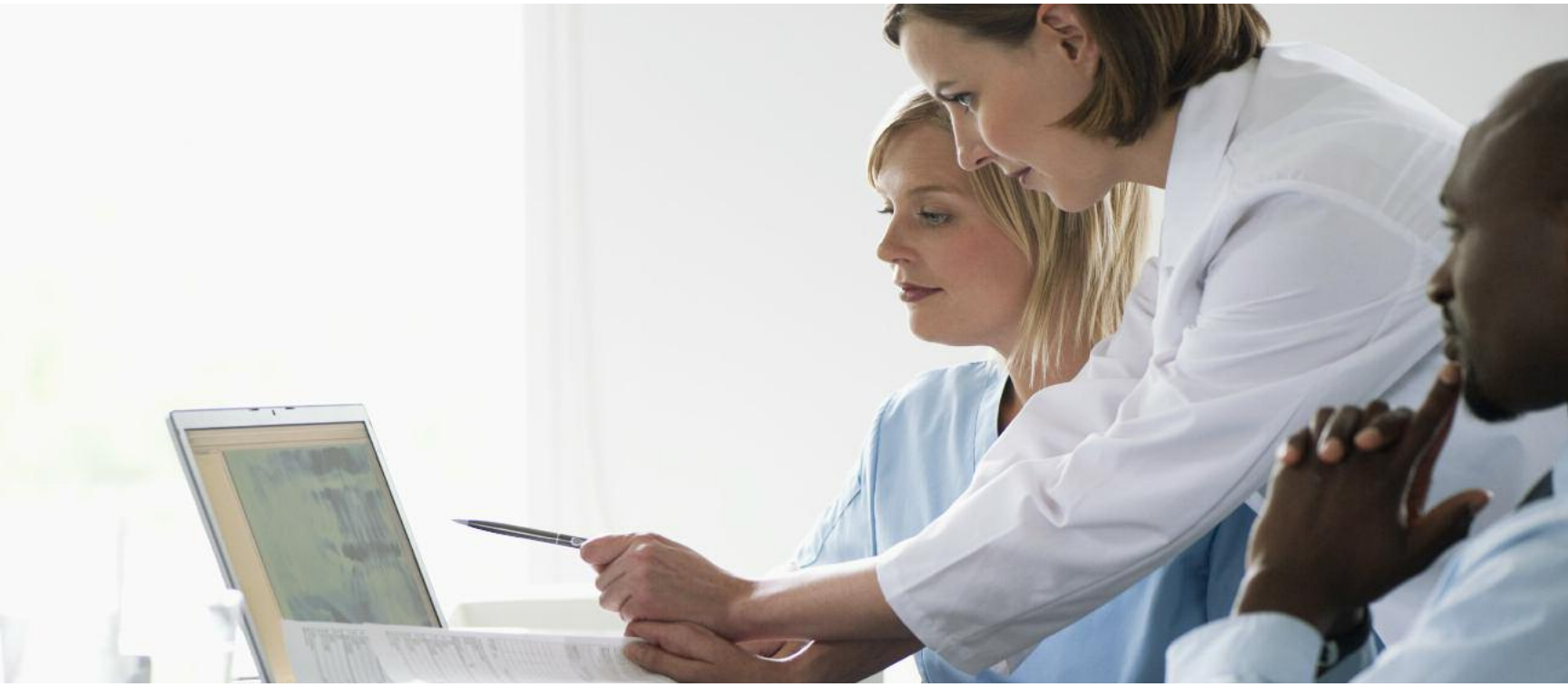
STEVE GULYAS, PH.D.
Senior Director, Late Phase Data Services, OptumInsight

Question the Status Quo

In summary, late-phase research is a growing and highly customized area requiring a specialized team — one that is grounded in core data management principles yet understand the nuances of late phase work and can adapt it for tailored settings. Remembering to question common data management principles and implementing those differences with proper systems can go a long way to building an effective data management strategy. PV

One size doesn't fit all phases.

Experience the difference of dedicated Late Phase data management.



Late Phase trials are diverse. So are your needs. By working with a team focused solely on Late Phase data management, you can leverage the global expertise, secure systems, and creative solutions needed to tackle the unique and complex challenges that Late Phase clinical trials, observational studies, and registries.

Standing behind our experienced staff is the equally powerful Smart Measurement® System (SMS) for Late Phase, an end-to-end EDC and CTMS solution from Optum. This comprehensive, cloud-based solution can lower your costs and increase your access to real-time data by offering a unified, easy-to-use interface with robust reporting capabilities.

www.optuminsight.com/life-sciences

Partner with an industry leader in Late Phase data management, contact Optum today at 215.675.4269 or Theresa.geary@optum.com to learn more.

Optum is a leading health services business whose more than 35,000 worldwide are dedicated to making the health system work better for everyone.

OPTUM™