Optum™ is a world leader in health outcomes and late phase research. We uniquely couple expert study design consultation with rich data sets to enhance the success of late phase studies, helping you achieve both your scientific and commercial objectives while maintaining regulatory compliance.

Efficient execution of late phase research requires a multifaceted approach that involves demographic data mining, scientific study design and analysis, therapeutic expertise, epidemiology and pharmacovigilance expertise, risk management, global regulatory affairs expertise, and deep knowledge of real-world research. Our focus on specialised expertise allows us to integrate these areas for a competitive advantage, which culminates in helping sponsors demonstrate the actual value of their products in the market.

Leaders in research excellence
Members of the Optum research team have backgrounds in diverse areas, including the pharmaceutical industry, academia, pharmacology, health economics, epidemiology and marketing. In fact, 85 percent of our researchers hold advanced graduate-level degrees, including 40 percent who hold doctorate-level degrees such as MD, PhD, DrPH and PharmD. We also receive robust protocol development and program support from scores of board-certified physicians involved in medical and scientific affairs and epidemiologists throughout the organisation. This high level of training and rich depth of expertise translates into a dedicated research team that is well experienced in the appropriate blending of scientific and commercial objectives in the design and implementation of post-marketing studies.

Wide-ranging late phase research capabilities
Optum specialises in the design, implementation and results dissemination of the following types of late phase research:

- Registries—disease, product and safety
- Phase IV trials (approve products)
- Consumer Health care/OTC trials
- Community–based and naturalistic studies
- Health economics and outcomes research (prospective, observational studies) - cost-effectiveness, burden of illness, PRO/Qol, chart review survey (direct to physicians or patients)
- Health economic piggyback trials

Produce the real-world proof you need to succeed in a post-marketing environment
Leveraging unparalleled data assets to improve study design and execution

Our late phase research team has access to longitudinal health data for millions of covered patient lives and nearly half a million physicians. This unique data asset includes such health care data sets as administrative data, pharmacy claims data, physician and hospital claims data, laboratory results data, and socioeconomic elements.

These secondary data assets can be leveraged to facilitate robust study design and streamline study execution. For instance, the data can be analysed to determine/confirm sample size; assess/improve study protocol feasibility; identify targeted investigators and patients; and improve the efficiency of recruitment and execution of the study.

Integrated and automated data collection and management systems

Optum is on the forefront of developing and utilising integrated health care technology solutions. We have automated and integrated technology that offers real-time data accessibility and reporting to provide clients with timely and effective data management. Experience has also taught us that having flexible and simple-interface data solutions greatly enhances the success of late phase research involving the key populations of research-naive sites.

OptumInsight regularly applies the following technologies to create "fit for purpose" client solutions:

- IVRS
- EDC
- CDataFax (optical character recognition)
- Web portal
- E-Clinical (web-based study management)
- ePro
- Web-based investigator training

Remote site management

OptumInsight also offers sponsors a site management centre (SMC) composed of in-house CRAs to manage investigator sites remotely. The SMC provides cost-effective site management solutions designed to maintain the integrity of study results. Its dedicated staff assists sites with their regulatory document collection, IRB approval, protocol training, patient enrolment, data submission and cleaning, and any other site-related needs. This approach reduces the site burden so as not to interfere with the routine daily practice of the investigators and helps foster valuable site relationships. The SMC can also provide full central monitoring or traditional on-site monitoring via certified CRAs, depending upon trial requirements.

Enhance the success of your late phase studies

To learn more about how Optum’s deep knowledge of late phase research can support your products, please contact us at +61 3 9525 6320 or kathryn.collopy@optum.com

Manage investigator sites remotely and cost-effectively to maintain the integrity of your study results