



Clinical Trial Outcome Databases

Harnessing the wealth of publically available clinical trial outcomes data to enable drug development and commercial decision-making

Decisions are made along the development path of a compound to maximize the probability of its success. Making these decisions requires considerations and predictions of the drug’s product profile relative to those of key competitors in the market. Further, the growing power of the payers and accompanying reimbursement pressures are making the need for comparative effectiveness even more crucial. As such, a thorough understanding of the data available for all the potential competitors has become one of the critical needs in the decision-making process.

It is within the context of this critical drug development need that we created a series of therapeutic area-based Clinical Trial Outcomes Databases. Based on years of experience exploring and analyzing publically available data to perform model-based meta-analyses for our clients, we created a set of databases that comprise key attributes (ie, always up-to date, analysis ready, flexible and high quality) that make them relevant and effective in supporting drug development decisions. These databases are curated and updated regularly by our scientists to assure relevance.

Inform Go/No Go, Portfolio, Marketing and Trial Decisions

Certara Strategic Consulting provides Clinical Trial Outcomes Databases that capture summary-level data on the efficacy and safety of drugs on the market or in development for specific therapeutic areas. Depending on the indication, each database could include anywhere between 30 to 1000 clinical trials and represent aggregate information for up to hundreds of thousands of patients.

Certara’s well-organized and analysis-ready Clinical Trial Outcomes Databases are used to form a quantitative framework to leverage valuable external data to provide key development insights:

- Comparative effectiveness
- Scaling of endpoints
- Quantify impact of treatment, time and patient characteristics on therapeutic outcome
- Biomarker, efficacy and safety outcomes
- Commercial viability

Available Databases*

CNS & Pain	Oncology	Immunology	CV, Metabolic & Other
<ul style="list-style-type: none"> • Schizophrenia • Alzheimer’s • Migraine • Neuropathic pain • Chronic pain • Lower back pain • Osteoarthritis pain • Secondary stroke 	<ul style="list-style-type: none"> • Non-small cell lung cancer • Metastatic breast cancer • Acute-lymphoblastic leukemia • Non-Hodgkin’s lymphoma 	<ul style="list-style-type: none"> • Relapsing-remitting multiple sclerosis • Rheumatoid arthritis • Psoriasis, Psoriatic arthritis • Ulcerative colitis • Systemic lupus erythematosus • Ankylosing spondylitis • Sjogren’s disease 	<ul style="list-style-type: none"> • Types 1 and 2 diabetes • HCV • HBV • Glaucoma • NASH • Thrombosis • Idiopathic pulmonary fibrosis

* Others available upon request.

Information is organized by trial, arm, patient demographics, treatment regimen, and outcomes (totaling more than 200 fields) for analysis-ready queries. The understanding gained from the analysis of these databases can be used to select an optimal dose, predict trial results, characterize biomarker to endpoint relationships, bridge across various patient populations, quantify the benefits relative to competing treatment options, and quantify the probability of success of a compound or clinical trial. A clear understanding of how your compound can be best positioned against existing and developing competitor drugs will enable you to more effectively manage your portfolio, make go/no go decisions, and drive the future marketing for your drug.

KEEP Platform

To optimize use of the clinical trials databases, we have KEEP, Knowledge Enhancing and Enabling Platform. KEEP provides a user-friendly interface to the databases, enabling quick and informative access. KEEP benefits include:

- **Knowledge repository clinical trial data.** KEEP contains the most current available trial information allowing users to scope specific drug development decisions, such as study design, patient and treatment data.
- **Exploratory analysis platform.** Multiple databases are accessible on one platform for comparative analysis and multi-variable filtering. KEEP helps users to see relationships between endpoints, subpopulations, etc, to provide early insight.
- **Problem-solving system.** Delivering a 'faster time to insight,' users can analyze the competitive landscape on a target drug, enrich internal knowledge on a therapeutic area, and answer myriad questions to guide trial development decisions.
- **Communication and visualization tool.** Users can interact, plot and summarize data in real time to share results with colleagues and stimulate ideas and form key decisions.

Multiple Applications for Clinical Databases



Publicly available clinical trial data represent an underutilized source of information and if properly extracted and analyzed, provide a great value for comparative effectiveness and overall drug development.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.