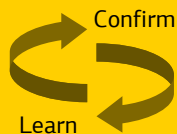


## Drug Development Phases

Discovery | Pre-Clinical | Phase - I | Phase - II | Phase - III | IV

Data Availability



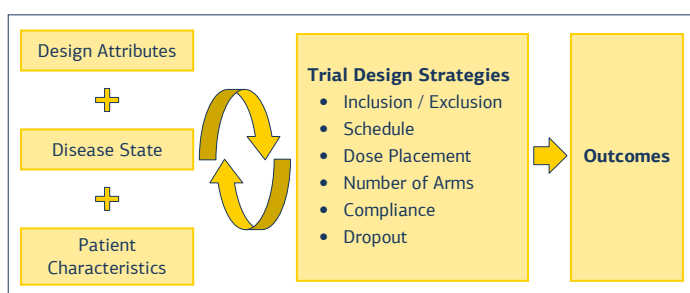
Knowledge Base

## Clinical Pharmacology Custom Services

In recent years, there has been a steady decrease in the number of NCEs for regulatory approvals due to high attrition rate in various phases of drug development. To bridge the gap between cost and time there is a need for alternative approaches such as PK / PD modeling and simulation (M&S).

- Predictive modeling tools provide invaluable information to better streamline the drug development process
- Modeling approaches prove useful in determining relationships between biomarker responses, drug levels and dosing regimens of new drugs, faster and at a lower cost

Optimal use of M&S will lead to fewer failed compounds in late stage development, fewer study failures and smaller number of studies needed to support the registration.



### Characteristics of the data fields

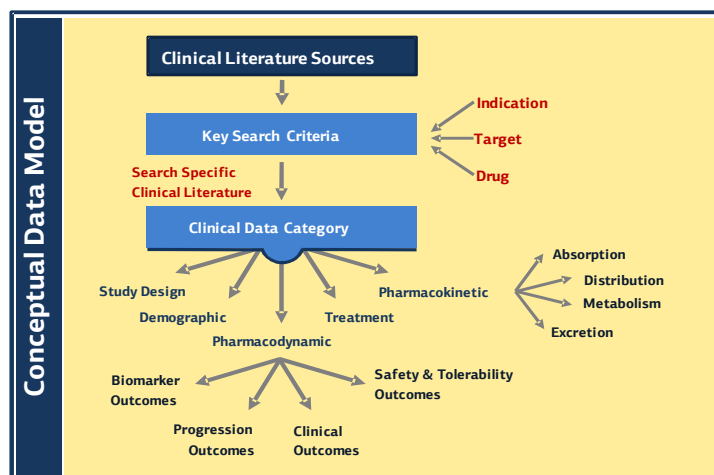
- Literature source information
- Study design information
- Demographic information
- Treatment information
- Pharmacodynamic information
- Pharmacokinetic information

### Key Features

- Client defined specifications and literature
- Rigorous QC to ensure high quality
- Protection of Intellectual Property
- Updates on a regular basis
- Well defined process
- Client defined data formats

### Literature Sources

- Journal publications
- Clinical trial registries
- Conference posters
- Regulatory reviews
- Proprietary data



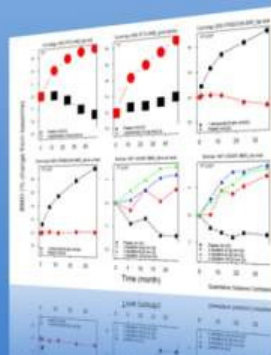
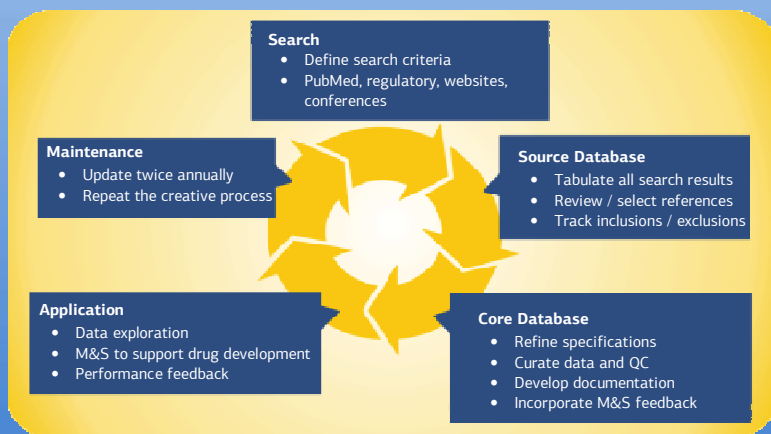
GVK Biosciences (GVK BIO), Asia's leading Contract Research Organization, delivers customized data curation services to the life sciences industry. GVK BIO's scientists analyze data to transform biological patterns into knowledge.

- Building and maintaining indication specific clinical trial outcome databases for use in M&S efforts
- Rich experience across therapeutic areas (> 50 indications covered)
- High quality deliverables and adherence to timelines
- Manual curation by qualified scientists



Our data helps to build quantitative models from the "competitive landscape" for different treatments that enable decision-making in clinical programs





## Clinical Trial Outcome Database



Quantitative Solutions Inc. (QS) founded by Jaap Mandema and Russ Wada, is a leading scientific consultancy service provider to the pharmaceutical and biotech industry. QS develops quantitative models of clinical PK, efficacy and safety data to enable better drug development decisions.

GVK BIO has collaborated with QS to market the existing QS core clinical trial outcome databases and to develop/market additional databases in selected disease areas. These databases capture summary level data for the clinical safety and efficacy outcomes from publicly available data sources.

The databases are designed to assist companies conduct comparative efficacy and safety analysis, link/scale biomarkers to clinical outcomes, predict/ improve trial outcome and develop product differentiation strategies. They will be supported by customization and M&S consulting services provided by GVK BIO and QS, respectively, to ensure maximum flexibility and benefits to the clients.

### Key Features

#### Comprehensiveness

Includes information for marketed drugs as well as drugs in development; data sources include journal publications, conference posters, regulatory reviews, etc.

#### Ease of tracking

All clinical trial publications are listed in a separate source database and linked to unique clinical trial names.

#### Flexibility

Design allows for quick updates and expansions to include additional indications / drugs / endpoints / trials.

#### Model-friendliness

Designed and reviewed by experienced modelers to ensure highest quality and usability for M&S to support drug development strategies.

#### Customizability

Can be augmented with clinical trial data proprietary to the client (this information goes into a separate proprietary database and will be owned by the client).

#### Why Use Our Databases?

- Designed and managed by experienced modelers with strong expertise in meta-analysis
- Supported by multiple clients and proven valuable in drug development decision making
- Updated semi-annually to enable time-critical analysis and decisions
- Backed by GVK BIO custom curation services and M&S consulting services offered by QS

#### Currently Available Databases

- Rheumatoid Arthritis
- Osteoporosis
- Neuropathic Pain
- HCV
- Depression
- Schizophrenia
- Alzheimer's
- Dyslipidemia
- Diabetes
- Glaucoma

#### Q1 Launch

- Oncology (Breast Cancer, Pancreatic Cancer, Colorectal Cancer, NSCLC)
- Allergy & Respiratory



Quantifying the World's Clinical Trial Efficacy, Tolerability, and Safety Information to Enable Good Drug Development Decisions

