Clinical Pharmacology Comparator Database - Modelling Perspective

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Abstract

Developing an innovative drug is too expensive and 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. 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. Publicly available clinical trial data represent an underutilized source of information and if properly extracted and analyzed, provide a great value proposal. It is within the context of this critical drug development need, a comparator data base model is required which supports model based meta-analysis (MBMA) which helps in seeking answers for specific research questions during drug development. Through Comparator Outcome Databases (COD) we enable clients to capture summary level data for the clinical safety and efficacy outcomes. Data sources we use that facilitate quick data analysis are- publicly available data sources (PubMed, Cochrane, Trial registries, FDA Summary Basis of Approvals) and proprietary data sources (Embase, OVID, CSRs).

The comparator data base model can greatly improve the efficiency and quality of pharmaceutical drug development process.

Schematic Representation of steps involved in Comparator database development

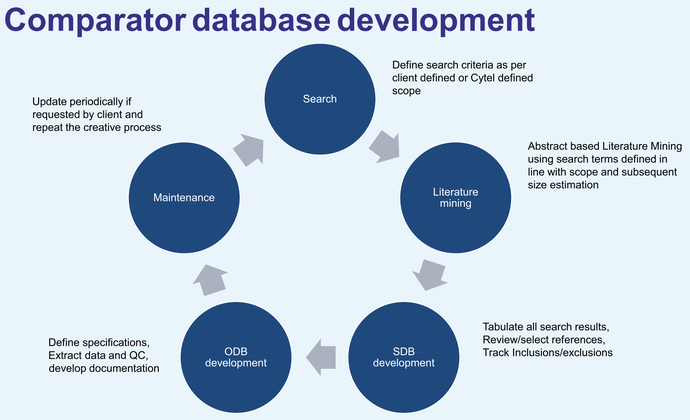

Figure 1: Different steps involved in development of COD

Objective

The purpose of this presentation is to explain the pivotal role of comparator database in the drug development process.

What we do? :

We at Cytel will extract summary level clinical outcome data along with detailed information on treatment, patient population, and trial characteristics are captured.

- Globally, as the researchers from various therapeutic areas have a problem in extracting the clinical trials data, through our Comparator Outcome Databases (with a focused scope and clinical literature in a client desired data structure), we enable clients to capture summary level data for the clinical safety and efficacy outcomes.
- In addition to clinical outcome data, detailed information on treatment, patient population, and trial design will be captured.

How we do? :

Steps in comparator database development

1. Scoping

Search Parameter	Criteria
Objective	Clinical effectiveness of the Rx for disease
Disease Population	
Treatments	
Clinical Phase	
Study Design	
Data Sources	MEDLINE, EMBASE, COCHRANE
Publication Year	
Language	
Inclusion Criteria	
Exclusion Criteria	

2. Literature mining

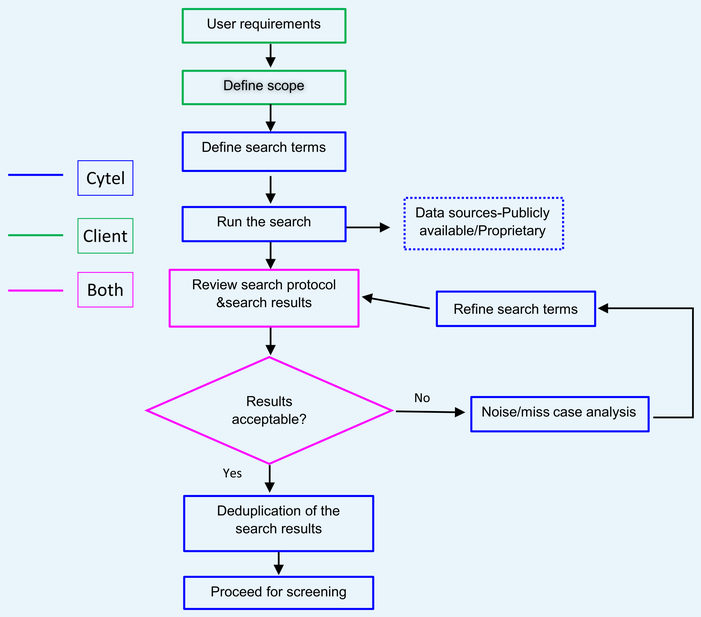

Figure 2: Process involved in literature mining

3.Source database (SDB) screening/Short listing of the publications

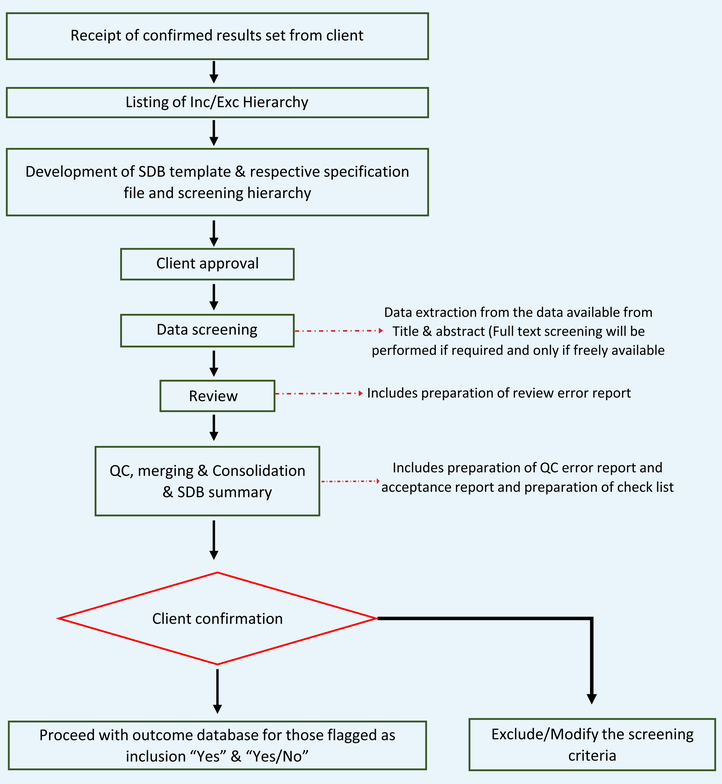

Figure 3: Process involved SDB screening

4. Core Outcome database (ODB) development

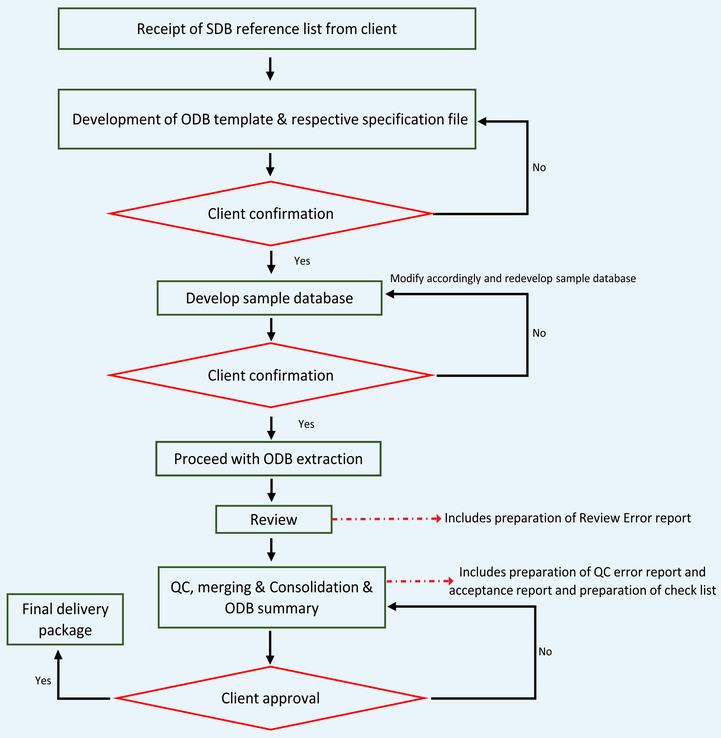

Figure 4: Process involved ODB development

Why we do? :

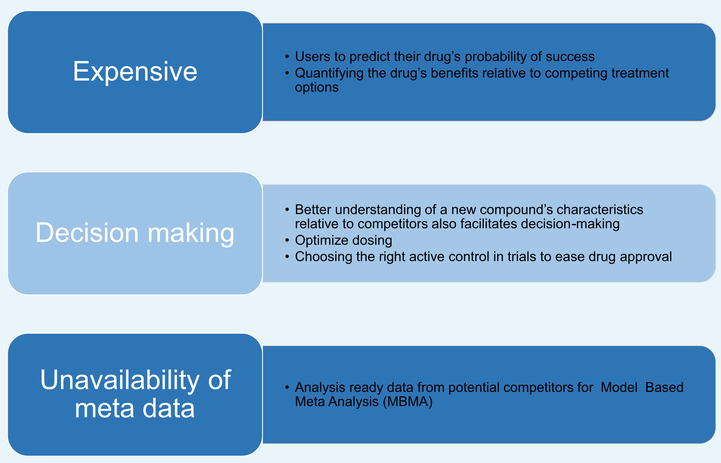

Figure 5: Solutions to problems during drug development using COD

Conclusions

- We have designed this database to assist clients in conducting comparative efficacy and safety analysis, linking/scaling biomarkers to clinical outcomes, predicting/improving trial outcome and developing product differentiation strategies. This even ensures maximum flexibility and benefits