

Strategic Medicine Case Study – Maximizing Clinical Trial Success: Hypothesis Generation & Trial Design

PONTE

PONTE, "Efficient Patient Recruitment for Innovative Clinical Trials of Existing Drugs to other Indications", aims at providing a platform following a Service Oriented Architecture (SOA) and Semantic approach that will offer a mechanism for optimizing the integrated analysis of the clinical, molecular and commercial aspects of a potential clinical trial to support improved identification and recruitment of optimally eligible patients.

The initial application of this platform is in drug repositioning with specific focus on mitigating patient safety risks, reducing clinical trial costs and improving clinical trial efficacy. Work towards this direction involves decision support mechanisms fed with information retrieved from a semantic search engine; the latter operating on top of a data representation linking validated data within drug and disease knowledge databases, clinical care and clinical research information systems and data on competitive intelligence.

The Challenge

As a result of the global economic crisis, spiraling costs associated with the development of new drugs, and risks inherent in early stage drug development, pharmaceutical companies around

the world are shifting their focus away from early-stage R&D and are instead examining opportunities for re-positioning existing drugs that may not have been successful for their initial clinical indications.

The three primary reasons for considering a repositioning approach center upon realization of new/additional knowledge about the disease itself, the drug target, or the drug molecule. Development of concepts and ontologies based on these three perspectives naturally converge and overlap, however critical issues such as clinical presentation, likely co-morbidities, secondary pathway response, competitive intelligence and intellectual property restrictions need to be identified prior to trial design and initiation and evaluated in a systematic manner.

Failure to identify these critical issues early often results in less than favorable trial outcomes, patient safety issues, and a missed revenue opportunity/new drug approval for the sponsoring company.

Hypothesis Generation & Trial Design

Strategic Medicine (SMI), a global provider of disease stratification products and services, is participating in PONTE towards the development of a computational platform that supports the design of clinical trials and

Maximizing Clinical Trial Success through Hypothesis Generation and Trial Design

evaluates inclusion/exclusion criteria to aid in patient recruitment through linking to EHR's and external data resources.

This process begins with the development and evaluation of the hypotheses upon which the clinical trial is based. In this manner, the platform extends the conventional bottom-up integration of multiple data sources into a novel top-down approach that identifies critical issues through need-based scenarios and links the concepts and queries to the appropriate underlying data sources, both public domain and private. This hypothesis generation approach integrates concepts from the clinical, molecular and business domains to uniquely enable early evaluation of constraints, potential side-effects, risk of success, and population size which support the critical decision making necessary to maximize clinical trial success.

The Outcome

This integrated and comprehensive approach helps to enhance the

assignment of risk, evaluation of potential market size/share, provide early identification of side-effects, identify at-risk patient populations and improve the overall success rate of the clinical trial.

By integrating the clinical, molecular and commercial factors within a single environment, better assessment of the potential "business case" can be made and early criteria/decisions can be made to support both success and early termination of a trial.

Lastly, this approach has been shown to be useful to "reverse engineer" existing trial designs to identify critical components and concepts that were not adequately considered in the initial design phase.

About Strategic Medicine

Founded in 2007, Strategic Medicine is committed to improving the quality and effectiveness of healthcare through the research, development and implementation of its proprietary patient and disease stratification

models. Strategic Medicine's mission is to improve clinical outcomes through better patient and disease stratification.

The company addresses a fundamental problem in medicine that is increasingly problematic for patients, healthcare providers, and payers alike.

SMI offers disease stratification products and services driven by clinical need and supported by its rapidly expanding knowledge base and improved implementation of diagnostic technology.

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