IQVIA

Fast-Tracking Clinical Trials

The Linguamatics NLP platform enabled Eli Lilly and Company to assist in the design of new clinical trials and increase speed to business insight

QUICK FACTS

Situation: Eli Lilly needed a solution for expediting the extraction, analysis and synthesis of specific statistics from oncology and diabetes clinical trials records. Doing so would enable the organization to understand the competitive landscape, and focus ongoing research and trial planning.

Solution: The Linguamatics NLP text mining solution, expert support team and specialist knowledge of pharmaceutical research delivered all this and more.

Success: The NLP platform reduces costs, time and errors by speeding up research, and increasing precision and recall of data extracted. Clinical statisticians are able to automatically access and analyze current trusted data. Health outcome researchers can rapidly answer questions from payers.

Situation

The clinical trials stage of drug development is a costly business. Speed to market is vital both to the bottom line and to improving patients' lives. Technologies that expedite and focus competitor analysis are key enablers, as Eli Lilly and Company's Principal Research Scientist Eric Su was only too aware.

Charged with finding a scalable solution to extracting summary statistics from oncology and diabetes trials in clinical trial databases (ClinicalTrials.gov and TrialTrove), Eric was looking for a solution that was agile and scalable, and that could extract facts and synthesize knowledge. Finding such a solution would enable Eli Lilly to better understand the competitive landscape, where to aim future clinical trials and how to best enable its meta-analysis. Ultimately, it would enable Eli Lilly to save time and money, and, potentially, contribute to better patient outcomes.

Solution

Eric realised that text mining was the way forward and that a real-time, natural language processing (NLP)-based solution would save time and money, and also reduce laborious manual effort for the clinical trial teams. He chose such a solution: the Linguamatics NLP platform.

The Linguamatics NLP platform is an agile, scalable, real-time NLP-based text mining solution. It is currently used by 18 of the world's top 20 pharmaceutical and biotech companies during many stages of the drug development pipeline. Various government bodies, including the FDA, and healthcare providers such as Kaiser Permanente, also rely on the NLP platform.

"[Linguamatics NLP] provides data that would take tens or hundreds of times longer with tedious manual work. It enables downstream calculations to provide insight. Some work would not have been done or done comprehensively without [the platform]."

— Eric Su, Principal Research Scientist, Eli Lilly and Company

Figure 1: Illustration Of Data For Clinical Trial Summary Statistics

ClinicalTrials.gov
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Efficacy and Safety of Dapagliflozin, Added to Therapy of Patients With Type 2 Diabetes With Inadequate Glycemic Control on Insulin

This study has been completed.	**ClinicalTrials.gov Identifier:**
Sponsor:	NCT00673231
AstraZeneca	First received: May 6, 2008
	Last updated: September 25, 2013
Collaborator:	Last verified: September 2013
Bristol-Myers Squibb	History of Changes
Information provided by (Responsible Party):	
AstraZeneca	

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▶ **Purpose**

This study is being carried out to see if Dapagliflozin in addition to insulin is effective and safe in treating patients with type 2 diabetes when compared to placebo (identical looking inacti

Title page in ClinicalTrials.gov for NCT00673231, a trial of Dapagliflozin for type 2 diabetes.

Measured Values

	Placebo	Dapagliflozin 2.5mg	Dapagliflozin 5mg	Dapagliflozin 10mg
Number of Participants Analyzed [units: participants]	188	198	210	192
Adjusted Mean Change in Body Weight [units: kg] Least Squares Mean (95% Confidence Interval)	0.02 (-0.34 to 0.38)	-0.98 (-1.33 to -0.63)	-0.98 (-1.32 to -0.64)	-1.67 (-2.02 to -1.31)

A snapshot of some of the study results tables from ClinicalTrials.gov.

Doc	n	Measure Title	Least Squares Mean	Units	Weeks	Actual Treatment	LowerLimit	UpperLimit
▼ NCT00673231	188	Adjusted Mean Change in Body Weight	0.02	kg	24	Placebo	-0.34	▶ 0.38
	192	Adjusted Mean Change in Body Weight	-1.67	kg	24	Dapagliflozin tablet oral 10 mg total daily dose once daily 24 weeks	-2.02	-1.31
	198	Adjusted Mean Change in Body Weight	-0.98	kg	24	Dapagliflozin tablet oral 2.5 mg total daily dose once daily 24 weeks	-1.33	-0.63
	210	Adjusted Mean Change in Body Weight	-0.98	kg	24	Dapagliflozin tablet oral 5 mg total daily dose once daily 24 weeks	-1.32	-0.64
▼ NCT01294423	86	Adjusted Mean Change in Body Weight	-2.13	kg	24	Dapagliflozin : Dapagliflozin 5mg/matching placebo for Dapagliflozin 10mg oral dose	-2.65	-1.60
	87	Adjusted Mean Change in Body Weight	-0.84	kg	24	Placebo : Matching placebo for Dapagliflozin 5mg/10mg oral dose	-1.36	▶ -0.32
	88	Adjusted Mean Change in Body Weight	-2.22	kg	24	Dapagliflozin : Dapagliflozin 10mg/matching placebo for Dapagliflozin 5mg oral dose	-2.73	-1.71

Structured results table from the NLP platform, showing the adjusted mean change in body weight data extracted from the NCT00673231 table, with number of patients, treatment arm, outcome statistic and numeric metrics extracted automatically.

THE NLP PLATFORM SUPPORTS BUSINESS AND HEALTHCARE DECISIONS

Solutions based on keyword searching simply retrieve sets of documents that researchers have to read through. Linguamatics' NLP-based text mining solution, however, can identify the key facts, interpret the meaning, and extract and present facts in a structured form for researchers to review, analyze and summarize.

Using the NLP platform's text mining capabilities would accelerate the Eli Lilly research team's ability to synthesize knowledge across clinical trial databases, and generate actual insights that would support business and healthcare decisions.

THE NLP PLATFORM IMPROVES DRUG TRIALS' EFFICIENCY AND EFFECTIVENESS, INCREASING SPEED TO MARKET

The Linguamatics NLP platform helps clinical researchers to pull out precise information, numeric and otherwise. For example, inclusion and exclusion biomarker metrics can be standardized, meaning a precise, semantically normalized, structured data output, rather than unstructured text that is hard to research.

Improving the efficiency and effectiveness of drug trial planning in this way reduces the cost of the whole trial, and has the potential to minimize the time before the drug reaches the market.

Success ─────────────────

THE NLP PLATFORM SPEEDS UP AND FUTURE-PROOFS RESEARCH, REDUCES ERRORS AND COST

Eric describes accessing key clinical endpoints with and without the NLP platform:

"[Linguamatics NLP] enables us to extract efficacy endpoints in the form of summary statistics. Before [the NLP platform], some of my colleagues in clinical statistics were going into databases and clinical journals and copying and pasting relevant data into Excel. This is intensive, repetitive and very boring for PhD level statisticians. It is also prone to error. Pasting data into the wrong cell as the spreadsheet grows is typical.

"The alternative solution, pre-[NLP], was to outsource the extraction of summary statistics data. This is expensive, you don't know the quality standard, and, within a few months, the report from the vendor is out of date."

THE NLP PLATFORM ENABLES IMPROVED CLINICAL TRIAL DESIGN AND INFORMED ANSWERS FOR PAYERS

The NLP platform's interactive information extraction tools further improved Eric's results, by increasing recall and precision, integrating key information from different clinical trial sources and ensuring future data could be easily captured through periodic running of the queries.

"A public law that has been in place since 2007 requires companies and academic institutes to post results of all their clinical trials of approved drugs in ClinicalTrials.gov, making this a really amazing treasure trove. [Linguamatics NLP] enables us to go into this database to extract data from hundreds of thousands of clinical trials and transform data into knowledge for drug development," concludes Eric.

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