



Real World Evidence Vaccine Safety Data Analyzer (VSDA)

from Data to Insights...

POINT OF VIEW PAPER

APRIL 2013

HCL

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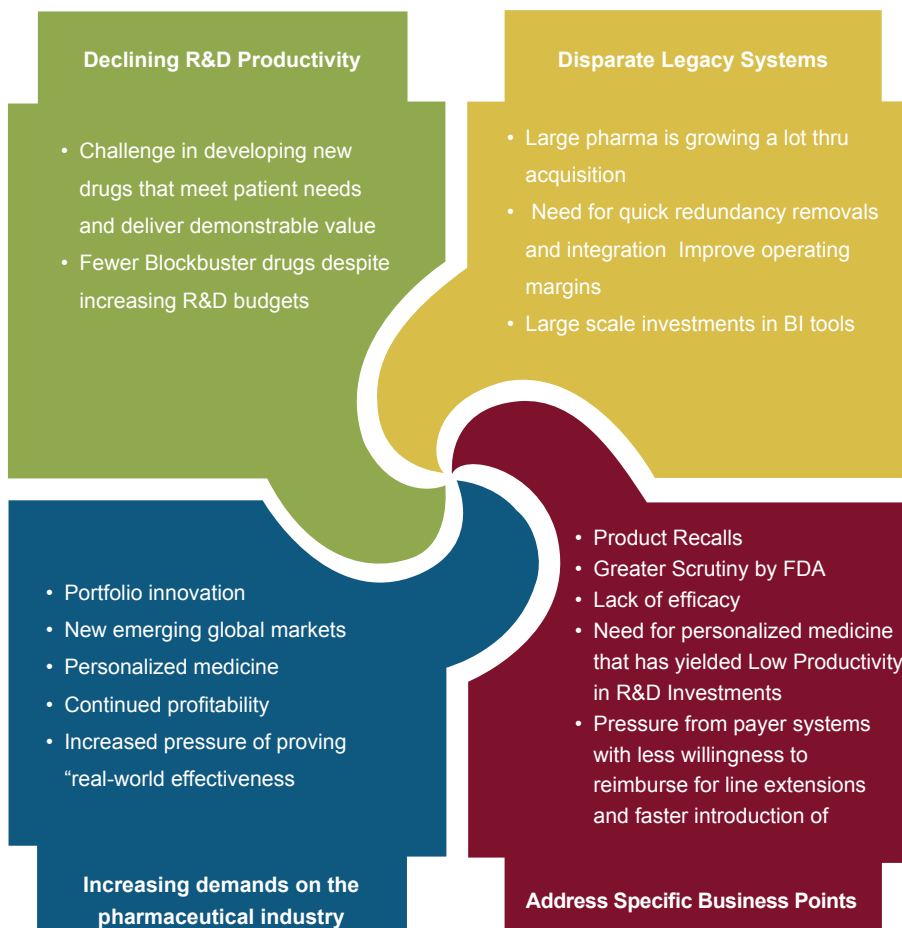
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REAL WORLD DATA ANALYTICS: KEY INDUSTRY CHALLENGES AND TRENDS

Product recalls, greater scrutiny by FDA, lack of efficacy and need for personalized medicine challenge pharmaceutical R&D organizations to develop new drugs that meet patient needs and deliver demonstrable value. Increasing demands on the pharmaceutical industry include portfolio innovation, new emerging global markets, personalized medicine, continued profitability, and increased pressure of proving “real-world effectiveness.” They must respond with complete and accurate evidence that allow decisions to be made around the value of a product, safer use and better patient care.

Pharmaceutical customers and regulators are now eager to mine the vast expanse of real world data, made available due to proliferation of Information Technology at point of care as well as, improvement in data capturing, storing and processing.

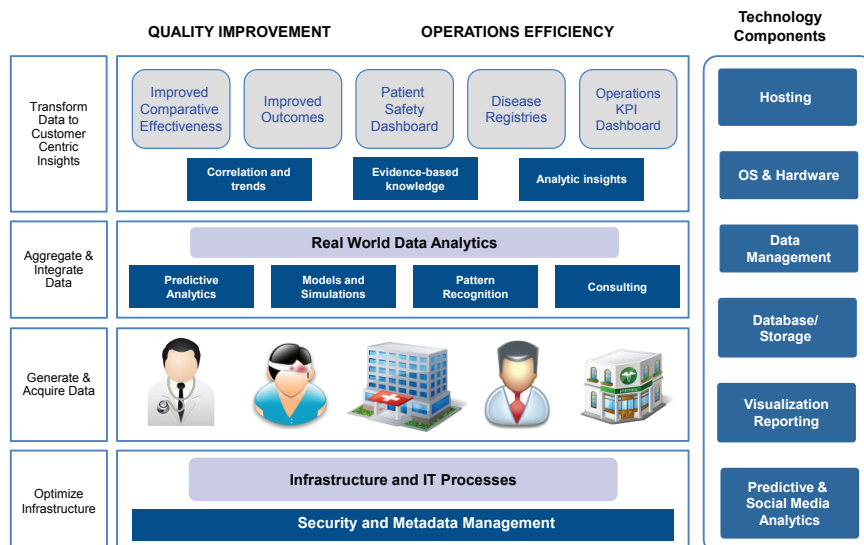
BUSINESS PAIN POINTS



The RWE stakeholders now have an opportunity to use the data to:

- Characterize diseases and patient populations by understanding real world trends like those of epidemiology, treatment patterns, and patient adherence and disease management opportunities
- Develop new products and therapies by assessing use of competitive products in the market, designing inclusion and exclusion criteria for clinical trials, performing predictive models on virtual trials, identifying patients for recruitment, and identifying unintended uses and indications
- Assess products and therapies already in use by observing drug safety, comparing product effectiveness, assessing health economics, and designing pay-for-performance criteria
- Target products and services by identifying underserved patient populations, high-cost areas for risk-based product pricing, and sub-populations with superior product response, and tracking message effectiveness through prescribing behaviour

By forming partnerships and building internal and external capabilities, pharmaceutical companies can shape the opportunities that RWD offers and equip themselves to establish or defend market-leading positions



By integrating data from across the enterprise and delivering self-service reporting and analysis, HCL wants to help various real world data stakeholders take well informed decisions that improve outcomes.

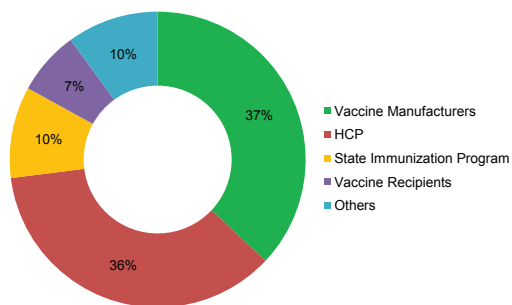
VSDA: OBJECTIVES OF PROOF OF CONCEPT

To develop Vaccine Safety Data Analyzer (VSDA) Platform for using the VAERS (Vaccine Adverse Event Reporting System) data that could help showcase and demonstrate HCL's analytics capability in pharma/healthcare domain using RWD (real world data), which could be useful to for decision making.



VSDA: DATABASE USED

The Vaccine Adverse Event Reporting System (VAERS) was started in 1990 as a national passive surveillance system for adverse events occurring after vaccination. VAERS is administered jointly by the Centers for Disease Control and Prevention's National Immunization Program and the Food and Drug Administration's Center for Biologics Evaluation and Research.



About 11,000 reports are received by VAERS each year: 10-15% involve hospitalization, permanent disability or considered life-threatening, about 2% involve deaths. Reports of adverse event are accepted by VAERS regardless of whether the vaccination is shown to have caused the adverse event.

Reporting to VAERS is voluntary and anyone may report vaccine adverse events. Reports are made by physicians, nurses, vaccine manufacturers, parents, persons affected by adverse events and others.

VSDA: KEY COMPONENTS AND BUSINESS IMPACT

- VSDA is a tool that analyses VAERS (Vaccine Adverse Event Reporting System) data to draw out insights on safety of various vaccines in use based on their adverse events (AE) reporting
- The platform can carry out a comparative safety analysis of various vaccines based on the reported AE incidences
- The platform demonstrates HCL's analytics capability surrounding pharma/healthcare data analysis, interpretation and recommendation
- Analysis of vaccine data by this platform could be useful to the stakeholders in decision making process based on its analysis, information and insight generation

- Geography/ State
- Age, sex and dose
- Site of administration
- Symptom count by vaccine and by manufacturer
- Specific AE (adverse events)/ by vaccine type/ vaccine brands/ age of vaccination)
- Co-administered vaccines
- By type of vaccine
- By manufacturer
- By vaccines
- Co-administered drugs
- Hospitalization and no. of hospital days

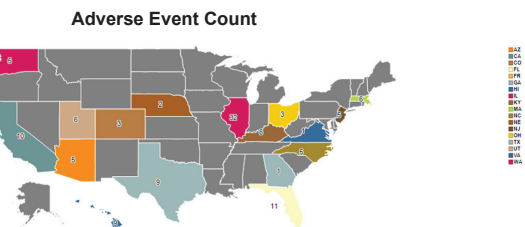
VSDA: CAPABILITIES

- Analysis of data and the results can be presented in a dashboard with statistical representation of data in the form of graphs/ charts
- Ability to export analytical charts directly into power point presentations
- Customer-centric insights can be drawn based on the analysis of data

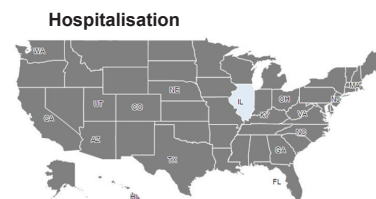
VSDA: EXAMPLES OF KEY BUSINESS QUESTIONS THAT CAN BE ANSWERED BY USING THIS PLATFORM:

- How many adverse events were reported due to BCG vaccine between 2006 - 2011? What was the geographical location of such AEs in United States? How many of the adverse events lead to hospitalization and for many days?
- What are the major symptoms reported in analysis of adverse events due to vaccines from 2006 - 2012?

- Which vaccines gave the highest % of “injection site erythema” as adverse event? Which manufacturer’s vaccine was responsible for highest incidence of injection site erythema?



- What was the total number of AEs reported per manufacture from 2006 - 2011?



- Which “Flu” manufacturer had the highest % of adverse

VSDA: VOICE OVER DEMO

Demonstration of VSDA's working and business analysis can be downloaded from either of these sites:

- <https://www.dropbox.com/sh/zooh0n7a90ybdp0/xCnVz1-bA8?m>
- <http://www.sendspace.com/file/oanwp4>

HCL DIFFERENTIATORS

HCL along with its partners, has trained resources in various business analytics techniques like Modeling and Simulation; Revenue Forecasting; NPV and eNPV analysis; Regression Algorithms; Decision Tree; Neural Networks; Association Rules; Clustering; Statistical Control Process; Time-Series; Supervised & Unsupervised Models; Boosting Algorithms

WE BRING TOGETHER MULTIPLE COMPETENCIES TO DRIVE THE ROI FOR BUSINESSES.

- Domain Focus by bringing in knowledge of business/ issues specific to Therapeutic areas/ Brands/ Products for different departments like R&D, Sales & Marketing, Merging historical data with current trends, events, expert opinion & customer sentiments to reveal business behavior
- BI Integration by Readiness in implementation with experience in latest technologies. Strong support for maintenance and future upgrades/ changes
- Advanced Market analytics through capability of utilization of data from multiple sources/ legacy systems to provide enhanced recommendations by overlaying external information on account level analytics.
- Rich ecosystem of partners like Oracle, TIBCO, SAS, Vertica, Greenplum, Marklogic, SAP, Microsoft, IBM. Tools are no constraint. We use SAS, VBA, .Net, Business Objects, MicroStrategy, MS Access/ Excel & In-house Tools and can adapt to new technologies

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ABOUT HCL

About HCL Technologies

HCL Technologies is a leading global IT services company, working with clients in the areas that impact and redefine the core of their businesses. Since its inception into the global landscape after its IPO in 1999, HCL focuses on 'transformational outsourcing', underlined by innovation and value creation, and offers integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and BPO. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multi-service delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers our 85,194 transformers to create a real value for the customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of US\$ 4.4 billion (23,499 crores), as on 31 Dec 2012 (on LTM basis). For more information, please visit www.hcltech.com

About HCL Enterprise

HCL is a \$6.2 billion leading global technology and IT enterprise comprising two companies listed in India – HCL Technologies and HCL Infosystems. Founded in 1976, HCL is one of India's original IT garage start-ups. A pioneer of modern computing, HCL is a global transformational enterprise today. Its range of offerings includes product engineering, custom & package applications, BPO, IT infrastructure services, IT hardware, systems integration, and distribution of information and communications technology (ICT) products across a wide range of focused industry verticals. The HCL team consists of over 90,000 professionals of diverse nationalities, who operate from 31 countries including over 500 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. For more information, please visit www.hcl.com

