Social Media and Pharmacovigilance

Business Case 2015Q1

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Executive Summary

There is an enormous opportunity for pharma to access up to date feedback on their drugs enabling them to act faster and more efficiently than previous reporting methods allowed.

In particular Pistoia needs to meet the challenge of an unmet need in Asia and deliver innovative science. The approach should be measurable with a realistic funding plan against the backdrop of potentially high costs. The project should first be targeted at Japan which has a fast growing and exciting pipeline but without the political complexities of other parts of Asia. Pistoia should connect with current projects and learn from completed prototypes. The Agile project management methodology should be adopted for this project.

The main benefits will be: staying competitive, higher quality of information, awareness of adverse events as early as possible, detecting trends, collecting real world evidence and increased profitability. Ultimately driving pharma forward, and improved drugs for patients.

Introduction

The purpose of this business case is to explore the value proposition for a social media pharmacovigilance project that would further progress the opportunity to unlock the value of the vast information captured by social media and at lowest risk to the industry.

Recent technology and the explosion of social media has driven a wave of change particularly in the way drug experiences, both positive and negative, are shared across the world in a matter of seconds. It is clear that Pharmaceutical and Biotechnology companies need to, and indeed are, responding to this change to develop their own strategy for social listening, including designing frameworks, protocols and guidance for employees, in order to compete in this market. The Tufts Centre for the Study of Drug Development White Paper concludes that, social listening is actively used in many industries for a variety of purposes that may be adapted to clinical research. For example, CISCO reported achieving 281% return on investment from social listening through reducing marketing costs and obtaining valuable insight into their customer needs.

Social media is available to most people, is easy to use and holds a vast amount of information about how drugs are being received across the patient population. To “unlock” the value in this information, will involve working with language and technology experts to develop algorithms to filter the information for value. One aspect of social media that is growing in use is sentiment analysis. This is intertwined with and pivotal to the results of any more detailed data mining activity. There are tools readily available that will analyse the information captured by social media and deduce an overall +ve or - ve result, which is a clear indicator of how a drug or company is being received. Sentiment analysis
also records neutral results and these are of special interest because this number reflects the potential population still to be influenced. There are projects ongoing to develop platforms for data mining social media, for example work ongoing by the Innovative Medicines Initiative (IMI) and this will be summarised in the report below.

Although sharing views via social media is easy to use, the unstructured format posted in a semi-anonymous fashion tests the traditional standards for defining a reportable event. The current “official” criteria for reporting an Adverse Event (AE) to a regulatory agency include: identifiable reporter, identifiable patient, suspect drug and adverse event. Changes in how the regulatory authorities work with pharmaceutical companies and patients will be challenging but is essential. One of the key areas of research in the Tufts study was the use of Social and Digital Media Communities in Pharmacovigilance and AE reporting and a number of findings are currently being shared in presentations and publications. A summary of the relevant finding from this US based report will be described in this business case.

It may be possible to collaborate with other interested parties, the intention being to reduce effort and duplication but this approach brings some potential disadvantages too, for example, large stakeholder groups that are slow to make decisions. For this reason, the benefits of working together should be carefully measured against any disadvantages of the project becoming too big and harder to manage.

The IMI have funding and an agreed program of work, including developing a mobile platform that could be used by patients to report AEs, as well as providing them with up to date information about drug side effects. This work is Euro centric. The US is also actively working with Social Media, particularly, how to influence the regulators in order to maximise value of the information gathered from social media but to minimise risk to the Pharma industry. Pistoia is interested in investigating how Social media and pharmacovigilance is working and developing in Asia and this opportunity will be explored further in this business case. This untapped market could be an exciting and innovative opportunity for Pistoia to explore new technology and breaking science to ensure that we are responding to real patient needs.

Specification and cost

The first two deliverables could take place in parallel and after a review and decision on the value of their findings, the third may start.

Asia – where to start?

Lead an investigation and deliver a report detailing how social media is being used in Asia and given that Asia is so vast and made up of many very different countries and languages, select one to work with initially. The investigation should include cultural differences affecting the way information is shared in that country, how pharmacovigilance is managed and the strength and interest in the drug pipeline for that country, i.e. what information is valuable to us.
Within Asia the three biggest pharmaceutical markets are China, Japan and South Korea, all have their own “version” of social media and perhaps, very different ways of approaching the use of social media. China, with a population of 1.3 billion, could be an obvious choice, but China has a growing appetite for generic drugs and is quickly becoming the world’s largest generic market. By 2015, China's generic market will be close to $82 billion (Pharma and Healthcare 2/3/14). Healthcare in China is increasingly political, the biggest customer, the government, is responsible for the funding mechanism. The controlled culture will affect the freedom of information shared on social media and for these reason I would not recommend to start working with China on this activity.

South Korea, with a population of 50.22 million, also is a country heavily controlled by the government which influences the freedom of approach using social media and this adds an additional level of complexity, which I suggest is avoided for now.

My recommendation is to start with Japan, with a population of 127.3 million and a fast growing and exciting pipeline. Pistoia recently acquired new members Chemaxon and BIOVIA, from Japan, and with their support, could set up reference group to pursue the project. Pistoia presented at a conference in Tokyo this summer and received much interest.

**Actions:**

1. Set up a contact group in Japan who can represent how social media is being used regarding pharmacovigilance and agree ways of working together.
2. Agree which social media tool to use and why.
3. Analyse cultural differences in how the social media tool is used e.g. how “rich” is the data captured, compared to Europe and US
4. Agree the value statement that Pistoia will deliver over and above work ongoing in the US and Europe

**Skills and Time:**

- Project Manager/Business Analyst - 2 days/ week over 3 months
  - Stakeholder management, facilitation of contact group
  - Planning, coordinating input from contact team
  - Analysis of various social media tools, different cultures

**Exclusions:**

What the project will not do is try to work with Asia as a whole or attempt more than one language at the start.

**Language data mining**

Connect with current ongoing projects and learn from completed prototypes to find the strongest language technology companies to work with that specialise in Asian languages. This technology is evolving constantly, is much specialised and could be extremely expensive. For this reason it is important to look for opportunities to collaborate with other projects where appropriate, and spend the Pistoia effort on delivering additional value. Develop a statement of work between Pistoia and the chosen language technology company according to agreed deliverable.
Actions:

1. Identify who (ongoing projects) to work and set up collaboration(s) with agreed remit
2. Review and shortlist 3 language technology companies as potential partners
3. Define specification, including costs, risks, time etc and commission selected 3 companies to draft response
4. Select from top 3

Skills and Time:

- Project Manager 2 days/week, over 3 months
- Technical developer 1 day/week, over 3 months
  - Planning, coordination, analysis of work, vendor management
  - Technical assessment, analysis, reviewing existing companies

Exclusions:
What the project will not do is repeat work already done or works with more than one language or social media type.

Design Prototype Project

Agree realistic prototype that will deliver a data mining tool for a chosen data set of interest in Asia, on a chosen social media tool. The specification for the prototype will include success criteria that will indicate if there is value in the output, when compared to the cost and resource used to deliver it. It is the intention of the tool to deliver an information set that is unique to the Pistoia project, and will give insight to the pharmacovigilance activity in Japan.

For example, in one pharma company there is a dedicated team responsible for social listening and data mining. An example Dashboard prototype ran during late 2013. This topic for data mining was a new vaccine launch and the result highlighted a 62% +ve response to the news. There must be much to learn from such ongoing activities.

Actions:

1. Define scope and specification of prototype and gain agreement from Pistoia
2. In Parallel, present funding options to Pistoia, for the prototype but also for potential expansion. There is no point delivering a successful prototype is there is no possibility of taking it further.
3. Develop tool according to the specification and demonstrate its value

Skills and Time:

- Project Manager - 2 days/week, over 6 months
- Technical developer - 2 days/week 6 months
  - Planning, producing specification, risk/benefits analysis, vendor management
  - Development of tool, coding, working with supplier
Prototype data mining

During discussions I learnt that a software company had carried out a development of a prototype tool that would be used for data mining information captured by social media, for the benefit of Pharma and the patient. That company chose to target one disease area, and only data captured in one country. I understand that the prototype was stopped because it was too costly in effort and time and too complex to filter from the massive amount of information captured and real value. It is important that as part of this deliverable we understand more about this prototype and why it was stopped.

Project management style

The Project Management methodology that would best suit the activities described in this business case is the Agile methodology.

Agile Project management is an interactive and incremental method of managing project activities and the Agile processes are known to harness change for the customers competitive advantage. It depends on business people and project team members working very closely, which is essential in this field of fast changing requirements and new technology. The early and continuous delivery of software and a flexible approach will be an essential formula to success.

The IMI project WEBADR is using an AGILE methodology and has 5 work packages, the fifth, developing the mobile application will be delivered for the first country and then using the strength of the agile approach will be adapted for the next country.

Competitor analysis

The Innovative Medicines Initiative (IMI) is a public-private healthcare partnership between the EU and the members of the European pharma association EFPIA. In July 2013, the IMI announced a new initiative called WEB-RADR (Web Adverse Events) which was part of their ninth call for proposals. This is in response to recognition of “highly disruptive and interrelated changes in the consumer technology market” which have led to “many people sharing their medical experiences publically on the internet”. The IMI believes that patient data on AEs available through social media could provide an “extremely valuable source of medical insight”, especially in terms of Pharmacovigilance.

The IMI plan to fund WEB-RADR through a consortium made up of biotechnology companies, small and medium enterprises (SMEs), regulators, payers, academics, and non-profit organisations. From a total budget of 135 million euros, the IMI have committed 4.56 million euros to the WEB-RADR project, for 3-year project duration.

The two main goals that WEB-RADR will deliver are a technology and policy framework for mining publically available (and licensed) web and social media content and a mobile platform that could be
used by patients to report AEs, as well as providing them with up to date information about drug side effects. This extensive information resource would be valuable for patients, carers and healthcare professionals. Furthermore, such data could be used to analyse AEs reported across the world and so provide an essential source for pharmacoepidemiologic research.

On September 10th 2014, a kick off meeting and workshop took place for WEB-RADR and the activity can be followed by using the web site http://web-radr.eu/.

The IMI recognise this is still a new field and there are many problems to overcome, not least, whether an AE reported on social media is genuine or not, but they consider the value is worth the effort.

The Tufts Center for the Study of Drug Development (Tufts CSDD) conducted a study of current and anticipated use of social and digital media communities in clinical research and produced a white paper that is currently on circulation. A working party was set up, made up of 20 Pharmaceutical and Biotechnology companies and contract research organisations (CROs) during March 2013 and December 2013 to address some of the concerns about usage of social and digital media and to consider how to optimise the value of the information. A key deliverable was to develop principles and policies that would enable maximum value and also minimise the risk in how social media is being used.

One of the five primary areas studied during this 9 month period was Social and Digital Media Community Use in Pharmacovigilance and Adverse Event Reporting. This topic was given the most attention by participating companies because it caused greatest concern. The study recognised that currently regulatory bodies have not provided clarity on guidelines specifically addressing the use of social and digital media in clinical research. Social media raises many concerns; top most is handling adverse event reporting. Other concerns, as a consequence of adverse event reporting, include early drop out from clinical trials, incorrect medical advice regarding safety and efficacy and violation of patient privacy and confidentiality. Most companies report fragmented and uncoordinated use of social media with little policy or guiding practice in place.

Summary of findings:

- The majority of companies (9 out of 12) that were involved in the study, admitted they were not “actively” gathering AEs from Social media, of the 9 companies that report using social media to “passively” monitor AEs, 5 use combination of automated and manual processes to identify individual case safety reports (ICRs)
- Guidance by Health authority and industry are high level and do not address key issues for example “control” of social media site:
- Raising questions such as “when a social media site is deemed to be company controlled?” and “what happens if an AE is discovered on a non-company controlled site?”
- Frequency of monitoring: no clear guidance on what “regularly” might mean
- Information gathered over time: guidance documents don’t address the scenario when an AE is posted on social media over a period of time and only the combined postings contain reportable AE information.
- Standards for reporter authentication:
• Standards for source material there are no regulations and little guidance to what is considered primary source material in the context of social media.
• Responsibilities of companies that engage in aggregate data collection and signal detection from social media.

The TUFTS study also researched social listening and summarised:

7 of the 13 sponsors reported they regularly use “social listening” to learn about marketed drugs, three companies outsource the practice completely and four have internal teams working with external providers. Half of the companies conduct social listening on a daily basis, the other half sporadically. The primary goals of social listening are to: understand community attitudes and behaviour, identify trends, monitor perceptions of product and company listening, adjust marketing campaigns, gauge community receptivity, learn about competitors, gain insight into product service improvements and gather input that may shape further research.

The results of the Tufts report are being presented at industry conferences in the US and Europe and findings are being prepared for publication. There are plans to convene a roundtable with the Department of Health and Human Services, including the FDA, congressional committees, other government agencies, and non-profit organizations.

The Tufts study has covered a number of key gaps in the regulations and industry standards and has put forward some considerations based on best practices and lessons learned. Pistoia is interested to follow up on the progress of these proposals and learn from any decisions.

Benefits and disbenefits

Taken from a paper by Wendy Blackburn executive president of digital pharms marketing agency – InTouch solutions

Benefits

• To stay competitive, it is essential to have a social media presence, giving improved reputation by being a company that listens to public opinion, but this alone is not enough, the value is in what you do with the output.
• Increased probability of capturing adverse events, it is believed today that many go unnoticed
• Find out information early enough to prevent an adverse event, due to easy access of information and ease of sharing with regulators
• Improved “quality” of information collected by social media because everyone has a voice, no matter their class, culture, religion etc. and therefore the information collected will be a closer reflection of society
• Able to detect trends/patterns of reported adverse events by analysing social media data
• Gather most up to date information about drug / company, including sentiment analysis and use to make improvements
• Collecting real world evidence that will help shape development of existing and new drugs
• Closer to patients, helps to build trusting relationships,
• Its free,( to share) quick easy to use, readily available
• Find out information early enough to prevent an adverse event

Disbenefits

• Social media is still new, involving complex technology that is constantly changing.
• It is very time consuming and resource hungry to keep up with the many different forms of social media and what the latest information is about a given topic.
• Similarly to be able to respond, given the relevant information, for example running a blog is very time consuming and some companies are now employing people for these roles.
• Social media is difficult to measure by traditional means

Sustainability

Cost is the biggest factor of developing data mining software to extract the value from social media for pharmacovigilance and so before any real project is started a funding model would need to be established.

Communications

Pistoia's response to the challenge of social media and pharmacovigilance and indeed the outcome of the recommendations should be socialised amongst the pharma community and interested parties. This will be a key step in the request for funding.

The communication plan could include:

• Publications for example in eyeforpharma or Patient Week
• Presentations at a conference, following a publication/press release
• Panel discussion, perhaps including representation from the Tufts study and WEB-RADR project.

There should be 2 or 3 events per year to maintain the momentum and interest in this topic.
Conclusion

The explosion of social media raises new challenges for pharmacovigilance and adverse event reporting but also huge opportunities for pharma to access up to date feedback about their drugs enabling them to act faster and more efficiently than with previous reporting methods. Allison Blass, former social media monitor for several big pharma brands states that “Adverse events are the best market research you can get”. The work ongoing with IMI, Tufts to progress this sentiment offer great learnings and experience, so far, based within Europe and the US.

There is therefore a challenge for Pistoia to pick up an unmet need in Asia and deliver innovative new science. This will however come at a high cost and therefore should be started in a small and measurable project and funding plans should be explored at the earliest opportunity. The approach must be targeted and realistic.

Appendix 1

Organisations contacted

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<td>Roche</td>
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