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Real World Awareness (RWA) Systems: A Pharmaceutical Industry Application

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Abstract
In this paper, we describe the evaluation of a real-world awareness (RWA) prototype designed to help managers perform environmental scanning in the pharmaceutical industry. RWA in the pharmaceutical industry consists of not only the tracking and tracing of drugs but also of pattern recognition for relevant events – both internal and external to the company - which can affect a company's drug research and development plans, marketing effectiveness, and ultimately its profitability. Based on interview insights from a German pharmaceutical company, we identify several objects of perception relevant to real-time identification and advanced anticipation of events. Our study provides a first glimpse into the potential of RWA for companies in the pharmaceutical industry, and generates insights for design of future RWA systems.

Keywords
Business Intelligence, Design Science, Environmental Scanning, Knowledge Management, Pharmaceutical Industry, Real World Awareness (RWA), Strategic Management

1. Introduction
The pharmaceutical industry today faces several transparency challenges related to tracking and tracing products along the entire supply chain in order to prevent drug counterfeiting, parallel imports and quality issues during storage and transportation. These contemporary issues are discussed worldwide – not only in the business and popular press, but also in the academic literature (Chircu et al., 2014). However, existing research has so far neglected one of the main components of pharmaceutical industry transparency: the real-time identification and advanced anticipation of events that are relevant to managers of pharmaceutical organizations. This ability to scan a company's environment, collect real-time information, and respond to it efficiently and effectively has been called real-world awareness, or RWA (Heinrich, 2006).

RWA systems are information technology (IT) systems that can reduce or eliminate problems with information capture, event forecasting, and company responses. They connect the natural world (people, products, inputs and resources) and the virtual world (internal IT systems and local, regional and global information networks) by capturing objects of perception (O'Brien, 2015) – information a company needs to attend to in order to make sense if its environment.

As the RWA concept is still in its infancy, there are few, if any, studies investigating which objects of perception should be included in a real-world implementation of a RWA system. Following a design science approach, this paper presents a novel prototype for RWA support in the pharmaceutical industry, and evaluates it using interviews with a pharmaceutical company in Germany. The evaluation provides preliminary insights into what objects of perception matter and should be monitored for effective environmental scanning in the pharmaceutical industry.

2. Study description and methodology

In this study, we adopt a design science perspective to design and evaluate a RWA prototype in a real-world setting. We apply the design science methodology (Vaishnavi & Kuechler, 2004; Riege et al., 2009) as follows. We identified the problem and documented its importance through a review of academic papers (for RWA importance) and industry sources (for importance of RWA to the pharmaceutical industry). We defined the goals for the solution (gathering objects of perception from a variety of sources) and then designed and developed a RWA artifact with these goals in mind. We customized the generic RWA prototype for the pharmaceutical industry, as described in section 3, thus demonstrating the artifact's applicability to a specific context. We then evaluated the artifact using a real-world company, as described in section 4. Results from this evaluation can be used for prototype iteration. Last, but not least, we communicated the results to the larger community in this scholarly paper, as recommended in the design science methodology.

Artifact evaluation in design science can follow three basic approaches (Riege et al., 2009):

- Evaluation of the artifact against an identified research gap: This evaluation is performed on the basis of fixed or pre-defined requirements obtained from a review of existing research, and checks the correct construction of the artifact (but ignores real-world conditions).
- Evaluation of the research gap against the real world: The representativeness of the research results the artifact is based on is evaluated, but the artifact itself is not.
- Evaluation of the artifact against the real world (or a section of the real world): The constructed artifact is used under real world conditions and the researchers measure whether or not it generates the expected results.

In this paper, we employ the third approach to test the artifact – in our case the pharmaceutical industry RWA prototype - against the real world – i.e. potential users. We are interested in how users react to the prototype (Arnowitz et al., 2006), and how they perceive the prototype's support for their information gathering requirements and its overall value. An important advantage of prototypes is the strong feedback received from the end users about their practical experiences and as well as for reviewing and clarifying relevant system requirements (Sultanow 2010; Sultanow et al., 2011). Thus, the information obtained from the prototype evaluation can be used in future iterations to improve the design and evaluate the results, as recommended in the design science literature (Vaishnavi & Kuechler, 2004).

3. A RWA prototype for the pharmaceutical industry

Previous research has proposed models for real-time notification systems for actors in spatially and temporally distributed collaborative networks (Sultanow 2010; Sultanow & Weber, 2011; Sultanow et al., 2011; Sultanow et al., 2015). In this paper, we build on this existing research to show how a RWA prototype developed for the pharmaceutical industry can be evaluated.

The prototype creates a realistic world metaphor using geographic visualization of global events in the four-dimensional space/time structure. The prototype displays decision-relevant information that has been extracted from various Internet sources. Tags on the world map indicate where the identified events are taking place; additional information about each event can be obtained by clicking on a particular item. The prototype can display specific events from a company's internal databases as well as economic, market and competition-related events from the Internet, using sources such as industry information services, news agencies, government news feeds, etc. Figure 1 shows an example of the event view of the prototype, displaying events on potential competitors within a specific medical therapy (hematology-oncology) (see Figure 1).

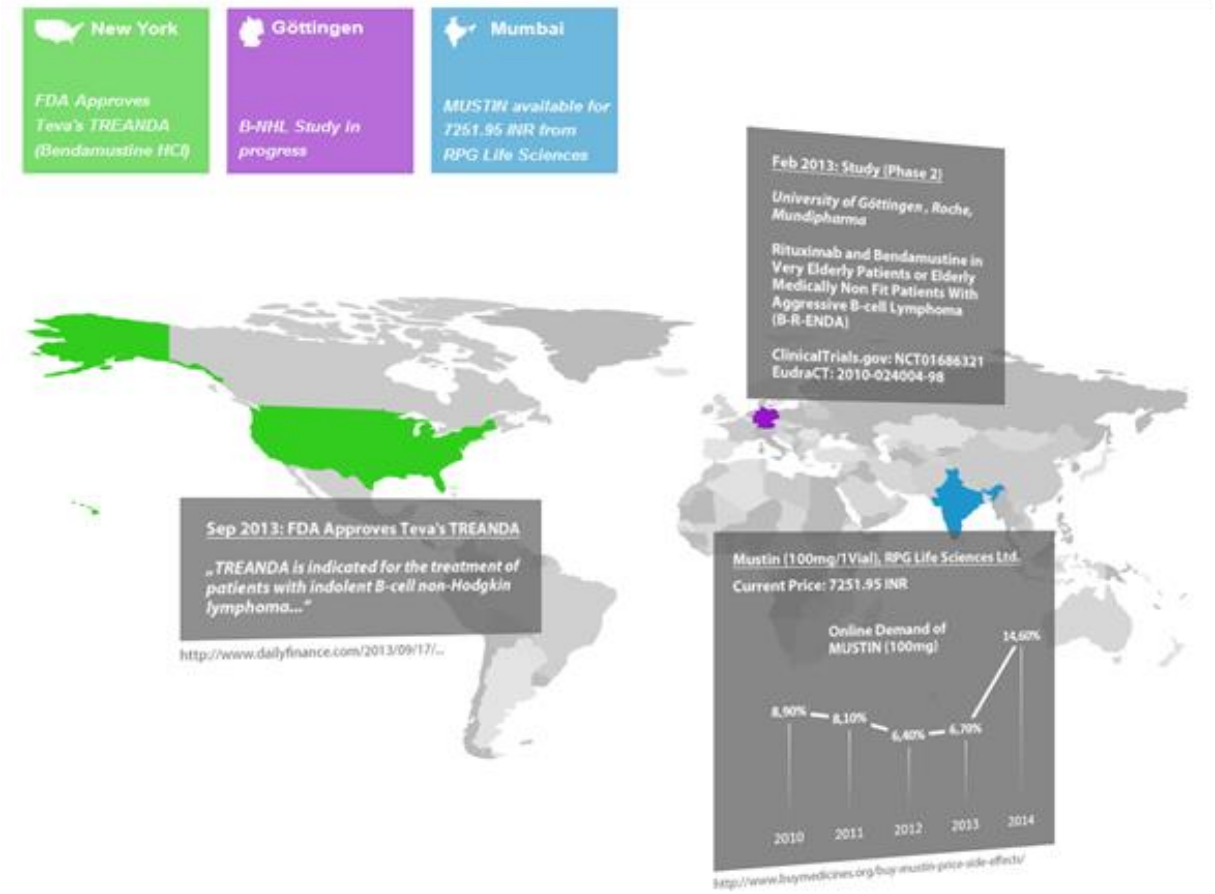

Figure 1. RWA Prototype – Even View for Potential Competitors for Hematology-Oncology Therapies
Based on: (Sultanow, forthcoming 2015)

4. Prototype evaluation

A first evaluation of the prototype has been performed with the European company Mundipharma Deutschland GmbH & Co. KG, which is an organization "working on the commercialization of innovative products to treat asthma, rheumatoid arthritis and non-Hodgkin's lymphoma" (Mundipharma, 2015). This company represents a revelatory case that allows us to fully test the prototype features and their value and obtain rich, detailed insights (Yin, 1994); these can then be used to improve the prototype (Vaishnavi & Kuechler, 2004).

Interviews have been conducted with one RWA super-user, Dr. C., whose position was the most relevant to the present RWA prototype evaluation. Dr. C. is a doctor employed by the company as a "pharmaceutical scout" responsible for screening external activities in the field of oncology therapy for the early detection of potential competitors. Scouts are "drug-company scientists [… who] are playing an increasingly vital role as hunters of new medicines from outside their labs to refresh aging product rosters." (Rockoff, 2014). Thus, Dr. C. has been chosen as an evaluator because his scout role is the most central, from a RWA perspective, within the company. This is consistent with existing environmental scanning research, which reports scanning is done by an individual manager in most companies surveyed (Majid & Kowtha, 2008). The interviews were semi-structured. We described the basic idea of the evaluation method and importance of RWA, and then asked about managerial awareness needs that can be met using the RWA prototype. We summarize these needs below.

RWA assumes the ability to collect other industry players' strategies – such as expansion plans, budget planning and intentions to create new alliances, for both collaboration partners and competitors. This information is directly related to a company's strategic planning. According to Dr. C., such information is exchanged in personal networks – during occasional meetings with employees from other companies at trade fairs, during lunches or evening events. This information could be stored in the RWA artifact and used to take preventive measures such as planning a counter-campaign in response to a competitor's upcoming marketing campaign.

The RWA artifact can help companies scan official sources such as official company reports, trade registry entries and financial news about domestic and foreign investments or acquisitions. In this context, pricing pressures and market entry by competitors were mentioned as major situations which warrant preventive measures (e.g. against an anticipated loss of sales). Companies can monitor the Lauer-Taxe (a database of all finished medical products in Germany) for price changes. They can also detect various indicators of market entry. For example, entry by a company from a low-cost country (such as India) in the German, European or the whole western pharmaceutical market is a reliable indicator of a strong price reduction for generic drugs. Another indicator is the official registration and subsequent publication of a parallel import – a legal practice in which a distributor can bypass the official distribution network set by a pharmaceutical manufacturer for Germany, and import a product from a different country where the product has a lower price (due to differences in government pricing rules or manufacturer policies for that country). Similarly, for biologic drugs, the introduction of biosimilars (drugs highly similar to the original in composition and with no clinical differences from the original) can be anticipated if studies comparing biosimilars to the original are detected. However, for generic drugs, admission is much easier and usually includes no safety and efficacy studies.

The interviews emphasized the importance of detecting market entry – both for new competitors and new competing products of old competitors: if such entry can be anticipated, then the organization can make plans in advance to prevent negative effects. This can be achieved by properly monitoring the regulatory process for drug approvals. Before a drug or a medical device is authorized, the manufacturer must conduct clinical trials in four phases. The trials, which start relatively early in the development process, have to be recorded in specialized registers (databases) such as EudraCT (European Union Drug Regulating Authorities Clinical Trials), EudraPharm (European Union Drug Regulating Authorities Pharmaceutical Database) or DRKS (German Clinical Trials Register).

Understanding this process can enable a company detect possible competitive situations well in advance. Based on our interviews, we constructed a knowledge event model for drug authorization together with Mundipharma Deutschland GmbH & Co. KG (see Figure 2). Based on this model, Dr. C. indicated that a concrete detection action can be monitoring the trial databases via mining processes in the therapy areas a company is focusing on – for example, by identifying new records (clinical trials, etc.) whose contents match relevant keywords for the company, such as B-cell non-Hodgkin lymphoma (B-NHL) or pain therapy. The RWA client can visualize these events on a world map (see Figure 1 earlier in this paper). Dr. C emphasized that with this method the knowledge about the development of new competing products is intercepted about a decade before the date on which the product can be brought to market. If the knowledge is not detected, or if the company does not take any action during the 10 years it usually takes to approve a competing drug, the company may suffer a decrease in established drug sales.

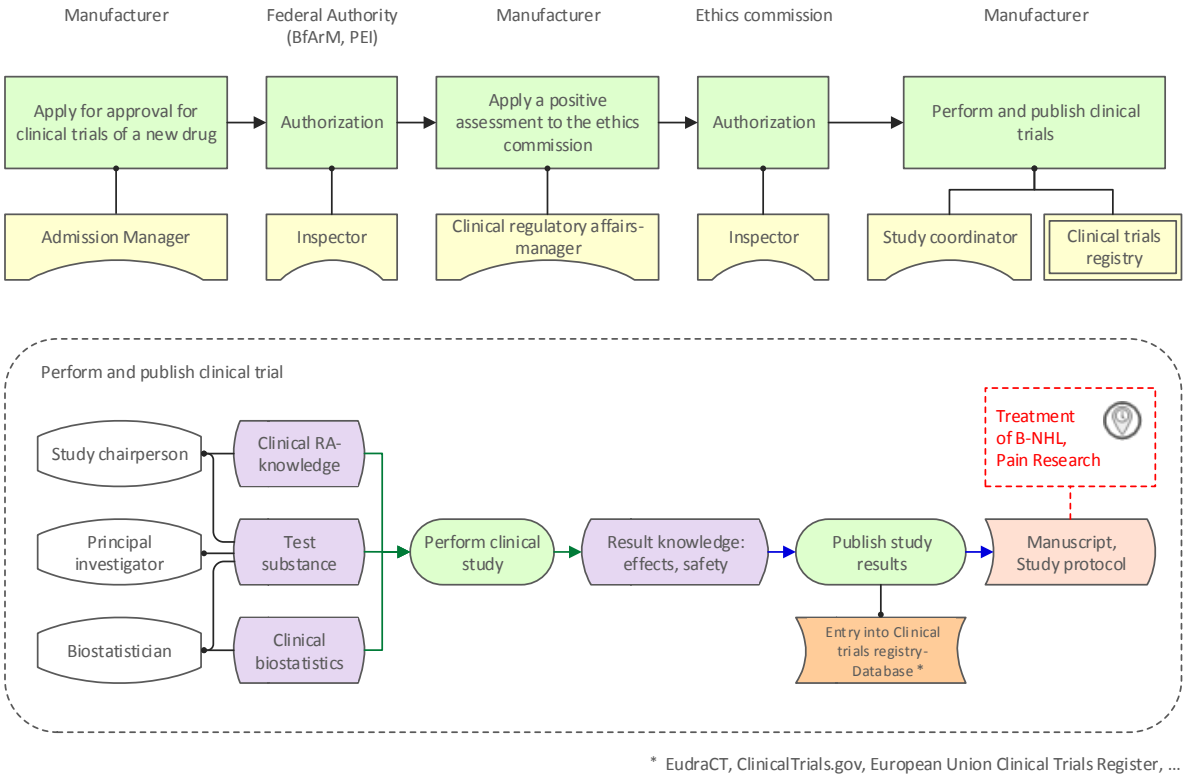

Figure 2. Knowledge Event Model for Launching Drugs in the German Market. Based on: (Sultanow, forthcoming 2015)

6. Conclusions, expected contributions and future work

RWA in the pharmaceutical industry consists of not only the tracking and tracing of drugs but also of pattern recognition for relevant internal and external events which can affect a company's drug research and development plans, marketing effectiveness, and ultimately its profitability. As a result, managers want to capture information in real time, anticipate upcoming events, and prevent negative consequences. However, what information (or more generally, objects of perception) to capture and how this information can help managers are still open questions. Our work will make several contributions along these lines.

First, we provide an initial taxonomy of objects of perception that matter and should be monitored for effective environmental scanning in the pharmaceutical industry. This can help spur future studies investigating each object of perception category in more detail, and the relative importance of each category in a company's decision-making processes. Our analysis of the prototype evaluation data reveals that objects of perceptions can be classified as:

- Informal information, such as insider knowledge about customers, R & D, quality assurance data, corporate strategies of cooperating and competing companies;
- Official objects of perception, such as market entry by competitors, price developments;
- Artifacts, such as new studies on potential competing drugs; and
- Organization structures, such as roles, tasks and knowledge of members of their own organization and colleagues from networked organization.

Second, we have started to develop a RWA perception model that highlights different types of control RWA affords for the organization in the strategic decision-making process. Traditionally, controls have been focused on protecting the organization against risks –from an internal process perspective (Ratliff et al., 1998). Our model shows how RWA can create strategic controls focused on the external business environment: monitoring/postventive controls (to detect and document changing business environment conditions, such as new regulations, and create new rules or processes to support these changes), intervention controls (to detect problems as they happen and take corrective action to eliminate or limit the problems), preventive controls (to anticipate future risks and take proactive action before problems happen), and continuous controls (to enable continuous monitoring, intervention, and prevention). This extends studies on business process controls (Ratliff et al., 1998) and environmental scanning (Chen & Huang, 2014; Majid & Kowtha, 2008; Myburgh, 2004), and supports further theory development for RWA.

In conclusion, our study provides a first glimpse into the potential of RWA for companies in the pharmaceutical industry, generates insights for design of future RWA systems, and suggests an emerging theoretical base for the study of RWA as a tool for competitive advantage. We are currently working with additional companies to validate and extend the prototype, and develop the theoretical framework further. Other future work can investigate the value of the objects of perceptions identified here in more detail through more case studies of companies in the pharmaceutical industry. In addition, the ethical and legal implications of RWA can be further studied. Capturing official / formal internal and external information from existing documents and news feeds is relatively straightforward. However, capturing informal information from managers' personal networks is not a trivial task – and this could be investigated in future research as well, together with the technologies that could support this process (such as mobile and social networking technologies).

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