Key Intelligence Topics (KITs) and Key Intelligence Questions (KIQs) in Safety Signal Intelligence

Abstract - Key Intelligence Topics (KITs) and Key Intelligence Questions (KIQs) are routinely used in various intelligence endeavors. This presentation will explore their application to cross-functional signal intelligence in a biopharmaceutical company. We will describe the rationale for choosing the KIT/KIQ approach, highlighting some of the key challenges shared across traditional intelligence and safety signal intelligence. Our methodology for implementing a KIT/KIQ process across Safety, Product Complaints and Medical Inquiries will be described in detail. We will also share results of early work to visualize and analyze cross-functional data. Future work on cross-functional governance and approaches to question management will also be discussed. These topics are relevant to preserving corporate memory and enabling collaborative collection, analysis and production of intelligence products.

Keywords – Pharmacovigilance, Drug safety signal detection, Signal intelligence, Spontaneous reporting systems, Adverse event databases, Cross-functional data, Heterogeneous databases, Vocabulary management, Data mining algorithms, High dimensional data

1 Introduction: Shared Challenges

The purpose of this paper is to explore the application of the Key Intelligence Topic (KIT) / Key Intelligence Question (KIQ) process to cross-functional (the functions relevant to this paper are Safety-Adverse Event, Manufacturing-Product Complaints and Medical-Information Inquiries) signal intelligence and data integration within a biopharmaceutical company. We will also attempt to draw out some possible similarities across intelligence efforts directed to the protection of citizens and those within the biopharmaceutical sector directed to the safety of patients. Both communities might benefit from a shared exploration of the KIT/KIQ methodology to their data and information fusion efforts. Let’s begin the discussion by reflecting on both unique and shared challenges within and across the two communities.

On September 11, 2001 the challenges associated with a failure of intelligence became very clear to the world. [1]

Likewise, in the biopharmaceutical industry, marketed products are facing more complex challenges once they enter the general patient population. In rare instances, these challenges can include Adverse Events and – even rarer – product failures and market withdrawals. These latter challenges in the biopharmaceutical industry might also be considered a failure of intelligence. We could possibly reduce / eliminate their occurrence, identify and/or respond to them more quickly, and avoid similar challenges in the future if we approached them with a much stronger “intelligence” mindset. [2]

First, for the purposes of this paper we will define intelligence as the deliberate collection of targeted data which, after thoughtful evaluation and appropriate analysis will provide the information to make a decision. Intelligence is both a process and a product. The process is designed to provide the product. And, most importantly, the intelligence product should provide just the information needed to make a decision. In other words the intelligence product will provide what the decision maker must know to make the decision; no more, no less. [3]

While the two domains, e.g. traditional intelligence and safety signal intelligence are quite different, the practitioners in both are acutely aware that their respective environments are undergoing dramatic and accelerating rates of change. For instance, in the Federal Intelligence community it has been widely acknowledged that the nature of the threat changed dramatically in the 1990’s. And this change occurred before our intelligence capability could shift to meet the resulting new threat. What was formerly a highly symmetric challenge; well defined, readily identified and easily characterized became highly asymmetric – difficult to define, almost impossible to identify and very challenging to characterize.

Meeting this new, asymmetric challenge has been the work of many in the ISIF community and elsewhere across global intelligence-related organizations. Identifying the most critical threats, prioritizing the right KITs, asking the right KIQs, identifying relevant indicators, recognizing early warning signals [4] across multiple domains, fusing those signals together, applying appropriate assessment models [5] to make sense of them and presenting actionable intelligence; all of these are relevant to both domains. Our citizens and our patients need us to do each
of these steps very well to both protect their lives and enhance the quality of the lives they live.

To carry these thoughts a step further – whether the individual is called a citizen or a patient, protecting the life and wellbeing of that individual can intersect the two domains across numerous shared disciplines and methodologies, e.g. epidemiology, biostatistics, text mining and many others. In the biopharmaceutical industry Pharmacovigilance (PV) is the traditional discipline applied to address patient safety. From a paper by Drs Shibata and Hauben, PV is “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any drug-related problem.” [6]

Safety signal intelligence is an expansion of that discipline to include cross-functional data from Manufacturing and Medical. Whether it’s a Severe Acute Respiratory Syndrome (SARS) outbreak, the result of a malicious actor releasing a toxic agent into the water supply or the unintended consequence of a therapeutic product in a patient population; all three events share a need to provide actionable intelligence to decision-makers tasked with the responsibility to protect human life and wellbeing.

A major premise of this paper is that there would be value in sharing best practices and lessons learned across domains. It is this notion of collaboration, e.g. learning and discovering together: looking for similarities across sectors, identifying ‘adjacent possibilities’ [7] and learning from each other’s disciplines and practice, that is the fundamental premise for this paper.

In the following sections we will set further overall context highlighting specific categories for intelligence improvement across people, process and technology. Our communities share many of these categories in common and should revisit them on a regular basis. These improvement categories can be our way-points to ensure that we stay on the right course for sustainable improvement to protect our citizens and our patients. In the closing sections of this paper we will explore detailed principles and practices of KITs and KIQs applied within a biopharmaceutical, cross-functional signal intelligence program. We will close the paper with a discussion of ongoing and future work on cross-functional governance and business processes.

2 Why Does Intelligence Fail?

Since “9-11” many books, papers, presentations and programs have explored and enumerated the many varied reasons for that failure of intelligence. One of the most cited sources is The 9/11 Commission Report. [8] In analyzing the reasons for the intelligence failure, The Report grouped the “Why-s” into a Bureaucratic and Analytic framework. Key categories around bureaucratic failures were related to: failure of imagination, institutional design, policy, dated capabilities, management stove piping and no/poor intelligence sharing. Analytic failures were grouped in the following categories: underestimation by senior leaders to receive warnings, subordination of intelligence to policy, communication barriers, unavailability of information, ‘received opinion’ or conventional wisdom treated as fact, ‘mirror imaging’ or judging an unfamiliar situation based solely on the familiar, over-confidence in what you think is occurring, complacency toward the need for urgent or more timely action, and not ‘connecting the dots’. It is noteworthy to observe that one sees rather similar lists when assessing the reasons for a failure of a therapeutic product; both bureaucratic and analytic.

2.1 How Does Intelligence Improve

In the recent National Intelligence Strategy (NIS) [9] the Federal Intelligence community established a set of Mission and Enterprise Objectives; largely to continue its efforts to ‘course-correct’ in a post-9-11 world. The NIS Mission objectives speak to an entirely different domain from biopharmaceutical research and development (R&D). However, the Enterprise Objectives and their associated goals would find many shared elements in biopharmaceutical corporate strategies. For instance, many biopharmaceutical companies have very senior-level, cross-functional programs to advance patient safety through improved signal detection and signal intelligence. Many key objectives in this program include the same ones found in the NIS: streamline business processes, improve information integration and sharing, streamline partnerships, advance science and technology R&D, develop the workforce, etc.

Finally, the NIS Enterprise Objectives highlight the important intersection of people, process and technology. Whether it’s the Federal Intelligence community or biopharmaceutical industry programs to advance patient safety – all three elements must advance to be successful and continuously improve. While there are many opportunities for knowledge and technology transfer and sharing of lessons learned across the two communities, the focus of this paper is what one company has done with KITs and KIQs applied to biopharmaceutical patient safety.

3 Critical Thinking and Analysis

3.1 Role of Questions

At some point during most intelligence-related meetings someone will observe that, in intelligence, the right questions rarely get asked. We must understand this problem and find ways to address it for the KIT/KIQ process to be successful. If one revisits the research related to critical thinking there are many models to help assist our review of this important challenge. Asking the right questions fundamentally starts with the basic principles of critical thinking. We must have a way of
considering and understanding how we think critically about problems, how we reason; both individually and collectively.

The Foundation for Critical Thinking (http://www.criticalthinking.org/) has a very interesting model, e.g. the Elements of Reasoning. [10] The model asserts that all reasoning: 1) has a purpose, 2) is an attempt to figure something out, settle some question, solve some problem, 3) is based on assumptions, 4) is done from some point of view, 5) is based on data, information and evidence, 6) is expressed through, and shaped by, concepts and ideas, 7) contains inferences by which we draw conclusions and give meaning to data, and 8) leads somewhere, has implications and consequences.

The Elements of Reasoning model is intended to support a soundness of thinking based on a set of intellectual standards including: clarity, accuracy, precision, relevance, depth, breadth, logic, significance and fairness. Even a cursory review of this model, its intellectual standards and associated concepts (see the model below) reveal its importance to our KIT/KIQ process. Before delving into the details of KIT/KIQ we must consider this model and its implications for a process that is SO dependent on our asking the right questions. As we further institutionalize the KIT/KIQ process within our organization, we will need to include introductory and / or regular refresher training on critical thinking and these types of models. Paul Richard’s basic model for the Elements of Reason is included below.

3.2 Role of Analysis

Assuming that one has asked the right questions, [the important step of source assessment is left to another time] we must thoughtfully consider our approaches to analysis. There are numerous analytic models employed across our communities. One interesting model applied to the work of intelligence is found in Jeffrey Cooper’s “Curing Analytic Pathologies.” [11] Cooper’s Pathologies would point us toward an honest re-evaluation of several accepted practices in both public and private intelligence functions. These pathologies include:

- Inefficient Account Structure – work is highly subdivided and strong ownerships assigned that ultimately encourage collection and analytic stove piping
- Evidence-Based Scientism – an overemphasis on descriptive and explanatory intelligence that belittles or leaves little room for imagination, intuition, and / or curiosity
- Tyranny of Current Intelligence – response to urgent needs routinely supplant strategic assessments and long-term research
- Neglect of Research – Short term tasking prevent longer term research that stunts the development of analyst expertise
- Over-emphasis on Production – Means replaces the Ends; process metrics, e.g. number of reports produced vs. value of reports to clients
- Neglect of Anticipatory Intelligence – lack of predictive intelligence against new emerging threats ensures a continuing failure to anticipate and act or warn
- Loss of “Keystone Species” and “Intellectual Middleware” - loss of intellectual capital due to organization’s reductions in force skews analyst demographics and erodes tacit knowledge
- Lack of Analytic Tools and Methods of Validation – the focus on results takes precedence over continuous improvement of tools and processes to produce those results.
- Hindrances of Security Mindset – over protection of sources and methods, e.g. organizational or data turf issues; artificial and outdated mission distinctions prevent critical collaboration

4 The KIT/KIQ-Driven Intelligence Cycle

In the first three sections of this paper we have suggested some similarities across the two intelligence domains; particularly why they may fail based on post 9-11 reports and studies. We also introduced some basic challenges associated with asking the right questions and common pitfalls to analyzing the answers to those questions. With this general background in place, let’s now drop down a level and dig into the intelligence process itself and the role of KITs and KIQs.

4.1 High-Level Intelligence Overview

The intelligence process describes the way intelligence is obtained, from the first realization of a need for intelligence to its final delivery to those who will make decisions based, at least in part, on its findings. The process begins and ends with the decision maker(s) and other intelligence users who could benefit from the intelligence. It is in discussions with the decision makers (Planning Requirements & Direction) that the intelligence needs of the organization are identified and plans are
developed to satisfy those needs. This is the foundation step. The plans that are subsequently developed will guide the rest of the process and will most directly determine whether the intelligence effort will be successful.

Intelligence needs are called Key Intelligence Topics, or KITs; one sentence preferably, but no more than a brief paragraph. The information identified in the plans as necessary to satisfy those intelligence needs are called the Key Intelligence Questions, or KIQs (“kicks”). KIQs describe what information must be gathered in order to understand the KIT. They are small, discrete questions. “Indicators”, e.g. 1-M discrete data points – are identified and mapped to the KIQs. Indicators comprise the set (1 or more) of data that must be gathered to answer a KIQ (Question) and address the KIT (Topic). Indicators are usually specific facts or occurrences that are an observable or knowable entity. They can be discretely defined and referenced to a specific source.

Once the KITs and KIQs are identified, a plan is developed to collect the answers to the KIQs (Collection). The plan is executed during the collection step, using either secondary sources, primary sources or both. Once collected, the data are analyzed. The raw data are organized into usable information and assimilated into the base of what is already known about the KITs (Analysis and Processing). Using analytic frameworks appropriate to the data and the intent of the research, intelligence is developed upon which the decision maker can act (Production). Finally, the intelligence is delivered to the decision maker(s) and, as appropriate, to other users who have a need for it (Dissemination).

4.2 KIT/KIQ and Safety Signal Intelligence

The KIT/KIQ Process, as developed from the Federal Intelligence community for use in Signal Intelligence, was adapted to not only provide a systematic methodology for understanding and collecting pertinent information but also to influence and inform the development of a new cross-functional business processes and the design of systems to support those new processes.

Business Process Owners, representing each of the cross-functional areas, brought forth several intelligence needs based on their domain knowledge and experience. Each intelligence need was contextualized into one or more case studies which were used to represent a KIT. The case studies were approximately ½ - 1 page in length and described the essence of a real-world call or contact to the company from a patient, physician or care-giver. The primary focus of the KIT/KIQ workshops were to read the case study and identify what questions would need to be answered within and across the three functions to understand the reason for the call or contact, and what action / response was required by the company.

For the first workshop series, three case studies were used to facilitate the generation of KIQs; for the second workshops, six case studies were used. Accompanying each case study was a list of questions that were used to spur the generation of KIQs. These questions included: What additional information would be useful to better understand what happened to the patient? What data in the global safety database would be informative in assessing the risk and risk factors for the same or similar adverse event? These prompts provided a relatively standardized structure in which to guide workshop attendees in their thinking, however in later workshops, the questions were not as necessary.

4.2.1 Planning KIT/KIQ Workshops [13]

The KIT/KIQ workshop provides a venue and process by which cross-functional business members give input and expertise to the generation of KIQs. These workshops were in-person, face-to-face workshops that promote interaction between members triggering shared exploration of the KIT. Each workshop was approximately 2-3 hours in length with 10-15 Cross-functional Business Members, representing each business functional area.

Cross-functional Business Members were chosen for their intimate knowledge of functional business processes and experience understanding implications outside of their function. Generally, due to the intensive nature of the KIT/KIQ sessions, requiring much attentiveness and focus, workshops were planned during the morning hours in order to capitalize on attendees’ energy level.

4.2.2 Executing KIT/KIQ Workshops

Workshop attendees are split up in to smaller groups of 4-6 people, ensuring a diverse representation of the business functions is present. A group leader was assigned from the business to facilitate and lead discussions. Scribes were provided by the Signal Intelligence core team to capture the discussion, comments and most importantly KIQs from the sessions.

Groups were given 20-30 minutes to rapidly generate KIQs that would be helpful in understanding the KIT. Workshop attendees were told not to regard the feasibility or “know-ability” of these KIQs, but rather generate anything that would be useful. This provided a forum for
rapid information sharing for the KIT/KIQ process and across the functions. Groups, with their leader, were rotated to the next scribe and case study after the 20-30 minutes was up.

Scribes did not move with the groups to provide consistency in the generation of KIQs for that particular case study and also to introduce diversity in the team dynamics, preventing stagnation. Scribes kept KIQs generated with previous groups hidden for the purpose of preventing bias or influence from previous groups on current groups. This resulted in quite a few duplicate KIQs, which helped to validate the KIQs but also to show areas of shared and silo’ed understanding across the functions and functional members.

The particular group, case study, and question were recorded from each KIQ generation session; retaining this information is crucial to maintain the integrity of the KIT/KIQ process, being able to track KIQs back to the original case study, group, and question. In addition, the consolidation of information from the KIQs further down the process creates some understanding gap between KIQs and the context in which they were generated; being able to track back to the case study and group helps to address this issue.

### 4.2.3 Outputs of the KIT/KIQ Workshops

The workshops produced almost 250 unique KIQs. Some examples include: Is there a cluster of product replacement requests by SKU? How often do we receive inquiries about off-label use of our products? What are the off-labels indications inquired about? Are there any Adverse Event reports for off-label indications? Has the # of inquiries about difficulty of drug administration increased? How many and what product complaints and adverse events have been reported for the same product lot? Do the patterns of reports differ by dose? Is there any unique pattern associated with a particular dose? What geographic locations are trending up or down in report volume? For what products? Over what time period? Etc… After each KIT/KIQ workshop the KIQs were carefully reviewed, categorized, and coded. These processes are described in detail in the next section.

### 4.2.4 Analyzing KIT/KIQ Workshop Results

The KIQ analysis process takes the output from KIT/KIQ workshops and begins some preliminary work to consolidate and categorize the KIQs that were generated. The methodology results in a list of unique, categorized KIQs in which to move forward with developing and distilling the ultimate outcome. The KIQ analysis process was performed by the SI Core team, utilizing the scribes from the actual workshops. Each scribe was responsible for submitting the list of KIQs from their case study, tagged with the group ID, case study, and question. This is considered the raw output of the workshops. A standard Excel template was used to structure this output to provide easier consolidation of workshop outputs.

In order to understand the coverage of the KIQs generated, a categorization methodology was used for high level analysis of the results. The categories were developed from the output of the first workshop. The categories function as a high-level baseline for the contents of the generated KIQs; the results from the following workshops were categorized using this baseline to understand if any new categories were needed. This evolution of categories allowed for the validation of the output from the KIT/KIQ process around a set of KITs to be relevant to future information needs. The categories also enabled analysis of the proportions of generated KIQs. As one would expect, the data profiles for different series of case studies showed different distributions of high level categories. Finally, the KIQs were mapped to existing coding vocabularies to test the vocabulary coverage against the specific questions asked by business clients. Our analytic and visualization approaches rely on the vocabularies as an important feature set. We must identify and close vocabulary gaps to ensure high quality representations of the data depending on robust, underlying feature sets. The vocabulary work is the subject of a related paper in this session. [14]

### 5 Re-Use of KIT/KIQ Workshop Results

One of the stated purposes of the KIT/KIQ workshops was to help drive requirements for new cross-functional systems to collect and manage cross-functional signal intelligence data. The presentation of this high-dimensional data in a meaningful and actionable way to end users is a key program requirement.

In late 2010, the team delivered a set of prototypes exploring different visualizations of cross functional data. KIQ indicators were integrated across different dimensions, e.g. geographical, temporal, semantic, etc. The team was charged to explicitly identify and leverage techniques and practices from other industries, e.g. ‘adjacent possibilities’. Two examples of these techniques are Tree Maps [15] and Horizon Graphs [16] more frequently used in the financial sector. We also needed to use technology that was extensible and aligned with our company’s strategic direction.
At a high level we developed demonstration prototypes that:  Aggregated data across data streams in near-real-time; visualized data with advanced filtering and cross-functional integration capabilities; and introduced a statistical model for identifying correlations between data streams.

Some of the more detailed business requirements for these prototypes were: 1) maintain data source provenance, 2) arrange clusters and outliers by geographic location, 3) plot multiple data types on a single map with ‘overlay’ capabilities for correlation examination, 4) implement filter functions to allow subset analysis, 5) support drill-down capability for exploratory analysis of further data details, 6) present time series analysis to show temporal changes in the data, 7) Highlight both spikes and more subtle events that depend on rate of change algorithms, 8) display time trends of data from multiple sources indicating the presence of concurrent or lagged relationship, 9) incorporate data from ‘external factors’ that may explain primary indicator data spikes or trends, 10) support vocabulary linkage, e.g. metadata mapping to add an improved semantic dimension to the analysis of data from multiple, varied sources.

5.1 Exploration of Novel Approaches for Cross-Functional Safety Signal Intelligence

While still very early, it is important to include a reference to research we are just beginning on new analytic and visualization methodologies. In particular, the development and use of correlation surfaces and the application of feature set approaches against our coding vocabularies have provided new and exciting views across our data. These novel approaches, quite common across the Information Fusion community, are less well known in the world of safety signal intelligence. Their promise is very intriguing and most compelling for us. The correlation surface below would perhaps allow us to test hypotheses related to lead and lag times between Adverse Events, Product Complaints and Medical Inquiries. For an excellent treatment of early research in this area see the paper in this session by Streit and Silver. [17]

6 Ongoing Care and Feeding of KITs and KIQs

The KIT/KIQ process produces several related artifacts including topics, questions, indicators, analysis and results. If an organization is to develop and manage an active KIT/KIQ collection, a unique knowledge and analytic repository is required. The repository must be developed around a robust data model and include various query, analytical and visualization capabilities. One example of such a system is the Structured Evidential Argumentation System (SEAS) developed by a team at SRI, Intl. in Menlo Park, CA. (http://www.ai.sri.com/~seas/index.html )

The exploration of a platform like SEAS presents interesting opportunities for us to experiment with different approaches to organizing the corporate memory and collective reasoning of our intelligence activities. All the chains of evidence for each answer are preserved and documented for each question. The entire reasoning process is ‘linked’ together and can be accessed and manipulated by both individuals and groups of individuals. The next steps in our KIT/KIQ work will include the exploration of an appropriate methodology and platform for our project. The SEAS system is one interesting example of this type of platform. [18,19]

7 Signal Intelligence Governance and Cross-Functional Business Process

As we look toward the future of safety signal intelligence we must institutionalize the new capability within our company’s organizational design. This requires clear ownership for the new capability within the business. In addition, we must also define new cross-functional business processes and a governance model for resourcing, funding and decision-making.

To help us in this important work, we plan to extend our KIT/KIQ processes, case studies and results to inform our preparation for a series of tabletop, system and decision-making exercises with the same business participants from our KIT/KIQ workshops. Just as prototypes help users experience the future functionality of new systems we envision these exercises as a way for business stakeholders to experience new processes and systems related to cross-functional safety signal intelligence.

7.1 Governance and Business Process Exercises

Our current plans include 3 separate workshops. Each workshop would require extensive planning, detailed preparation, careful facilitation and timely, data-driven
after action reviews. In particular, the second workshop would need additional time and resources in planning and preparation as prototype systems would be used to simulate the users’ interaction with each other and system agents in a highly collaborative virtual workspace. The third and final exercise elevates the visibility of this new capability and these exercises by the inclusion of senior leaders, e.g., senior decision-makers from each of the 3 functional areas. This final exercise will require its own special planning and execution; quite unique from the first two.

7.1.1 Table-Top Brainstorming Exercise

The first workshop will be table top or paper-based brainstorming exercise based on 1 or 2 scenarios described in 2-3 page written descriptions.[20] These scenarios will be chosen by cross-functional representatives from the 3 business areas and include important indicator data from our KIQs, including specific timelines and milestone trigger events. We would ask participants from the 3 functional areas to discuss how they would respond to each scenario, the arrival of new data, the passing of time, system trigger-based alerts and normal changes in the data. What must be known to address each scenario? What questions / KIQs must be answered? What data would they need to answer critical must-know open questions? What data sources are primary? Secondary? Who would collect that data? How would they integrate the data to answer cross-functional questions? How would they make decisions? Who would they escalate to if something urgent was discovered? How would they share data with each other? What analytic methodologies would be required?

Finally, and to the foundational premise of this paper, we will take some important lessons from our Federal intelligence colleagues and include the following questions for brainstorming. For each scenario: where would they need to be careful of “received opinion” or “mirror imaging”? Where would there be a possibility of underestimating the importance of a question or data set? What information is missing or unavailable? What do they do about that? Is there any risk in their response of “over confidence” or “complacency?” Is there a possibility of any failure to “connect the dots”? What is the likely impact if they fail to connect the dots? How do they avoid this failure? What management or institutional challenges could impact this process; both positively and negatively? What should be done to address those?

7.1.2 System-Simulation Exercise

In preparation for the System-Simulation Exercise [21], we will complete an extensive review of results from the brainstorming exercise. We will take those same scenarios, the same data sets and questions and augment them with new data and scenario event milestones. In particular, we will note those areas in the first exercise where participants encountered or anticipated a challenge or barrier.

All of these data will be used as inputs to drive the design and development of a set of prototypes for participant use in the system-simulation exercise. While always a bit contrived and artificial, this system-driven exercise will focus on understanding how the participants might actually interact with each other and the scenarios in a virtual, system-driven environment. In this exercise we would test user reaction times, capture and examine click logs, test user acceptance or struggles with UI design of reports and outputs, reactions to system alerts, etc.

Finally, while it is almost always assumed that a system will help the individual analyst or group of analyst, we want to be alert to identify any points in the exercise where the system seems to get in the way or create artificial barriers for the participants. This last point about the system is why we are designing the first exercise to be a purely paper-based one. Let’s first understand how just the humans act in the process itself, before introducing the system.

7.1.3 Decision-Making Exercise

The final exercise raises the visibility of the entire process by including senior leadership from across the 3 functional areas. Building on the same scenarios, this exercise would walk these leaders through the proposed processes found in the draft Charter for Signal Intelligence.

The walk-through would be accomplished through the lens of the results of the first two exercises; brainstorming and system simulation. These senior leaders would hear and experience the story of those exercises from the participants. The participants would use all the inputs and outputs of the first two exercises and the prototypes to present their own version of the cross-functional scenarios to the senior leaders. Based on their exercise experiences, they will define specific characteristic profiles for both success and failure. Finally, the participants will revise and present a recommended Charter for Cross-Functional Governance and the accompanying first-level Business Context Diagrams (BCD). [22] They will be the super changes agents for cross-functional safety signal intelligence within and across their functions and the company.

8 Conclusion

The role of signal intelligence is vital for both the public and private sectors tasked with protecting their citizens and / or patients. This article has attempted to draw connections across some of the most important shared intelligence challenges faced today in both sectors. There is much we could learn from each other and, perhaps, learn together more quickly thereby advancing our respective missions. The use of the KIT/KIQ approach has been highlighted as one example of a cross-over
methodology, e.g. an adjacent possibility for a new way of
thinking about and executing a multi-functional, high-
dimensional intelligence capability. Given our successes
this far, we will continue to explore its fit-to-purpose to
improve safety signal intelligence for our company and
most importantly, our patients.

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