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TECHNOLOGY + COMPLIANCE
= IMPROVED MODELS OF CARE IN LIFE SCIENCE SERVICES

Compliance is a broad and extremely important area in almost every industry and more so in life sciences as it directly and indirectly impacts patient lives. Because the life science industry is continuously evolving, we are challenged to incorporate solutions into our planning that address potential complexities inherent with this evolution. This complex regulatory environment touches practically every facet of our business. And, it is precisely for this reason that there are so many organizations, both internal and external, within companies and government agencies focused on ensuring that everyone is compliant regardless of the function or group they belong to – Finance, IT, Security, Regulatory, Clinical, Commercial, Safety, Medical Affairs, Devices, Caregiver and also the patient for compliance with her medication.

The cost of noncompliance in each of these functions grows year-after-year in spite of the focus and governance that has been put into place. Some of the reasons are as follows:

- **HUMAN NEGLIGENCE AND INCORRECT JUDGEMENT** – Human factors that cannot be eliminated and can happen at any time. Automation technology and analytics are being utilized by many organizations to reduce errors due to negligence and to improve decision making, thereby enhancing compliance.

- **BEHAVIOR CHANGE** – This is a big driver of noncompliance, and may be a result of a number of factors including changes in social and economic conditions and professional or personal perceptions that have formed over time. Many companies are now hiring anthropologists to understand behavior patterns and predict noncompliant behavior by leveraging internal and external data sources and analytics to make interventions and minimize noncompliance.

- **THE COMPLEXITY OF PROCESS** – Having a very rigorous and cumbersome process to ensure compliance sometimes is counterproductive, causing people to procrastinate due to the time it may take to complete the activity. Making sure the process is simple and easy to implement as well as leveraging the different communication channels available within the organization is key to ensuring greater compliance.

- **LACK OF ADEQUATE AND MEANINGFUL TRAINING** – Many organizations educate and communicate the need for and importance of compliance through web-based, mandatory training courses. Ensuring that everyone understands the broader impact of noncompliance both qualitatively and quantitatively is likely to better ensure success in compliance. For example, a security policy that is noncompliant could shut down the operations of the entire company for weeks resulting in reputation loss, decline in revenue and impact to patient lives.

Technology advancements over the past decade have not only enabled various communication channels but also the effectiveness of the content shared across these channels. It is imperative that organizations and the industry leverage newer technologies to communicate and intervene as appropriate in order to increase compliance and reduce the costs and loss of noncompliance.

When you think about the barriers and roadblocks to implementing a successful compliance program in healthcare for your key stakeholders, you immediately think about the regional emerging and changing regulations on patient privacy and data protection. But, you now need to expand this thinking to international requirements, i.e.: GDPR in the European Union. How do we protect patient data when data protection agencies themselves are finding challenges keeping cloud-based information safe? How can we minimize and prevent noncompliance through meaningful interventions both process-wise as well as by leveraging technology? And, once these processes are in place, there is a need for ongoing "validation" of all software used to increase compliance. As an industry, we need to define what is considered proper validation and how it is implemented regionally and globally. And, then we need additional training on how to conduct validation and apply it to all needs. This is a discussion that should happen every day. Is there a foundation of compliance within the culture of the organization you serve? It truly needs to be one of the top priorities and upheld throughout the organization, including the vendor partners that work with us.

Innovations in technology – all done with the goal to address patient needs and improve health outcomes – come with their own set of challenges mostly due to the lack of regulation around these emerging technologies. As the needs of our customers evolve, we must also evolve our thinking to plan for the compliance of the future. Machine learning is just the beginning. The future includes technologies that are relevant and exciting such as Predictive Analytics (PA) leveraging Artificial Intelligence (AI), Automation and Blockchain. With digital technologies becoming pervasive and mainstream across all business functions, we need leaders within our organizations to address and implement the business priorities in deciding technology's impact in achieving greater compliance.

The life science industry is one of the most regulated industries and to work in this environment, we need to understand the industry's pain points to best design products/services that meet patient needs. As the industry moves to a value-based, patient-centered care model, compliance must let go of a cost-focused model and move to one that delivers value. Technology is key to improving the health outcomes of our number one stakeholder – the patient – and ultimately will help us improve our model of care. This is how we will navigate in this changing environment and prepare for the future.

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