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For 2019, I am excited about a couple of initiatives. The first is the Global Safety Reporting Harmonization Working Group, which will release the Global Safety Reporting Reference Model (GSRM) this summer. Lack of global harmonization has been the largest problem in Safety Reporting because there are over 40 different regulatory frameworks for safety reporting worldwide. The noteworthy feature of GSRM is that it contains executable regulatory intelligence, which can be integrated into a safety distribution system. This enables precision distribution of safety reports to the right person at the right time anywhere in the world. Roche, Celgene and Covance have implemented earlier versions of this model and seen reductions of 50% in volume of safety reports distributed. This subject is of special interest to me because I have the privilege of introducing this topic at DIA 2019 in San Diego.

The second important initiative is the work that is being done on Serious Adverse Event (SAE) intake systems. The current state of inbound SAE reporting involves submission of potential SAEs by phone, fax, email, or PDF. These initial reports are often processed and tracked manually, and routed through Clinical Operations, Drug Safety, and Medical Writing departments who use different systems and find it difficult to collaborate. Covance is implementing a scalable, end-to-end, global workflow system to optimize triaging, tracking, processing and review of SAE reports in order to solve these problems. It is expected to generate higher case closure rates, improved compliance/on-time reporting, better quality, improved metrics reporting, collaboration and workload management, and increased client satisfaction. Without doing such foundational operational work to enable us to efficiently process millions of adverse events from diverse sources, we will never have the quality data necessary to produce future artificially intelligent systems.

For the coming years, I am anxious and excited about the future of drug safety. Adverse drug reactions are currently 4th leading cause of death in US. With our aging population living longer, taking more medications and more vulnerable to drug-drug interactions, the situation is going to worsen before it improves. Conversely, there are exciting advances in hardware (GPUs, Cloud Computing) and machine learning (big data, attention-based neural networks, expert-defined Bayesian networks) that will help us realize the FDA’s vision of proactive pharmacovigilance. If operational improvements are made now to take advantage of future technological breakthroughs, then we can avert the coming iatrogenic crisis.