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Application of systems thinking and systems engineering principles to enhance safety and pharmacovigilance through real-time informatics

Vigilance is the action or state of keeping careful watch for possible danger or difficulties. Conceptually and operationally, vigilance requires contemporaneous access to critical safety-relevant data or information to enable analysis and assessment of potential risks. Medicinal products provide valuable methods for diagnosis, prevention and treatment of disease, and also carry significant potential for adverse reactions resulting in injury or harm, even death. Several industries, including transportation, aerospace and nuclear power generation, have long-standing and well-developed safety systems based on systems thinking—appreciating that data flowing through critical interactions among diverse systems components generates signals that can reliably be used to effectively monitor the complex environment for indications of impending component or system failures well before a critical incidents occur with potential catastrophic results. Remarkably, the pharmaceutical and medical device industries have as yet failed to develop a comparable capability, instead relying on often out-moded, inefficient processes to support the critical function of pharmacovigilance. Through application of systems engineering principles to the drug development/clinical research process, and with effective application of information technology and informatics, it is possible to realize a system for continuous real-time pharmacovigilance, and potentially, predictive pharmacovigilance, to dramatically enhance drug and device safety. This presentation will describe a vision for such a system and proposals for its realization.

Biography

Greg Koski is internationally recognized as a leader in the realm of systems thinking and technology to improve the clinical research process. He is Co-founder and President of the Alliance for Clinical Research Excellence and Safety (ACRES), a global multi-sector non-profit collaborative working in the public interest to build a shared open-system to promote accountable research while enhancing quality, efficiency and safety.

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