A General Method to Objectively Perform Risk-Benefit Analysis

Risk Management Working Group (RMWG) Meeting

Tuesday, January 16, 2024

2:00 – 3:30 PM EST (Eastern Time, US and Canada)

11am-12:30pm PST | 1-2:30pm CST | 7-8:30pm GMT (London) | 8-9:30pm CET (Paris)

Cross-Industry Outreach:

The novel ideas and concepts in this presentation were developed within the context of the medical device industry, and are the subject of discussions with the U.S. Food and Drug Administration (FDA) and the technical committee for ISO 14971, *Medical devices – Application of risk management to medical devices,* regarding a new guidance or standard on benefit-risk analysis. However, these ideas and concepts are generally applicable, and therefore potentially useful across most other industries. With this in mind, the presenter welcomes participation from a diversity of attendees.

Presentation Abstract:

Ever since the phrase "First, do no harm" was coined, the requirement that the benefits of a medical procedure outweigh its risks has been central to medicine. In addition to regulators' universal requirement that a manufacturer show their product's benefits exceed its risks before allowing product sales, 'benefit exceeds risk' is also central to product availability, documentation compliance, and enforcement decisions. Despite the central importance of benefit-risk analysis, most analyses today present benefits and risks as unrelated facts (even in FDA guidance publications), making comparison difficult and the defense of conclusions as to which is bigger easy to challenge. This presentation shows a novel, systematic approach to benefit-risk analysis. The approach's cornerstone is to use the same metric to measure both benefit and risk. Measuring both benefit and risk with the same metric makes comparisons of the amount of benefit and risk straightforward and intuitive – leading to conclusions that are significantly more objective and defensible.

INCOSE

International Council On Systems Engineering

This is a virtual (Zoom) meeting. Registration is required to obtain the Zoom "Join" and "Add to Calendar" links:

REGISTER TO ATTEND

Presenter: Richard Matt – Past President, INCOSE Chicagoland Chapter; Member, Risk Mgmt WG

Richard Matt

Richard Matt's 30 year career was spent in equal parts of product development and documentation remediation. His experience includes a broad range of medical products, from every product Class (I, II, and III) to every type of combination product. During this time, Richard has observed many instances where a company needed a more-objective approach to assess whether a product's benefits exceed its risks. While this method was developed in response to that perceived need, its uses have grown to include applications in AI, individual healthcare, and defending company compliance.

Flyer v1, 28Dec2023

LEARN MORE about the INCOSE RMWG: Visit **www.incose.org/risk-management**