International Alliance for
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# 9th Annual IABS Statistics Workshop
# Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

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**Title: When is a Bayesian answer the right answer to a CMC question?**

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The thesis of this talk is that coherent modeling is essential in properly addressing CMC questions. CMC statisticians should assume leadership roles in soliciting group scientific knowledge needed to justify and share useful models. Addressing CMC questions involves decision making and risk assessment in the face of uncertainty and variability. Ideally, it is a group effort that leverages knowledge and skill from diverse stakeholders to form a shared vision (model). Such models are built on prior knowledge.

They describe the quantitative causal relationships between variables, parameter uncertainty, and measurement variability. The model frames the CMC question and directs study design. It provides a basis for continuous knowledge building and prediction as acquired data better inform model parameter values. Models from different development domains can potentially be linked in chains and/or hierarchies to facilitate knowledge building on larger scales, connecting CMC questions to patient experiences. Statistical stakeholders are skilled in the art of uncertainty modeling and probabilistic risk prediction.

As such, statisticians are uniquely qualified to serve a leadership role in soliciting group scientific knowledge, build group consensus around predictive models, and identify links among models in different development domains. Some tools for communicating and interrogating hierarchical models such as causal diagrams, directed acyclic graphs, and full probabilistic modeling will be illustrated in typical CMC contexts.