

# COOK®

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Division of Dockets Management  
HFA -305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
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**Re: Comments on "Draft Guidance for Industry and FDA Staff: Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials"**

These comments are filed in behalf of the Cook Group Inc. Cook is a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine, and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography, and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells over 15,000 different products which can be purchased in over 60,000 combinations.

On behalf of Cook, I would like to commend the FDA Center for Devices and Radiological Health for producing an outstanding and timely guidance document on this very important topic. Below are some brief comments regarding the document that may be pertinent to future discussion and revision.

It is well-known among statisticians that the use of Bayesian methods requires significant knowledge of the mathematics, model building, and model checking, as well as the programming skills required to perform these tasks. Although the document provides ample references, and recommends that consultation be made with the statistical experts, there is inadequate emphasis on the need for a statistical expert to perform the required study planning and data analysis.

Section 5.5 mentions that prior distributions that are too informative may not be desirable. Suggested remedies for this include discounting the prior information and/or increasing the stringency of the decision rule. There is, however, no discussion on the amount of information that may be too much. Although I recognize that this may be a

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device-specific issue, some general guidelines would be helpful. Additionally, the study sponsor is interested in having quite strong prior information, as, *a priori*, this provides assurance of study success. Strong prior information may be well-justified depending upon its origin (e.g. a GCP clinical study performed outside the United States).

With medical device trials it is often the case that numerous study centers are only able to contribute a small number of patients to the study. This creates problems with justification of pooling multi-center data. A Bayesian hierarchical model has a clear advantage over frequentist methods in this situation. This may be emphasized as an additional benefit of the methodology.

Again, on behalf of the Cook Group, I congratulate the Agency on producing outstanding draft guidance and I look forward to reviewing the final guidance when it becomes available.

Sincerely,

A handwritten signature in cursive script, appearing to read "Scott Snyder".

Scott Snyder, Ph.D.  
Manager, Biostatistics and Clinical Data Management  
Cook/Med Institute