Review of the CDRH/CBER Bayesian Guidance

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On February 5, 2010, the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) issued a final Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials The guidance furthers the US Food and Drug Administration's efforts to foster innovation, efficiency, and sound science in the industry The guidance joins, after two and a half centuries, two seminal concepts: scientifically rigorous, prospective clinical trials and Bayes rule The appearance of the guidance represents a paradigm shift in allowing the objective use of...