

The End Point Is Just the Beginning

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Abstract

Clinical trials to support registration of new drugs are arduous, lengthy, and expensive. Diabetes treatment trials intended to seek indications for glycemic control are facilitated by the regulatory acceptance of glycosylated hemoglobin (A1C) as a validated intermediate efficacy end point. However, A1C outcomes are not meaningful when taken outside of the context of hypoglycemia risks. Current regulatory guidance indicates that A1C efficacy end points and hypoglycemia safety end points be considered separately. A composite end point for diabetes treatment trials that integrates A1C and hypoglycemia risk into a single measure is proposed. An example would be "percentage of patients achieving A1C <7% without unacceptable hypoglycemia." The benefits and limitations of such an approach are discussed.

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Abbreviations: (A1C) glycosylated hemoglobin, (NPH) neutral protamine Hagedorn

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