

**This particular Kidney Health Initiative project focused on products related to hemodialysis vascular access, with the goal of clarifying appropriate trial end points that could subsequently inform clinical, regulatory, and coverage decisions” Hurst et al (2017).**

Abstract:

In an effort to foster innovation and new product development, the American Society of Nephrology and the US Food and Drug Administration partnered to form the Kidney Health Initiative in 2012. Part of the Kidney Health Initiative’s mission is to foster development of therapies by creating a collaborative environment where the US Food and Drug Administration and the greater nephrology community can interact to optimize product evaluation.

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This particular Kidney Health Initiative project focused on products related to hemodialysis vascular access, with the goal of clarifying appropriate trial end points that could subsequently inform clinical, regulatory, and coverage decisions. Both the lack of common definitions and the lack of consensus on trial end points have been viewed as barriers to innovation in this area. Toward this end, the Kidney Health Initiative convened teams of expert stakeholders to address these issues for each major vascular access category (arteriovenous grafts, arteriovenous fistulas, and central venous catheters), and each team provided recommendations. This commentary provides an overview of the US Food and Drug Administration centers that regulate hemodialysis vascular access and certain laws and regulations that affect these products as well as our perspectives on some of the issues raised and end points proposed by the Kidney Health Initiative teams. The standardized definitions and clinical trial end points proposed by the teams represent an important step forward to improve innovation in this area.

Reference:



Hurst, F.P., Lee, R.E., Thompson, A.M., Pullin, B.D. and Silverstein, D.M. (2017) FDA Regulatory Perspectives for Studies on Hemodialysis Vascular Access. Clinical Journal of the American Society of Nephrology. July 24th. .

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