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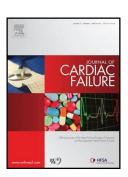
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### ACCEPTED MANUSCRIPT

# Why Has a Run-In Period Been a Design Element in Most Landmark Clinical Trials? Analysis of the Critical Role of Run-In Periods in Drug Development

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Disclosures: Dr. Packer was the principal investigator of many landmark clinical trials with a run-in period, but these were completed and presented years ago, and he has no recent or current personal, professional or institutional financial relationship with the sponsors of these trials (GlaxoSmithKline, Novartis and Boots Pharmaceuticals). Dr. Packer has recently consulted for Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, Cardiorentis, Celyad, Daiichi Sankyo, Relypsa and Sanofi.

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