

Presentation Outline

TREAT

Marc Pfeffer, MD, PhD

Dzau Professor of Medicine, Harvard Medical School,
Cardiovascular Division, Brigham and Women's Hospital

Introduction

Paul Eisenberg, MD, MPH, FACC

Global Regulatory Affairs & Safety, Amgen Inc

Clinical Perspective

Allen R. Nissenson, MD, FACP, FASN

Professor of Medicine, Associate Dean, Director,
Dialysis Program, David Geffen School of Medicine, UCLA

Benefit/Risk

Preston Klassen, MD, MHS

Global Development, Amgen Inc

Risk Management

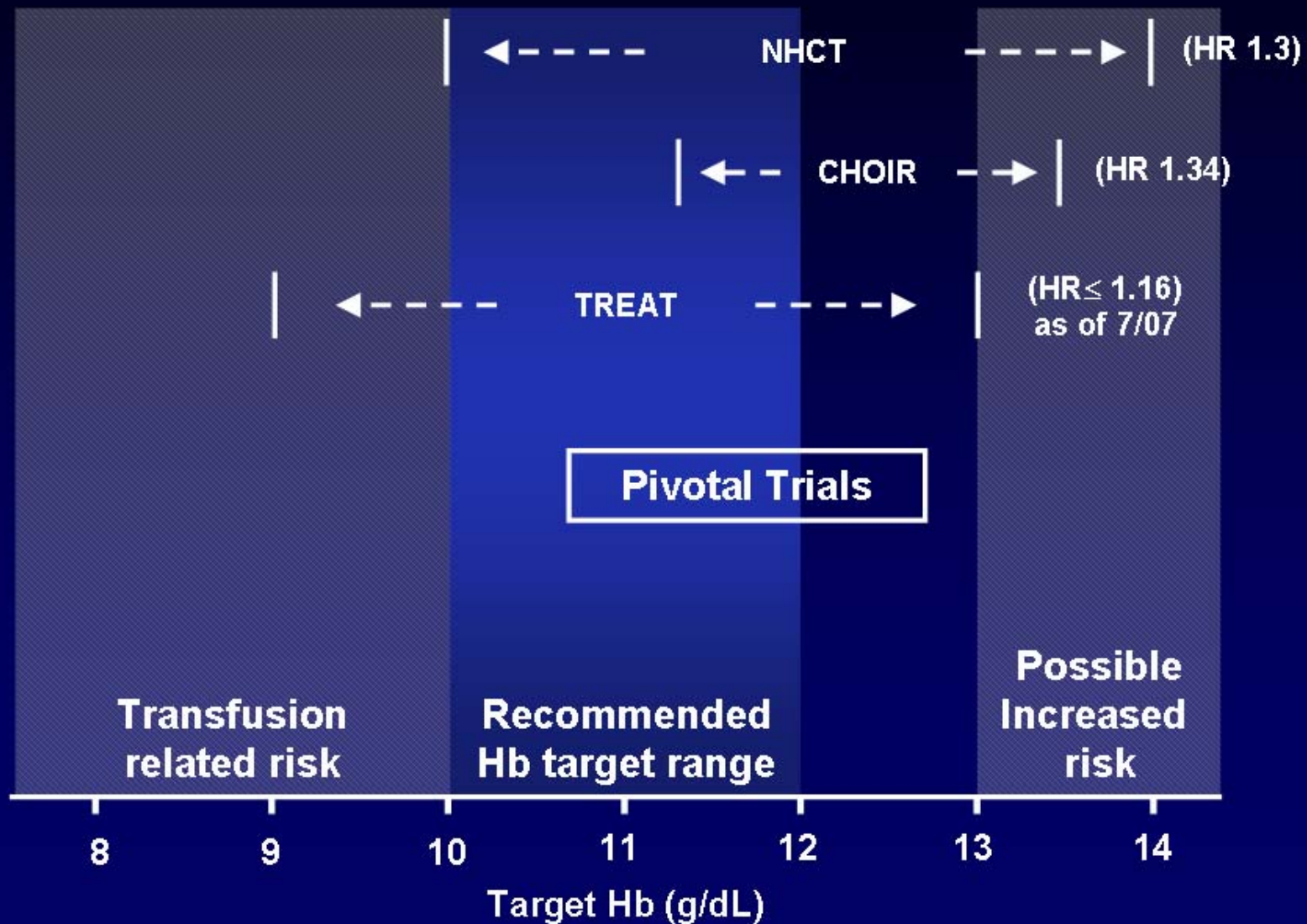
Paul Eisenberg, MD, MPH, FACC

Global Regulatory Affairs & Safety, Amgen Inc

Sponsors Are Committed to Additional Risk Management on Key Issues

- **Hb target**
- **ESA responsiveness**
- **Hb cycling**

Hb Target



Risk Management Summary

Hb target

ESA responsiveness

Hb cycling

Risk Management Summary

	Risk Management	Additional Risk Assessment
Hb target	Label – target 10-12 g/dL Dose according to current label Physician and patient education (eg medication guide)	TREAT study RCT to evaluate Hb target based on TREAT outcome

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ESA Responsiveness

- **Proposed definition of hyporesponsiveness in product labeling**
 - Unable to achieve desired Hb target within range of 10-12 g/dL despite use of appropriate dose titrations per label over a 12 week period
- **Patient management**
 - Evaluate for reversible causes
 - Use lowest dose to maintain stable Hb
 - Periodically reassess responsiveness
- **Additional RCTs to refine risk management**

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Erythropoiesis-Stimulating Agent (ESA) Therapy in Chronic Renal Failure (CRF)

Joint Meeting Between the
Cardiovascular and Renal Drugs &
Drug Safety and Risk Management
Advisory Committees

11 September 2007