

EFFECTING Heart Failure

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Trial Design

- Cardiopulmonary exercise testing
 - Prognostically important
 - Objective measure of functional capacity
- However....CPX is often difficult test in a clinical trial setting
 - Quality
 - Reproducibility
 - Ensuring maximal effort
 - Completeness

Meeting the Guiding Principles

- **Right Patient:** Real World vs. Clinical Trial World
 - Able to do a CPX
 - Screening led to a bias population? (525→174)
- **Right Intervention:** Complete, blinding...
 - Open label, assessor blinded
 - On good background therapy
- **Right Outcomes:** Complete without bias
 - Missing from primary analysis?
 - Missing from per-protocol analysis?

Outcomes Matter!

- Heart Failure is a syndrome characterized by DYSPPNEA, FATIGUE....
 - **Exercise capacity is an outcome that matters to patients!**
- What about the imbalance in readmissions?
 - Small numbers, small numbers....
 - Perhaps imbalance in baseline characteristics

What should be done next?

- Ferric carboxymaltose has been shown to improve...
 - Global assessment
 - NYHA class
 - 6 minute walk
 - Peak V02
- Now what?
 - Outcomes Patients Prefer
 - Survival
 - Worsening heart failure
 - Every day functional status...
 - **Larger, longer trials**