Protopal Report for

Clinical Trial Protocol CRLX030A2301 / NCT01870778

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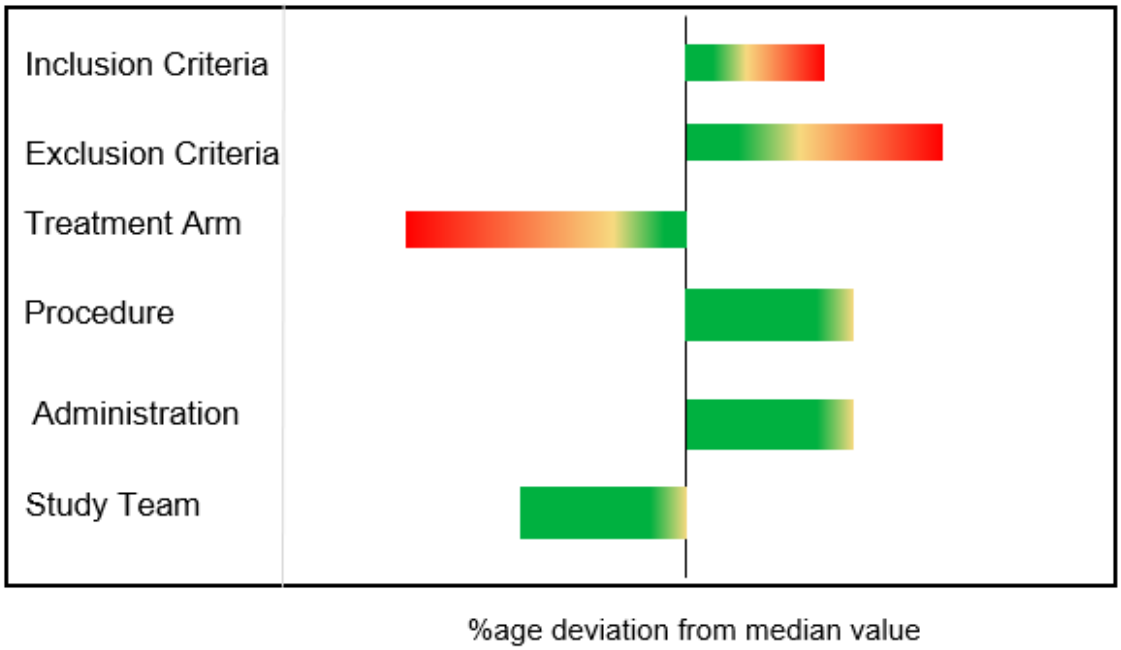
Contents

Summary

Analysis:

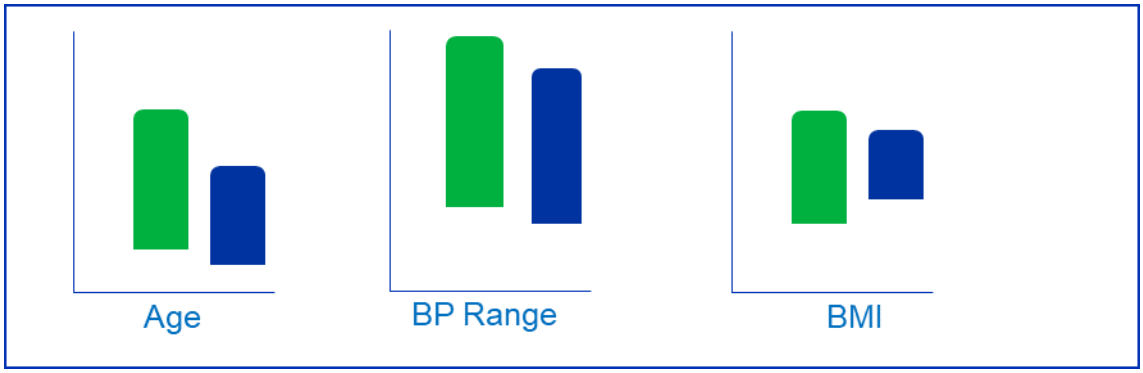


Recommendation:

Overall Risk for the reference study is high in the area Inclusion Criteria, Exclusion criteria and Treatment arm.

Inclusion Criteria

Analysis:

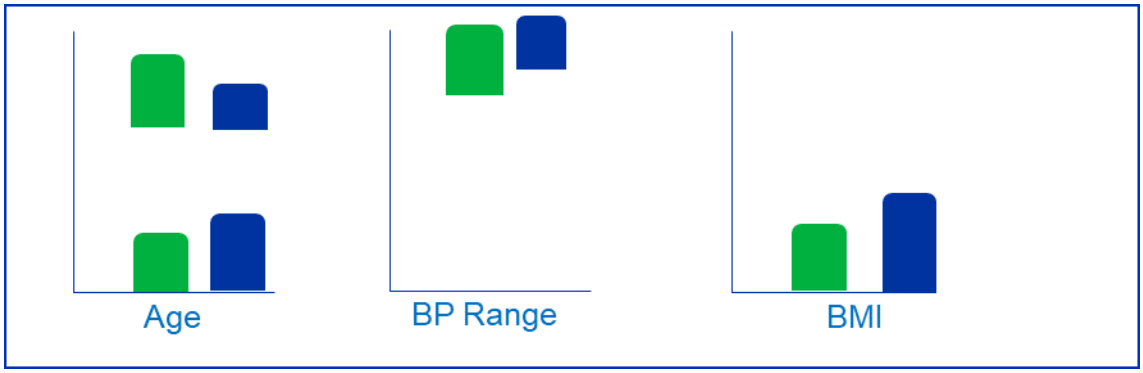


Recommendation

- Male or female 18 - 65 years of age, with body weight ≤160 kg
- Systolic BP ≥125 mmHg at the start and at the end of screening
- Able to be randomized within 16 hours from presentation to the hospital, including the emergency department~ *found in 60% of similar protocols*
- Hospitalized for AHF with the anticipated requirement of intravenous therapy (including IV diuretics) for at least 48 hours ~ *found in 50% of similar protocols*

Exclusion Criteria

Analysis:

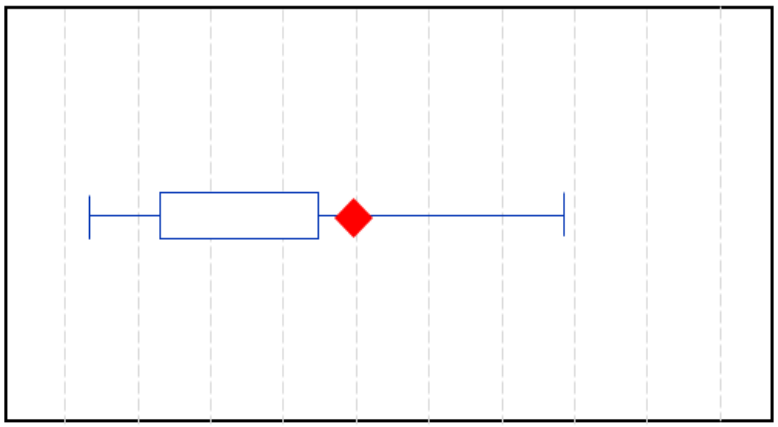


Recommendation

- Patients with blood pressure > 180 mmHg at the time of randomization or persistent heart rate > 130 bpm
- Temperature >38.5°C (oral or equivalent) or sepsis or active infection requiring IV antimicrobial treatment

Treatment Arm

Analysis:



n = number of treatment arms

Box plot indicates the median, first quartile and third quartile range

◆ = *number of treatment arms in reference study*

Recommendation:

Number of study arms in reference study – 5

Median study arms in past studies – 3.2

Analysis:

The number of treatment arms in the reference study is more than the medium number of arms from the similar studies.

Either increase the number of subjects in each arm for patient enrolment shall be an issue during study conduct