Quality of life is increasingly used as a secondary endpoint to supplement morbidity and mortality data in clinical trials in CHF for which regulatory bodies such as EMA (Tab. I) and FDA (Tab. II) have drafted guidelines. The aim of the present study was to compare the draft guidelines and to discuss their implications.

### Methods

#### Results

The current guidelines from EMEA and the FDA were reviewed and analyzed with regard to methodological and design issues.

#### Implications

The observed differences in recommended quality of life methodology create difficulties in conducting international multicenter studies that accomodate both the European and US agency requirements. Both guidance documents fall to address pertinent questions such as duration of follow-up, patients lost to follow-up, and patient selection biases, and how to account for mortality. Without guidance on design issues, future studies may vary considerably in scope and quality, which makes impossible to compare the results.

### OBJECTIVES:

Quality of life is increasingly used as a secondary endpoint to supplement morbidity and mortality data in clinical trials in CHF for which regulatory bodies such as EMA (Tab. I) and FDA (Tab. II) have drafted guidelines. The aim of the present study was to compare the draft guidelines and to discuss their implications.

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CONCLUSION:
The draft guidelines incorporating quality of life outcomes are welcomed. However, further and more detailed guidance is required as well as greater degree of harmonisation between the EMEA and the FDA.