Statistical Design and Analysis of a Non-Inferiority Clinical Trial- BioMimics 3D Vascular Stent

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Background and Problem

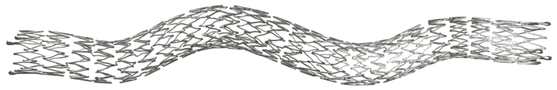
Objectives of Project

1. To define and justify a non-inferiority margin for a BioMimics 3D stent using historical and published evidence.
2. To develop statistically appropriate non-inferiority trial design parameters from a bio statistical perspective.
3. Develop a Shiny app to determine and visualize different sample size requirements under varying design assumptions and inferiority margins.
4. To analyse and interpret simulated trial data and evaluate non-inferiority conclusions.
5. To critically reflect on the limitations and assumptions inherent to non-inferiority designs.

Definitions

Case-study: Biomimics 3D stent

what is it x x xx x x x x



Meta-analysis

maybe include image of plot?

continued

Margin-Jinn

Margin-Jinn is an interactive Shiny application developed as part of this project in order to support the statistical planning of non-inferiority clinical trials. The application enables visual exploration of sample size requirements across several different design parameters. Through dynamic plots and real-time updates, the app highlights the sensitivity of sample size modelling assumptions that are often fixed or under-examined during trial planning.

In our project Margin-Jinn is applied to the BioMimics 3D vascular stent to explore, justify and critically assess sample size choices under realistic design scenarios, reflecting the role of statistical decision-making in early-stage clinical trial design.

https://github.com/FilipMKgit/Margin-Jinn

Next Project Steps

- Extend the BioMimics 3D case-study through simulation of non-inferiority trial data under realistic design assumptions.
- Analyse simulated trial outcomes to assess non-inferiority conclusions for the proposed stent design.
- Further explore the assumptions, limitations, and interpretational caveats inherent to non-inferiority clinical trials.

References