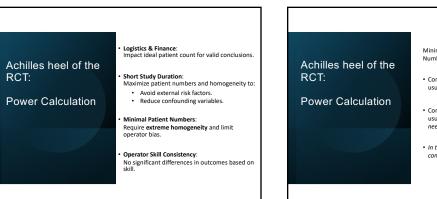






Controlled Clinical Trials

- Why was the CCT in the MedTech arena fallen into disgrace?
 - Too often "control" was not genuine "control"
 - Too much risk for "Operator Dependent Self-Importance" or simply, Ego (2)
 - Statistics more important. Sensitivity, Specificity, Positive and Negative Predictive Value, Overall Accuracy etc.
 - Finally the holy-grail : the Randomized Clinical Trial



Minimal Numbers versus Maximal Numbers in RCT's NMA NUS

- Conclusion with minimal numbers is usually: 'more studies' are needed...
- Conclusion with maximal global numbers usually "subanalysis and substudies needed" which patients really benefit...
- In the meantime, inappropiate conclusions circulate

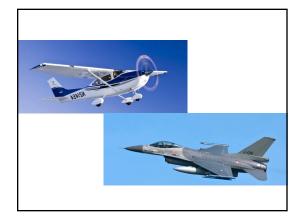
Achilles heel of the RCT:

Power Calculation

Personalized Medicine should be the current standard of Care

 But in the MedTech the outcome of a new technique is not only biased for the individual patient characterictics(genetically), but also socioeconomic risk factors are confounders

and last but not least the operator skills of the physician



RCT's | The Concept of Evidence

Rethinking "Evidence-Based" in MedTech

- Evidence should be clear to both the eye and the mind.
- Our perception isn't as objective as we believe.
- Avoid misusing "Evidence-Based" to control healthcare costs.
- Innovation in MedTech shouldn't be hindered by RCT flaws or the misuse of evidence.

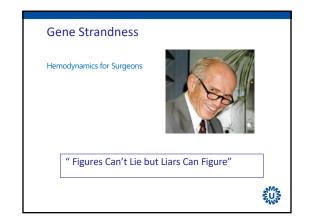
Conclusion | Take Home Message

The Real Evidence in MedTech

•True evidence lies in relentless pursuit of superior training and smart solutions.

•Should we reconsider the value of **CCTs** (Controlled Clinical Trials)?

NA NA



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