

What Do RWD Bring to the Evaluation of HTE (of Medical Devices)?

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- Medical device trials
 - Modest size
- Limitation of subgroup analysis in device trials
 - Inadequate power
 - Spurious findings
- Real world data
 - Large N --- opportunities
 - Limitations of observational studies --- challenges
- Beyond HTE for patient subpopulations
 - Heterogeneity due to operator skills
 - Heterogeneity of benefit-risk profile and patient preference