SIMULATIONS Statistical Analysis

Using a **time-varying covariate** in the Cox proportional hazards model discerns early/late treatment efficacy. **Use with caution**.

Use of time-varying covariate in assessing disease remission in the early and late phases of treatment with application to RITAZAREM trial.

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BACKGROUND

RITAZAREM, an open-label, multi-centre RCT, aims to assess the efficacy of rituximab compared to the current standard of care in the prevention of relapse in ANCA-associated vasculitis.

Design: N = 170 patients, 1:1 allocation, 90% power at α = 5% for HR = 0.42.

Outcome: time to disease relapse.

Primary analysis: Cox proportional hazard model for overall efficacy & time-varying covariate to investigate during/post treatment efficacy.

METHODS

1. Censoring and relapse times simulated with a Weibull distribution (sample N = 167, 83 events).
2. Simulated $HR_{early} \neq HR_{late} \in (0.3\text{-}0.9)$
3. True change point for HR τ = 20.
4. Relapse times after change point simulated with a conditional Weibull distribution.

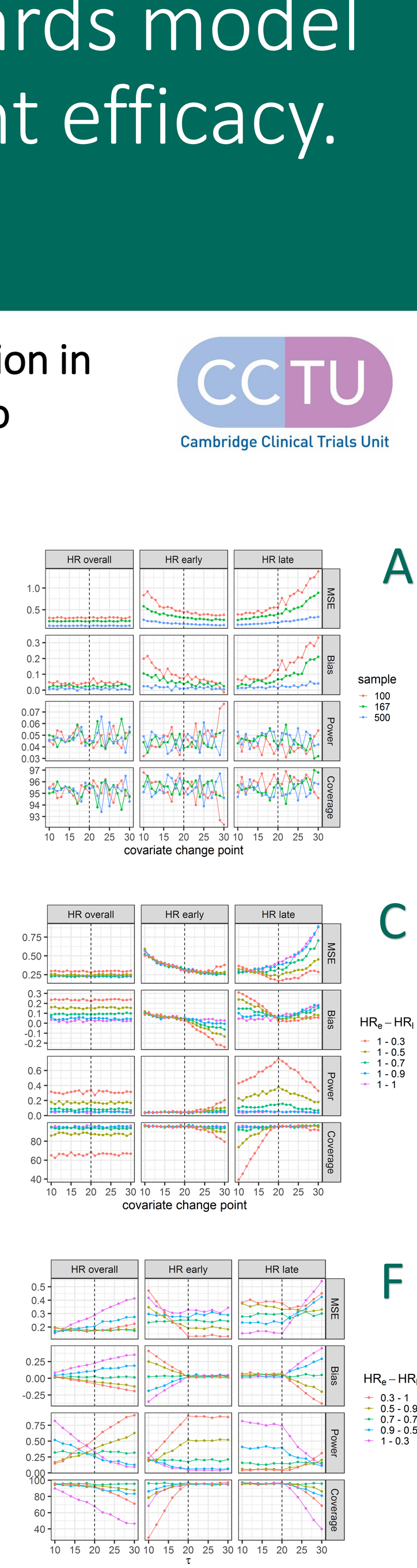
RESULTS

Simulations (n=1000) investigate the operational characteristics of the model under a variety of assumptions:

A. **Null hypothesis**
B. **Constant overall efficacy**
C. **Early efficacy**
D. **Late efficacy**
E. **Different early/late efficacy**
F. **Wrong change point τ**

DISCUSSION

- First point
- Second point
- Third point



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