Lessons learned from conducting major trials

Survival Improvement with Colecalciferol in Patients on Dialysis- The SIMPLIFIED Registry Trial

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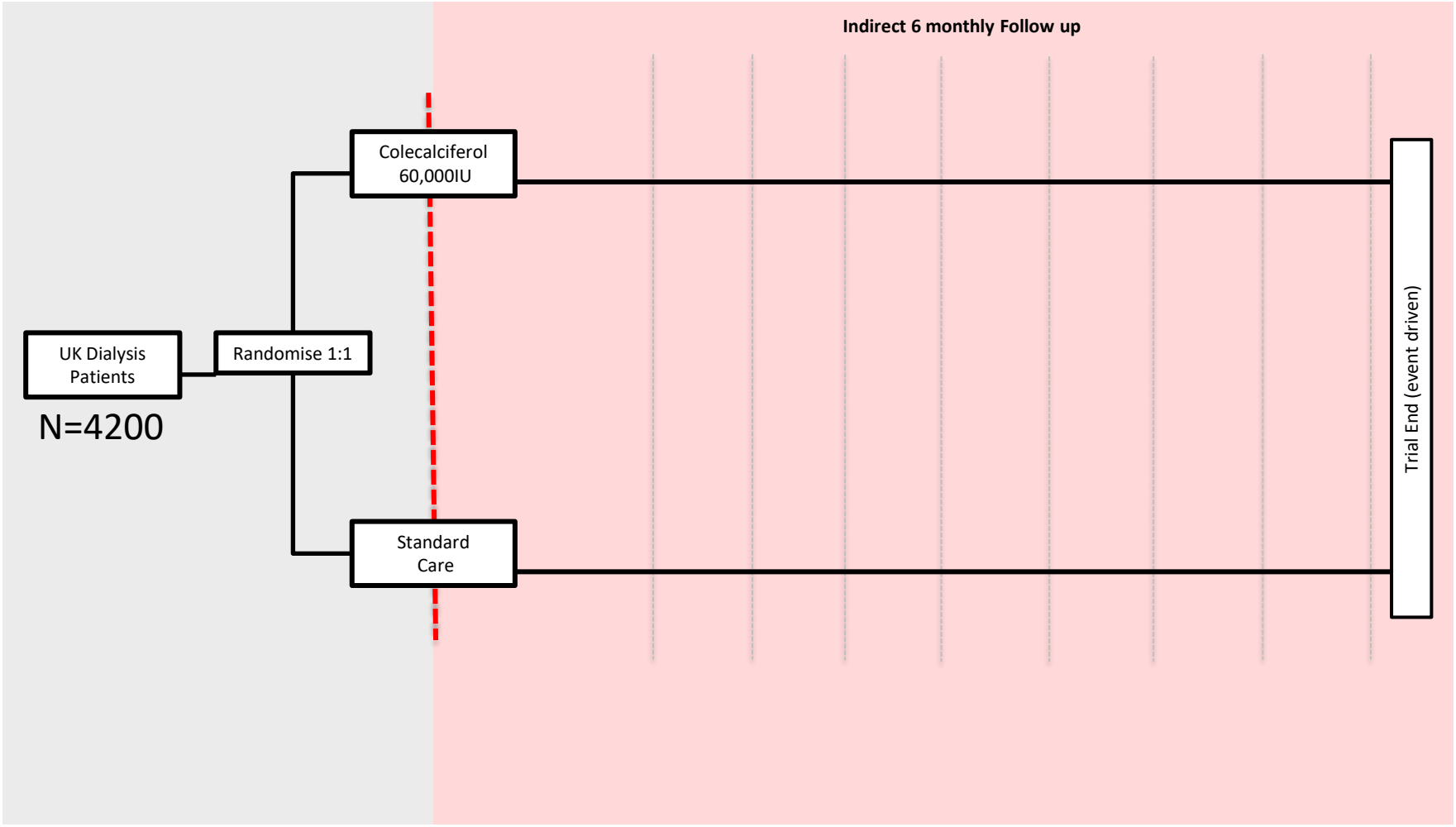
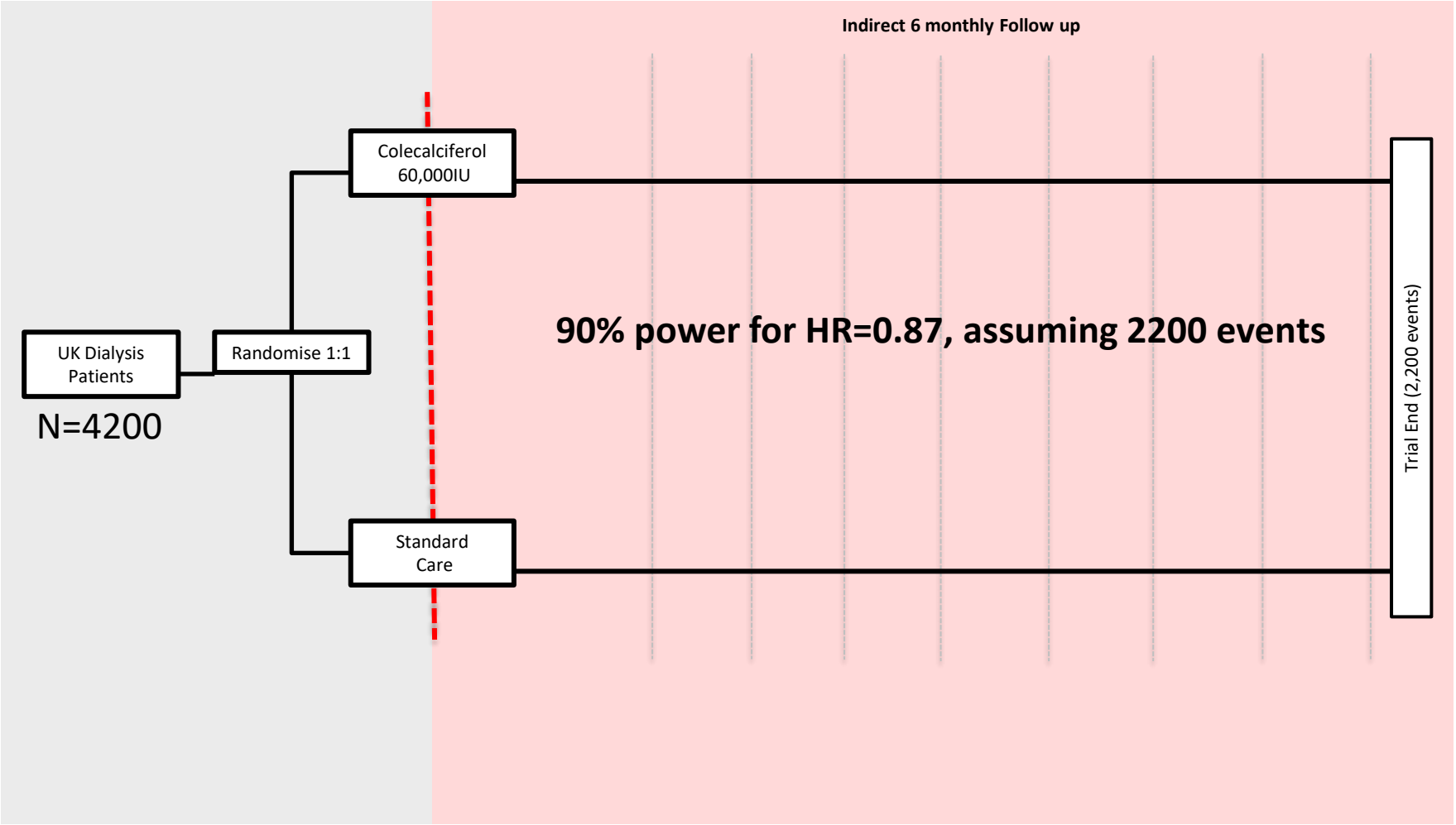
Disclosures

No relevant disclosures

SIMPLIFIED Trial Design



SIMPLIFIED Trial Design



Primary endpoint

All cause mortality

Secondary endpoints

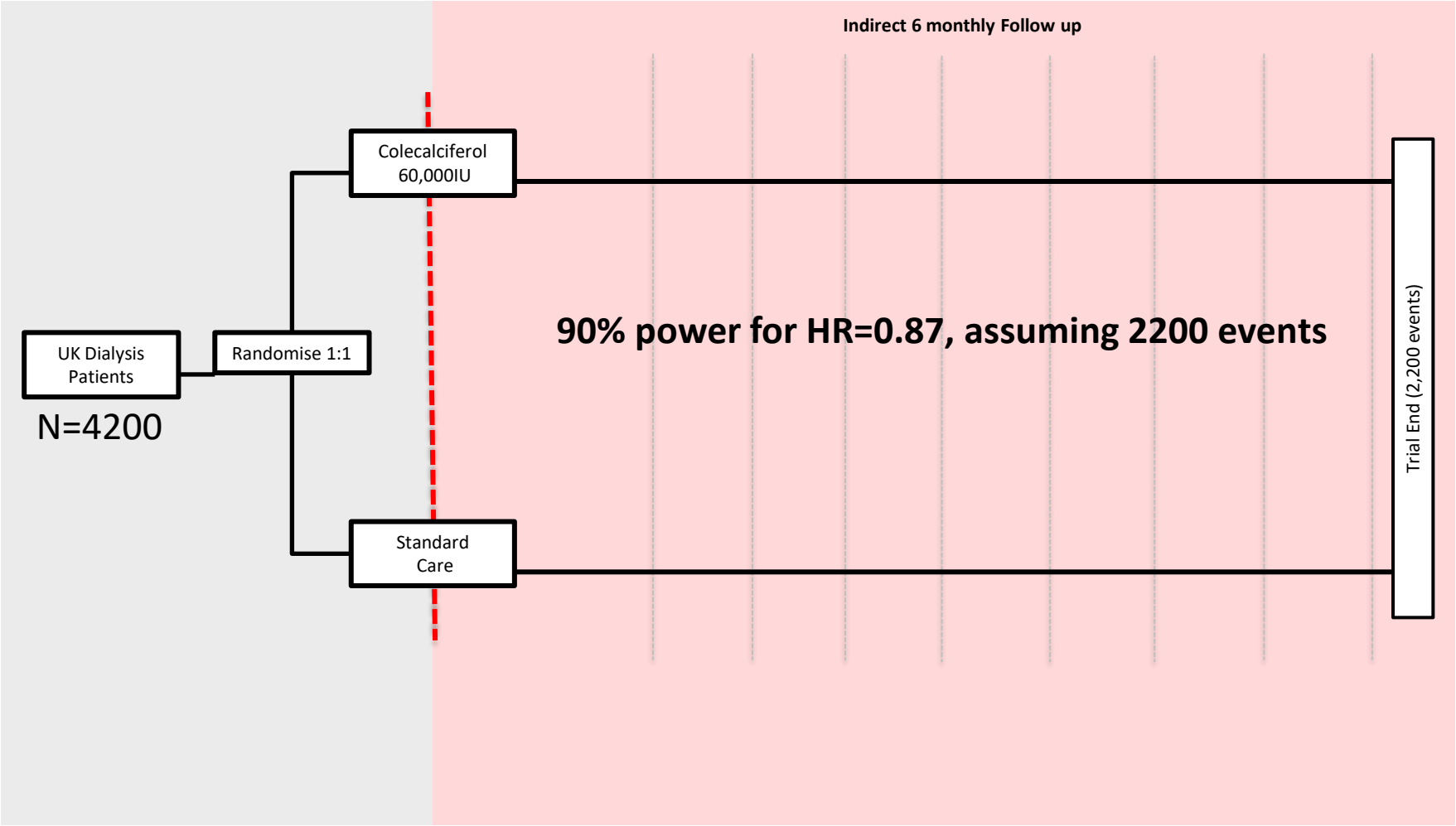
HRQoL (EQ5D)

Incidence of hospitalization for
- CV events (ACS, Heart Failure, Arrhythmia, Stroke)
- Infections
- Fractures

Incidence of Malignancy

Cost Effectiveness

SIMPLIFIED Trial Progress



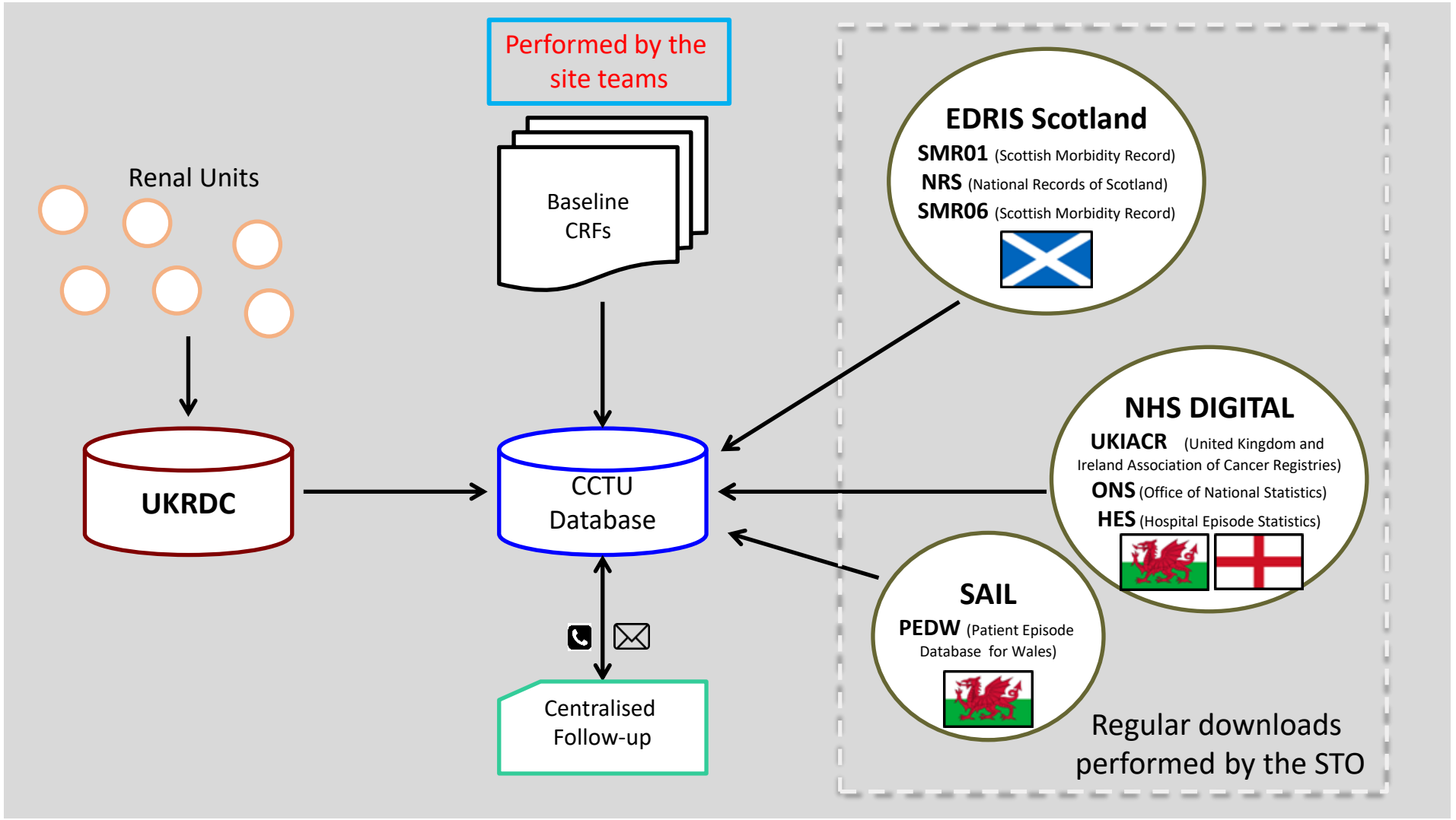
Year	Number of Recruits
2017 (Mar-Dec)	195
2018	886
2019	837
2020	558
2021	370
2022	447
TOTAL	**3293**

	Number of events
Deceased	917
Withdrawn	352
Transplanted	420

SIMPLIFIED Trial Pragmatic Features

- Data linkage – utilising routinely collected healthcare data
- Centralised study follow up
- Remote approach and consent process

SIMPLIFIED Trial Data Linkage



SIMPLIFIED Trial Data Linkage

BENEFITS

- **EFFICIENCY**
  - Minimising workload for sites
  - No endpoint CRFs
  - No SAE reporting

CHALLENGES

- Contracting
- Increasing costs
- “Real time” data
- Inability to query data

Centralised study Follow-up - Eq5D questionnaires

Issues…….

- Questionnaire fatigue
- Relevance of Eq5D to dialysis patients
- Involvement of individuals outside local care team

Remote Approach and Consent

- Enabled recruitment to continue throughout COVID-19
- Facilitated recruitment from satellite dialysis units
- Increasing participation for home dialysis patients

Summary

- Pragmatic design (no in person study visits) allowed trial to continue throughout Covid-19
- Using routinely collected healthcare data for primary and secondary endpoints and safety reporting is possible
- Centralised follow up and PROMs for trials recruiting dialysis patients need further consideration

Acknowledgements

- Dr Thomas Hiemstra – original chief investigator
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