


Registry Based RCT

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Overview

- Registry based randomised trials
 - What
 - Why
 - Issues for RESAR applicability
 - Possible study questions
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Registries – strengths and weaknesses

Advantages	Disadvantages
Continuous	Difficult to infer causal relationship
Description of treatment landscape / patterns of care	Risk of confounding
Large heterogeneous population	Missing data / variable data quality
Capable of identifying rare events	Limitations of interoperability
Relatively inexpensive	

Registry based RCT

- prospective randomised trial that uses a clinical registry for one or several major functions for trial conduct and outcomes reporting
 - » James et al. Nat Rev Cardiol 2015
- untapped potential of observational research to inform clinical decision making
 - Randomisation removes confounding
- combining the major strengths of a conventional RCT (patient stratification and randomization) with pre-existing registry infrastructure
- Replace CRF with registry data forms
- Rapid patient recruitment by consecutive enrolment using generous eligibility criteria, enhancing the generalisability of results due to inclusion of a real-world population
- Much lower costs than RCT

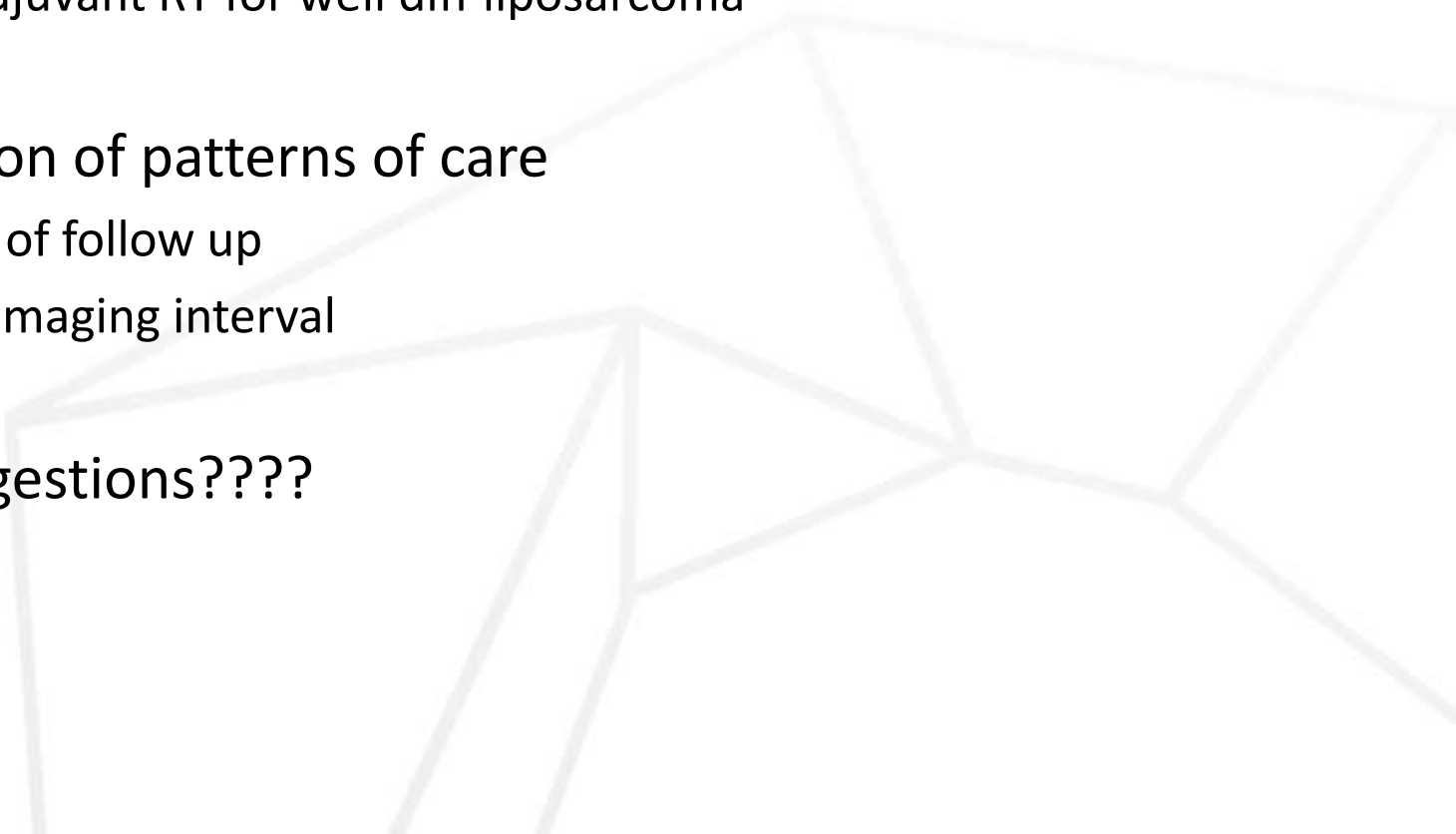
Registry RCT for RESAR

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Difficulty of real-time centralisation of data	<ul style="list-style-type: none">- each site runs own randomisation- Multiple identical minor RCT and final study is analysed as a 'meta-analysis'

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Who would be the sponsor?	<ol style="list-style-type: none"> 1. May require >1 sponsor

Potential RRCT questions

- Randomisation of distinct subsets of patients to current standard of care without strong supportive evidence
 - eg neoadjuvant RT for well diff liposarcoma
 - Investigation of patterns of care
 - patterns of follow up
 - optimal imaging interval
 - Other suggestions????
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DISCUSS

