# **Delivering Value for Money in Clinical Trials:** Value-Adaptive Designs for Efficient Delivery of Publicly Funded Trials

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#### Value-adaptive designs

- Aim to deliver evidence-based, value for money research for the NHS.
- Involve adaptive data collection processes.

## Methods

- Engaged with stakeholders from across the NIHR on the potential use and implementation of valueadaptive methods in NIHR research.
- Applied the value-based sequential design with adaptive stopping to two retrospective case studies.
- Consider the cost-effectiveness of the research process, accounting for estimated effectiveness, its precision and the cost of carrying out the clinical trial.



Figure 1: Value-based sequential two-arm design with adaptive stopping

	CACTUS case study	HERO case study
(%	<b>increase over original trial)</b>	(% increase over original trial)
Expected sample size (maximum sample size)		
Original trial	95	124
Value-based one-stage	132 (+39%)	177 (+43%)
Value-based sequential	100 (+5.3%)	174 (+40%)
Expected cost associated with conducting the proposed trial design		
Original trial	£1.22m	£0.84m
Value-based one-stage	£1.39m (+14%)	£0.92m (+11%)
Value-based sequential	£1.24m (+1.6%)	£0.92m (+10%)
Expected net monetary benefit		
Original trial	£3.54m	£52.0m
Value-based one-stage	£3.60m (+1.7%)	£52.0m (+0.01%)
Value-based sequential	£3.85m (+8.8%)	£52.1m (+0.19%)

**Table 1:** Summary of results from case studies using a value-adaptive design

### Value-adaptive designs have the potential to deliver cost-effective and innovative studies that give robust evidence to inform practice and policy

#### Opportunities



effective cost-effective and More treatments to the NHS sooner.



Inform the choice of which research to pursue to maximise expected health economic benefit.



Facilitate more trials for a fixed budget.





Appropriate computing and management required e.g. interim at processes analyses.



Additional clinicians support for interpreting and implementing results.



Flexibility required in planned budgets.



Complement existing approaches to inform optimal trial design.

Addressing the perceived learning curve to implement methods.

With increased experience and application of value-adaptive designs there is great Discussion promise for more efficient publicly funded research. Further work is required to address identified challenges.

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