



THE UNIVERSITY *of* EDINBURGH

Edinburgh Research Explorer

## Modelling cost-effectiveness and value of information in clinical trials to inform stop go decisions: results from the arctic study

**Citation for published version:**

Smith, A, Hall, P, O'dwyer, J, Hulme, C, Cohen, D & Gregory, W 2015, 'Modelling cost-effectiveness and value of information in clinical trials to inform stop go decisions: results from the arctic study', *Trials*, vol. 16, no. Suppl 2, pp. O27. <https://doi.org/10.1186/1745-6215-16-S2-O27>

**Digital Object Identifier (DOI):**

[10.1186/1745-6215-16-S2-O27](https://doi.org/10.1186/1745-6215-16-S2-O27)

**Link:**

[Link to publication record in Edinburgh Research Explorer](#)

**Document Version:**

Publisher's PDF, also known as Version of record

**Published In:**

Trials

**Publisher Rights Statement:**

© 2015 Smith et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated

**General rights**

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

**Take down policy**

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact [openaccess@ed.ac.uk](mailto:openaccess@ed.ac.uk) providing details, and we will remove access to the work immediately and investigate your claim.



ORAL PRESENTATION

Open Access

# Modelling cost-effectiveness and value of information in clinical trials to inform stop go decisions: results from the arctic study

Alison Smith<sup>1\*</sup>, Peter Hall<sup>2</sup>, John O'Dwyer<sup>1</sup>, Claire Hulme<sup>1</sup>, Dena Cohen<sup>1</sup>, Walter Gregory<sup>1</sup>

From 3rd International Clinical Trials Methodology Conference  
Glasgow, UK. 16-17 November 2015

## Background

Trial interim analyses are traditionally based on an assessment of efficacy and safety. Early evaluation of cost-effectiveness and a quantification of the societal value of further research could provide additional information to inform stop-go decisions.

## Objective

To assess the potential utility of early cost-effectiveness analysis (CEA) and value of information analysis (VOIA) within the context of a randomised clinical trial.

## Methods

The ARCTIC trial randomised patients with previously untreated Chronic Lymphocytic Leukaemia to receive fludarabine, cyclophosphamide, mitoxantrone and low dose rituximab (FCM-miniR) or fludarabine, cyclophosphamide and rituximab (FCR; standard care). An interim efficacy analysis was conducted after 103 patients had completed therapy. CEA and VOIA were conducted using a Markov decision model, based on subsequent data from 200 patients.

## Results

The trial was terminated early based on the results of the interim efficacy analysis. FCM-MiniR was not expected to be cost-effective over a lifetime horizon, producing an average lifetime cost saving of £7,708 and health loss of -0.67 QALYs. The VOIA, however, suggested a high value of further research due to uncertainty around key parameters. Whilst the CEA results support the interim efficacy findings, the VOIA results highlight the cost of

trial termination in terms of potential population net health loss (1,050 QALYs) by foregoing the opportunity to collect additional data.

## Conclusion

Early evaluation of cost-effectiveness within clinical trials could provide useful information in addition to efficacy data for interim analyses. Future research proposals should incorporate CEA and VOIA at interim analysis, allowing research-value to influence stop-go decisions.

## Authors' details

<sup>1</sup>University of Leeds, Yorkshire, UK. <sup>2</sup>University of Edinburgh, Edinburgh, UK.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-O27

**Cite this article as:** Smith *et al.*: Modelling cost-effectiveness and value of information in clinical trials to inform stop go decisions: results from the arctic study. *Trials* 2015 **16**(Suppl 2):O27.

### Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at  
[www.biomedcentral.com/submit](http://www.biomedcentral.com/submit)



<sup>1</sup>University of Leeds, Yorkshire, UK

Full list of author information is available at the end of the article