



The
University
Of
Sheffield.



Consensus Workshop on Utilising Benefit-Risk Methodologies Within Clinical Trials



Date: Wednesday 4th & Thursday 5th September 2019

Location: Leopold Hotel, Sheffield, S1 2GZ, UK

We would like to invite you to participate in a workshop for the **Benefit-Risk Assessment to Inform Non-Inferiority and Superiority Study Designs (BRAINS)** project.

This consensus workshop is an opportunity for those with expertise in the use of Benefit-Risk (B-R) methodologies and/or NHIR funded clinical trials to contribute towards guidelines which will assist researchers in the effective application of B-R methodology within clinical trials. Participant's contribution will be acknowledged in the guidance document and subsequent publications, if desired.

The workshop is the third stage of the BRAINS project. Prior to the workshop, a survey and literature review will have been conducted. Results of these will be circulated to participants prior to the event to aid and inform discussions.

Workshop Program:

1. Brainstorming round - panel members will be asked to record their preferences for selecting trial designs and related appropriate B-R methodologies. After this, a 'round robin' sharing of ideas will explore potential approaches before a structured group discussion
2. A preliminary rating round will be completed to ascertain preferences for selecting trial designs and related appropriate B-R Methodology, the results of which will be considered within a second structured group discussion
3. A second, final round of rating will be completed to elicit final preferences and approaches

If you are interested in attending or have any questions please contact Steven Julious (s.a.julious@sheffield.ac.uk) or Nikki Totton (n.v.totton@sheffield.ac.uk) directly.

*Travel expenses, overnight accommodation and subsistence
during the workshop will be provided for all participants*
