Patient preferences for outcomes in clinical trials: implications for medicines optimization
Holmes, Emily; Marson, A.G.; Hughes, Dyfrig

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O16 Improving the testing of treatment effect in clinical trials with time to event outcomes
Song Yang1, Ross Prentice
1National Heart, Lung, and Blood Institute, NIH; 2Fred Hutchinson Cancer Research Center
Correspondence: Song Yang
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This abstract is not included here as it has already been published.

O17 Value-added use of clinical study data: a biolincc perspective on creating well-annotated data packages for the wider scientific community
Leslie Carroll1, John Adams1, Corey Del Vecchio3, Karen Mittu1, Kevin Zhou1, Jane Wang1, Carol Giffen1, Elizabeth Wagner1, Sean Coady3
1Information Management Services, Inc.; 2Translational Blood Science and Resources Branch, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute; 3Epidemiology Branch, Prevention and Population Sciences Program, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute
Correspondence: Leslie Carroll
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Introduction
The National Heart, Lung, and Blood Institute (NHLBI) established the Biologic Specimen and Data Repositories Information Coordinating Center (BioLINCC) www.biolincc.nhlbi.nih.gov in 2008 to provide online access to NHLBI data and biospecimen resources. To assist non-study centers coordinating center was required in nearly all reviews to prepare and obtain missing information such as algorithms for calculated analysis variables, explanatory data labels, code books, key variables used in analyses, annotated forms, and biospecimen linking files. To date, over 600 publications are known to have resulted from requestors using BioLINCC resources.

Conclusion
Efficient preparation of study data and documents is essential to maximizing the scientific utility of study resources. Preparing data for release to the general scientific community requires a significant commitment of time and effort to ensure investigators, not affiliated with the original study, have sufficient information to effectively conduct secondary analyses.

O18 Patient preferences for outcomes in clinical trials: implications for medicines optimization
Emily Holmes1, Anthony G. Marson2, Dyfrig A. Hughes1
1Bangor University; 2University of Liverpool
Correspondence: Emily Holmes
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Background
Drug choices for given therapeutic indications are often guided by clinical trial evidence, however, patients may consider outcomes beyond those measured as primary endpoints within trials in their decision to adhere to medication. Discrete choice experiments (DCEs) are a valid method that has been used to quantify patient preferences for drug outcomes. Data from DCEs may be combined with the results of clinical trials to provide a more patient-orientated perspective on drug choice.

Objective
To demonstrate the impact of incorporating patients’ benefit-risk preferences into the results of clinical trials, using a case study of preferences for anti-epileptic drugs (AEDs).

Methods
Preference weights for outcomes of AEDs (12-month remission, fewer seizures, depression, memory problems, aggression, foetal abnormality) were derived from a web-based DCEs of 414 adult patients with epilepsy. Rates for each of these outcomes were extracted from a large randomised controlled trial comparing the effectiveness of new and standard AEDs (SANAD), and from a systematic review of treatments of epilepsy in pregnancy. The preference weights were combined with the clinical event rates to estimate of patient utility for each AED. The probability of patients preferring each AED was then calculated as the ratio of exponentiation of the utility of each individual AED to the sum of the exponentiation of the utilities of all AEDs. Results were compared to rankings of AEDs as indicated by clinical trials.

Results
The rank order of AEDs based on trial data for remission: lamotrigine, carbamazepine, topiramate, oxcarbazepine, then gabapentin, changed when patient benefit-risk preference was considered. The probability of patients with partial epilepsy preferring each AEDs was, in descending order: carbamazepine (0.29), lamotrigine (0.26), oxcarbazepine (0.24), gabapentin (0.15), topiramate (0.07). Women with the potential to become pregnant had a preference probability of: lamotrigine (0.31), oxcarbazepine (0.21), gabapentin (0.20), carbamazepine (0.19), topiramate (0.09). Comparable results were found for patients with generalised or unclassified epilepsy. Changes to ranking ordering are explained by patients’ stronger preferences for reducing the risk of AEs than for improving treatment benefit. In return for a 1% improvement in 12-month remission, the maximum acceptable risk of adverse events was: depression 0.31%, memory problems 0.30%, aggression 0.25%. The maximum acceptable risk of adverse event in exchange for a 1% improvement in 12-remission was, for women with the potential to become pregnant was: depression 0.56%, memory problems 0.34%, and foetal abnormality 0.20%.

Conclusions
DCEs represent a robust method for quantifying benefit-risk preferences that can be analysed alongside clinical trial data, to provide a patient-orientated perspective on the optimal choice of treatment.