**Title: MOUSE – Mapping OUtcomes measured in pre-clinical Studies against randomised phase 3/4 Effectiveness trials. Do core outcome sets developed for phase3/4 effectiveness trials translate to pre-clinical research?**

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**Introduction**

Translational failure from pre-clinical animal studies to clinical trials has been noted in a number of disease areas. Whilst multiple contributory factors including poor study conduct and reporting have been acknowledged, little attention has been given to whether outcomes measured in pre-clinical studies are relevant to those considered important in clinical trials. Core Outcome Sets (COS) aim to reduce waste in research by defining a minimum set of outcomes to be used in all trials of a particular condition. However, these have been developed for phase 3/4 effectiveness trials and their utility in pre-clinical research is unknown.

**Methods**

To better understand the translatability of outcomes a systematic review of outcomes used in preclinical pharmacological interventions for type 2 diabetes in mouse models will be completed. We will extract exact descriptions of outcomes and categorise these according to the COMET taxonomy. The list of outcomes will then be compared to outcomes identified in a systematic review of phase 3/4 trials of glucose lowering interventions. Preclinical outcomes will also be reviewed against the outcomes considered most important, and recently included in a COS, by people with type 2 diabetes, healthcare professionals, researchers, and policymakers.

**Timing of Potential Results**

Results of the pre-clinical systematic review and extracted outcomes will be presented. The core outcome set for glucose lowering interventions for type 2 diabetes and systematic review of phase 3/4 studies have been completed.

**Potential Relevance & Impact**

This review of pre-clinical studies will enable better understanding of the outcomes measured at different phases of research and the translatability of COS. The use of established COS in pre-clinical studies may also provide a way for patients to influence pre-clinical research to make it more relevant to their needs, and contribute to the refinement of animal studies and overall reduction of animals in research.