

**Name & email supervisor(s):** Dr Kieran Bromley

**Length and dates of internship:** August/September 2024 [4 weeks between 01/08/2024 – 30/09/2024]

**Host department:** School of Medicine, Keele University  
Choose an item.

**How will the internship be conducted:**

- In person at the university
- Virtual/ from home
- Both are possible, depending on preference of student

**Title internship project:**

Systematic review of feasibility progression criteria in pilot and feasibility studies.

**Summary of the internship project:** *(max 250 words, can include hyperlinks to further information)*

There are many aspects of conducting a clinical trial that require careful consideration before funding is given for a large study. Therefore, researchers usually carry out smaller-scale (pilot and feasibility studies (PAFS)) to understand if a full-scale trial is worth doing and could be successfully conducted. It is important to consider pre-defined progression criteria for PAFS outcomes to inform on whether to progress or not to a main trial.

The aim of this study is to carry out a systematic review of the literature scoping different progression criteria for PAFS. Focus will be on PAFS studies published in high-ranking and relevant journals (e.g. Pilot and Feasibility studies journal, BMJ Open) in the last 3 years. Importantly, the reviewer will ascertain the cut-off values used for the progression outcomes within these studies for decision-making purposes. The review will seek to identify values that have been used for decision-making in relation to progression, identify reasons for non-progression and extract any suggestions for possible amendments to support continuing to a main trial.

The intern will also be tasked to perform a specific sub-study of all papers that have cited the Lewis et al. (Pilot Feasibility Stud. 2021; 7:40) publication to ascertain what progression cutoff values and sample sizes have been used following the methods that were detailed in that paper (119 citations, to date); the methodology importantly provided a way of deriving a sample size calculation for PAFS that is directly related to the set feasibility progression criteria.

**Learning objectives:**

Learning to carry out a systematic review in medical research  
Learning how to extract key data for evaluation  
Evaluating and summarising the extracted data  
Writing up the methods and findings for reports and publications

**Any further information:**