To whom it may concern,

I am writing to you as the President of the Academy of Medical Sciences with regard to the open consultation on the NICE Reviewing our methods for health technology evaluation: consultation.¹

The Academy of Medical Sciences promotes advances in medical science, and works to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost medical science experts drawn from academia, industry, and the health and care system.

The Academy of Medical Sciences supports NICE's decision to review its health technology evaluation methods. Innovations in biomedical research need to be matched by novel and effective ways to assess them, and we are pleased that this review proposes new ways to incorporate important areas such as health inequalities, severity of disease, real world evidence, novel endpoints and outcome measures into health technology assessment (HTA). Effectively scrutinising the sources of evidence, and their validity in answering research questions, will be essential to accommodating these new areas into the HTA process. The Academy's 2017 working group report, Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines, outlines the key considerations for making these judgements about the robustness of evidence sources.²

A number of other recent workshop reports from the Academy have highlighted specific considerations for some of the areas covered within the methods review. The Academy’s 2018 FORUM workshop report, Next steps for using real world evidence, outlines the opportunities that real world evidence could provide, as well as some of the questions that remain about its use.³ By pioneering the use of real world evidence in HTA, NICE can send a clear signal to the UK and global research community to help invigorate this burgeoning field. In addition, the Academy's 2017 FORUM workshop report, Looking to the future: oncology endpoints, summarises the case for surrogate outcome measures and patient-reported outcome measures in supporting accelerated assessment.⁴ Supporting the use of these measures where appropriate could enable patients to access valuable therapies sooner. Patient-reported outcome measures may be especially important when an assessment is looking at severity of disease and quality of life measures, which may

² Academy of Medical Sciences (2017). Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines https://acmedsci.ac.uk/file-download/44970096
³ Academy of Medical Sciences (2018). Next steps for using real world evidence https://acmedsci.ac.uk/file-download/7021031
⁴ Academy of Medical Sciences (2017). Looking to the future: oncology endpoints https://acmedsci.ac.uk/file-download/41135280
otherwise be difficult to assess. The Academy’s 2019 FORUM workshop report, *Adaptive trials: acceptability, versatility and utility*, which was produced in partnership with NICE, makes the case for complex innovative design (CID) trials, including basket trials, as an innovative way for the UK to continue to be a world leader in global research.\(^5\) CID trials have come to the fore during the COVID-19 pandemic and opportunities to make these trials more commonplace should be pursued. By incorporating these novel trials into assessments, NICE is supporting the ecosystem of researchers developing novel methodologies and trial sponsors wishing to put them into practice.

Finally, in December 2020 the Academy held a FORUM workshop, *Precision prevention for modifiable health risks*, which discussed some of the evidence requirements for the effective HTA of risk prediction tools in healthcare. We will be happy to provide you with a copy of the summary report of this workshop when it is published early next year.

We would be very happy to expand on these points or provide further evidence as requested and look forward to remaining engaged with NICE’s work in this area.

Yours sincerely,

Dame Anne Johnson DBE PMedSci

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\(^5\) Academy of Medical Sciences (2019). *Adaptive trials: acceptability, versatility and utility* [https://acmedsci.ac.uk/file-download/36842538](https://acmedsci.ac.uk/file-download/36842538)