



**NOTICE OF DETERMINATION**  
**CORE PARTICIPANT APPLICATION**  
**MODULE 4 - NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Introduction**

1. In my [Opening Statement](#) on 21 July 2022, I explained that Modules would be announced and opened in sequence, with those wishing to take a formal role in the Inquiry invited to apply to become Core Participants for each module. On 5 June 2023, the Inquiry opened Module 4 and invited anyone who wished to be considered as a Core Participant to that Module to submit an application in writing to the Solicitor to the Inquiry by 30 June 2023.
2. The Inquiry has published the [Provisional Outline of Scope](#) for Module 4, which states that this module will consider a range of issues relating to the development of Covid-19 vaccines and the implementation of the vaccine rollout programme in England, Wales, Scotland and Northern Ireland. Issues relating to the treatment of Covid-19 through both existing and new medications will be examined in parallel. Further modules will be announced and opened in due course, to address other aspects of the Inquiry's Terms of Reference.
3. On 19 June 2023 the Inquiry received an application from the National Institute for Health and Care Excellence (NICE) ("the Applicant") for Core Participant status in Module 4. This Notice sets out my determination of the application.

**Application**

4. Applications for Core Participant status are considered in accordance with Rule 5 of the Inquiry Rules 2006, which provides:

*5.—(1) The chairman may designate a person as a core participant at any time during the course of the inquiry, provided that person consents to being so designated.*

*(2) In deciding whether to designate a person as a core participant, the chairman must in particular consider whether—*

- (a) the person played, or may have played, a direct and significant role in relation to the matters to which the inquiry relates;*
- (b) the person has a significant interest in an important aspect of the matters to which the inquiry relates; or*
- (c) the person may be subject to explicit or significant criticism during the inquiry proceedings or in the report, or in any interim report.*

*(3) A person ceases to be a core participant on—*

- (a) the date specified by the chairman in writing; or*
- (b) the end of the inquiry.*

5. In accordance with the approach set out in my Opening Statement and the Inquiry's [Core Participant Protocol](#), I considered whether the application fulfils the requirements set out in Rule 5(2) in relation to the issues set out in the Provisional Outline of Scope for Module 4.

### **Summary of Application**

6. The Applicant is the National Institute for Health and Care Excellence (NICE), a non-departmental public body under the Health and Social Care Act 2012. A key area of the Applicant's work is the production of guidance relating to medicines and medical technology and guidelines for use in clinical settings, social care, public health and medicines practice. The application is put on the basis that the Applicant played a direct and significant role in matters to which Module 4 relates (Rule 5(2)(a)).
7. In relation to the pandemic, the Applicant explains that it took part in a multi-agency initiative to design and implement the Research to Access Pathway for Investigational Drugs in Covid-19 (known as 'RAPID C-19'). RAPID C-19's aim was to facilitate rapid patient access to therapeutics for Covid-19 when they were proven to be beneficial and before more formal mechanisms of clinical and cost effectiveness assessments were undertaken. RAPID C-19 was established on 29 April 2020 and the Applicant provided the secretariat function and evidence synthesis when identifying medicines showing promise in clinical trials. The Applicant explains that it also made a large number of recommendations on antivirals and therapeutics through its guidelines programme.

## Decision for the Applicant

8. Module 4 will consider a range of issues relating to the development of Covid-19 vaccines and the implementation of the vaccine rollout programme in England, Wales, Scotland and Northern Ireland. Thematic issues relating to unequal vaccine uptake will be examined, to include the identification of groups which were the subject of unequal uptake, potential causes of such unequal uptake and the Government response. The module will also address issues of public concern relating to vaccine safety. Issues relating to the treatment of Covid-19 through both existing and new medications will also be examined.
9. I have considered with great care everything that is said in the application. Having done so, I have decided, in my discretion, to designate the Applicant as a Core Participant in Module 4. I consider that the Applicant, through its work on the RAPID-C19 initiative, played a direct and significant role in the development, trials and use of new therapeutics during the pandemic, in addition to the use of existing medications. The Applicant therefore meets the requirements of Rule 5(2)(a).

## Legal Representation

10. Applications for designation as the Recognised Legal Representative of a Core Participant are governed by Rules 6 and 7 of the Inquiry Rules 2006, which provide:

*6.—(1) Where—*

- (a) a core participant, other than a core participant referred to in rule 7; or*
- (b) any other person required or permitted to give evidence or produce documents during the course of the inquiry,*  
*has appointed a qualified lawyer to act on that person's behalf, the chairman must designate that lawyer as that person's recognised legal representative in respect of the inquiry proceedings.*

*7.—(1) This rule applies where there are two or more core participants, each of whom seeks to be legally represented, and the chairman considers that—*

- (a) their interests in the outcome of the inquiry are similar;*
- (b) the facts they are likely to rely on in the course of the inquiry are similar;*  
*and*
- (c) it is fair and proper for them to be jointly represented.*

*(2) The chairman must direct that those core participants shall be represented by a single recognised legal representative, and the chairman may designate a qualified lawyer for that purpose.*

*(3) Subject to paragraph (4), any designation must be agreed by the core participants in question.*

*(4) If no agreement on a designation is forthcoming within a reasonable period, the chairman may designate an appropriate lawyer who, in his opinion, has sufficient knowledge and experience to act in this capacity.*

11. I am satisfied that NICE has appointed Mr Mark Thompson of DWF Law LLP as its qualified lawyer in relation to this Module. I therefore designate Mr Thompson as NICE's recognised legal representative in accordance with Rule 6(1).

12. Directions will be given in relation to applications for an award under section 40(1)(b) of the Inquiries Act 2005 of expenses to be incurred in respect of legal representation, at the forthcoming preliminary hearing. I will determine any such applications in accordance with the provisions of section 40 of the Inquiries Act 2005, the Inquiry Rules 2006, the [Prime Minister's determination](#) under section 40(4) and the [Inquiry's Costs Protocol](#).

**Rt Hon Baroness Heather Hallett DBE**  
**Chair of the UK Covid-19 Inquiry**  
**17 July 2023**