|  |  |  |
| --- | --- | --- |
| Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank): | | [Insert organisation name] |
| Name of commentator person completing form: | | [Insert name] |
|  | Targeted Questions We are most interested in receiving responses to the following questions: | |
| Q1 | In light of a reduction in in vitro evidence generation for COVID-19 treatments, is the in vitro data methods framework still a useful document for decision-making? | |
| Q2 | When should NICE consider changes in in vitro neutralisation data to inform decision-making? | |
| Q3 | Is there a specific threshold of in vitro neutralisation above which clinical efficacy can be assumed? Does this depend on the availability of PK-PD data to link to clinical outcomes? | |
| Q4 | What methodology should be used to calculate estimates of cost-effectiveness based on in vitro neutralisation data? | |
| Q5 | How could in vitro data be generated and used to confirm ongoing clinical and cost-effectiveness of COVID-19 treatments? | |
| Q6 | What other alternative approaches could NICE consider to meet the challenge of treatment effectiveness changing with variants? | |

|  |  |
| --- | --- |
| **Comment number** | General comments on *In vitro data on neutralising monoclonal antibodies for COVID-19: methods framework* Insert each comment in a new row.  Do not paste other tables into this table, because your comments could get lost – type directly into this table. |
| 1 | How should NICE consider changes in in vitro neutralisation data to inform decision-making? |
| 2 |  |
| 3 |  |
| 4 |  |
| 5 |  |
| 6 |  |

|  |
| --- |
| **Checklist for submitting comments**   * Use this comment form and submit it as a Word document (not a PDF). * Do not paste other tables into this table – type directly into the table. * Please underline all confidential information, and separately highlight information that is ‘commercial in confidence’ in turquoise and information that is ‘academic in confidence’ in yellow. If confidential information is submitted, please submit a second version of your comments form with that information replaced with the following text: ‘academic / commercial in confidence information removed’. See the [NICE Health Technology Evaluation Manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) (section 5.4) for more information. * Do not include medical information about yourself or another person from which you or the person could be identified. * Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.   **Note:** We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.  Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory committees. |