## Response document for consultation on MHRA draft guidance on randomised controlled trials generating real-world evidence to support regulatory decisions

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| About You Name: |
| Position: |
| Organisation: |
| Email: |
| Please indicate if you are responding to this consultation as an individual or on behalf of an organisation Individual  Organisation  |
| General comments  | Stakeholder number  (To be completed by MHRA) | General comment (if any) | Outcome (if applicable)  (To be completed by MHRA) | | --- | --- | --- | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |
| 2. Specific comments on text  | Title and section number of the relevant text | Comment and rationale; proposed changes  *(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome  (To be completed by MHRA) | | --- | --- | --- | |  | Comment:  Proposed change (if any): |  | |  | Comment:  Proposed change (if any): |  | |  | Comment:  Proposed change (if any): |  | |  | Comment:  Proposed change (if any): |  |   Please add more rows if needed |
| 3. Would you be happy for the MHRA to contact you in order to discuss your responses in further detail? Yes  No  |
| 4. The MHRA may publish consultation responses. Do you want your response to remain confidential? Yes  Partially\*  No   \*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete. |

Responses can be continued onto a separate page if required. This form should be returned by email rwe@mhra.gov.uk to arrive by **11 December 2020.** Contributions received after that date cannot be included in the exercise.