

## Coordinated Assessment Pathway Process Guidance

MHRA is working with the HRA to test a new coordinated assessment pathway which involves our two organisations sharing information during our assessment of medical device clinical investigations. For this process we require the MHRA Devices application to be submitted first and then the REC application to be submitted as soon as MHRA has confirmed the devices application to be valid. Our two organisations will then share information on our findings with one another. It is envisaged that the MHRA assessment will be shared with the REC before the REC meeting and the REC discussion will be shared with MHRA.

PLEASE NOTE the following:

- to participate in this process, you must be in a position where both the MHRA Devices and REC applications have been prepared and are ready to be submitted (but have not been submitted yet)
- the application to MHRA Devices will need to be submitted **first** and the application to REC can only be submitted once MHRA has confirmed that the devices application is valid. Therefore both applications should be ready to be submitted at the time of submitting the MHRA application.
- it will be important that you work with colleagues responsible for making the submissions to MHRA and REC to ensure the process is followed.
- it will not be possible for the applicant to request review by a specific REC. To ensure a streamlined process, HRA will appoint the REC to review your application.

### Taking part:

If this is something that you would be interested in participating in, please inform MHRA in advance of submitting any applications by emailing [CI-applications@mhra.gov.uk](mailto:CI-applications@mhra.gov.uk) with "MHRA/HRA Coordinated assessment pathway" in the subject line and further information will be provided.

In order to verify that your study is appropriate for this process, please confirm the following in your email about your study:

- 1) The REC application has not yet been made
- 2) The study does not involve adults lacking capacity
- 3) The study is not also a CTIMP
- 4) The estimated application date
- 5) The IRAS Project ID number (if available)