Routemap

Substantial Amendments

Recruitment Phase

The Substantial Amendment station follows the Audit station and precedes the Addition of New Sites & Investigators station. This process occurs in parallel with Safety Reporting, Progress Reporting, Ongoing Management & Monitoring, and GCP & Serious Breach Reporting. It also has the potential to occur simultaneously with an MHRA Inspection, Audit, Addition of New Sites & Investigators, Urgent Safety Measures, Temporary Halt, and Early Termination. Substantial Amendments are a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

Amendments are changes made to a research project after approval from a review body has been given. For amendments to projects conducted at NHS/HSC sites, guidance can be found on the Integrated Research Application System (IRAS).

Amendments are now prepared using the Amendment Tool (V1.6). The Tool will automatically assign a recommended amendment category based on each type of change made as part of the amendment. It is the sponsor's responsibility to ensure the Amendment Tool is completed correctly, and to confirm the outcomes align with their own expectation of how the amendment should be processed. The completed amendments should be submitted as directed on the 'Submission Guidance' tab in the Amendment Tool.

For CTIMPs, the MHRA website and the IRAS website provides guidance on submitting amendments to the MHRA*. The IRAS website provides information on

how to inform participating sites of amendments.

***Note**: The amendment tool can now be used to notify the MHRA of substantial amendments in place of the Annex 2.*

Further reading:

- Addition of New Sites & Investigators station