

Addition of New Sites & Investigators



Recruitment Phase

Addition of New Sites & Investigators station follows the Substantial Amendments station and precedes the Urgent Safety Measures 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, Substantial Amendments, Urgent Safety Measures, Temporary Halt, and Early Termination. Addition of New Sites & Investigators is a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

For CTIMPs conducted at NHS/HSC sites, the addition of a new site and/or addition or change of a Principal Investigator, is no longer considered a substantial amendment. This has been implemented to speed up the site set-up process. No changes have been made to the classification of amendments relating to new sites/change of PI at **non**-NHS sites.

If a site is added in a nation not previously involved in the project, this should be indicated at the relevant question of the [Amendment Tool](#) and made clear in the covering letter when submitting the amendment to the lead nation.

The contact details for sites in the UK (Research and Development (R&D) organisations) can be accessed from the [NHS R&D forum](#) website.

All changes to sites and / or investigators should be communicated to the Funder at the earliest opportunity.

Further Reading

- [Substantial Amendments Station](#)
- IRAS: [Amendment guidance - all review bodies](#)