

Site Selected Email Template (NHS/HSC Sites) user guidance

Purpose

The Site Selected Email is the formal notification from the commercial sponsor (or delegated agent) to an NHS or HSC organisation, confirming that the organisation has been selected to participate as a site in a commercial-contract clinical trial or clinical investigation.

The email is a key milestone within the site set-up process. The date of the email should be given as the Date Site Selected for reporting purposes. This UK template email standardises the communication between sponsor (or agent) and their selected sites, confirming key information shared. It is the end of assessment of site capability and confirms that sponsor and site have also reviewed anticipated capacity requirements. That they agree there is a reasonable prospect of securing the capacity required to deliver the study according to the agreed project start-up plan. It is the start of the next stage, of collaboratively arranging to deliver the project at site, in line with agreed set-up timelines.

When should the email be sent?

Sponsors (or delegated agent) should send the email to the required recipients at the site when:

- site selection activities have been completed
- the sponsor has decided to include the site in the project
- the sponsor and site have agreed (during site selection conversations) the expected project start-up plan
- there is sufficient confidence that the site will be capable of delivering the project

The email should be issued as soon as the site has been formally selected.

Key messages communicated by the email

The email confirms that:

- the site has been formally selected
- the sponsor and site agree that the project can be delivered at the site
- capacity planning and project set-up activities should commence immediately (or where a later date has been agreed, set-up activities should begin on this date)
- both parties will work to the agreed timelines provided in the project start up plan. Any dates of other local requirements should be provided by the site during the site selection conversations and documented in the site selection

discussion notes and attached to the email, for example, local processes for required site licences or site GMO committee dates.

- any changes affecting delivery or timelines should be communicated promptly by all parties
- delays should only result in adjustment of the plan where a clear rationale has been discussed and agreed
- where the sponsor has information or documents available, these should be provided to the site or provided as available to assist earlier set up
- that the site has agreed to provide first or second national resource reviewer for the NVCR process (or where this remains to be confirmed)

LPMS reporting requirements

Following receipt of the Site Selected Email, the site should record the agreed **Date Site Selected** (date of the email, or agreed alternative date provided by the sponsor) within LPMS.

If the site believes sponsor due diligence has not been completed sufficiently to justify site selection and does not have the capacity or capability to deliver the project according to the stated plan, and/or requires support to resolve, the site should raise this concern to the sponsor and copy in research.agreements@hra.nhs.uk. Copying HRA will allow for monitoring of such occurrences. Where support from the HRA (or devolved nation equivalent) is requested, this should be made explicit at the start of the email. This ensures accurate performance reporting and transparency within the UKCRD performance framework.

Before sending the email, the sponsor or agent should:

- confirm all contact details are correct
- verify recruitment targets have been discussed and agreed
- ensure proposed dates are realistic and achievable
- ensure timelines align with any project-wide plans
- resolve any outstanding queries from site selection discussions which are crucial to the sites capability to participate
- attach any relevant site selection discussion notes or actions (including the resolutions to any crucial actions as per the above), and any **known** relevant information for site set-up