

Gaining Virtual Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store for Monitors, Auditors and Regulatory Inspectors

DLV-GEN-WI-004

Relates to:-

[DLV-GEN-T-002 Non-Trust IT Remote Monitoring Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store Request Form](#)

[DLV-GEN-T-003 Monitors, Auditors and Regulatory Inspectors Approvers list \(access to Electronic Systems\)](#)

Procedure/Method

1. As soon as the study/trial team is notified of a monitoring visit or regulatory body inspection, they must request access to the Electronic Health Record (eRecord), BadgerNet Maternity, BadgerNet Neonatal and Document Store for participants in the study. IT will need **5 days' notice** for new accounts
2. Send a copy of [Non-Trust IT Remote Monitoring Access Request Form](#) (Appendix 1) to the designated Monitor or Regulatory Inspector to be completed including their date of birth and signature. The completed form must be returned to the designated approver.

NB: Regulatory Inspectors will not provide their date of birth or sign the form.

The requirement for confidentiality concerning inspection information by inspectors performing their statutory duties is set out in law in the Human Medicines Regulations 2012, Regulation 332.

The Team Lead or Matron will sign the form to verify the request for access is appropriate

3. The study team must confirm that the applicant holds an employment contract with the Sponsor, CRO or authorised delegate.
4. The study team must verify the identity of the applicant by review of a government issued photographic identification e.g., passport, national identity card, driving licence etc.
5. Confirm the start and end date on the [request form](#)
Please note that the request cannot be submitted via the application form more than 14 days in advance of the visit. IT will only accept a single application per visit.

6. On receipt of the completed forms and confirmation of the duration of the visit, submit the completed forms to the **Designated Approver** for authorisation. Authorisation can only be given by **Designated Approvers** IT will not accept requests from anyone else.
7. A **Designated Approver** (see [Appendix 2](#)) must:
 - a. ensure that the forms have been signed and an end date is provided
 - b. submit the completed forms with the expiry date to nhsnewcastle@service-now.com
 - c. ensure the email subject is **MHRA Auditors New Account Request** (If anything other than this text is entered into the **Subject Line**, a ticket will **NOT** be logged).

This process will automatically log a ticket to the **Service Desk** and the **Designated Approver**, and **Trust Supervisor** will receive 2 emails from the Service Desk (one is generic and the other contains the reference number for the request).

If an email containing a reference number has not been received within 10 minutes of sending the email, please contact the IT Service Desk.

8. An end date **MUST** be provided for duration of the Monitor, auditor and regulatory inspector visit. Without this, the account will not be enabled. (The access request form is for one visit only. If the same monitor is revisiting, this form will have to be resubmitted to request the account is reactivated/re-enabled).
9. IT Service Desk will enable access for the duration of the monitoring visit/inspection by issuing access to the person supervising the request on behalf of the Monitor or regulatory body.
10. Monitors will not have direct access to systems, unless using remote access via Swivel Pin. The supervisor facilitating the session will be responsible for enabling the Monitor/Inspector on Microsoft Teams virtual platform and access to the information they require.
11. **To Enable Existing Accounts**, which have already been set up. A **Designated Approver** (see [Appendix 2](#)) or **Trust Supervisor** must:
 - a. email nhsnewcastle@service-now.com containing the Monitor/Inspectors name, username name and/or DOB (if known).
 - b. provide an end date after which the account can be disabled (without this, the account will not be enabled)

- c. ensure the email Subject Line is **MHRA Auditors Enable Existing Account** (If anything other than this text is entered into the subject line this will **NOT** log a ticket).

This process will automatically log a ticket to the Service Desk and the **Designated Approver**, and **Trust Supervisor** will receive 2 emails from the Service Desk (one is generic and the other contains the reference number for the request).

If an email containing a reference number has not been received within 10 minutes of sending the email, please contact the IT Service Desk.

Please give **24 hours'** notice for enabling existing accounts.

12. The completed request and approvals must be stored in the study site file

Appendices

1. [DLV-GEN-T-002 Non-Trust IT Remote On-site Access to eRecord, BadgerNet Maternity, BadgerNet Neonatal and Document Store Requests Form](#)
2. [DLV-GEN-T-003 Monitors, Auditors and Regulatory Inspectors Approvers List \(Access to Electronic Systems\)](#)