

# Electronic Records v External Monitors – A solution!

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## We wanted to create a process for external sponsors to view patients' records without breaching data protection

With the introduction of EVOLVE, An Electronic Document Records Management System (EDRMS), R&D needed to help find a way to facilitate the monitoring by our external sponsors.

### Team approach

Working together with the IT Department we designated a laptop which was wiped clean of all applications apart from the EVOLVE system.

### Training

Members of the R&D Team received EVOLVE training from IT with the assurance that consent forms would be checked, allowing access to medical records from the members of the NHS organisation where the research is taking place.

### Process

The research teams send the R&D facilitators a list of the patient's hospital numbers, initials and study numbers selected for the monitoring visit together with a copy of the participant's signed consent form.

Connecting the password-protected laptop to the internet is simple using the internet cable. The exporting process and checks, including creating passwords for the record, can begin.

Each record is saved on the desktop as the patient's study number for easy access by the monitor. The password is provided to the monitor once they are on site.

The internet connection is then removed and the monitor can access all of the saved information required as if they were working on the live system.

Once the monitor has completed the visit all records are then deleted from the desktop, including the recycled bin.

### Auditing

The facilitator in the R&D team, who has accessed the record, will email the R&D Manager stating how many records have been downloaded, the name of the study and details of the monitoring visit, this is filed for audit.

A copy of the monitoring report is held in the R&D office to complete the audit trail.

### Feedback

We have had positive feedback from our external monitors who have been impressed and welcomed this approach.

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