



NOTAT

FAQ – Clinical Suite

Access	
Q1. Does everyone with access to the system have his or her own unique user id and password?	Yes
Q2. Does the system require the user to change their password periodically?	Yes
Q3. Is there an automatic log-off after a period of inactivity?	Yes
Q4. Will external monitors/auditors/inspectors have direct read-only access to the system?	Yes
Q5. Will external monitors/auditors/inspectors access be limited to viewing data belonging to the defined study/study subjects only?	Yes

Audit trails	
Q1. Does the system generate electronic audit trail information for all entries and actions that create, modify, or delete data in the system?	Yes
Q2. Is the audit trail secure (i.e. not editable by any user)?	Yes
Q3. Does the audit trail show: a. Who made the change? b. When the change was made (date and time)? c. Reason for change? d. Previously recorded data?	Yes Yes No Yes
Q4. Will audit trail be accessible to monitors and auditors/inspectors in a readable format?	Yes

System Maintenance	
Q1. Is there data backup in case of system failure?	Yes
Q2. Are backup stored in a secure location different from source data?	Yes
Q3. Is there a backup plan in case of system failure to support the ongoing activities and protect/restore the data in the system?	Yes