Information about electronic Records Management System

Version I – Date:
Midt Denmark Region

System Name: MidtEPJ	Version Number: RM36 Release Date: 2022.09.25		
Questions	**Yes**	**No**	Detailed clarification: If yes, please specify *how* the question is fulfilled If no, please specify reason for this / alternatives
A. Computerised System			
1. Are there some data transferred from one electronic system to another electronic system?	Yes		System are central and have integrations to paraclinical systems, export to national systems etc
2. Did the site test the software before it was applied to manage patient data?	Yes		
3. Were the test results documented?			Eletronic (Testrail)
4. Does the site have written policy on: a. System validation b. Problems management (i.e. system failure...) c. System use	Yes		Yes to all
5. Does the system have a virus scanning program?	Yes		
6. If the network is connected to the internet, is there any firewall?	Yes		

B. Access			
1. Do the users receive training for operations they have to do in the system?	Yes		
2. Are there any ID and passwords for users to access the system?	Yes		
3. Is each user provided with his/her own password (not shared password)?	Yes		
4. Are the users required to change the password periodically?	Yes		
5. Is there an automatic log-off after a period of inactivity?	Yes		
6. Is the name of the person who recorded clinical observations displayed?	Yes		
7. Is it possible to edit the list of users who were authorized to make data changes during the study?			Maybe, which list are in question ?

8. Are monitors, auditors, inspectors provided with read-only access, limited to specific patients participating in a specific ongoing clinical trial? a. If so, how does the individual gain access? b. how is limited access tracked?	Yes	No	We have an solution to control access, but currently we don't grant access, but have an manual process. All change in system are recorded to very high detail.

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Questions	Yes	No	Detailed clarification
C. Audit trails			
1. Can the system capture and display all time sequenced data such as:			
a. All changes?	Yes		
b. All deletions?	Yes		
c. Who changed?	Yes		
d. When changed (time and date)?	Yes		
e. Why changed?	Yes		
2. Does the system have function of clock protection?		No	System are 24/7/365
3. Is the audit trail protected from modifications and from being inactivated?	Yes		
4. Do monitors, auditors, inspectors have access to audit trail?		No	

D. System maintenance			
1. Is there routine data backup?	Yes		
2. Has the back-up process been tested and verified by vendor or site so the integrity of the back-up can be assured?	Yes		
3. Are backup stored in a secured location (e.g. different from source data location...)?	Yes		
4. Does the site have written policy for restoring data from damaged files?	Yes		

E. Archiving			
1. Does the site ensure that reasonable and useful access to electronic records (including audit trail) is possible during 15 years after end of trial? (After implementation of Clinical Trials Regulation, EU No 536/2014, 25 years will apply)	Yes		
2. Does the system allow generating electronic copies of electronic records?	Yes		Possible to generate pdf documents of medical record
3. Does the system allow generating paper copies of electronic records?	Yes		
4. In case of update or change of system, does the site ensure that all electronic data will be maintained in new system?	Yes		

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Electronic Records Management Systems in the Danish public healthcare sector are regulated by Danish law e.g. "Lov om krav til sikkerhed for net- og informationssystemer inden for sundhedssektoren", Law No. 440, May 8 2018.

The electronic Records Management System described in this document is in accordance with The General Data Protection Regulation (GDPR) (EU) 2016/679.

Update of this his document is required if the electronic Records Management System described in this document is changed. Verification of answers in this document is required every second year.

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Signature:

Date: 2025.04.01