Information about electronic Records Management System

Version I – Date: 23 Oct 2023

Aarhus University Hospital

System Name: Columna Clinical Information System (MidtEPJ)	Version Number: RM39 Release Date: 24 September 2023		
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		Several auxiliary systems are integrated with the EMR, including diagnostic imaging and clinical laboratory.
2. Did the site test the software before it was applied to manage patient data?	Yes		Testing is carried out by the central IT department before any update to the system.
3. Were the test results documented?	Yes		
4. Does the site have written policy on: a. System validation b. Problems management (i.e. system failure...) c. System use	Yes		
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		System access is based on two-factor logon.
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		Passwords must be changed twice per year.
5. Is there an automatic log-off after a period of inactivity?	Yes		The user is logged out after 20 minutes idle time.
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?		No	

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?		No	Monitor access is not limited to study participants, but lookups are reviewed to ensure that only relevant records are accessed.

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		Original data is retained in the log and users are legally obligated to document the reason for making corrections to the EMR.
2. Does the system have function of clock protection?	Yes		
3. Is the audit trail protected from modifications and from being inactivated?	Yes		
4. Do monitors, auditors, inspectors have access to audit trail?	Yes		All system interaction is logged and the log for specified events can be retrieved upon request.

D. System maintenance			
1. Is there routine data backup?	Yes		A "mirrored" read only copy of the system is continually generated and available in case of system failure. Complete backup is saved for 1850 days (5 years)
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		Data is stored in three separate locations.
4. Does the site have written policy for restoring data from damaged files?	Yes		

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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		The content of the clinical trial master file is archived for at least 25 years after the end of the trial. Electronic health records (source data) are saved indefinitely and beyond the statutory requirement of at least 10 years. There is no policy of deleting patient data, except if required under GDPR.
2. Does the system allow generating electronic copies of electronic records?	Yes		
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		

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.

Name and title: Michael Werenberg Mikkelsen,
Head of Health Informatics and Digitalisation
Aarhus University Hospital

Date: 3/11-2023

Signature: