Information about electronic Records Management System

Version I – Date: 2018-11-29

Regionsyd

System Name: CAMBIO COSMIC	Version Number: 1 Release Date: 2018-11-29		
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?	X		E.g. FMK, Sundhedsjournal
2. Did the site test the software before it was applied to manage patient data?	X		The System is tested by both vendor and RSD
3. Were the test results documented?	X		A Qualitycenter managementsystem (HP) is used
4. Does the site have written policy on: a. System validation b. Problems management (i.e. system failure…) c. System use	X		
5. Does the system have a virus scanning program?		X	Servers and PC's have virus scanning programs
6. If the network is connected to the internet, is there any firewall?	X		

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

b. How is limited access tracked?			

Questions	Yes	No	Detailed clarification
C. Audit trails			
1. Can the system capture and display all time sequenced data such as:			
a. All changes?	X		
b. All deletions?	X		Unless unsigned documents or similar
c. Who changed?	X		
d. When changed (time and date)?	X		
e. Why changed?		X	Not necessarily. i.e. changing a word in the record does require an explanation
2. Does the system have function of clock protection?	X		
3. Is the audit trail protected from modifications and from being inactivated?	X		
4. Do monitors, auditors, inspectors have access to audit trail?	X		

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

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)	X		The law prohibits deletion of medical records for a period of ten years after the last recording of data, but the site has no policy or intention of deleting anything outside of the statutory requirement. Including Audit trailing.
2. Does the system allow generating electronic copies of electronic records?	X		
3. Does the system allow generating paper copies of electronic	X		

records?			
4. In case of update or change of system, does the site ensure that all electronic data will be maintained in new system?		X	Access to old date will be maintained

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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