## Clinical & Systems Transformation (CST) Cerner Fact Sheet

## Vancouver General Hospital - Vancouver Coastal Health

## Study related source documentation is captured on the Electronic Health Record (EHR) – CST Cerner. The Go-Live date for the EMR was April 2018. The Vancouver General Hospital onboarded to use as of November 2022.

The EMR (CST Cerner) is a clinical information system, designed for collecting, storing, amending and retrieving information relevant to health care delivery. The system supports defined clinical workflows through automation of information delivery and health-care task requests. CST Cerner is interfaced with other downstream systems such that patient results from those systems will flow back into CST Cerner. Some data is also faxed or scanned into CST Cerner and becomes part of the source.

**EMR System**

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| System Name and Version Number | Name: Cerner Millennium  Version: 2018.09.01 |
| EMR Manufacturer | Oracle Cerner (formerly Cerner Corporation |
| Owner of the EMR system used | Vancouver Coastal Health/Provincial Health Services Agency/Providence Health Care |
| System Validation Date | Oct 2017: Date of first comprehensive system integration testing completion. Repeated multiple times since. |
| System Validation Certificate Date | November 7, 2022 : US CMS (Centers for Medicare & Medicaid Services)  June 14, 2021: Information Security Management System ISO/IEC 27001:2013  Validation documentation provided upon request of auditors/ inspectors |
| Compliance | ICH GCP Section 4.9 and any applicable national or regional standards /regulations |
| Standard Operating Procedures (SOPs) or equivalent documents exist for the use/ operations/ maintenance of the computer system(s) | Yes. Documents provided for review upon request of auditors/inspectors. |
| 1. Will these SOPs/equivalent documents be provided for review upon request of auditors/inspectors? | Yes |
| Original paper documents | Cerner includes scanned original paper documents. Documents can be accessed by monitor for verification. |
| Will the original paper documents be accessed by the monitor for verification? | Yes. |
| 1. Will validation documentation be provided upon request of auditors/inspectors? | Yes. |
| 1. Does everyone with access to the EMR/EHR system have their own unique User ID and password? | Yes. |
| 1. Does the EMR/EHR system require the user to change his/her password periodically? | Yes. |
| 1. Will external study monitors and auditors/inspectors be given a unique User ID and password? | Yes. |
| 1. Will external users’ access be limited to viewing data belonging to the defined study/study subjects only? | Yes. |
| 1. Is there documented training for persons that use and maintain the computer system(s)? | Yes. Cerner Learning Journey is required for prospective users looking for access. |
| 1. Can previously entered data be changed by the original data creator or by another user? | No. |
| 1. Does an admin support/study nurse/study coordinator enter data on behalf of an investigator? | No |
| 1. Are any records transcribed from audio files into EMR system? | Yes |
| 1. If yes, is documented process available outlining how data transcribed from audio source is verified and certified for accuracy and integrity? | Transcriptions are reviewed and electronically signed by the author in the EMR system. |

**Audit Trail**

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| Does the EMR system use an automated audit trail that automatically captures all entries and actions that create, modify, or delete data in the medical record? | Yes |
| Is the electronic audit trail secure? (i.e., stored in a secure manner and not editable by any user) | Yes |
| Information included in the audit trail: | User ID/name who performed the action  Date and time of action  Reason for change (Optional)  Show previously recorded data |
| Will audit trail be accessible to monitors and auditors/inspectors in a readable format? | Yes |
| Will the audit trail be retained as long as the electronic record is required to be stored? | Yes |
| 1. Does the audit trail show: 2. 1. Who Made Changes 3. 2. Date/Time when changes were made 4. 3. Reason for change 5. 4. Previously Recorded data | 1. Yes. 2. Yes. 3. Yes. 4. Yes. |

**User Access and Control**

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| Is there documented training for persons that use and maintain the computer system(s)? | Yes. Multi-step training including online courses, a self-directed module, and completion of learning assessment quizzes are mandatory before access is granted. |
| Does everyone with access to the EHR system have their own unique User ID and password? | Yes |
| Will training documentation be provided upon request of auditors/inspectors? | Yes |
| Will external study monitors, auditors/inspectors have access to the system? | Yes. Access is to the medical information of subjects who have signed the study’s Informed Consent for the duration of the study. Access is granted once documented training is completed on the system. Direct read-only access will be given for the duration of the study or required time period. |
| Will external study monitors, auditors/inspectors be given a unique User ID and password? | Yes |
| Will external users’ access be limited to viewing data belonging to the defined study/study subjects only? | Yes. |
| Other controls to limit access to the EMR: | User accounts lock after several failed log in attempts  Periodic password change  Automatic log off after an idle period  End dates of accounts based on hire or other term limits |

**Protection, Storage and Archiving**

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| 1. Can previously entered data be changed by the original data creator? | Yes for some types of documentation. Information in the clinical chart can be changed by both the author and other users (audit trail is maintained).  For documentation that a researcher does (e.g. “dyn doc” notes), only an addendum can be added but the original text cannot be edited. |
| 1. Can previously entered data be changed by another user? | As above, some types of documentation and information can be. Audit trail is maintained.  For documentation that a researcher does, (e.g. Dynamic documentation), no. Only addendum can be added. |
| 1. Can an administrative support/study nurse/study coordinator enter data on behalf of an investigator? | No |
| 1. After the clinical study has concluded, will the patient data from the computer system be archived in a read-only electronic format or archived in a printed format? | Read-only electronic format. The clinical study related source will remain accessible after study closure. |
| 1. If No archival is scheduled, will the clinical study related source remain accessible after study closure? | Yes. |
| 1. Is there a back-up plan in case of system failure to support ongoing activities and protect/restore the data in EMR? | System databases are housed off-site in a secure location, with system standard protections in place.  Onsite, 724 computers have their own UPS (uninterruptible power source) that provides emergency power to the 724 PC when the main power source fails. The UPS is plugged into red plugs where there will be emergency power but the UPS prevents the computer from losing power when it transitions from regular to emergency power. For units where there is no emergency power available (like Diamond Centre) the UPS is configured to shut the machine down when it detects the UPS battery is low. |
| 1. System Back-up Frequency | A replicated database is maintained in near real-time in sync with the CST Cerner production database. |

I attest that the above FACT document to the best of my knowledge the information provided is an accurate and true summary of the compliance of the Electronic Medical Record System and procedures that will be used in the conduct of the clinical trial.

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| **Qualified/Principal Investigator** | |
| Signature: |  |
| Printed Name: |  |
| Date: |  |