**ICH GCP and CFR Part 11 Compliance Statement**

17th August 2012

Core Medical Solutions (CMS) is a leading supplier of clinical information systems with interests across the Asia Pacific region. Led by the BOSSnet Clinical Information System and a suite of associated products and applications, our company has deployed innovative healthcare solutions to hospitals throughout Victoria.

One of our popular products is the BOSSnet Digital Medical Record (DMR). Many hospitals in Victoria have deployed this as a means of improving access to patient information and reducing the need for paper copies. The DMR enables authorised users the ability to create, review and audit all data entered/stored within the system.

Based on the statement above and the checklist attached, we believe the BOSSnet DMR fully complies with the FDA 21 CFR Part 11 requirements for electronic records. Our DMR provides a true representation of the paper medical record, thus eliminating the need to reproduce paper copies for research/clinical trial purposes. All access to the DMR is controlled/managed by highly trained system administrators. Any action within the system is audited and reportable using outcome reports.

If you would like further information on this matter please contact our representatives:

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The BOSSnet DMR complies with all the criteria which is set out below to assess the appropriateness of electronic systems for trails:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Key Question** | **Yes** | **No** | **Not Sure** |
| 1 | Are there unique identifiers and passwords to access the system? | See full size image |  |  |
| 2 | Are there measures in place to keep passwords confidential (not shared)? | See full size image |  |  |
| 3 | Does the system automatically suspend or log off a user after a specified period of inactivity?  | See full size image |  |  |
| 4 | Is access to certain functions controlled based upon the user's role (e.g., read, write, change, delete)?  | See full size image |  |  |
| 5 | Is there a list of individuals authorised to access each function?  | See full size image |  |  |
| 6 | Is there an audit trail for capturing changes to information in the system?  | See full size image |  |  |
| 7 | Is the original information as well as the new information still available after the change is made? (Attach example if appropriate)  | See full size image |  |  |
| 8 | Are the audit trail entries date- and time- stamped?  | See full size image |  |  |
| 9 | Does the audit trail indicate who made a change? | See full size image |  |  |
| 10 | Is the audit trail protected from modification by users? | See full size image |  |  |
| 11 | Are the audit trail and other security settings protected from being turned off? | See full size image |  |  |
| 12 | Is the data in the system backed up (either via a network connection or external hard drive, for example) in case of system failure or loss of data at an appropriate frequency | See full size image |  |  |
| 13 | Can this backed up data be restored? | See full size image |  |  |
| 14 | Has the restoration of backup data been tested? | See full size image |  |  |
| 15 | Are electronic signatures used in the system? | See full size image |  |  |
| 16 | Are electronic signatures protected from intentional or unintentional misuse? | See full size image |  |  |
| 17 | When a signature is applied to a record, is it protected from cutting and pasting to other records?  | See full size image |  |  |
| 18 | Are the name of the signer and the meaning of the signature displayed? | See full size image |  |  |
| 19 | When a signed record is altered, is the signature made invalid?  | See full size image |  |  |
| 20 | Will the sponsor CRA be able access the data for monitoring?  | See full size image |  |  |
| 21 | Is the system capable of restricting the CRA’s access to ONLY those patient records of sponsor trial participants? | See full size image |  |  |
| 22 | Is there documentation maintained on installation and training?  | See full size image |  |  |
| 23 | Is there documentation maintained on system maintenance and upgrades? | See full size image |  |  |
| 24 | Is there a policy for addressing the availability of data for a defined retention period?  | See full size image |  |  |