

Observational study to determine the rate of occurrence of invasive mould disease and treatment outcomes in at-risk patients: a European prospective invasive mould disease audit (PIMDA)



PIMDA Study: Database Operations and Security

1. Gezondheidsmeter/CuravistaHealth

Gezondheidsmeter/CuravistaHealth is an online database, designed, programmed and owned in full by Curavista bv, a limited company from Geertruidenberg, the Netherlands.

The use of the database was notified to the Dutch Notified Body for Privacy (CBP) and referenced **m1408979**.

Gezondheidsmeter/CuravistaHealth has been used in multiple clinical studies, all under approval of Medical Ethical Committees. Two recent letters of approval for studies/registries in which Gezondheidsmeter/CuravistaHealth is used have been attached (in Dutch).

2. Database location

The database is located at separate premises within The Netherlands. For security reasons the exact location cannot be revealed in this document, but will be provided to notified bodies on request. The premises are entirely devoted to physical database hosting and have all usual physical and environmental protections in place including:

- Physical access control
- Electronic access control
- Environmental control (humidity, temperature, energy supply)
- Environmental protection (fire, water, force)

Curavista databases are located in a protected area on a shared rack. A dedicated rack can be made available at incremental costs. Access to the premises is limited to dedicated personnel only, and visitors (such as auditors) are allowed only if accompanied by Curavista's database manager and after prior notification.

3 Server configuration

Figure 1 gives a graphic representation of the server configuration and internal communication. Sequentially, there is a firewall prior to the webserver, followed by the application server and finally the database server. However, there is no communication between the file servers and database in

the absence of a request from a user so there is no requirement for an additional firewall between the file servers and the database.

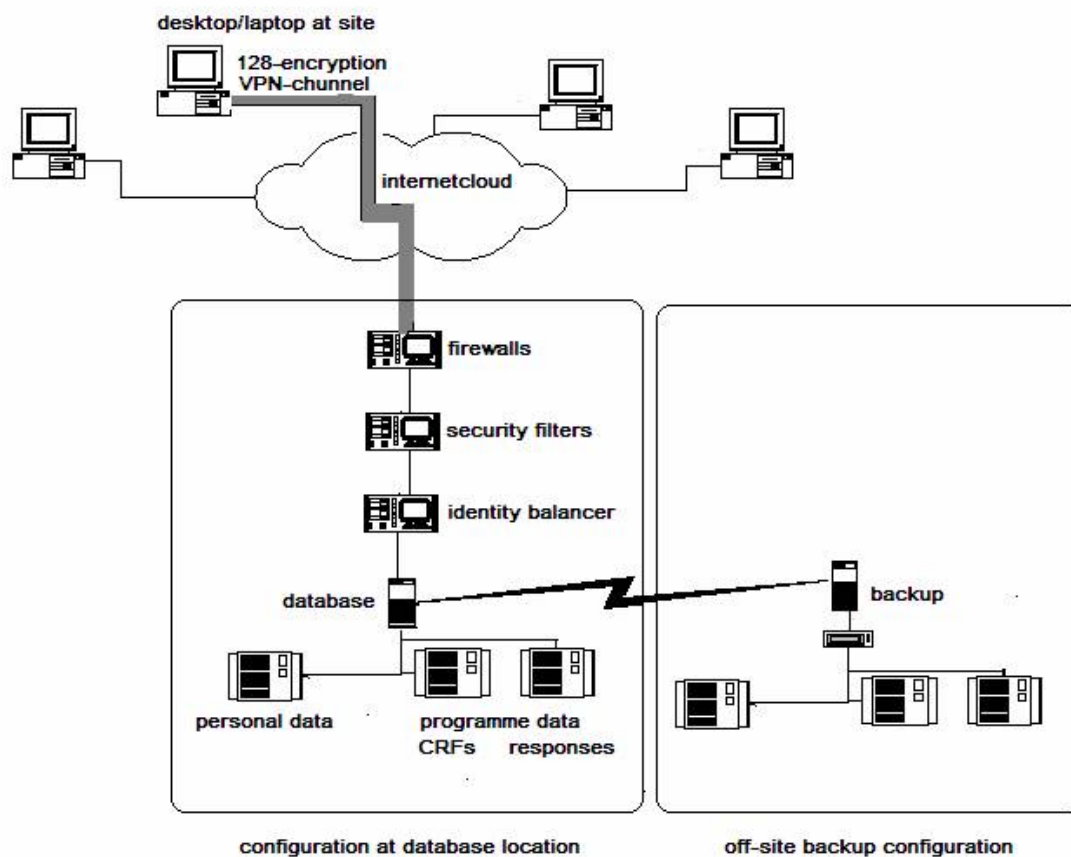


figure 1

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4 Communications

Transmission of on-line data on the internet is subjected to the https-protocol, using a 128bit ssl-certificate. Transmission of data can only be guaranteed when workstations are configured according to ex-works Microsoft standard.

Data storage is transmitted to the off-site storage using a VPN.

Participants are required to change their password at first login.

5. Data storage

The application is able to separate personal data (name, address, gender, age) from medical data (answers to questionnaires). An algorithm, only known to the development team, that have no access to the database, links the two data sets (if this is required by the particular study).

Note: The PIMDA study will record only gender and age. No other personal data will be collected. See section 11 below.

6. Back-ups

All data is continuously backed up online in a second system using the archive log mechanism from Oracle. This online back-up is supported by another procedure: the second system has Oracle in redo log modus, taking the log automatically in this second Oracle instance. All exceptions (potential errors) are reported online in sysopp.

Every day an Oracle export is processed and transported to an off-site location. The exports are stored in 7-day cycles and thereafter in chronological order (week, month, year). These backups are stored on tape and every three months a random selection of a set of tapes is checked.

7. Management of external patches and updates

The application stores all information (data) in an Oracle rdbms database. Patches from Oracle are automatically received and assessed. The patches are installed based on urgency, use on and applicability to the application. Updates on viruses and other potential attacks will be installed via subscriptions to public (anti-virus software and software that is only available under controlled circulation communities. Updates on viruses and other potential attacks will be installed via subscriptions to public and controlled circulation communities.

8. Restore

Restore takes advantage of the separation in data. In case of major crash, restore can be performed in a maximum of three hours, because encryption is not necessary (one part of the database only contains personal data without medical data and the other part contains the reverse). Nonetheless, these data are protected by additional passwords. All data on portable media are encrypted. As PIMDA only contains a database assigned reference ID, the database with personal data is virtually empty.

9. Confidentiality measurements

All personnel and third-party collaborators are bound by general accepted confidentiality agreements, covering and superseding the period of employment and/or co-operation.

10. Auditing

A site-audit can be arranged for, taking into account a notification period, as the database centre has to be informed and database management needs to be present.

Passive auditing of the Application is allowed, after consultation of Suppliers' Project Manager.

11. Specific functions for PIMDA-registry

As an additional confidentiality precaution, inclusions in the PIMDA-database are assigned a database reference instead of being included on a named patient basis. A special function has been programmed to service this add-on. The investigator has to maintain records which link the assigned database reference to the individual participant.

12. Appendix

On request, copies can be provided of METC-approvals (in Dutch) for studies and registries for which the Gezondheidsmeter/ CuravistaHealth database is used.

- 1a/1b concern a one year follow-up study about the impact of Herpes Zoster and PHN (Post-Herpetic Neuralgia, debilitating zoster-related pain) on quality of life and cost in the 50+ population in the Netherlands. The approval from the national METOPP was reinforced by the METC from the University of Utrecht (appendix 1c).
- 2a/ 2b concern a five year registry of patients with Multiple Sclerosis or Clinical Isolated Syndrome, a potential predecessor of MS.

Contact information

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