



Tardis - Working Practice Document, No. 003

Computer Systems and Disaster Recovery

The main computing elements in the TARDIS Trial comprise of a set of 'applications' to provide data entry and reporting for Trial Investigators, and trial administration and data maintenance facilities for Trial Management staff.

The applications consist of the following:

The Trial Website/TARDIS Database

Data for the Trial is stored in a MySQL database with a website, built using PHP, providing login access to the database using an Investigator ID, Password and Personal Identification Number (PIN) combination (i.e. 'account' information). Within the database, the password is internally stored in MD5 encoded form. The website provides randomisation for patients; baseline data, day 7 data, day 35, hospital event data, scan data, Outcome/Serious Adverse Events (SAE) data, follow up data and Outcome/Serious Adverse Events (SAE) adjudication information.

The database itself resides on a UNIX server. The Information Services department of the University of Nottingham are responsible for the availability, maintenance and security of the UNIX server and other related hardware (webservers) and software (e.g. MySQL, PHP, Apache, etc).

MySQL databases are backed up nightly to disk, which in turn is backed-up by the file back-up system (to tape).

Investigator Account Manager

The Investigator Account Manager consists of a separate dynamic website, also built using PHP, which allows appropriate TARDIS Trial management staff to create and manage 'Investigator' login accounts. The Investigator Account Manager website is supported by the (MySQL) TARDIS database.

Patient Details Database

A limited number of TARDIS staff (Trial Co-ordinator and Follow Up Coordinator) have web access to a FileMaker Pro database in order to record patient contact details. Web access is limited to IP addresses within the University of Nottingham. The primary purpose of this database is for use by the UK 90-Day Follow-up Coordinator. Details of all patients are held so that patients could be contacted if necessary. This database resides on a separate server to that of the TARDIS database, namely an Apple OS-X server, housed in the Nottingham Trial Office with regular back-ups being taken. The patient details database will be deleted at the end of the trial to protect patient confidentiality.

Contact Database

A FileMaker Pro database is maintained to record contact information (name and address, e-mail, phone correspondence) between TARDIS staff and staff at the Trial centres and prospective participant centres. The database resides on the same Apple OS-X server used by the Patient Database and again with regular back-ups being taken.

The FileMaker Pro databases are backed up onto the Attix 5 system which is encrypted and password secured.

TARDIS E-mail

In addition, there is a generic tardis@nottingham.ac.uk e-mail address, which stores incoming mail from centres and outgoing mail from Nottingham Trial Office staff. The mail is sorted and stored in folders corresponding to each centre. Outgoing mail is always sent from the accounts of individual TARDIS office staff and copied to the generic TARDIS account for a history. If necessary, incoming mail to the generic TARDIS account is forwarded to individual TARDIS staff to deal with. The e-mail system in use is Microsoft Outlook. The e-mail system being maintained by the Information Services department who are responsible for its availability and security.

Website security

Access to the website is via HTTPS / SSL (GlobalSign being the signing authority for the SSL certificates) on a configuration of two Apache web servers running the PHP module.

Hosting

The TARDIS database host machine is a Sun Enterprise 250 with 2 x 400MHz processors and 2GB of RAM with 4 x SCSI Seagate disks that are in mirrored paired configuration. The website is stored on a pair of Hitachi AMSSCO Storage Area Networks (SANs) located at separate sites. The web pages are served by two load balanced web servers. The web servers (known locally as Web3 and Web4) are both Sun T2000 with 8GB RAM. A minimum configuration would be two networked servers, one running a webserver (Apache with PHP) and the other running MySQL.

Back-ups

The current backing-up policy for the University filestore (including MySQL databases) is
 Full - every Friday
 Incremental - everyday

These back-ups are taken to tape with the tapes being stored at a different site to that of the database server. Tapes are kept for four weeks and then recycled.

Disaster recovery

The TARDIS database can be rebuilt using the last good back-up. Back-ups are taken nightly using MySQL's mysqldump facility. In the event of hardware failure, a good/latest back-up file can be loaded into a new or alternative MySQL installation.

Website failure

In the event of a database or website type failure, all the PIs and other Investigators involved in the study are emailed with a standard message, example below:

"Dear Investigator

The TARDIS website is inaccessible at present. If you wish to randomise a patient when the TARDIS website is down, please call the TARDIS office directly during office hours +44 (0)115 823 0210, or out of office hours use our emergency numbers detailed below, and we can do this manually for you:

+ 44 (0)779 867 0726 or + 44 (0)7850 306 318

Please complete paper copies of CRFs during this time and then submit relevant data when the website is working again. We apologise for any inconvenience this may cause but thank you for your patience during this time."

The TARDIS website (or main University home page if it is a major web outage) is updated to display the following message:

"The TARDIS web site is currently unavailable.

To randomise a patient please call +44 (0)115 823 0210 during UK office hours, or refer to the TARDIS Trial Office Contacts sheet for the out of hours contact numbers (sent previously).

If you have any queries, please ring +44 (0)115 823 0210 or email tardis@nottingham.ac.uk.

We apologise for any inconvenience this may cause."

The IT technician liaises with Information Services, on why the failure has occurred and when it is likely to be resolved and re-instated.

Once the web-site is fully functional again, the Investigators will be informed by email.

Data Archiver

(under development)

Document Archiver

(under development)