DATA MANAGEMENT PLAN

Deliverable Nr 6.2-M6

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DOCUMENT

HISTORY

V	D	Status of document / Reason of change (responsible person)

1	20-08-2019	First draft (TEC)
2	25-09-2019	Final version to review (TEC)
3	2	Final review (UAVR)
4	3	Final version (all)

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This Data Management Plan aims at illustrating all the data that will be generated and/or collected throughout the project lifetime; how it will be stored and managed; what are the measures to ensure the data quality and security; who owns the data and how they can be re-used if possible.

The NeuroStimSpinal consortium is aware of and will make necessary efforts to follow the FAIR data management policy suggested by European Commission, meaning making data findable, accessible, interoperable, and reusable.

ABBREVIATIONS AND ACRONYMS

adECM: adipose decellularized extracellular matrix
CA: Consortium Agreement
DMP: Data Management Plan
DOI: Digital Object Identifier
EU: European Union
FAIR: Findable, Accessible, Interoperable, Reusable
GA: Grant Agreement
GBM: Graphene based material
IPR: Intellectual Property Right
ORD: Open Research Data
SCI: spinal cord injury
WP: Work Package

1 INTRODUCTION

This document describes the Data Management Plan (DMP), as Deliverable 6.2 on Month 6, for NeuroStimSpinal project. The purpose of this DMP is to ensure the data generated and collected in the project will follow the FAIR data management policy, meaning making data findable, accessible, interoperable, and reusable.

According to the guidelines provided by EU Horizon 2020 programmes (European Commission, 2018), following information will be included in this DMP:
- Methods to handle the research data during and after the end of project
- Descriptions of the datasets that will be collected, processed, and/or generated, such as data type, format, volume, source, etc.
- Methodologies and standards that will be adopted for the data management
- Level of accessibility/confidentiality of the data
- Methods to curate and preserve the data during and after the end of the project

Nevertheless, some important remarks are to be noticed. The encouragement to conduct the DMP is to serve as a tool to assist the project having good data management practice. The information has been collected and checked with consortium and may be updated in future versions of the DMP (D6.5, due M30; D6.7, due M48).

2 DATA SUMMARY

2.1 Purpose of Data Generation and Collection

The purpose of data generation and collection in the NeuroStimSpinal project is to achieve the objective of the project: to contribute with a solution for spinal cord injury (SCI).

2.2 Data Generation and Collection

Most of the datasets will be generated from work package (WP) 2 to WP5 from the experiments throughout the project lifetime. Descriptions of the datasets are categorized into both qualitative and quantitative aspects (as shown in Table 1). There are total 13 datasets being identified at current stage. The information has been checked with partners and new information will be updated with contributions of each partner.

TABLE 1 DATASET INFORMATION TEMPLATE

Work Package	Which WP and deliverable are this dataset related to
Dataset Name	The name of the dataset should be easily to search and find
Dataset Description	Brief description of the dataset
Responsible	The lead partners responsible for the dataset generation/collection

partners	
Purpose	The purpose of the data collection/generation and its relation to the objectives of the project
Type	Types of data could be report, paper, interview, expert or organization contact, details, video, audio, presentation, or note
Format	Data formats could be XLSX, DOC, PDF, PPT
Volume	The size of the dataset (units: GB/MB) and the number of files
Source	The origin of the data
IPR Owner	Which project participant(s) own the intellectual property right (IPR)
Re-use existing Data	Identification if any existing data being reused and how they are used
Beneficiary	To whom the data may be useful

TABLE 2 DATASET INFORMATION FOR WP1

Work Package 1	
Work Package	WP1-6, all deliverables
Dataset Name	Deliverables from work package one to six
Dataset Description	The dataset includes all the deliverable reports from work package one to six required in the GA
Responsible partners	UAVR and all the lead partners for each deliverable
Purpose	To ensure the project implementation and document the results in proper manner
Type	Reports
Format	XLSX ☐ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Partners contribution
IPR Owner	Involved partners who write the report
Re-use existing Data	Yes ☐ No ☒
Beneficiary	NeuroStimSpinal consortium and public if the deliverables are openly accessible

TABLE 3 DATASET INFORMATION FOR WP2

Work Package 2	
Work Package	WP 2, Deliverable D2.1, D2.3, D2.4, D2.5 and D2.6
Dataset Name	WP2_A device for electrical stimulation of adECM/GBM scaffolds
Dataset Description	The dataset will contain data collection about the development of the controller board, associated software and firmware and the electrical interface to the scaffolds
Responsible partners	UAVR
Purpose	To bring enough data to ensure the correct electrical stimulation of the scaffolds
Type	Reports
Format	XLSX ☐ DOC ☒ PDF ☒ PPT ☐

Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation in UAVR
IPR Owner	Involved partners who write the reports
Re-use existing Data	Yes☒ No ☐ Tecnalia has expertise in develop stimulation devices and screen-printing electrodes.
Beneficiary	consortium

TABLE 4 DATASET INFORMATION FOR WP3

Work Package 3	
Work Package	WP3, deliverables D3.1 and D3.3
Dataset Name	WP3_Procedure for preparing different shaped GBM/adECM scaffolds
Dataset Description	The dataset will contain data collection about the preparation and characterization of different shaped GBM/adECM scaffolds
Responsible partners	UAVR
Purpose	To bring enough data to ensure the homogeneous control of the production of the scaffolds
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	UAVR and partners with critical contributions
Re-use existing Data	Yes ☒ No ☐ Tecnalia has some data about the adECM obtained before NeuroStimSpinal application which will be used as starting point for WP3
Beneficiary	All technical consortium
Work Package	WP3, deliverables D3.2 and D3.4
Dataset Name	WP3_Procedure for biological functionalization of the different scaffolds
Dataset Description	The dataset will contain data collection about the biological functionalization and the evaluation the bioactivity
Responsible partners	UAVR and Stemmatters
Purpose	To bring enough data to carry out an optimal biological functionalization
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	UAVR and partners with critical contributions
Re-use existing Data	Yes ☒ No ☐ There are data obtained before NeuroStimSpinal application which will be used as starting point for WP3.
Beneficiary	consortium

TABLE 5 DATASET INFORMATION FOR WP4

Work Package 4	
Work Package	WP4, deliverables D4.1, D4.2 and D4.3
Dataset Name	WP4_ ENPCs adhesion, growth and differentiation of ENPC process of neurogenesis and synaptogenesis
Dataset Description	The dataset will contain data collection about the results of in vitro adhesion, growth and differentiation of ENPCs in the adECM/GBM scaffolds as well as the process of neuritogenesis and synaptogenesis with and without ES.
Responsible partners	FORTH
Purpose	To demonstrate the ability for adhesion, growth and differentiation of ENPCs as well as the process of neuritogenesis and synaptogenesis in the adECM/GBM scaffolds
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	FORTH and partners with critical contributions
Re-use existing Data	Yes ☐ No ☒
Beneficiary	consortium
Work Package	WP4, deliverables D4.6 and 4.7
Dataset Name	WP4_Toxicological effects of adECM/GBM and to their degradation products
Dataset Description	The dataset will contain data collection about the results of toxicological effects on cell lines from different organs and tissues exposure to adECM/GBM and to their degradation products
Responsible partners	FORTH
Purpose	To analyse the toxicological effect adECM/GBM and to their degradation products on different neural liver, kidney and lung cell lines
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	FORTH and partners with critical contributions
Re-use existing Data	Yes ☐ No ☒
Beneficiary	consortium
Work Package	WP4, deliverables D4.3
Dataset Name	WP4_ In vitro immune response of adECM/GBM scaffold
Dataset Description	The dataset will contain data collection about the results in vitro studies with macrophages (innate immune system) and T lymphocytes (adaptive response) cultured on adECM/GBM
Responsible	UCM

partners	
Purpose	To demonstrate the absence immune response of the scaffolds
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	UCM and partners with critical contributions
Re-use existing Data	Yes ☐ No ☒
Beneficiary	consortium

TABLE 6 DATASET INFORMATION FOR WP5

Work Package 5	
Work Package	WP5, deliverables D5.1
Dataset Name	WP5_Biocompatibility of adECM/GBM in an in vivo model
Dataset Description	The dataset will contain data collection about the implantation procedure and the results of biocompatibility and efficacy studies in the injured SC after local exposure to the scaffold matrices in an in vivo preclinical model
Responsible partners	Lead: SKU-RU, Partners involved: FORTH
Purpose	To confirm the biocompatibility in an in vivo system
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	SKU-RU and partners with critical contributions
Re-use existing Data	Yes ☐ No ☒
Beneficiary	All technical consortium
Work Package	WP5, deliverables D5.2
Dataset Name	WP5_ Host systemic reaction to scaffolds
Dataset Description	The dataset will contain data collection about host systemic reaction to scaffolds giving an integrative perspective of host systemic reaction to scaffold.
Responsible partners	Lead: SKU-RU Partners involved: FORTH
Purpose	To evaluate an integrative perspective of host systemic reaction to scaffold
Type	Reports
Format	XLSX ☒ DOC ☒ PDF ☒ PPT ☐
Volume	Expected Size: GB☐ MB☒
Source	Lab experimentation of the partners involved
IPR Owner	SKU-RU and partners with critical contributions
Re-use existing Data	Yes ☐ No ☒
Beneficiary	consortium
Work Package	WP5, deliverables D5.3 and D5.4

Dataset Name	WP5_Neuroreneration in preclinical in vivo models as response to implanted adECM/GBM scaffolds
Dataset Description	The dataset will contain data collection about the implantation procedure and the results of neuroreneration within the injured SC, as well as functional recovery, after local exposure to the scaffold matrices in preclinical in vivo models.
Responsible partners	Lead: SKU-RU, Partners involved: FORTH, Stemmatters, UAVR
Purpose	To confirm neuroregeneration and functional recovery in an in vivo system
Type	Reports
Format	XLSX ⊠ DOC ⊠ PDF ⊠ PPT □
Volume	Expected Size: GB□ MB⊠
Source	Lab experimentation of the partners involved
IPR Owner	SKU-RU and partners with critical contributions
Re-use existing Data	Yes □ No ⊠
Beneficiary	All technical consortium

TABLE 7 DATASET INFORMATION FOR WP6

Work Package 6	
Work Package	WP6, deliverables D6.3, D6.9 and D6.10
Dataset Name	WP6_Dissemination and communication plan
Dataset Description	The plan will contain data related to dissemination and communication issue
Responsible partners	TECNALIA
Purpose	To manage the issues related to dissemination and communication
Type	Report
Format	XLSX □ DOC ⊠ PDF ⊠ PPT □
Volume	Expected Size: GB□ MB⊠
Source	Partners contribution
IPR Owner	All partners with critical contributions
Re-use existing Data	Yes □ No ⊠
Beneficiary	All consortia
Work Package	WP6, deliverables D6.1
Dataset Name	Website
Dataset Description	Content of the website
Responsible partners	TECNALIA
Purpose	To disseminate the NeuroStimSpinal project
Type	Web
Format	XLSX □ DOC ⊠ PDF ⊠ PPT □
Volume	Expected Size: GB□ MB⊠
Source	Partners contribution
IPR Owner	Consortium

Re-use existing Data	Yes ☐ No ☒
Beneficiary	Consortium
Work Package	WP6, deliverables D6.2, D6.5 and D6.7
Dataset Name	WP6_Data Management Plan
Dataset Description	This dataset includes all the questionnaires answered by each partner in the consortium about the datasets that will be generated within the project lifetime and how they will be managed during and after the end of project
Responsible partners	All partners are responsible to fill out the questionnaire that is designed, distributed, and collected by TECNALIA
Purpose	To conduct the Data management plan tailor-made for NeuroStimSpinal project
Type	Questionnaires and report
Format	XLSX ☐ DOC ☒ PDF ☐ PPT
Volume	Expected Size: GB☐ MB☒
Source	Project partners
IPR Owner	Partners who fill out the questionnaire
Re-use existing Data	Yes ☐ No ☒
Beneficiary	Whole consortium
Work Package	WP6, deliverables D6.4, D6.11 and D6.12
Dataset Name	WP6_Exploitation Plan
Dataset Description	This dataset includes all the questionnaires answered by each partner in the consortium for the information about the KERs, IPR strategy and protection, market analysis, and exploitation
Responsible partners	TECNALIA
Purpose	To conduct the Exploitation plan tailor-made for NeuroStimSpinal project
Type	Report
Format	XLSX ☐ DOC ☒ PDF ☐ PPT
Volume	Expected Size: GB☐ MB☒
Source	Project partners
IPR Owner	Partners who fill out the questionnaire
Re-use existing Data	Yes ☐ No ☒
Beneficiary	All consortia
Work Package	WP6, deliverables D6.6 and D6.8
Dataset Name	WP6_ Workshop organization
Dataset Description	To increase the visibility of the project and disseminate outstanding results related to adECM/GBM scaffold for neural applications
Responsible partners	UAVR
Purpose	To conduct the organization a workshop
Type	Dissemination format (leaflet, email…)
Format	XLSX ☐ DOC ☒ PDF ☒ PPT ☒
Volume	Expected Size: GB☐ MB☒
Source	Project partners

IPR Owner	Partners
Re-use existing Data	Yes ☐ No ☒
Beneficiary	NeuroStimSpinal consortium

3 FAIR DATA

The NeuroStimSpinal project will dedicate to make the datasets collected or generated in the project comply to European Commission's FAIR data policy – "Findable, Accessible, Interoperable, Reusable".

3.1 Making data Findable

For published articles, a Digital Object Identifier (DOI) as a unique and permanent code to identify will be assigned by the corresponding journal. In other case, the identification mechanism will depend on the repository that the NeuroStimSpinal project adopts if any.

Common naming conventions:
Naming conventions:
>   NEUROSTIMSPINAL_<DX.Y/WPX/TX.Y>_<Title>_ <Version>_<Date>.filetype

Where:
<DX.Y> Deliverable number, e.g. "D2.3" for Deliverable 2.3.
<WPX> Work Package identifier, e.g. for example "WP1" or "WP2".
<TX.Y> Task number, e.g. "T3.1" for Task 3.1.
<Title> Short description of document.
<Version> Version identifier, e.g. 'v1'.
<Date> Date in "yyyymmdd" format.

Example:
NEUROSTIMSPINAL_D1.1_Quality Assurance Plan (I)_v1_20180208.docx.

3.2 Making data openly accessible

According to Article 29.1 in the GA, each beneficiary must disseminate the project results as soon as possible by disclosing them to the public through appropriate means, unless the legitimate interests would be infringed. The main results are expected to be exploited industrially, and therefore some data cannot be made available for verification and re-use by persons and organisations external to the consortium.

Any dissemination data linked to exploitable results will not be put into the open domain if they compromise its commercialization prospects or have inadequate protection.

Categories of outputs that NeuroStimSpinal will give Open Access (free of charge) include:
- Scientific publications
- Research data (Key datasets accompanying publications that are needed to validate the results)
- Other research data that may be of interest to scientist and/or industry
- Deliverables (public)

A restricted access will be provided to the members of the consortium only for templates (deliverables templates) and documents concerning internal meetings (minutes of meeting). Dissemination and outreach material will be openly available via the NEUROSTIMSPINAL website.

For scientific publications, each partner must take measures to ensure open access, meaning providing online access for any user without additional charge, to all peer-reviewed scientific publication relating to its results in accordance with the Article 29.2 in the GA. Following the open data underlying principle in Horizon 2020 all publications arising from the activities of this project will be deposited in institutional or thematic repositories (ZENODO, RIA) and will be published according to the gold model of publishing either in open access journals or the open access model in subscription-based journals. Where this is not possible for any reason we will use the green model.

Currently, the NeuroStimSpinal project considers using Microsoft Teams as a collaborative tool to deposit project related data and documentation. The data which is owned by the Consortium will be deposited as soon as possible, in the repository with open access rights.

3.3   Making data interoperable

The NeuroStimSpinal project aims to collect and document the data in a standardized way to ensure the datasets would be easy to understand, reuse and interoperate among different parties who are interested in utilizing them. Standard technical terminology will also be used to facilitate inter-disciplinary interoperability.

3.4   Data re-use

Data reusability means the easiness to re-use the data for further researches or other purposes. In NeuroStimSpinal project, the datasets have high reusability in that normally no special methods or software is required to re-use the data. The time of reusability for those research data which will be made available to re-use will be the duration of the project.

The procedures to ensure the highest data quality and validity include internal reviews as well as peer reviews if the articles or documents would be published through scientific journals.

Additionally, quality control of data at different stages from data collection, data entry or digitalization, and data checking is crucial in the NeuroStimSpinal project in that many research experiments would be conducted throughout the lifetime of the project. Following measures referred to the Good Practice Note of Research Data Management (CGIAR, 2017) are offered as references for the consortium partners to follow in order to ensure data quality.

- Stage 1: Data collection
    - Calibrate the instruments to ensure the measurement accuracy
    - Take multiple measurements, observations, or samples to ensure the data reliability
    - Double confirm the truth of the record with adequate experts in the relevant domains
    - Unify standardized methods and standard operating procedures
- Stage 2: Data entry or Digitalization
    - Set out validation rules in data entry software
    - Use controlled vocabularies, anthologies, code lists and choice list to minimize the occurrence probability of human mistakes
    - Follow the naming conventions for the variables including names, dates, versions to avoid confusion
- Stage 3: Data checking
    - Double check the coding accuracy and out-of-range values
    - Check data completeness, appropriate naming conventions used
    - Choose random samples to verify the consistency with original data
    - Conduct statistical analysis to detect if any errors or abnormal values exist

4   ALLOCATION OF RESOURCES

Estimated cost for making the data FAIR: the estimated cost of the article processing charges is in average 3.500€ per publication. Considering an estimate publications per year per partner from the second to fourth year of the project, the total cost of making the data openly accessible for the NeuroStimSpinal project is about 70.000€. The associated costs are covered by the author and/or co-authors of the publication as agreed in the NeuroStimSpinal grant agreement (eligible costs in Horizon 2020 projects).

Responsibilities for data management: Any member of the Consortium can upload content in the repository. The content will be approved by the coordinator of NeuroStimSpinal. All approved items cannot be deleted. New versions of the content

can be uploaded together with previous versions; all versions are simultaneously available.

Value of long-term preservation: the value of long-term preservation is on ensuring and facilitating the accessibility and usability of the presents data. It involves planning, resource allocation and application of preservations methods that have been described in Section 3. The goal is the accurate reordering of authenticated content over time, so it remains usable as technological advances render original software obsolete.

5   DATA SECURITY

Currently, the NeuroStimSpinal project considers using Microsoft Teams as the intranet/repository to manage, share, and collaborate for the data and documents related to the project. The access is restricted to the persons authorized (access granted by the coordinator).

The next recommendations should be followed for data security:

- Data should be stored in at least two different locations to avoid data lost
- Data should be encrypted whenever necessary (e.g. confidentiality issues)
- The use of USB flash drives should be limited
- Follow a systematic labelling procedure in order to insure coherence along the datasets.

Meanwhile, most of the consortium partners have their own provisions in place for data security within organizations:

UAVR:
UAVR has an informatics technical department that services the whole university digital infrastructure, namely hosting and housing of sites and servers. These services are based on a private cloud structure, that includes redundant storage and real-time backup mechanisms, namely as follows:

Access controls: Every worker in UAVR has his/her own password-protected user account to access the information systems, managed by an IdM. The password must satisfy complexity requirements and shall be changed every two years. The access to networks folders and programs where information is stored/managed depends on user permissions which are decided by factors such as division, role in the company, role in the project, etc. The permissions are implemented in an automatic way, based on the authorization of the project owner or other formal authorized channels.

Backup: UAVR has two-level backup. The first level is the system "previous versions" service that allows a user to recover a copy of the work (5 copies a day, two weeks

period) by his/her own. The second level is assured by snapshots-based backup with daily, weekly and monthly copies. The primary goal of this backup is disaster recovery, other types of recovery will require a formal procedure.

TEC:

Access controls: Every worker in TECNALIA has his/her own password-protected user account to access the systems. The password must satisfy complexity requirements and shall be changed every 90 days. The access to networks folders and programs where information is stored/managed depends on user permissions which are decided by factors such as division, role in the company, role in the project, etc. The permissions are managed by administrators only and must be asked by authorized persons through authorized channels.

Backup: TECNALIA has two-level backup. The first level is the system "previous versions" service that allows a user to recover a copy of the work (5 copies a day, two weeks period) by his/her own. Moreover, every day TECNALIA makes full backup of the working information. There are daily, weekly, monthly and yearly copies. The recover from this backup requires a formal procedure.

UCM:

Access controls: Every researcher in the UCM group has his/her own password-protected user account to access the systems. The password must satisfy complexity requirements and the access to networks folders and programs where information is stored/managed. The permissions are managed by authorized persons through authorized channels.

Data protection: The Universidad Complutense de Madrid has an Information Security and Protection Unit (Unidad de Seguridad y Protección de la Información, USPI) and an Office of the Data Protection Delegate (Oficina del Delegado de Protección de Datos, DPD) for information security and privacy (data protection).

SKU-RU:

As part of an academic hospital, the SKU-RU partner is bound to strict governmental regulations regarding data security management. Security precautions are established according to the ISO27001 and ISO27002 standards, and are updated on regular basis that allows (digital) data protection from unauthorized access from inside and outside the organization

FORTH:

FORTH's policy is following a decentralised approach for data management. For security reasons, the equipment used for experiments and data acquisition is offline. Each organisation employee is responsible for initial data transfer between the equipment and their computers for data processing. After data processing, the data is being uploaded to cloud services for data storage. Currently, FORTH is using DROPBOX,

GOOGLE DRIVE and NEXT CLOUD for data storage and sharing. These services are protecting against accidental data deletion for 180 days.

FORTH has a policy that Researchers: Should be able to retrieve experimental data after ten years, after experiments.
Results from EU projects should be published under open access and use open data platforms such as Zenodo.

STEMMATTERS:
Access control: Stemmatters' documentation is stored in a shared, digital repository (NAS) secured within Company premises under restricted access and responsibility of the IT Assistant only. Access to NAS repasitary and file modification depends on the specific user's permissions to access specific folders. The IT Assistant is responsible for administration of access permissions and for approval of file deletion by users. Quality Management System (QMS)-sensitive documentation is kept under the sole responsibility of Management System Director (MSD). No users have permission to modify, upload or download QMS controlled documents without MSD approval and direct intervention. Passwords are managed according to an internal QMS procedure. Access to NAS data requires preliminary approval by the company CEO (for confidentiality purposes) followed by MSD (training on QMS controlled documentation use).

Backup: Stemmatters implements a three-level backup system. Stemmatters' documentation is stored in a Master NAS within the company (first-level). A secondary NAS equipment is used for daily backup from the Master NAS (second level). Monthly backups (third level) to an external drive are mandatory and managed by the IT Assistant in a secure location outside the Company premises. Such monthly backups are stored for at least two years. Employees only have access to data on the Master NAS through their individual ID and passwords.

GRAPHENEST:
Access Controls: Each team member at Graphenest has an individual password-protected user account that allows access to the shared repository. Passwords are managed according to an internal procedure. The access to the shared repository is categorized according to the employee's division and role in the company. Any modifications to the permissions for a given employee is reviewed by Graphenest's administration through the appropriate internal channels.

Backup: Graphenest's backup system is subdivided at two levels. Sensitive and relevant information stored at the shared repository is backed up daily based on a restore point procedure (first level). All information at Graphenest is copied to its full extent periodically (monthly and yearly). Access to the backups and restore points can be accomplished via an internal procedure