
Safely Empowering Study Team Management of DataFax User Account

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History



- 1991 → DataFax 1st release
- 1992 → Preventative Cardiology and Therapeutics Research Program
- 1999 → PHRI with research focus on CVD

Present → Genomics, stroke, perioperative medicine, thrombosis, CV surgery, renal, obesity, childhood obesity, trauma and implementation science etc.

To date, PHRI studies have enrolled almost 1,000,000 participants worldwide, have sites in 86 countries over 6 continents



Why Alternative DataFax User Management

With this growth and the support of EDC our DataFax user base had changed from few users to 100s and then 1000s of users



Challenges with Dfsystem:

- Limited search capability
- Enforcing standards
- Manual password resets
- Lack of granularity
- Reports on user database

Why Alternative DataFax User Management



- Study coordinators are responsible for training and site activations
- Would send request to DataFax Admin who would create roles and users
- Send back the reports to study coordinators who would then report back to sites
- We explored delegating user account management to defined DataFax study administrators but study admin rights were greater in scope than desired

Solution...



First iteration using DFuserdb and scripts in Unix to streamlined account management:

- Requests submitted used predefined excel template
- ↓
- Perl scripts parsed the requests and create input files
- ↓
- Import user updates into DataFax using DFuserdb
- ↓
- Check Consistency of User database
- ↓
- Send confirmation to requesters

Limitations:

- Involved some manual steps
- Access to latest roles

Challenges

- Within PHRI we have other systems:
 - ROME (study website) for randomizations, drug logistics, and other study support services
 - LIMS
 - Active directory
- A decision was made to integrate DataFax user management with other systems within PHRI
- A new ROME Central was designed that is authoritative source for all the user account:
 - Single point of entry – <https://rome.phri.ca>
 - Single sign-on – 1 user name, 1 password
 - Simple, stable and secure – hosted at DBRI
 - Unified account management – DataFax, Web, IVRS, etc.

ROME Central

- Provides centralized account management for all systems hosted at the PHRI
- The intended users of the system are:
 - System admin
 - Full access and use ROME to manage all aspects of all the systems
 - Study account managers
 - Have access to few ROME systems and DataFax studies account
 - Have access to only few less critical roles
 - Manage and monitor access to the study specific Rome systems and DataFax studies they are responsible for
 - General users
 - Use the system to authenticate themselves, manage their own profile, and access any systems they are authorized to access

ROME Central

- Backend
 - SQL server
 - Is the primary data store for accounts, applications, security roles, and security role assignments
- Frontend
 - The server-side web API is implemented as a Microsoft ASP.NET MVC application hosted in IIS
 - The client application is implemented as an ExtJS application that can be accessed using any supported web browser over the internet
- Integration
 - DataFax DFuserdb import/export integration

ROME Central



Screenshots

Rome Central

Login

User Name: *

Password: *

Remember User Name:

[Forgot Password](#)
[Forgot User Name](#)

Login

Rome Central

User Accounts

Search Filters

Advanced

Type: Select an account type

Country: Select a country

System: Select a system

- DataFax Study
- LIMS
- Referral
- Rome

Sites:

Search

Surname	Givensname	Affiliation	Phone	Username	Email
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Rome Central

Personnel Details

Details

Type: Internal

Name: Title: Nidhi Jethoo

Affiliation: PHRI Mobile:

Country: Canada Fax:

Email: nidhi.jethoo@phri.ca Language: English

Email 2: Phone:

Change Control

Created By: PHRIStudyProdSqljgt Created Date: 2012-06-20 10:52:11

Modified By: B130|nidhi Modified Date: 2013-04-18 15:33:45

Accounts

Type	Username	Active
		YES

Unauthorized use of this system is strictly prohibited.

Rome Central

Study Security Role & Permissions

Study & Security Role

Study: * 033 - Dialysis_Registry

Security Role: * Coordinator

System Permissions

- EditCheckDeveloper
- Statistician
- ViewOnly

Sites: *

Patients: *

✓

Rome Central

DataFax Account Details

Account Details | **Revoke Router Access**

User Name: yousufs Full Name: Sadia Yousuf
 Router Access: YES Active: YES
 Password Expiry: 2014-11-13 13:23:36

Change Control

Created By: PHRI\StudyProdSqlAgt Created Date: 2012-06-20 10:52:11
 Modified By: PHRI\StudyProdSqlAgt Modified Date: 2014-08-15 09:32:25

Study or DataFax Admin Access

Admin Access: None

Selected Studies:

Study Roles & Permissions

<input type="checkbox"/>	Study Id	Study Name	Security Role
<input type="checkbox"/>	035	[REDACTED]	Coordinator
<input type="checkbox"/>	040	[REDACTED]	Coordinator
<input type="checkbox"/>	054	[REDACTED]	Coordinator
<input type="checkbox"/>	057	[REDACTED]	Coordinator_view
<input type="checkbox"/>	193	PHRI Demo Database	CoordinatorImportPDF

Rome Central Account Details

Account Details

User Name: yousufs Locked: NO
 Active: YES Last Locked:
 Initial Activation: 2013-09-27 08:35:21 Password Changed: 2014-05-28 14:32:27
 Last Deactivation: Password Expiry: 2014-08-26 14:32:27
 Last Activation: 2013-09-27 08:35:21 Last Login: 2014-08-13 14:44:16

Change Control

Created By: PHRI\StudyProdSqlAgt Created Date: 2012-06-20 10:52:11
 Modified By: PHRI\romewebagent Modified Date: 2014-08-13 14:40:35

Administrative Access

Admin Access: Account Manager

Selected Studies: 035 - NAVIGATE ESUS, 193 - PHRI Demo Database, 217 - NAVIGATE ESUS - Linked Development study, NAVIGATE ESUS

System Security Roles & Permissions

Rome Systems

<input type="checkbox"/>	Application	Security Role	Sites	Depots
<input type="checkbox"/>	NAVIGATE ESUS	Study - Coordinator	ALL	ALL

ROME Central

- This distributed DataFax account management out to the study teams
- Empowered them to create and manage user accounts rights for only their specific studies
- Wait times were reduced from hours, and at times days, to essentially no delay as the study teams could initiate the changes themselves
- Fully integrated with DataFax and other ROME systems
- Enforced standards such as naming conventions or access levels
- Audit and easy reporting of permission changes
- Better search capabilities

Future Plan

- Implement role management using ROME Central
- Implement more checks such as validating center id ranges with existing centers database