EDGE Validation

The purpose of this document is to provide a sample and guidance for writing and executing system validation for the EDGE licensee and/or sub-licensees. Organization lead administrators must conduct test cases independently or specific to their site operations to ensure that EDGE is operating correctly and meeting applicable requirements based on 21CFR11[1]. A risk assessment must be performed to determine the level of validation required (full or reduced). This document is to be completed as part of a Computer System Validation Package that includes a Full Validation Master Plan, Guidance Document and Risk Assessment Tool.

Any significant changes to the EDGE system hardware or software including updates may require an update to the site system validation as outlined in your site system Validation Master Plan (VMP[2]).

Requirements:

Requirements List based on 21CFR11

Req#	**Requirement Description**
R01	EDGE shall provide the ability to generate accurate and complete copies of records in both printed and electronic form suitable for inspection and review.
R02	EDGE shall protect records from corruption to enable their accurate and ready retrieval throughout the records retention period.
R03	EDGE shall limit system access to authorized individuals.
R04	EDGE shall use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.
R05	EDGE shall not obscure previously recorded information for record changes.
R06	EDGE shall retain audit trail documentation for a period at least as long as required by federal regulation for electronic records and shall be available for audit.
R07	EDGE shall use operational system checks to enforce permitted sequencing of steps and events, as appropriate.
R08	EDGE shall use authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
R09	EDGE shall determine that persons who develop, maintain, or use electronic record systems have the education, training, and experience to perform their assigned tasks.
R10	EDGE shall employ at least two distinct identification components such as an identification code and password.

[1] *"CFR - Code of Federal Regulations Title 21". U.S. Food & Drug Administration. U.S. Food & Drug Administration. Retrieved 15 September 2016*

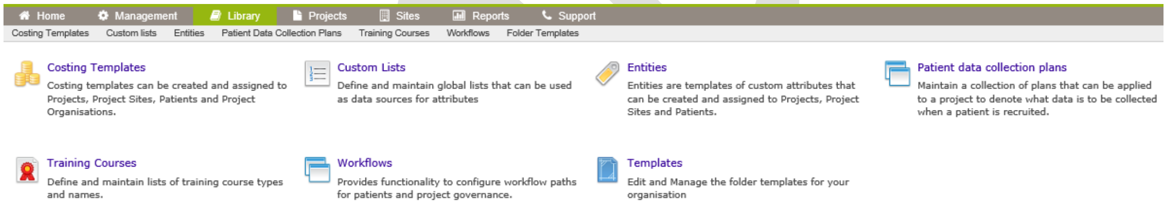
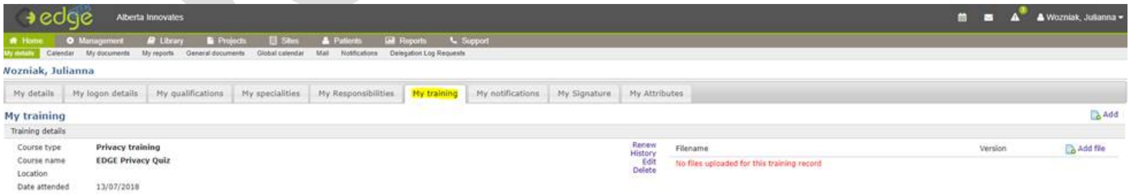
[2] General Principles of Software Validation; Final Guidance for Industry and FDA Staff (FDA, Center for Devices and Radiological Health, Center for Biologics Evaluation and 330 Research, 2002)

Req#	Requirement Description
R11	EDGE shall maintain the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.
R12	EDGE shall ensure that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).
R13	EDGE shall use transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to EDGE security unit, and, as appropriate, to organizational management.

Specifications:

Spec#	Spec Description
S01	**Security Considerations** – Security components of the system, requirements for gaining access, setting and changing passwords and password requirements. Other issues related to system vulnerability such as lock outs and in-activity parameters**:** *System:* • EDGE organizational, operational and technological processes and procedures are required to comply with the requirements of ISO/IEC 27001:2005, as appropriate. • Where relevant, UoS will use ISO/IEC 27002:2005 as a basis for auditing compliance with the relevant agreements and for investigating alleged breaches of privacy or security. • Hosting Security: EDGE-Alberta is hosted by Q9 Networks, which has hosting facilities in Ontario, Alberta and British Columbia. • Security measures for Q9 hosting facilities are the subject of a 2014 audit conducted by PWC.15,16. The audit report is confidential, but has been reviewed by the University of Southampton and Alberta Innovates. The auditor found no exceptions. *Access Controls:* • EDGE requires the use of a username and password for access. Users sign on to the application using these credentials. • EDGE passwords must be at least eight characters long and must include uppercase characters (A-Z), lowercase characters (a-z) and numbers (1 -9) or symbols. Passwords are encrypted. The password expiration policy is set at 180 days by default. Site administrators can shorten this period. • The URL of the sign on/log-in page uses SSL/TLS (HTTPS:) security. Any attempts to open under HTTP are forced to HTTPS. This encrypts the session between the client browser and the application within the hosting environment. • To access the EDGE System, each user is required to enter the username and a password that is automatically generated from the EDGE System upon completion of registration requirements. Once users are created they need to validate themselves via a link before they can use EDGE and immediately change their password. • A list of all authenticated users is maintained in EDGE.

Spec#	Spec Description
	• User access roles include “read only” and “read/write”. All EDGE users have read access to the research projects for which they are authorized; only a subset have read/write access. On a project-by-project basis there is a ‘manager’ who can manipulate the project record and a ‘clinical’ user who has project-specific access to the personal health information of project participants or patients • Logical controls restrict access to specific systems to authorized individuals and to the functions each individual can perform on the system. Logical controls within EDGE prevent access to data that does not belong to the site. • The sub-licensor (Alberta Health Services) and the site local EDGE administrator are responsible for creating and managing the issue of EDGE passwords to their authorized staff in accordance to the licence agreement and to ensure that they are aware of and comply with the data protection regulations. Authorized users who are designated by the site, and who have received EDGE training, are set up by the Alberta Innovates EDGE Coordinator as the site administrator for the site. Thereafter, the addition of other authorized users becomes the responsibility of the site administrator. • The site administrator will: o keep up-to-date details of all their organization’s users; o ensure that each end user successfully completes the EDGE privacy training and complies with applicable policies, procedures and legal requirements; o updating access controls for site staff; o implement all site-specific controls on access controls.
S02	**Audit Trails** - A log which shows who has accessed the system and what operations they performed. • EDGE application has a complete audit of system access and actions; all activities are time date and user stamped. These actions are reportable in the audit reports functionality of EDGE. • The history of data entry in attributes can be audited by users using both internal application functionality and the audit reporting functionality. Each entry is time and date stamped.
S03	**Data Backup** – Documentation showing where, and how often system back-ups are performed. • Q9 has data backup and recovery procedures in place, including offsite backup. • As outlined in the Master Services Agreement between the licensor Alberta Innovates and the contractor the University of Southampton (UOS), Q9 networks provide cloud and managed hosting services in Canada to host the EDGE data as a subcontractor of UOS. • Q9 maintains fully redundant facilities in Canada and have been audited to meet the stringent metrics of SSAE-16.
S04	**System Review and Decommissioning:** • A periodic review process must be performed by the Principal User, QA Lead or both to verify that the EDGE computer system is still performing in accordance with the validation, operates in compliance with any applicable regulations and is being correctly utilised by the end-users and administrators.

Spec#	Spec Description
	• This review should take place every two years from the initial validation or after each major revision/update of the system. This can be in the form of an audit. The process for system review and decommissioning should be documented in the validation summary report. • In the event the EDGE computer system identified is no longer required or redundant, a controlled, documented decommissioning process should follow. Attention should be made to the EDGE system data, and where that data is not archived or may no longer be accessible if the EDGE system is decommissioned. In such a situation, migration and/or archiving of data should be considered, addressed and documented. Archiving may be in the form of printed paper copies of data appropriately labelled, signed and dated.
S05	**Training –** Documentation showing staff are trained on the system to perform system activities**:** • Each organizational lead local administrator or super-user has the responsibility to meet their own organizational needs for privacy training as well as ensure EDGE users receive AI-outlined privacy training. Training must be documented. • Training in EDGE is accessed via the Library > Training Courses. The Training courses specific to the user's organization will be listed in Training Courses.  Home Management Library Projects Sites Reports Support Costing Templates Custom lists Entities Patient Data Collection Plans Training Courses Workflows Folder Templates Costing Templates Costing templates can be created and assigned to Projects, Project Sites, Patients and Project Organisations. Custom Lists Define and maintain global lists that can be used as data sources for attributes Entities Entities are templates of custom attributes that can be created and assigned to Projects, Project Sites and Patients. Patient data collection plans Maintain a collection of plans that can be applied to a project to denote what data is to be collected when a patient is recruited. Training Courses Define and maintain lists of training course types and names. Workflows Provides functionality to configure workflow paths for patients and project governance. Templates Edit and Manage the folder templates for your organisation • EDGE Admins will need to enter the privacy quiz into to the training courses. The training course information when completed is to be entered within the EDGE system in My details > My training. The EDGE user will be responsible for uploading the course completion details including the Course type, Course name, Date attended and any proof of completion of the course training.  edge Alberta Innovates Wozniak, Julianna Home Management Library Projects Sites Patients Reports Support My details Calendar My documents My reports General documents Global calendar Mail Notifications Delegation Log Requests My details My logon details My qualifications My specialities My Responsibilities My training My notifications My Signature My Attributes Add Renew History Edit Delete Add file Wozniak, Julianna My training Training details Course type Privacy training Course name EDGE Privacy Quiz Location Date attended 13/07/2018 Filename Version No files uploaded for this training record

Traceability Matrix:

Requirement #	Specification
R01	S01 Security
	S02 Audit Trail
	S03 Data Back-up
	S04 System Review and Decommissioning
R02	S01 Security
	S02 Audit Trail
	S03 Data Back-up
	S04 System Review and Decommissioning
R03	S01 Security
R04	S02 Audit Trail
R05	S02 Audit Trail
R06	S02 Audit Trail
R07	S04 System Review and Decommissioning
R08	S04 System Review and Decommissioning
R09	S05 Training
R10	S01 Security
R11	S01 Security
R12	S01 Security
R13	S01 Security

Test Case:

Test Cases identify the conditions under which a tester will determine whether a system or one of its features is working as it was intended. Test cases should be developed at the site to support the list of requirements of the system. Evidence (i.e. system screen shots) should be provided in these cases to support the validation.

EXAMPLE TEST CASE: ACCESS CONTROLS

T1: Precondition: Configure system with a Read-only user role. Ensure a document that contains editable data is uploaded.

a. Log in as User configured as a Read-only user
b. Verify that the User cannot edit a document
    i. Take a screenshot of the options presented to the User.

T2: Precondition: Configure system with a Read-only user role. Ensure a document is uploaded.

c. Log in as User configured as a Read-only user
d. Verify that the User cannot delete a document
    i. Take a screenshot of the options presented to the User

T01: System access controls – User login

Description: A user must have a unique user name and password to access the EDGE application.

Precondition: None

a) Navigate to the EDGE login screen, https://edge-canda.ca
b) Take a screen shot of the login page.

Expected outcome: The login screen will have prompts for a unique user name and password to access the system. A forgotten password link will also be present on the login screen.

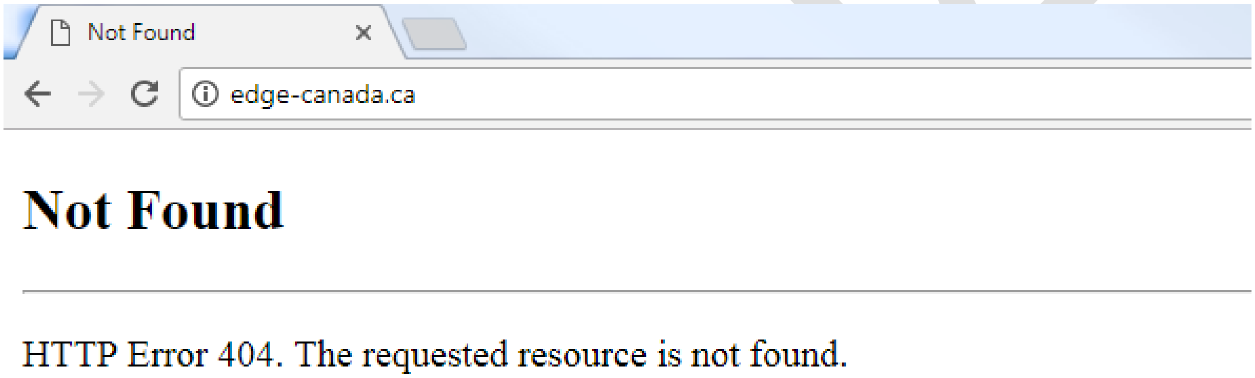
T02: System encryption verification

Description: EDGE sessions are encrypted under SSL/THS (HTTPS:) security. The application cannot be opened under HTTP.

Precondition: None

a) Enter the URL http://edge-canada.ca.
b) Take a screen shot of the page the user is directed to.

Expected outcome: Directed to a page not found error message similar to the screen shot below



Not Found

HTTP Error 404. The requested resource is not found.

T03: List of Authenticated Users

Description: A list of all authenticated users is maintained in EDGE at all times.

Precondition: An authenticated user with administrator access is logged into EDGE. The following actions take place under the administrative user's login account.

a) Select the *Management* tab
b) Click *Users.*
c) Search for 2 known active users and 2 known inactive accounts. Verify the accounts are active or inactive as expected.
d) Take a screen shot of the user list.

Expected outcome: An exhaustive list of active, inactive and deleted users is accessible under Management > Users. Inactive users will have a red 'X' beside their name in the *active* column. Active users are identified with a green '√'.

T04: Project access controls

Description: a registered user with Read-only access to a Project should be able to view documents, attributes and workflows but not edit or delete.

Precondition: The User must already have an active EDGE account and be assigned with read only access to an EDGE project record. A published document, attributes and workflow must be associated with the project.

a) Log in to EDGE with the read only user account.
b) Open the project record the User has read-only access to.
c) Click the files tab
    a. Verify that the user can download a file
    b. Verify the user cannot upload a file
    c. Take a screen shot of the options presented to the user
d) Click on the attributes tab
    a. Verify the user cannot modify or delete attributes
    b. Take a screen shot of the options presented to the user
e) Click on the workflow tab
    a. Verify the user cannot modify or delete workflows
    b. Take a screen shot of the options presented to the user

Expected result: The user, with read only access to the project will be able to download files for viewing and view attributes and workflows. The read only user will not see the option to add a new file, attribute or workflow. The edit, delete and audit (attribute only) features will not be available to the user.

T05: Project attribute audit feature viewable on the project record

Description: Users with *Manage* access to a project are able to view the audit history of each attribute saved to the project record. The audit trail is time and date stamped with the user account that the change was made by.

Precondition: The system must be configured with a user assigned with *Manage* access to an EDGE project record. An attribute is uploaded to the project and been modified several times.

a) Log in to EDGE with the managing user account.
b) Open the project record the User has *Manage* access to.
c) Click on the attributes tab.
    a. Verify the user can see the audit history of the attribute by clicking on the *audit* button to the right of the attribute.
    b. Take a screen shot of the audit trail viewable to the user.

Expected result: A pop-up window will appear when the audit button is selected. A time and date stamped view of the historical data entered in the field will be viewable. The user that completed each update to the field will be named.

T06: System audit record

Description: The EDGE application has a complete audit trail of system access and project, project site and patient related actions. These actions can be viewed in the systems audit trail.

Precondition: An authenticated user with administrator access is setup in the EDGE application. The following actions take place under the administrative user's login account:

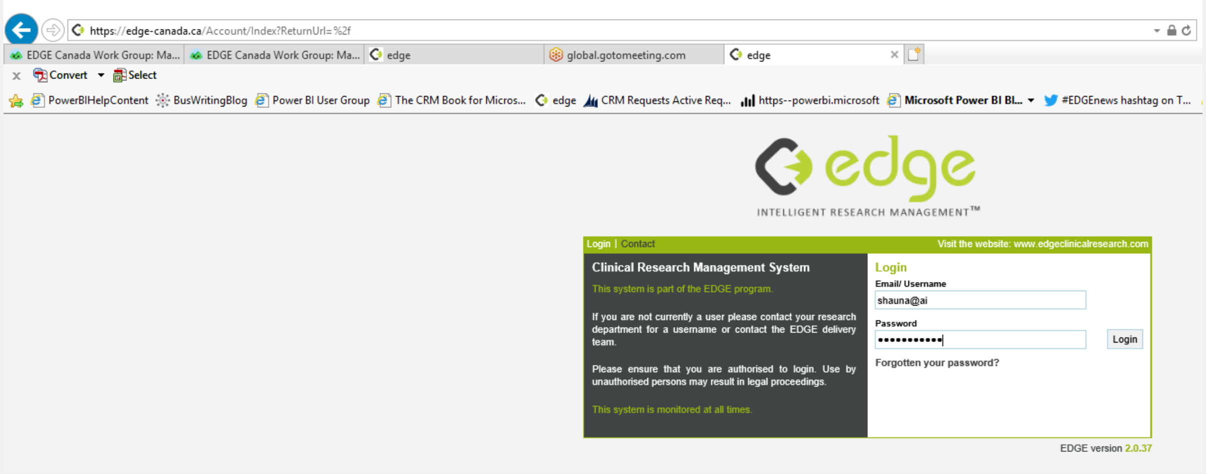
a) Log in to EDGE using the administrative user account.
b) Under the *Reports* tab, select *Audit report.*
c) Verify that the date, user, action and context filters are working as expected.
d) Take a screen shot of the audit report.

Expected result: The audit trail will show the date, action type, context, user and the description (data) of each login or creation or update of a project, project site or patient record in EDGE. The audit trail can be sorted through with the use of date (month/year), user, action and context fields.

Test Execution and Review

The goal of this document is to create a checklist to map each of the test cases and whether they pass the criteria defined in each case.

Test Case	P/F	Tester Initials	Test Date	Review Initials	Review Date	Notes
T01	✓ Pass ☐ Fail	SM	7 NOV 2018			


https://edge-canada.ca/Account/Index?ReturnUrl=%2f
EDGE Canada Work Group: Ma...
EDGE Canada Work Group: Ma...
edge
global.gotomeeting.com
edge
Convert
Select
PowerBIHelpContent
BusWritingBlog
Power BI User Group
The CRM Book for Micros...
edge
CRM Requests Active Req...
https--powerbi.microsoft
Microsoft Power BI Bl...
#EDGEnews hashtag on T...
edge
INTELLIGENT RESEARCH MANAGEMENT™
Login | Contact
Visit the website: www.edgeclinicalresearch.com

Clinical Research Management System

This system is part of the EDGE program.

If you are not currently a user please contact your research department for a username or contact the EDGE delivery team.

Please ensure that you are authorised to login. Use by unauthorised persons may result in legal proceedings.

This system is monitored at all times.

Login

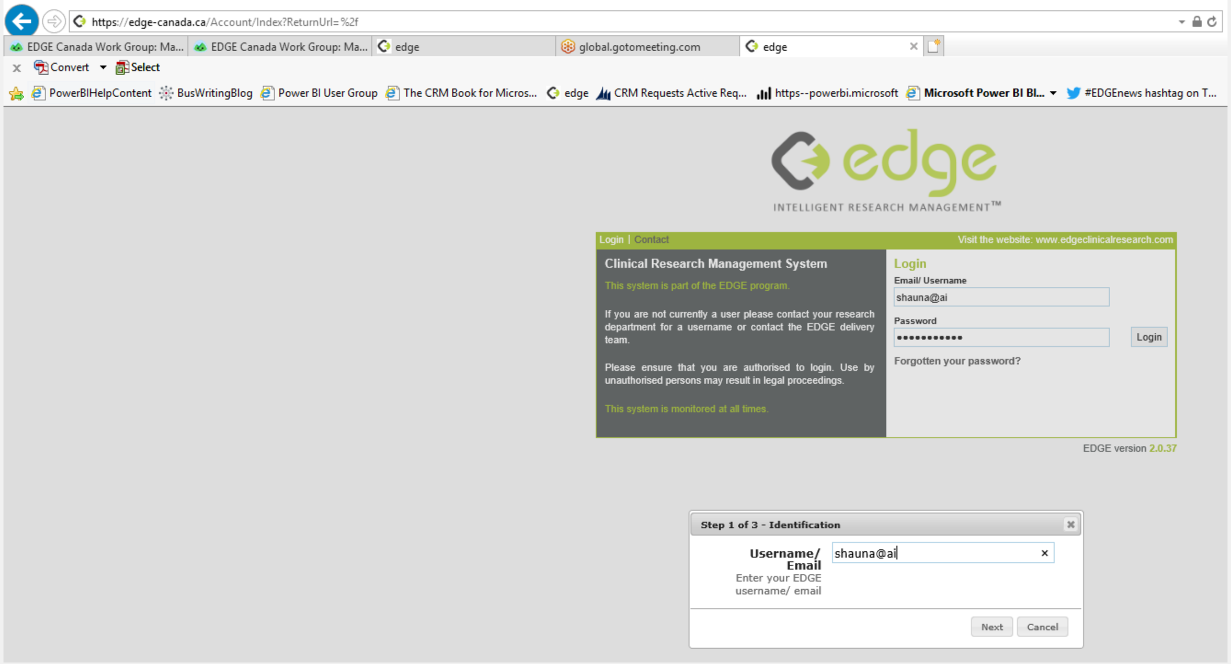
Email/ Username: shauna@ai

Password: ●●●●●●●●●●●

Login

Forgotten your password?

EDGE version 2.0.37



https://edge-canada.ca/Account/Index?ReturnUrl=%2f

Visit the website: www.edgeclinicalresearch.com

Clinical Research Management System

This system is part of the EDGE program.

If you are not currently a user please contact your research department for a username or contact the EDGE delivery team.

Please ensure that you are authorised to login. Use by unauthorised persons may result in legal proceedings.

This system is monitored at all times.

Login

Email/ Username: shauna@ai

Password: ●●●●●●●●●●●

Forgotten your password?

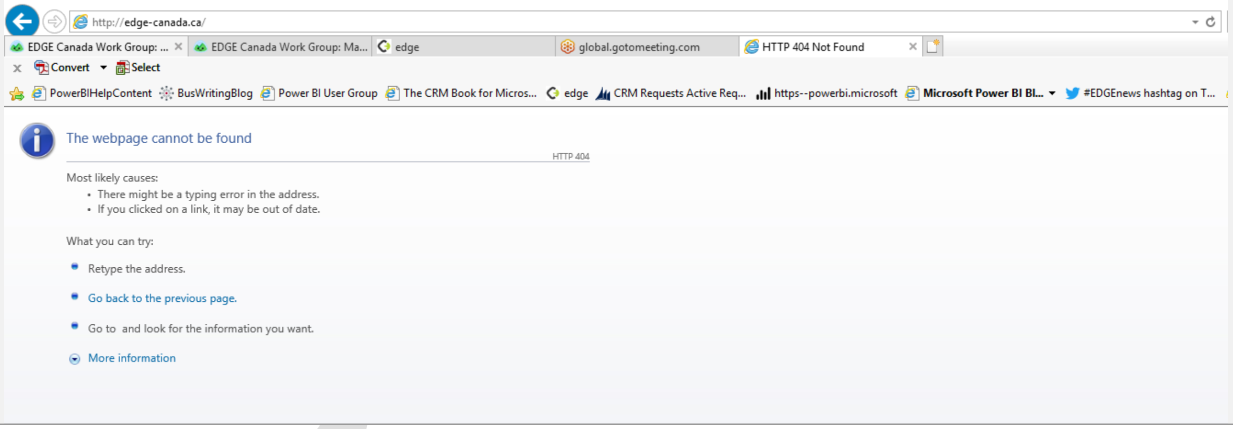
EDGE version 2.0.37

Step 1 of 3 - Identification

Username/ Email: shauna@ai

Enter your EDGE username/ email

T02	✓ Pass ☐ Fail	**SM**	**7 NOV 18**			



http://edge-canada.ca/

The webpage cannot be found

HTTP 404

Most likely causes:

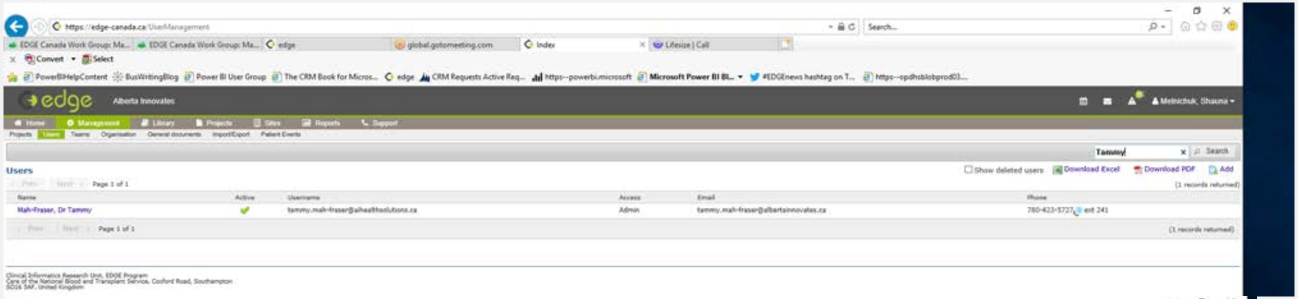
- There might be a typing error in the address.
- If you clicked on a link, it may be out of date.

What you can try:

- Retype the address.
- Go back to the previous page.
- Go to and look for the information you want.
- More information

T03	✓ **Pass** ☐ **Fail**	**SM**	**7 NOV 18**			

Two (2) Active Users



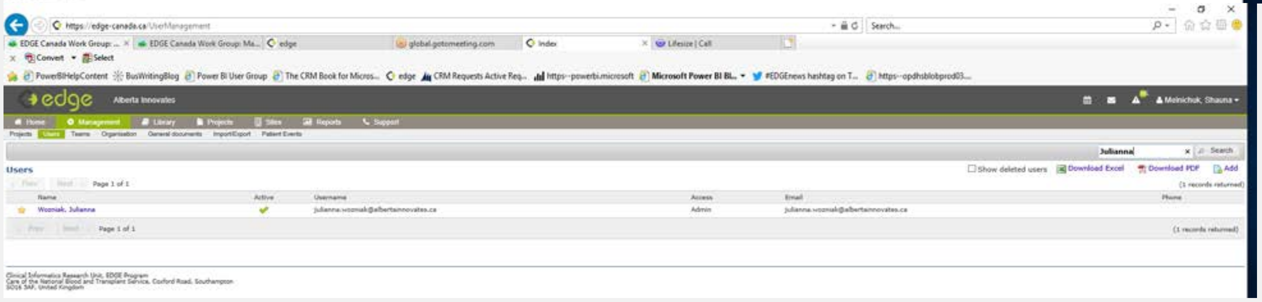
Tammy

Users

Page 1 of 1 (1 records returned)

Name	Active	Username	Access	Email	Phone
Mah-Fraser, Dr Tammy	✓	tammy.mah-fraser@alhealthsolutions.ca	Admin	tammy.mah-fraser@albertainnovates.ca	780-423-5727 ext 241

Clinical Informatics Research Unit, EDGE Program
Care of the National Blood and Transplant Service, Coxford Road, Southampton
SO16 5AF, United Kingdom



Julianna

Users

Page 1 of 1 (1 records returned)

Name	Active	Username	Access	Email	Phone
Wozniak, Julianna	✓	julianna.wozniak@albertainnovates.ca	Admin	julianna.wozniak@albertainnovates.ca	

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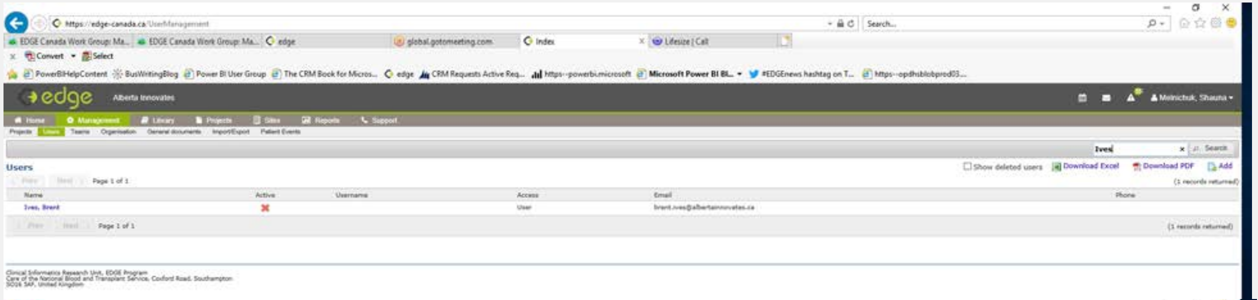
Two (2) Inactive Users



Ives

Users

Page 1 of 1 (1 records returned)

Name	Active	Username	Access	Email	Phone
Ives, Brent	✖		User	brent.ives@albertainnovates.ca	

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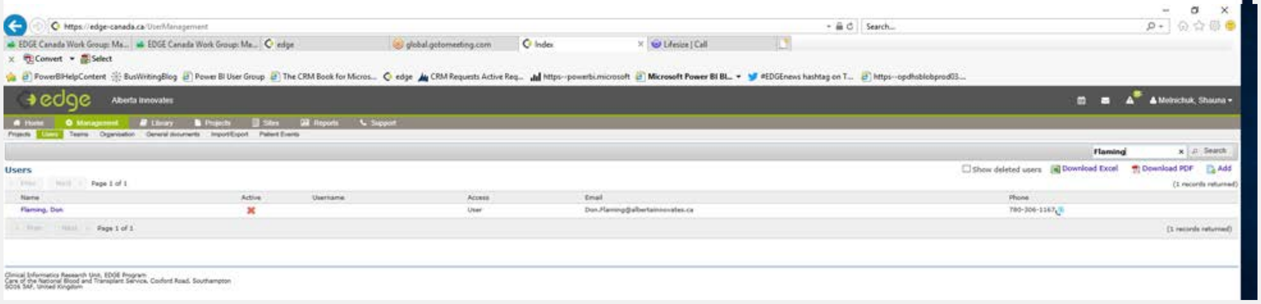

Flaming

Users

Page 1 of 1 (1 records returned)

Name	Active	Username	Access	Email	Phone
Flaming, Don	✖		User	Don.Flaming@albertainnovates.ca	780-306-1167

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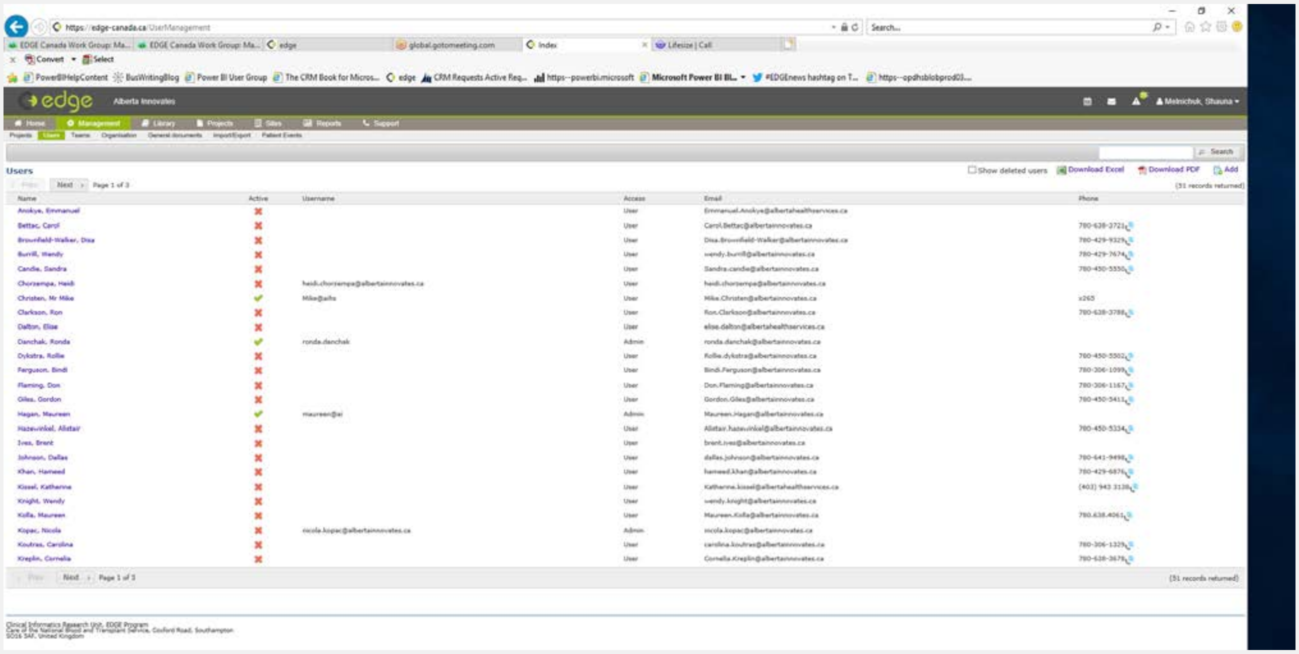
SO16 5AF, United Kingdom

User List



Users

□ Show deleted users

Page 1 of 3

(51 records returned)

Name	Active	Username	Access	Email	Phone
Anokye, Emmanuel	✗		User	Emmanuel.Anokye@albertahealthservices.ca	
Bettac, Carol	✗		User	Carol.Bettac@albertainnovates.ca	780-638-3721
Brownfield-Walker, Disa	✗		User	Disa.Brownfield-Walker@albertainnovates.ca	780-429-9329
Burrill, Wendy	✗		User	wendy.burrill@albertainnovates.ca	780-429-7674
Candie, Sandra	✗		User	Sandra.candie@albertainnovates.ca	780-450-5550
Chorzempa, Heidi	✗	heidi.chorzempa@albertainnovates.ca	User	heidi.chorzempa@albertainnovates.ca	
Christen, Mr Mike	✓	Mike@aihs	User	Mike.Christen@albertainnovates.ca	x265
Clarkson, Ron	✗		User	Ron.Clarkson@albertainnovates.ca	780-638-3788
Dalton, Elise	✗		User	elise.dalton@albertahealthservices.ca	
Danchak, Ronda	✓	ronda.danchak	Admin	ronda.danchak@albertainnovates.ca	
Dykstra, Rollie	✗		User	Rollie.dykstra@albertainnovates.ca	780-450-5502
Ferguson, Bindi	✗		User	Bindi.Ferguson@albertainnovates.ca	780-306-1099
Fleming, Don	✗		User	Don.Fleming@albertainnovates.ca	780-306-1167
Giles, Gordon	✗		User	Gordon.Giles@albertainnovates.ca	780-450-5411
Hagan, Maureen	✓	maureen@ai	Admin	Maureen.Hagan@albertainnovates.ca	
Hazewinkel, Alistair	✗		User	Alistair.hazewinkel@albertainnovates.ca	780-450-5334
Ives, Brent	✗		User	brent.ives@albertainnovates.ca	
Johnson, Dallas	✗		User	dallas.johnson@albertainnovates.ca	780-641-9498
Khan, Hameed	✗		User	hameed.khan@albertainnovates.ca	780-429-6876
Kissel, Katherine	✗		User	Katherine.kissel@albertahealthservices.ca	(403) 943 3138
Knight, Wendy	✗		User	wendy.knight@albertainnovates.ca	
Kolla, Maureen	✗		User	Maureen.Kolla@albertainnovates.ca	780.638.4061
Kopac, Nicola	✗	nicola.kopac@albertainnovates.ca	Admin	nicola.kopac@albertainnovates.ca	
Koutras, Carolina	✗		User	carolina.koutras@albertainnovates.ca	780-306-1329
Kreplin, Cornelia	✗		User	Cornelia.Kreplin@albertainnovates.ca	780-638-3679

Page 1 of 3

(51 records returned)

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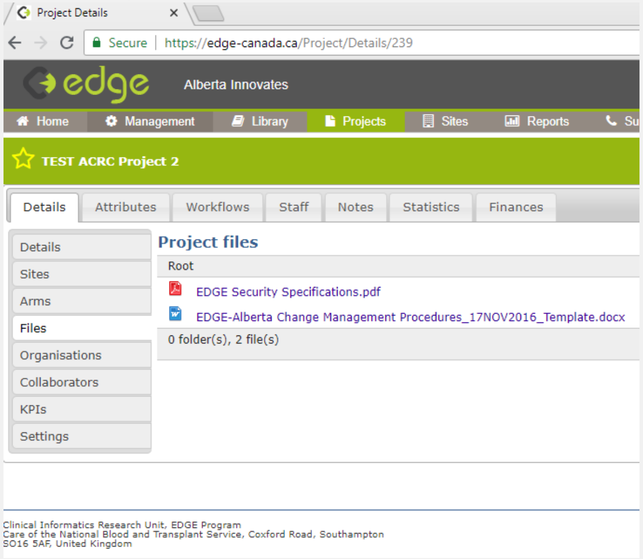
T04	**✓Pass** **☐ Fail**	JW	7 NOV 18			

a) Ability to download a file



Project files

Root

EDGE Security Specifications.pdf

EDGE-Alberta Change Management Procedures_17NOV2016_Template.docx

0 folder(s), 2 file(s)

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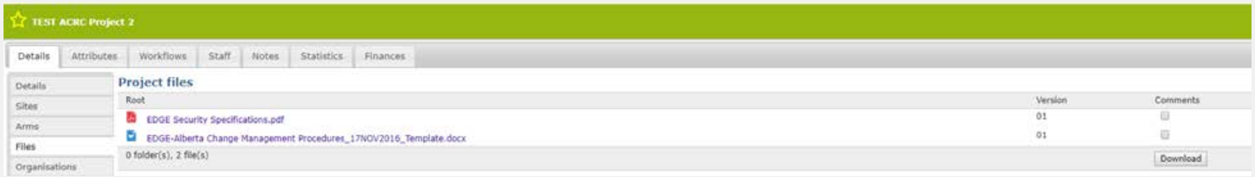
Care of the National Blood and Transplant Service, Coxford Road, Southampton
SO16 5AF, United Kingdom

b) Cannot add a file

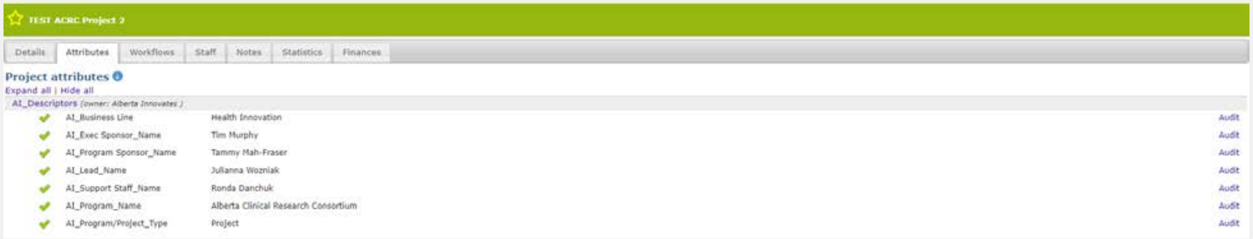


Project files

Root	Version	Comments
EDGE Security Specifications.pdf	01	☐
EDGE-Alberta Change Management Procedures_17NOV2016_Template.docx	01	☐

0 folder(s), 2 file(s)

c) User cannot modify or delete attributes

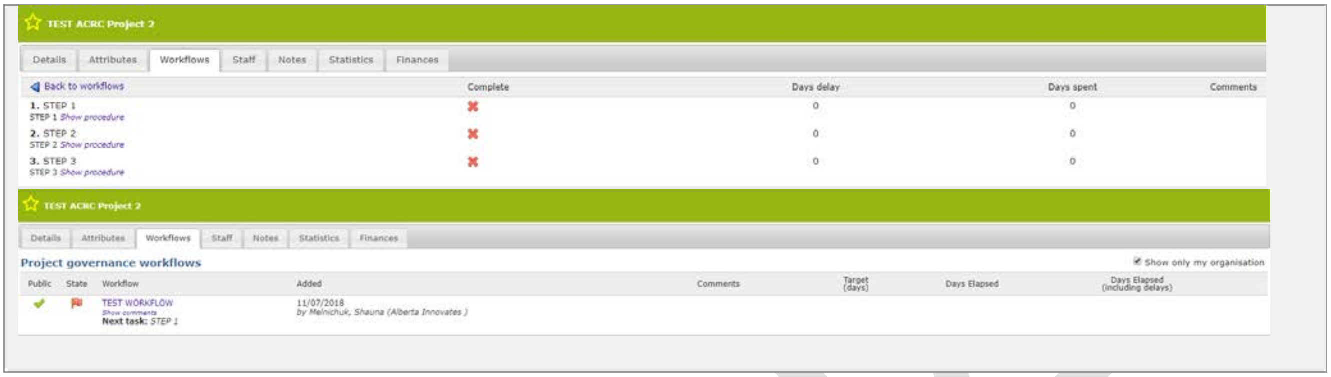


Project attributes

AI_Descriptors *(owner: Alberta Innovates)*

✓	AI_Business Line	Health Innovation	Audit
✓	AI_Exec Sponsor_Name	Tim Murphy	Audit
✓	AI_Program Sponsor_Name	Tammy Mah-Fraser	Audit
✓	AI_Lead_Name	Julianna Wozniak	Audit
✓	AI_Support Staff_Name	Ronda Danchuk	Audit
✓	AI_Program_Name	Alberta Clinical Research Consortium	Audit
✓	AI_Program/Project_Type	Project	Audit

d) User cannot modify or delete workflow



TEST ACRC Project 2

Details | Attributes | Workflows | Staff | Notes | Statistics | Finances

Back to workflows	Complete	Days delay	Days spent	Comments
1. STEP 1 STEP 1 *Show procedure*	✗	0	0	
2. STEP 2 STEP 2 *Show procedure*	✗	0	0	
3. STEP 3 STEP 3 *Show procedure*	✗	0	0	

TEST ACRC Project 2

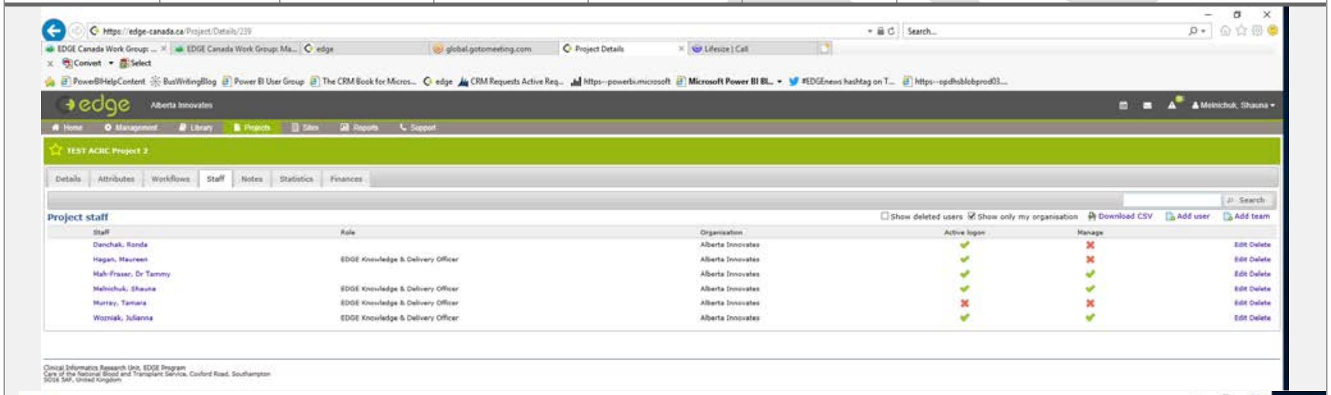
Details | Attributes | Workflows | Staff | Notes | Statistics | Finances

Project governance workflows

☑ Show only my organisation

Public	State	Workflow	Added	Comments	Target (days)	Days Elapsed	Days Elapsed (including delays)
✓	⚑	TEST WORKFLOW *Show comments* **Next task:** *STEP 1*	11/07/2018 *by Melnichuk, Shauna (Alberta Innovates)*				

T05	✓ **Pass** ☐ **Fail**	**SM**	**7 NOV 18**			



https://edge-canada.ca/Project/Details/239

EDGE Canada Work Group: ... | EDGE Canada Work Group: Ma... | edge | global.gotomeeting.com | Project Details | Lifesize | Call

Convert | Select

PowerBIHelpContent | BusWritingBlog | Power BI User Group | The CRM Book for Micros... | edge | CRM Requests Active Req... | https--powerbi.microsoft | Microsoft Power BI Bl... | #EDGEnews hashtag on T... | https--opdhoblobprod03....

edge Alberta Innovates — Melnichuk, Shauna

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TEST ACRC Project 2

Details | Attributes | Workflows | Staff | Notes | Statistics | Finances

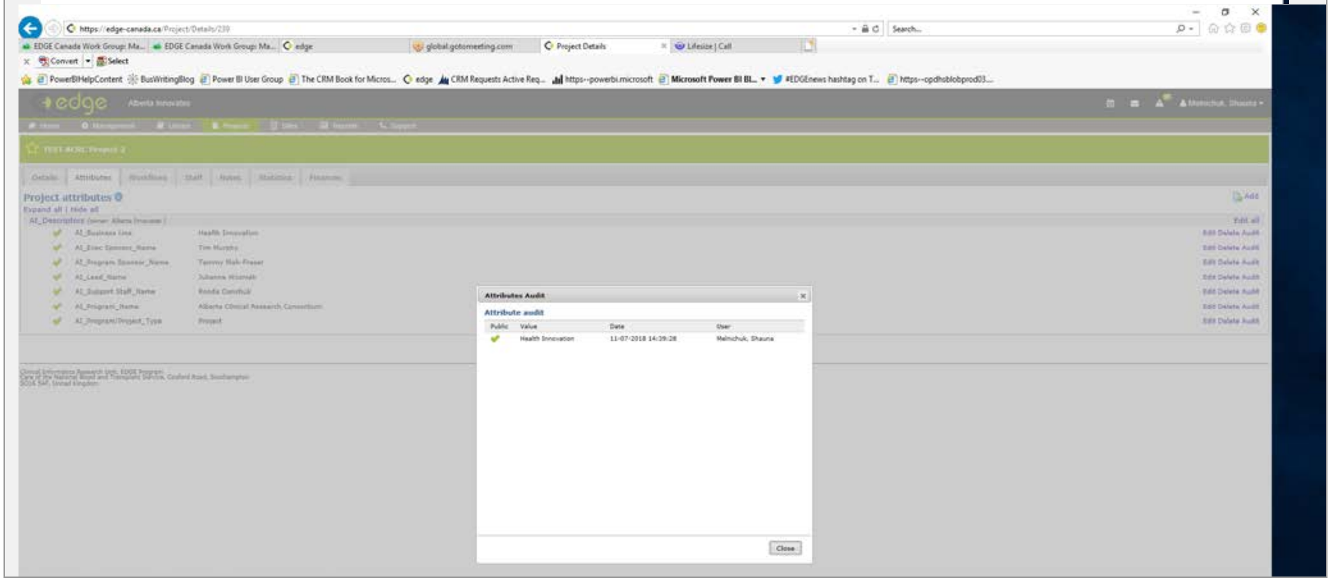
Search

Project staff

☐ Show deleted users ☑ Show only my organisation | Download CSV | Add user | Add team

Staff	Role	Organisation	Active logon	Manage	
Danchak, Ronda		Alberta Innovates	✓	✗	Edit Delete
Hagan, Maureen	EDGE Knowledge & Delivery Officer	Alberta Innovates	✓	✗	Edit Delete
Mah-Fraser, Dr Tammy		Alberta Innovates	✓	✓	Edit Delete
Melnichuk, Shauna	EDGE Knowledge & Delivery Officer	Alberta Innovates	✓	✓	Edit Delete
Murray, Tamara	EDGE Knowledge & Delivery Officer	Alberta Innovates	✗	✗	Edit Delete
Wozniak, Julianna	EDGE Knowledge & Delivery Officer	Alberta Innovates	✓	✓	Edit Delete

Clinical Informatics Research Unit, EDGE Program
Care of the National Blood and Transplant Service, Coxford Road, Southampton
SO16 5AF, United Kingdom



https://edge-canada.ca/Project/Details/239

EDGE Canada Work Group: Ma... | EDGE Canada Work Group: Ma... | edge | global.gotomeeting.com | Project Details | Lifesize | Call

Convert | Select

PowerBIHelpContent | BusWritingBlog | Power BI User Group | The CRM Book for Micros... | edge | CRM Requests Active Req... | https--powerbi.microsoft | Microsoft Power BI Bl... | #EDGEnews hashtag on T... | https--opdhoblobprod03....

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TEST ACRC Project 2

Details | Attributes | Workflows | Staff | Notes | Statistics | Finances

Project attributes

Add

Expand all | Hide all

AI_Descriptors (owner: Alberta Innovates) — Edit all

✓	AI_Business Line	Health Innovation	Edit Delete Audit
✓	AI_Exec Sponsor_Name	Tim Murphy	Edit Delete Audit
✓	AI_Program Sponsor_Name	Tammy Mah-Fraser	Edit Delete Audit
✓	AI_Lead_Name	Julianna Wozniak	Edit Delete Audit
✓	AI_Support Staff_Name	Ronda Danchuk	Edit Delete Audit
✓	AI_Program_Name	Alberta Clinical Research Consortium	Edit Delete Audit
✓	AI_Program/Project_Type	Project	Edit Delete Audit

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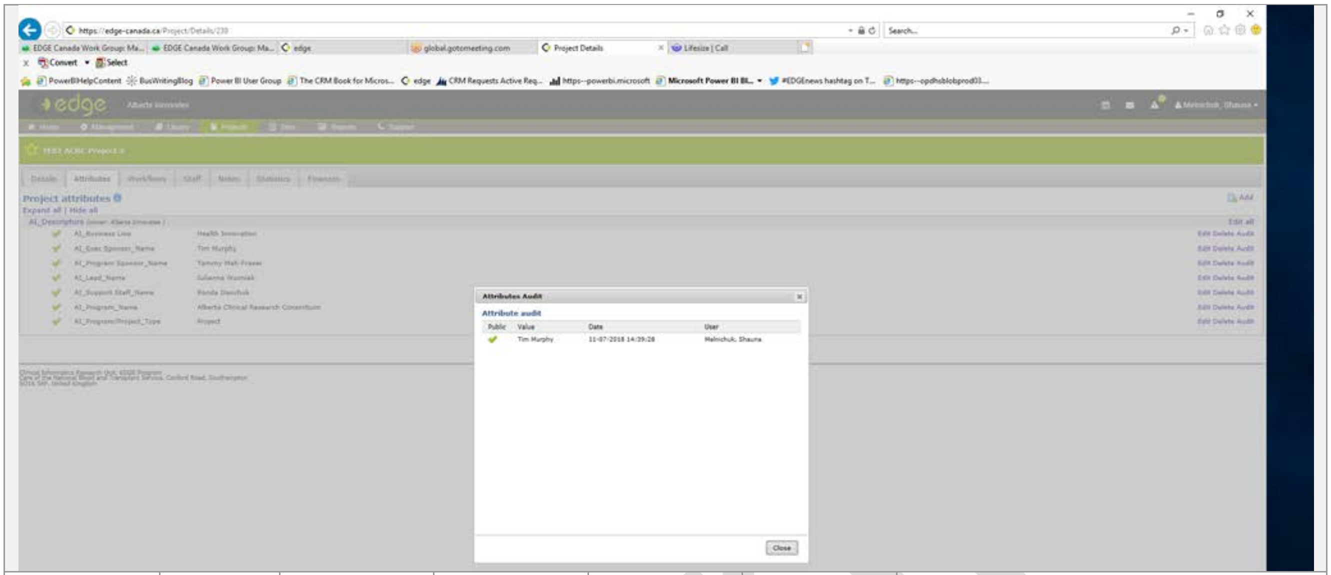
Care of the National Blood and Transplant Service, Coxford Road, Southampton
SO16 5AF, United Kingdom

Attributes Audit

Attribute audit

Public	Value	Date	User
✓	Health Innovation	11-07-2018 14:39:28	Melnichuk, Shauna

Close



https://edge-canada.ca/Project/Details/230

TEST ACRC Project 2

Project attributes

Expand all | Hide all

AI_Descriptors (owner: Alberta Innovates)

✓	AI_Business Line	Health Innovation	Edit Delete Audit
✓	AI_Exec Sponsor_Name	Tim Murphy	Edit Delete Audit
✓	AI_Program Sponsor_Name	Tammy Mah-Fraser	Edit Delete Audit
✓	AI_Lead_Name	Julianna Wozniak	Edit Delete Audit
✓	AI_Support Staff_Name	Ronda Danchuk	Edit Delete Audit
✓	AI_Program_Name	Alberta Clinical Research Consortium	Edit Delete Audit
✓	AI_Program/Project_Type	Project	Edit Delete Audit

Clinical Informatics Research Unit, EDGE Program
Care of the National Blood and Transplant Service, Coxford Road, Southampton
SO16 5AF, United Kingdom

Attributes Audit

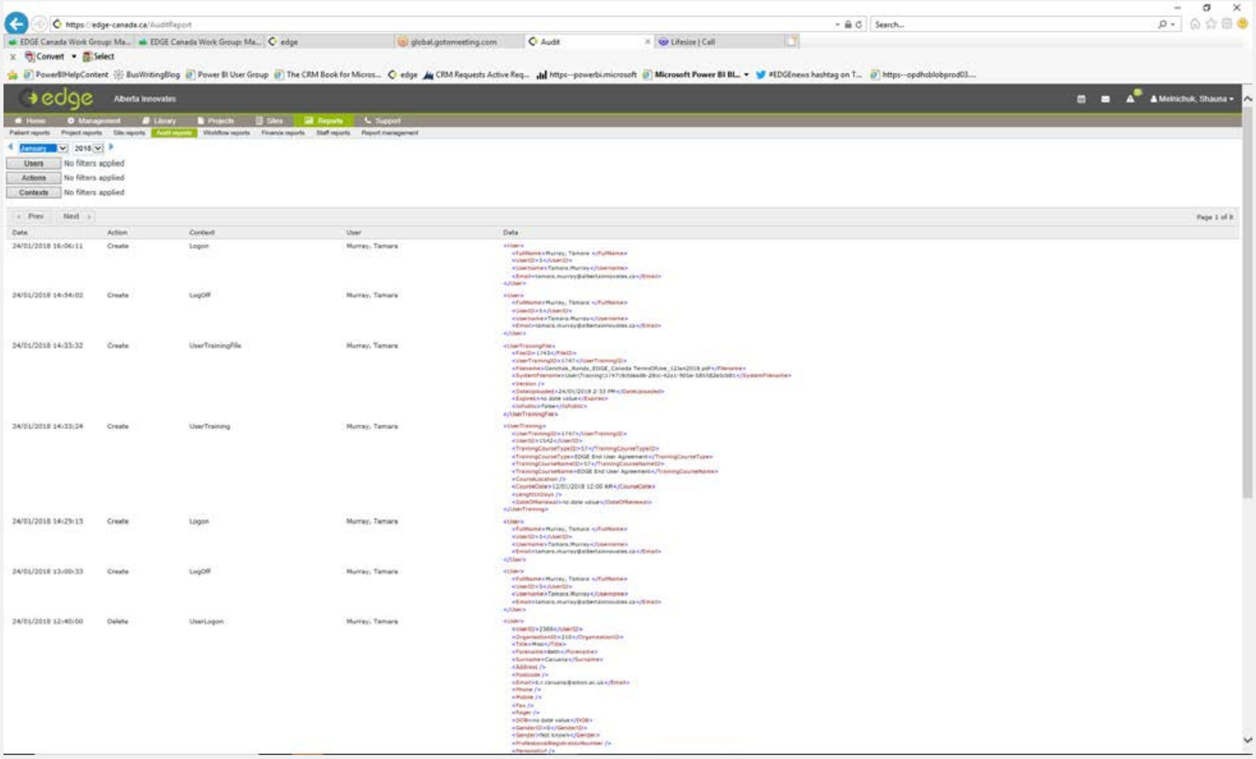
Attribute audit

Public	Value	Date	User
✓	Tim Murphy	11-07-2018 14:39:28	Melnichuk, Shauna

Close

T06	✓ Pass ☐ Fail	**SM**	**7 NOV 18**			

January 2018 Audit Report Details



https://edge-canada.ca/AuditReport

January 2018

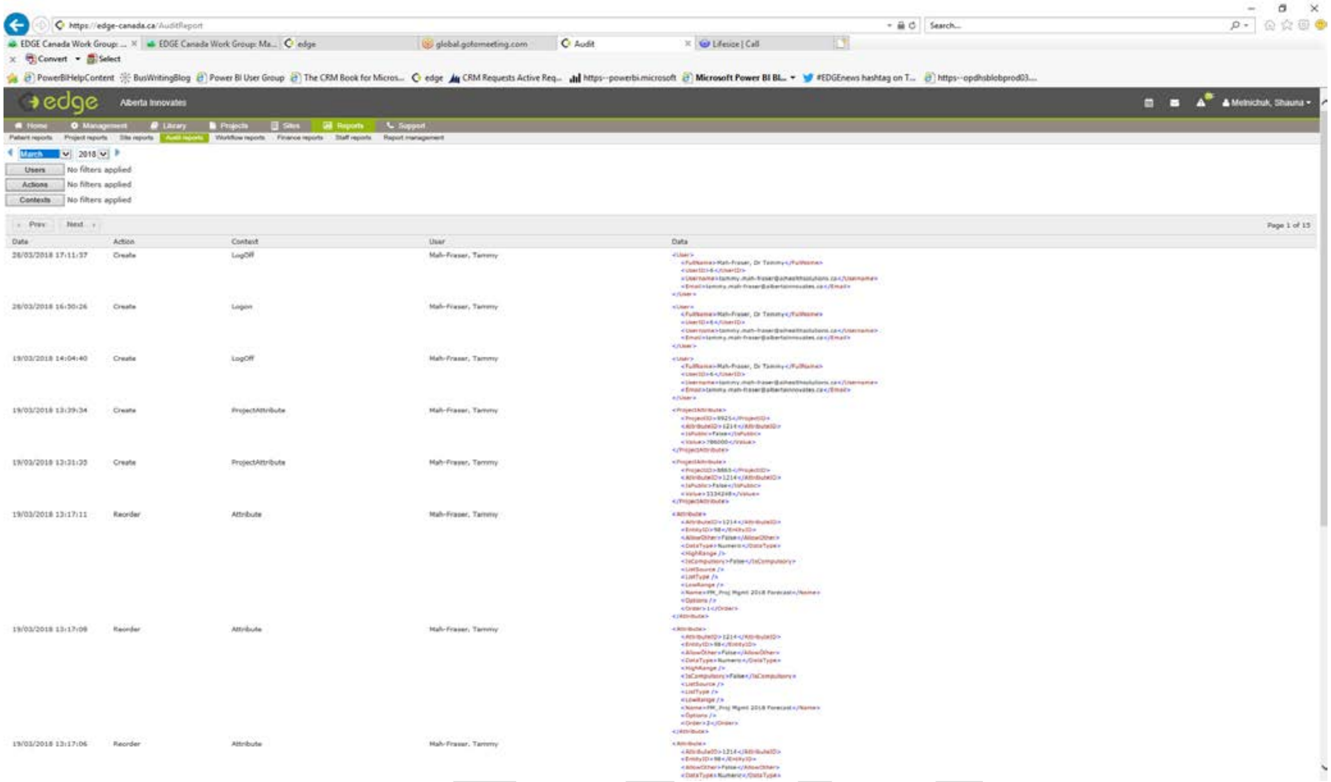
Users No filters applied

Actions No filters applied

Contexts No filters applied

Date	Action	Context	User	Data
24/01/2018 16:06:11	Create	Logon	Murray, Tamara	<User> <FullName>Murray, Tamara </FullName> <UserID>5</UserID> <Username>Tamara.Murray</Username> <Email>tamara.murray@albertainnovates.ca</Email> </User>
24/01/2018 14:54:02	Create	LogOff	Murray, Tamara	<User> <FullName>Murray, Tamara </FullName> <UserID>5</UserID> <Username>Tamara.Murray</Username> <Email>tamara.murray@albertainnovates.ca</Email> </User>
24/01/2018 14:33:32	Create	UserTrainingFile	Murray, Tamara	<UserTrainingFile> <FileID>1745</FileID> <UserTrainingID>1747</UserTrainingID> <Filename>Danchuk_Ronda_EDGE_Canada TermsOfUse_12Jan2018.pdf</Filename> <SystemFilename>UserTraining\1747\9c0daed8-28cc-42a1-905e-585582e5c0d1</SystemFilename> <Version /> <DateUploaded>24/01/2018 2:33 PM</DateUploaded> <Expires>no date value</Expires> <IsPublic>False</IsPublic> </UserTrainingFile>
24/01/2018 14:33:24	Create	UserTraining	Murray, Tamara	<UserTraining> <UserTrainingID>1747</UserTrainingID> <UserID>1542</UserID> <TrainingCourseTypeID>57</TrainingCourseTypeID> <TrainingCourseType>EDGE End User Agreement</TrainingCourseType> <TrainingCourseNameID>57</TrainingCourseNameID> <TrainingCourseName>EDGE End User Agreement</TrainingCourseName> <CourseLocation /> <CourseDate>12/01/2018 12:00 AM</CourseDate> <LengthInDays /> <DateOfRenewal>no date value</DateOfRenewal> </UserTraining>
24/01/2018 14:29:15	Create	Logon	Murray, Tamara	<User> <FullName>Murray, Tamara </FullName> <UserID>5</UserID> <Username>Tamara.Murray</Username> <Email>tamara.murray@albertainnovates.ca</Email> </User>
24/01/2018 13:00:33	Create	LogOff	Murray, Tamara	<User> <FullName>Murray, Tamara </FullName> <UserID>5</UserID> <Username>Tamara.Murray</Username> <Email>tamara.murray@albertainnovates.ca</Email> </User>
24/01/2018 12:40:00	Delete	UserLogon	Murray, Tamara	<User> <UserID>2388</UserID> <OrganisationID>210</OrganisationID> <Title>Miss</Title> <Forename>Beth</Forename> <Surname>Caruana</Surname> <Address /> <Postcode /> <Email>b.r.caruana@aston.ac.uk</Email> <Phone /> <Mobile /> <Fax /> <Pager /> <DOB>no date value</DOB> <GenderID>0</GenderID> <Gender>Not known</Gender> <ProfessionalRegistrationNumber /> <PersonalUrl />

March 2018 Audit Report Details



https://edge-canada.ca/AuditReport

March 2018

Users No filters applied
Actions No filters applied
Contexts No filters applied

Page 1 of 15

Date	Action	Context	User	Data
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28/03/2018 16:50:26	Create	Logon	Mah-Fraser, Tammy	<User> <FullName>Mah-Fraser, Dr Tammy</FullName> <UserID>6</UserID> <Username>tammy.mah-fraser@ahealthsolutions.ca</Username> <Email>tammy.mah-fraser@albertainnovates.ca</Email> </User>
19/03/2018 14:04:40	Create	LogOff	Mah-Fraser, Tammy	<User> <FullName>Mah-Fraser, Dr Tammy</FullName> <UserID>6</UserID> <Username>tammy.mah-fraser@ahealthsolutions.ca</Username> <Email>tammy.mah-fraser@albertainnovates.ca</Email> </User>
19/03/2018 13:39:34	Create	ProjectAttribute	Mah-Fraser, Tammy	<ProjectAttribute> <ProjectID>8925</ProjectID> <AttributeID>1214</AttributeID> <IsPublic>False</IsPublic> <Value>786000</Value> </ProjectAttribute>
19/03/2018 13:31:35	Create	ProjectAttribute	Mah-Fraser, Tammy	<ProjectAttribute> <ProjectID>8865</ProjectID> <AttributeID>1214</AttributeID> <IsPublic>False</IsPublic> <Value>1134248</Value> </ProjectAttribute>
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19/03/2018 13:17:08	Reorder	Attribute	Mah-Fraser, Tammy	<Attribute> <AttributeID>1214</AttributeID> <EntityID>98</EntityID> <AllowOther>False</AllowOther> <DataType>Numeric</DataType> <HighRange /> <IsCompulsory>False</IsCompulsory> <ListSource /> <ListType /> <LowRange /> <Name>PM_Proj Mgmt 2018 Forecast</Name> <Options /> <Order>2</Order> </Attribute>
19/03/2018 13:17:06	Reorder	Attribute	Mah-Fraser, Tammy	<Attribute> <AttributeID>1214</AttributeID> <EntityID>98</EntityID> <AllowOther>False</AllowOther> <DataType>Numeric</DataType>

Approver	Name	Signature	Date
Test Personnel			
Test Personnel			
Principal Investigator (if applicable)			
Quality Assurance Lead (if applicable)			