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eCTD (Electronic Common Technical Document):

- ❖ eCTD is defined as an interface for industry to Agency for transfer of regulatory information.
- ❖ Here, the registration application is transferred electronically from the industry to regulatory authority.
- ❖ eCTD contains five modules.
- ❖ First module is for submission of administrative and prescribing information, which is specific for each region.
- ❖ Modules 2-5 are common across all the regions.

Functionality of eCTD Admin:

- ❖eCTD admin will be able to assign role and it's operations to the user.
- ❖eCTD Admin will be able to create a project.
- ❖eCTD Admin will be able to create user/user group.
- ❖eCTD Admin will be able to create master data.
- ❖eCTD Admin will be able to view reports.
- ❖eCTD Admin will be able to publish and submit projects.

Getting Started:

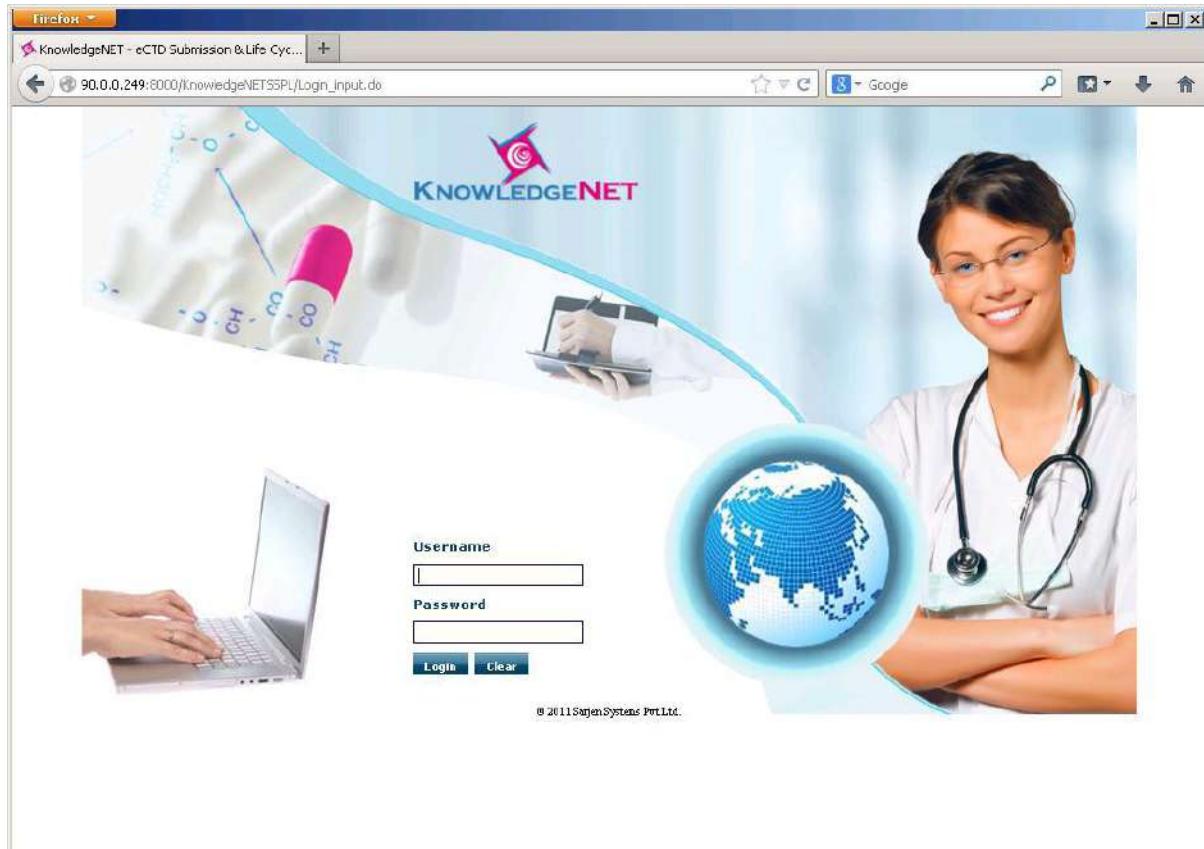
Following section provides an overview of the KnowledgeNET eCTD functionalities.

To start the application:

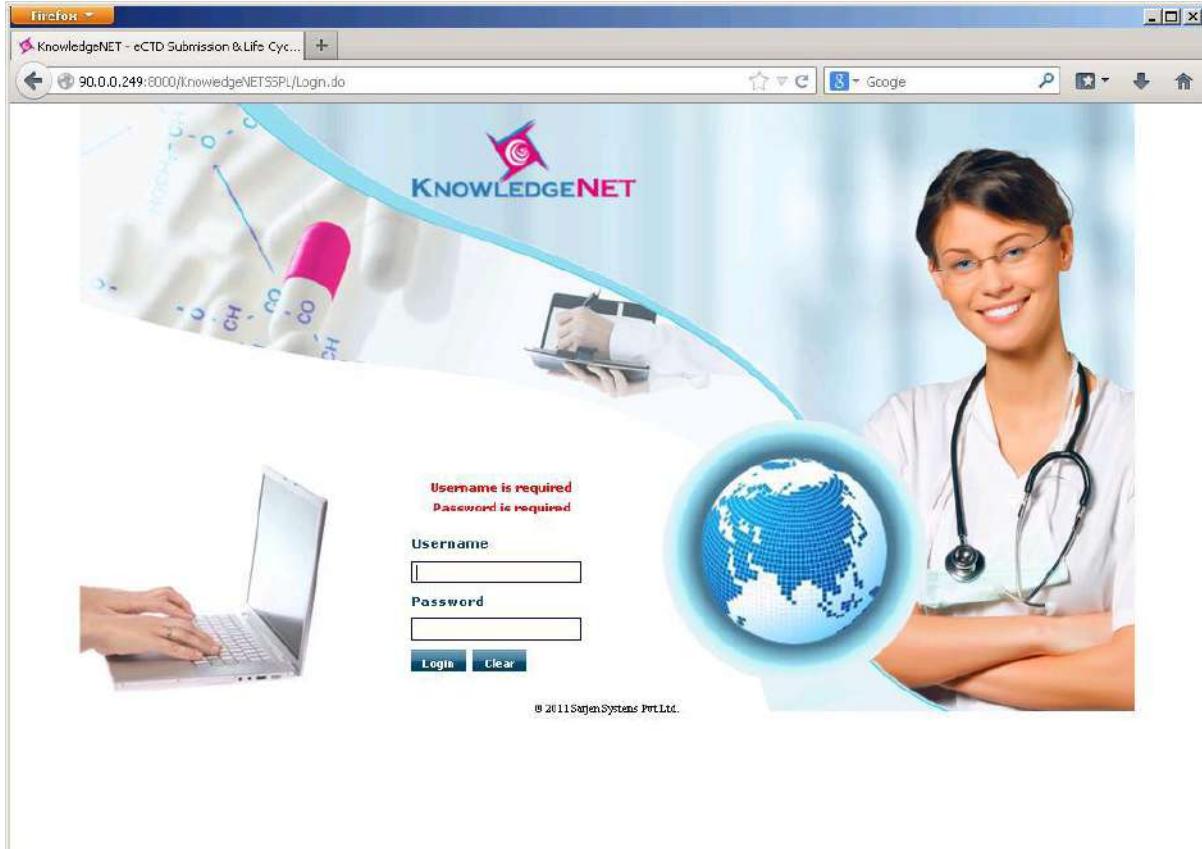
- Give the URL: <http://50.245.216.249:8000/KnowledgeNET-Test/>
- It will display the below screen:

Login Screen

- In log in screen, enter User Name and Password.



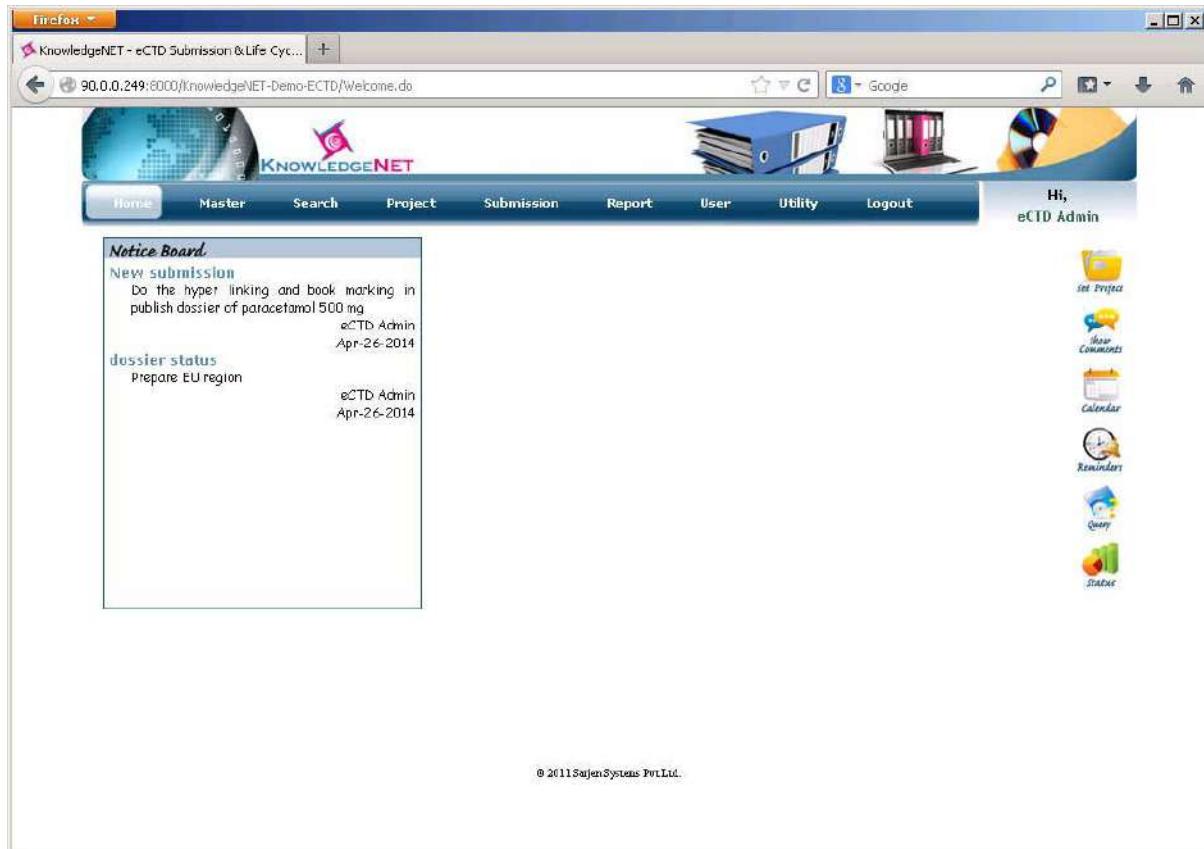
Log in without entering Username and Password



- User must have to enter correct username and password to log in the application.
- It cannot be blank, otherwise above message will be displayed.

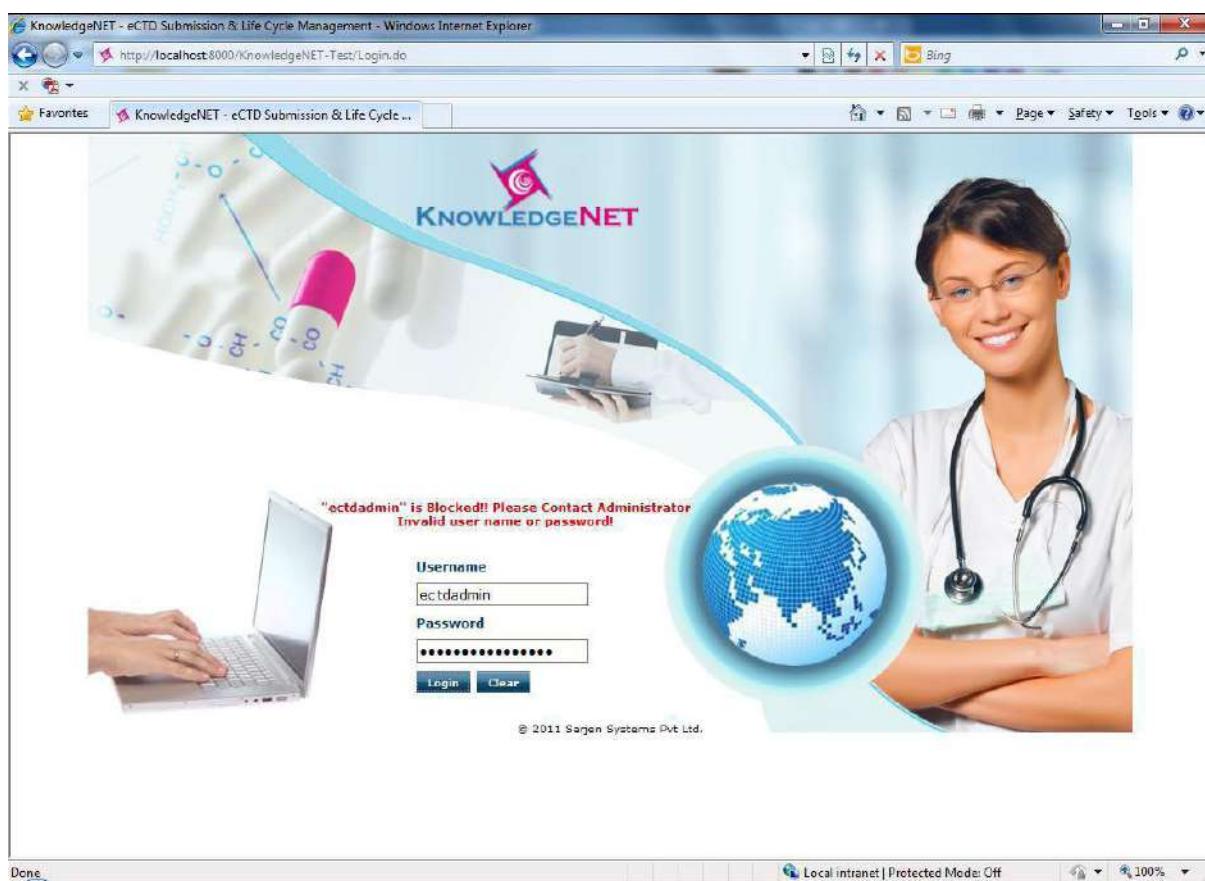
On Entering User Name and Password

- Click on “Login” button.
- On clicking “Login”, it will display the Home Page if the username and password is valid.

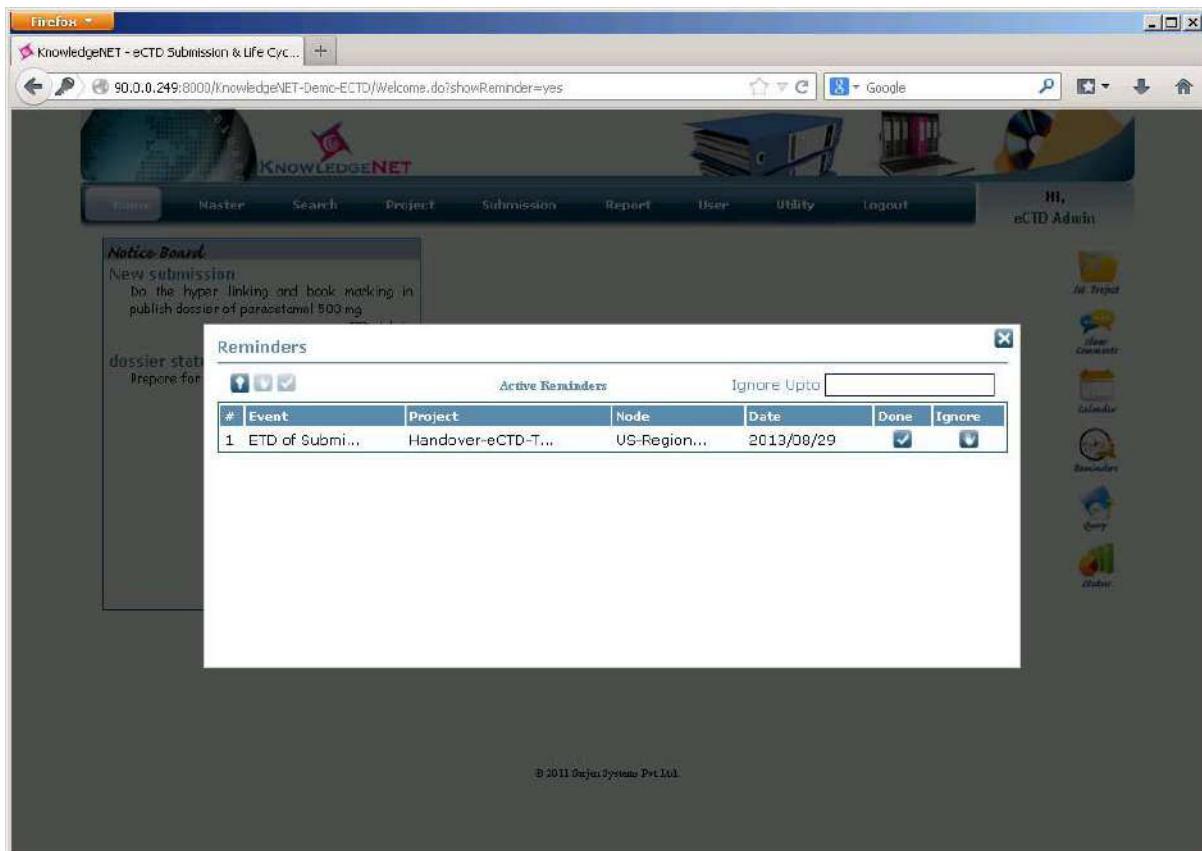


Blocked User Notification

- If user enters in-correct password more than 3 times then that user will be blocked.
- For unlocking, it needs to contact to the Administrator.



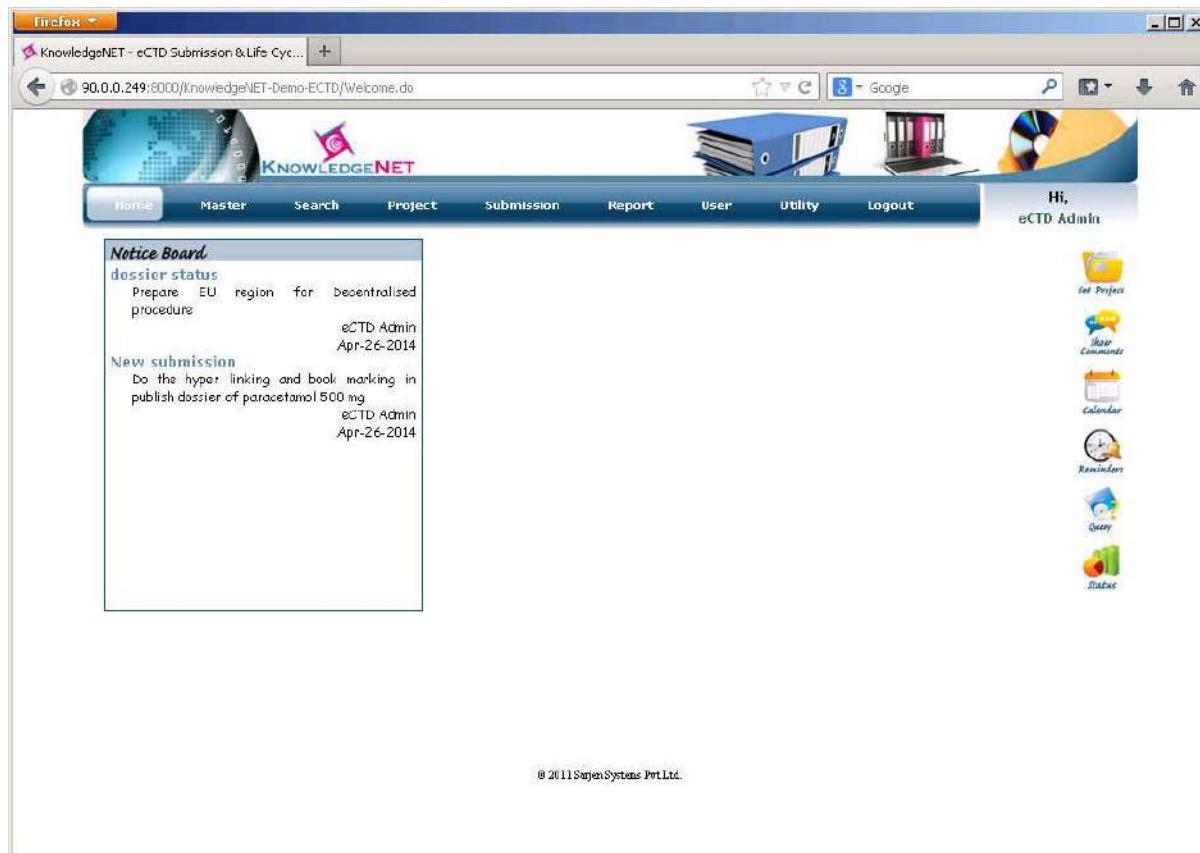
After Login



- After log-in with the correct username and password the above screen will get displayed.
- Pop-up renders active reminders which allow much functionality.

Home screen

- Post login screen (Welcome Page) will display the menu items as shows: -
 - Master
 - Search
 - Project
 - Submission
 - Report
 - User
 - Utility
 - Logout

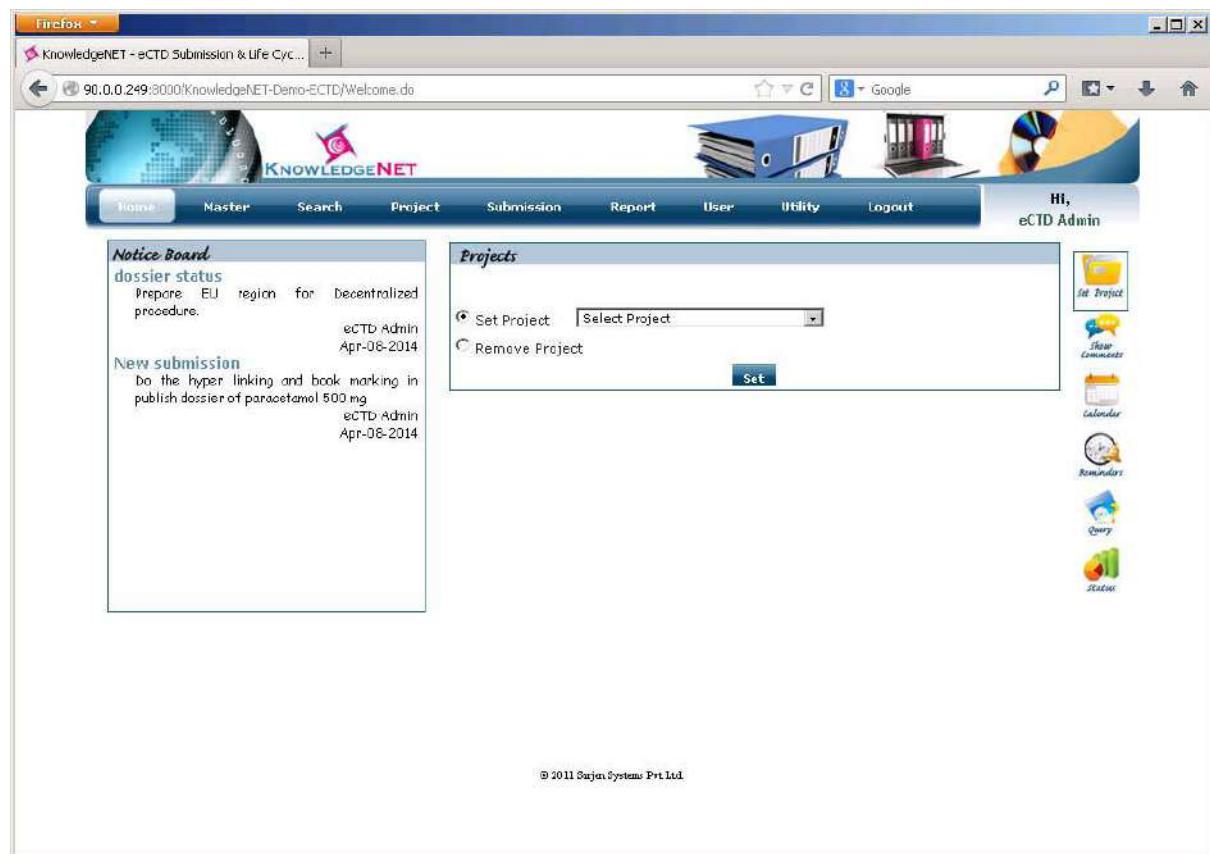


- Post login screen (Welcome Page) will display the menu items in **right panel:-**



Set Project Tab

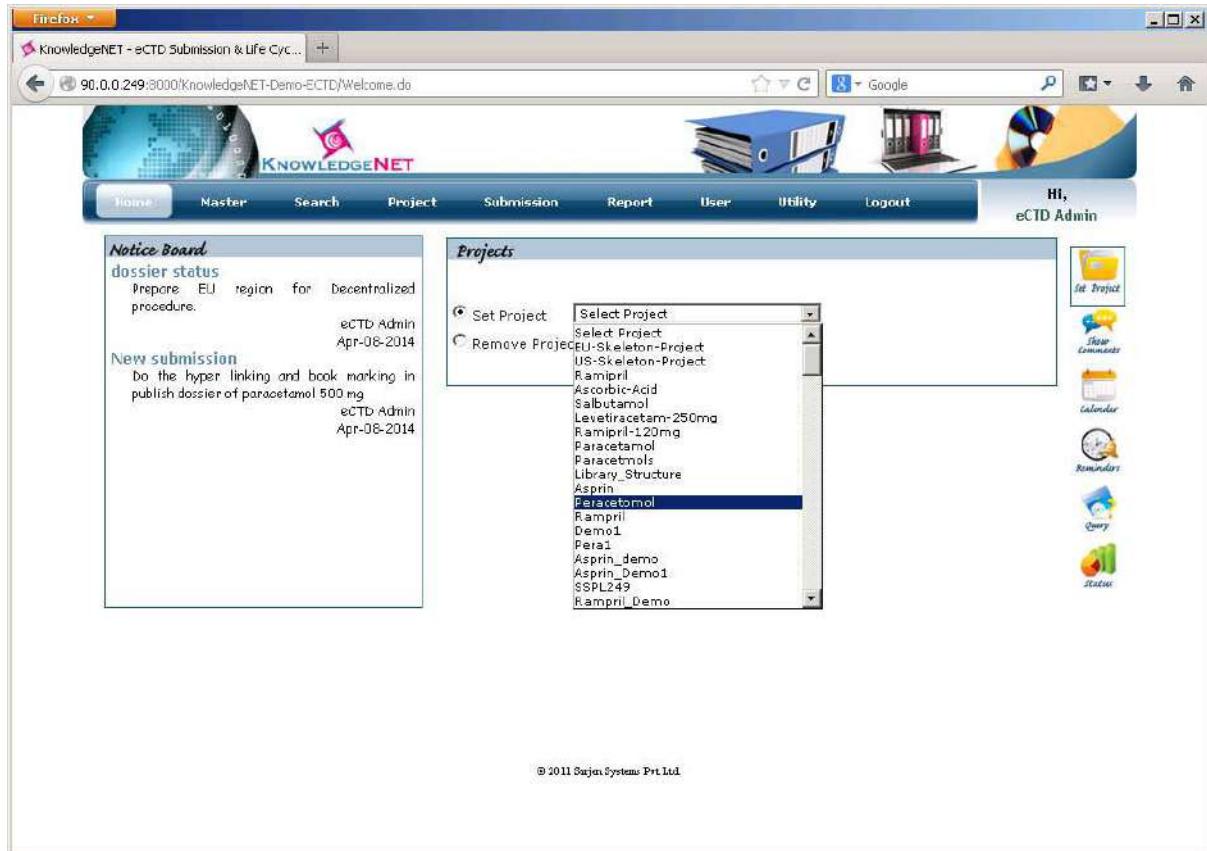
- On clicking “Set Project button” on right side, below screen will get displayed.
- Select any project that needs to be set as default project and click on “Set” button.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page features a blue header with the KnowledgeNET logo and a navigation menu including Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A "Hi, eCTD Admin" greeting is visible on the right. On the left, there's a "Notice Board" section with two entries: "dossier status" and "New submission". The "Projects" section on the right contains a "Set Project" form with a dropdown menu labeled "Select Project" and a "Set" button. To the right of the form is a vertical sidebar with icons for "Set Project", "Stop Comments", "Calendar", "Reminders", "Query", and "Logout". At the bottom of the page, a copyright notice reads "© 2011 Surjan Systems Pvt Ltd".

Auto-completer: Selection of Project

- The below screen shows the selection of project.

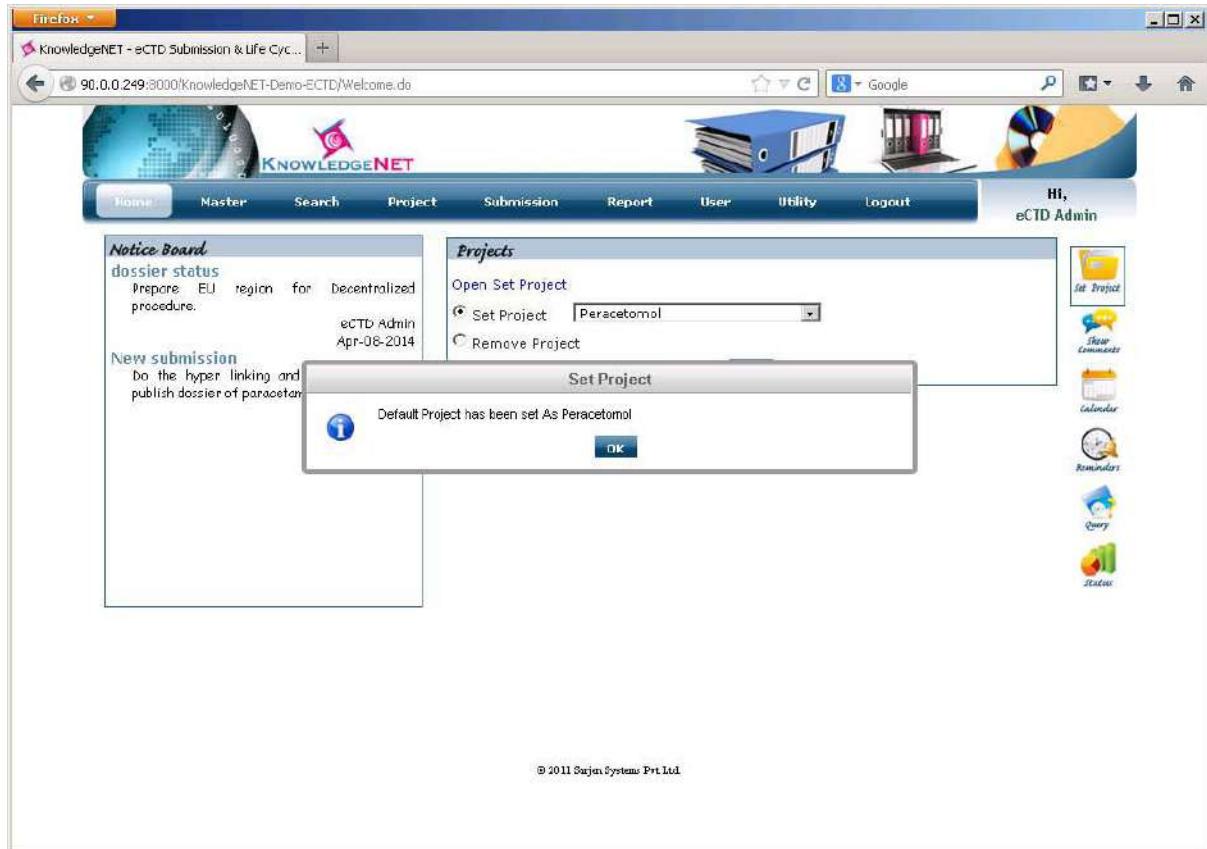


The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page has a blue header bar with the KnowledgeNET logo and navigation links: Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, eCTD Admin" is displayed on the right. On the left, there is a "Notice Board" section with two entries: "dossier status" (EU region for Decentralized procedure) by eCTD Admin on Apr-08-2014, and "New submission" (link to paracetamol 500 mg dossier) by eCTD Admin on Apr-08-2014. The main content area is titled "Projects". It contains two radio buttons: "Set Project" (selected) and "Remove Project". Below them is a dropdown menu titled "Select Project" listing various projects: EU-Skeleton-Project, US-Skeleton-Project, Ramipril, Ascorbic-Acid, Salbutamol, Levetiracetam-250mg, Ramipril-120mg, Paracetamol, Paracetamols, Library_Structure, Asprin, Paracetamol (highlighted in blue), Ramipril, Demo1, Pera1, Asprin_demo, Asprin_Demo1, SSPL249, and Ramipril_Demo. To the right of the dropdown is a vertical sidebar with icons for Set Project, Start Comments, Calendar, Reminders, Query, and Status.

- By clicking on “Set” Button, the selected project will be set as default and a message will get displayed as shows below.

Set Project: After Selection

- By clicking on “Set” Button the selected project will be set as default and a message will get displayed as shows below.



- Default project will be set as ‘Paracetamol and on clicking “Open Set Project”, it will open the project that is set with its ectd structure.
- This default project will appear in different forms as: -
 - Manage Project
 - Submission Details
 - Publish And Submit
- On selecting ‘Remove Project’, the default project set will be removed and an alert will appear for the same.



Show Comments Tab

- ✓ Below Set Project, click on 'Show Comments'
- ✓ A pop-up window of 'Comments' get display and it will show user the all message present in 'Inbox' and all show the sent item.
- ✓ Click on Sent, below screen get display.

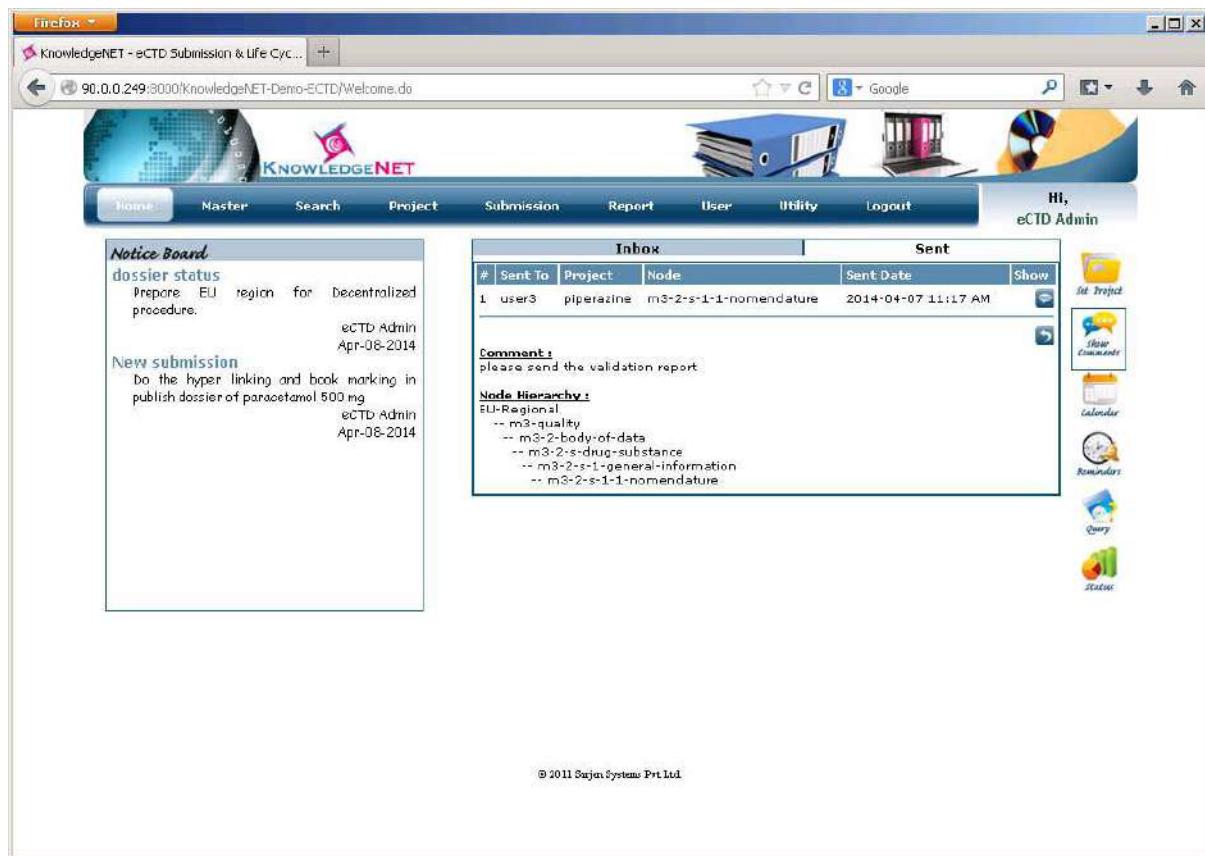
	Sender	Project	Node	Sent Date	Show
1	user3	piperazine	m3-2-s-1-1-nomenclature	2012-12-07 03:21 PM	
2	user4	Levetiracetam	m2-2-introduction	2012-11-27 03:56 PM	
3	user4	Levetiracetam	m2-2-introduction	2012-11-27 02:22 PM	
4	eCTD User	Levetiracetam-250mg	m2-2-introduction	2011-06-08 12:03 PM	

Page No: 1/1 Goto Page: 1

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- Click on Inbox it shows received comments.

- In project grid click on ‘Show’ in front of project ‘pps-tablet-50mg’, below screen get display and it show received comments for project.



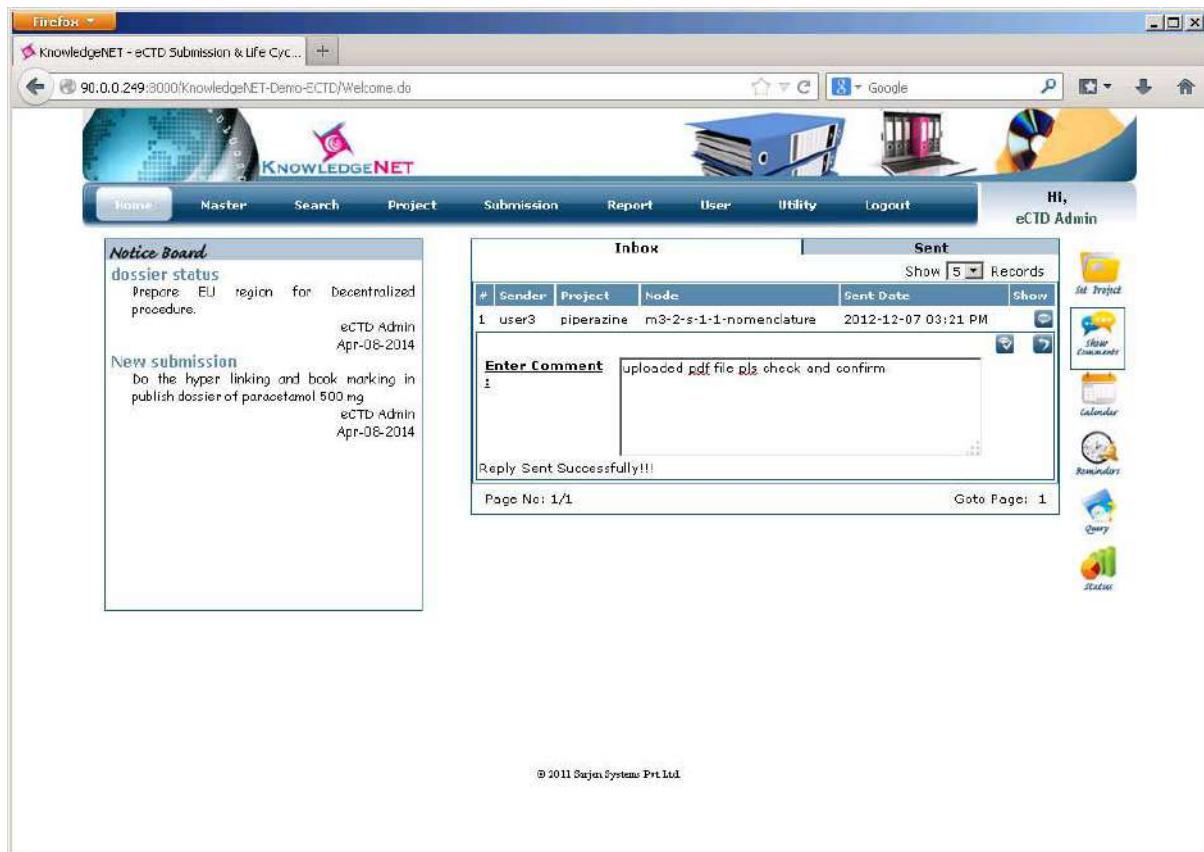
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page has a blue header bar with the KnowledgeNET logo and navigation links: Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile for 'eCTD Admin'. On the left, there's a 'Notice Board' section with two entries: 'dossier status' (Prepare EU region for Decentralized procedure) and 'New submission' (Do the hyper linking and book marking in publish dossier of paracetamol 500 mg). The main content area is titled 'Inbox' and shows a table with one row:

#	Sent To	Project	Node	Sent Date	Show
1	user3	piperazine	m3-2-s-1-1-nomenclature	2014-04-07 11:17 AM	

Below the table, there's a 'Comment' section with the message: 'Please send the validation report.' and a 'Node Hierarchy' section listing nodes under 'EU-Regional': m3-quality, m3-2-body-of-data, m3-2s-drug-substance, m3-2s-1-general-information, and m3-2-s-1-1-nomenclature. To the right of the inbox, there's a sidebar with icons for 'Set Project', 'Show Comments', 'Calendar', 'Reminders', 'Query', and 'Status'.

- Click on icon  for reply, an 'enter comment' pop-up appears.

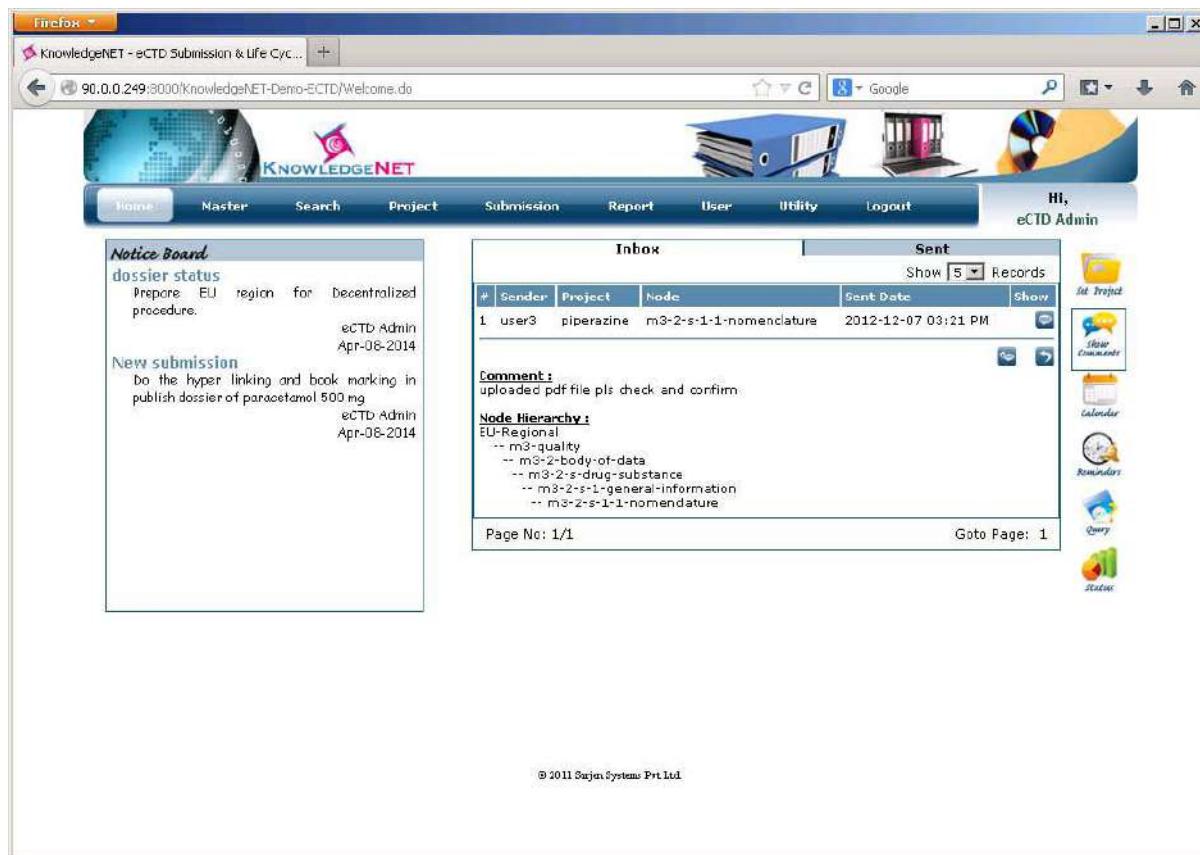
- User enter the comments in comments tab, below screen get display.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page header includes the KnowledgeNET logo and navigation links: Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a greeting for 'eCTD Admin'. On the left, there's a 'Notice Board' section with two entries: 'dossier status' (Prepare EU region for Decentralized procedure, by eCTD Admin on Apr-08-2014) and 'New submission' (Do the hyper linking and book marking in publish dossier of paracetamol 500 mg, by eCTD Admin on Apr-08-2014). The main content area shows an 'Inbox' and 'Sent' table. The 'Sent' table has one record: user3 sent piperazine (m3-2-s-1-1-nomenclature) on 2012-12-07 03:21 PM. Below the table is a 'Enter Comment' text area containing the message 'uploaded pdf file pls check and confirm'. A success message 'Reply Sent Successfully!!!' is displayed. On the right side, there's a sidebar with icons for 'Std Project', 'Show Comments' (which is selected), 'Calendar', 'Reminders', 'Query', and 'Status'.

Show Send Comment

- Click on Sent, Sent comments get display.
- In project grid, click on 'Show' in front of project 'piprazine-tablet-50mg', below screen get display and it show all comments related to project.
- Click on icon  to go back.



The screenshot shows a web browser window for the KnowledgeNET platform. The URL is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The main menu includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user is logged in as "eCTD Admin". On the left, there's a "Notice Board" section with "dossier status" and "New submission" notices. The right side features an "Inbox" and "Sent" tab. The "Sent" tab is active, showing a table of comments. One comment from "user3" on project "piperazine" is listed with the node "m3-2-s-1-1-nomenclature" and sent date "2012-12-07 03:21 PM". The comment text is "uploaded pdf file pls check and confirm". Below the table, a "Node Hierarchy" tree is shown under "EU-Regional". The footer contains copyright information: "© 2011 Surjan Systems Pvt Ltd".



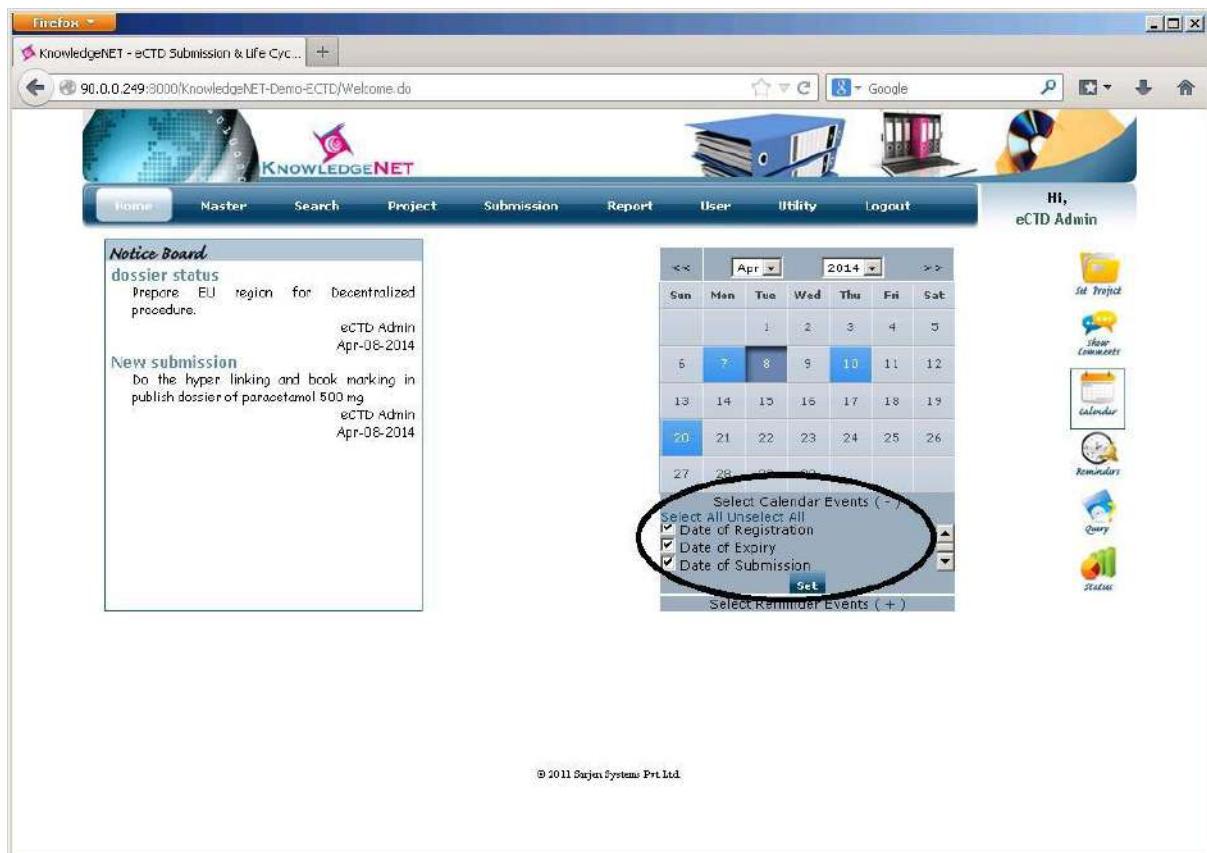
Calendar Tab

- Below Show Comments, click on 'Calendar'
- A pop-window of 'Calendar' gets display and it will show user the upcoming events (if Attributes will set at the time of project creation).

The screenshot shows a web browser window for the KnowledgeNET platform. The main menu includes Home, Master, Search, Project, Submission, Report, and User. On the left, there's a 'Notice Board' section with two items: 'dossier status' and 'New submission'. The 'dossier status' item is dated Apr-08-2014. The 'New submission' item is dated Apr-08-2014. A central modal window titled 'Date of Registration' shows a calendar for April 2014. The date '10' is highlighted with a red circle and has a black arrow pointing to it from the text 'Date of Registration us-testing-sareri' located above the calendar. The sidebar on the right contains icons for 'Sel Project', 'Show Comments', 'calendar' (which is selected), 'Reminders', 'Query', and 'Status'.

- User can set the Calendar Events and the Reminder Events for Date of Registration, Date of Expiry and Date of Submission etc....

- Check all required events for both Calendar and Reminder and then click on Set.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page features a blue header bar with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A "Hi, eCTD Admin" greeting is visible on the right. On the left, there's a "Notice Board" section with two entries:

- dossier status**: Prepare EU region for Decentralized procedure. eCTD Admin Apr-06-2014
- New submission**: Do the hyper linking and book marking in publish dossier of paracetamol 500 mg eCTD Admin Apr-06-2014

The main content area contains a calendar for April 2014. A modal dialog box is overlaid on the calendar, titled "Select Calendar Events (-)". It contains the following options:

- Select All Unselect All
- Date of Registration
- Date of Expiry
- Date of Submission

At the bottom of the dialog are "Set" and "Select Reminder Events (+)" buttons. The "Date of Submission" checkbox is highlighted with a red oval.



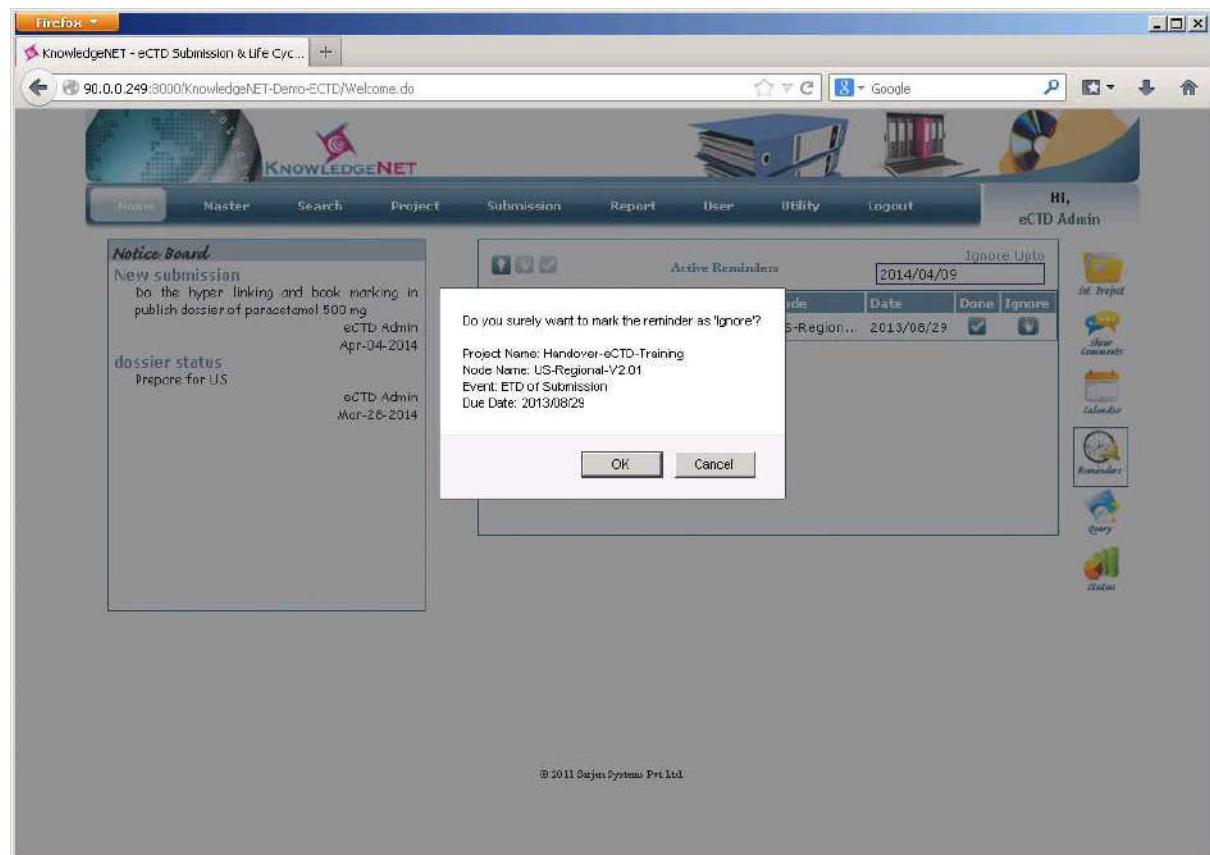
Reminder Tab

- Below Calendar, click on 'Reminder'
- A pop-up window of 'Reminder' gets display and it will show all 'Active Reminders'.

#	Event	Project	Node	Date	Status
1	Compliance o...	Test-Azerbaijan	AZERBAIJAN	18 month	Done
2	Compliance o...	Test-Azerbaijan	AZERBAIJAN	18 months	Done
3	Renewal Expi...	Ramipril	US-Region...	2011/06/13	Done
4	Renewal Regi...	Ramipril	US-Region...	2011/06/30	Done
5	Date of Sent...	Ramipril	US-Region...	2011/07/05	Done
6	Date of Subm...	Salbutamol	EU-Regional	2011/08/02	Done
7	Date of Subm...	Paracetamol	EU-Regional	2011/08/11	Done
8	Dossier Inti...	Salbutamol	EU-Regional	2011/08/15	Done
9	Dossier Inti...	Paracetamol	EU-Regional	2011/08/20	Done

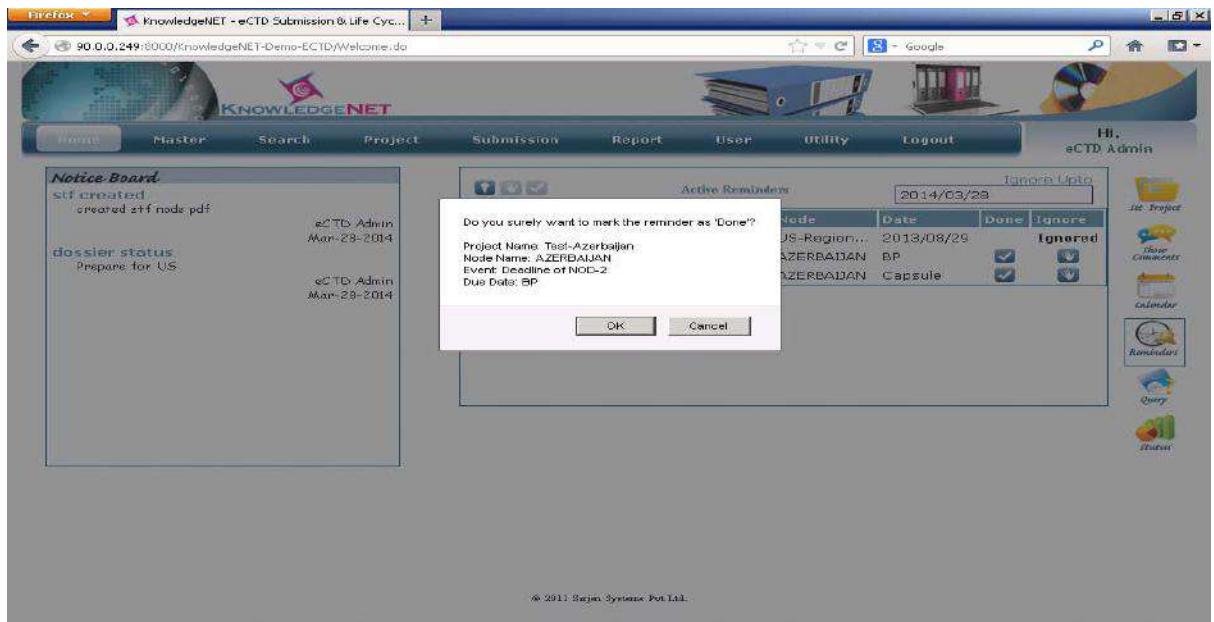
- In front of Event such as Date of Registration, click on 'Done' and/or ignore
- If click on 'Done' event show in Done grid and if click on 'Ignore' event show in Ignore grid
- Click on icon Ignored Reminders, and It will show user all 'Unignore Reminders'
- **Note: User can neglect the reminder any time by just click on Unignore.**
- Click on icon Done Reminders and It will show user all 'Done Reminders'

- If User wants to 'Ignored' and specific reminder for a specific time than select the date in "Ignored Up to".
- And in grid click on ignored, a pop-up messages appears
- Click on "Ok" to Ignored the Reminder.



- If User wants to 'Done' and specific reminder then in grid click on Done, a pop-up messages appears

- If User wants to 'Done' and specific reminder then in grid click on done, a pop-up messages appears.
- Click on "Ok" to Done the Reminder.





Query Tab

- Below Reminder, click on Query Tab.
- A pop-up window of 'Query' gets display and it will show user the all 'Query', add/edit in Query Management.

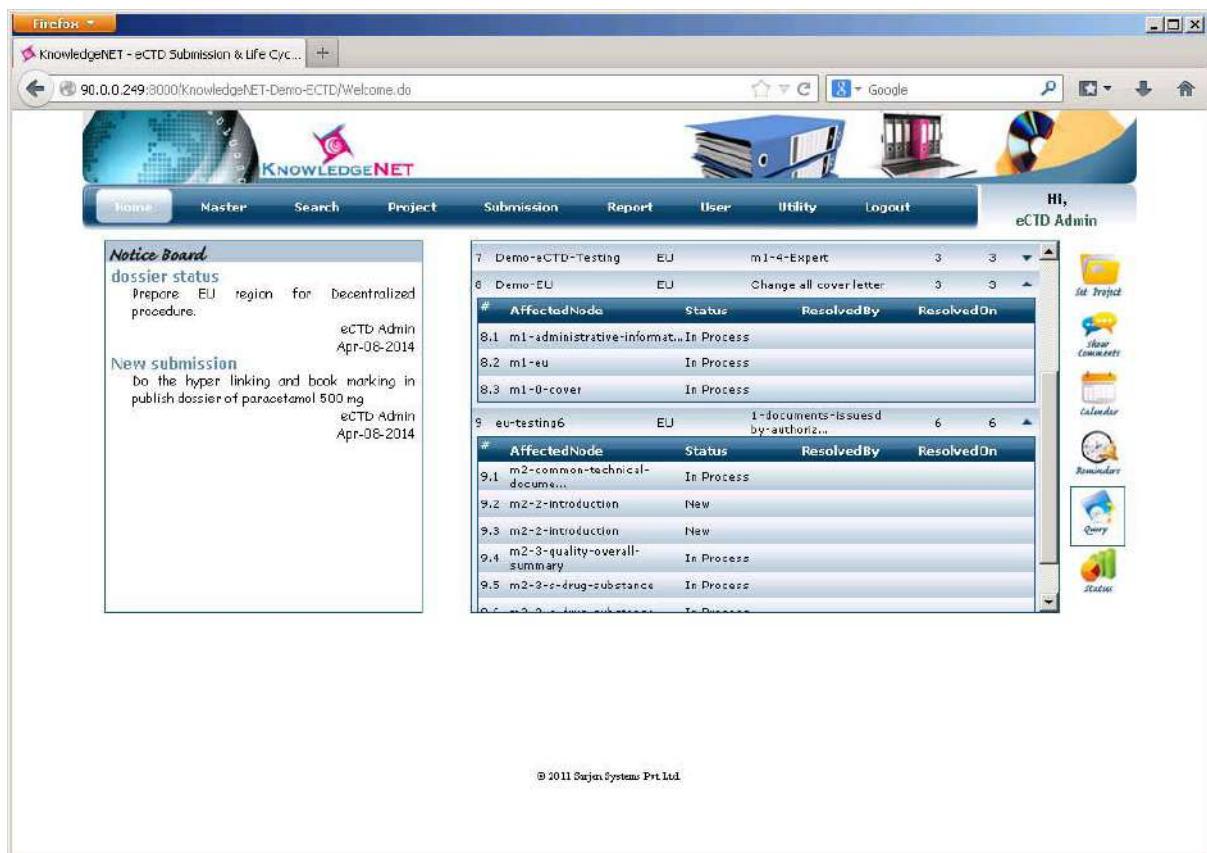
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management system. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The main menu at the top includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. On the right, a sidebar for 'eCTD Admin' lists icons for Set Brief, Show Comments, Calendar, Reminders, and Status, with 'Query' currently selected. The central area features a 'Notice Board' section with two entries: 'New submission' (by eCTD Admin on Apr-04-2014) and 'dossier status' (by eCTD Admin on Mar-26-2014). To the right is a large table titled 'AffectedNode' showing a list of queries for project 'Rimipril'. The table columns are #, Project, Country, QueryTitle, Total, and Un Res. The data in the table is as follows:

#	Project	Country	QueryTitle	Total	Un Res.
1	Rimipril	US	Doc is missing	2	1
2	Rimipril	US	also upload word file	9	9
#	AffectedNode	Status	ResolvedBy	ResolvedOn	
2.1	m1-administrative-information	New			
2.2	m1-regional	New			
2.3	m1-2-cover-letters	New			
2.4	m1-3-administrative-information	New			
2.5	m1-2-cover-letters	New			
2.6	m1-14-labeling	New			
2.7	m1-14-1-draft-labeling	New			
2.8	m1-14-1-3-draft-labeling-text	New			
2.9	m1-14-1-3-draft-labeling-text	New			
3	Rimipril Demo	US	Doc is missing	4	4

Note: User can see the status of Query for individual project.



- Below Query, click on Status.
- A pop-up window of 'Status', get display and it will show User the status of projects Region wise, product wise and Dossier Status.

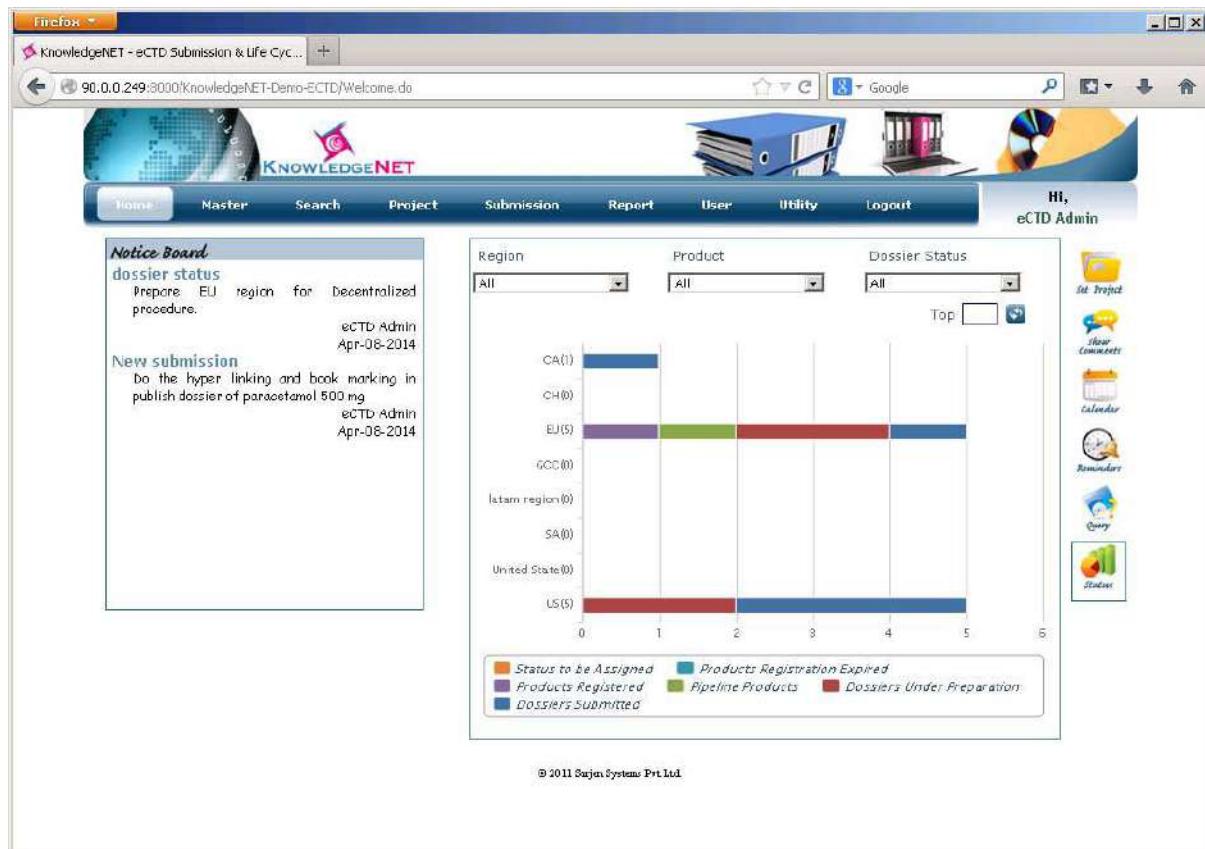


#	AffectedNode	Status	ResolvedBy	ResolvedOn
8.1	ml-administrative-information	In Process		
8.2	ml-eu	In Process		
8.3	ml-0-cover	In Process		
9	eu-testing6	1-documents-issued by-authoriz...	6	6
9.1	m2-common-technical-document...	In Process		
9.2	m2-z-introduction	New		
9.3	m2-z-introduction	New		
9.4	m2-3-quality-overall-summary	In Process		
9.5	m2-3-s-drug-substance	In Process		

Note: User can see the status of Query for individual project.

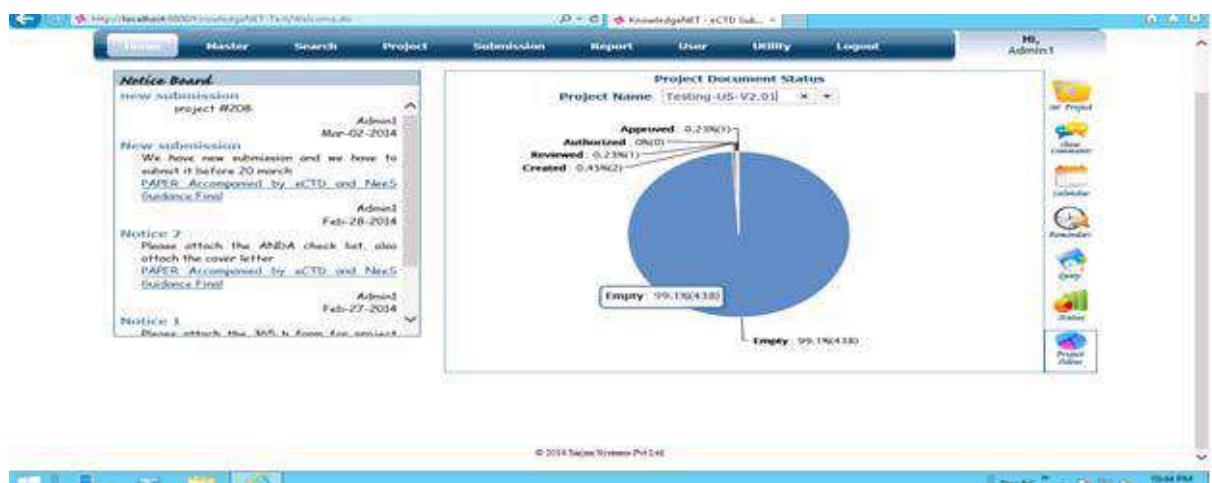
Status

- Below Query, click on Status.
- A pop-up window of 'Status' get display and it will show Admin the status of projects Region wise, product wise and Dossier Status.



Project Status

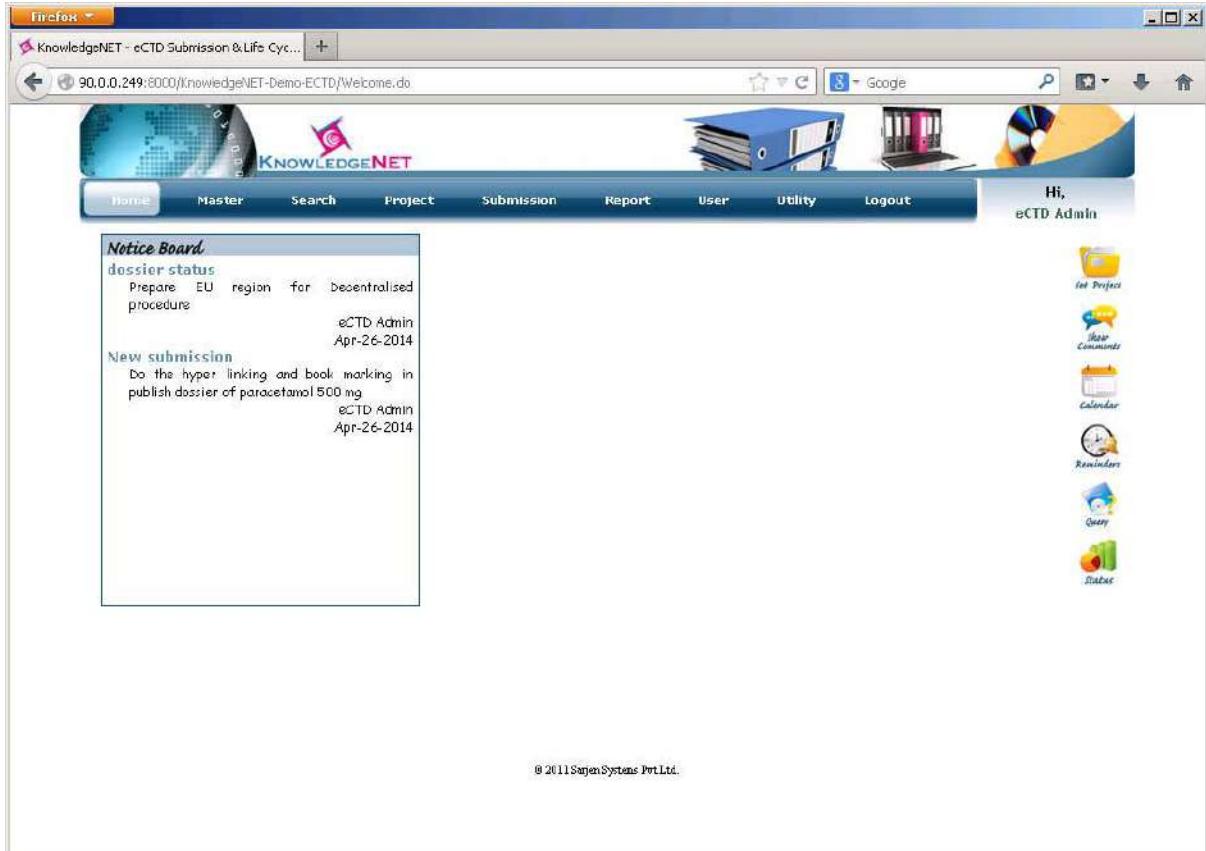
- The Project Status is last and final tab on dashboard
- After click on '**Project Status**', a pop-up window get display.
- Select the Project from Project list and than below screen apperas.



- After project selection, it show the complete status of project mean percentage of Approve files, Authorized files and Reviewed files and the remaining Empty nodes, show in above screen.

Notice

- User can set a notice for a specific user for a specific time period.
- The set notice show on dashboard of user from start date to end date of notice.
- Notice(shows in dashboard) can be Generated from **Master Menu** (Master> Notice)
- If Notice activate than show on dashboard.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The page features a blue header bar with the KnowledgeNET logo and various menu options: Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, eCTD Admin' is displayed on the right side. The main content area is titled 'Notice Board' and contains two entries:

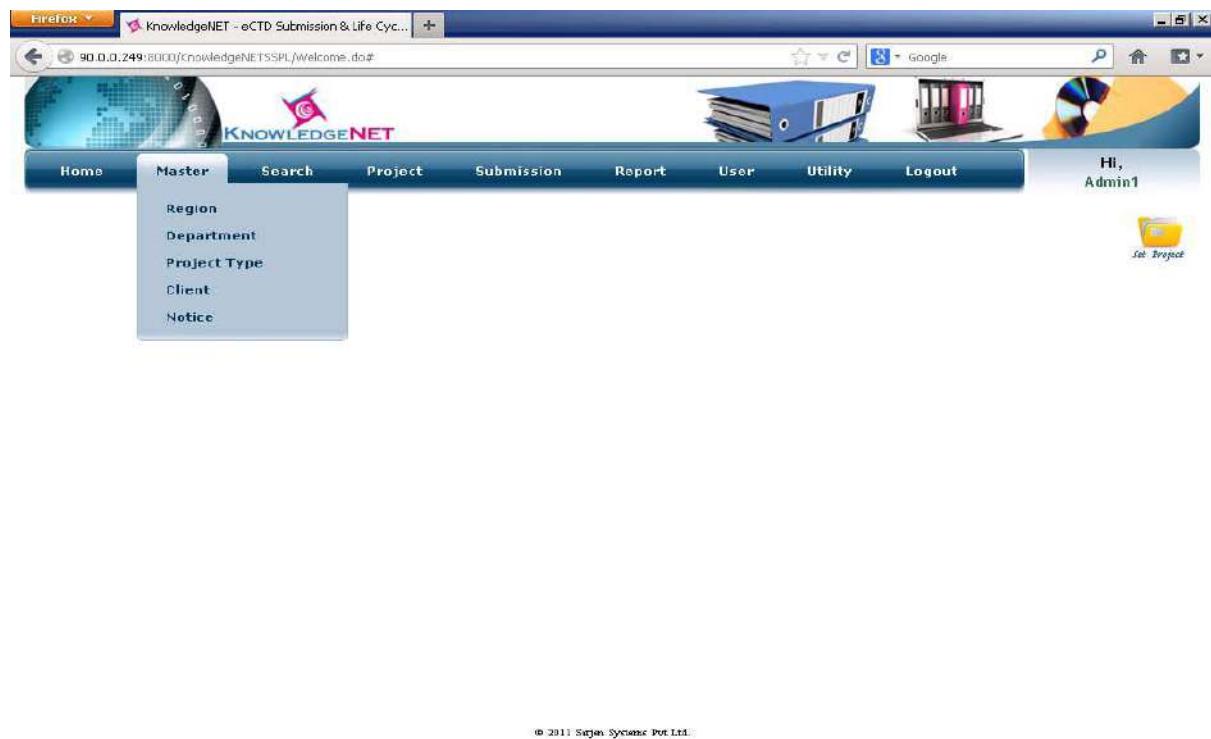
- dossier status**
Prepare EU region for decentralised procedure
eCTD Admin
Apr-26-2014
- New submission**
Do the hyper linking and book marking in publish dossier of paracetamol 500 mg
eCTD Admin
Apr-26-2014

To the right of the notice board, there is a vertical sidebar with icons for different functions: 'fed Projects', 'Web Communi...', 'Calendar', 'Reminders', 'Query', and 'Status'. At the bottom of the page, a copyright notice reads '© 2011 Sanjen Systems Pvt Ltd.'

Note: if user not want to activate the notice than uncheck the Active box

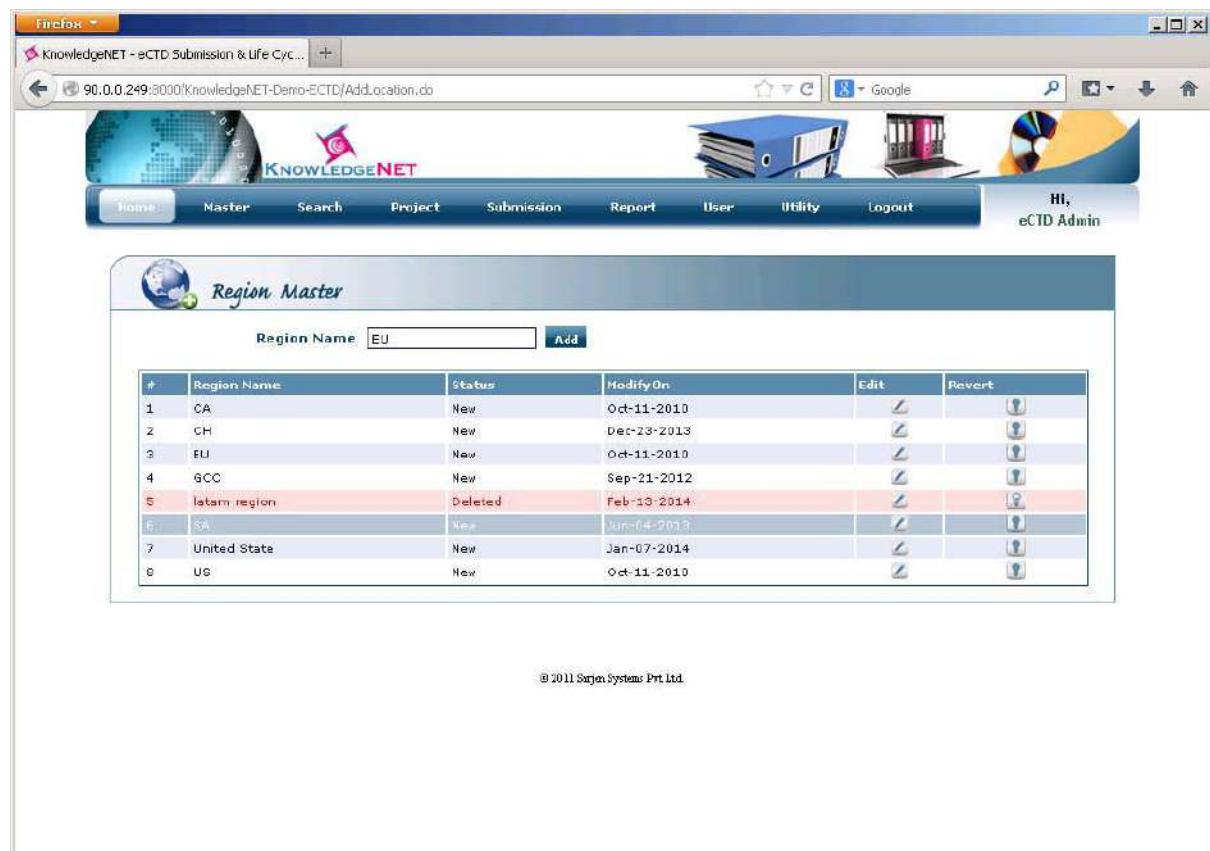
Master Menu

- “Master” Menu will display the submenu items as shows: -
- Region
- Department
- Project Type
- Client
- Notice



Master > Region

- Admin will be able to add, edit and inactivate the Region record (Region master).
- For each record, its “status” will be displayed as
 - ✓ For newly added record the status will be “New”.
 - ✓ For edited/reactivated record status will be “Edited”.
 - ✓ For inactivated record, the status will be “Deleted”.
- For each record its modification date will be displayed in “Modify On” column.



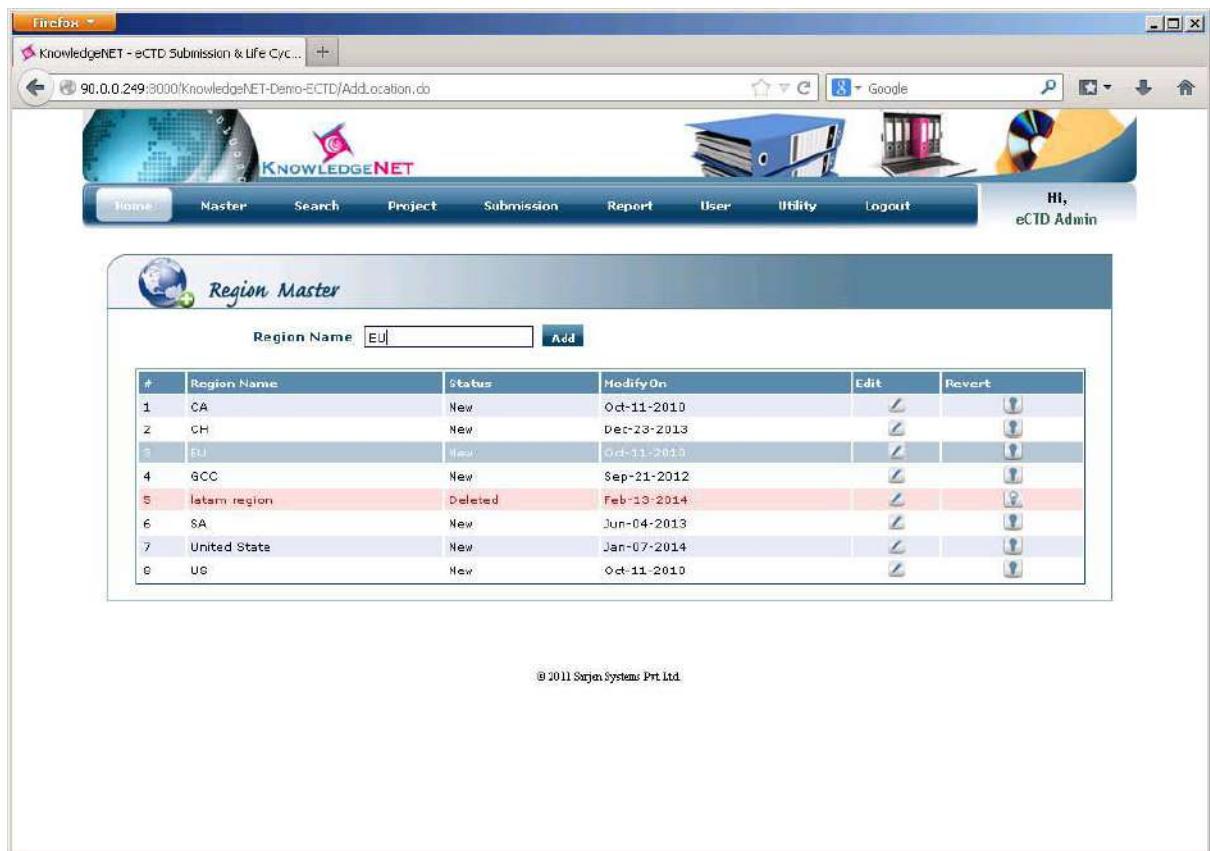
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Add.location.do. The page title is "Region Master". The main content area shows a table of regions:

#	Region Name	Status	Modify On	Edit	Revert
1	CA	New	Oct-11-2010		
2	CH	New	Dec-23-2013		
3	EU	New	Oct-11-2010		
4	GCC	New	Sep-21-2012		
5	letam_region	Deleted	Feb-13-2014		
6	SA	New	Jun-04-2013		
7	United State	New	Jan-07-2014		
8	US	New	Oct-11-2010		

At the bottom of the page, there is a copyright notice: © 2011 Surjan Systems Pvt. Ltd.

On adding "Region Name"

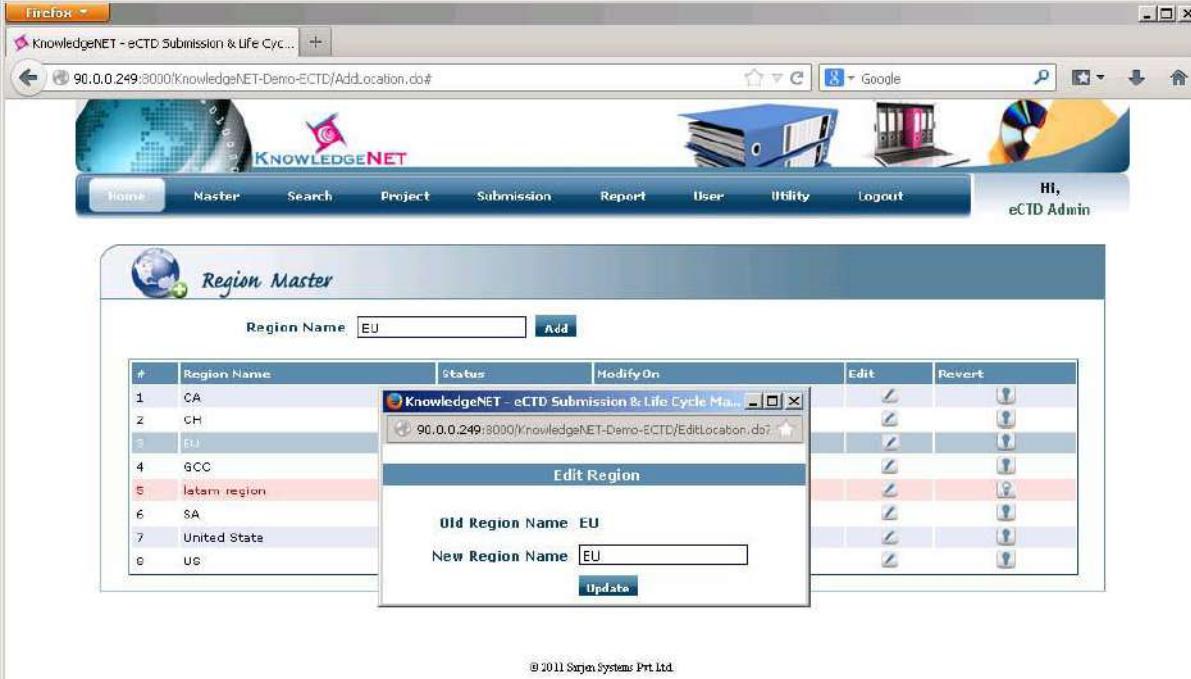
- To add the Region name, Admin has to mention the "Region Name" in the text box and click on "Add" button.



The screenshot shows the 'Region Master' page of the KnowledgeNET application. The page has a header with the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user 'Hi, eCTD Admin' is logged in. The main content area is titled 'Region Master' and contains a table of regions. The table has columns: #, Region Name, Status, Modify On, Edit, and Revert. A row for 'EU' is highlighted in blue. Other rows include CA, CH, GCC, and United States. A row for 'latam region' is marked as Deleted. An 'Add' button is located at the top of the table. The URL in the browser is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Add.Location.do.

#	Region Name	Status	Modify On	Edit	Revert
1	CA	New	Oct-11-2010		
2	CH	New	Dec-23-2013		
3	EU	New	Oct-11-2010		
4	GCC	New	Sep-21-2012		
5	latam region	Deleted	Feb-13-2014		
6	SA	New	Jun-04-2013		
7	United State	New	Jan-07-2014		
8	US	New	Oct-11-2010		

- In edit window, edit the record and click on “Update” button.
- On clicking “Update”, record will be updated as shows below screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-eCTD/Add.location.do#.

The main menu includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile for Hi, eCTD Admin.

The current page is the Region Master. It features a table with columns: #, Region Name, Status, Modify On, Edit, and Revert. The table contains the following data:

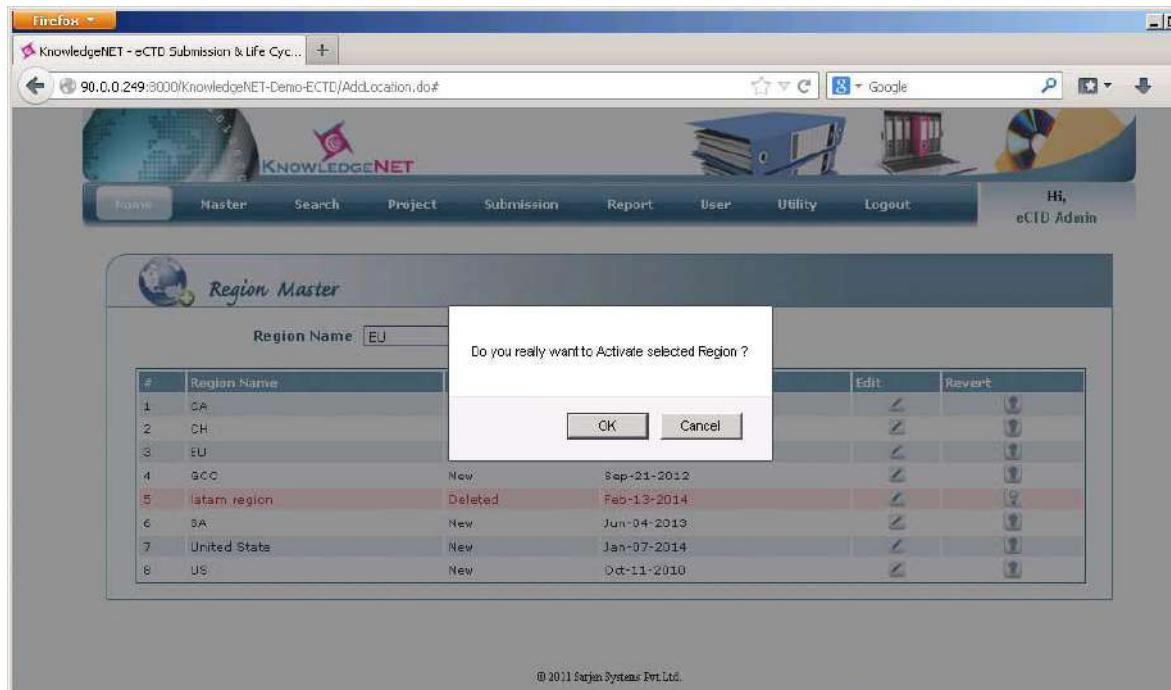
#	Region Name	Status	Modify On	Edit	Revert
1	CA				
2	CH				
3	EU				
4	GCC				
5	latam region				
6	SA				
7	United State				
8	US				

An edit dialog is overlaid on the EU row. The dialog has a title "Edit Region". It contains fields for "Old Region Name" (EU) and "New Region Name" (EU). At the bottom of the dialog is a blue "Update" button.

At the bottom of the page, there is a copyright notice: © 2011 Serjen Systems Pvt Ltd.

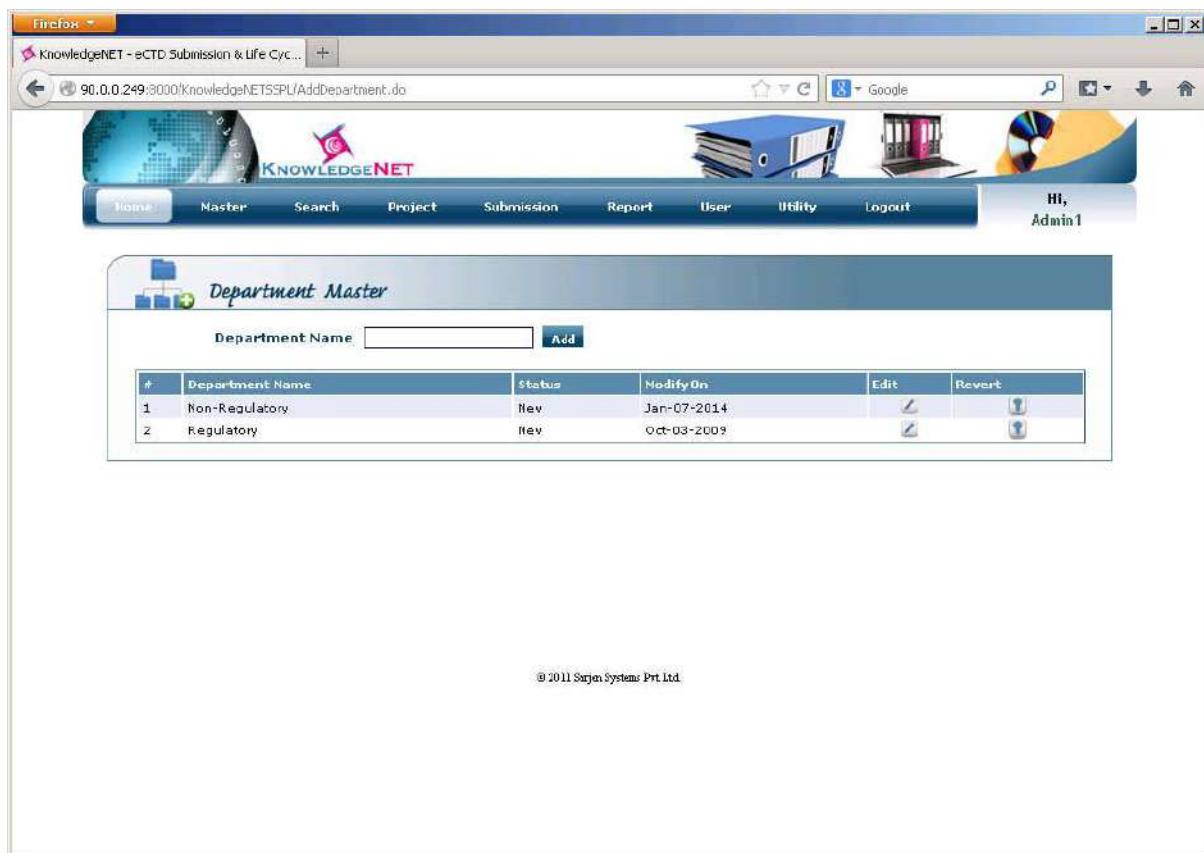
On clicking "Revert"

- On clicking "Revert", Admin will be able to inactivate the record.
- It will display the message window as below.



Master > Department

- Admin will be able to add, edit and deactivate the Department record (Department master).
- For each record, its "status" will be displayed as
 - ✓ For newly added record the status will be "New".
 - ✓ For edited/reactivated record status will be "Edited".
 - ✓ For deactivated record, the status will be "Deleted".
- For each record its modification date will be displayed in "Modify On" column.



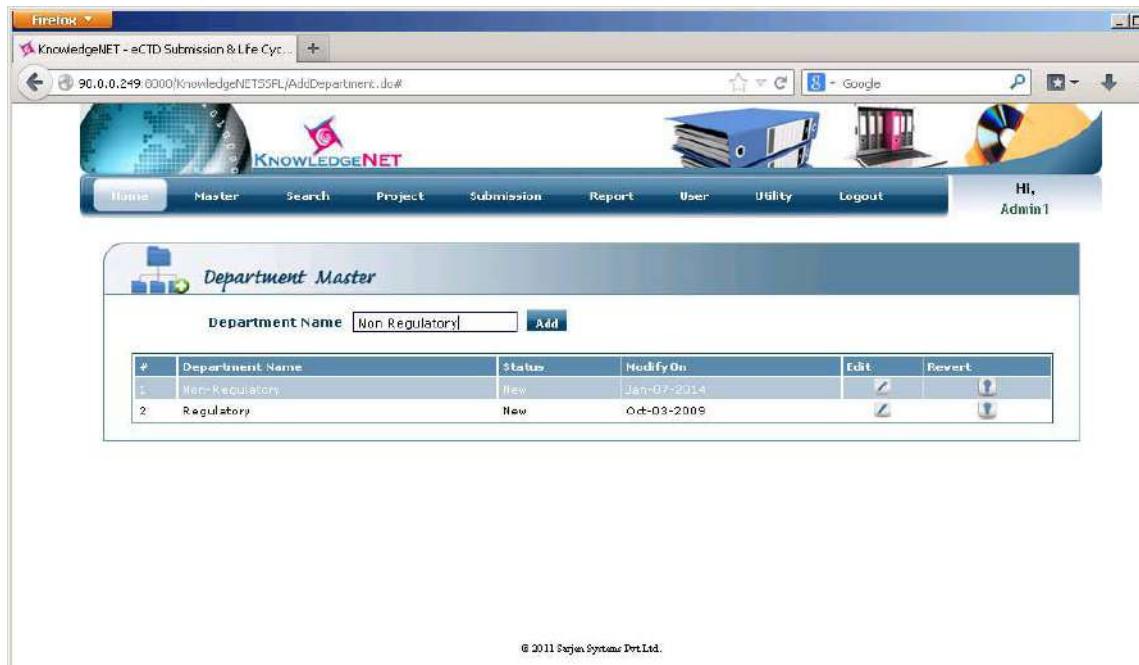
The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET/epl/AddDepartment.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The header includes the KnowledgeNET logo, a search bar, and links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session is shown as "Hi, Admin1". The main content area is titled "Department Master" and contains a form with a "Department Name" input field and an "Add" button. Below the form is a table with two rows of data:

#	Department Name	Status	Modify On	Edit	Revert
1	Non-Regulatory	New	Jan-07-2014		
2	Regulatory	New	Oct-03-2009		

At the bottom of the page, there is a copyright notice: "© 2011 Sarjeet Systems Pvt Ltd."

On adding “Department Name”

- To add the Department name, Admin has to mention the “Department Name” in the text box and click on “Add” button.



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:0000/knowledgeNET55PL/AddDepartment.do#.

The page title is "Department Master". The main content area contains a table with the following data:

#	Department Name	Status	Modify On	Edit	Revert
1	Non-Regulatory	New	Jan-07-2014		
2	Regulatory	New	Oct-03-2009		

The browser status bar at the bottom indicates "© 2011 Surjeet Systems Pvt Ltd."

On Clicking "Edit"**Editing Department Information**

The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Add.location.do#.

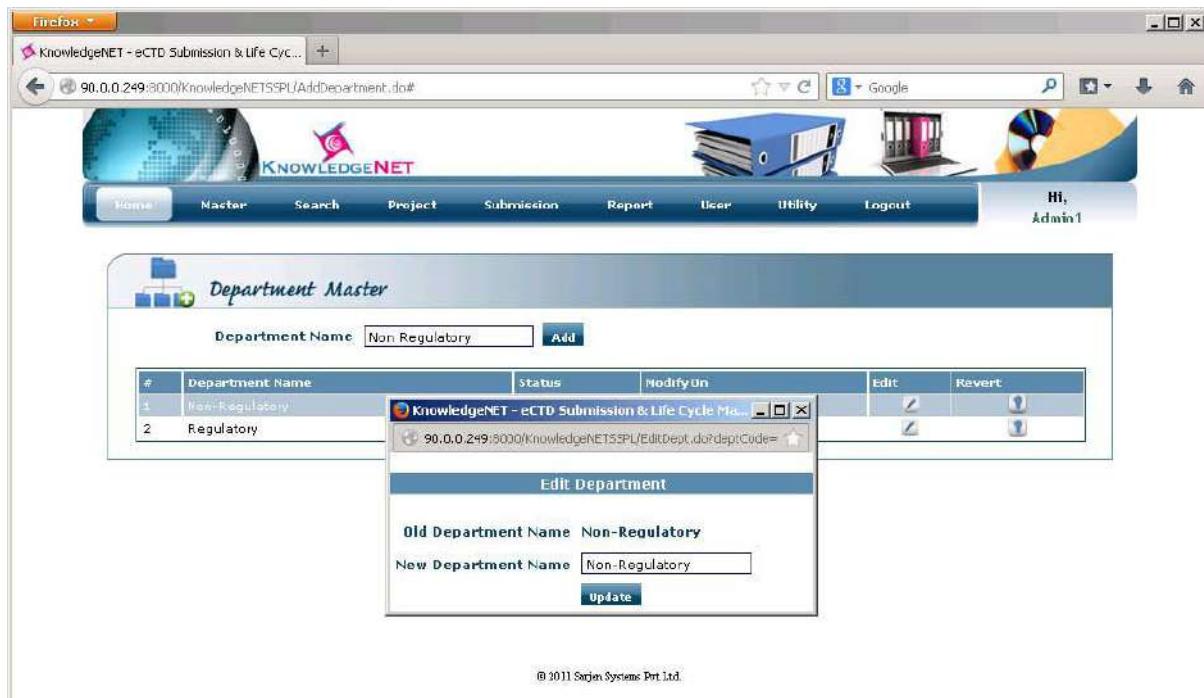
The page title is "Region Master". The header includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile for "Hi, eCTD Admin".

The main content area shows a table titled "Region Master" with the following data:

#	Region Name	Status	Modify On	Edit	Revert
1	CA	New	Oct-11-2010		
2	CH	New	Dec-23-2013		
3	EU	New	Oct-11-2010		
4	GCC	New	Sep-21-2012		
5	latam region	Deleted	Feb-13-2014		
6	SA	New	Jun-04-2013		
7	United States	New	Jan-07-2014		
8	US	New	Oct-11-2010		

At the bottom of the page, there is a copyright notice: "© 2011 Serjen Systems Pvt Ltd."

- In edit window, edit the record and click on "Update" button.
- On clicking "Update", record will be updated as shows below.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNETSSPL/AddDepartment.jsp#.

The main menu bar includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session is indicated by "Hi, Admin1".

The main content area displays the "Department Master" page. It features a table with two rows:

#	Department Name	Status	Modify On	Edit	Revert
1	Non-Regulatory				
2	Regulatory				

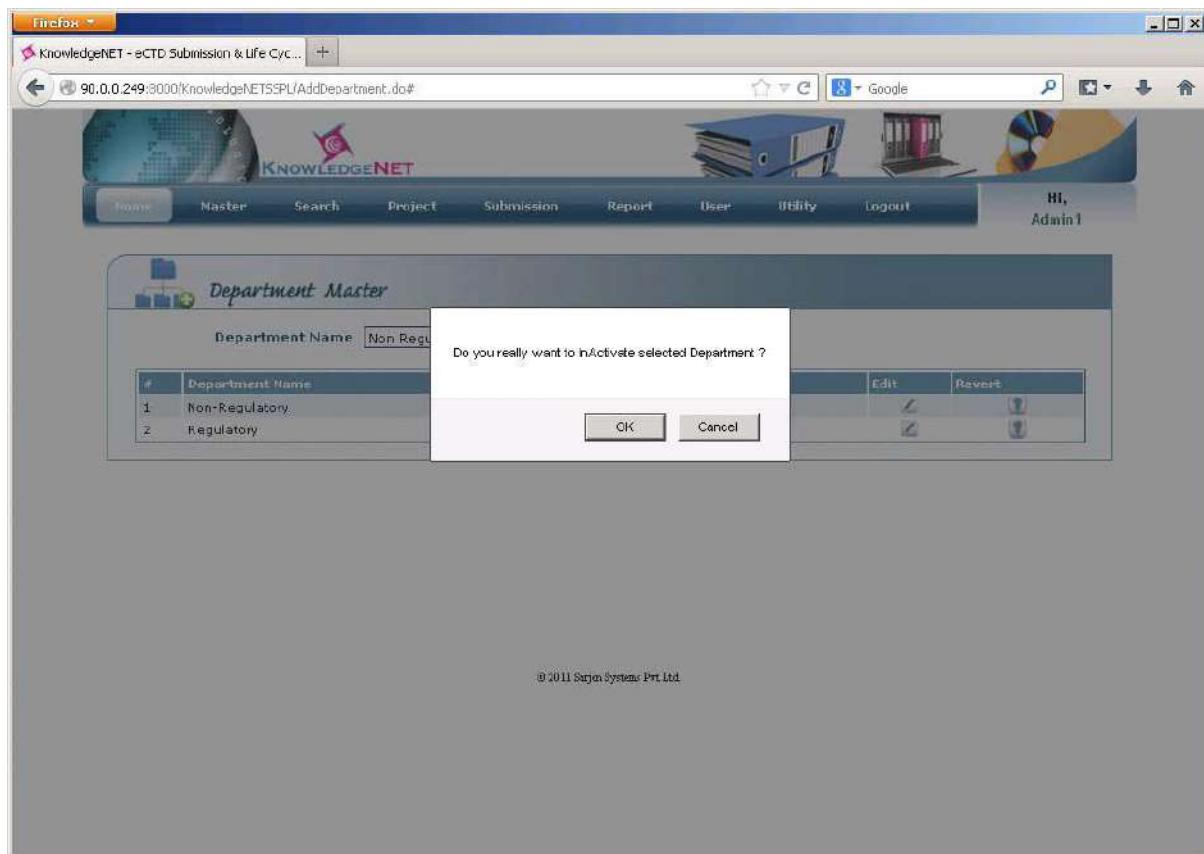
An "Edit Department" dialog box is open over the table, showing the following fields:

Old Department Name: Non-Regulatory
New Department Name: Non-Regulatory

At the bottom of the page, there is a copyright notice: © 2011 Sarjeet Systems Pvt Ltd.

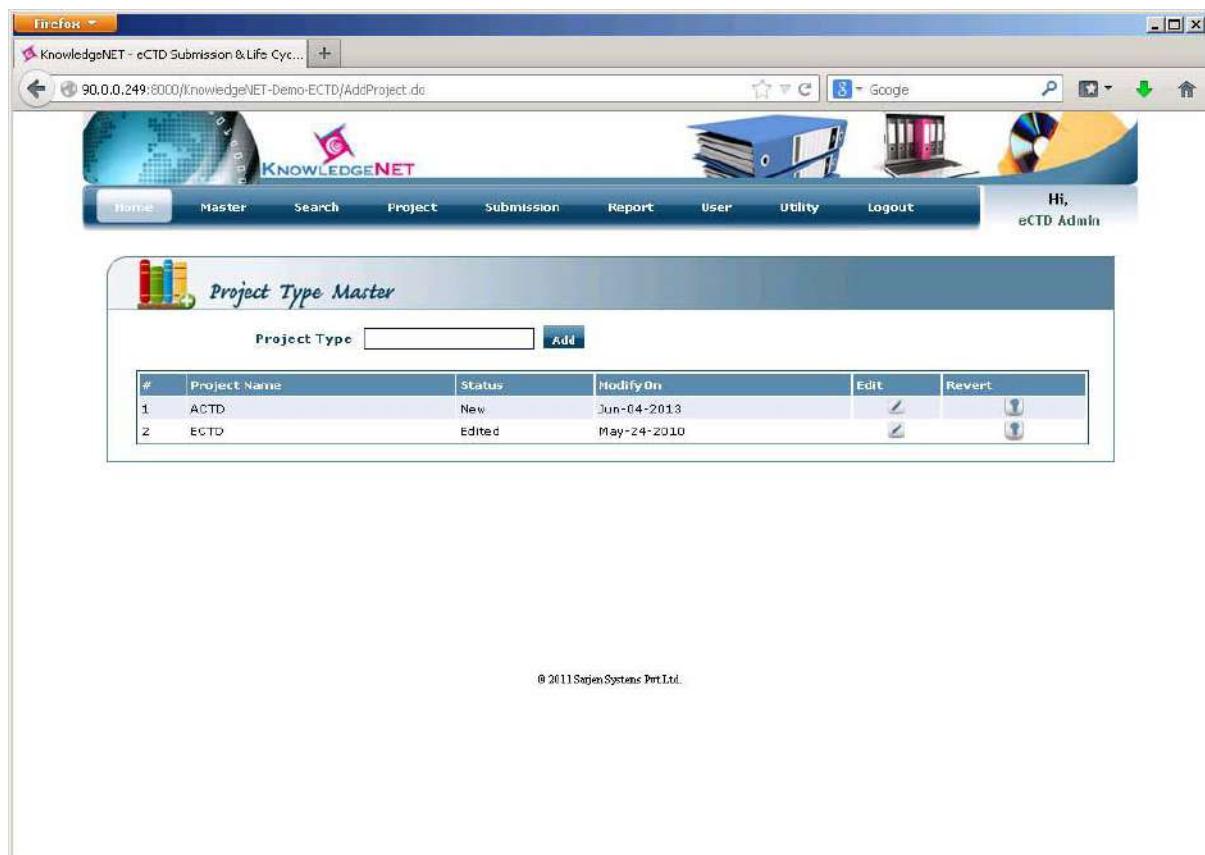
On clicking "Revert"

- On clicking "Revert", Admin will be able to inactivate the record.
- It will display the message window as below.



Master > Project Type

- Admin will be able to add, edit and deactivate the Project Type record (Project Type master).
- For each record, its "status" will be displayed as
 - ✓ For newly added record the status will be "New".
 - ✓ For edited/reactivated record status will be "Edited".
 - ✓ For deactivated record, the status will be "Deleted".
- For each record its modification date will be displayed in "Modify On" column.



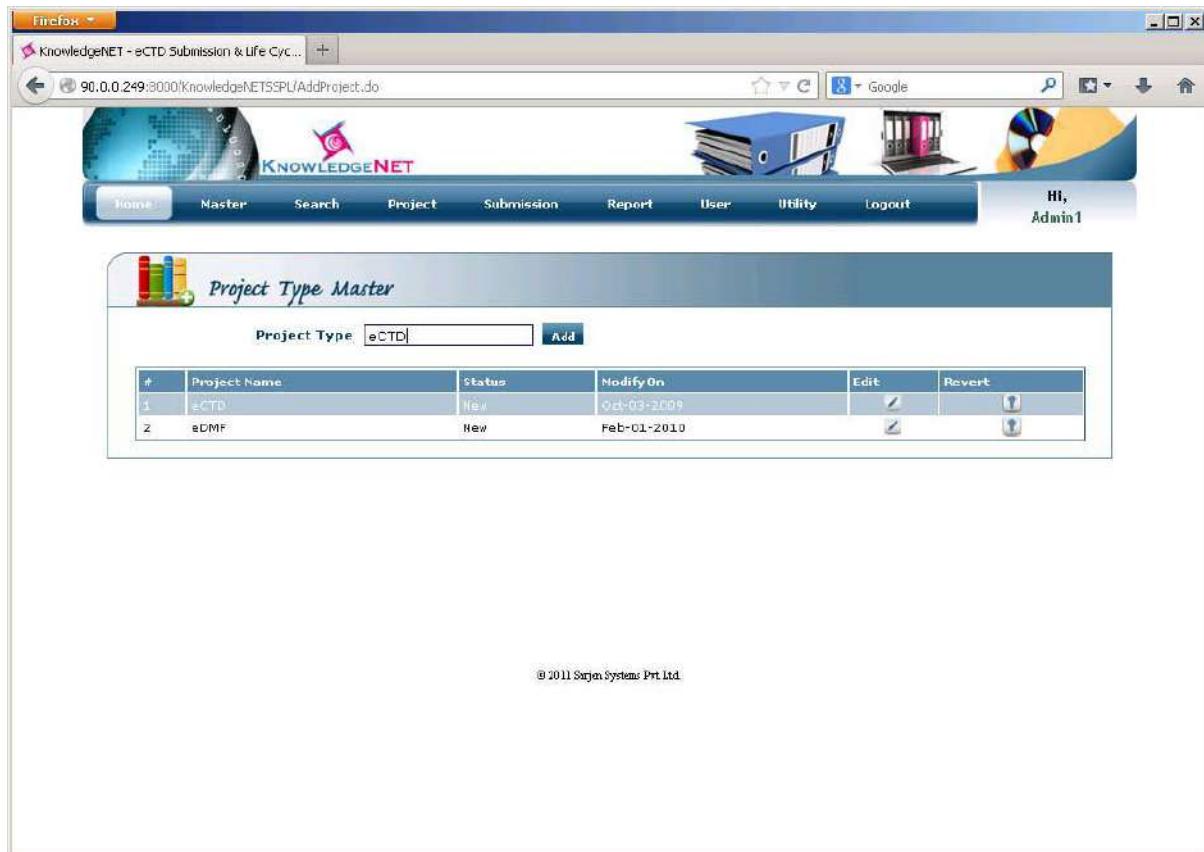
The screenshot shows a Firefox browser window displaying the KnowledgeNET Project Type Master page. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/AddProject.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, eCTD Admin' is visible on the right. The main content area is titled 'Project Type Master' and contains a table with two rows of project type data. The table columns are labeled: #, Project Name, Status, Modify On, Edit, and Revert. The data is as follows:

#	Project Name	Status	Modify On	Edit	Revert
1	ACTD	New	Jun-04-2013		
2	ECTD	Edited	May-24-2010		

At the bottom of the page, a copyright notice reads '© 2011 Sojen Systems Pvt Ltd.'

On adding “Project Type Name”

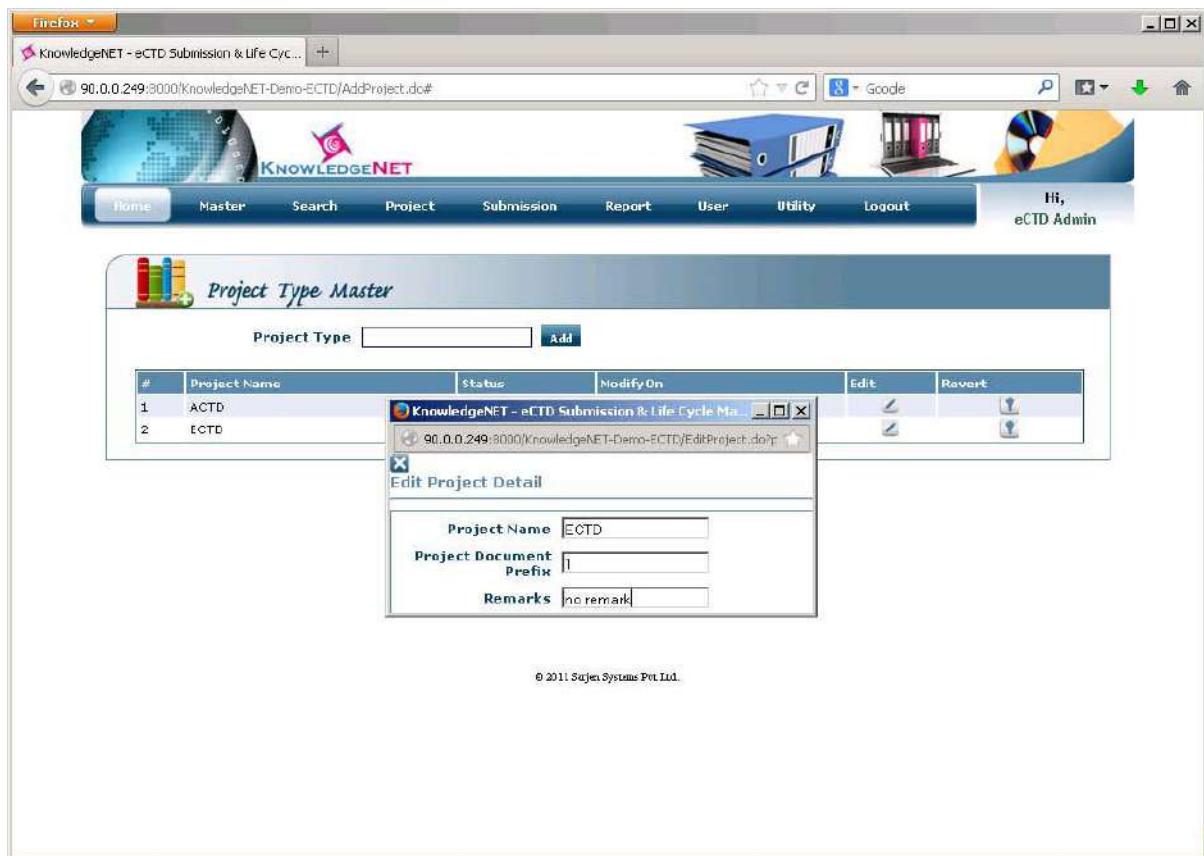
- To add the Department name, Admin has to mention the “Project Type Name” in the text box and click on “Add” button.



The screenshot shows a Firefox browser window displaying the KnowledgeNET Project Type Master page. The URL in the address bar is 90.0.0.249:3000/KnowledgeNETSPL/AddProject.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'Project Type Master' and contains a table with two rows. The first row has a 'Project Name' of 'eCTD' and a 'Status' of 'New'. The second row has a 'Project Name' of 'eDMF' and a 'Status' of 'New'. Below the table is an 'Add' button. At the bottom of the page, there is a copyright notice: '© 2011 Sajen Systems Pvt Ltd.'

#	Project Name	Status	Modify On	Edit	Revert
1	eCTD	New	04-03-2009	<input type="checkbox"/>	<input type="checkbox"/>
2	eDMF	New	Feb-01-2010	<input type="checkbox"/>	<input type="checkbox"/>

- In edit window, edit the record and click on “Update” button.
- On clicking “Update”, record will be updated as shows below.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/AddProject.do#.

The main page title is "Project Type Master". Below it is a table with columns: #, Project Name, Status, Modify On, Edit, and Revert. The table contains two rows:

#	Project Name	Status	Modify On	Edit	Revert
1	ACTD				
2	ECTD				

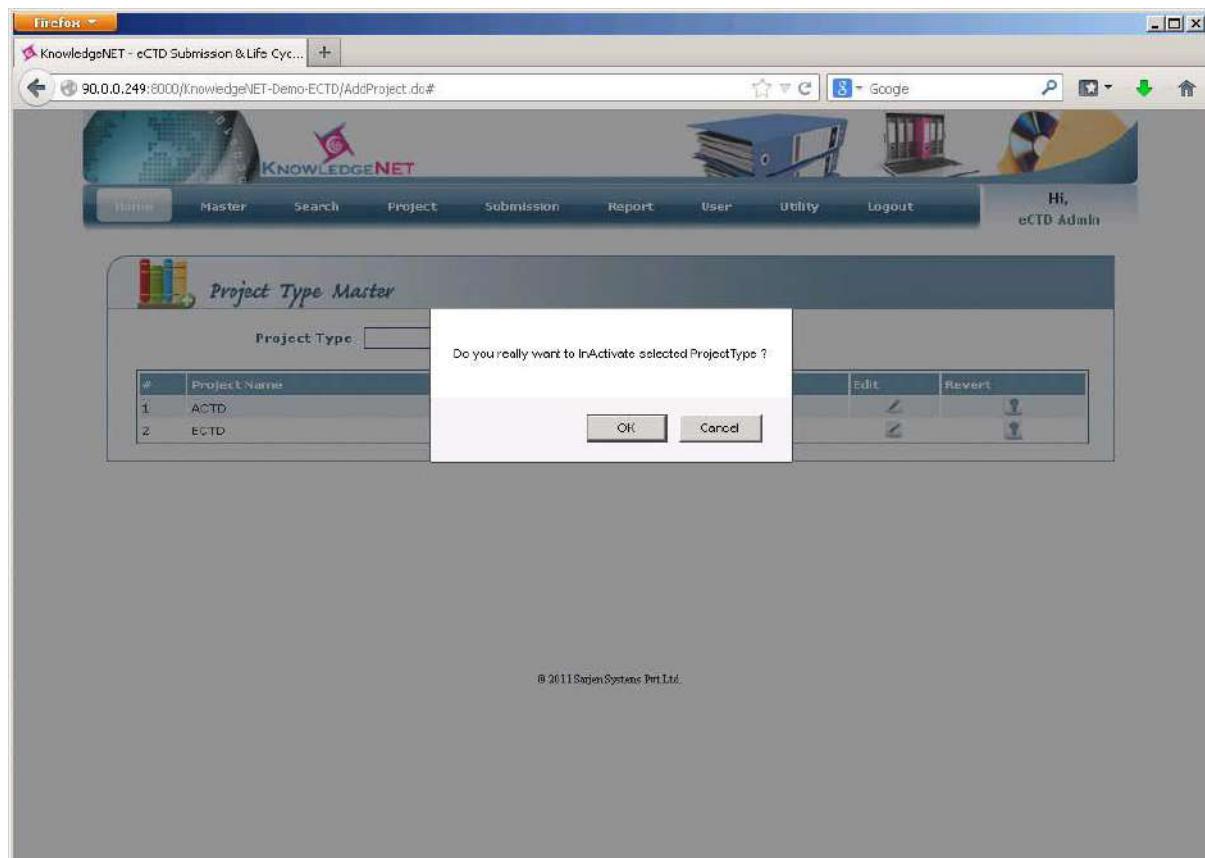
A modal dialog box titled "Edit Project Detail" is open in the foreground. It contains the following fields:

- Project Name: ECTD
- Project Document Prefix: 1
- Remarks: no remark

At the bottom of the page, there is a footer note: "© 2011 Sujen Systems Pvt Ltd."

On clicking “Revert”

- On clicking “Revert”, Admin will be able to inactivate the record.
- It will display the message window as below.



Master > Client

- Admin will be able to add, edit and deactivate the Client record (Client master).
- For each record, its "status" will be displayed as
 - ✓ For newly added record the status will be "New".
 - ✓ For edited/reactivated record status will be "Edited".
 - ✓ For deactivated record, the status will be "Deleted".
- For each record its modification date will be displayed in "Modify On" column.

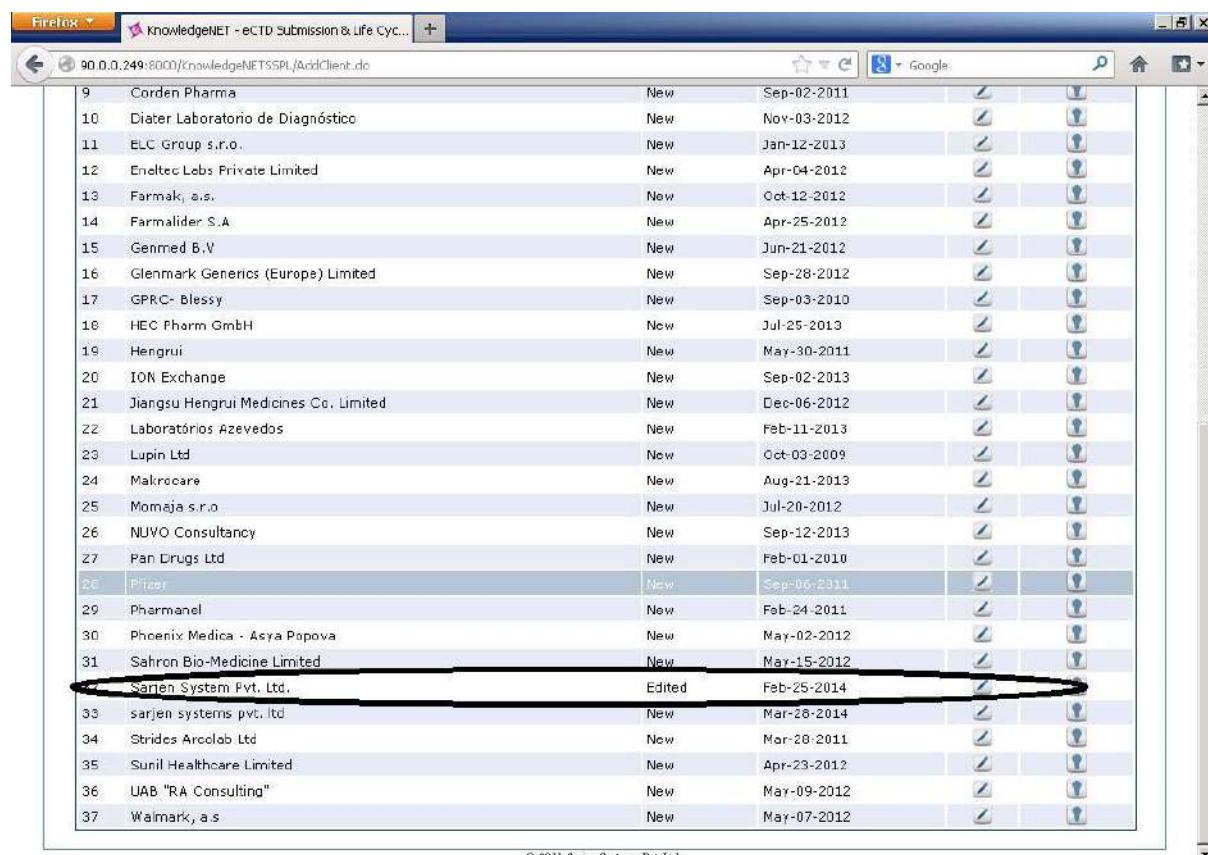
Client Master



#	Client Name	Status	ModifyOn	Edit
1	Sanjen systems pvt Ltd	New	Nov-20-2013	
2	Amneal Pharma Europe Limited	New	May-23-2013	
3	Austar Pharma	New	Aug-09-2013	
4	Cadiasun Pharma GmbH	New	Dec-17-2012	
5	CBG-MEB	Deleted	Jun-21-2012	
6	Celogen	New	Sep-14-2010	
7	Cinfa	New	Jan-08-2010	
8	Cipla	New	Aug-04-2011	
9	Corden Pharma	New	Sep-02-2011	
10	Diater Laboratorio de Diagnóstico	New	Nov-03-2012	

On adding “Client Name”

- To add the Client name, Admin has to mention the “Client Name” in the text box and click on “Add” button.



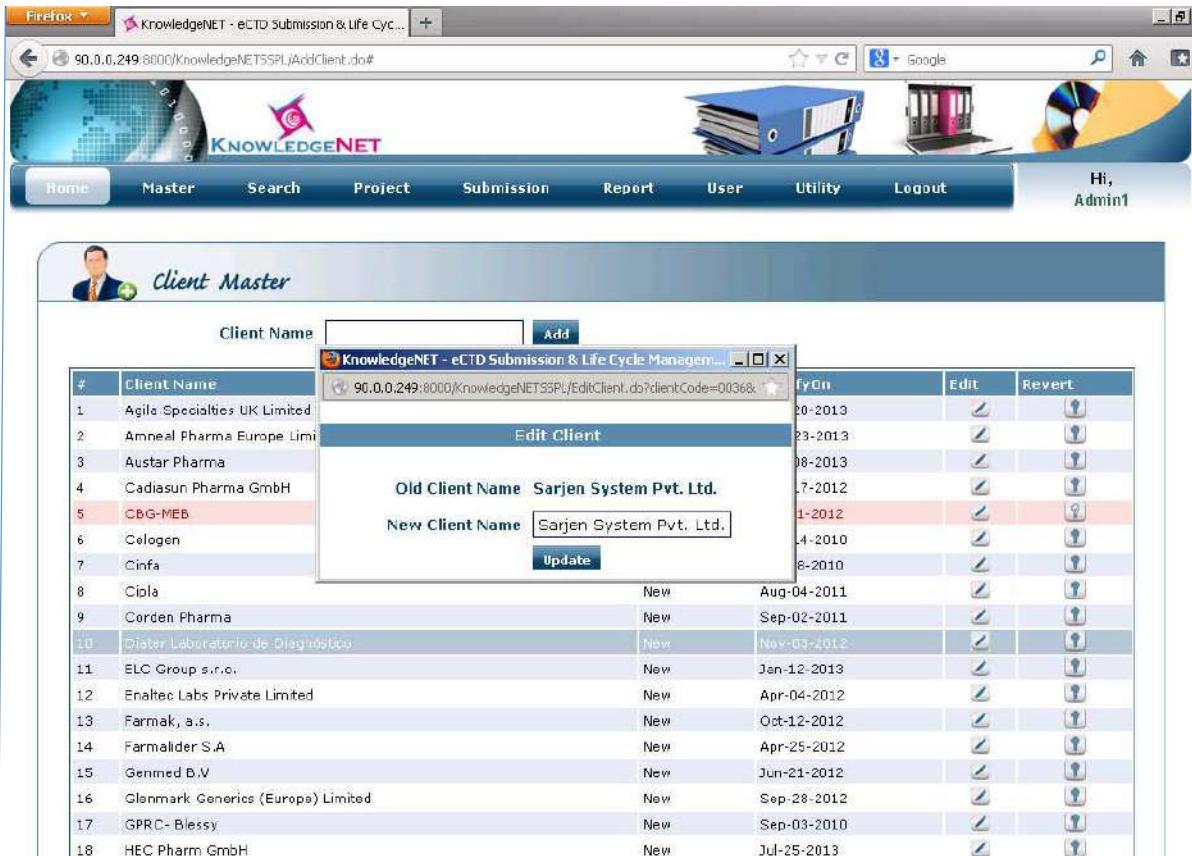
ID	Client Name	Status	Date	Action	Action	Action
9	Corden Pharma	New	Sep-02-2011			
10	Diater Laboratorio de Diagnóstico	New	Nov-03-2012			
11	ELC Group s.r.o.	New	Jan-12-2013			
12	Endotec Labs Private Limited	New	Apr-04-2012			
13	Farmak, a.s.	New	Oct-12-2012			
14	Farmalider S.A	New	Apr-25-2012			
15	Genmed B.V	New	Jun-21-2012			
16	Glenmark Generics (Europe) Limited	New	Sep-28-2012			
17	GPRC- Blessy	New	Sep-03-2010			
18	HEC Pharm GmbH	New	Jul-25-2013			
19	Hengrui	New	May-30-2011			
20	ION Exchange	New	Sep-02-2013			
21	Jiangsu Hengrui Medicines Co. Limited	New	Dec-06-2012			
22	Laboratórios Azevedos	New	Feb-11-2013			
23	Lupin Ltd	New	Oct-03-2009			
24	Makrocare	New	Aug-21-2013			
25	Momaja s.r.o	New	Jul-20-2012			
26	NUVO Consultancy	New	Sep-12-2013			
27	Pan Drugs Ltd	New	Feb-01-2010			
28	Pfizer	New	Sep-06-2011			
29	Pharmanet	New	Feb-24-2011			
30	Phoenix Medica - Asya Papova	New	May-02-2012			
31	Sahron Bio-Medicine Limited	New	May-15-2012			
32	Sarjen System Pvt. Ltd.	Edited	Feb-25-2014			
33	sarjen systems pvt. ltd	New	Mar-28-2014			
34	Strides Arcolab Ltd	New	Mar-28-2011			
35	Sunil Healthcare Limited	New	Apr-23-2012			
36	UAB "RA Consulting"	New	May-09-2012			
37	Walmark, a.s	New	May-07-2012			

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On clicking “Edit”

Editing Client Information

- On clicking “Edit”, User will be able to edit the Client record.
- It will display an edit window.



The screenshot shows a web browser window for Firefox displaying the KnowledgeNET Client Master interface. The URL in the address bar is 90.0.0.249:8000/KnowledgeNETSSPL/AddClient.do#.

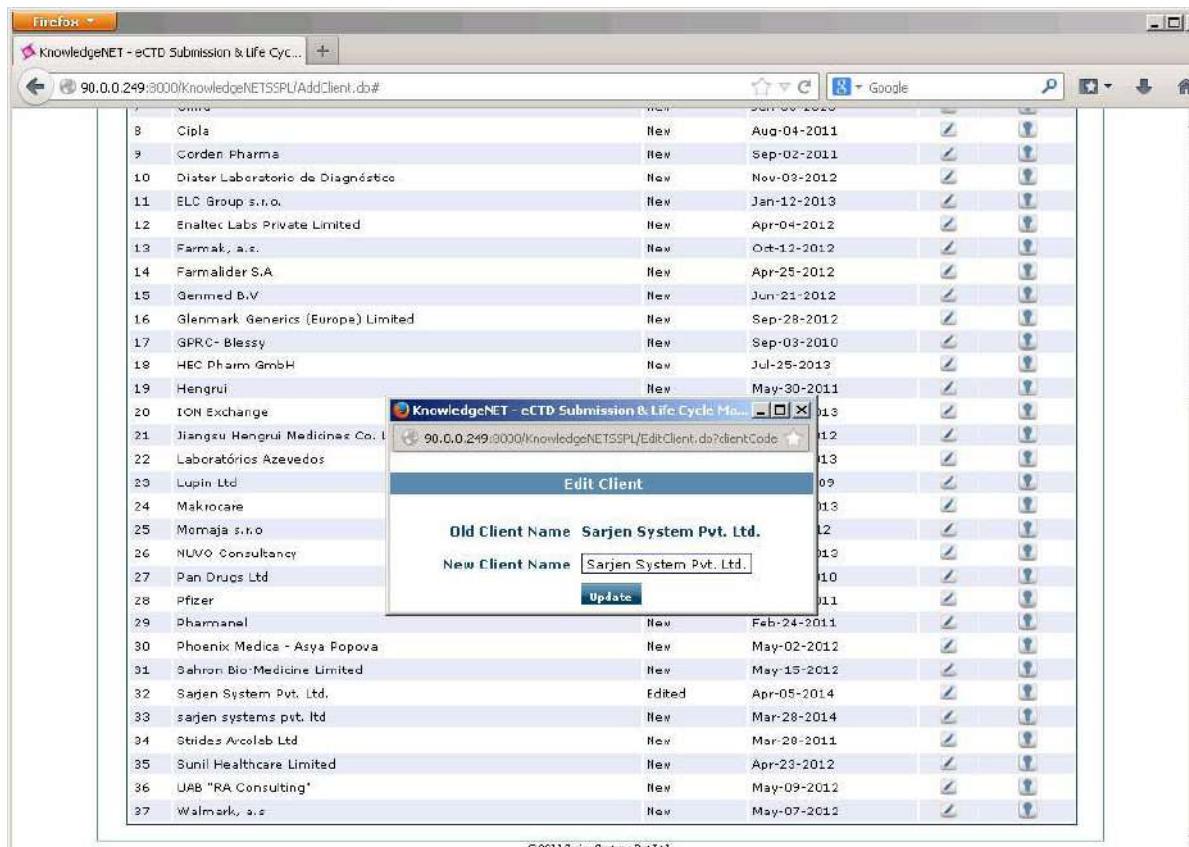
The main menu at the top includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session is indicated as Hi, Admin1.

The Client Master page lists 18 clients with their names and IDs. The client "CBG-MEB" is selected and highlighted in pink. An "Edit" button is visible next to its row.

A modal dialog box titled "Edit Client" is open over the list. It contains fields for "Old Client Name" (Sarjen System Pvt. Ltd.) and "New Client Name" (Sarjen System Pvt. Ltd.). Below these fields is an "Update" button.

To the right of the list, there is a table showing a history of changes with columns for "Fy On", "Edit", and "Revert". The table entries show various dates from 2010 to 2013, each with edit and revert icons.

- In edit window, edit the record and click on “Update” button.
- On clicking “Update”, record will be updated as shows below.



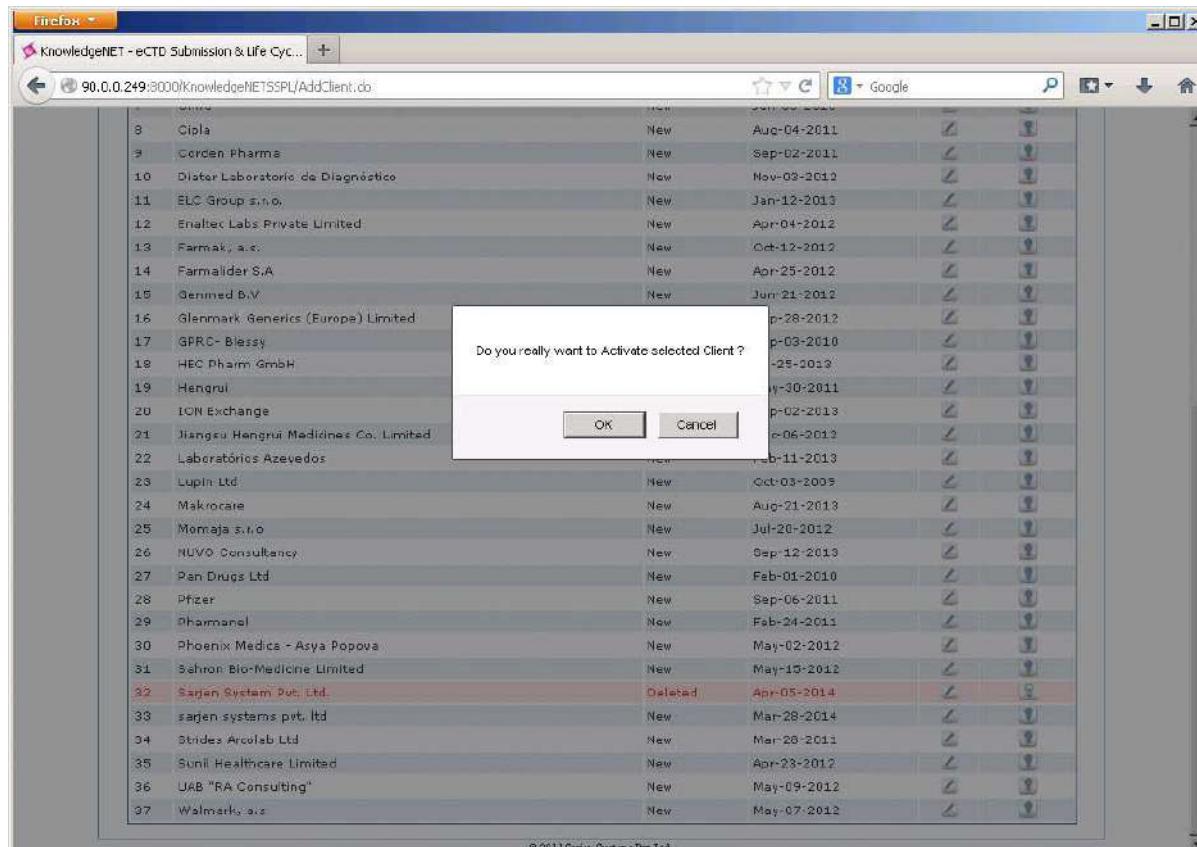
The screenshot shows a web-based application interface for managing clients. The main window displays a grid of client records with columns for ID, Client Name, Status, and Last Update Date. A modal dialog box titled "Edit Client" is open over the grid, showing fields for "Old Client Name" (Sarjen System Pvt. Ltd.) and "New Client Name" (Sarjen System Pvt. Ltd.). An "Update" button is visible at the bottom of the dialog. The URL in the browser bar is 90.0.0.249:8000/KnowledgeNETSSPL/EditClient.do?clientCode=13.

ID	Client Name	Status	Last Update
8	Cipla	New	Aug-04-2011
9	Corden Pharma	New	Sep-02-2011
10	Distar Laboratorio de Diagnóstico	New	Nov-03-2012
11	ELC Group s.r.o.	New	Jan-12-2013
12	Enaltec Labs Private Limited	New	Apr-04-2012
13	Farmak, a.s.	New	Oct-12-2012
14	Farmalider S.A	New	Apr-25-2012
15	Gennmed B.V	New	Jun-21-2012
16	Glenmark Generics (Europe) Limited	New	Sep-28-2012
17	GPR.C - Blessy	New	Sep-03-2010
18	HEC Pharm GmbH	New	Jul-25-2013
19	Hengrui	New	May-30-2011
20	ION Exchange	New	
21	Jiangsu Hengrui Medicines Co. Ltd.	New	
22	Laboratórios Azevedos	New	
23	Lupin Ltd	New	
24	Makrocare	New	
25	Momaja s.r.o	New	
26	NUVO Consultancy	New	
27	Pan Drugs Ltd	New	
28	Pfizer	New	
29	Pharmenol	New	Feb-24-2011
30	Phoenix Medica - Asya Popova	New	May-02-2012
31	Sahron Bio-Medicine Limited	New	May-15-2012
32	Sarjen System Pvt. Ltd.	Edited	Apr-05-2014
33	sarjen systems pvt. ltd	New	Mar-28-2014
34	Strides Avolab Ltd	New	Mar-28-2011
35	Sunil Healthcare Limited	New	Apr-23-2012
36	UAB "RA Consulting"	New	May-09-2012
37	Walmark, a.s	New	May-07-2012

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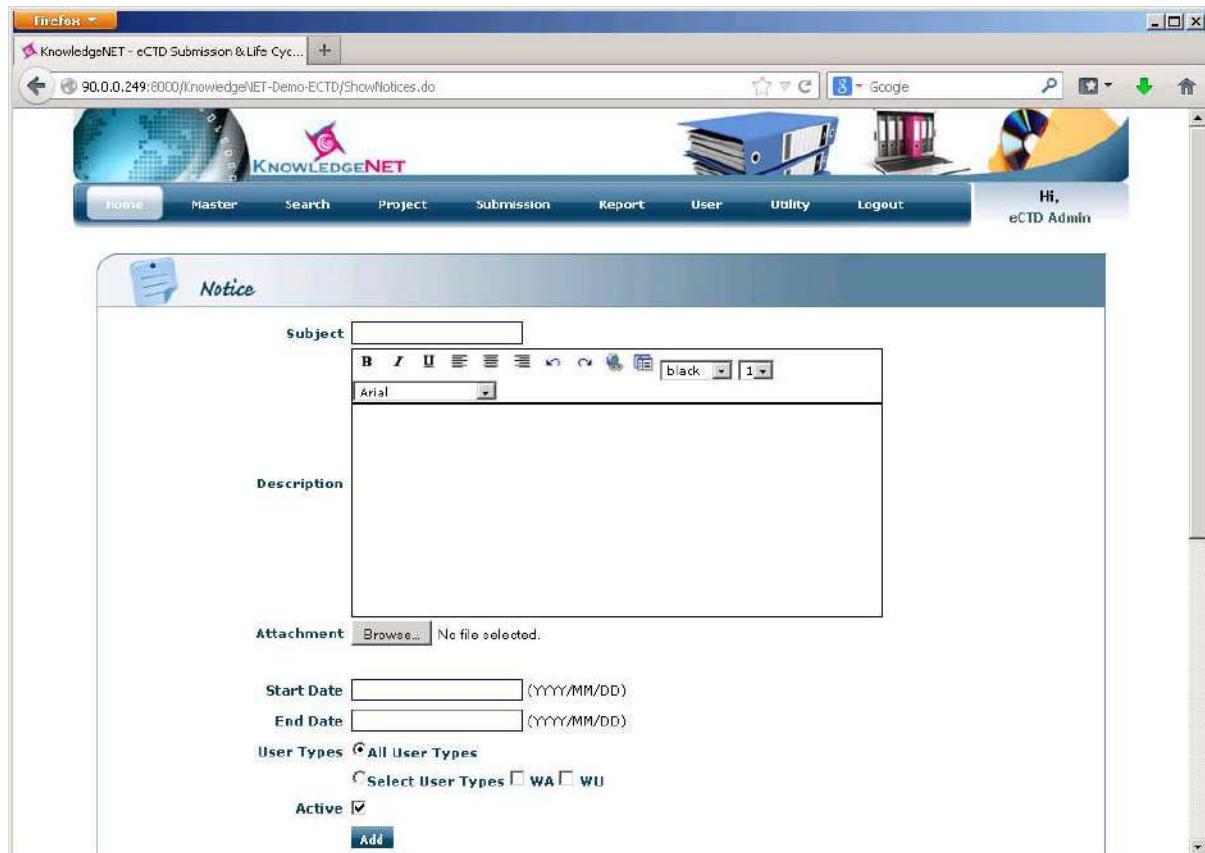
On clicking "Revert"

- On clicking "Revert", Admin will be able to inactivate the record.
- It will display the message window as below.



Master> Notice

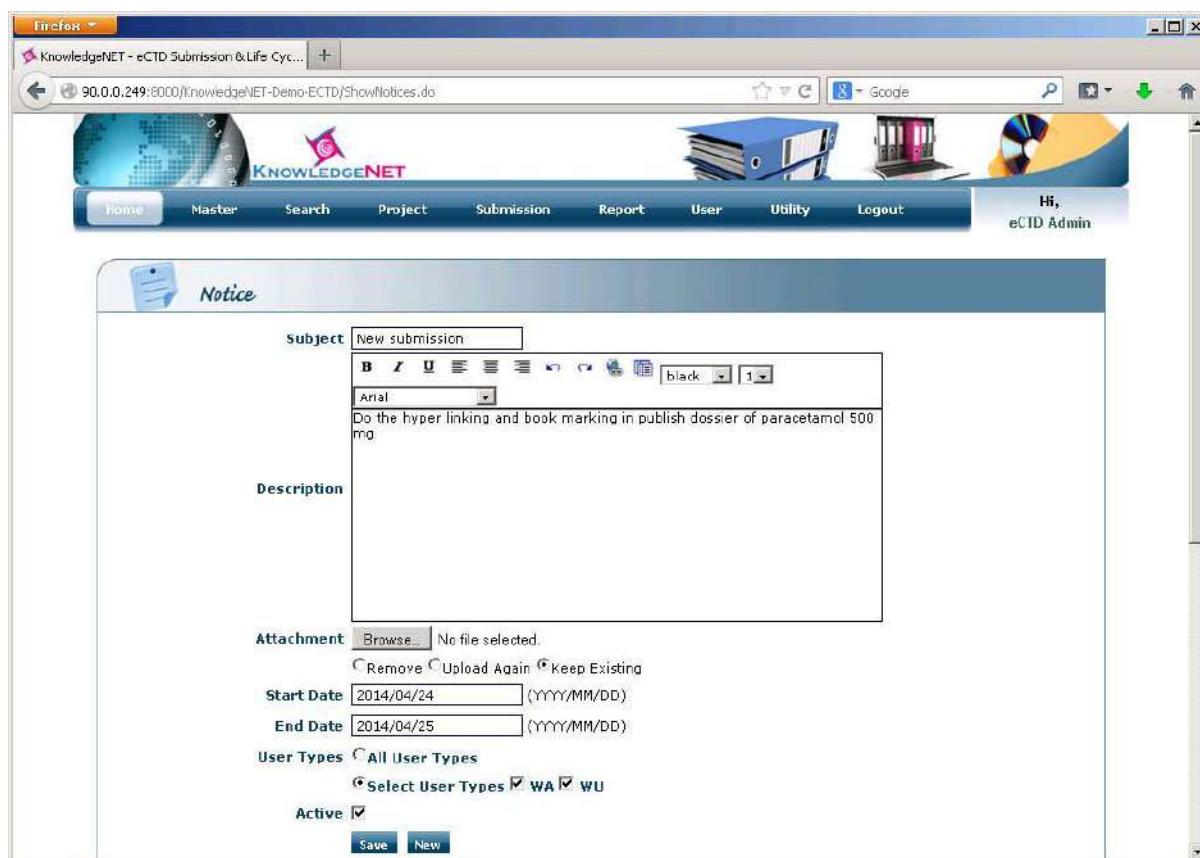
- After click on Master> Notice, the below screen get display.



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD>ShowNotices.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The main content area is titled "Notice". It contains fields for "Subject" (with a rich text editor), "Description" (a large text area), "Attachment" (a browse button showing "No file selected"), and date fields for "Start Date" and "End Date" (both in YYYY/MM/DD format). There are radio buttons for "User Types": "All User Types" (selected) and "Select User Types" (with checkboxes for "WA" and "WU"). A checkbox for "Active" is checked, and a "Add" button is at the bottom.

- Admin1 can set a notice for a specific user for a specific time period.
- The set notice show on dashboard of user from start date to end date of notice.

- Fulfill the all required information such as Subject of Notice, Description and Reference file, Notice start date to end date (display on dashboard) and User (all user and/or WA or WU) and if user want to active the notice then click on 'Active' check box.
- After that just click on 'Add'.

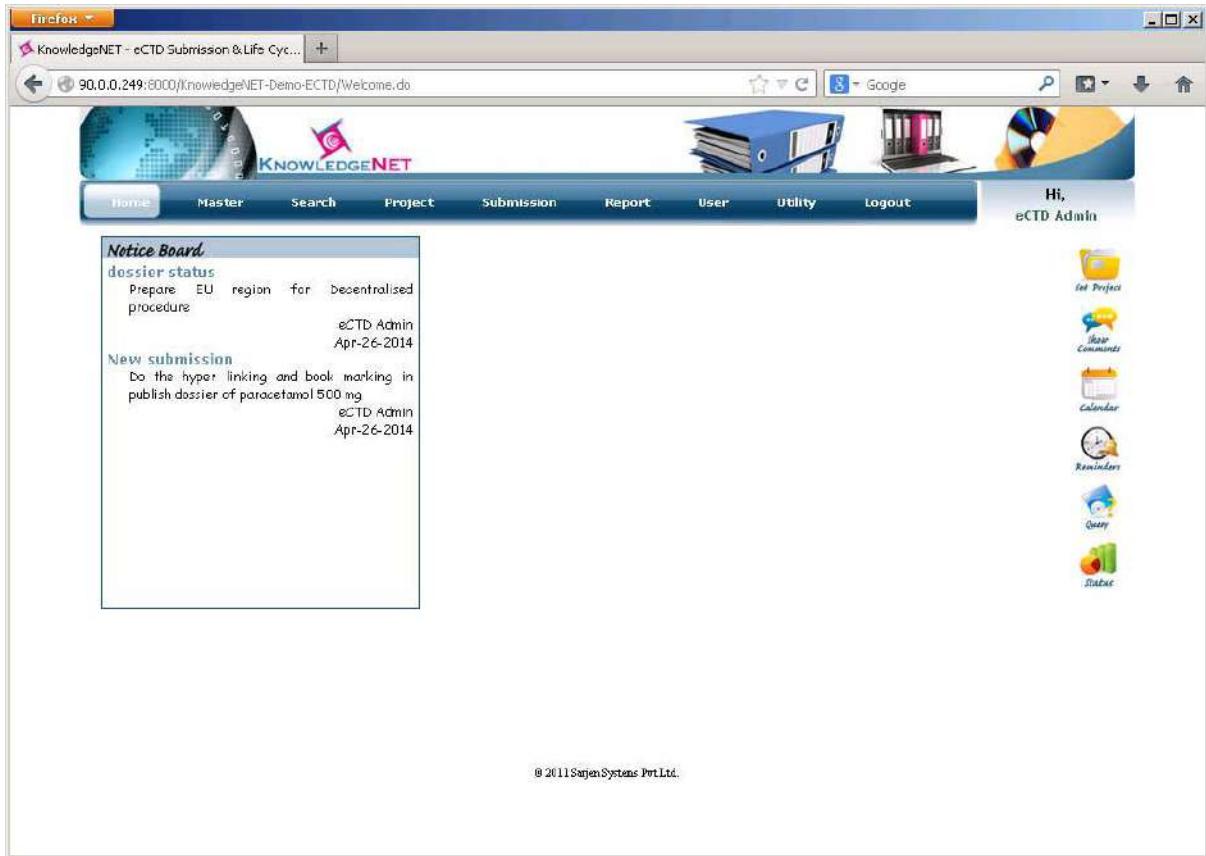


The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD>ShowNotices.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The header includes the KnowledgeNET logo, a search bar, and links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a welcome message for "eCTD Admin". The main content area is titled "Notice" and contains the following fields:

- Subject:** New submission
- Description:** Do the hyper linking and book marking in publish dossier of paracetamol 500 mg
- Attachment:** Browse... No file selected
- Start Date:** 2014/04/24 (YYYY/MM/DD)
- End Date:** 2014/04/25 (YYYY/MM/DD)
- User Types:** All User Types Select User Types WA WU
- Active:**

At the bottom are "Save" and "New" buttons.

- If Notice activate than show on dashboard.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/Welcome.do. The dashboard features a blue header with the KnowledgeNET logo and various navigation links: Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, eCTD Admin' is displayed next to a user icon. On the left, there is a 'Notice Board' section containing two items:

- dossier status**
Prepare EU region for Decentralised procedure
eCTD Admin
Apr-26-2014
- New submission**
Do the hyper linking and book marking in publish dossier of paracetamol 500 mg
eCTD Admin
Apr-26-2014

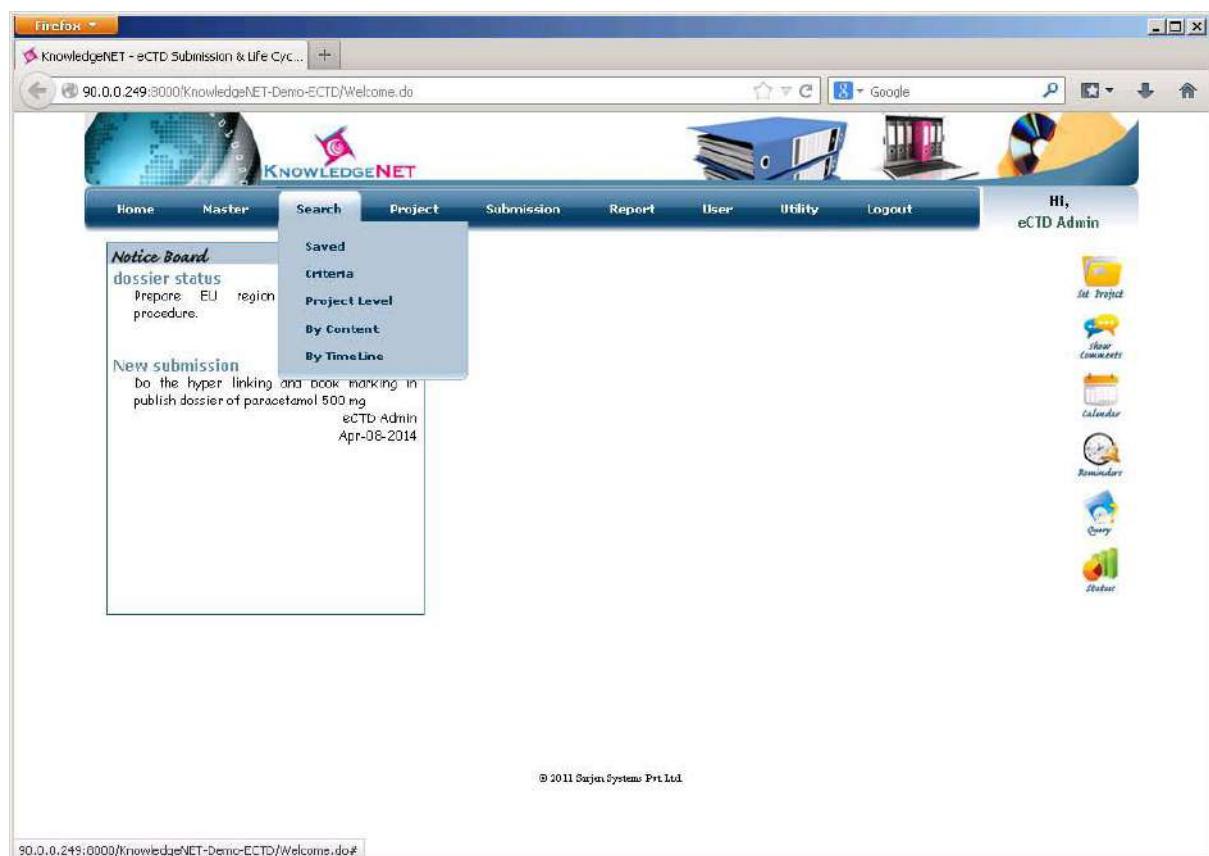
On the right side of the dashboard, there is a sidebar with icons for different functions: 'Edit Projects', 'New Comments', 'Calendar', 'Reminders', 'Query', and 'Status'. At the bottom center of the page, the copyright notice '@ 2011 Sarjen Systems Pvt Ltd.' is visible.

Note: if user not want to activate the notice than uncheck the Active box

Search Menu

- “Search” Menu will display the submenu items as shows: -

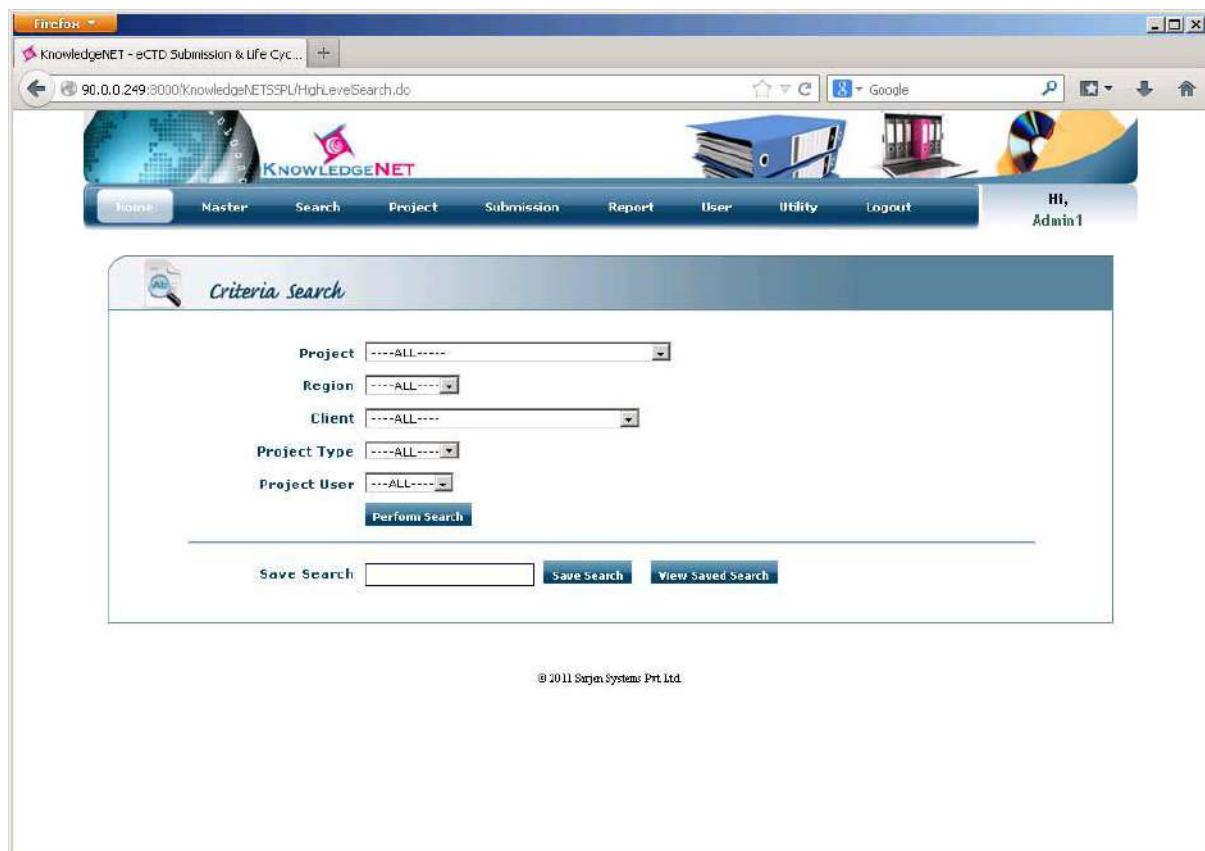
- Saved
- Criteria
- Project Level
- By Content
- By Timeline



- ❖ **Admin can perform criteria search through “Criteria Search”**
- ❖ **Criteria search is search performed on the basis of certain criteria of selection.**

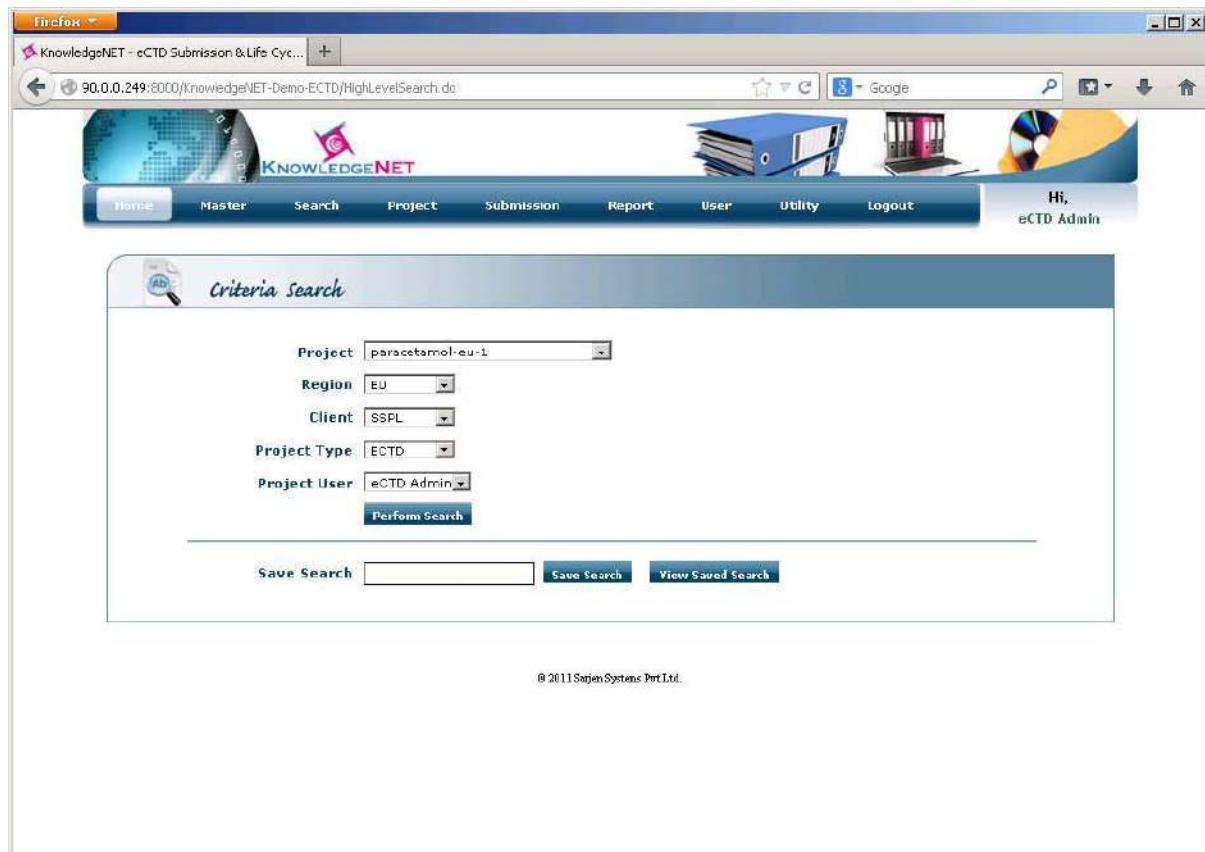
Search >Criteria

- The main page for ‘Content Search’ will get displayed.
- User can search the project by selecting some searching criteria such as “Project Name”, “Region”, “Client”, In the below screen, Admin has to mention “Project Name”, “Region”, “Client”, and select the “Project Type”, “Project User”, .



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSPL/HighLevelSearch.do. The page title is "Criteria search". The interface includes a header with the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, Admin1" is displayed on the right. The main content area contains five dropdown menus labeled "Project", "Region", "Client", "Project Type", and "Project User", all currently set to "----ALL----". Below these is a "Perform Search" button. At the bottom, there are "Save Search" and "View Saved Search" buttons. The footer of the page includes the text "© 2011 Sejjen Systems Pvt Ltd."

- After filling all the required details, click on “Perform Search” button and information related to project shows in below screen.



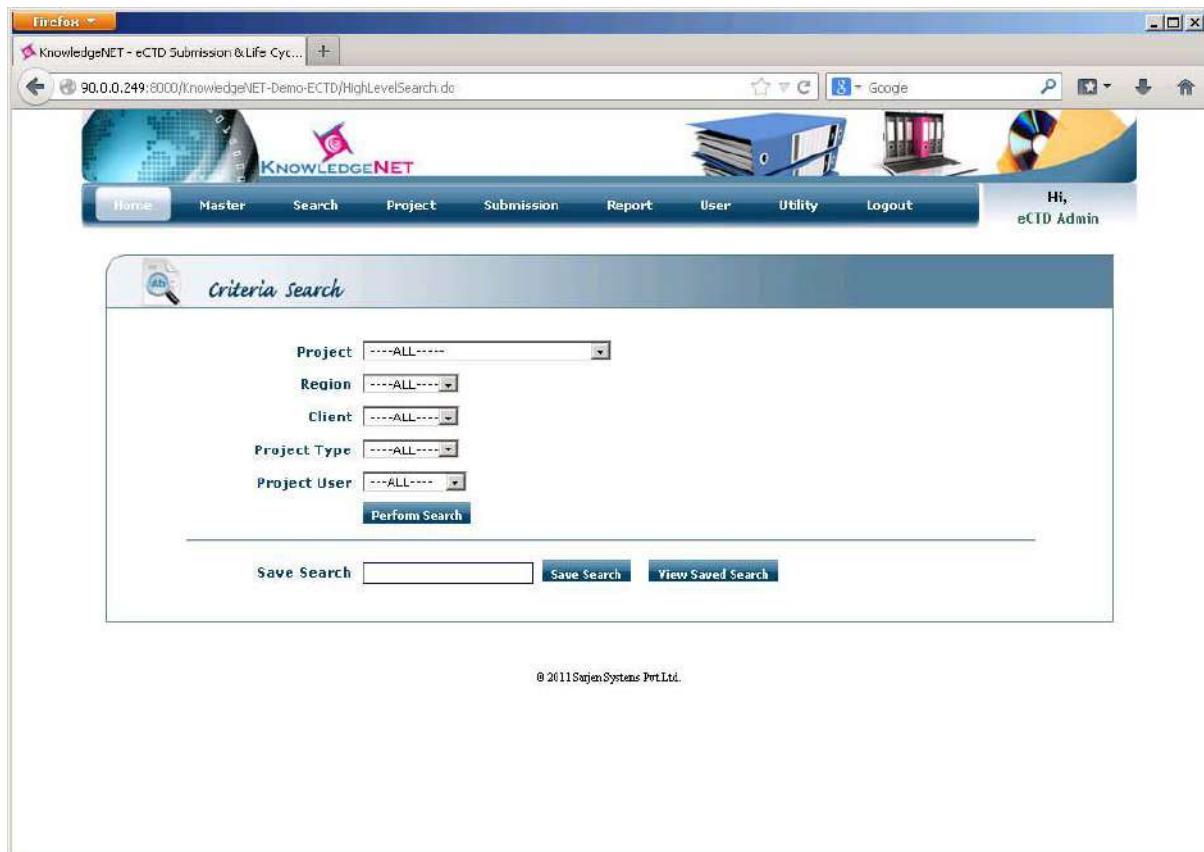
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/HighLevelSearch.do. The page title is "Criteria Search". The header includes the KnowledgeNET logo, a navigation menu with links to Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, and a greeting "Hi, eCTD Admin". The main content area contains a form with the following fields:

- Project: dropdown menu set to "paracetamol-eu-1"
- Region: dropdown menu set to "EU"
- Client: dropdown menu set to "SSPL"
- Project Type: dropdown menu set to "eCTD"
- Project User: dropdown menu set to "eCTD Admin"

A "Perform Search" button is located below the form. At the bottom of the search area, there are three buttons: "Save Search" (with an input field), "Save Search", and "View Saved Search". A copyright notice at the bottom of the page reads "© 2011 Sojourn Systems Pvt Ltd."

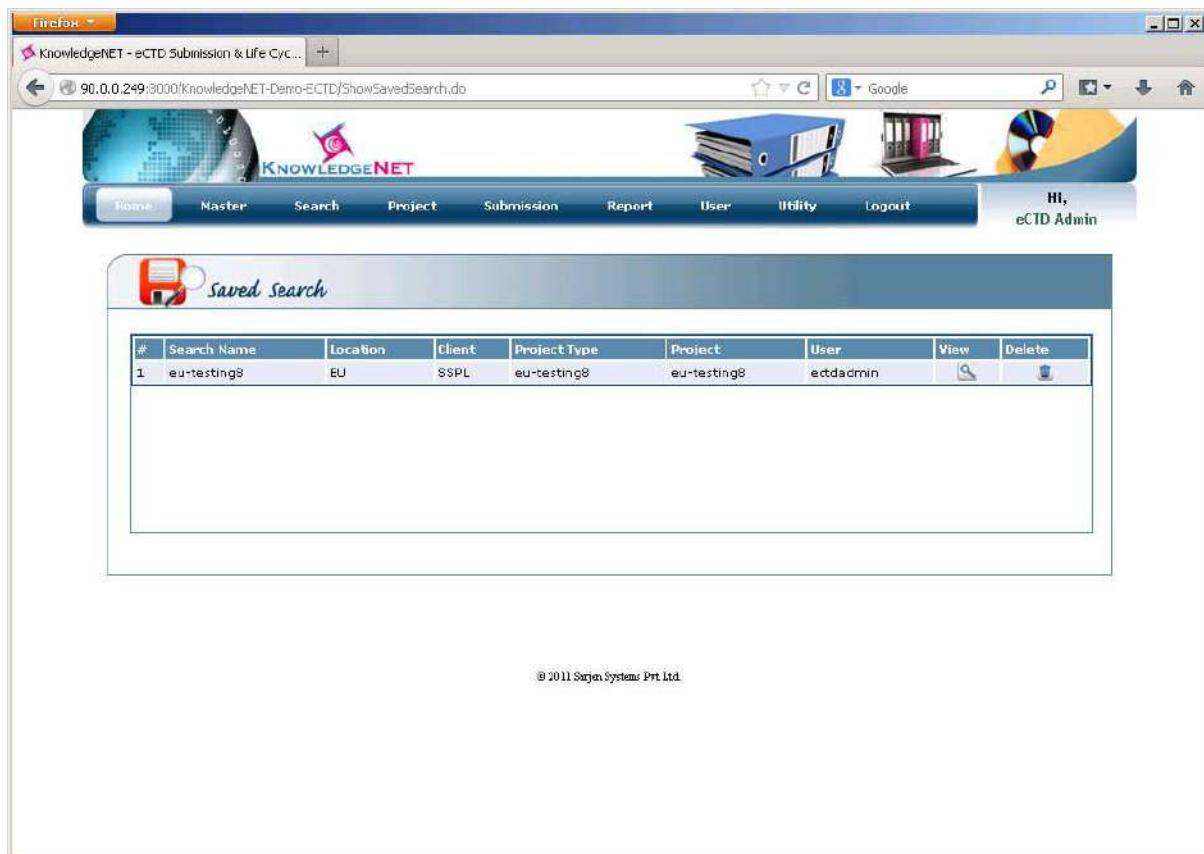
Criteria Search: Save Search

- After perform the criteria search, save the search by enter the search term in save search option



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/HighLevelSearch.do. The page title is "Criteria Search". The interface includes a header with the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session message "Hi, eCID Admin" is visible on the right. The main content area contains a form titled "Criteria Search" with dropdown menus for Project, Region, Client, Project Type, and Project User, all currently set to "----ALL----". Below the dropdowns is a "Perform Search" button. At the bottom of the form are three buttons: "Save Search" (with an input field), "Save Search", and "View Saved Search". A copyright notice at the bottom of the page reads "© 2011 Sarjen Systems Pvt Ltd."

- After filling the save search, click on “Save Search” button and information related to project is saved, and to view the saved project, click on “view Saved Search” as shows in below screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD>ShowSavedSearch.do. The page title is "Saved search". The header includes the KnowledgeNET logo, a navigation menu with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, and a welcome message "Hi, eCTD Admin". Below the header is a table titled "Saved search" with the following data:

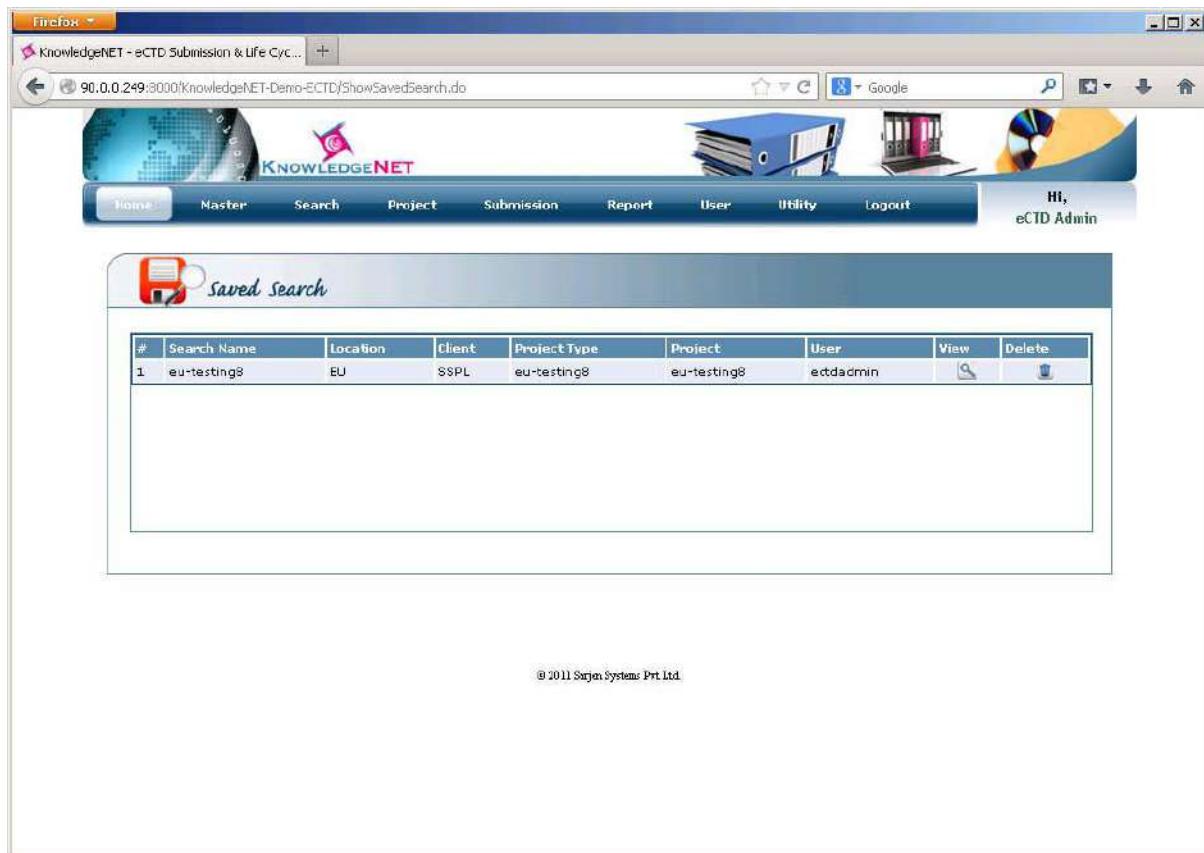
#	Search Name	Location	Client	Project Type	Project	User	View	Delete
1	eu-testing8	EU	SSPL	eu-testing8	eu-testing8	eCTDadmin		

At the bottom of the page, there is a copyright notice: "© 2011 Serjen Systems Pvt Ltd."

❖ **In Saved Search, it will display the saved search**

Search >Saved Search

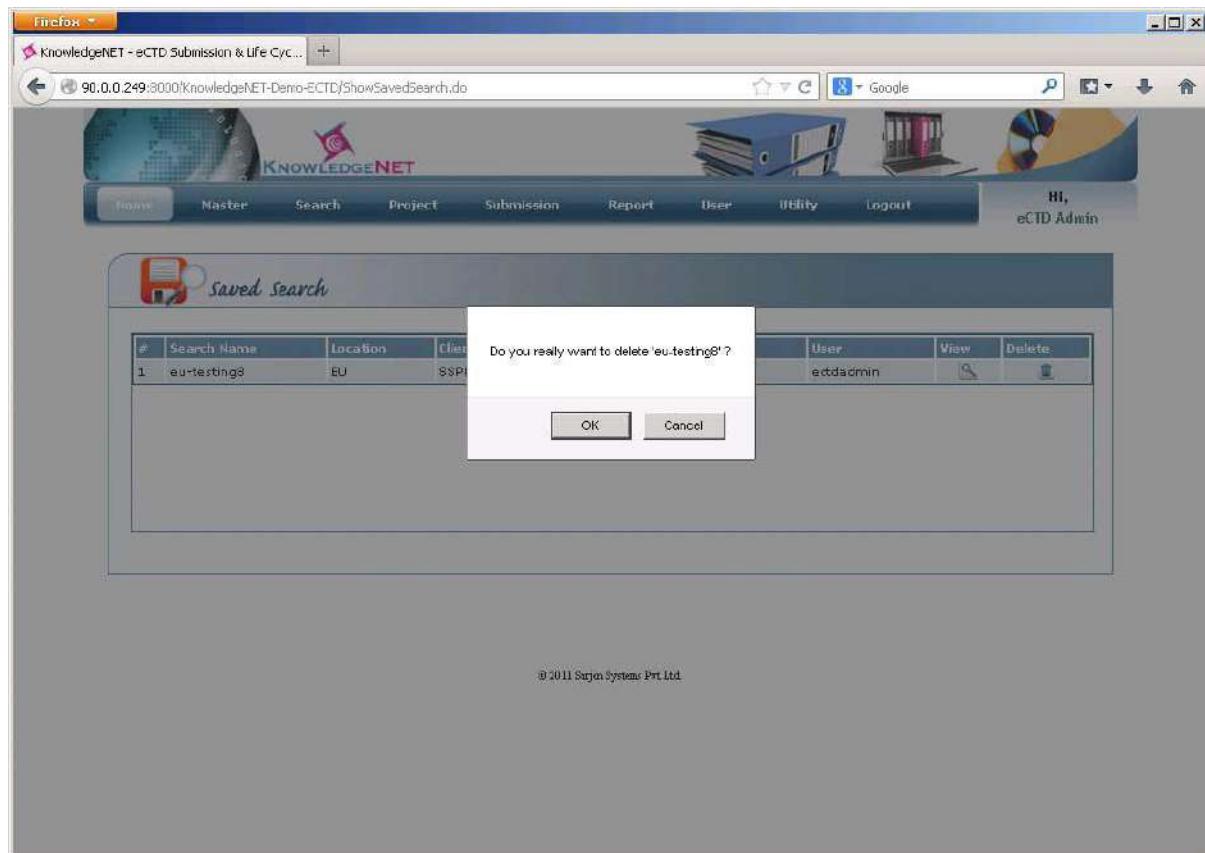
- On clicking “Save Search”, search result data will be saved.
- On clicking “View Saved Search”, it will show the saved search data (saved search)



#	Search Name	Location	Client	Project Type	Project	User	View	Delete
1	eu-testing8	EU	SSPL	eu-testing8	eu-testing8	ectdadmin		

- Here, Admin user will be able to access the search result saved based on a specific criteria.

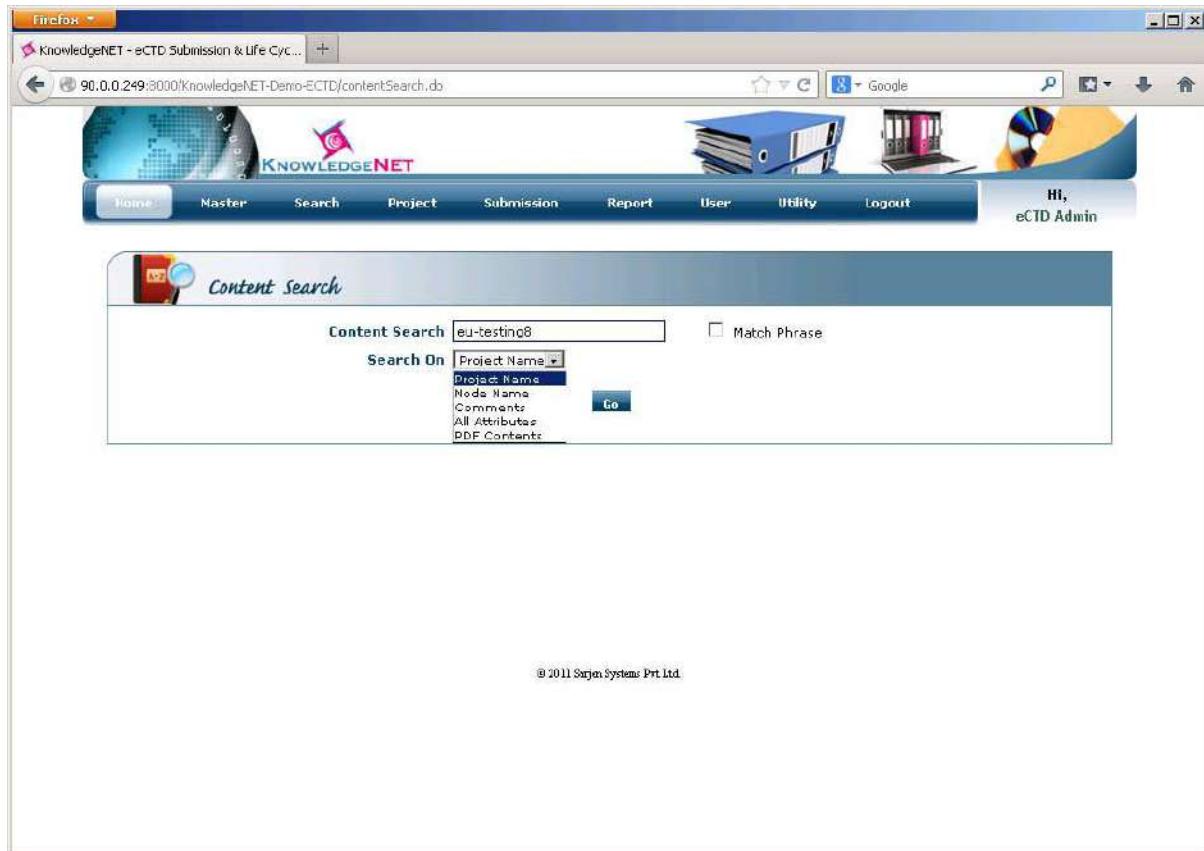
- User can View the search and also delete the saved search just click on Delete.
- A pop message gets display. If user want to delete the save click on 'Ok'



Note: If user not wants to delete the saved search then click on Cancel.

By Content Search

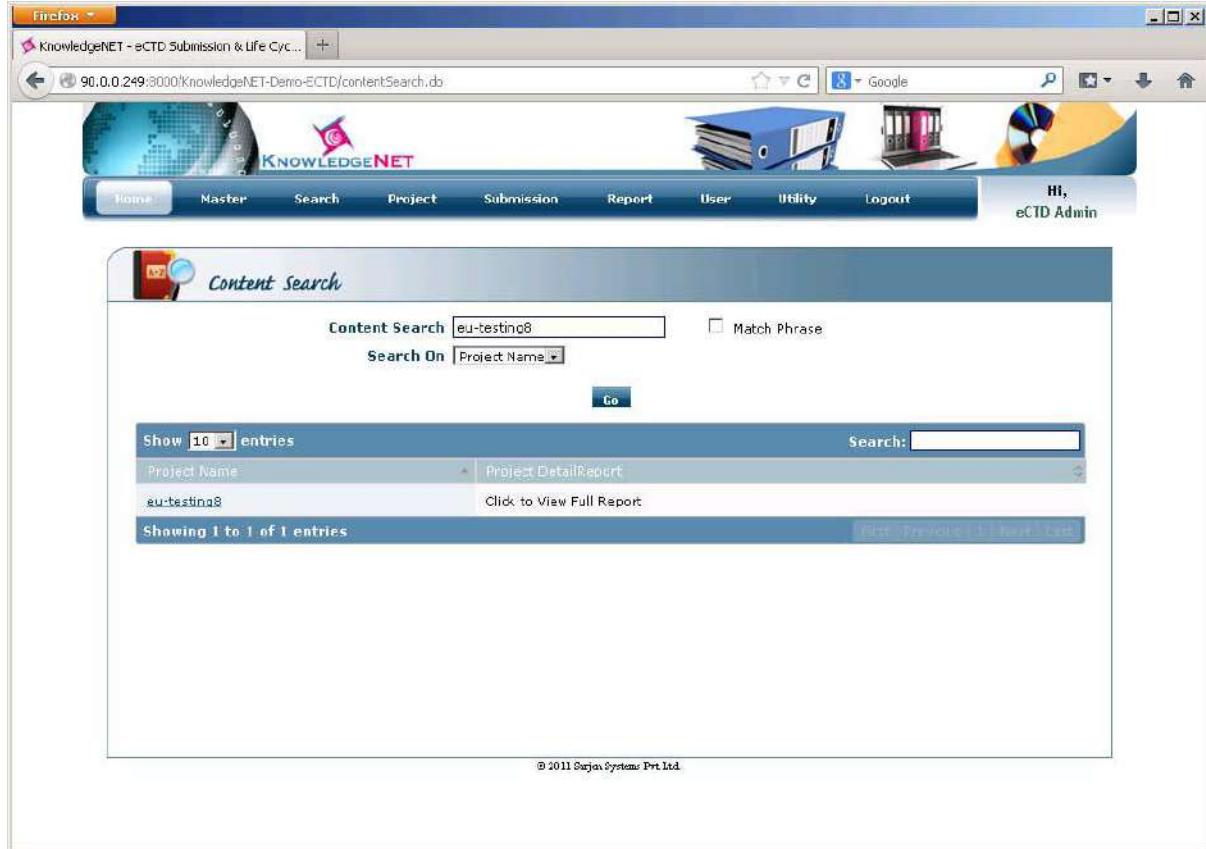
- The main page for 'Content Search' will get displayed.
- User can search the contents based on criteria as project name, node name, comments, attributes and in PDF as shows in below screen.



The screenshot shows a Firefox browser window displaying the 'Content Search' page of the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/contentSearch.do. The page has a blue header bar with the 'Content Search' title. Below it is a search form with fields for 'Content Search' (containing 'eu-testing8'), 'Match Phrase' (unchecked), and 'Search On' (set to 'Project Name'). A dropdown menu under 'Search On' lists 'Project Name', 'Node Name', 'Comments', 'All Attributes', and 'PDF Contents'. A 'Go' button is next to the dropdown. At the bottom of the page, there is a small footer note: '© 2011 Serjen Systems Pvt Ltd.'

Content Search: Search Result

- The below screen will get displayed on providing search criteria as project name and content to be searched.



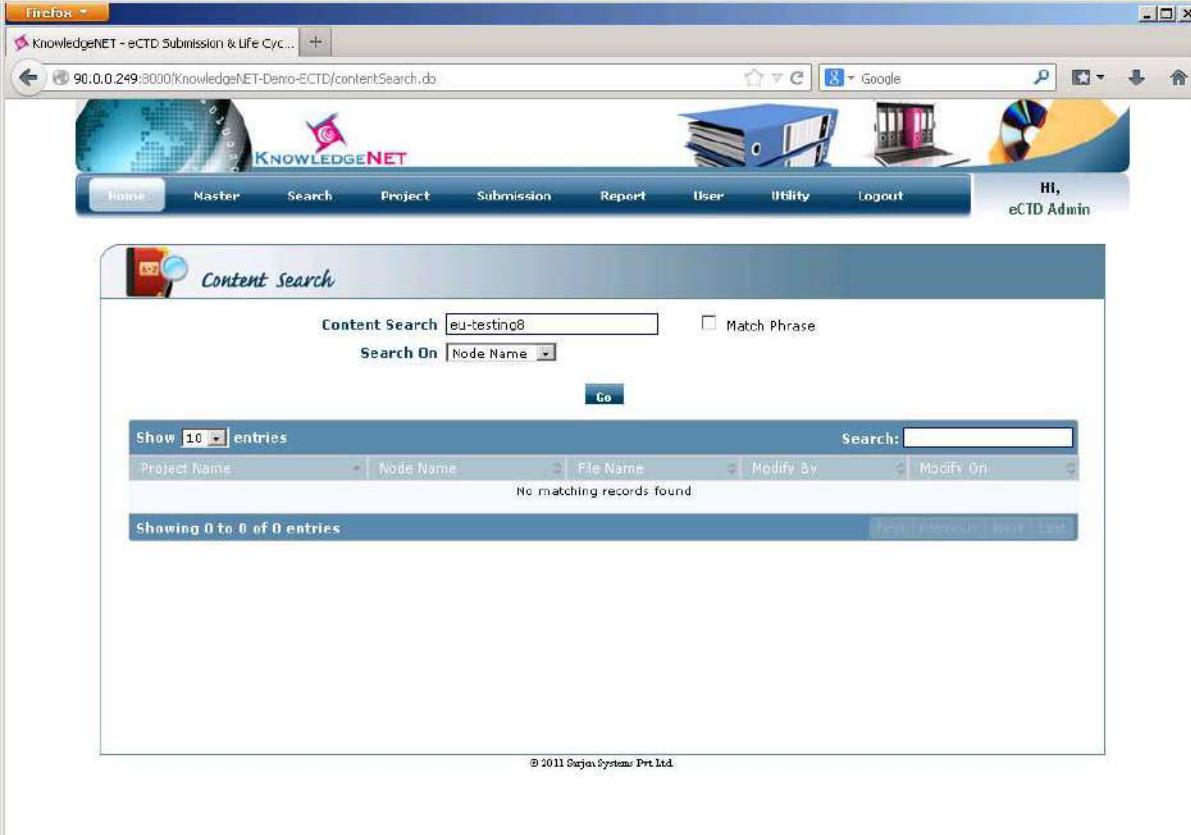
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/contentSearch.do. The page title is "Content Search". The search query "eu-testing8" is entered in the "Content Search" field. The "Search On" dropdown is set to "Project Name". The "Match Phrase" checkbox is unchecked. Below the search form, there is a table with one entry:

Project Name	Project Detail Report
eu-testing8	Click to View Full Report

At the bottom of the page, it says "showing 1 to 1 of 1 entries". The footer of the application includes the text "© 2011 Serjna Systems Pvt Ltd."

Content Search: Wrong Key Word

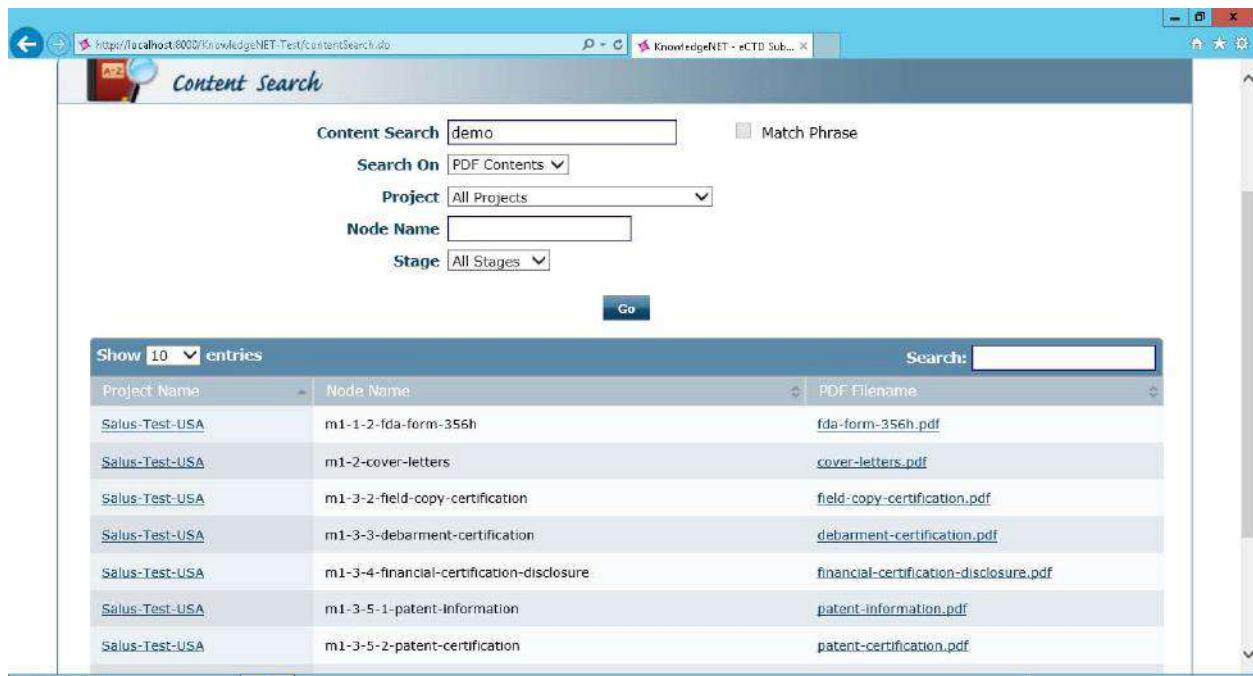
- If the search criterion does not match then the below page will get displayed showing the message in the grid.



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/contentSearch.do. The page title is 'Content Search'. The search criteria are set to 'eu-testing8' in the 'Content Search' field, with 'Match Phrase' checked and 'Search On' set to 'Node Name'. Below the search form, there are dropdown menus for 'Show' (set to 10), 'Project Name', 'Node Name', 'File Name', 'Modify By', and 'Modify On'. A message indicates 'No matching records found'. At the bottom, it says 'Showing 0 to 0 of 0 entries' and has links for 'First Page', 'Previous Page', 'Next Page', and 'Last Page'.

Content Search: PDF Content

- The below page will get displayed on providing the search criteria for 'PDF Content'

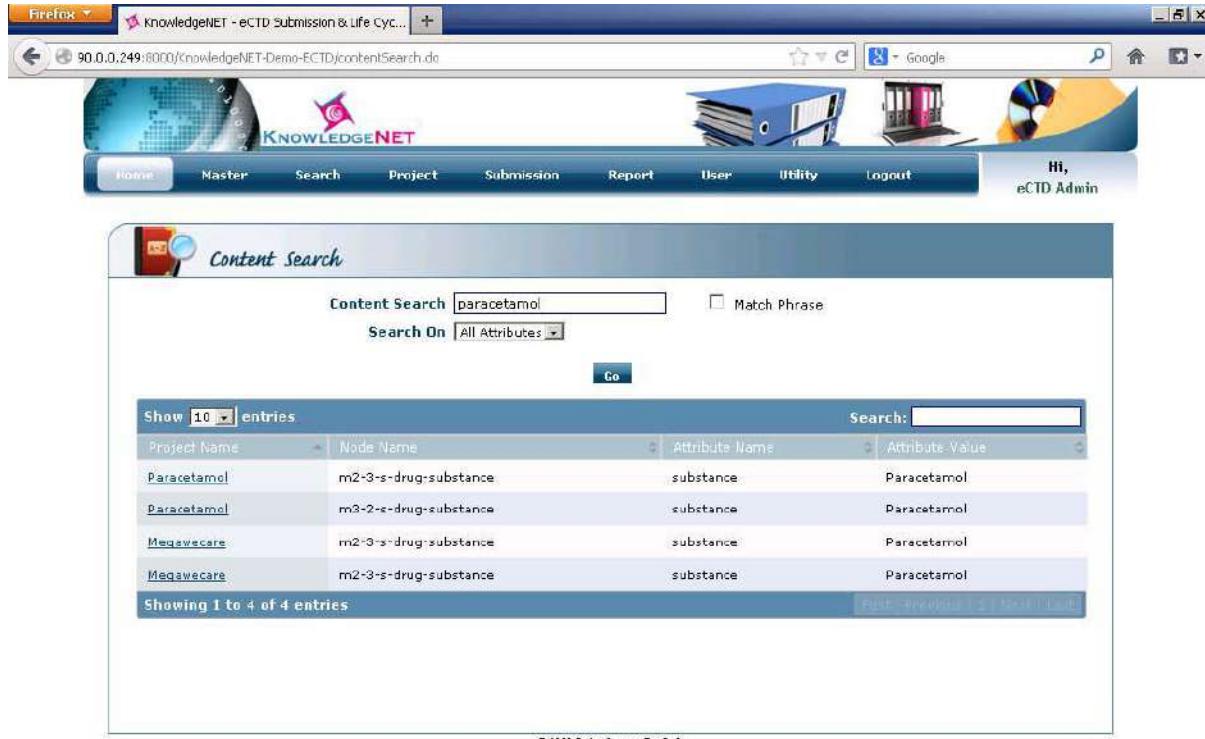


The screenshot shows a web-based application titled "Content Search". At the top, there is a search bar with the text "demo" and a checkbox labeled "Match Phrase". Below the search bar are dropdown menus for "Search On" (set to "PDF Contents"), "Project" (set to "All Projects"), "Node Name" (empty), and "Stage" (set to "All Stages"). A "Go" button is located to the right of the search bar. Below the search controls is a table with the following data:

Project Name	Node Name	PDF Filename
Salus-Test-USA	m1-1-2-fda-form-356h	fda-form-356h.pdf
Salus-Test-USA	m1-2-cover-letters	cover-letters.pdf
Salus-Test-USA	m1-3-2-field-copy-certification	field-copy-certification.pdf
Salus-Test-USA	m1-3-3-debarment-certification	debarment-certification.pdf
Salus-Test-USA	m1-3-4-financial-certification-disclosure	financial-certification-disclosure.pdf
Salus-Test-USA	m1-3-5-1-patent-information	patent-information.pdf
Salus-Test-USA	m1-3-5-2-patent-certification	patent-certification.pdf

Content Search: Attribute Search

- The below page will get displayed on providing the search criteria for 'Attribute Search'



The screenshot shows a Firefox browser window displaying the 'Content Search' feature of the KNOWLEDGE NET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-eCTD/contentSearch.do.

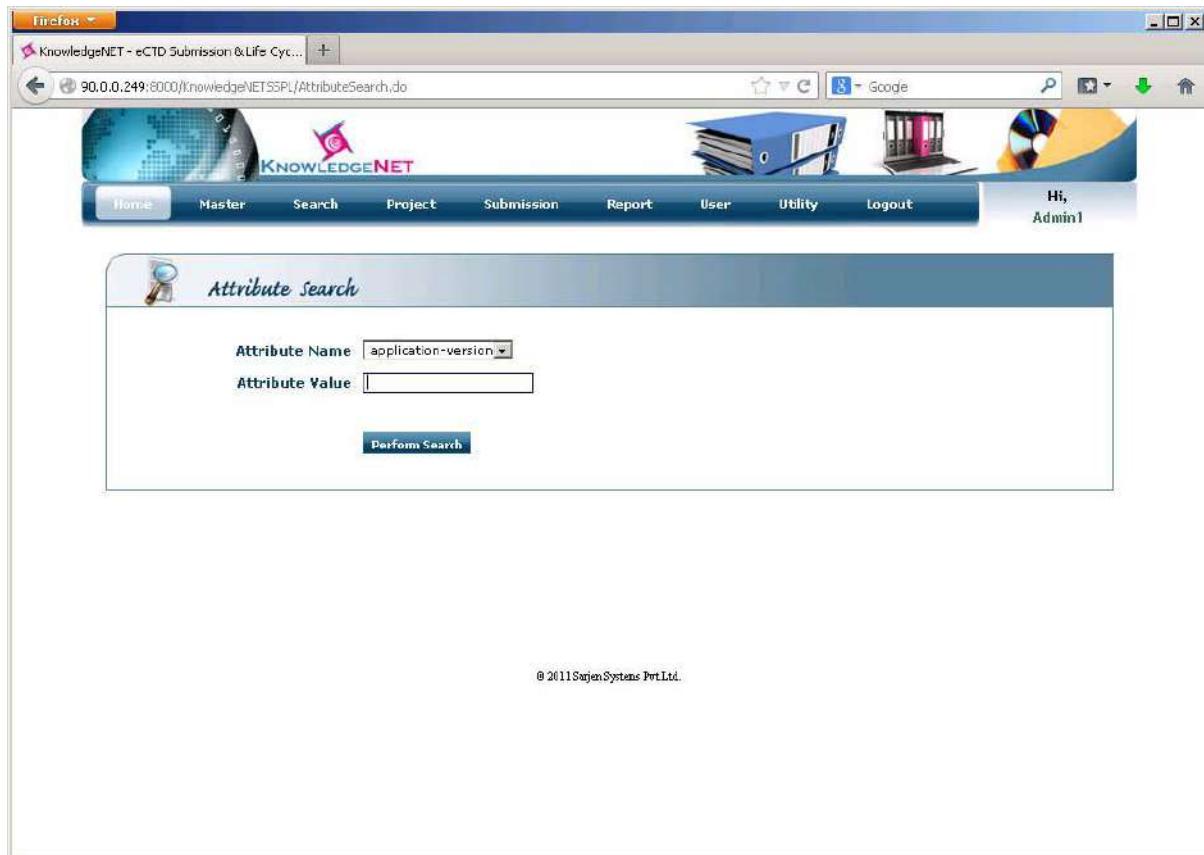
The interface includes a top navigation bar with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A 'Hi, eCTD Admin' greeting is visible on the right. Below the navigation is a search form titled 'Content Search' with a text input field containing 'paracetamol'. There is also a 'Match Phrase' checkbox and a dropdown menu for 'Search On' set to 'All Attributes'. A 'Go' button is present. The main content area is a table titled 'Content Search' showing four entries:

Project Name	Node Name	Attribute Name	Attribute Value
Paracetamol	m2-3-s-drug-substance	substance	Paracetamol
Paracetamol	m3-2-s-drug-substance	substance	Paracetamol
Megawecare	m2-3-s-drug-substance	substance	Paracetamol
Megawecare	m2-3-s-drug-substance	substance	Paracetamol

At the bottom of the table, it says 'Showing 1 to 4 of 4 entries'. The footer of the page includes the copyright notice '© 2011 Sorjon Systems Pvt Ltd.'

Search> Attribute

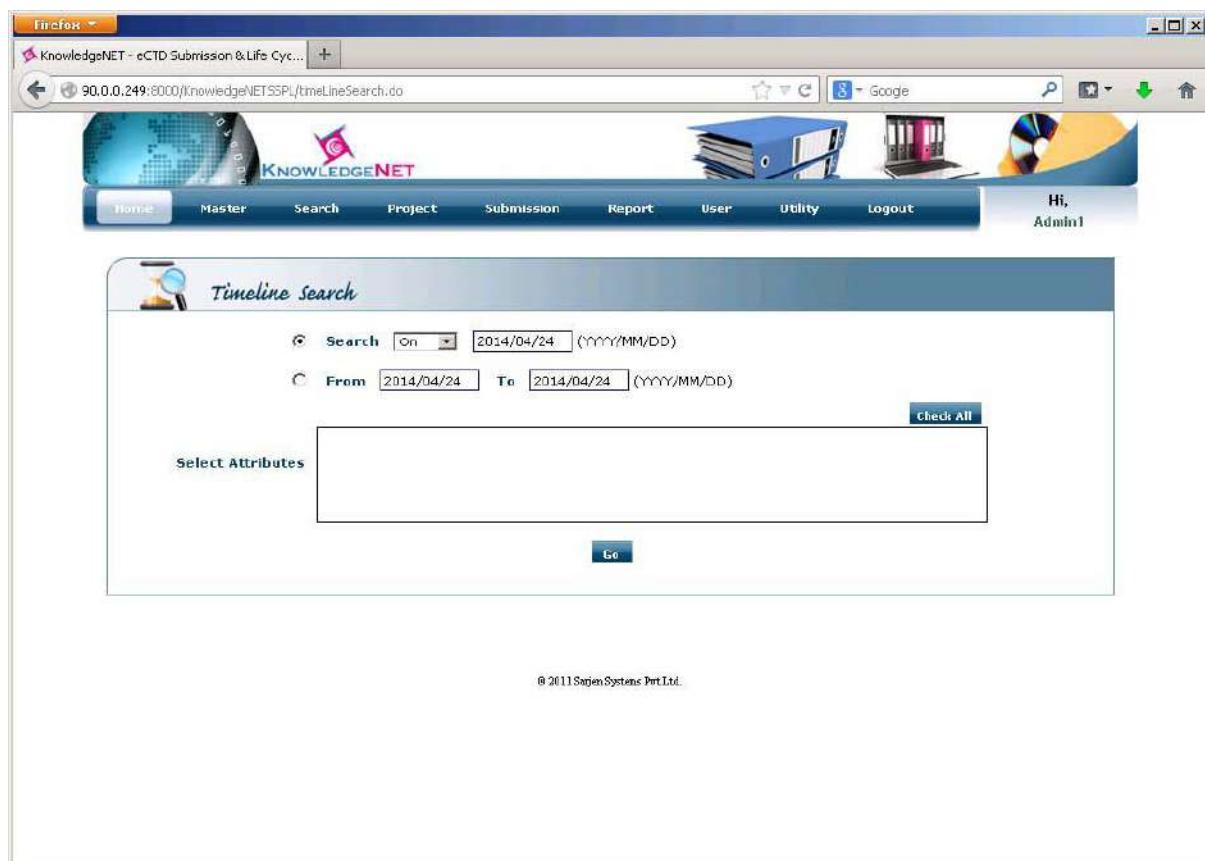
- The below page will get displayed on providing the search criteria for ‘Attribute’
- After filling the ‘Attribute Name’ and ‘Attribute value’, click on “Perform Search” button.



The screenshot shows a Firefox browser window displaying the KnowledgeNET web application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/AttributeSearch.do. The page has a blue header with the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message 'Hi, Admin1' is on the right. Below the header is a form titled 'Attribute search' with fields for 'Attribute Name' (set to 'application-version') and 'Attribute Value' (empty), and a 'Perform Search' button. At the bottom of the page, there is a small copyright notice: '© 2011 Saajan Systems Pvt Ltd.'

Search > Time Line Search

- User can search the project by selecting some searching criteria such as search before, after and on date and from date to date.
- Select the attribute set at the time of project creation such as date of registration, expiry date and many more.

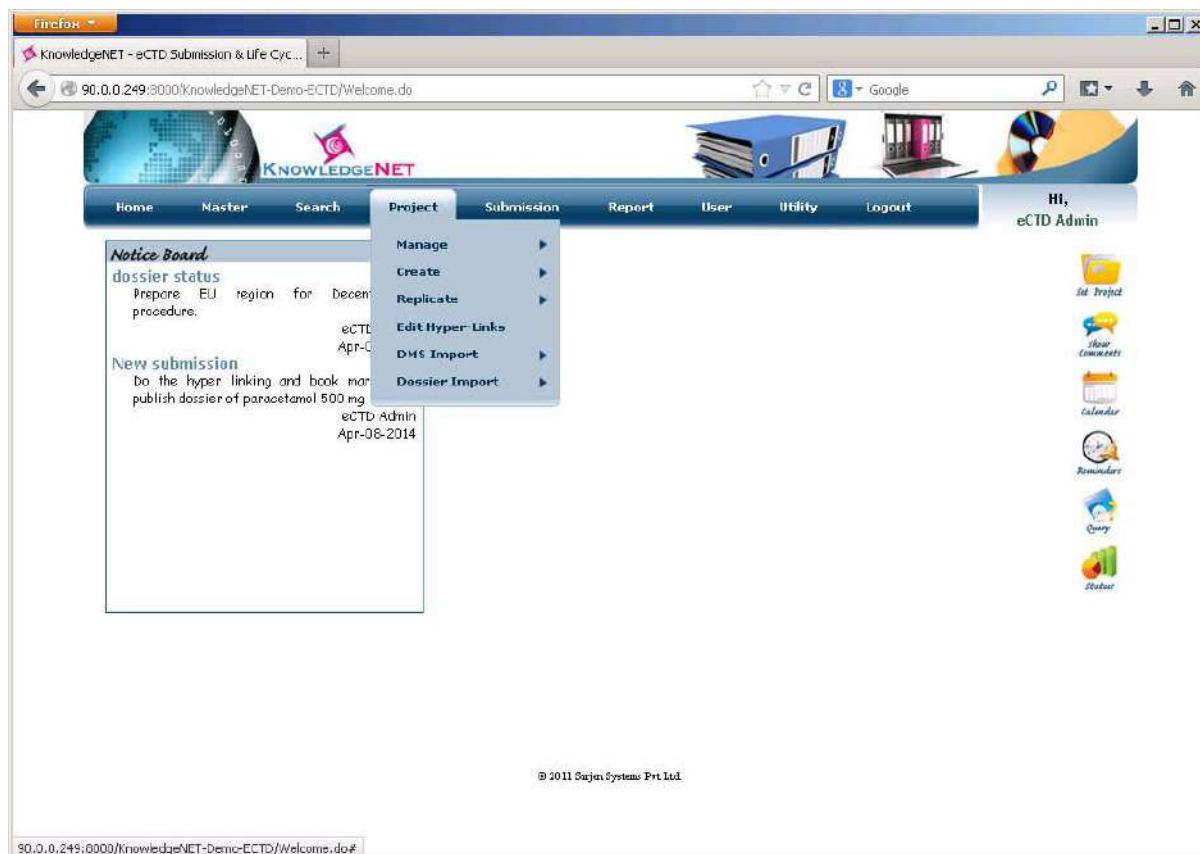


The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/timeLineSearch.do. The page title is "Timeline Search". The interface includes a header with the KnowledgeNET logo, a navigation menu with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, and a welcome message "Hi, Admin1". The main content area contains fields for "Search On" (set to "2014/04/24 (YYYY/MM/DD)"), "From" (set to "2014/04/24") and "To" (set to "2014/04/24"). There is also a "Select Attributes" section with a large empty box and a "Check All" button. A "Go" button is located at the bottom right of the search form. At the bottom of the page, there is a footer note: "© 2011 Sejen Systems Pvt Ltd."

Project Menu

– “Project” Menu will display the submenu items as shows: -

- Manage
- Create
- Replicate
- Edit Hyper-Links
- DMS Import
- Dossier Import

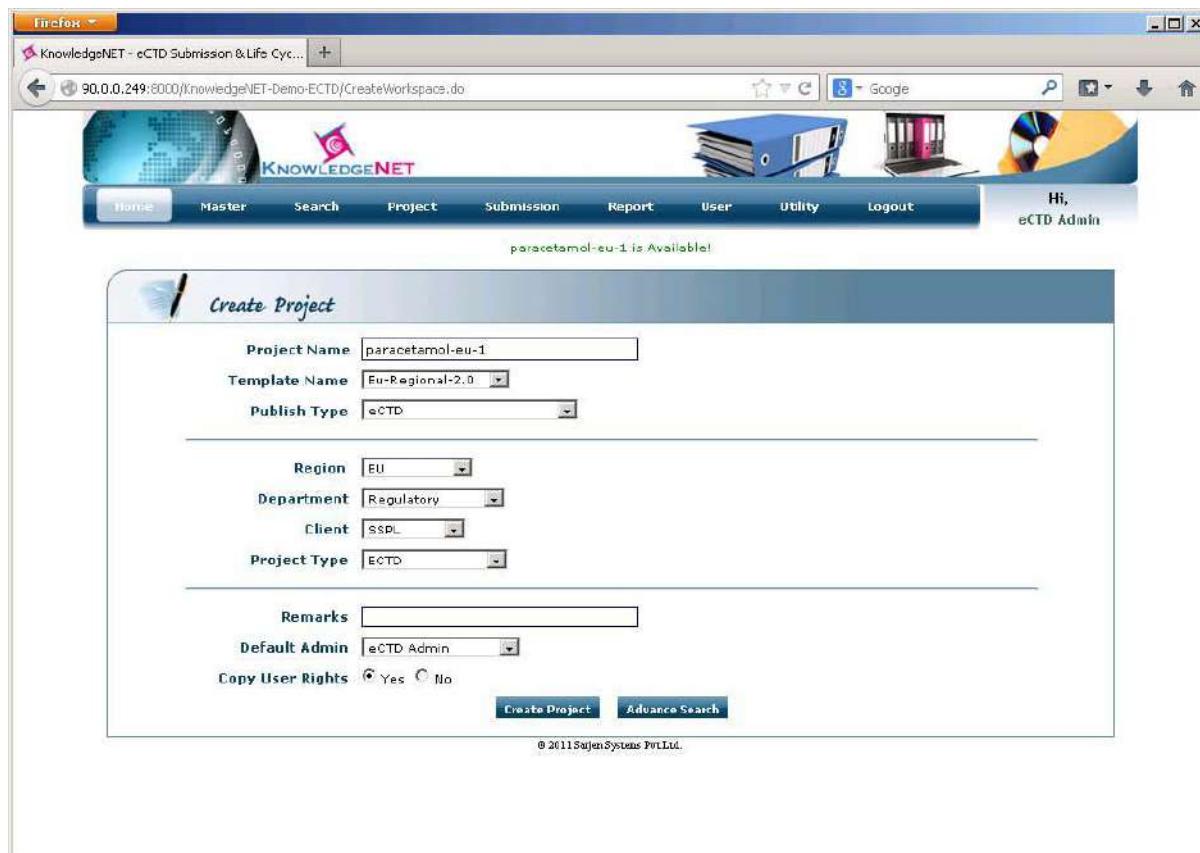


Create Project

- ❖ eCTD Admin will be able to create projects through “Create Project”.
- ❖ Template is a pre-loaded structure of eCTD which is to be submitted.
- ❖ Each template has modules: - m1, m2, m3, m4, m5 of which module-1 will be region specific and modules 2-5 will be common for all templates.
- ❖ Default Admin is the Admin who has all the rights of the project.

Project >Create >Project

- In the below screen, Admin has to mention “Project Name”, “Remarks”, and select the “Template Name”, “Publish Type”, “Region”, “Department”, “Client”, “Project Type” and “Default Admin”.

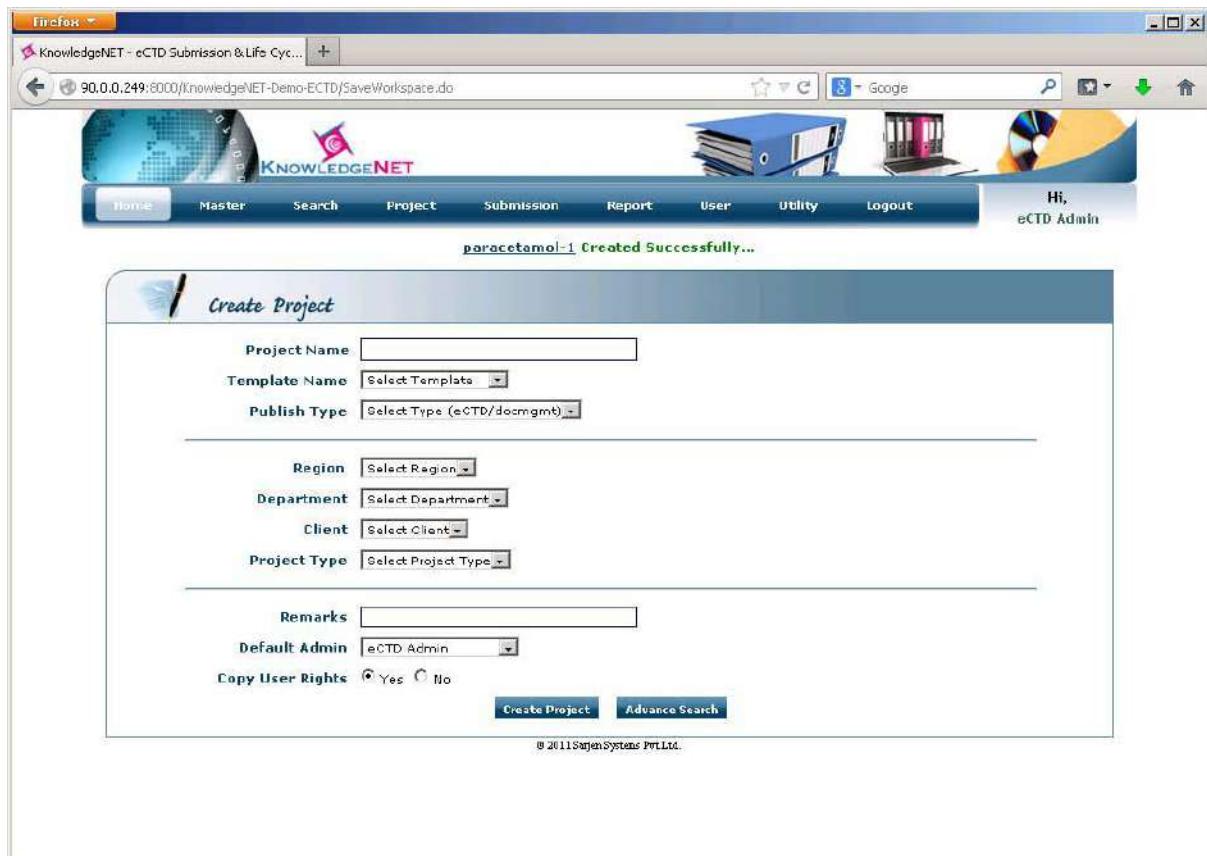


The screenshot displays the 'Create Project' interface. At the top, the browser title bar shows 'KnowledgeNET - eCTD Submission & Life Cyc...' and the URL '90.0.0.249:8000/knowledgeNET-Demo-ECTD/CreateWorkspace.do'. The main header includes the 'KNOWLEDGE.NET' logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, eCTD Admin' is visible on the right. The central form area is titled 'Create Project' and contains the following fields:

Project Name	paracetamol-eu-1
Template Name	Eu-Regional-2.0
Publish Type	eCTD
Region	EU
Department	Regulatory
Client	SSPL
Project Type	eCTD
Remarks	
Default Admin	eCTD Admin
Copy User Rights	<input checked="" type="radio"/> Yes <input type="radio"/> No

At the bottom of the form are two buttons: 'Create Project' and 'Advance Search'. A footer note at the bottom center reads '© 2011 SaizenSystems Pvt Ltd.'

- After filling all the required details, click on “Create Project” button and the project is created successfully if the project name is unique.



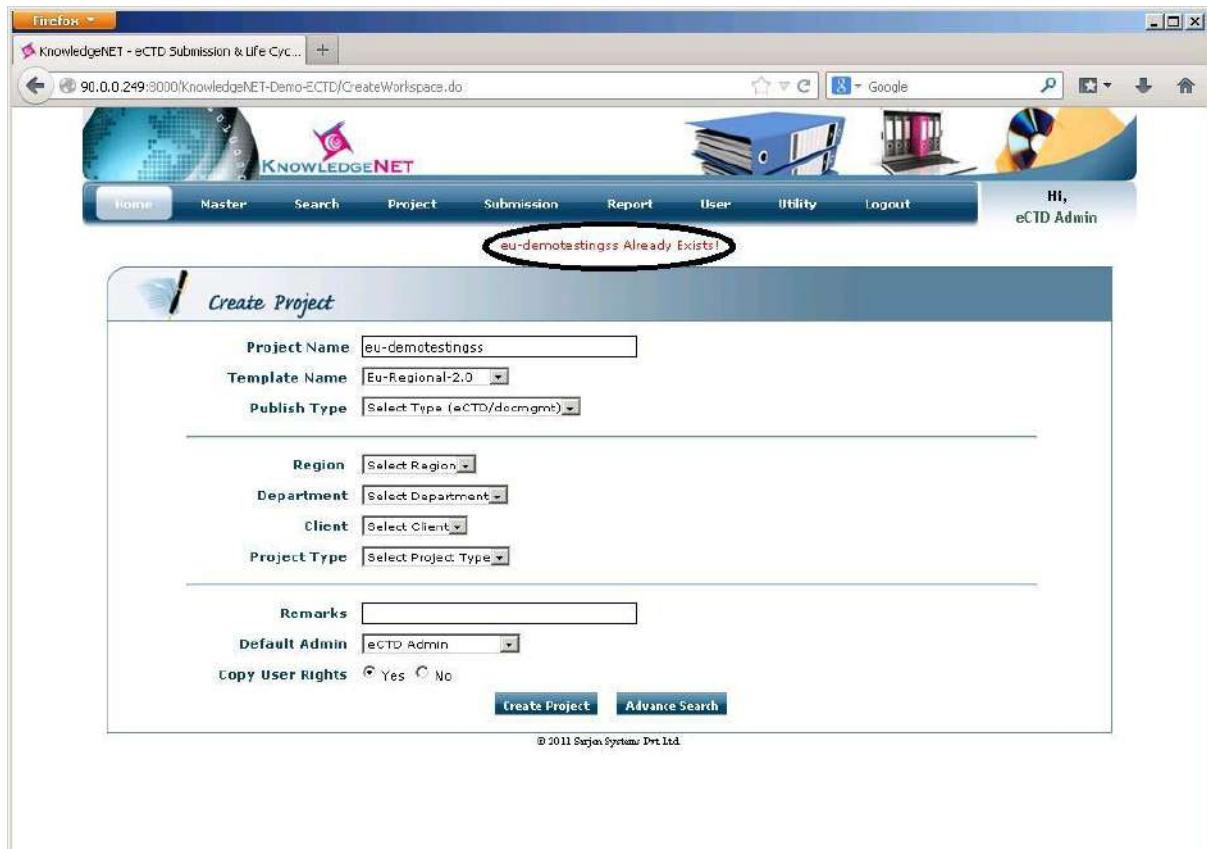
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/SaveWorkspace.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The main content area shows a success message: "paracetamol-1 Created Successfully...". Below this, there is a "Create Project" form with the following fields:

- Project Name: [empty input field]
- Template Name: Select Template [dropdown menu]
- Publish Type: Select Type (eCTD/docmgmt) [dropdown menu]
- Region: Select Region [dropdown menu]
- Department: Select Department [dropdown menu]
- Client: Select Client [dropdown menu]
- Project Type: Select Project Type [dropdown menu]
- Remarks: [empty input field]
- Default Admin: eCTD Admin [dropdown menu]
- Copy User Rights: Yes No

At the bottom of the form are two buttons: "Create Project" and "Advance Search". A copyright notice at the bottom of the page reads "© 2011 SanjenSystems Pvt Ltd."

- When a user enters a project name that already exists then the below screen gets displayed showing the message as '[Project name] already exists'.

- If the project name is not unique, then after entering the “Project Name” it will display a message as “Project Already Exists” at the top of the screen as shows below.

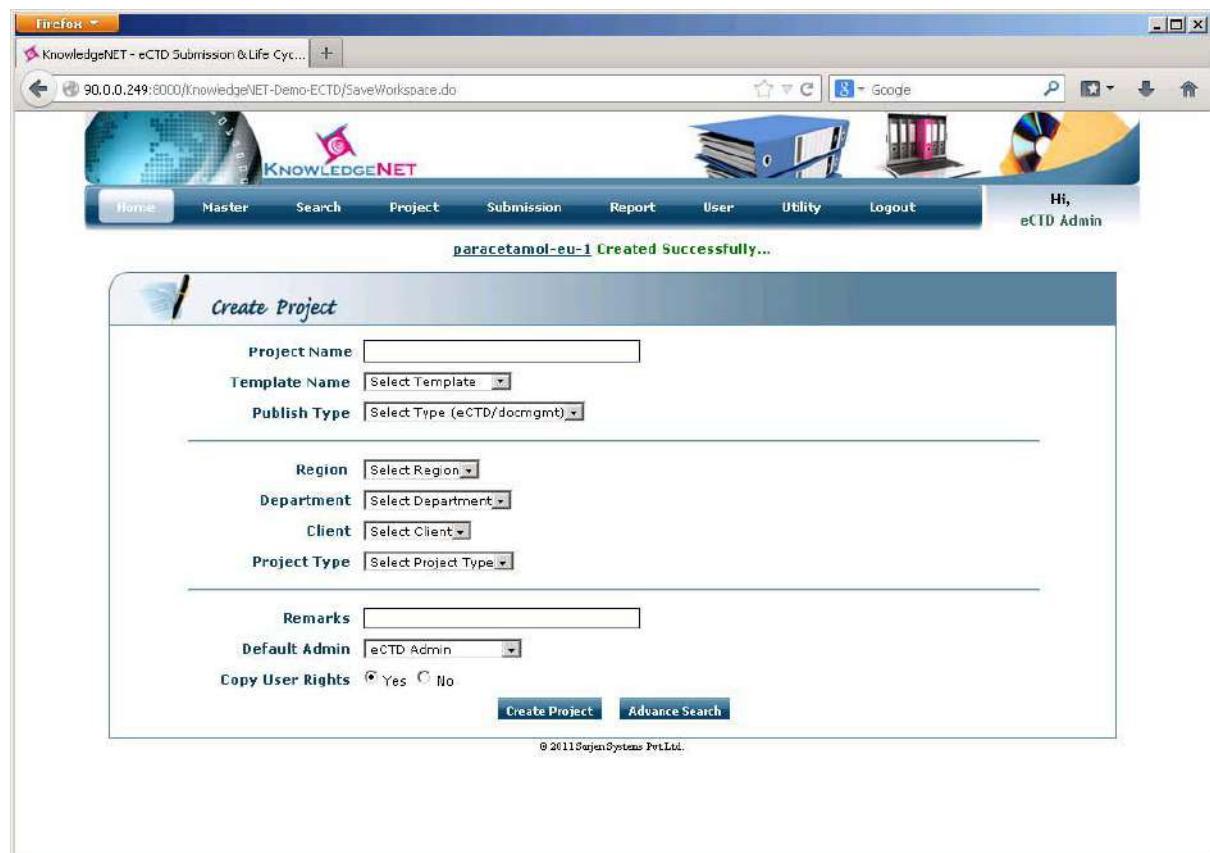


The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-eCTD/CreateWorkspace.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The main content area is titled "Create Project". The "Project Name" field contains "eu-demotestingss". Above the form, a red oval highlights the error message "eu-demotestingss Already Exists!". Below the form, the "Default Admin" dropdown is set to "eCTD Admin". Other fields include "Template Name" (Eu-Regional-2.0), "Publish Type" (Select Type (eCTD/docmgmt)), "Region" (Select Region), "Department" (Select Department), "Client" (Select Client), "Project Type" (Select Project Type), "Remarks" (empty), and "Copy User Rights" (radio buttons for Yes and No). At the bottom are "Create Project" and "Advance Search" buttons, and a copyright notice "© 2011 Surjan Systems Pvt Ltd".

- To view the created projects, Admin can click either on “Upper Hyperlink” or “Manage” [from the Project Menu].

After Creation of Project

- On providing the details for the creation of project, a message gets displayed in below screen.



paracetamol-eu-1 Created Successfully...

Create Project

Project Name:

Template Name:

Publish Type:

Region:

Department:

Client:

Project Type:

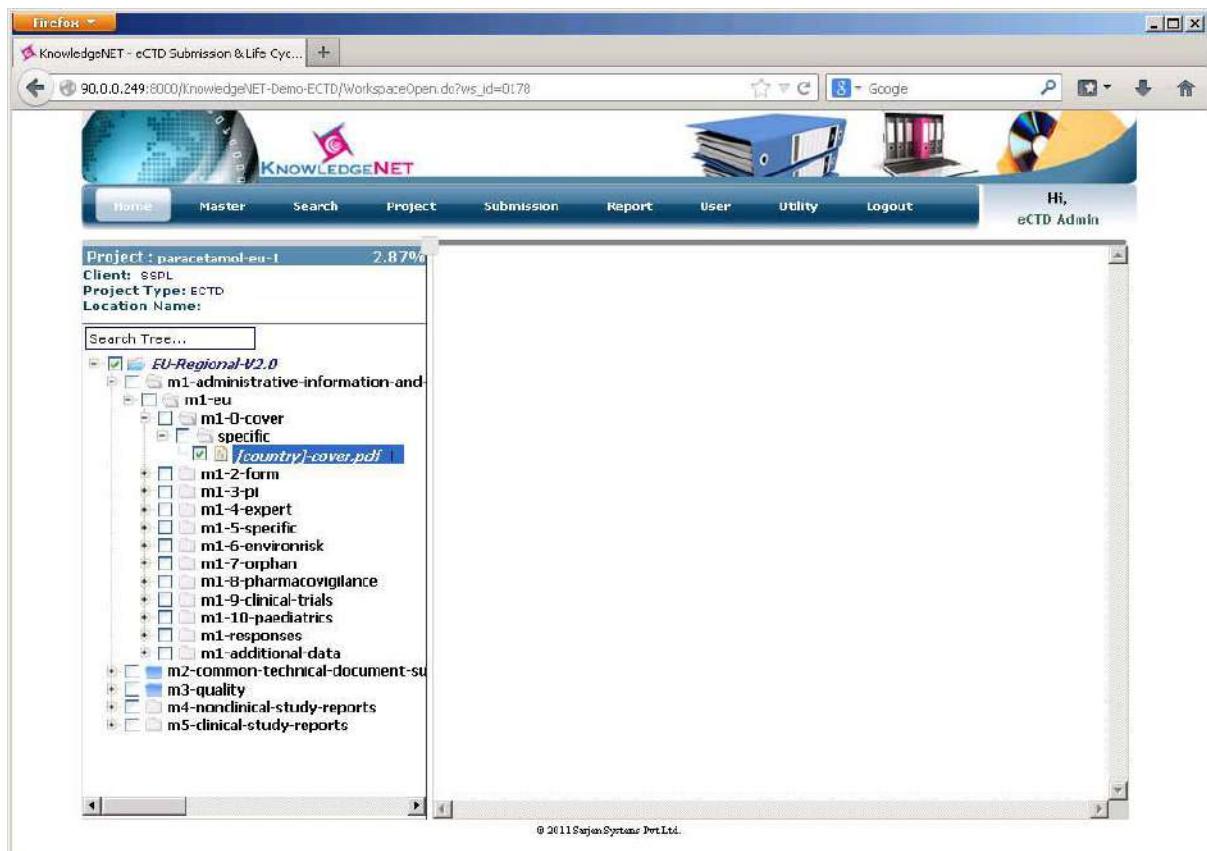
Remarks:

Default Admin:

Copy User Rights: Yes No

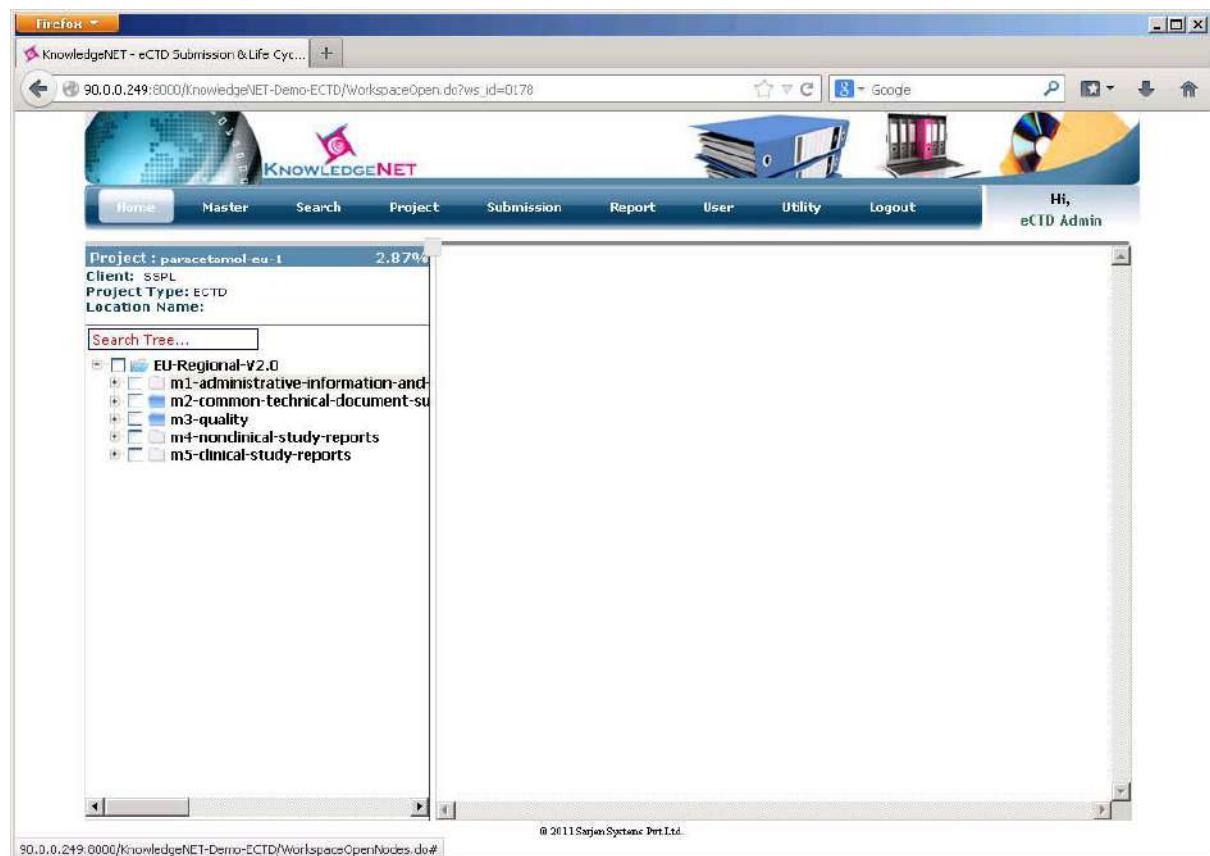
© 2011SajenSystems PvtLtd.

- By clicking on the created project name link ([paracetamol-eu-1 Created successfully...](#)), user will be navigated to the following form.

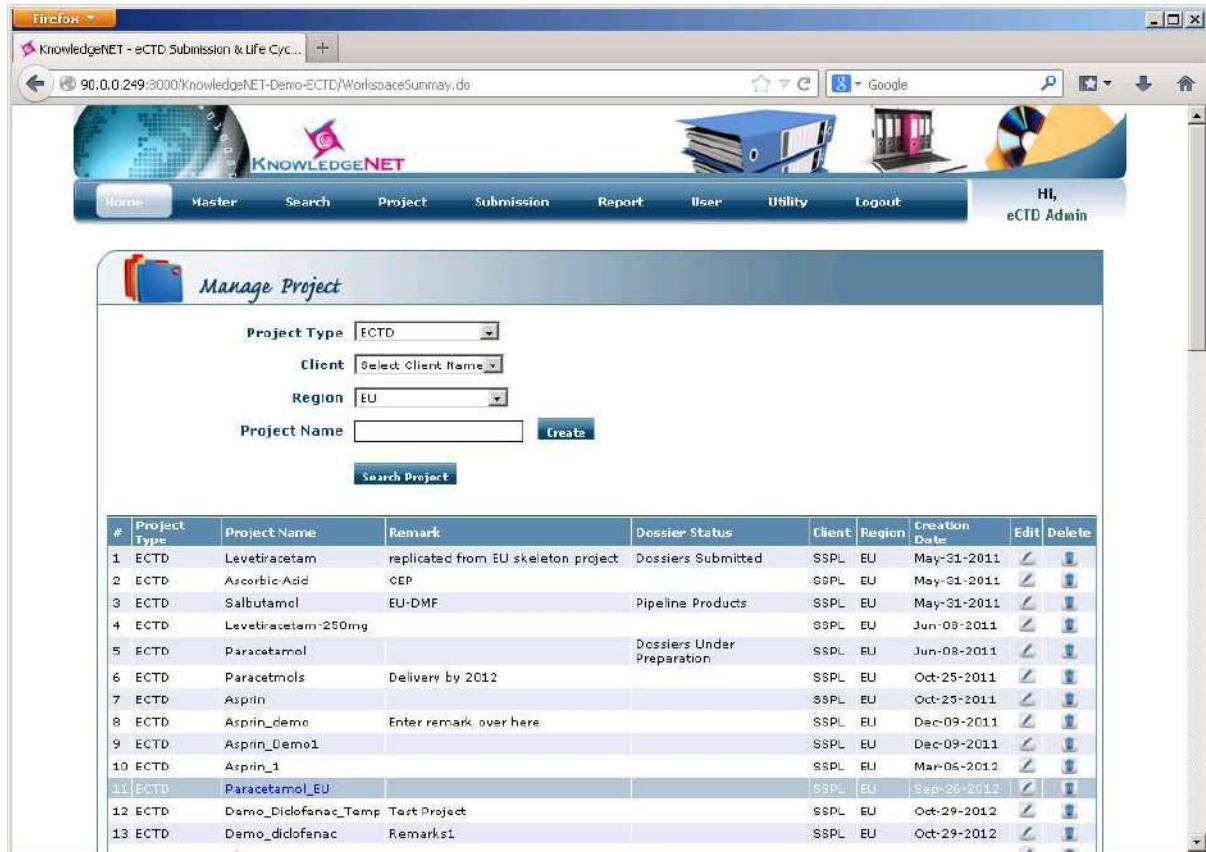


The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0178. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a greeting to "eCTD Admin". On the left, a sidebar displays project details: Project : paracetamol-eu-1, Client: SSPL, Project Type: ECTD, Location Name: EU-Regional-V2.0. Below this is a search bar labeled "Search Tree..." and a hierarchical file tree. The tree structure under "EU-Regional-V2.0" includes "m1-administrative-information-and-", "m1-eu", "m1-0-cover", "m1-1-form", "m1-2-form", "m1-3-pl", "m1-4-expert", "m1-5-specific", "m1-6-environmental", "m1-7-orphan", "m1-8-pharmacovigilance", "m1-9-clinical-trials", "m1-10-paediatrics", "m1-responses", "m1-additional-data", "m2-common-technical-document-sub", "m3-quality", "m4-nondclinical-study-reports", and "m5-clinical-study-reports". A specific file, "[country]-cover.pdf", is selected in the "m1-0-cover" folder. The status bar at the bottom right shows "© 2011 Sanjan Systems Pvt Ltd."

- By clicking on the created project name link, user will be navigated to the following form.



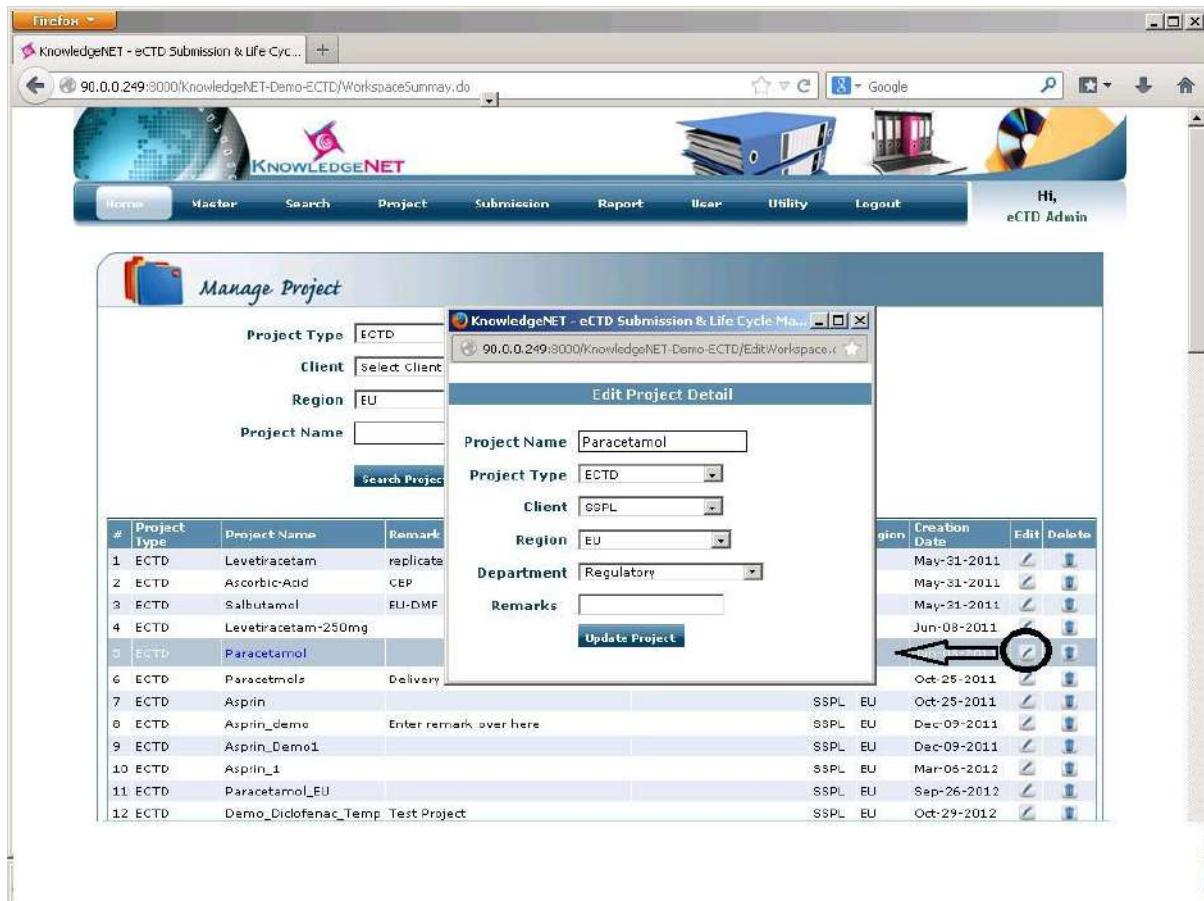
- ❖ If Admin wants to upload files to a project, then it can be done through clicking on project name from the list.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Admin interface. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceSummary.do. The page title is "Manage Project". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and "Hi, eCTD Admin". Below the navigation is a search bar with a "Search Project" button. A table lists 13 projects with columns for #, Project Type, Project Name, Remark, Dossier Status, Client, Region, Creation Date, Edit, and Delete. The table rows are numbered 1 to 13. The "Edit" and "Delete" columns contain icons for each row.

#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1	ECTD	Levetiracetam	replicated from EU skeleton project	Dossiers Submitted	SSPL	EU	May-31-2011		
2	ECTD	Ascorbic Acid	CEP		SSPL	EU	May-31-2011		
3	ECTD	Salbutamol	EU-DMF	Pipeline Products	SSPL	EU	May-31-2011		
4	ECTD	Levetiracetam-250mg			SSPL	EU	Jun-03-2011		
5	ECTD	Paracetamol		Dossiers Under Preparation	SSPL	EU	Jun-08-2011		
6	ECTD	Paracetamols	Delivery by 2012		SSPL	EU	Oct-25-2011		
7	ECTD	Aspirin			SSPL	EU	Oct-25-2011		
8	ECTD	Asprin_demo	Enter remark over here		SSPL	EU	Dec-09-2011		
9	ECTD	Asprin_Demo1			SSPL	EU	Dec-09-2011		
10	ECTD	Asprin_1			SSPL	EU	Mar-04-2012		
11	ECTD	Paracetamol_EU			SSPL	EU	Sep-26-2012		
12	ECTD	Demo_Diclofenac_Temp	Test Project		SSPL	EU	Oct-29-2012		
13	ECTD	Demo_diclofenac	Remarks1		SSPL	EU	Oct-29-2012		

- Here user can edit the project details as well as delete the project.



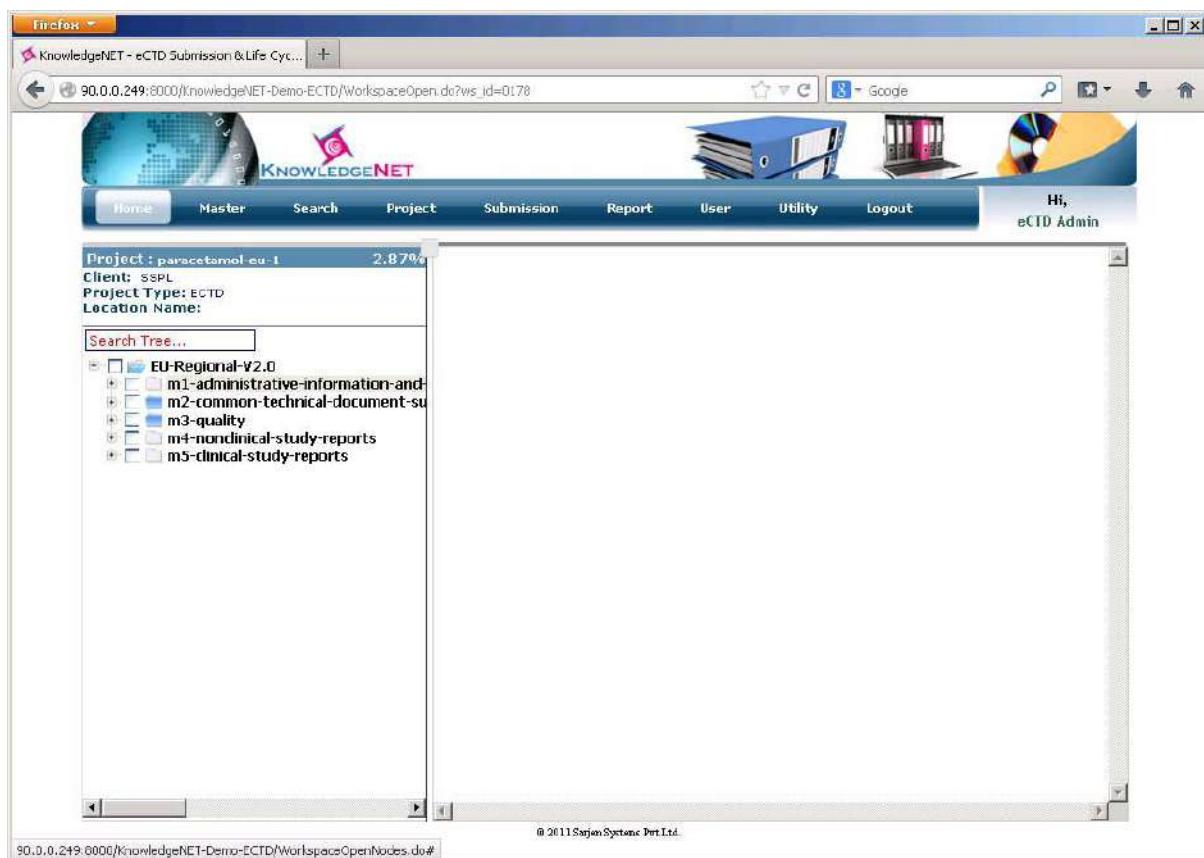
The screenshot shows a web-based application interface for managing projects. At the top, there's a navigation bar with links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a 'Hi, eCTD Admin' greeting. Below the navigation is a banner with the 'KNOWLEDGE NET' logo and some decorative icons. The main content area has a title 'Manage Project' with a sub-section 'Edit Project Detail'. In this sub-section, the 'Project Name' is set to 'Paracetamol'. There are dropdown menus for 'Project Type' (ECTD), 'Client' (SSPL), 'Region' (EU), and 'Department' (Regulatory). A text input field for 'Remarks' is also present. An 'Update Project' button is at the bottom of this form. To the left of the form is a table listing 12 projects with columns for Project Type, Project Name, and Remarks. To the right is another table showing project creation dates and actions like Edit and Delete. A red arrow points to the 'Edit' icon in the second row of the right-hand table.

#	Project Type	Project Name	Remarks
1	ECTD	Levetiracetam	replicate
2	ECTD	Ascorbic Acid	CEP
3	ECTD	Salbutamol	EU-DMF
4	ECTD	Levetiracetam-250mg	
5	ECTD	Paracetamol	
6	ECTD	Paracetamolz	Delivery
7	ECTD	Asprin	
8	ECTD	Asprin_demo	Enter remark over here
9	ECTD	Asprin_Demo1	
10	ECTD	Asprin_1	
11	ECTD	Paracetamol_EU	
12	ECTD	Demo_Diclofenac_Temp	Test Project

Region	Creation Date	Edit	Delete
EU	May-31-2011		
EU	May-31-2011		
EU	May-31-2011		
EU	Jun-08-2011		
EU	Oct-25-2011		
EU	Oct-25-2011		
EU	Dec-09-2011		
EU	Dec-09-2011		
EU	Mar-05-2012		
EU	Sep-26-2012		
EU	Oct-29-2012		

- Fill the all update information of project than click on 'Update Project'.

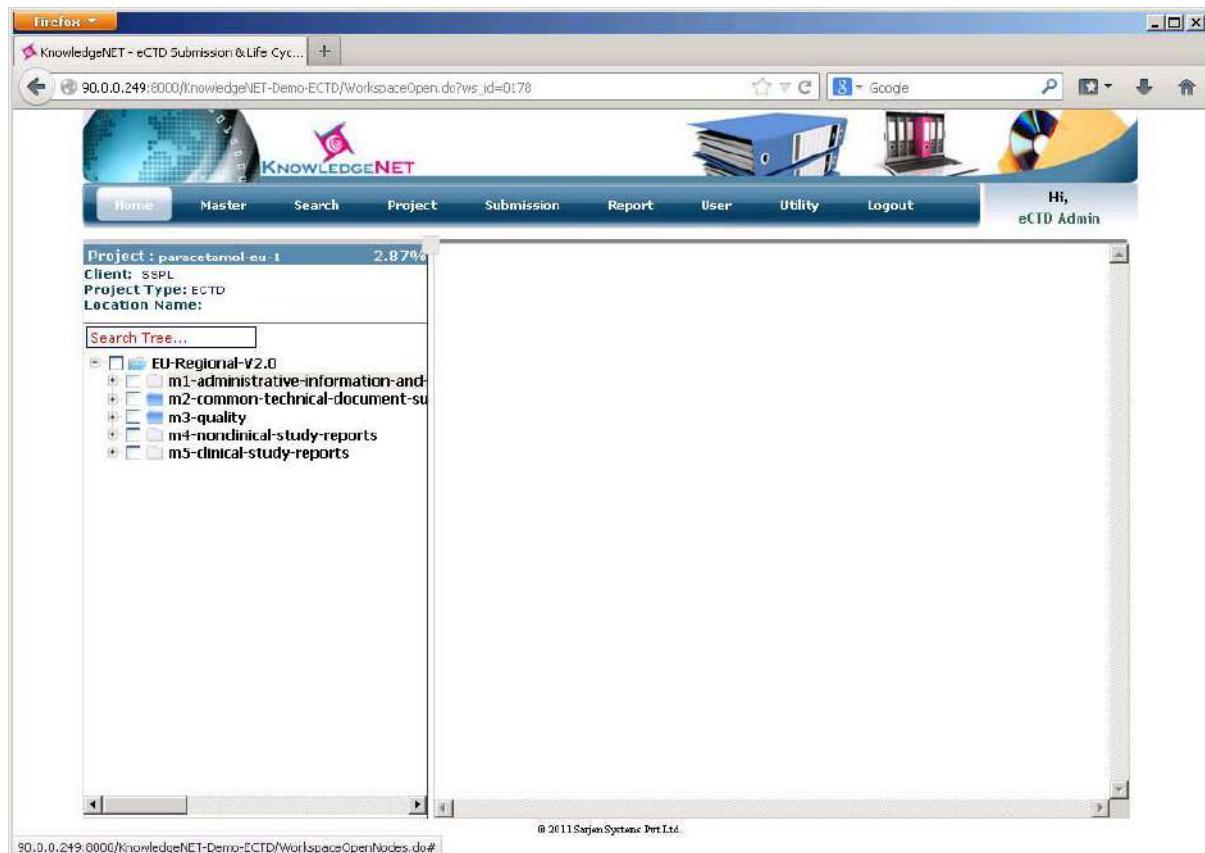
- On clicking the project name below screen will appear which shows the eCTD structure.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0178. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a welcome message for 'eCTD Admin'. A sidebar on the left displays project details: Project: paracetamol-eu-1 (2.87%), Client: SPPL, Project Type: ECTD, Location Name: EU-Regional-V2.0. Below this is a 'Search Tree...' input field and a hierarchical tree view under 'EU-Regional-V2.0' with nodes: m1-administrative-information-and, m2-common-technical-document-su, m3-quality, m4-nondlinical-study-reports, and m5-clinical-study-reports. The main content area is currently empty. The footer contains the copyright notice '© 2011 Sarjan Systems Pvt Ltd.' and the URL 90.0.0.249:8000/knowledgeNET-Demo-ECTD/WorkspaceOpenNodes.do#.

Attribute set on main node: EU-eCTD-v2.0

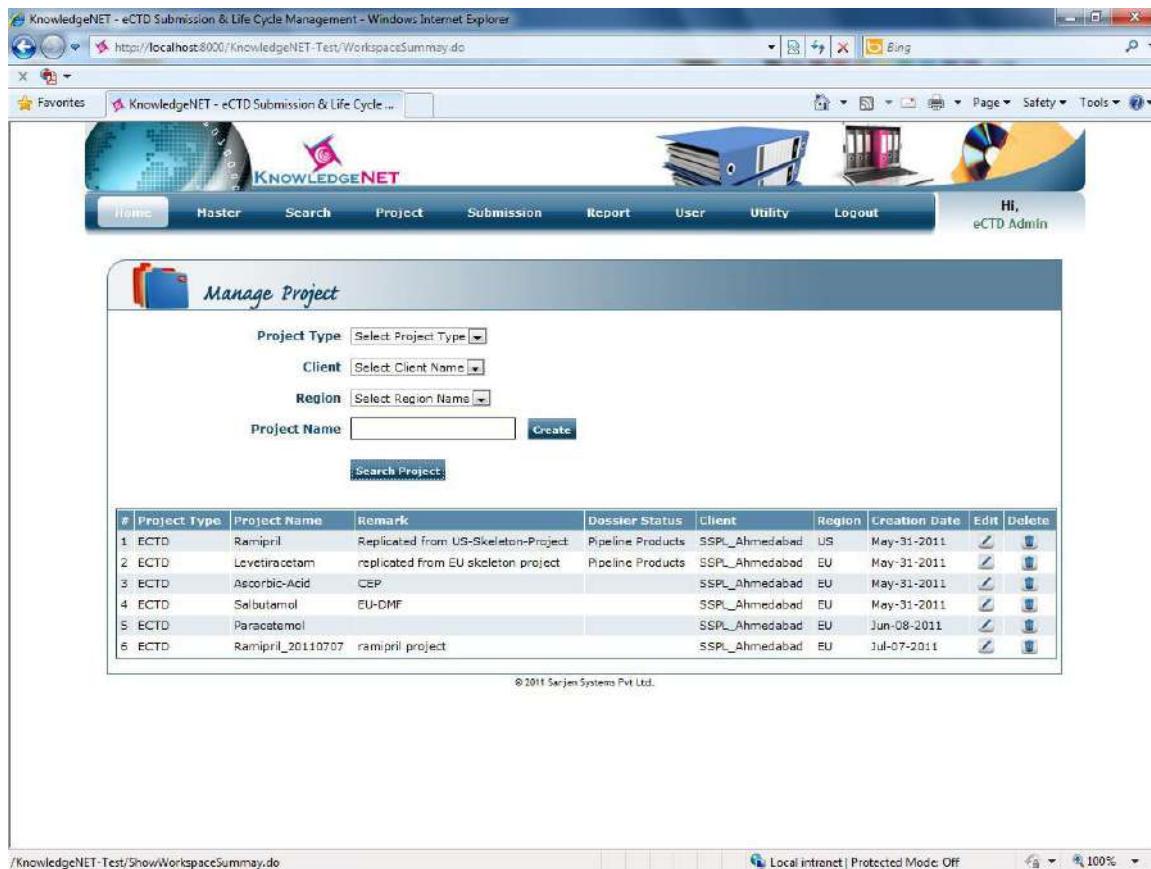
- Click on main node EU-eCTD-v2.0
- In right hand side all the attribute show.
- Select and fill the required attribute such as Dossier Status, Date of Registration, Date of Expiry and Date of Submission etc...



- After filling all required, click on 'Save', all selected attribute save for the specific project.

File Uploading, Lock Node and Send Comments:

- ❖ If Admin wants to upload files to a project, then it can be done through clicking on project name from the list.



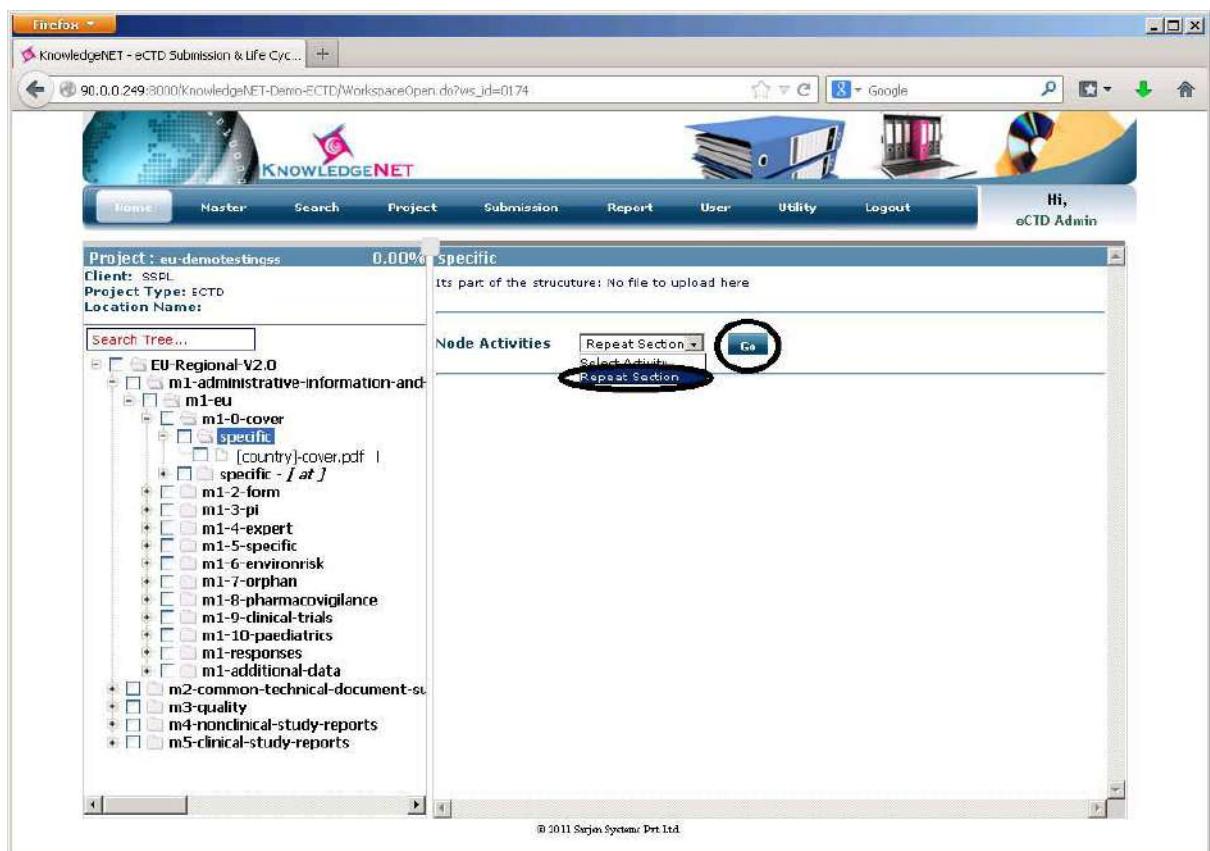
The screenshot shows a Microsoft Internet Explorer window displaying the 'Manage Project' page of the KnowledgeNET application. The page has a header with tabs: Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A 'Hi, eCTD Admin' greeting is visible on the right. The main content area is titled 'Manage Project' and contains several input fields: 'Project Type' (dropdown), 'Client' (dropdown), 'Region' (dropdown), 'Project Name' (text input), and a 'Create' button. Below these is a 'Search Project' button. A table lists six projects with columns: #, Project Type, Project Name, Remark, Dossier Status, Client, Region, Creation Date, Edit, and Delete. The table rows are as follows:

#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1.	ECTD	Ramipril	Replicated from US-Skeleton-Project	Pipeline Products	SSPL_Ahmedabad	US	May-31-2011		
2.	ECTD	Levetiracetam	replicated From EU skeleton project	Pipeline Products	SSPL_Ahmedabad	EU	May-31-2011		
3.	ECTD	Ascorbic-Acid	CEP		SSPL_Ahmedabad	EU	May-31-2011		
4.	ECTD	Solbutamol	EU-DMF		SSPL_Ahmedabad	EU	May-31-2011		
5.	ECTD	Paracetamol			SSPL_Ahmedabad	EU	Jun-08-2011		
6.	ECTD	Ramipril_20110707	ramipril project		SSPL_Ahmedabad	EU	Jul-07-2011		

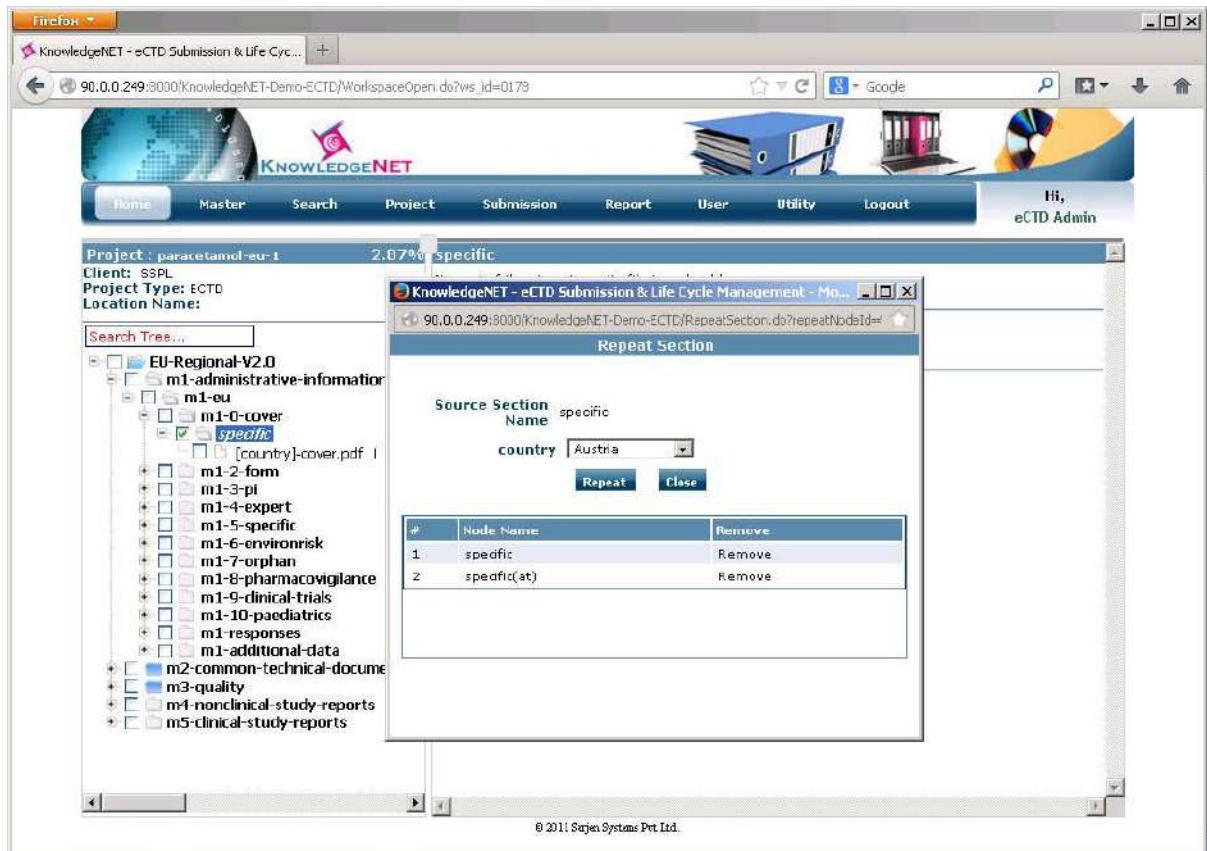
At the bottom of the page, there is a footer with the text '© 2011 Sarjan Systems Pvt Ltd.' and a status bar showing 'Local intranet | Protected Mode: Off' and '100%'.

Repeat Section: - Country Wise Repetition:

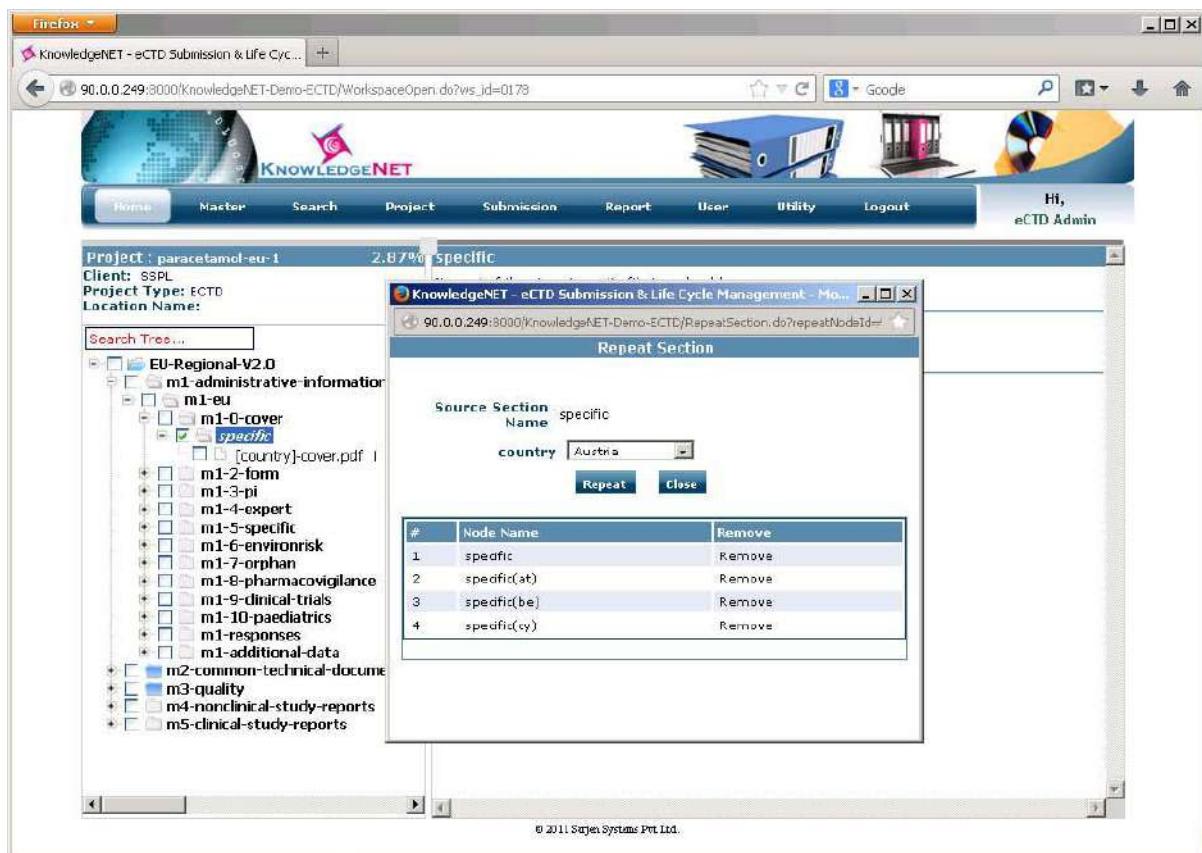
- User can select the leaf Node (such as select specific shows in below screen) then select Node Activities **Repeat Section** then click on "**Go**"



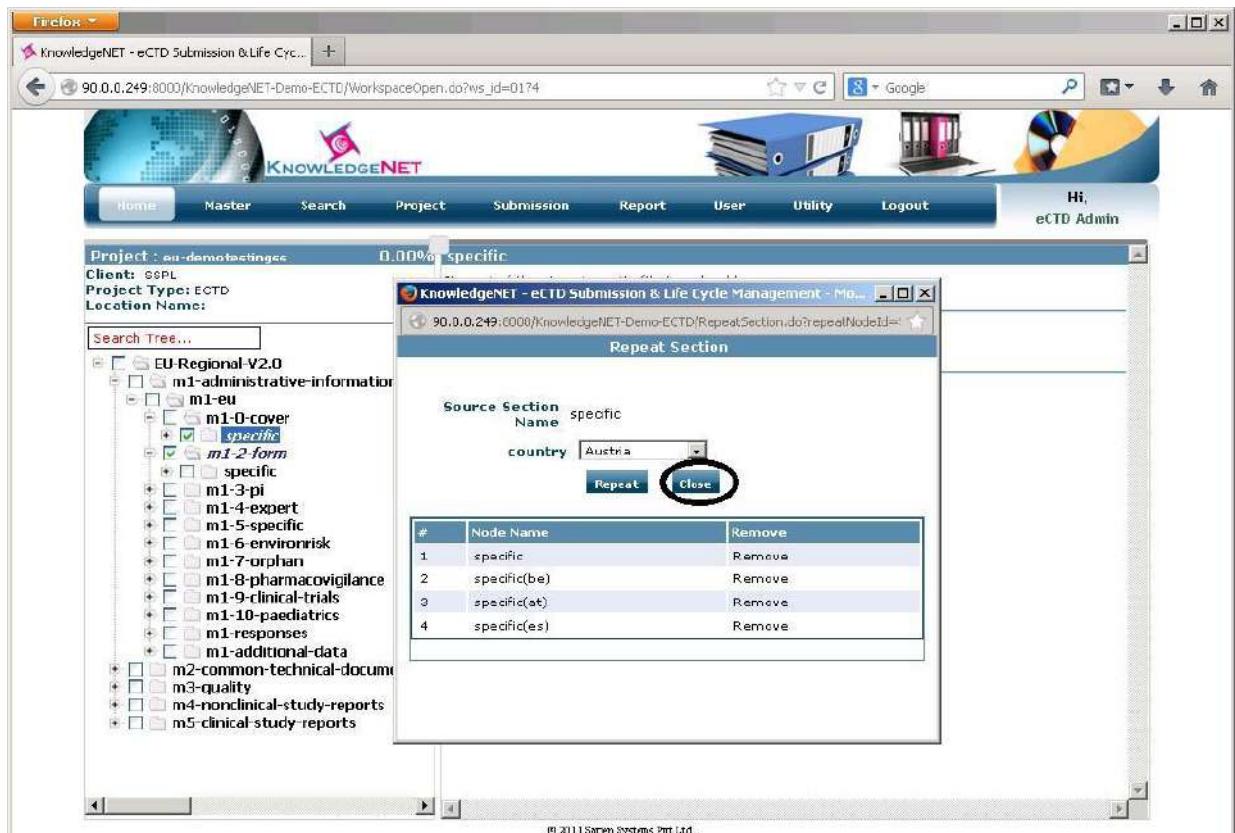
- User can repeat the leaf node country wise. Select the country Admin want to repeat.



- Select the country then click on 'Repeat' button.
- The below screen will get displayed.

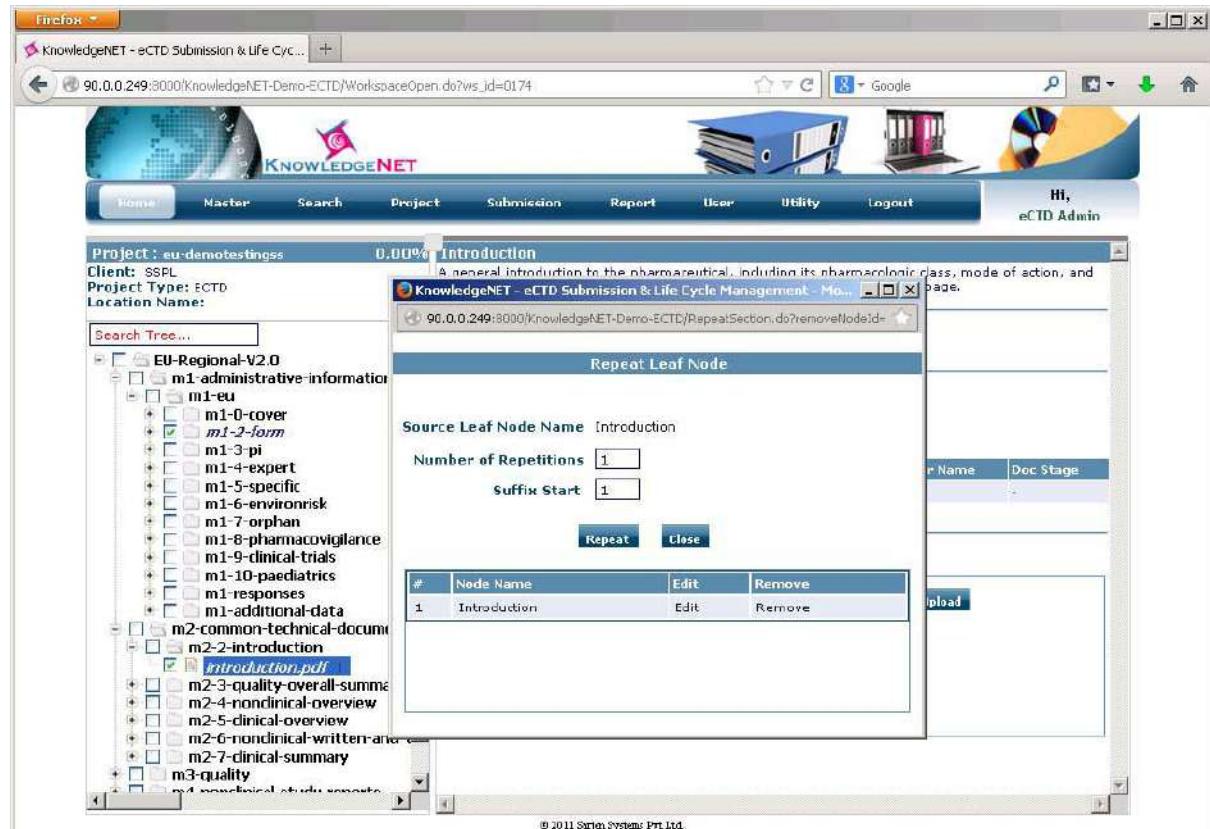


- Click on ‘Close’ button and tree structure will get refreshed as shows in below screen.



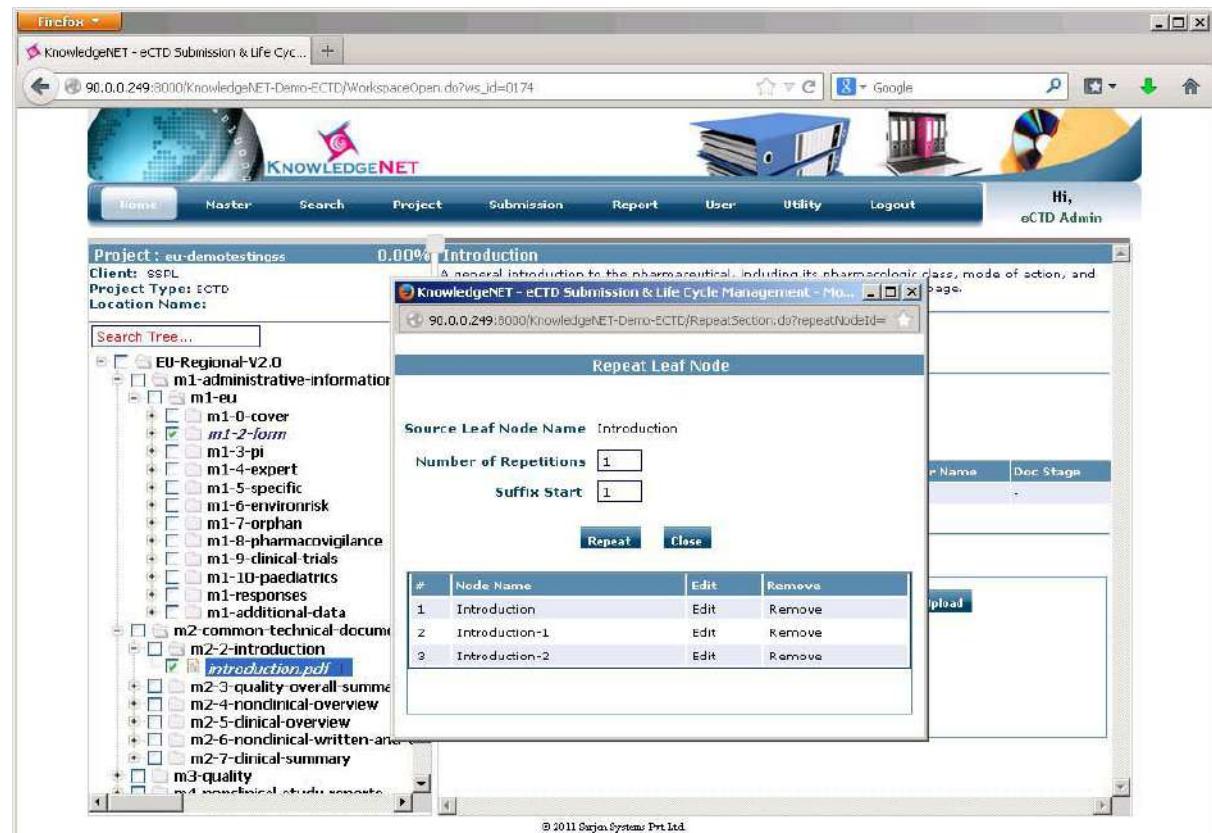
Repeat Section

- For Repeat node, click on leaf node which is shows in below screen on left side.
- Then select the “Repeat Section” from the drop down box and click on “Go” button.



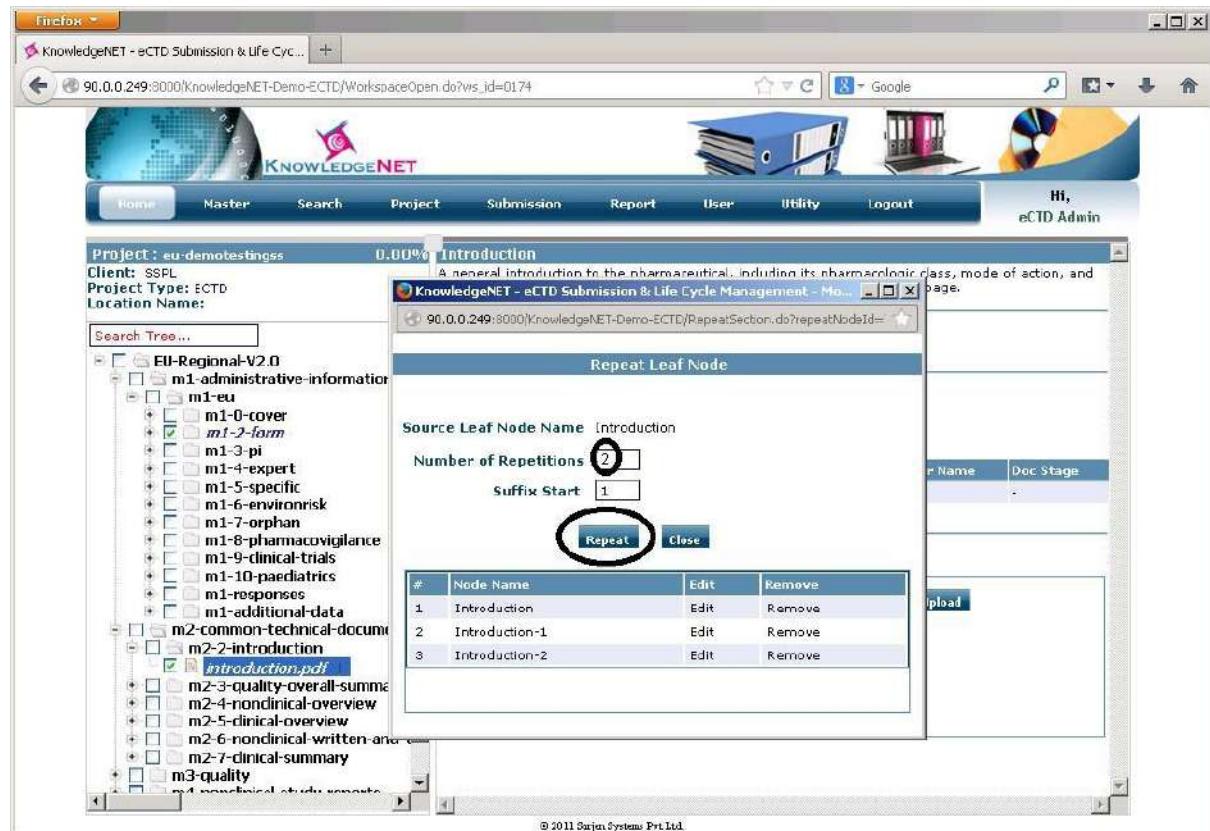
Repeat Section – No. Of Repetitions

- Enter the “Number of Repetitions” and enter the suffix start value and then click on “Repeat” button.



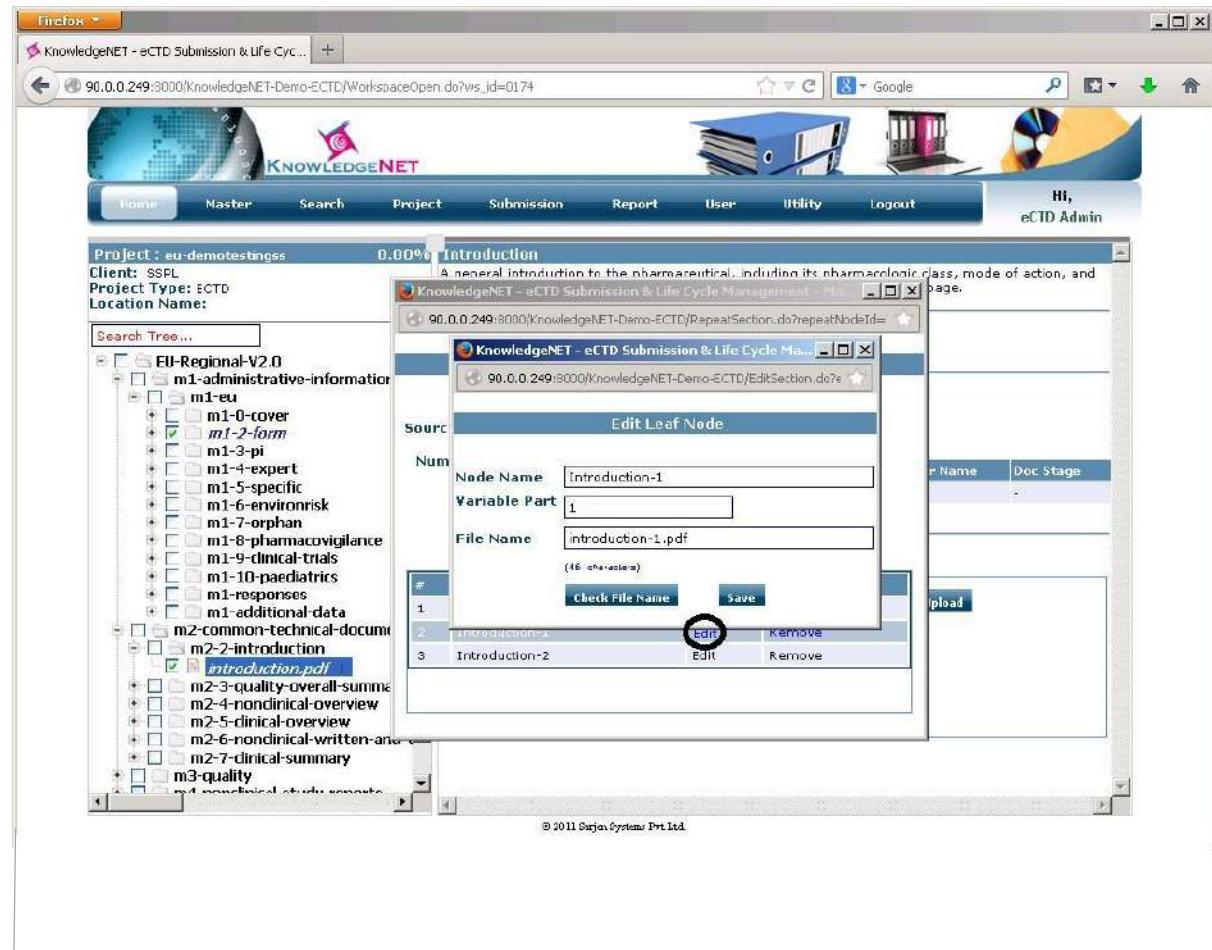
Repeat Section: – After Repetition

- The below screen shows the repetitions. User can click on ‘Edit’ link in the grid to edit the node name.
- The below small pop-up screen will get displayed.

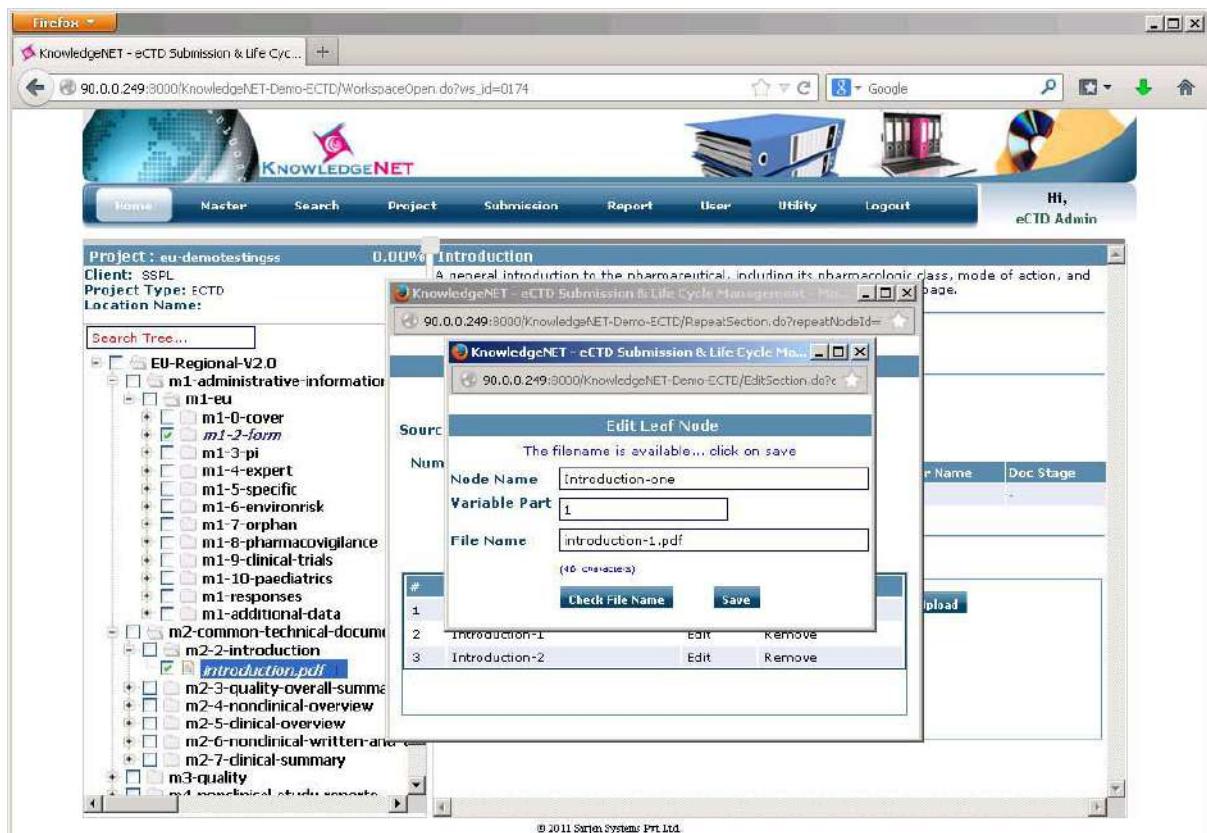


Repeat Section: - Editing Leaf Node.

- Edit the node name and click on 'Check File Name' button.

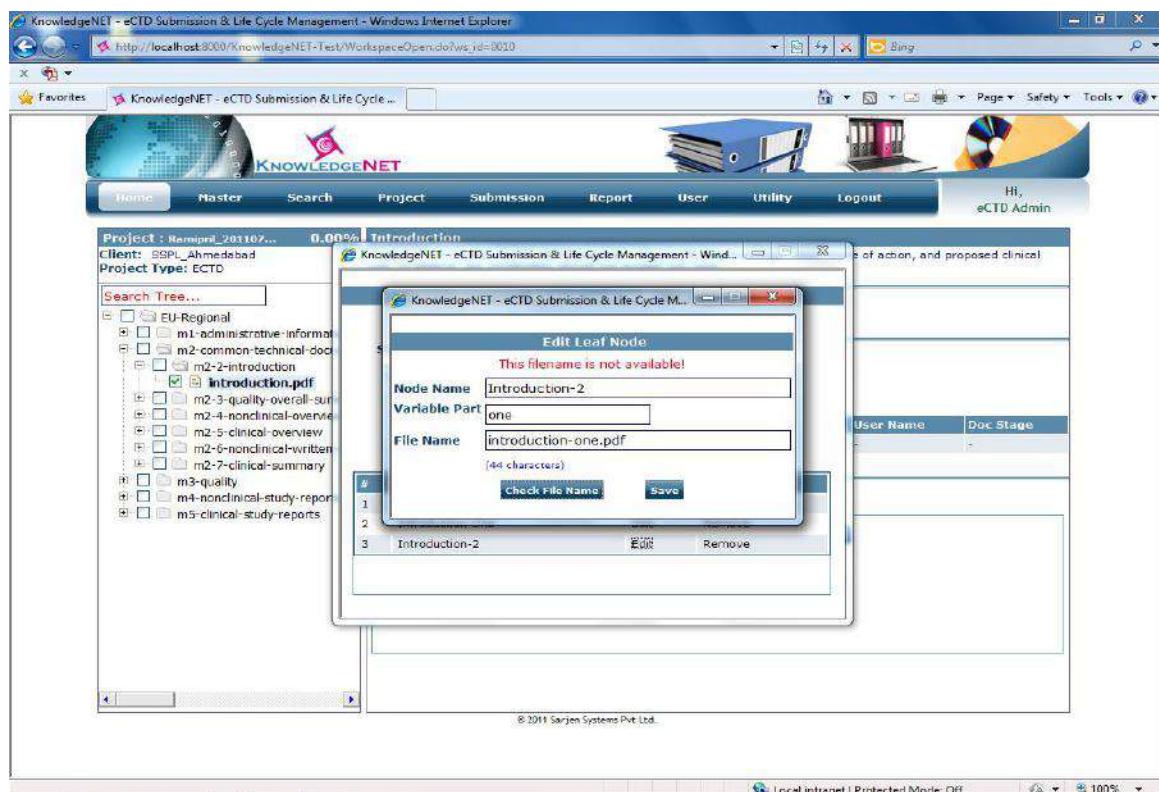


- A message will get displayed for the availability of file name as shows in below screen.



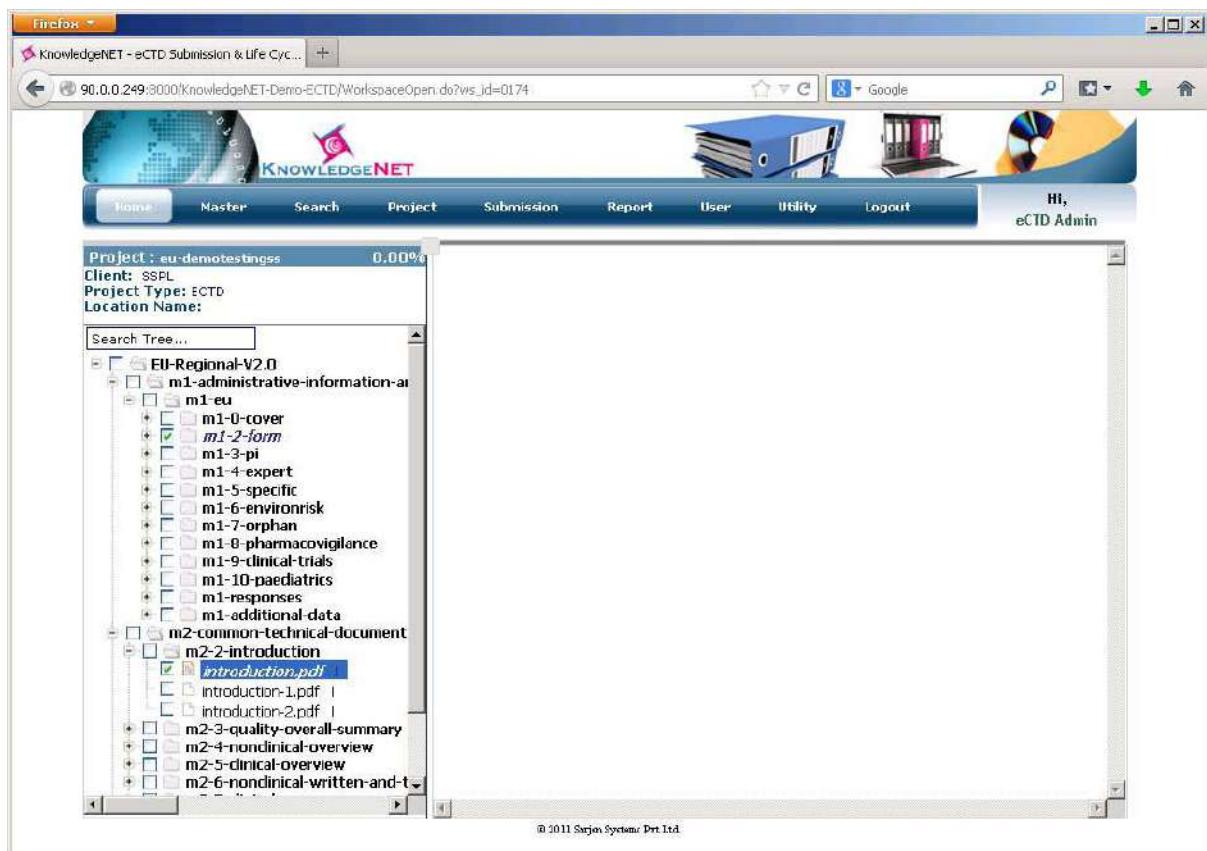
- It will not allow repetition of same file name.

- If the file name is available then a message will get displayed as shows in below screen. It will not allow a user to enter same file names.



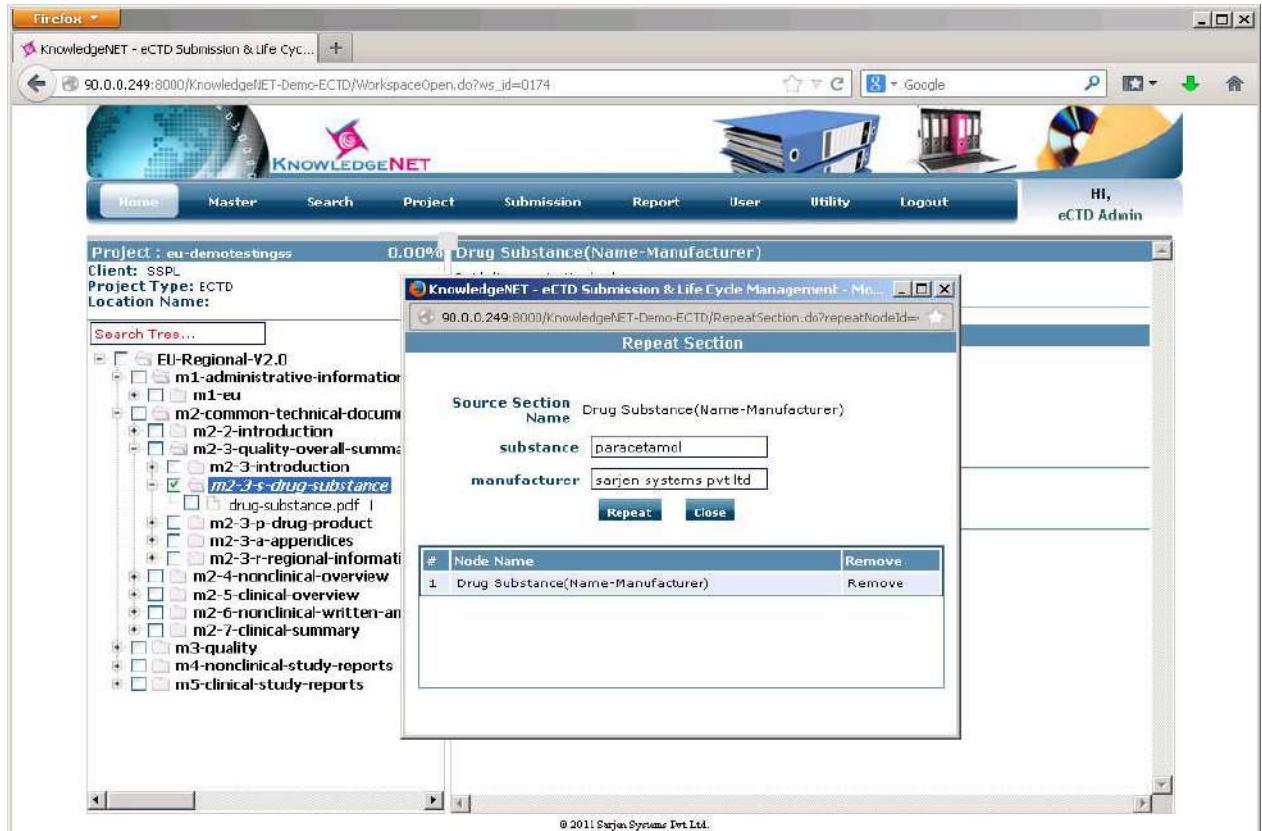
After Repetition

- On clicking ‘Close’ button, the pop-up will get closed and the tree structure will get refreshed.
- Go to the same leaf node and a user can see two repetitions as done before.



Repeat section: - Attribute Wise Repeat Form

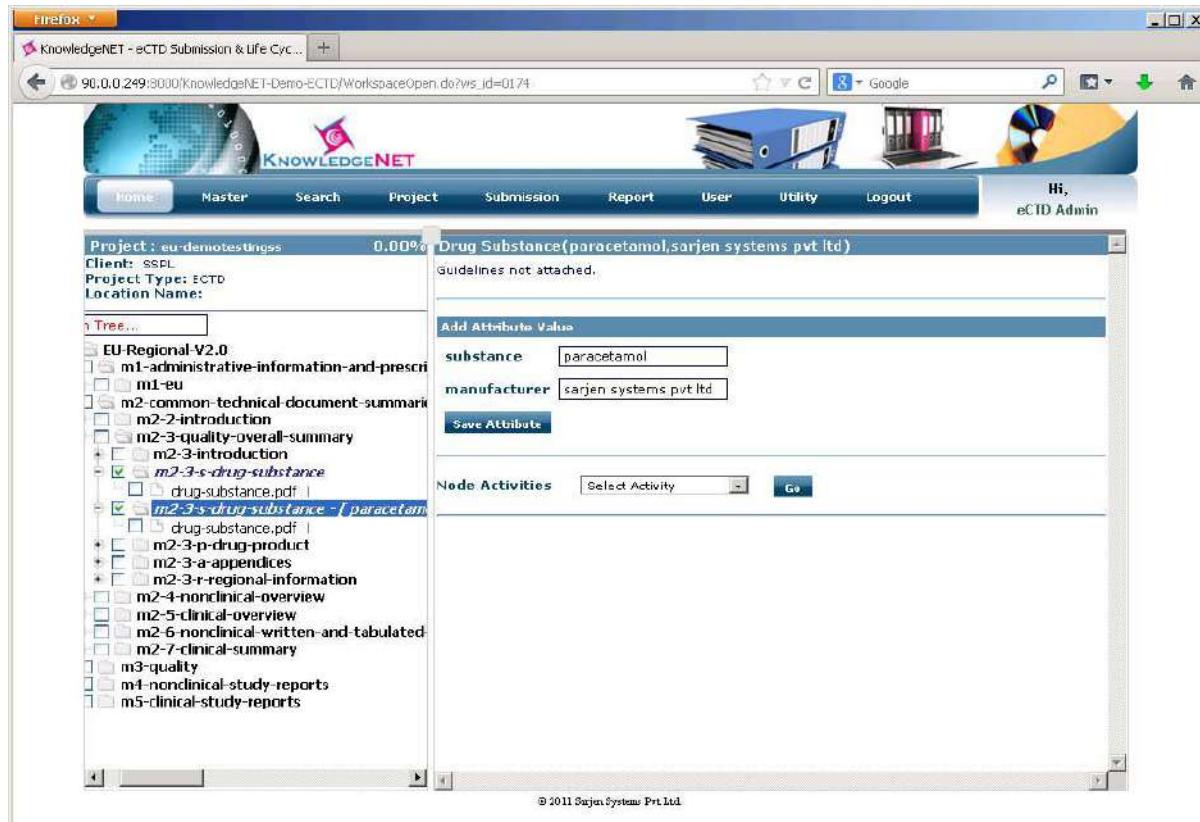
- Enter the attribute values Admin want to repeat the leaf node and click on ‘Repeat’ button.



- Click on ‘Close’ button to refresh the tree structure. The below screen will get displayed.

After Repetition Attribute Wise:

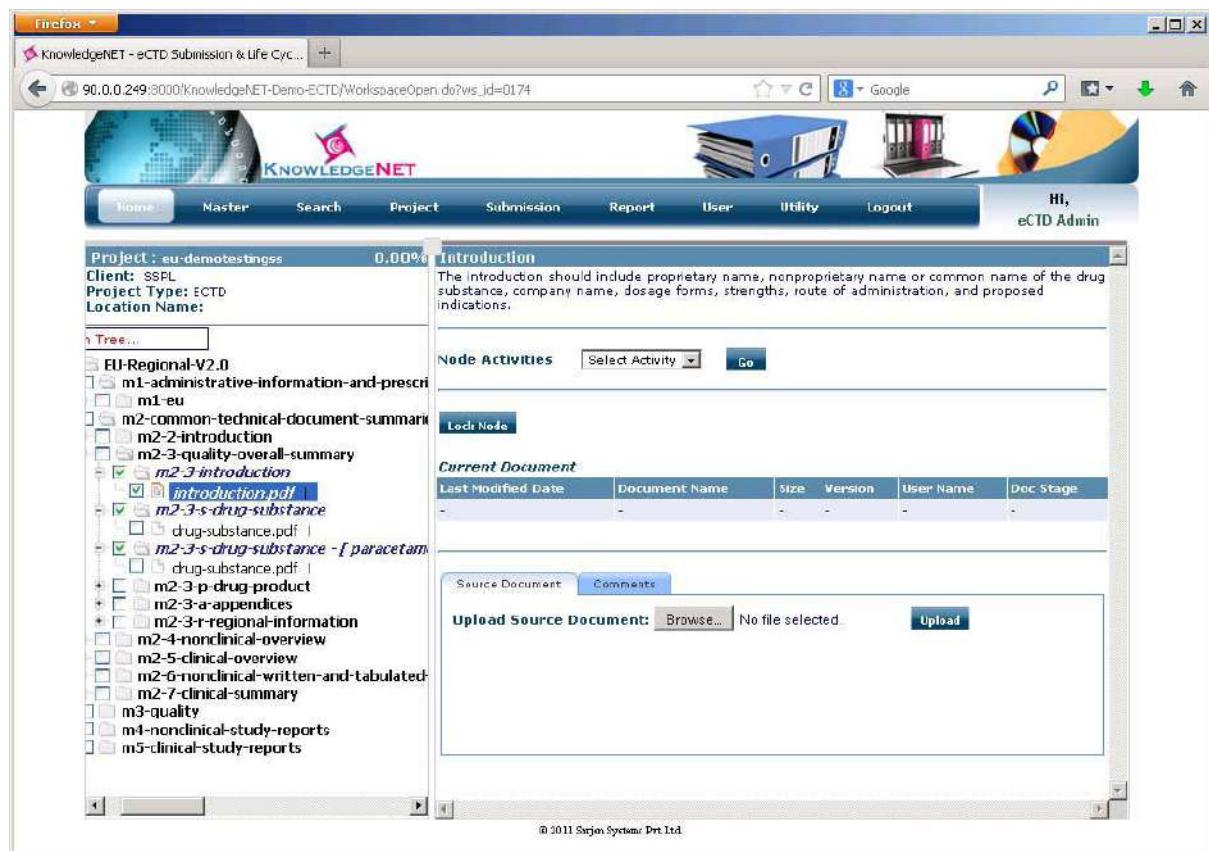
- The attribute names will be displayed on leaf node in tree structure on left hand side as shows in below screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET platform. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0174. The page title is "Drug Substance(paracetamol,sarjen systems pvt ltd)". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session is indicated as "Hi, eCID Admin". On the left, there is a tree view of project structure under "EU-Regional-V2.0", with several nodes expanded, including "m1-administrative-information-and-prescription", "m1-eu", "m2-common-technical-document-summary", "m2-2-introduction", "m2-3-quality-overall-summary", "m2-3-introduction", "m2-3-s-drug-substance", and "m2-3-s-drug-substance-[paracetamol]". The right panel contains sections for "Add Attribute Value" (with fields for substance and manufacturer) and "Node Activities" (with a dropdown menu). The footer of the page includes the copyright notice "© 2011 Sarjen Systems Pvt Ltd".

File Uploading

- Select the leaf node. Then click on “Lock Node” button.



The screenshot shows a web-based application for eCTD submission and life cycle management. The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user is logged in as 'eCTD Admin'. The main content area displays a project structure on the left and various document management features on the right.

Project Structure:

- Project: eu-denotestings
- Client: SSPL
- Project Type: ECTD
- Location Name:

Node Activities: A dropdown menu labeled "Select Activity" with a "Go" button.

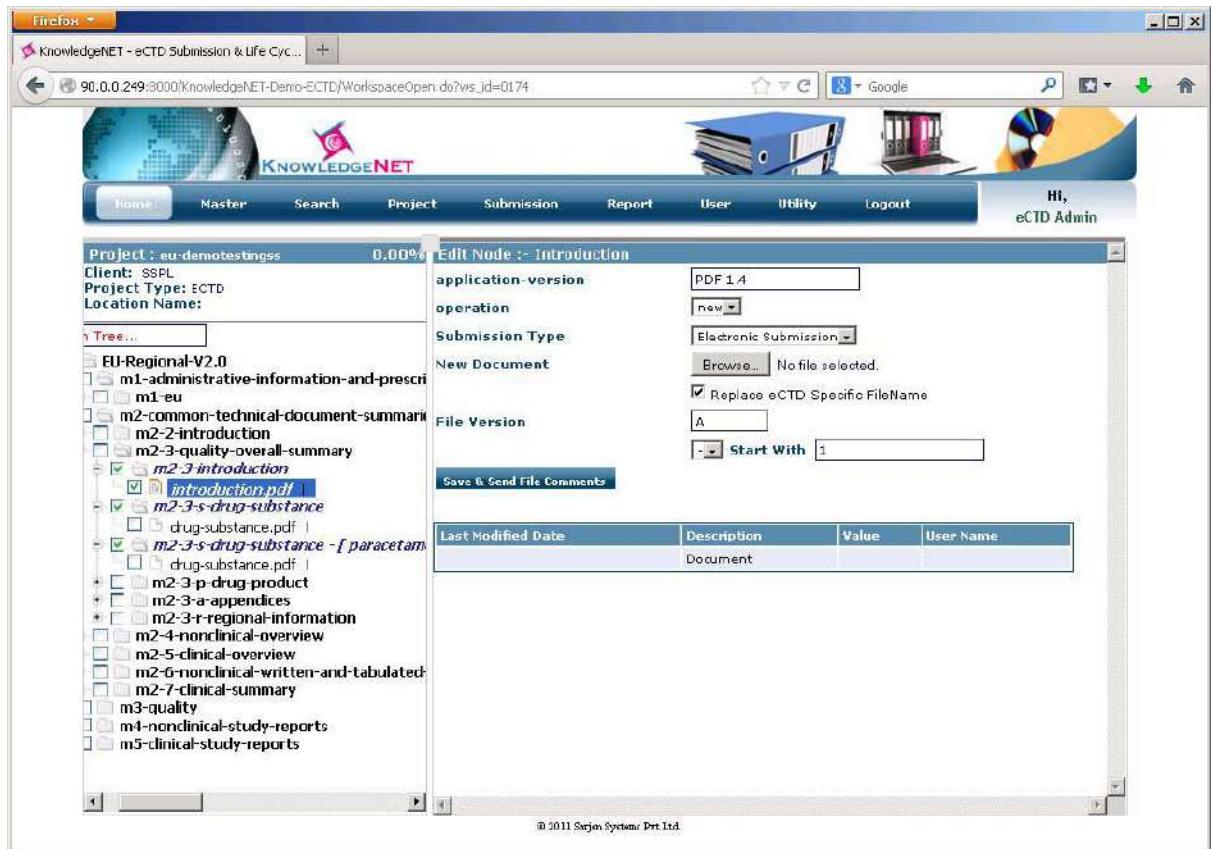
Current Document: A table showing document details:

Last Modified Date	Document Name	size	Version	User Name	Doc Stage

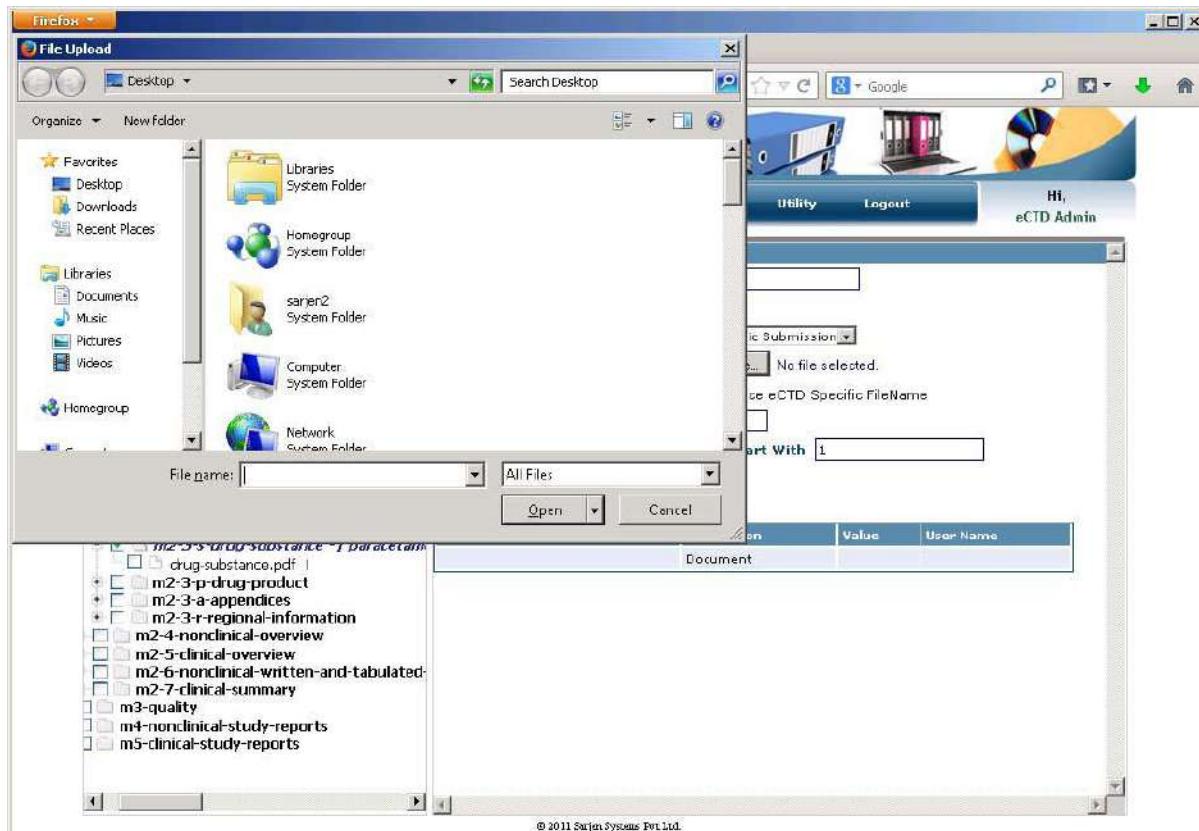
Source Document: A section for uploading files, showing "Upload Source Document" with a "Browse..." button and a message "No file selected".

Bottom Footer: © 2011 Surion Systems Pvt Ltd.

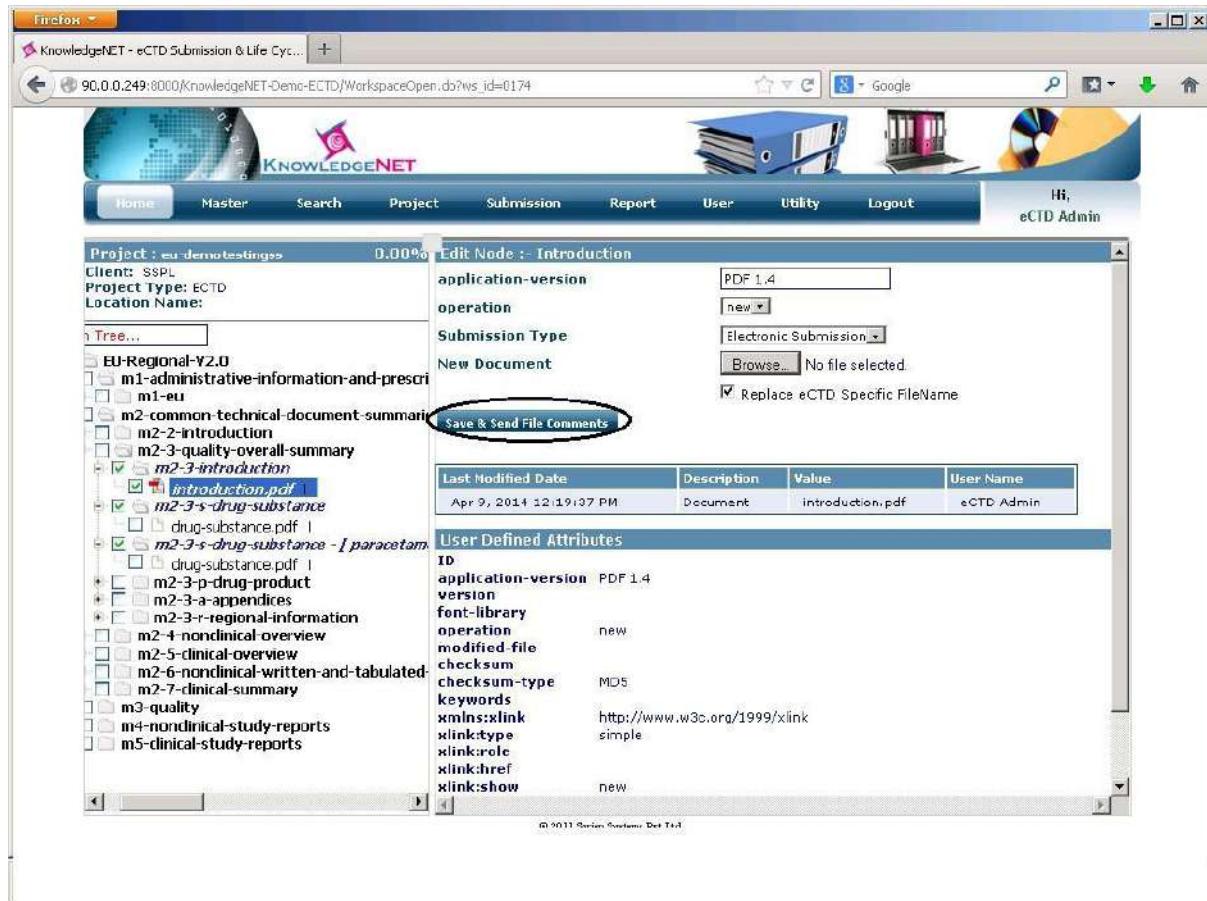
- On clicking “Lock Node”, below screen gets displayed from where a user can upload a file.



- On clicking “Browse” button, the file selection wizard will get open.

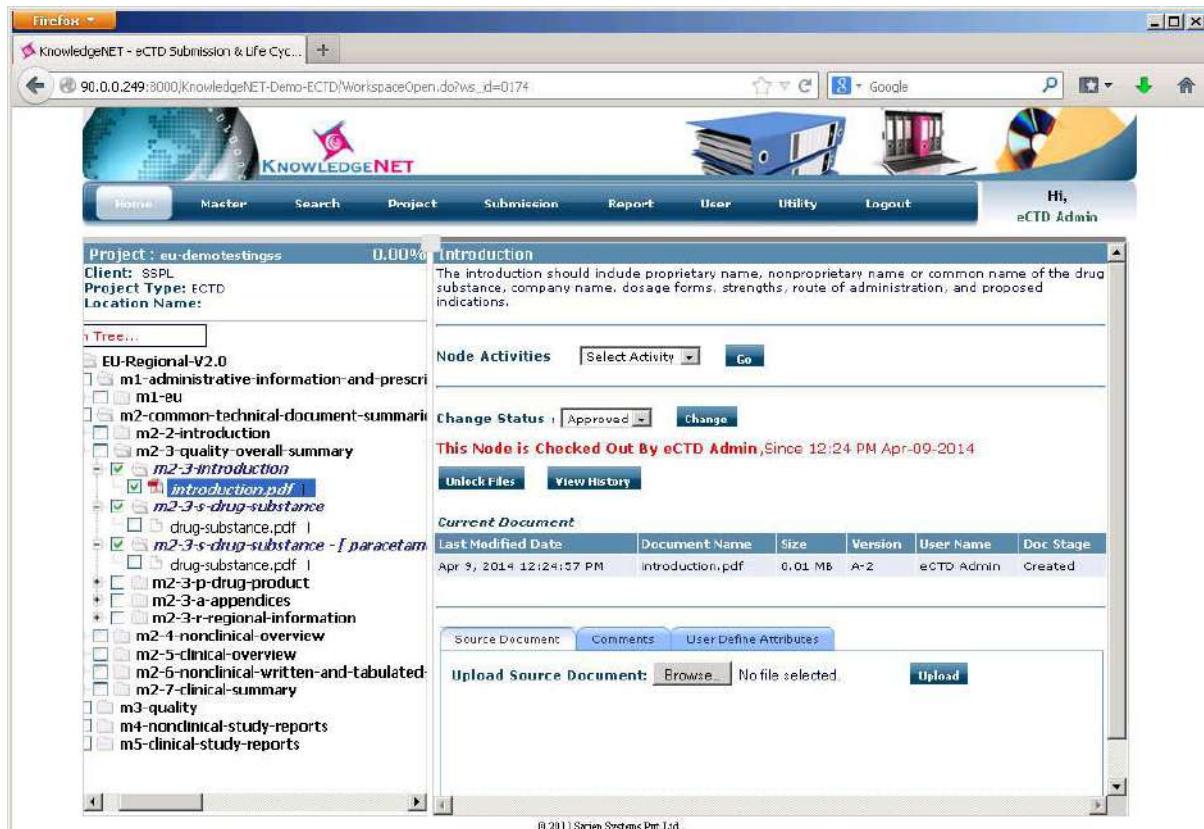


- After selecting file from specific location click on "Save & Send File Comments" to upload that file.



The screenshot shows the KnowledgeNET web application interface. The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile for 'eCTD Admin'. The main content area displays a project structure on the left and configuration settings on the right. The configuration section for the 'Introduction' node includes fields for 'application-version' (PDF 1.4), 'operation' (new), 'Submission Type' (Electronic Submission), and a 'Browse...' button with 'No file selected'. A checked checkbox labeled 'Replace eCTD Specific FileName' is also present. The 'Save & Send File Comments' button is highlighted with a blue oval. Below these settings is a table showing a log entry for 'introduction.pdf' with details like Last Modified Date (Apr 9, 2014 12:19:07 PM), Description (Document), Value (introduction.pdf), and User Name (eCTD Admin). The bottom of the page features a footer with the text '© 2011 Samsam Systems Dev Team'.

- The below screen shows two buttons “Unlock Files” and “View History”.
- On clicking “Unlock Files”, the node will be unlocked and will get saved in proper place on the File server.



The screenshot displays a web-based application for eCTD submission and life cycle management. The URL in the browser is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0174. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top navigation bar includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session is indicated as "Hi, eCTD Admin".

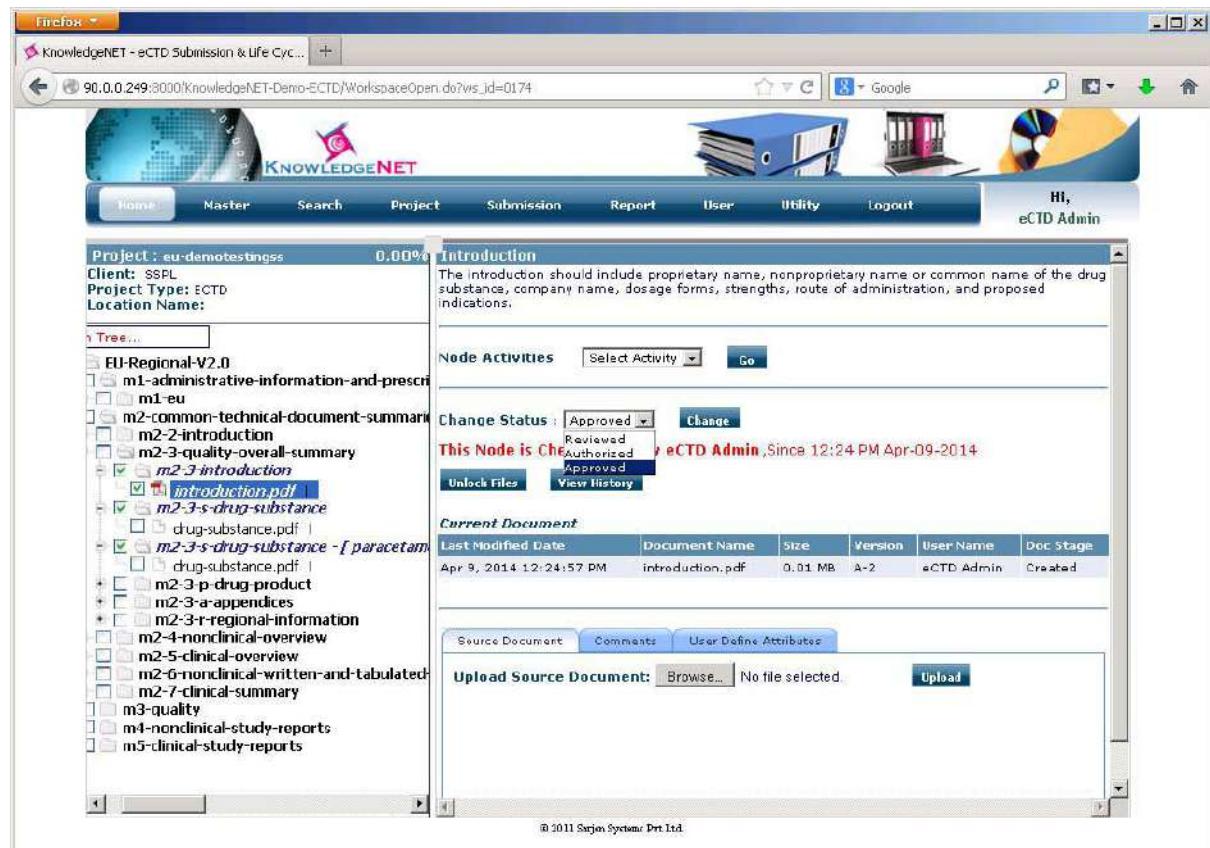
The main content area shows a project titled "Project: eu-demotestingss" with a progress of "0.00%". The client is listed as "SSPL" and the project type as "eCTD". The location name is "Location Name:". On the left, there is a tree view of the document structure under "EU-Regional-V2.0", including nodes like "m1-administrative-information-and-prescri", "m2-common-technical-document-summary", "m2-2-introduction", "m2-3-quality-overall-summary", "m2-3-introduction", "introduction.pdf", "m2-3-s-drug-substance", "drug-substance.pdf", "m2-3-s-drug-substance - [paracetam]", "drug-substance.pdf", "m2-3-p-drug-product", "m2-3-a-appendices", "m2-3-r-regional-information", "m2-4-nonclinical-overview", "m2-5-clinical-overview", "m2-6-nonclinical-written-and-tabulated", "m2-7-clinical-summary", "m3-quality", "m4-nonclinical-study-reports", and "m5-clinical-study-reports".

The central panel shows the "Introduction" document details. It includes a description: "The introduction should include proprietary name, nonproprietary name or common name of the drug substance, company name, dosage forms, strengths, route of administration, and proposed indications." Below this is a "Node Activities" section with a dropdown menu and a "Go" button. A "Change Status" button is set to "Approved". A message states "This Node is Checked Out By eCTD Admin, Since 12:24 PM Apr-09-2014". Two buttons are present: "Unlock Files" and "View History".

The "Current Document" table lists the document's metadata: Last Modified Date (Apr 9, 2014 12:24:57 PM), Document Name (introduction.pdf), Size (0.01 MB), Version (A-2), User Name (eCTD Admin), and Doc Stage (Created).

At the bottom, there is a "Source Document" section with tabs for "Comments" and "User Define Attributes". A "Upload Source Document" field includes a "Browse..." button, a message "No file selected", and an "Upload" button. The footer of the page reads "© 2011 Sejjen Systems Pvt. Ltd."

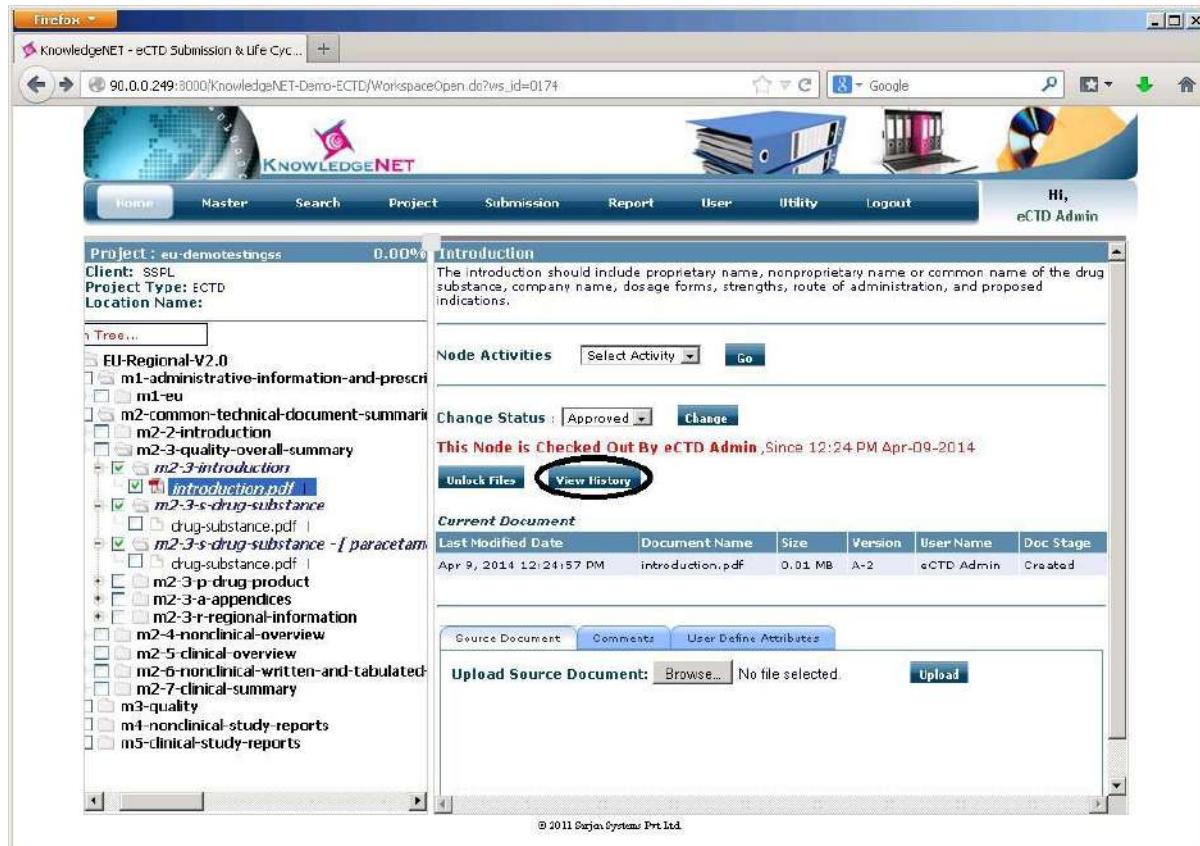
- User can select different stage values from drop down as shows in below screen.
- **Select any stage and click on 'Change' button. The column 'Doc Stage' in the grid which shows the document status will get change.**
- The files which have been approved will only go in submission. Thus if user wants a particular file in submission of project, then that file needs to be approved.



The screenshot shows the KnowledgeNET eCTD Submission & Life Cycle Management Module. The left sidebar displays a hierarchical tree view of project documents under 'EU-Regional-V2.0'. The main content area is focused on the 'Introduction' node, which is currently selected. The 'Node Activities' section includes a dropdown for 'Change Status' set to 'Approved' and a 'Change' button. Below this, a message states 'This Node is Checked by eCTD Admin, Since 12:24 PM Apr-09-2014'. The 'Current Document' grid lists the 'introduction.pdf' file with details: Last Modified Date (Apr 9, 2014 12:24:57 PM), Document Name (introduction.pdf), Size (0.01 MB), Version (A-2), User Name (eCTD Admin), and Doc Stage (Created). At the bottom, there is a section for uploading a source document with a 'Browse...' button and an 'Upload' button.

File History

- To view the file history, click on "View History" button.



The screenshot shows a Firefox browser window displaying the KnowledgeNET platform. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ETCD/WorkspaceOpen.do?vis_id=0174. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top navigation bar includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A "Hi, eCTD Admin" greeting is visible on the right. The main content area shows a project structure tree on the left with nodes like EU-Regional-V2.0, m1-administrative-information-and-prescri..., and m2-common-technical-document-summary. On the right, there is an "Introduction" section with a detailed description of what should be included in the introduction. Below it is a "Node Activities" section with a "Select Activity" dropdown and a "Go" button. A "Change Status" dropdown is set to "Approved" with a "Change" button. A message states "This Node is Checked Out By eCTD Admin, Since 12:24 PM Apr-09-2014". Two buttons, "Unlock Files" and "View History", are present; "View History" is highlighted with a red oval. A "Current Document" table lists the document's details: Last Modified Date (Apr 9, 2014 12:24:57 PM), Document Name (introduction.pdf), Size (0.01 MB), Version (A-2), User Name (eCTD Admin), and Doc Stage (Created). At the bottom, there are tabs for "Source Document", "Comments", and "User Define Attributes", followed by an "Upload Source Document" field with a "Browse..." button and an "Upload" button.

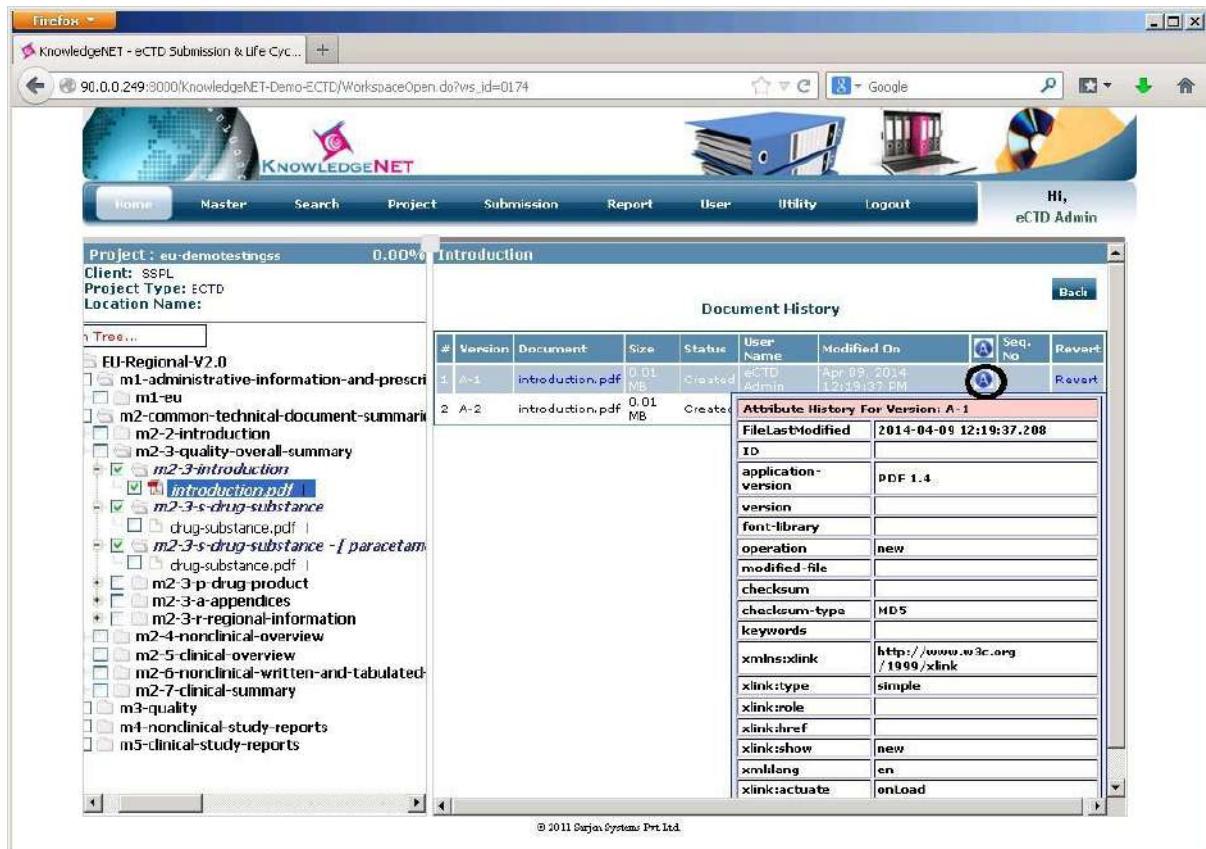
- User can see the document history and also open that file on clicking the file name.
- Click on “Back” button to go to previous screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0174. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, along with a greeting for "Hi, eCTD Admin". On the left, there is a tree view of project structure under "Project : eu-demotestingss". The tree shows various sections like EU-Regional-V2.0, m1-administrative-information-and-prescri..., and m2-common-technical-document-summary. In the center, a table titled "Document History" lists two versions of a file named "introduction.pdf". The table columns are #, Version, Document, Size, Status, User Name, Modified On, Seq. No, and Revert. The first row (A-1) was created by eCTD Admin on Apr 09, 2014, at 12:19:37 PM. The second row (A-2) was also created by eCTD Admin on Apr 09, 2014, at 12:24:56 PM. A "Revert" link is present next to each row.

#	Version	Document	Size	Status	User Name	Modified On	Seq. No	Revert
1	A-1	introduction.pdf	0.01 MB	Created	eCTD Admin	Apr 09, 2014 12:19:37 PM		Revert
2	A-2	introduction.pdf	0.01 MB	Created	eCTD Admin	Apr 09, 2014 12:24:56 PM		Revert

- Admin can also view the history of node of a replicated project with a different version as shows in the below screen shot.



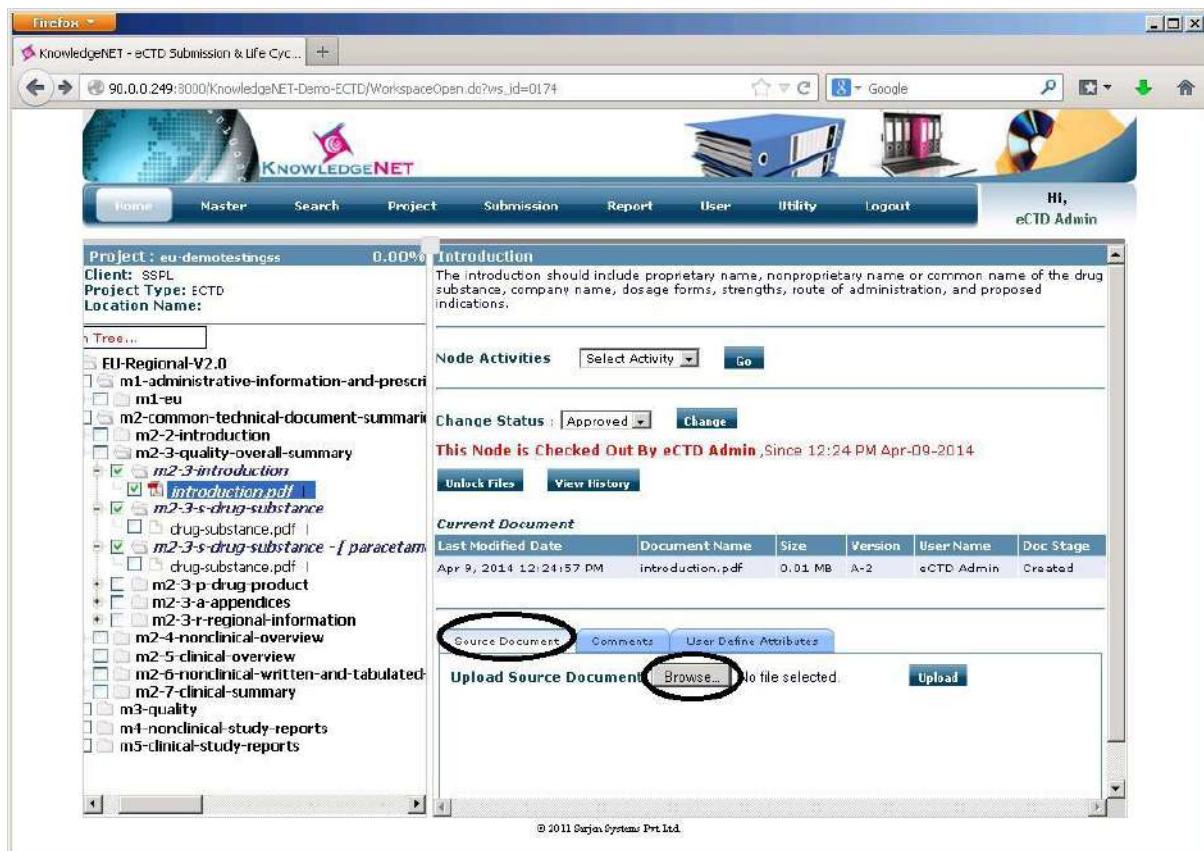
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceOpen.do?vs_id=0174. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top navigation bar includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a "Hi, eCTD Admin" greeting. On the left, there is a tree view of the project structure under "EU-Regional-V2.0", showing various sub-folders like m1-administrative-information-and-prescri... and m2-common-technical-document-summary. The main content area displays the "Introduction" section with a "Document History" table and an "Attribute History For Version: A-1" table. The "Document History" table has columns for #, Version, Document, Size, Status, User Name, Modified On, Seq. No, and Revert. It shows two versions: A-1 (introduction.pdf) and A-2 (introduction.pdf). The "Attribute History For Version: A-1" table lists various attributes with their values, such as FileLastModified (2014-04-09 12:19:37.208), application-version (PDF 1.4), and keywords (new).

#	Version	Document	Size	Status	User Name	Modified On	Seq. No	Revert
1	A-1	introduction.pdf	0.01 MB	Created	eCTD Admin	Apr 09, 2014 12:19:37 PM	A	Revert
2	A-2	introduction.pdf	0.01 MB	Created				

Attribute History For Version: A-1	
FileLastModified	2014-04-09 12:19:37.208
ID	
application-version	PDF 1.4
version	
font-library	
operation	new
modified-file	
checksum	
checksum-type	MD5
keywords	
xmns:xlink	http://www.w3.org/1999/xlink
xlink:type	simple
xlink:role	
xlink:href	
xlink:show	new
xmidlang	en
xlink:actuate	onLoad

Source Doc Upload

- User can upload a source document on clicking ‘Browse’ button shows on right side of screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cyc... application at 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0174. The interface includes a header with the KnowledgeNET logo, a navigation menu with links like Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, and a user profile 'Hi, eCTD Admin'. The main content area shows a project structure tree on the left under 'EU-Regional-V2.0' with nodes such as m1-administrative-information-and-prescri, m2-common-technical-document-summary, m2-2-introduction, m2-3-quality-overall-summary, m2-3-introduction, introduction.pdf, m2-3-s-drug-substance, drug-substance.pdf, m2-3-p-drug-product, m2-3-a-appendices, m2-3-r-regional-information, m2-4-nonclinical-overview, m2-5-clinical-overview, m2-6-nonclinical-written-and-tabulated, m2-7-clinical-summary, m3-quality, m4-nonclinical-study-reports, and m5-clinical-study-reports. On the right, there is an 'Introduction' section with a detailed description, 'Node Activities' dropdown, 'Change Status' to 'Approved', and a note that the node is checked out by 'eCTD Admin'. Below this is a 'Current Document' table showing 'introduction.pdf' details. At the bottom, there is a 'Source Document' tab, a 'Comments' tab, a 'User Define Attributes' tab, an 'Upload Source Document' section with a 'Browse...' button (circled in red), and an 'Upload' button.

- After uploading of a file, the data will get displayed in grid as shows in below screen.



The screenshot shows the KnowledgeNET eCTD Submission & Life Cycle Management Module interface. The top navigation bar includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A banner at the top right says "Hi, eCTD Admin". The main content area shows a project structure tree on the left under "EU-Regional-V2.0". A selected node, "introduction.pdf", is highlighted. To the right of the tree, there is an "Introduction" section with a brief description. Below this is a "Node Activities" section with a dropdown menu and a "Go" button. A "Change Status" button is set to "Approved". A message states "This Node is Checked Out By eCTD Admin, Since 12:24 PM Apr-09-2014". Below these are sections for "Current Document" and "Source Document", both showing a table with one row. At the bottom, there is a "Comments" section and a "User Define Attributes" section. The bottom right corner contains the copyright notice "© 2011 Surion Systems Pvt Ltd".

Set Ectd Attribute Value

- ❖ Some of the heading elements (nodes) in the eCTD backbone file have attributes associated with them.
- ❖ Attributes help in organizing (identifying) the file information.
- ❖ There are different types of attributes such as "substance", "manufacturer", "product name", "dosage form", "excipient" and "indication".
- ❖ Different attributes are attached on different files (heading elements).
- ❖ "Indication" attribute is to provide clinical indication (product used to cure kind of diseases).
- ❖ e.g. m2-common-technical-document-summaries is the heading element on which attribute-indication can be attached (examples of indication attribute- pneumonia, sepsis).
- ❖ "Drug substance" and "Manufacturer" attributes provide text to indicate the drug substance name or names of manufacturers of the drug substance. e.g. m3-2-s-drug-substance is the element, on which attribute-substance, manufacturer can be attached (examples of substance and manufacturer attribute-"Cure All USP, "China-DMF-999999").
- ❖ "Product Name", "dosage form" and "manufacturer" attributes provide text to indicate drug product names, dosage forms and manufacturers of drug product. E.g. m3-2-p-drug-product is the element on which attributes can be attached (examples of product name, dosage form, and manufacturer are cure All, Injection, China Plant 1 DMF-0000001).
- ❖ **Excipient Attribute**, its purpose is to provide text to indicate the excipient for which information is being provided. Example m3-2-p-4-control-of-excipients is the heading element on which attribute can be attached such as "corn syrup".

Following are the heading elements on which attributes are attached

Attribute Name	Applicable heading elements
substance	m3-2-s-drug-substance m3-2-a-1-facilities-and-equipment m3-2-a-2-adventitious-agents-safety-evaluation m2-3-s-drug-substance
manufacturer	m3-2-s-drug-substance m3-2-p-drug-product m3-2-a-1-facilities-and-equipment m3-2-a-2-adventitious-agents-safety-evaluation m2-3-s-drug-substance

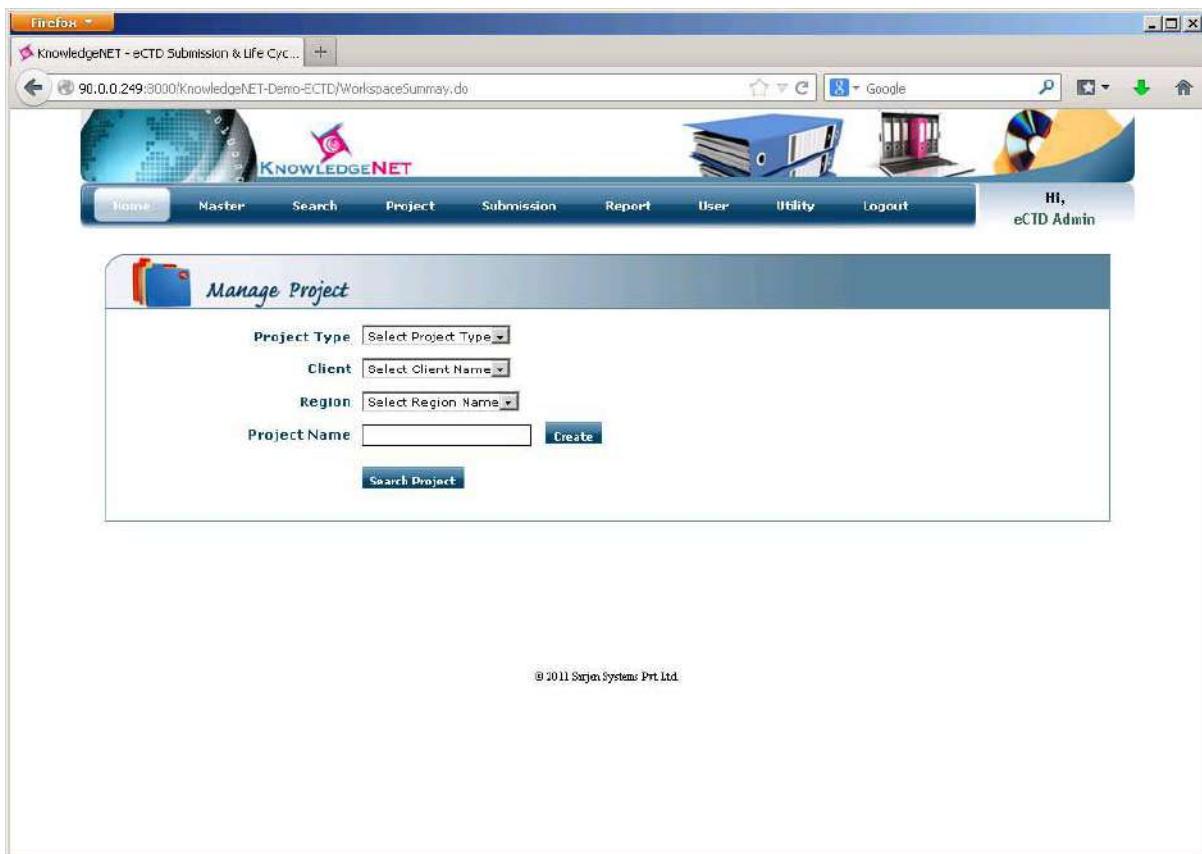
product-name	m3-2-p-drug-product m3-2-a-1-facilities-and-equipment m3-2-a-2-adventitious-agents-safety-evaluation m2-3-p-drug-product
Dosage form	m3-2-p-drug-product m3-2-a-1-facilities-and-equipment m3-2-a-2-adventitious-agents-safety-evaluation m2-3-p-drug-product
excipient	m3-2-p-4-control-of-excipients m3-2-a-3-excipient
indication	m2-7-3-summary-of-clinical-efficacy m5-3-5-reports-of-efficacy-and-safety-studies

Manage

Admin will be able to search the created projects through Manage menu.

Project >Manage

- From the below screen, user will be able to search the projects.
- On clicking “Search Project”, user will be able to view all the projects.
- User can also view the project(s) according to the selection criteria.



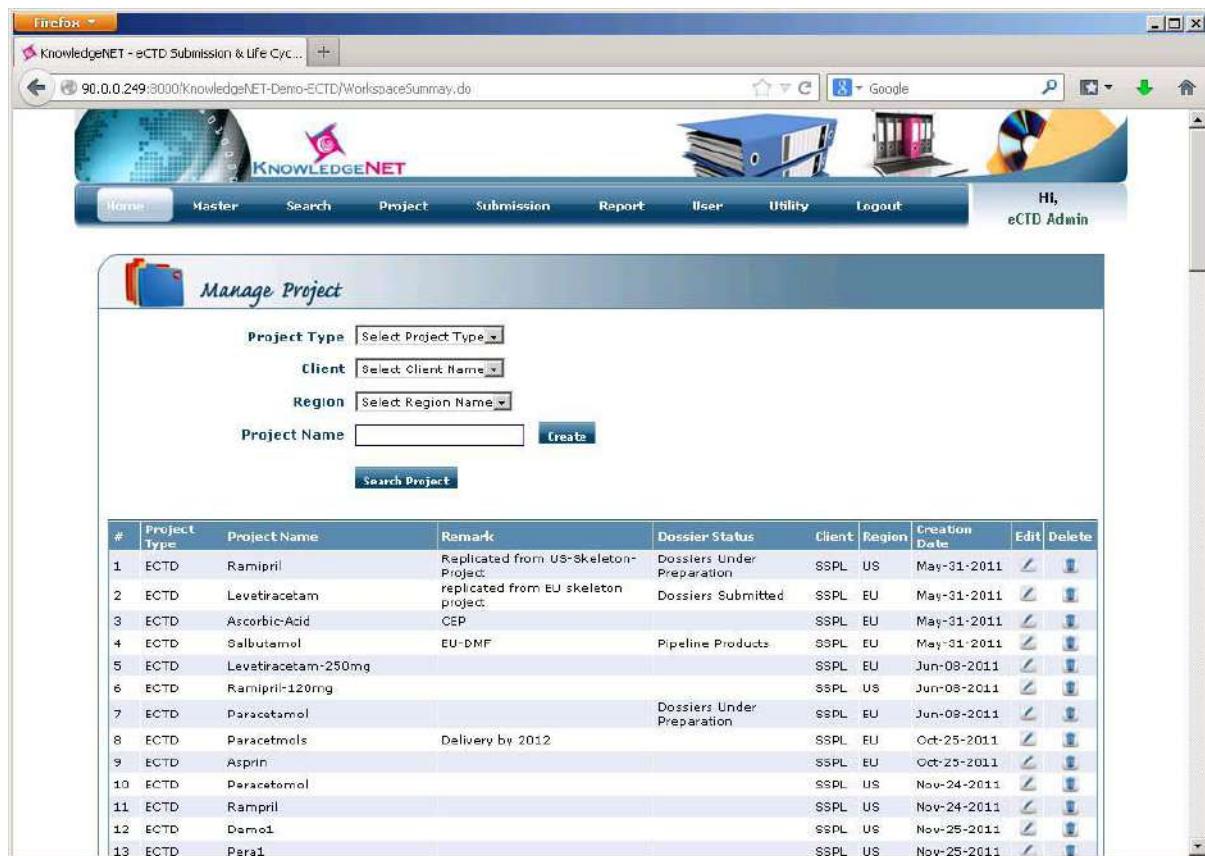
Example:

- If user wants to see the project/s having any particular project type then user has to select the “Project Type” and click on “Search Project”.
- If user wants to see the project/s having any particular client then user has to select the “Client” and click on “Search Project”.
- If user wants to see the project/s having any particular location then user has to select the “Region” and click on “Search Project”.
- If user wants to see any particular project mention project name in “Project Name” field and click on “Search Project”.

On clicking “Search Projects” [from the above screen]

Screen 1.1:

- For each project, grid will display respective “Project Type”, “Project Name”, “Remark”, “Client”, “Region” (Location) information and the “Creation Date” of the project.



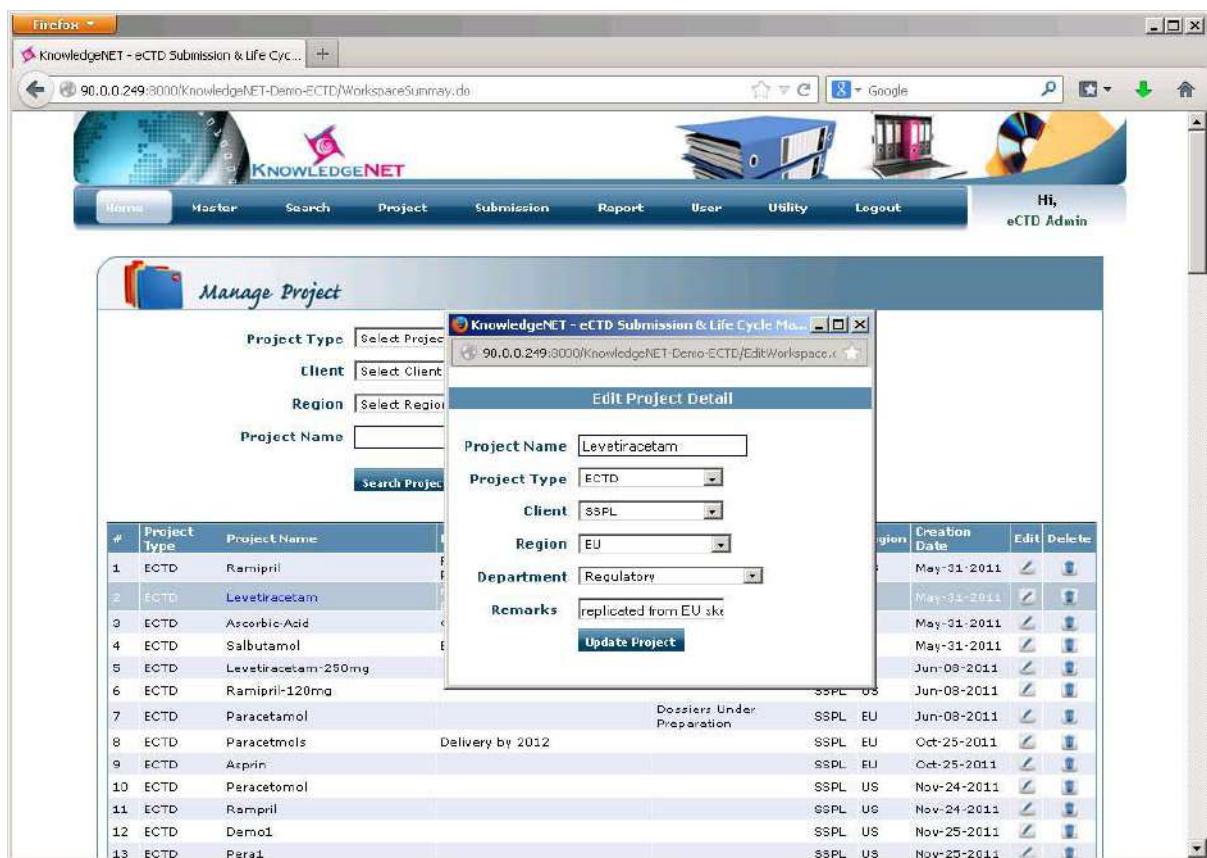
#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1	ECTD	Ramipril	Replicated from US-skeleton-Project replicated from EU skeleton project.	Dossiers Under Preparation	SSPL	US	May-31-2011		
2	ECTD	Levetiracetam		Dossiers Submitted	SSPL	EU	May-31-2011		
3	ECTD	Ascorbic-Acid	CEP		SSPL	EU	May-31-2011		
4	ECTD	Salbutamol	EU-DMF	Pipeline Products	SSPL	EU	May-31-2011		
5	ECTD	Levetiracetam-250mg			SSPL	EU	Jun-09-2011		
6	ECTD	Ramipril-120mg			SSPL	US	Jun-09-2011		
7	ECTD	Paracetamol		Dossiers Under Preparation	SSPL	EU	Jun-09-2011		
8	ECTD	Paracetmols	Delivery by 2012		SSPL	EU	Oct-25-2011		
9	ECTD	Asprin			SSPL	EU	Oct-25-2011		
10	ECTD	Paracetamol			SSPL	US	Nov-24-2011		
11	ECTD	Ramipril			SSPL	US	Nov-24-2011		
12	ECTD	Demo1			SSPL	US	Nov-25-2011		
13	ECTD	Para1			SSPL	US	Nov-25-2011		

- To edit the project information click on “Edit” icon, it will allow the user to edit the respective project information as below.

On Clicking "Edit" [from screen 1.1]

Screen 1.2:

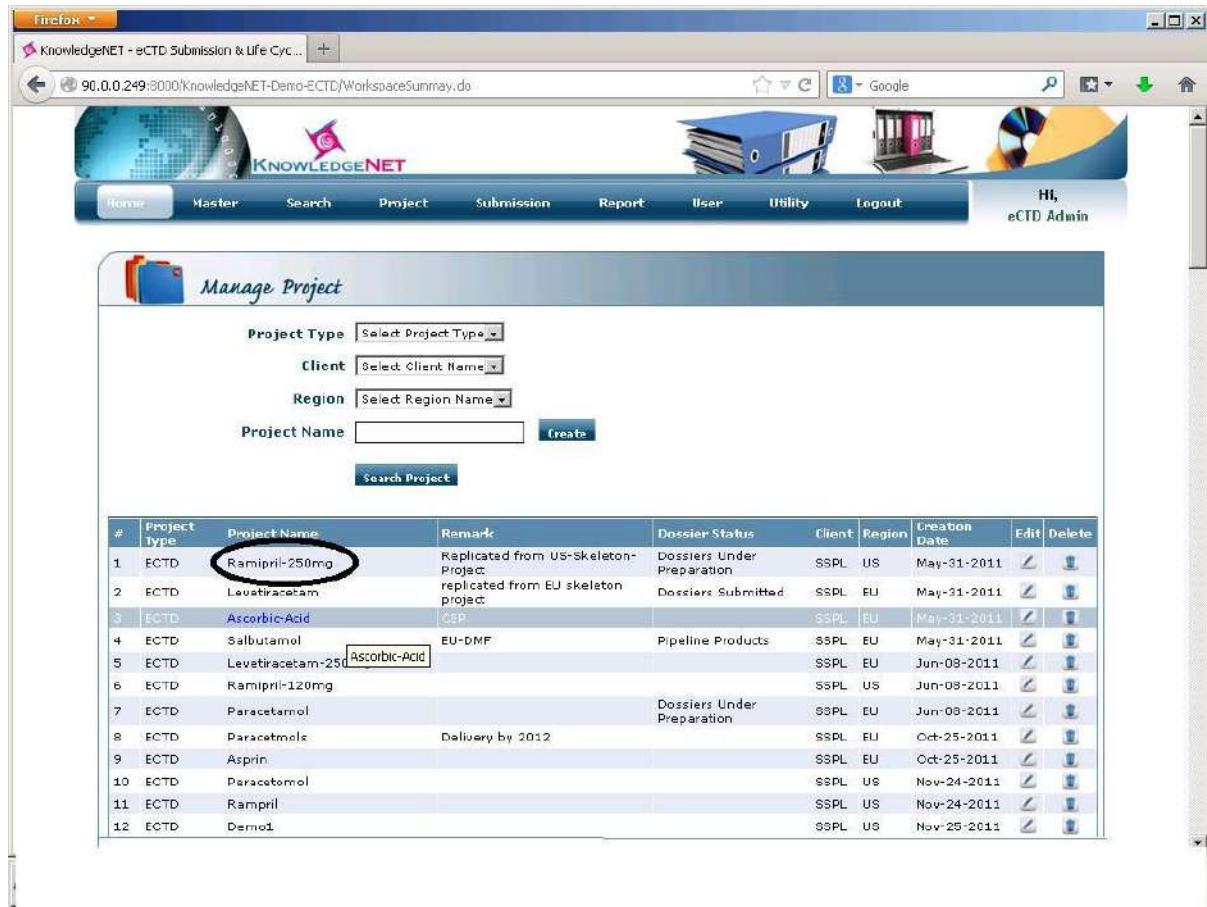
- On clicking “Edit” icon, below screen will be displayed which will allow the user to edit the project information.
- Update the project name.
- It will check for the availability of the project and will display a message whether this project name already exists or not.
- On clicking “Update Project”, record will be updated.



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The main page is titled 'Manage Project' and lists various projects with columns for Project Type, Project Name, and other details. An 'Edit Project Detail' dialog box is open over the main content, containing fields for Project Name (Levetiracetam), Project Type (eCTD), Client (SSPL), Region (EU), Department (Regulatory), and Remarks (replicated from EU site). A 'Update Project' button is at the bottom of the dialog. The background table shows the following data:

#	Project Type	Project Name	Dossiers Under Preparation	Region	Creation Date	Edit	Delete
1	eCTD	Ramipril		SSPL US	May-31-2011	<input type="button"/>	<input type="button"/>
2	eCTD	Levetiracetam		SSPL EU	May-31-2011	<input type="button"/>	<input type="button"/>
3	eCTD	Ascorbic Acid		SSPL EU	May-31-2011	<input type="button"/>	<input type="button"/>
4	eCTD	Salbutamol		SSPL US	May-31-2011	<input type="button"/>	<input type="button"/>
5	eCTD	Levetiracetam-250mg		SSPL US	Jun-08-2011	<input type="button"/>	<input type="button"/>
6	eCTD	Ramipril-120mg		SSPL US	Jun-08-2011	<input type="button"/>	<input type="button"/>
7	eCTD	Paracetamol		SSPL EU	Jun-08-2011	<input type="button"/>	<input type="button"/>
8	eCTD	Paracetamols	Delivery by 2012	SSPL EU	Oct-25-2011	<input type="button"/>	<input type="button"/>
9	eCTD	Aspirin		SSPL EU	Oct-25-2011	<input type="button"/>	<input type="button"/>
10	eCTD	Peracetomol		SSPL US	Nov-24-2011	<input type="button"/>	<input type="button"/>
11	eCTD	Ramipril		SSPL US	Nov-24-2011	<input type="button"/>	<input type="button"/>
12	eCTD	Demo1		SSPL US	Nov-25-2011	<input type="button"/>	<input type="button"/>
13	eCTD	Pera1		SSPL US	Nov-25-2011	<input type="button"/>	<input type="button"/>

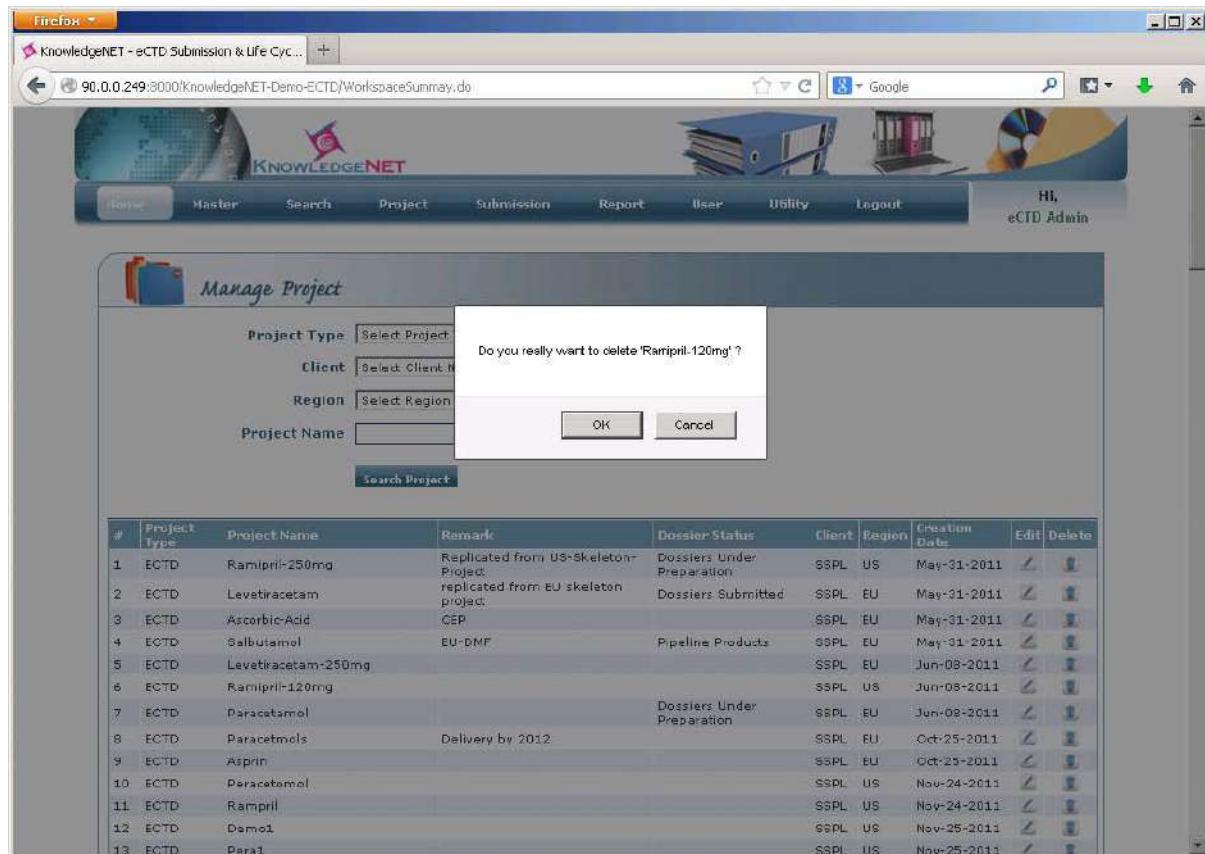
- On clicking 'Search Project', the grid displayed shows that a record is updated successfully.
- To delete a particular project click on "Delete" icon. It will ask for confirmation for delete.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceSummary.do. The main interface is titled 'Manage Project'. At the top, there are input fields for 'Project Type' (dropdown), 'Client' (dropdown), 'Region' (dropdown), and a 'Project Name' text input field with a 'Create' button. Below these is a 'Search Project' button. The main area is a grid table with the following data:

#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1	ECTD	Ramlipril-250mg	Replicated from US-Skeleton-Project. replicated from EU skeleton project.	Dossiers Under Preparation	SSPL	US	May-31-2011	<input type="checkbox"/>	<input type="checkbox"/>
2	ECTD	Levetiracetam		Dossiers Submitted	SSPL	EU	May-31-2011	<input type="checkbox"/>	<input type="checkbox"/>
3	ECTD	Ascorbic-acid	CSP		SSPL	EU	May-31-2011	<input type="checkbox"/>	<input type="checkbox"/>
4	ECTD	Salbutamol	EU-DMF	Pipeline Products	SSPL	EU	May-31-2011	<input type="checkbox"/>	<input type="checkbox"/>
5	ECTD	Levetiracetam-250	Ascorbic-Acid		SSPL	EU	Jun-09-2011	<input type="checkbox"/>	<input type="checkbox"/>
6	ECTD	Ramlipril-120mg			SSPL	US	Jun-09-2011	<input type="checkbox"/>	<input type="checkbox"/>
7	ECTD	Paracetamol		Dossiers Under Preparation	SSPL	EU	Jun-09-2011	<input type="checkbox"/>	<input type="checkbox"/>
8	ECTD	Paracetamols	Delivery by 2012		SSPL	EU	Oct-25-2011	<input type="checkbox"/>	<input type="checkbox"/>
9	ECTD	Asprin			SSPL	EU	Oct-25-2011	<input type="checkbox"/>	<input type="checkbox"/>
10	ECTD	Paracetamol			SSPL	US	Nov-24-2011	<input type="checkbox"/>	<input type="checkbox"/>
11	ECTD	Ramipril			SSPL	US	Nov-24-2011	<input type="checkbox"/>	<input type="checkbox"/>
12	ECTD	Demo1			SSPL	US	Nov-25-2011	<input type="checkbox"/>	<input type="checkbox"/>

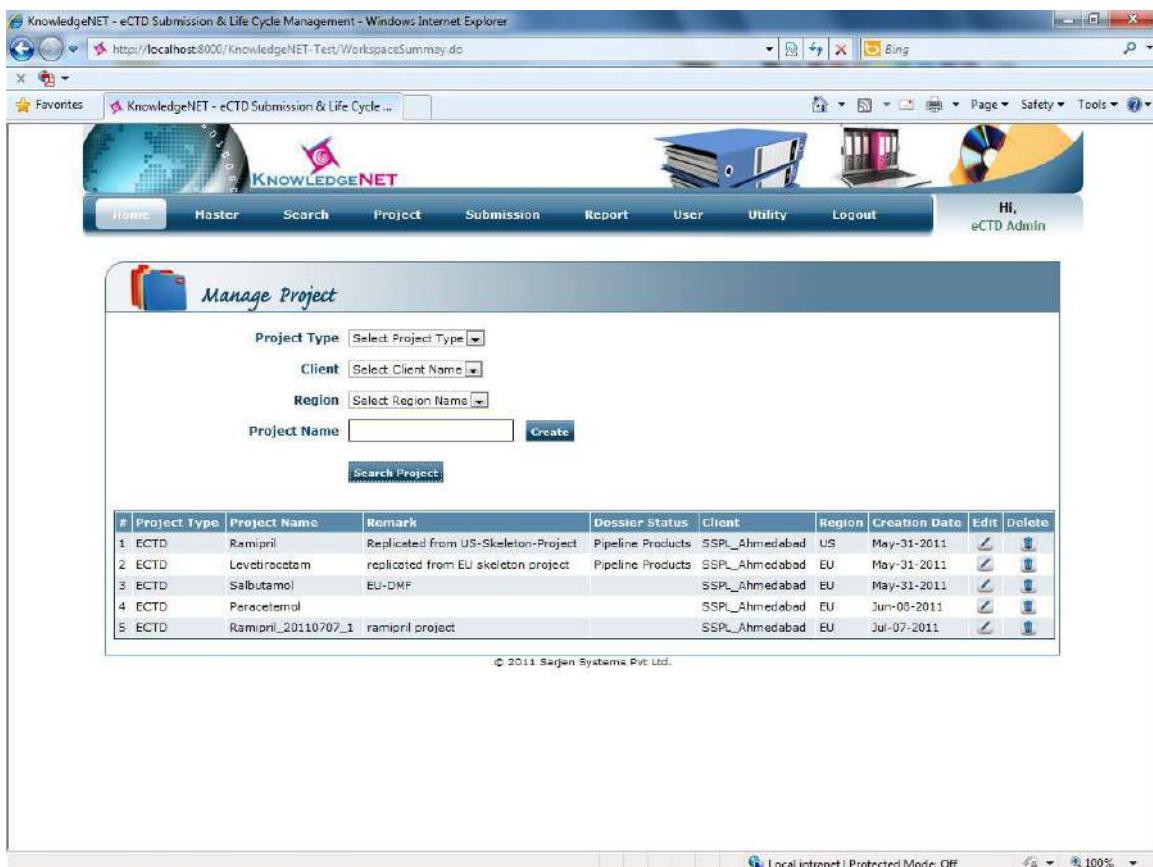
- If click on "Yes" button, it will delete the project and will display an alert message as shows in below screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/WorkspaceSummary.do. The page title is "Manage Project". A modal dialog box is centered on the screen, asking "Do you really want to delete 'Ramipril-120mg' ?" with "OK" and "Cancel" buttons. In the background, there is a table listing 13 projects. The columns are: #, Project Type, Project Name, Remark, Dossier Status, Client, Region, Creation Date, Edit, and Delete. The data in the table is as follows:

#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1	ECTD	Ramipril-250mg	Replicated from US-Skeleton-Project replicated from EU skeleton project.	Dossiers Under Preparation	SSPL	US	May-31-2011		
2	ECTD	Levetiracetam		Dossiers Submitted	SSPL	EU	May-31-2011		
3	ECTD	Ascorbic-Acid	CEP		SSPL	EU	May-31-2011		
4	ECTD	Salbutamol	EU-DMF	Pipeline Products	SSPL	EU	May-31-2011		
5	ECTD	Levetiracetam-250mg			SSPL	EU	Jun-08-2011		
6	ECTD	Ramipril-120mg			SSPL	US	Jun-08-2011		
7	ECTD	Paracetamol		Dossiers Under Preparation	SSPL	EU	Jun-09-2011		
8	ECTD	Paracetamols	Delivery by 2012		SSPL	EU	Oct-25-2011		
9	ECTD	Aspirin			SSPL	EU	Oct-25-2011		
10	ECTD	Paracetamol			SSPL	US	Nov-24-2011		
11	ECTD	Ramipril			SSPL	US	Nov-24-2011		
12	ECTD	Demol			SSPL	US	Nov-25-2011		
13	ECTD	Pera1			SSPL	US	Nov-25-2011		

- It shows that a project 'Ramipril-250mg' has been removed from the grid.



The screenshot shows the 'Manage Project' interface of the KnowledgeNET application. At the top, there are dropdown menus for 'Project Type', 'Client', and 'Region', and input fields for 'Project Name' and 'Create'. Below this is a search bar labeled 'Search Project...'. The main area contains a table with the following data:

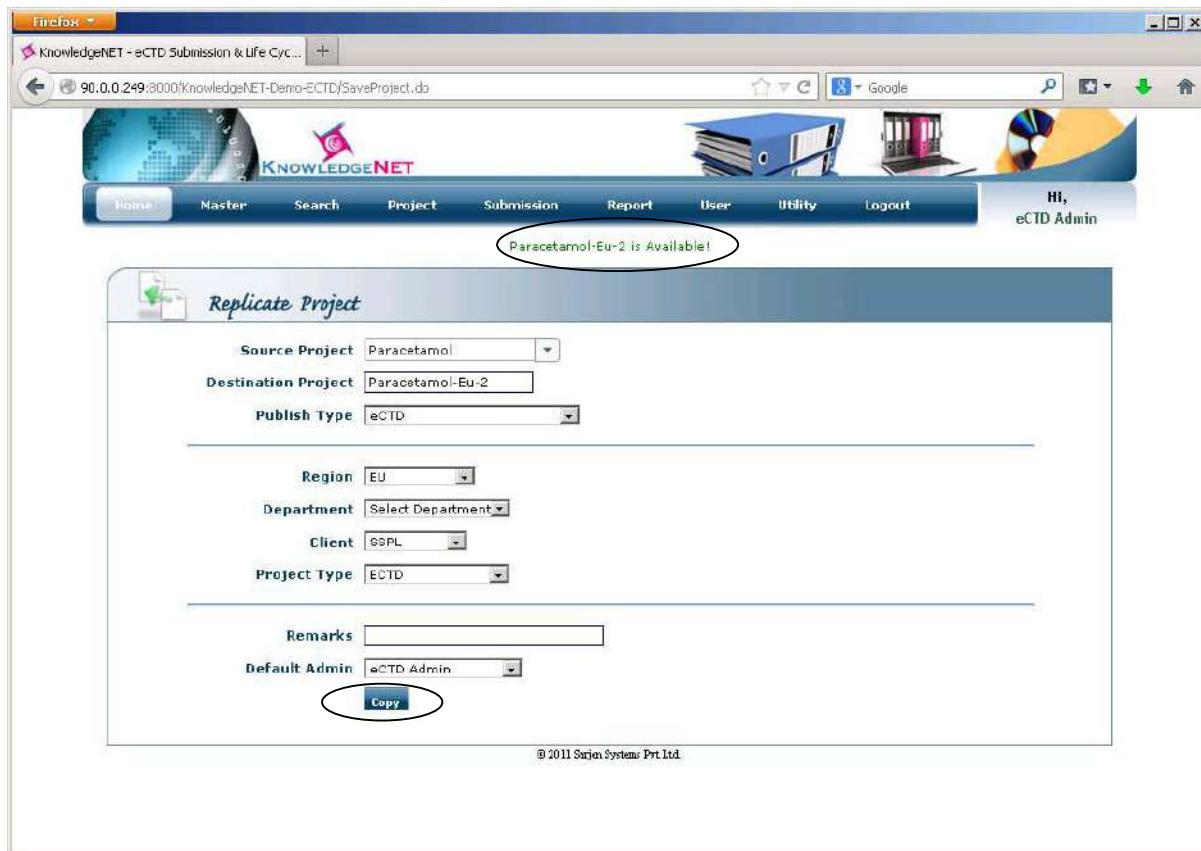
#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1	ECD	Ramipril	Replicated from US-Skeleton-Project	Pipeline Products	SSPL_Ahmedabad	US	May-31-2011		
2	ECD	Levetiracetam	replicated from EU skeleton project	Pipeline Products	SSPL_Ahmedabad	EU	May-31-2011		
3	ECD	Salbutamol	EU-DMF		SSPL_Ahmedabad	EU	May-31-2011		
4	ECD	Paracetemol			SSPL_Ahmedabad	EU	Jun-06-2011		
5	ECD	Ramipril_20110707_1	ramipril project		SSPL_Ahmedabad	EU	Jul-07-2011		

Replicate Project

- ❖ **If Admin wants to create a project which is similar to any existing project, then Admin can copy the source project to the destination project through "Replicate Project".**

Project >Replicate>From Project

- Select the source project.
- After selecting the source project, mention the "Destination Project" and select "Publish Type", "Region", "Department", "Client", "Project Type", "Default Admin" and add "Remarks".
- After mentioning all the details, click on "Copy".
- On clicking "Copy" button.



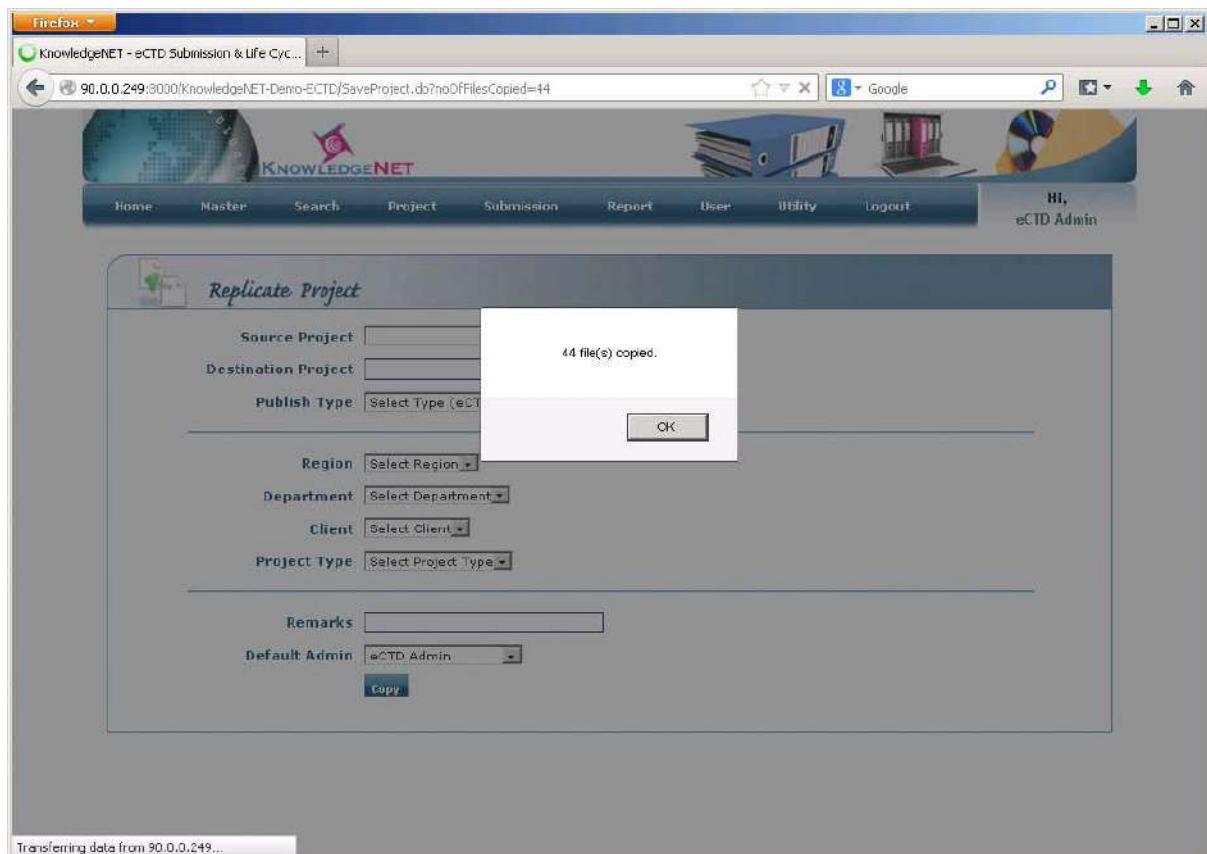
- If Admin want to copy the all files from source project then select the root node and click on "Copy Files" button of the below screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET-Demo-eCTD/saveAsProject.do?userCode=3&locationCode=0002&deptCode=00018. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a greeting for "Hi, eCTD Admin". Below the navigation bar, the main content area displays a hierarchical file tree under the heading "Paracetamol-Eu-2". The tree structure is as follows:

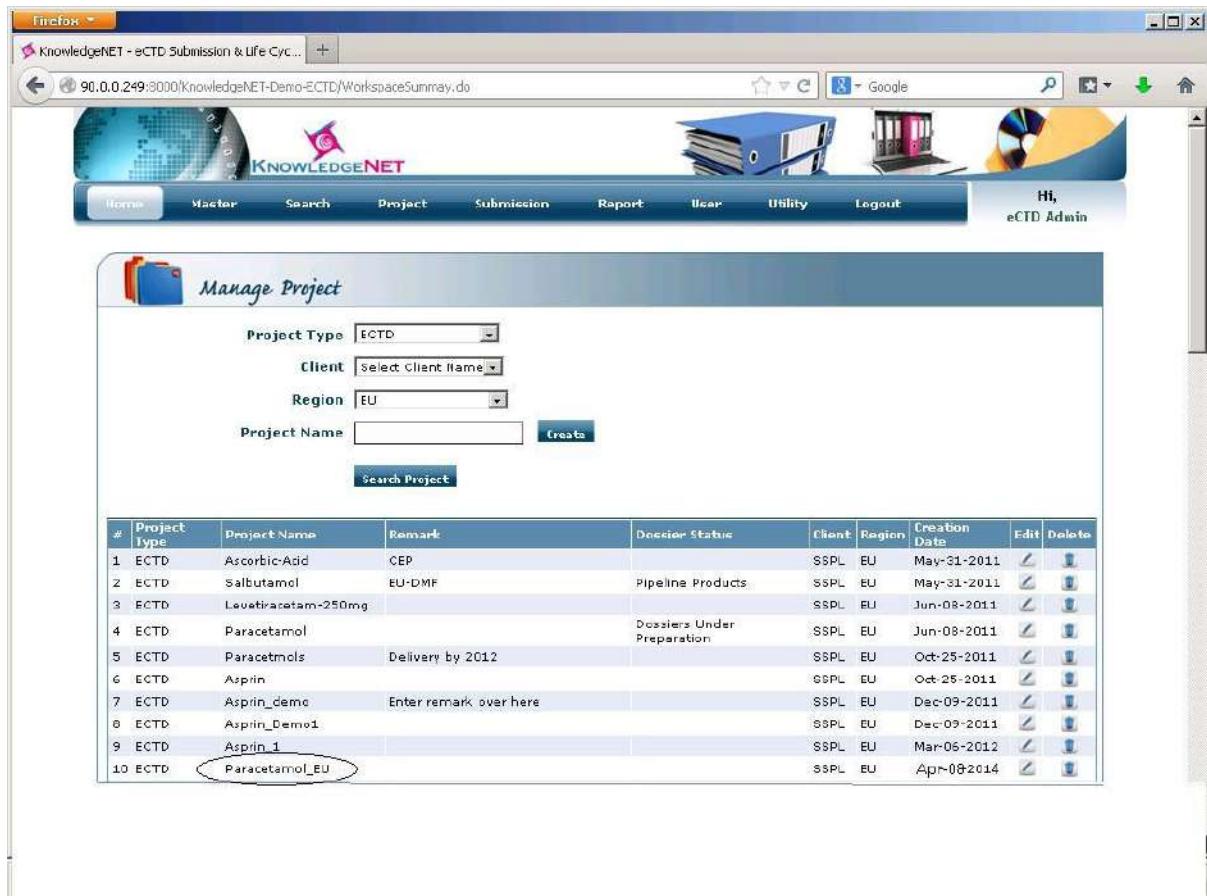
- EU-Regional
 - Administrative Information and Prescribing Information
 - Module 1 EU
 - Cover Letter
 - specific
 - cover letter for [country] Agency (File not Found)
 - specific(uk)
 - cover letter for United Kingdom Agency
 - specific(de)
 - cover letter for Germany Agency
 - specific(es)
 - cover letter for Spain Agency
 - Application Form
 - specific

- After selecting the node and by clicking on 'Copy Files' button, below message will get displayed in the form.



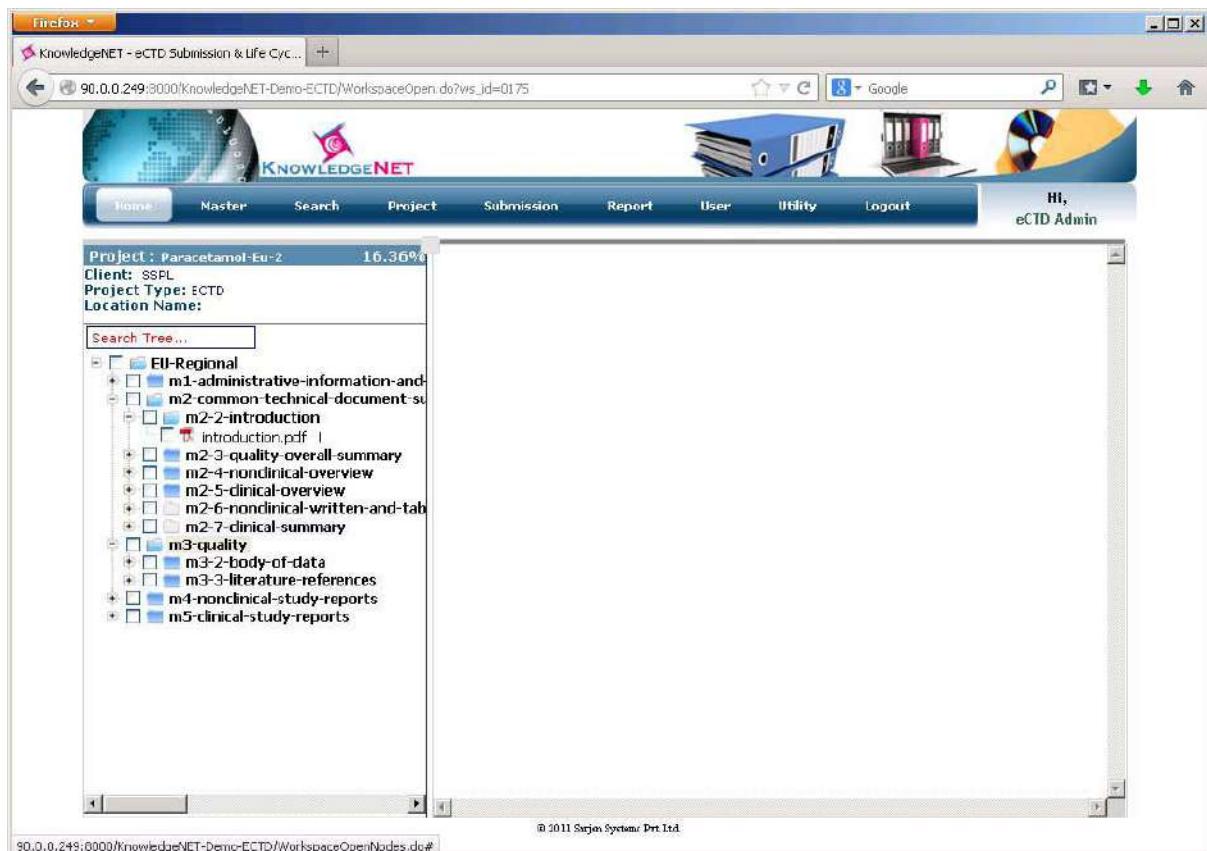
Replicate Project occur in Manage Project

- The below screen shows the replicated project in 'Manage Project' form.

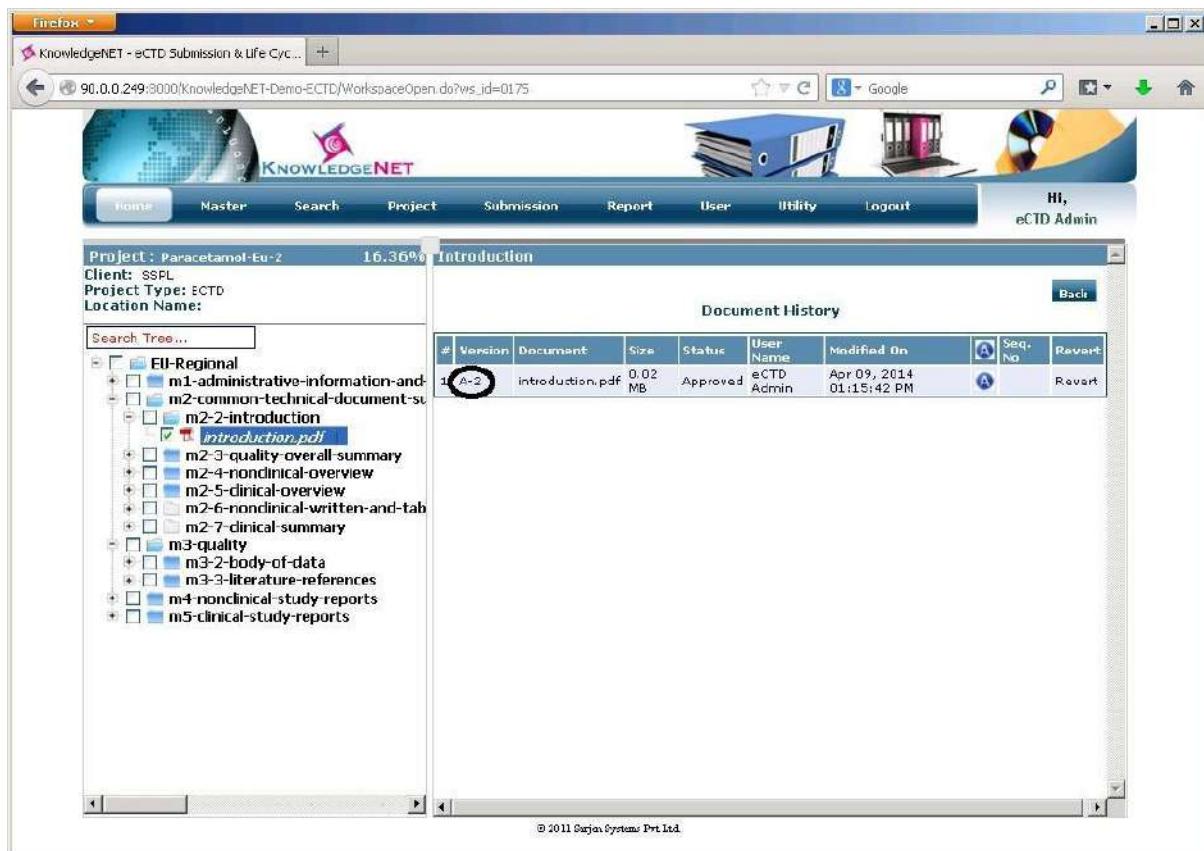


#	Project Type	Project Name	Remark	Dossier Status	Client	Region	Creation Date	Edit	Delete
1	ECTD	Ascorbic-Add	CEP		SSPL	EU	May-31-2011		
2	ECTD	Salbutamol	EU-DMF	Pipeline Products	SSPL	EU	May-31-2011		
3	ECTD	Levetiracetam-250mg			SSPL	EU	Jun-08-2011		
4	ECTD	Paracetamol		Dossiers Under Preparation	SSPL	EU	Jun-08-2011		
5	ECTD	Paracetamols	Delivery by 2012		SSPL	EU	Oct-25-2011		
6	ECTD	Aspirin			GSPL	EU	Oct-25-2011		
7	ECTD	Aspirin_demo	Enter remark over here		SSPL	EU	Dec-09-2011		
8	ECTD	Aspirin_Demo1			SSPL	EU	Dec-09-2011		
9	ECTD	Aspirin_1			SSPL	EU	Mar-06-2012		
10	ECTD	Paracetamol_EU			SSPL	EU	Apr-08-2014		

- In the below screen shot Admin can see that in the Replicated Project, a file that gets copied will appear as it is from where it is replicated.



- Admin can also view the history of node of a replicated project with a different version as shows in the below screen shot.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/WorkspaceOpen.do?ws_id=0175. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The top menu bar includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user session is shown as "Hi, eCTD Admin". On the left, there is a "Search Tree..." sidebar with a tree view of project structure. The main content area shows a progress bar at 16.36% and the title "Introduction". Below it is a "Document History" table:

#	Version	Document	Size	Status	User Name	Modified On	A	Seq. No	Revert
1	A-2	introduction.pdf	0.02 MB	Approved	eCTD Admin	Apr 09, 2014 01:15:42 PM	A		Revert

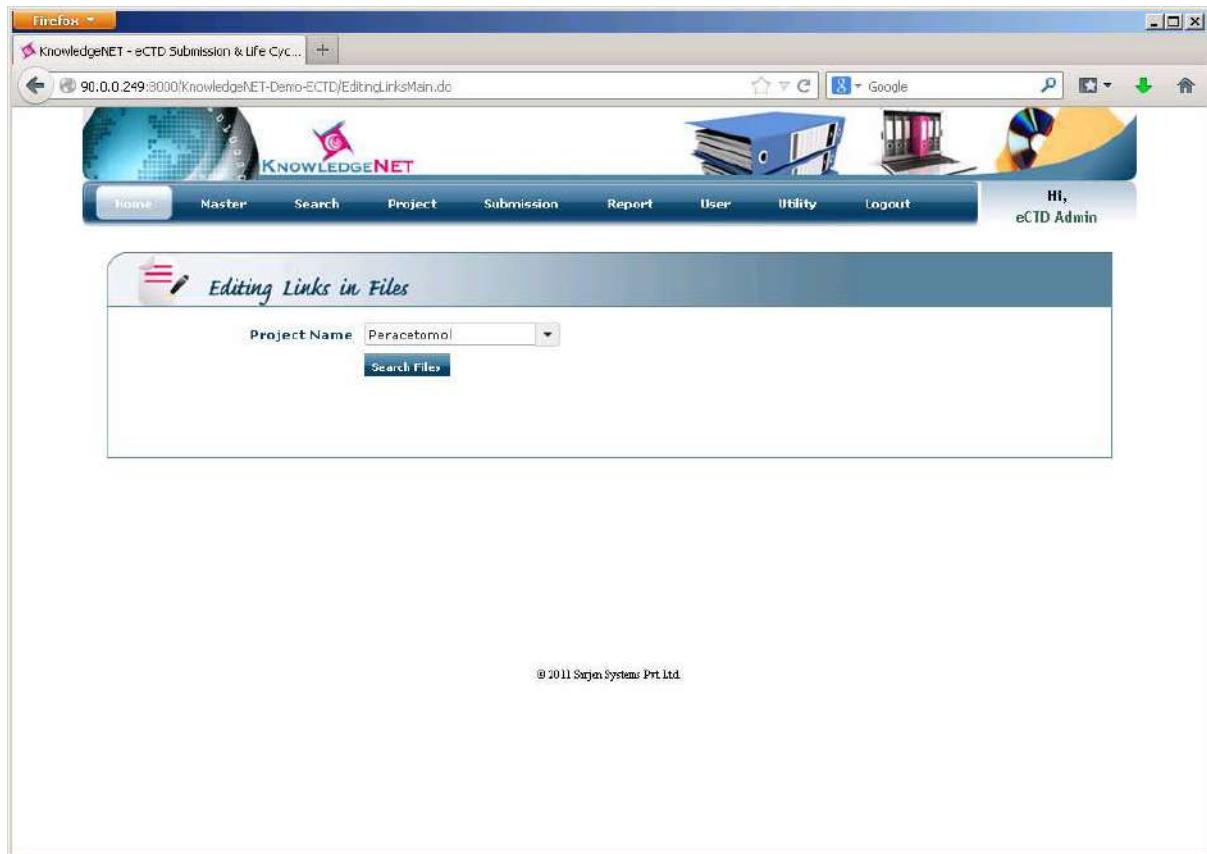
The "introduction.pdf" row in the table has a circled "A-2" version number and a checked status indicator. The footer of the page reads "© 2011 Sejtan Systems Pvt Ltd."

Edit Hyper-Links

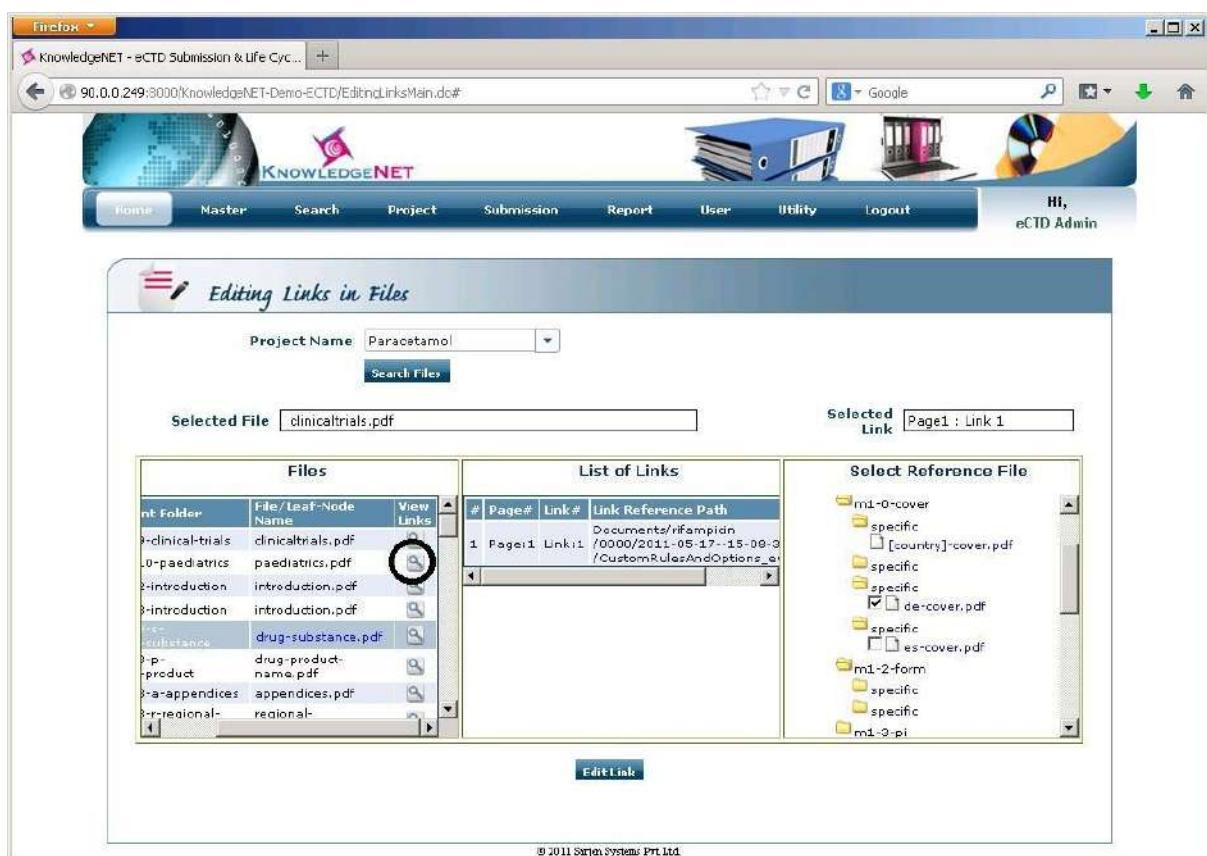
- ❖ **If Admin wants to edit any hyper-link from the uploaded file, it can be done through Edit Hyper-Links menu.**

Project >Edit Hyper-Links

- The below screen is the main page of “Edit Hyper-links”.



- Select a project containing hyper-links and click on "Search Files". On clicking "Search Files", below screen will get displayed.
- On clicking "View Links" icon from the grid, all the links from that file will get displayed.
- From that Admin can select any link that Admin want to edit.
- Select the link from the grid displayed in "List of Links" column after clicking on "View Links" icon.
- After that select reference file from "Select Reference File" column.
- Tick mark the file that Admin want to make it as a reference file when Admin click on the selected link and then click on "Edit Link" button.



Editing Links in Files

Project Name: Paracetamol

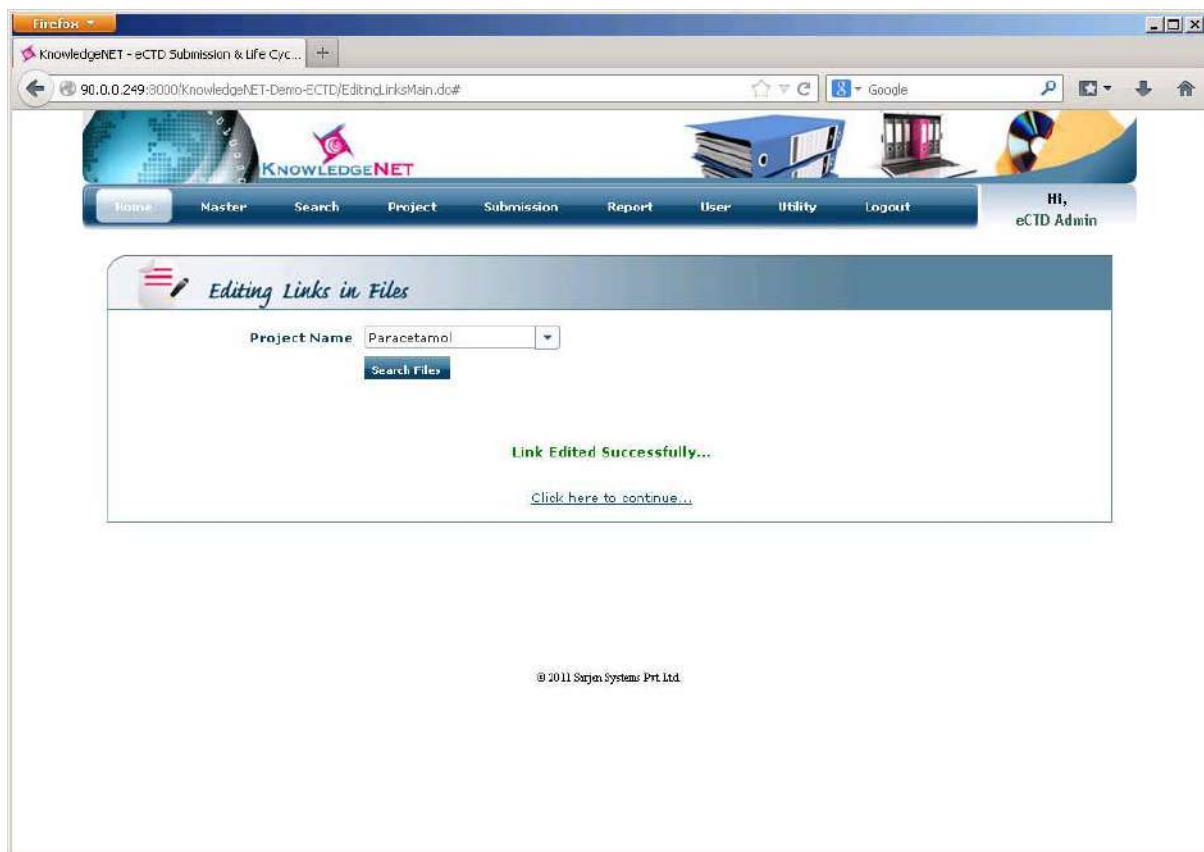
Selected File: clinicaltrials.pdf

Selected Link: Page1 : Link 1

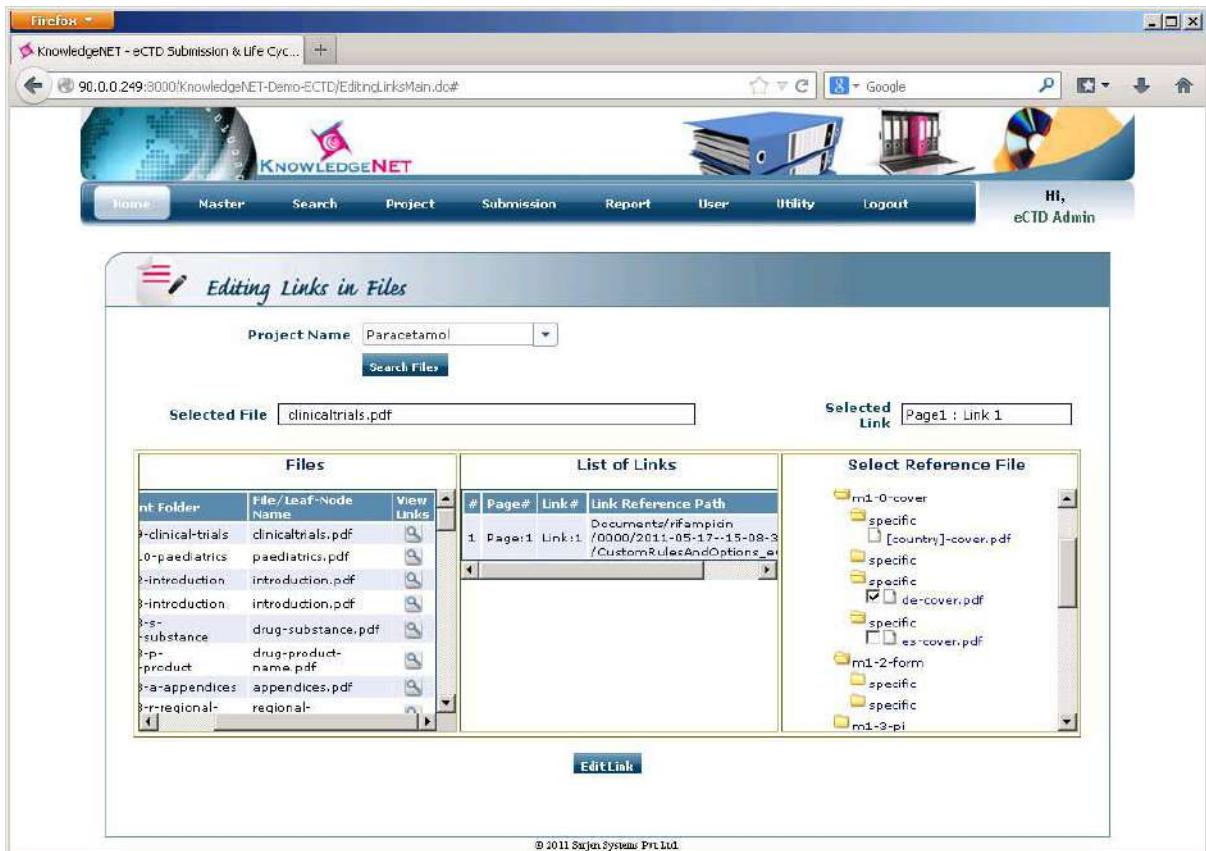
Files			List of Links			Select Reference File
File/Folder	File/Leaf-Node Name	View Links	#	Page#	Link#	Link Reference Path
1-clinical-trials	clinicaltrials.pdf		1	Page1	Link#1	/Documents/rifampicin /CustomRulesAndOptions_e...
2-paediatrics	paediatrics.pdf					
3-introduction	introduction.pdf					
4-drug-substance	drug-substance.pdf					
5-p-product	drug-product-name.pdf					
6-a-appendices	appendices.pdf					
7-regional-	regional-					

Edit Link

- On clicking “Edit Link” button, below screen will get displayed showing that “Link Edited successfully...” Click on “Click here to continue...” link and below screen will get displayed.



- The below screen shows that link is edited successfully as previous link in the grid got replaced by the targeted or referenced file link path.



The screenshot displays the 'Editing Links in Files' interface within a Firefox browser window. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET-Demo-ECTD/EditingLinksMain.do#.

The interface includes the following components:

- Header:** Features the KNOWLEDGE NET logo, a search bar, and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a greeting to the current user, Hi, eCTD Admin.
- Project Name:** A dropdown menu set to 'Paracetamol'.
- Selected File:** A text input field containing 'clinicaltrials.pdf'.
- Selected Link:** A text input field containing 'Page1 : Link 1'.
- Files:** A table listing files and their details:

File/Folder	Name	View Links
-clinical-trials	clinicaltrials.pdf	
-o-paediatrics	paediatrics.pdf	
-introduction	introduction.pdf	
-introduction	introduction.pdf	
-s-substance	drug-substance.pdf	
-p-product	drug-product-name.pdf	
-a-appendices	appendices.pdf	
-r-regional-	regional-	
- List of Links:** A table showing the current link entry:

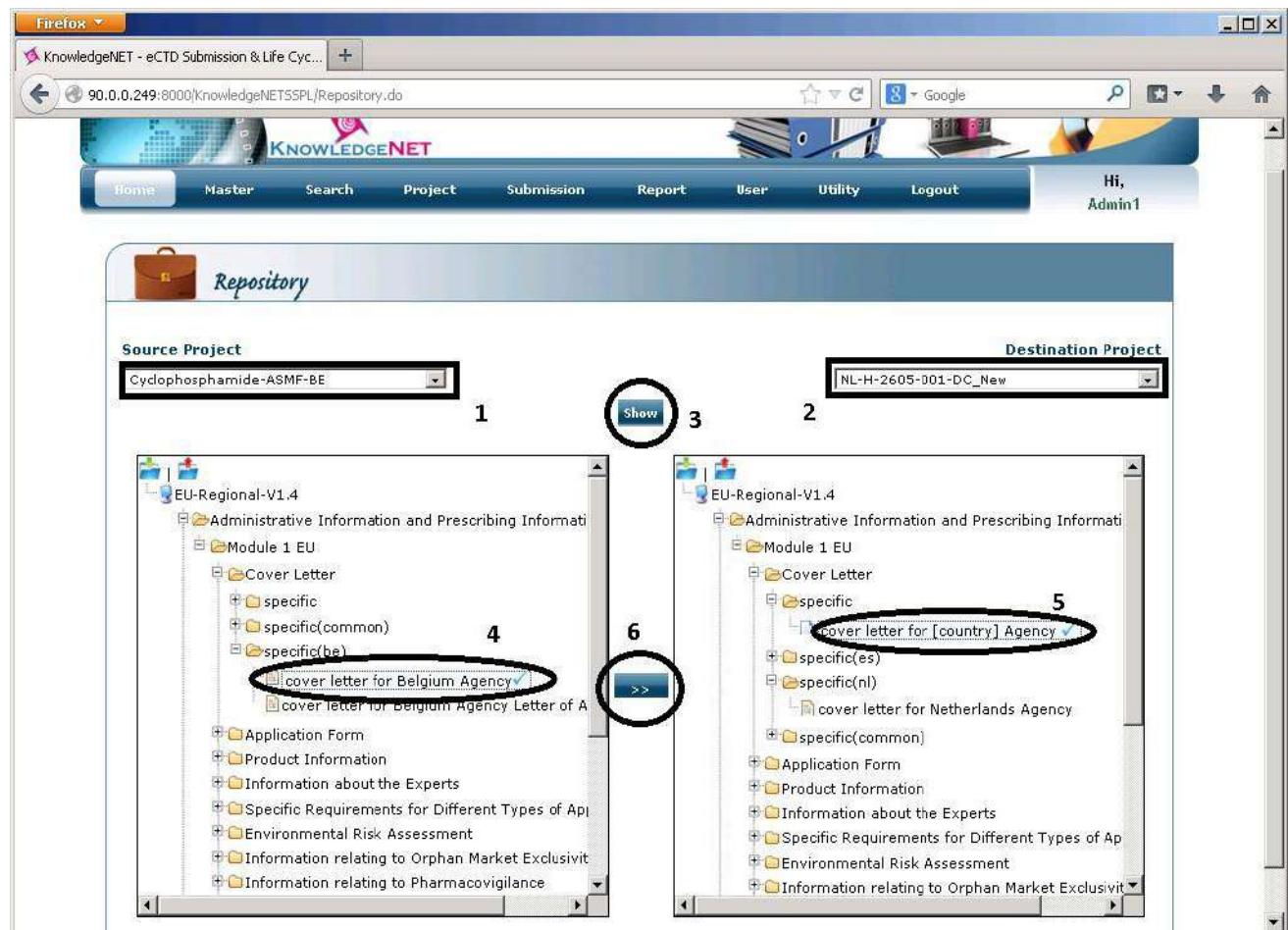
#	Page#	Link #	Link Reference Path
1	Page1	Link1	Documents/rifampicin/0000/2011-05-17--15-08-3/CustomRulesAndOptions_e
- Select Reference File:** A tree view of available files and folders:
 - m1-0-cover
 - specific
 - [country]-cover.pdf
 - specific
 - de-cover.pdf
 - specific
 - es-cover.pdf
 - m1-2-form
 - specific
 - specific
 - m1-3-pi
- Buttons:** 'Edit Link' button at the bottom center.

DMS Import

- ❖ If after Replication Admin wants to copy the some files from any existing project, then Admin copy the required files though source project to the destination project through "DMS Import Project".

Project >DMS Import>Repository

1. Select the "Source Project from list of projects
2. Then select the Destination Project".
3. Click on "show" to open both projects.
4. Select the specific files from source project.
5. Than selected the destination folder where you want to copy the selected file.
6. After selecting the destination click on forward option to copy the file.

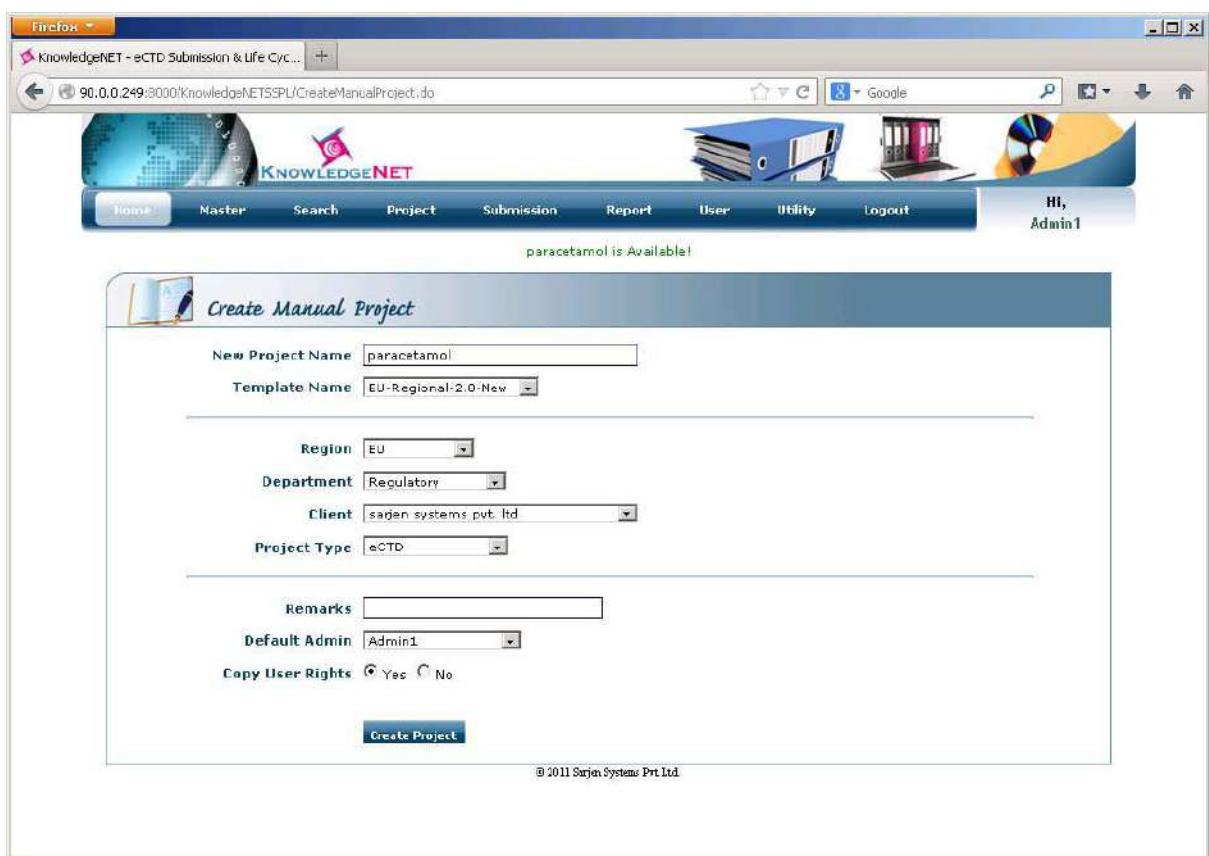


Dossier Import

❖ If Admin wants to Create a New Sequence, Previously Sequence not Created from our Systems, For e.g. User want to Create Direct 0001,0002,0003....etc. then follow below steps:-

Project >Dossier Import>Published Sequence

The below screen is the main page of "Dossier Import- Published Sequence"

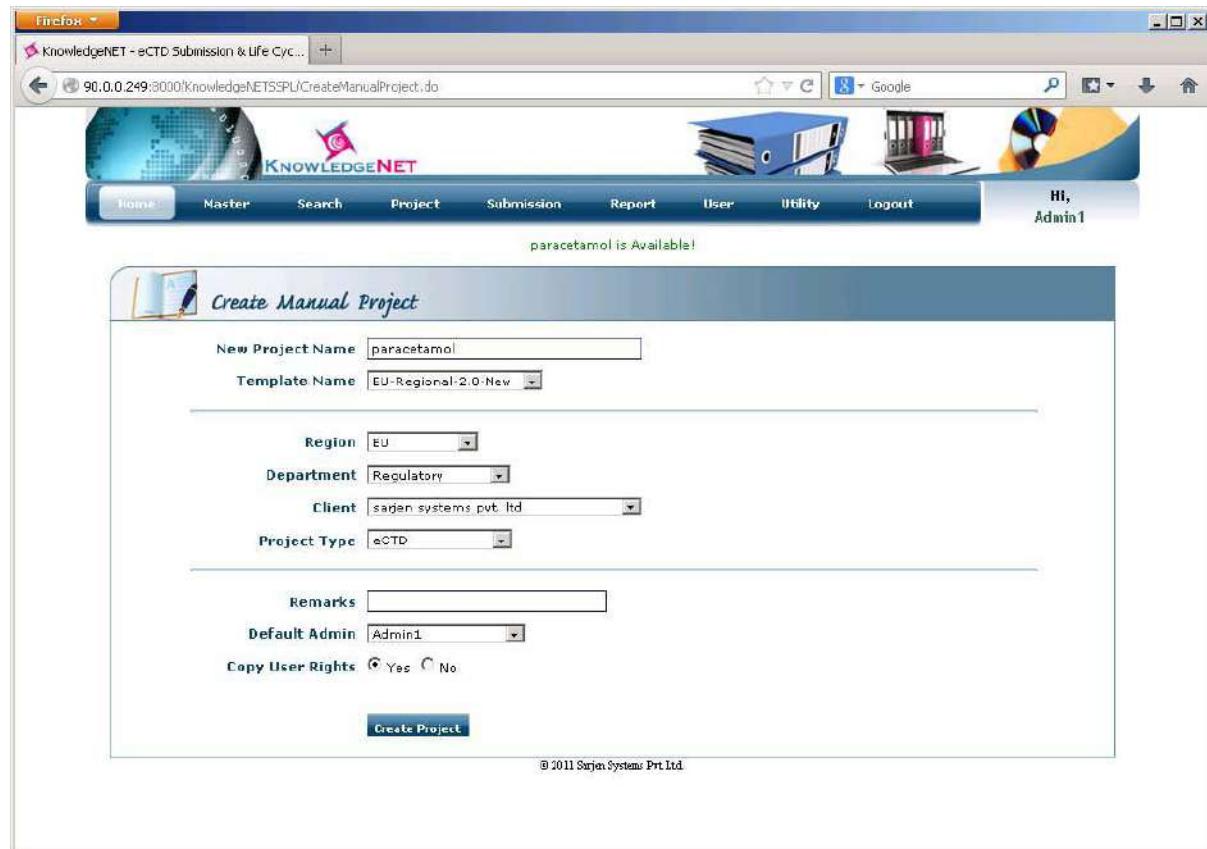


The screenshot shows a web application interface for creating a manual project. The browser title bar reads "Firefox - KnowledgeNET - eCTD Submission & Life Cyc...". The URL in the address bar is "90.0.0.249:8000/KnowledgeNETSSPL/CreateManualProject.do". The page header features the "KNOWLEDGE NET" logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, Admin1" is displayed on the right. A status message "paracetamol is Available!" is shown above the form. The main content area is titled "Create Manual Project" and contains the following fields:

New Project Name:	paracetamol
Template Name:	EU-Regional-2.0-New
Region:	EU
Department:	Regulatory
Client:	sajen systems pvt. ltd
Project Type:	eCTD
Remarks:	(empty)
Default Admin:	Admin1
Copy User Rights:	<input checked="" type="radio"/> Yes <input type="radio"/> No

A "Create Project" button is located at the bottom of the form. A copyright notice "© 2011 Sajen Systems Pvt Ltd." is visible at the bottom of the page.

- Create the new project.
- Enter the new project name, select the "Template name" and select "Region" "Department", "Client", "Project Type", "and Default Admin" and add "Remarks".
- After select and enter all the details, click on "Create project".

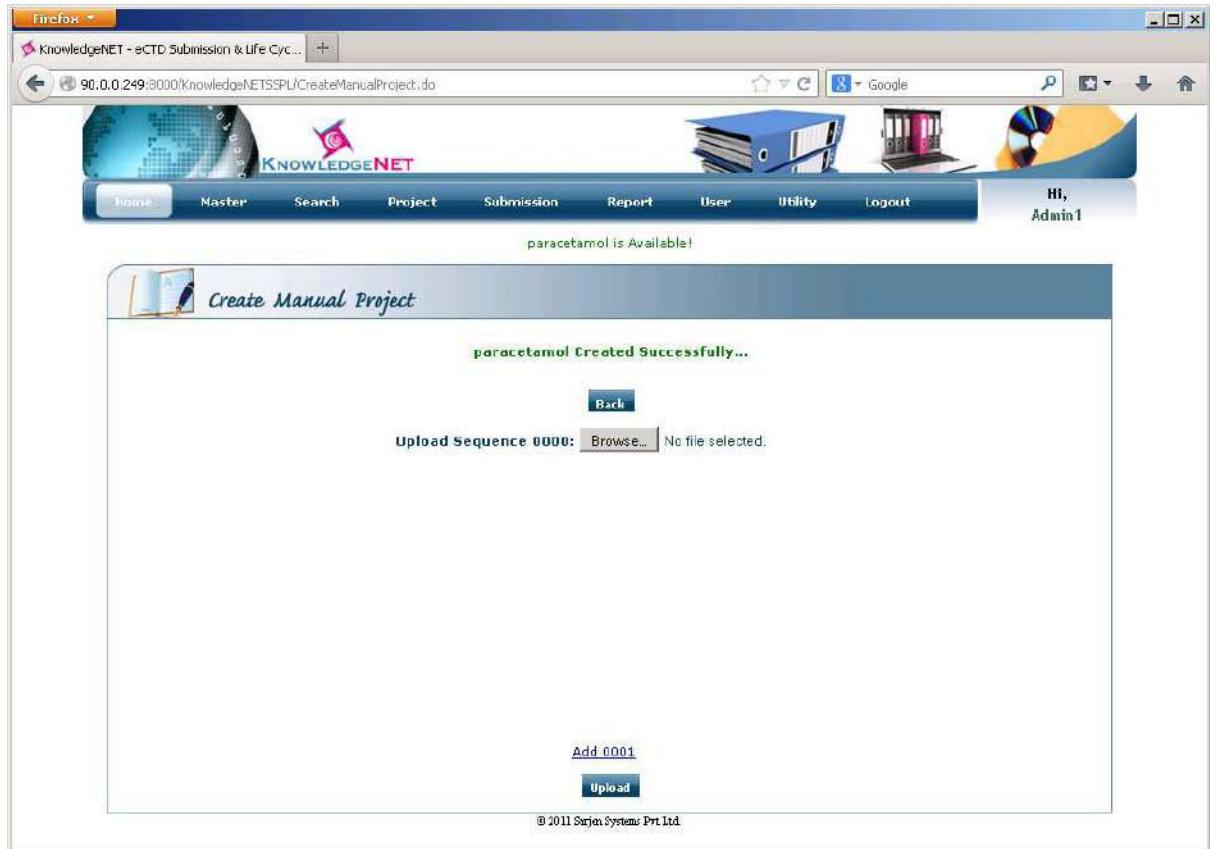


The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/KnowledgeNETSPU/CreateManualProject.do. The page title is "Create Manual Project". The form fields are as follows:

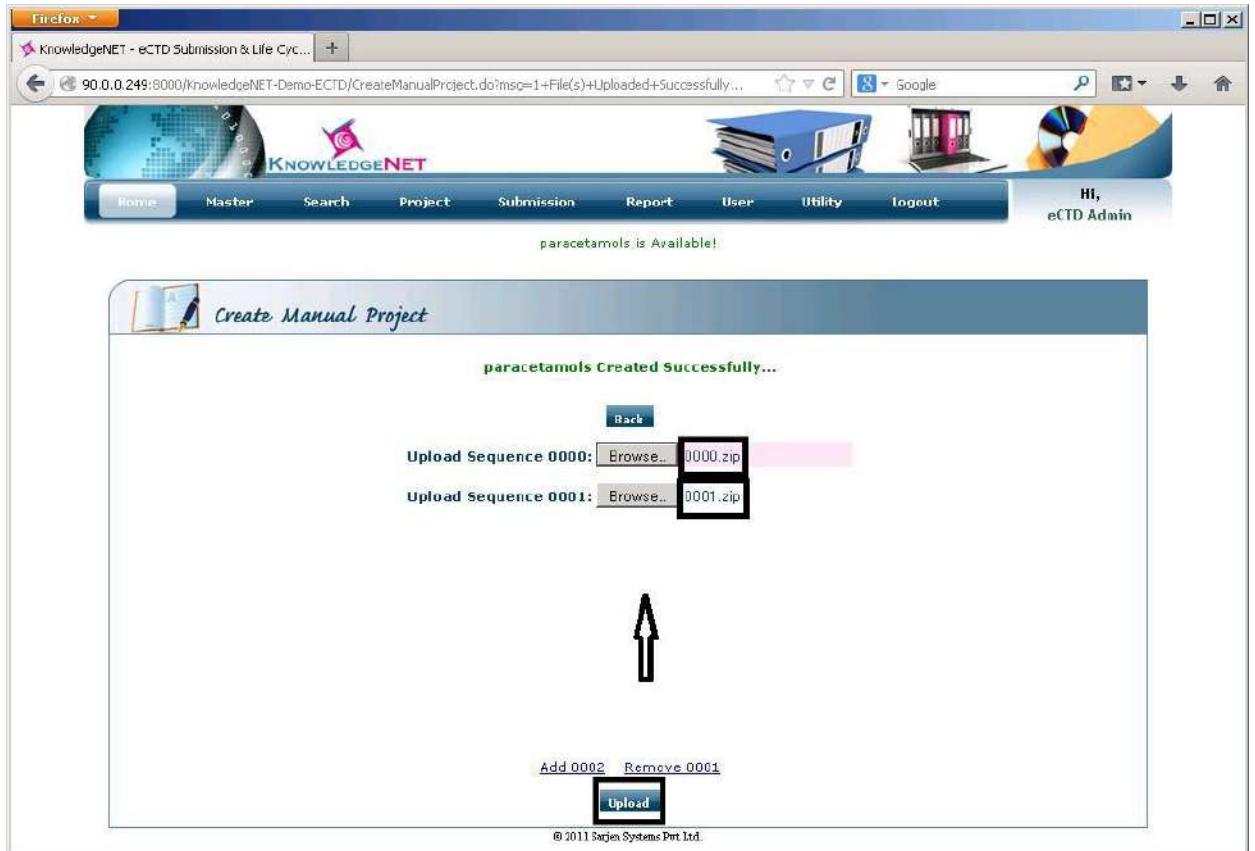
New Project Name	paracetamol
Template Name	EU-Regional-2.0-New
Region	EU
Department	Regulatory
Client	sarjan systems pvt. ltd
Project Type	eCTD
Remarks	(empty)
Default Admin	Admin1
Copy User Rights	<input checked="" type="radio"/> Yes <input type="radio"/> No

At the bottom of the form is a "Create Project" button. A status message "paracetamol is Available!" is displayed above the form area. The top right corner of the browser window shows "Hi, Admin1".

- On clicking “Create project” button, below screen will get displayed showing that “project create successfully (with project name)”

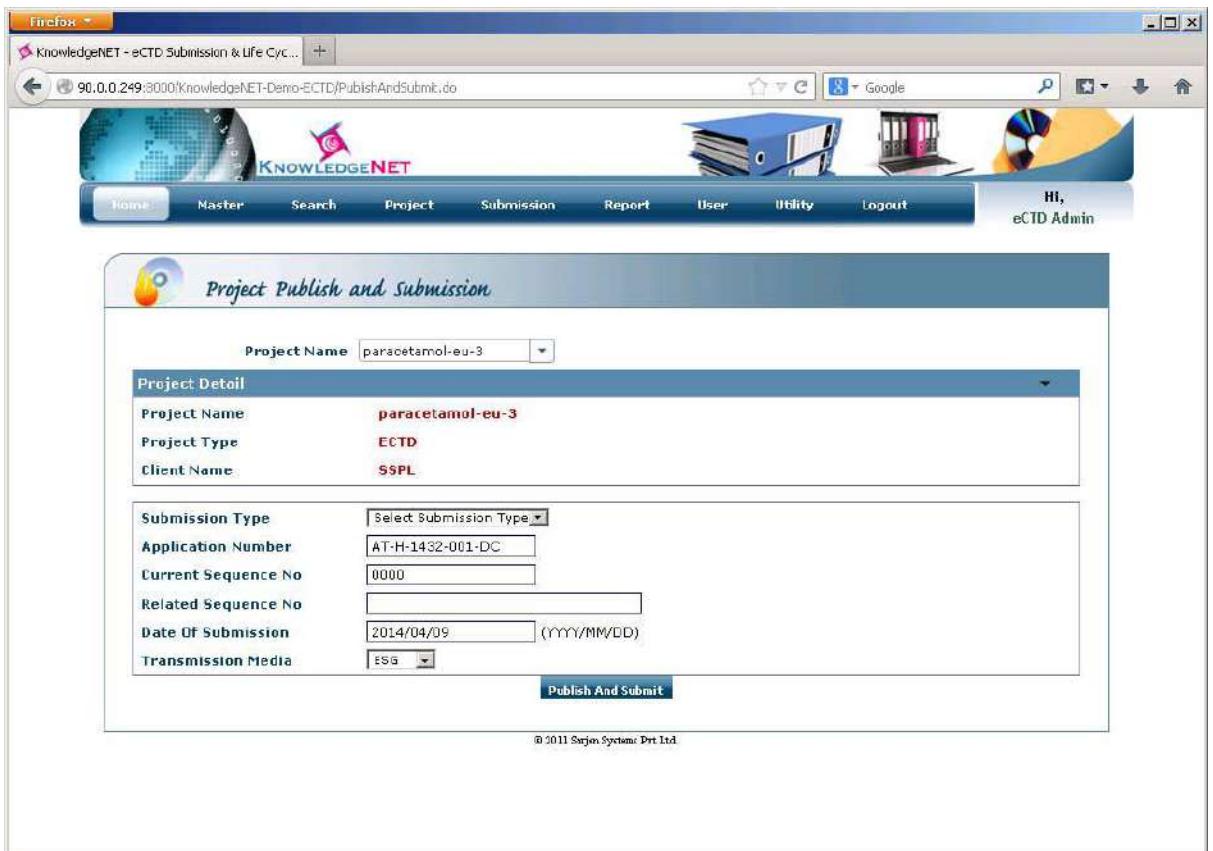


If Admin want to prepare 0002 sequence then Browse the previous two sequence (0000, 0001) in zip folder and then click on upload.



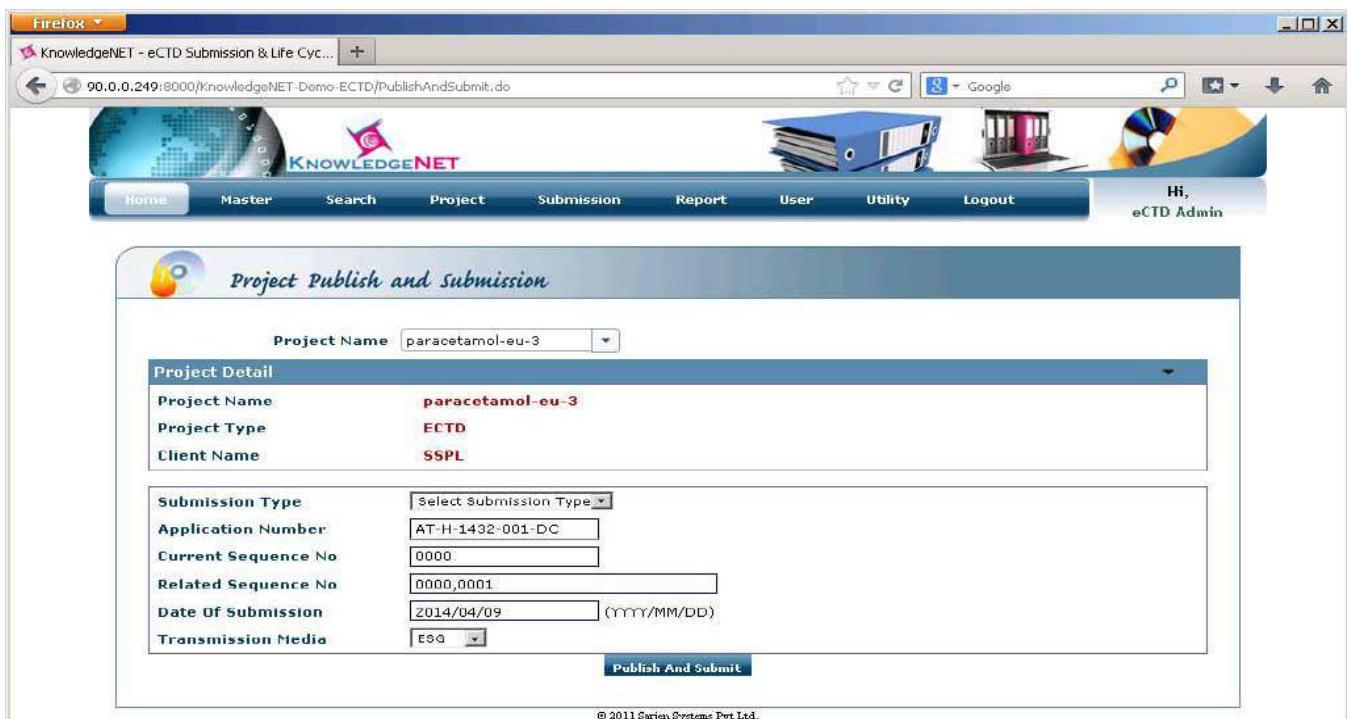
The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The title bar reads "Firefox" and the address bar shows the URL "90.0.0.249:8000/knowledgeNET-Demo-ECTD/CreateManualProject.do?msg=1+File(s)+Uploaded+Successfully...". The main content area is titled "Create Manual Project" and displays the message "paracetamols Created Successfully...". Below this, there are two "Upload Sequence" fields: "Upload Sequence 0000:" with a "Browse..." button and a highlighted input field containing "0000.zip", and "Upload Sequence 0001:" with a "Browse..." button and a highlighted input field containing "0001.zip". At the bottom of the page, there are buttons for "Add 0002", "Remove 0001", and a central "Upload" button. A large black arrow points upwards from the bottom of the page towards the upload fields.

- After uploading the previous sequence then follow the same procedure such as search the project from **project>manage** then uploaded the files in tree structure ,approved from my pending work, fill the submission details and then go to publish and submit page select your manual project from list as shows the screen below.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The page title is "Project Publish and Submission". The top navigation menu includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a greeting "Hi, eCTD Admin". The main form has a "Project Name" dropdown set to "paracetamol-eu-3". The "Project Detail" section contains fields for Project Name (paracetamol-eu-3), Project Type (ECTD), and Client Name (SSPL). The "Submission Type" dropdown is set to "Select Submission Type". Other fields include Application Number (AT-H-1432-001-DC), Current Sequence No (0000), Related Sequence No (empty), Date Of Submission (2014/04/09), and Transmission Media (ESG). A "Publish And Submit" button is at the bottom right of the form. The footer of the page reads "© 2011 Sejion Systems Pvt Ltd".

- In above screen required the mention of Current Sequence and also the **Related Sequence**.
- After fill the current sequence and related sequence click on "**Publish and Submit**" the below screen shows.

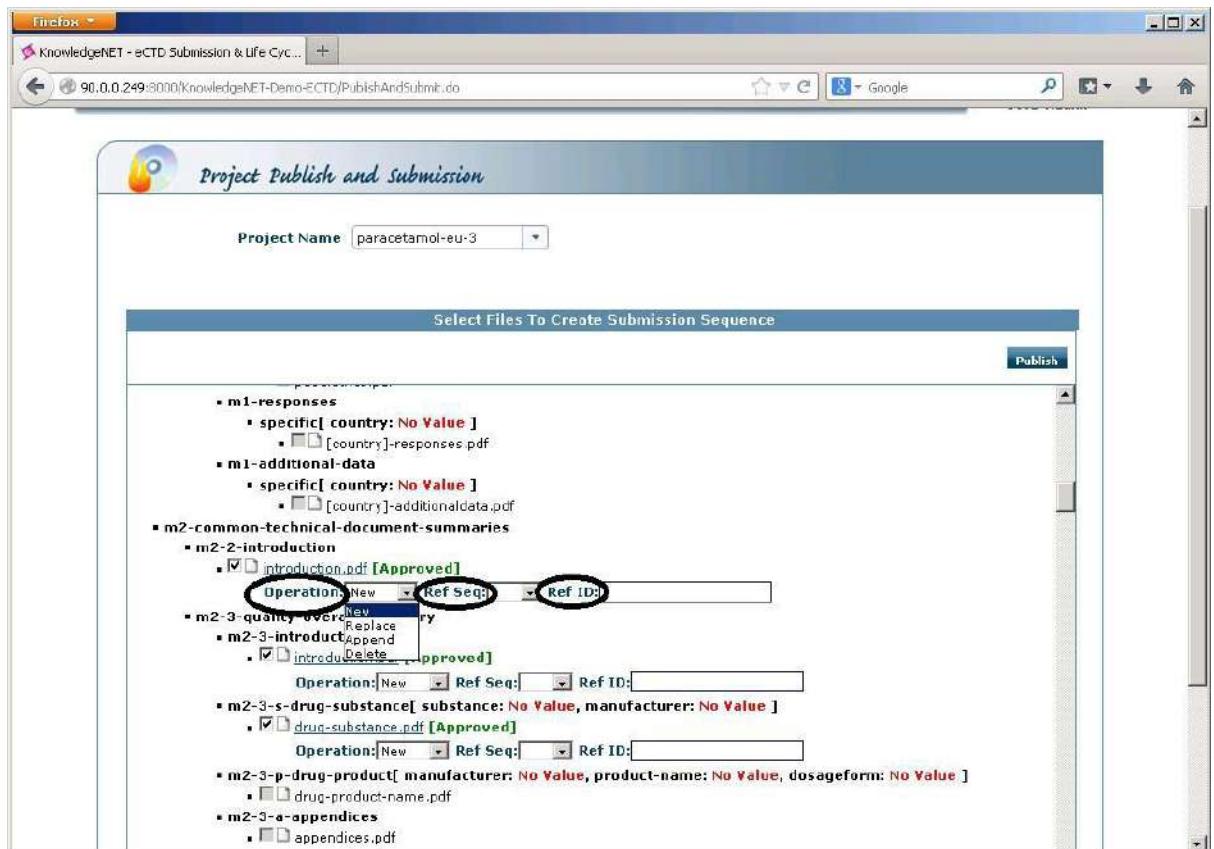


The screenshot shows a web application interface for 'Project Publish and Submission'. The browser title bar reads 'Firefox' and the address bar shows '90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do'. The page header features the 'KNOWLEDGE NET' logo. A navigation menu at the top includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a 'Hi, eCTD Admin' greeting. The main content area has a blue header 'Project Publish and Submission'. Below it, a form is filled with the following data:

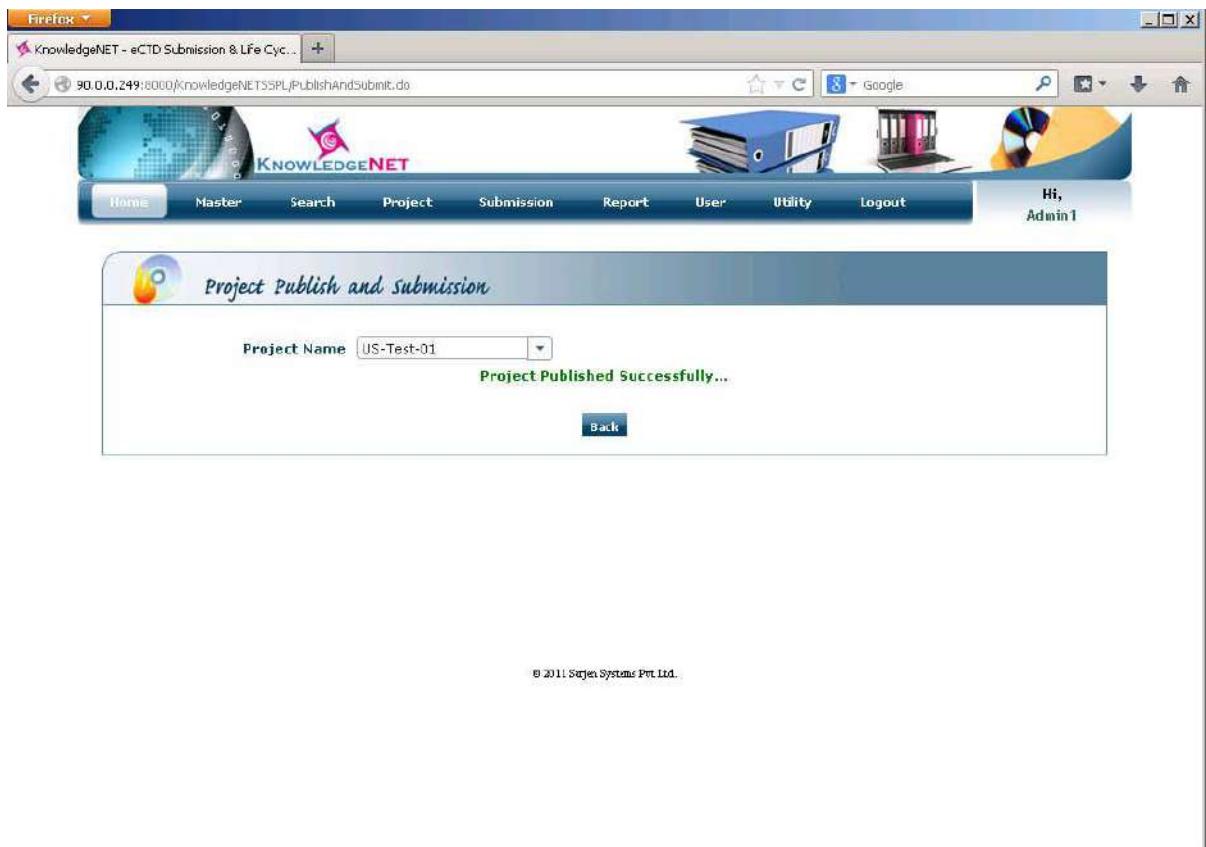
Project Name:	paracetamol-eu-3
Project Detail	
Project Name:	paracetamol-eu-3
Project Type:	ECTD
Client Name:	SSPL
Submission Type:	Select Submission Type
Application Number:	AT-H-1432-001-DC
Current Sequence No:	0000
Related Sequence No:	0000,0001
Date Of Submission:	2014/04/09 (YYYY/MM/DD)
Transmission Media:	ESG

A 'Publish And Submit' button is located at the bottom right of the form. At the very bottom of the page, a small copyright notice reads '© 2011 Surjan Systems Pvt Ltd.'

- In below screen shows the uploaded file required "operation" such as New, Replace, Append and Delete , and "Ref seq:"(for e.g. these uploaded file Replace from 0000 sequence) Ref ID: (in 0000 sequence file Ref ID).



- Above fill all such as **operation**, Ref Seq: and Ref ID: then click on “Publish” the below screen shows “Project Published Successfully”.



Submission Menu

❖ **Through Submission menu Admin can fill up the submission details of the project that is to be published**

- “Submission” Menu will display the submenu items as shows: -

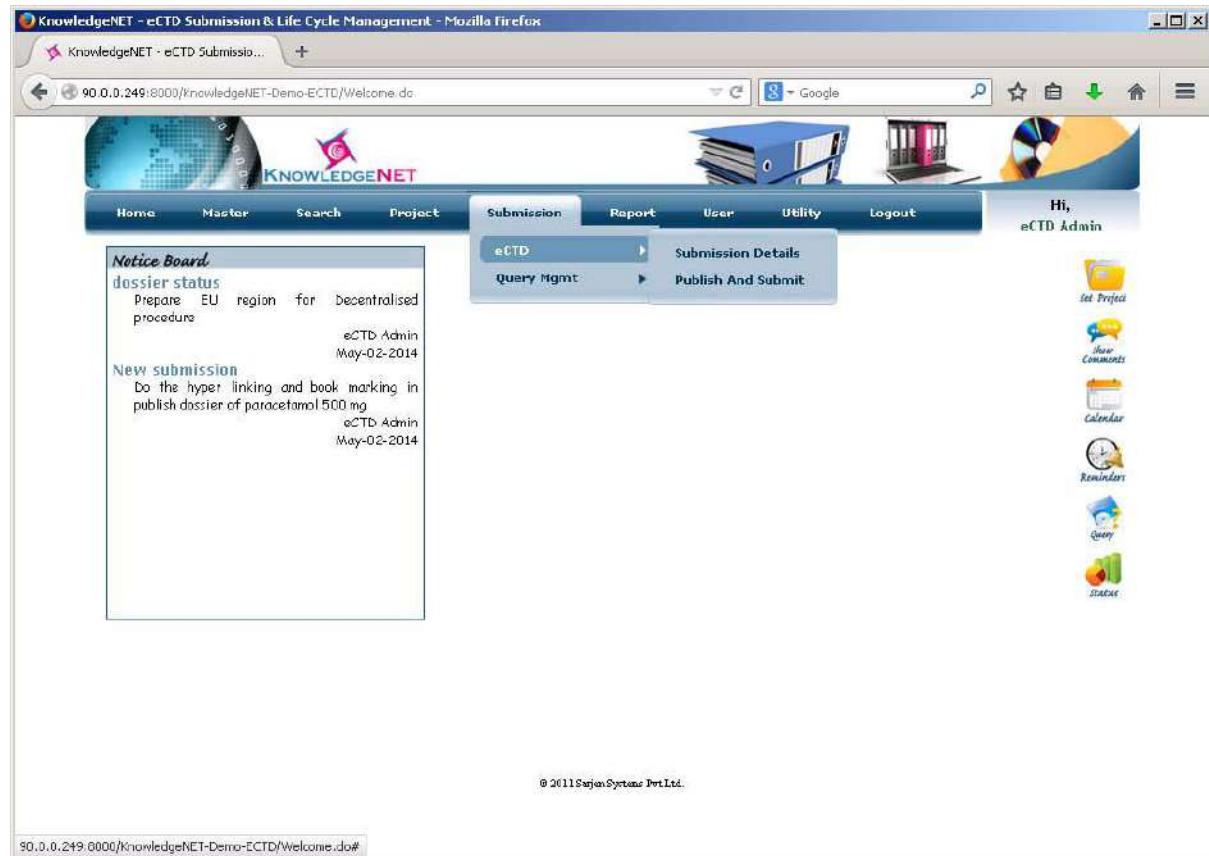
➤ eCTD-

- Submission Details
- Publish And Submit

➤ Query Mgmt.-

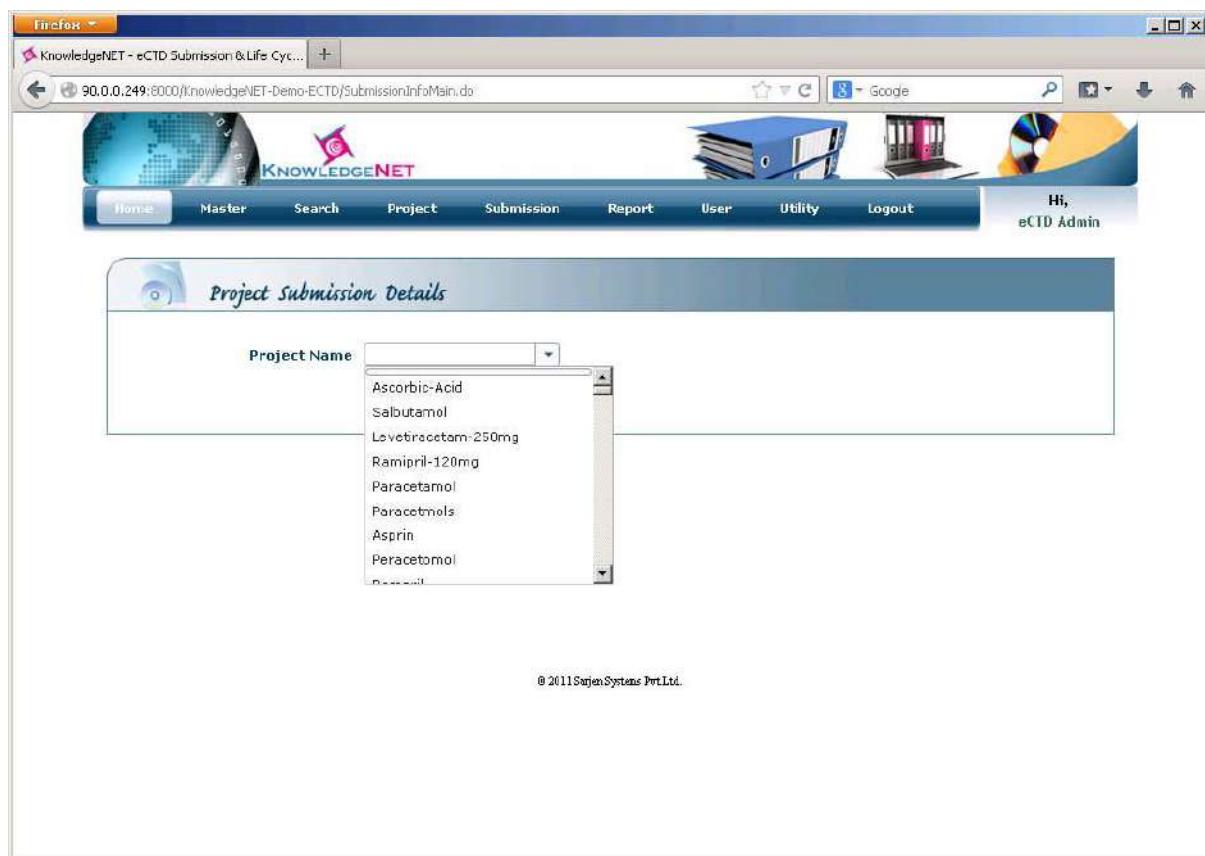
- Add/ Edit
- Change Status

Submission > eCTD >Submission Details

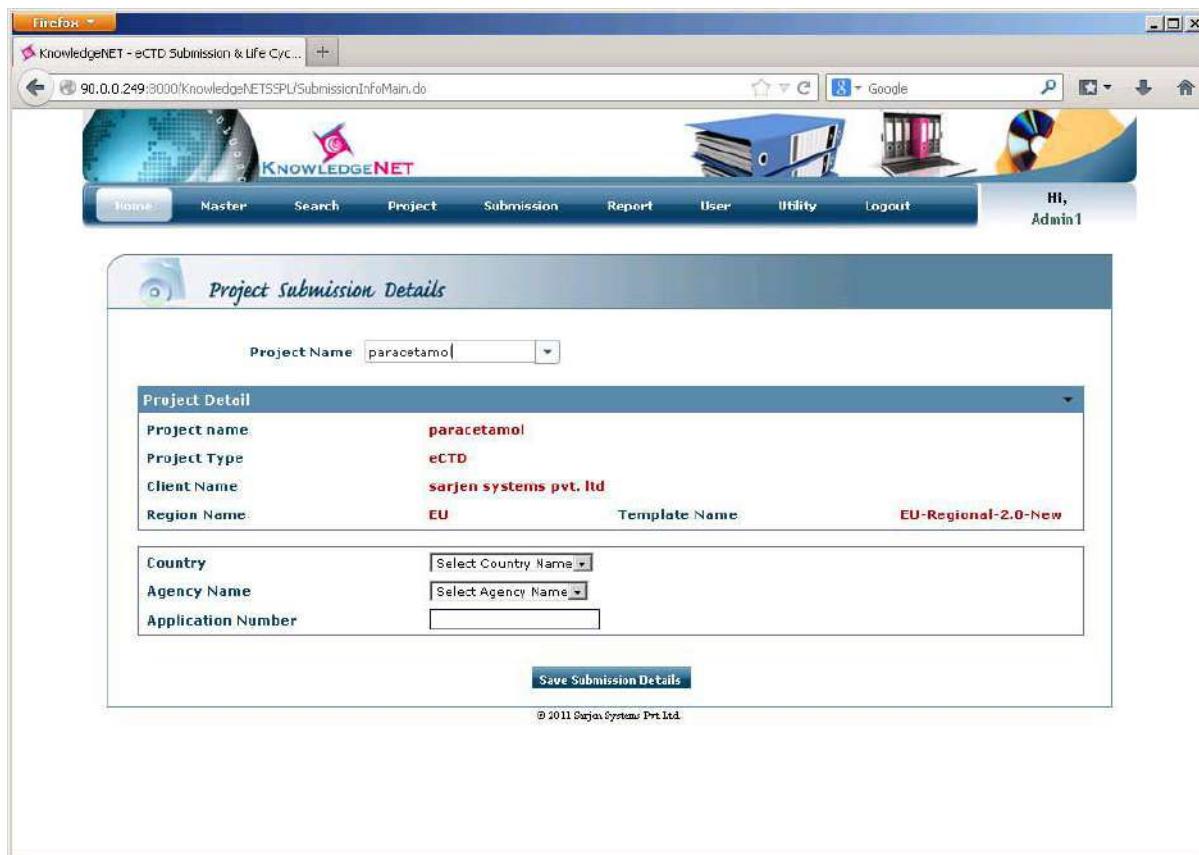


The screenshot shows a web browser window for the KnowledgeNET eCTD Submission & Life Cycle Management system. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/Welcome.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. The user is identified as "Hi, eCTD Admin". On the left, there's a "Notice Board" section with two entries: "dossier status" (Prepare EU region for Decentralised procedure) by eCTD Admin on May-02-2014, and "New submission" (Do the hyper linking and book marking in publish dossier of paracetamol 500 mg) by eCTD Admin on May-02-2014. The main content area shows a dropdown menu under the "Submission" tab: "eCTD" is selected, showing "Submission Details" and "Publish And Submit"; "Query Mgmt." is also listed. To the right of the menu is a sidebar with icons for Set Project, Show Comments, Calendar, Reminders, Query, and Status.

- Select a project from the auto-completer list.



- On selecting a project, submission details form will appear as shows in below screen.
- Admin has to fill the details as "Tracking Number", "High Level Number", "Applicant", "Invented Name", "INN" and "Submission Description" and select the "Country", "Regional Version", "Agency Name" and "Procedure Type".



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNETSPU/SubmissionInfoMain.do. The page title is "Project Submission Details". The top navigation menu includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, Admin1" is displayed on the right. The main content area contains a form with the following fields:
Project Name: paracetamol
Project Detail
Project name: paracetamol
Project Type: eCTD
Client Name: sarjen systems pvt. ltd
Region Name: EU Template Name: EU-Regional-2.0-New
Country: Select Country Name
Agency Name: Select Agency Name
Application Number: [empty input field]
At the bottom of the form is a "Save Submission Details" button and a copyright notice: © 2011 Sarjen Systems Pvt Ltd.

Note: In case of US project, application number should be provided instead of tracking number.

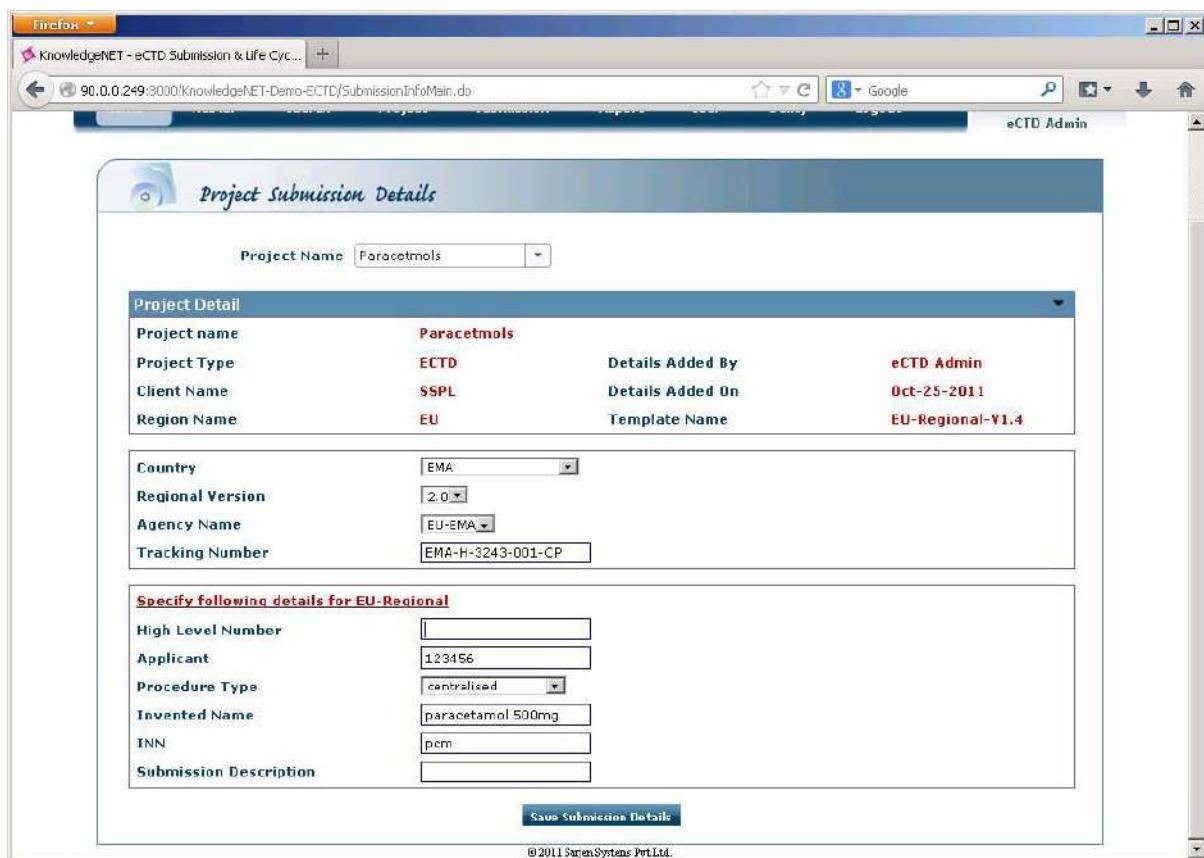
Note: In EU four types eCTD Filling (Submission) procedures as follow:-

1. Centralised Procedure:
2. National procedure:
3. Mutual Recognition procedure:
4. Decentralised procedure:

1. In Centralised Procedure (CP):

Admin has to fill the other details same as above, but in **country name** admin select the **EMA** (After selecting EMA) System generate automatically **Regional Version** and **Agency name** after that admin fill up other details.

- Below screen will be displayed.

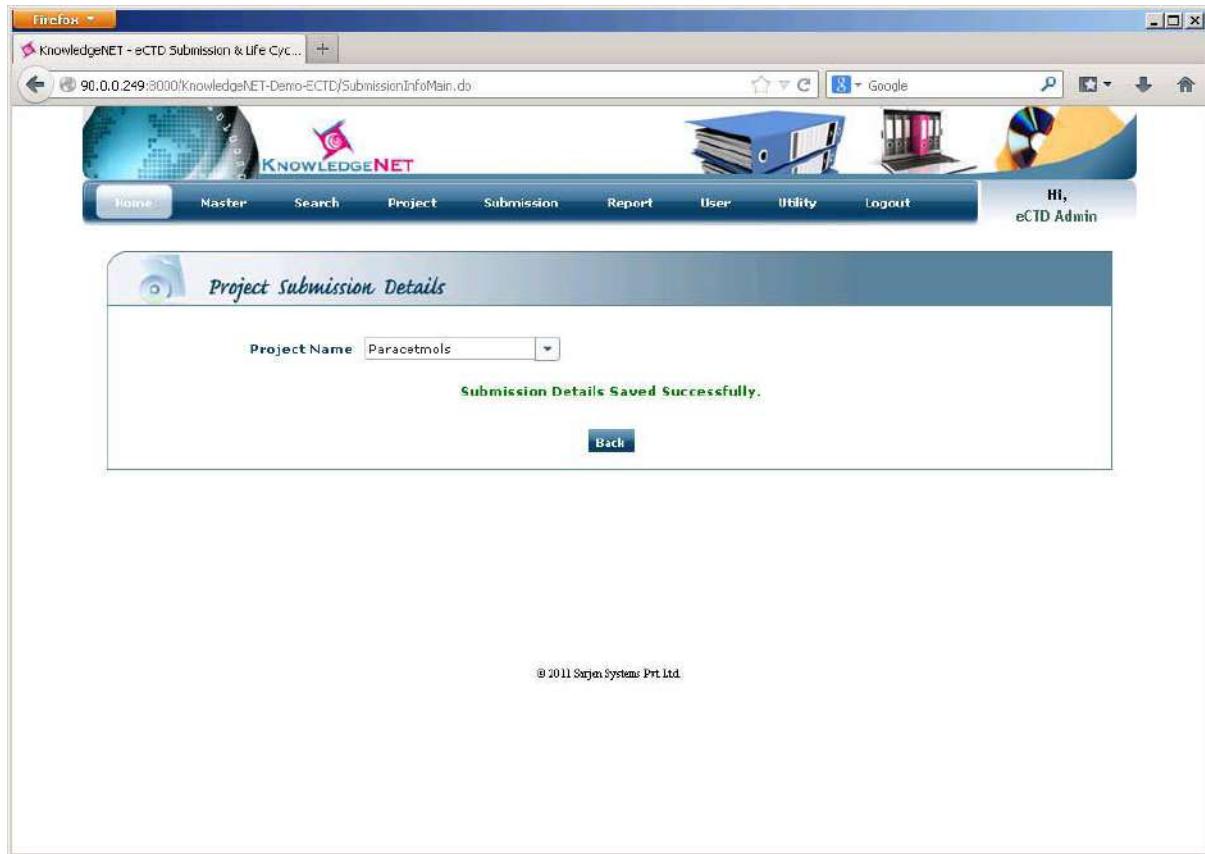


Project Detail			
Project name	Paracetmols	Details Added By	eCTD Admin
Project Type	ECTD	Details Added On	Oct-25-2011
Client Name	SSPL	Template Name	EU-Regional-V1.4
Region Name	EU		

Country	EMA
Regional Version	2.0
Agency Name	EU-EMA
Tracking Number	EMA-H-3243-001-CP

Specify following details for EU-Regional	
High Level Number	
Applicant	123456
Procedure Type	centralised
Invented Name	paracetamol 500mg
INN	pem
Submission Description	

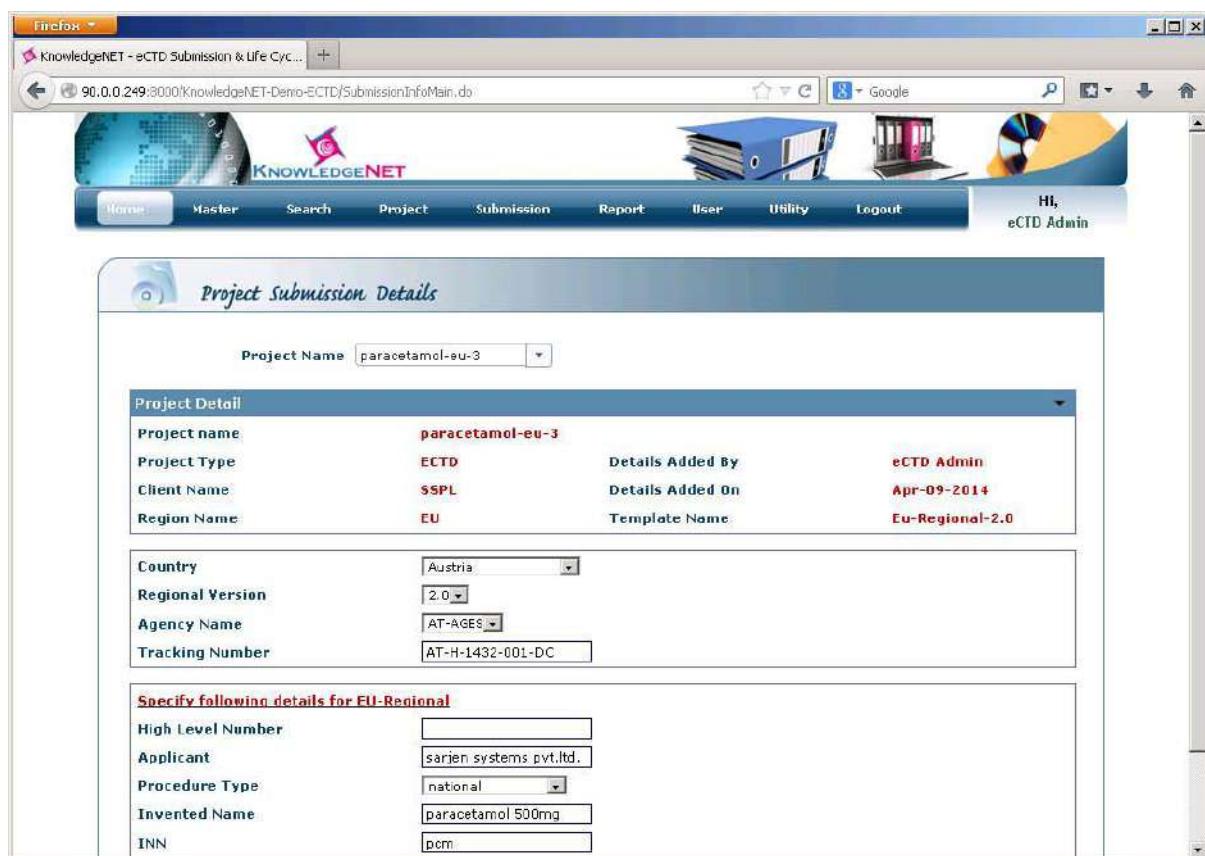
- On clicking “Save Submission Details”, below screen will be displayed.



- On clicking “Back” button, user will redirect to “Project Submission Details” Page.

2. National Procedure (NP):

- Admin has to fill the other details same as above (In Centralised procedure), but in **country name** Admin select the **Particular country name** (After selecting country) System generate automatically **Regional Version** and **Agency name**.
- Below screen will be displayed.



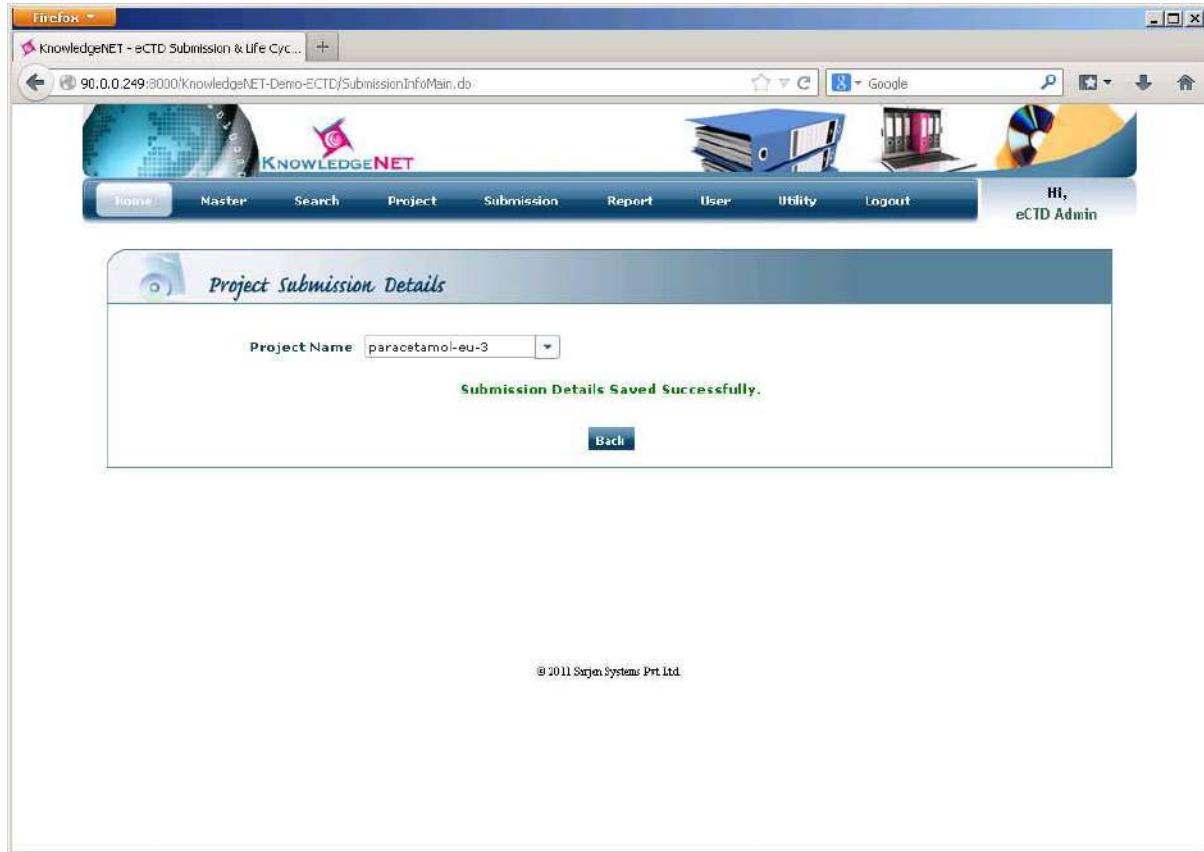
The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET-Demo-ECTD/SubmissionInfoMain.do. The page title is "Project Submission Details". The top navigation menu includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user session indicator "Hi, eCTD Admin". The main content area displays "Project Name: paracetamol-eu-3". A "Project Detail" section contains the following data:

Project name	paracetamol-eu-3	Details Added By	eCTD Admin
Project Type	ECTD	Details Added On	Apr-09-2014
Client Name	SSPL	Template Name	Eu-Regional-2.0
Region Name	EU		

Below this is a "Country" dropdown set to "Austria", a "Regional Version" dropdown set to "2.0", an "Agency Name" dropdown set to "AT-AGES", and a "Tracking Number" input field containing "AT-H-1432-001-DC". A section titled "Specify following details for EU-Regional" contains the following fields:

High Level Number	<input type="text"/>
Applicant	sarjen systems pvt.ltd.
Procedure Type	national
Invented Name	paracetamol 500mg
INN	pcm

- On clicking “Save Submission Details”, below screen will be displayed.

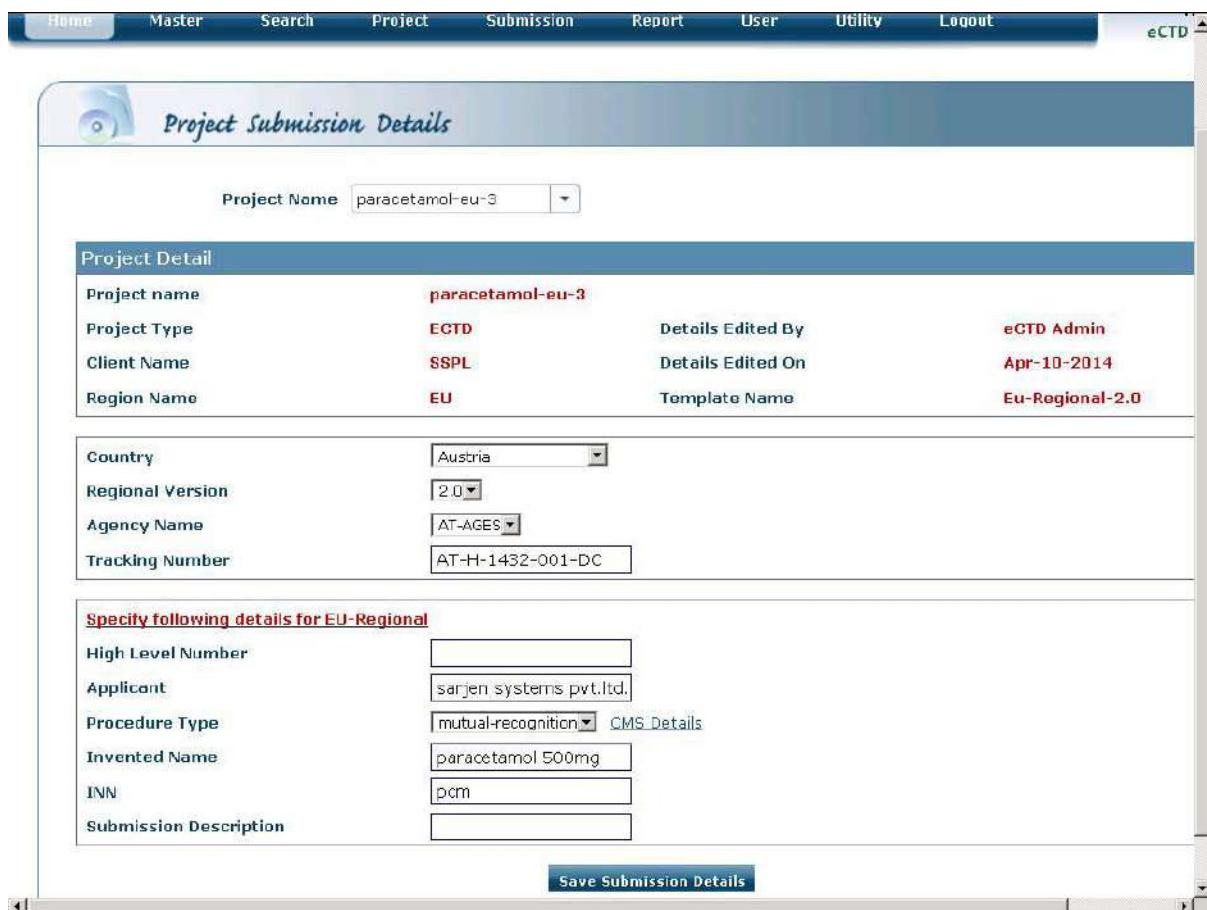


- On clicking “Back” button, user will redirect to “Project Submission Details” Page.

3. Mutual Recognition Procedure (MRP):

- Admin has to fill the other details same as above (IN C.P. & N.P.), but in **country name** admin select the one **RMS country** (After selecting RMS country) System automatically generate **Regional Version** and **Agency name** then admin select the **Procedure Type** Mutual Recognition procedure (MRP), after selecting the Mutual Recognition procedure system Create automatically a small pop up of [CMS Details](#).

- Below screen will be displayed.



The screenshot shows the 'Project Submission Details' page. At the top, there is a navigation bar with links: Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and eCTD. The 'Project' link is highlighted.

The main form is titled 'Project Submission Details'. It has a 'Project Name' field containing 'paracetamol-eu-3'. Below this is a 'Project Detail' section with the following data:

Project name	paracetamol-eu-3	Details Edited By	eCTD Admin
Project Type	ECTD	Details Edited On	Apr-10-2014
Client Name	SSPL	Template Name	Eu-Regional-2.0
Region Name	EU		

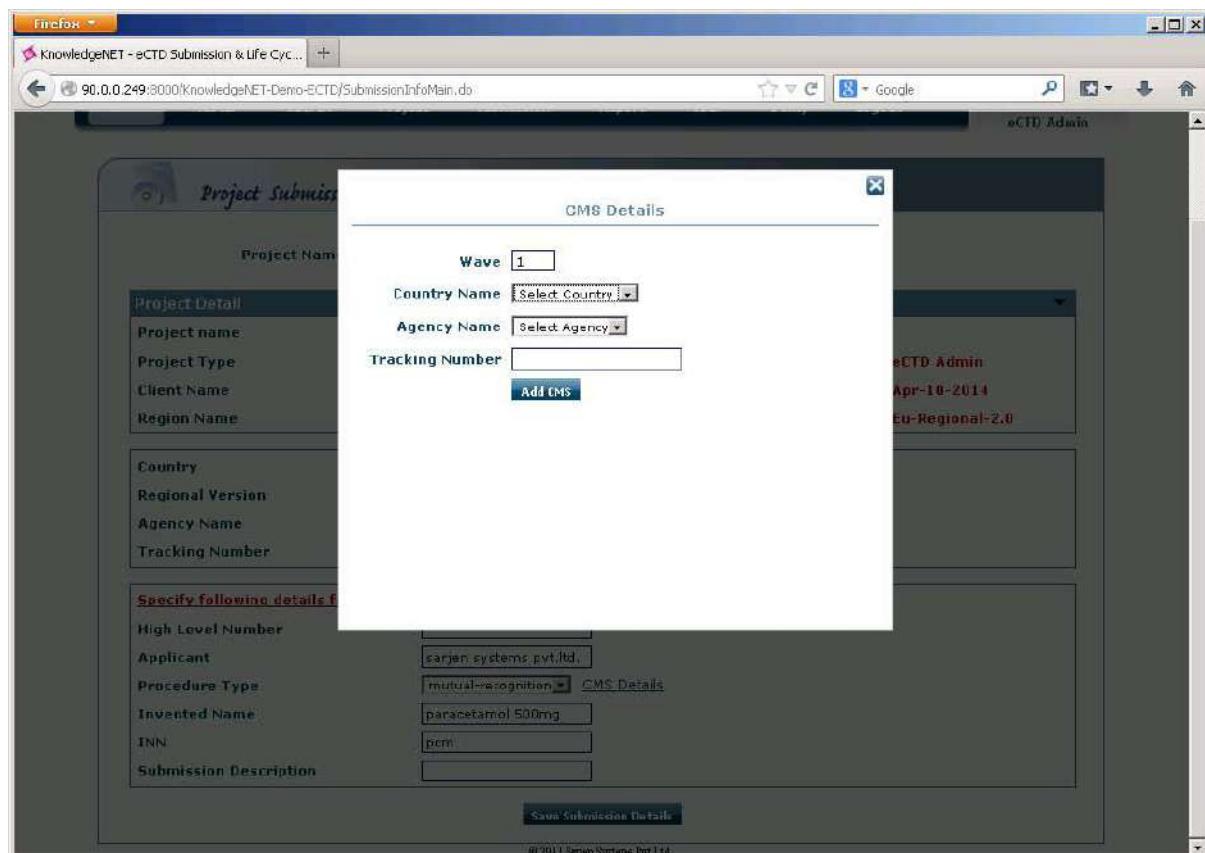
Below the project detail section are fields for 'Country' (Austria), 'Regional Version' (2.0), 'Agency Name' (AT-AGES), and 'Tracking Number' (AT-H-1432-001-DC).

Under the heading 'Specify following details for EU-Regional', there are several input fields:

High Level Number	<input type="text"/>
Applicant	sarjen systems pvt.ltd.
Procedure Type	mutual-recognition <input checked="" type="checkbox"/> CMS Details
Invented Name	paracetamol 500mg
INN	pcm
Submission Description	<input type="text"/>

At the bottom right of the form is a 'Save Submission Details' button.

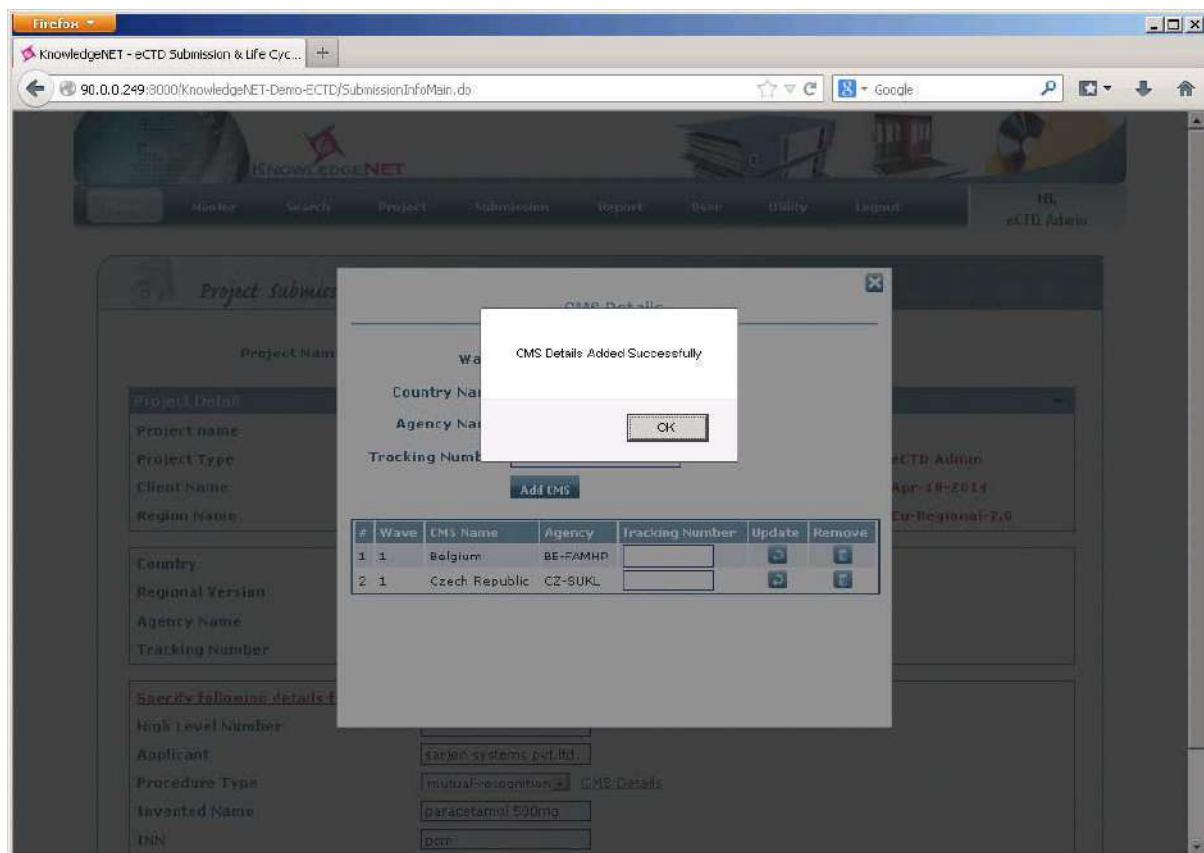
- On clicking “**CMS Details**”, a pop up shows, Below screen will be displayed



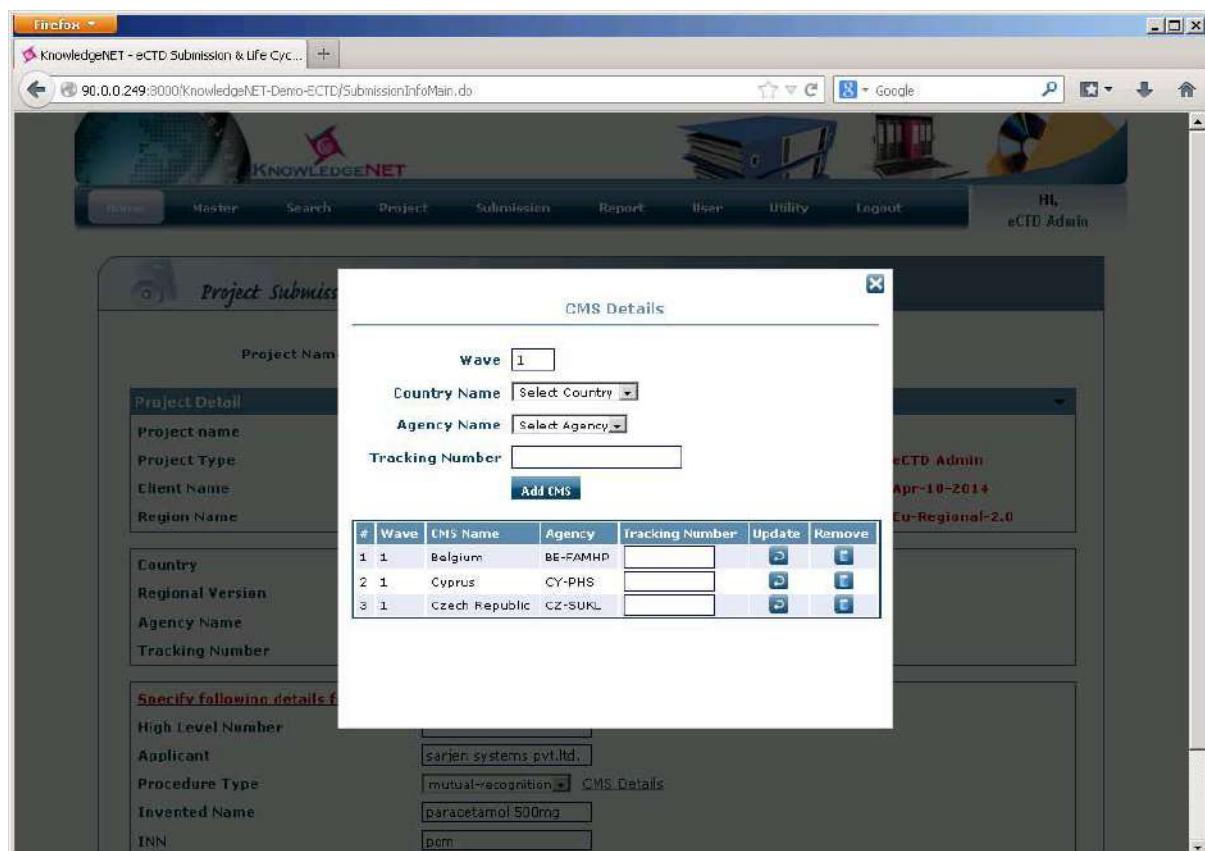
- Admin has to fill the details as "Wave", "Country Name", if admin select the **country name** system generate automatically **Agency Name** then click on "**Add CMS**" a pop up shows "**CMS** Details Added Successfully". Then click "**Ok**" and added another New CMS country.
- Below screen will be displayed

Note: **wave** is two types

1. **First (1) wave:** In first wave selected the CMS country first time.
2. **Second (2) wave:** If admin add any new country (other than previous country) in Related Sequence its show as Second wave in Tracking Table.



- Admin can update and Remove the CMS Details for particular country, if admin wants to Remove CMS country click on icon  Remove and admin wants to update Tracking Number click on icon  Update.
- Below screen will be displayed.

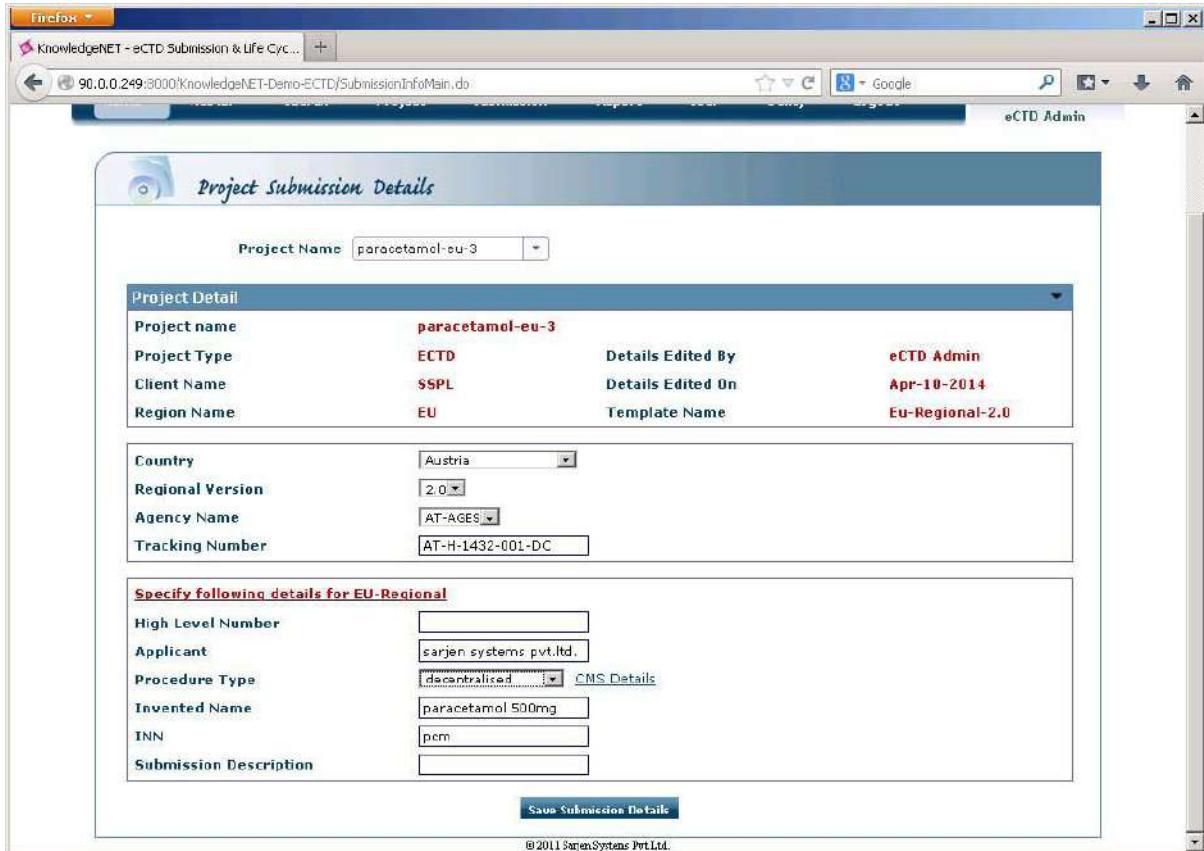


The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL is 90.0.0.249:3000/KnowledgeNET-Demo-ETCD/SubmissionInfoMain.do. The main menu bar includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and eCTD Admin. A sub-menu for eCTD Admin shows 'Apr-10-2014' and 'Eu-Regional-2.0'. On the left, there's a sidebar with sections like Project Detail, Country, Regional Version, Agency Name, and Tracking Number. The main content area has a 'Project Submission' header and a 'Specify following details for' section with fields for High Level Number, Applicant, Procedure Type, Invented Name, and INN. A modal dialog box titled 'CMS Details' is open in the center. It contains fields for Wave (set to 1), Country Name (dropdown menu), Agency Name (dropdown menu), and a Tracking Number input field. Below these is a 'Add CMS' button. A table lists three CMS entries: 1. Belgium, BE-FAMHP, with tracking number input fields and Update/Remove buttons. 2. Cyprus, CY-PHS, with tracking number input fields and Update/Remove buttons. 3. Czech Republic, CZ-SUKE, with tracking number input fields and Update/Remove buttons.

#	Wave	CMS Name	Agency	Tracking Number	Update	Remove
1	1	Belgium	BE-FAMHP	<input type="text"/>		
2	1	Cyprus	CY-PHS	<input type="text"/>		
3	1	Czech Republic	CZ-SUKE	<input type="text"/>		

4. Decentralised Procedure (DCP):

- Admin has to fill the details same as **MRP submission** procedure but admin select Procedure Types as **Decentralised**.



The screenshot shows a web application window titled "Project Submission Details". The "Project Name" field contains "paracetamol-eu-3". The "Project Detail" section displays the following information:

Project name	paracetamol-eu-3
Project Type	ECTD
Client Name	SSPL
Region Name	EU
Details Edited By	eCTD Admin
Details Edited On	Apr-10-2014
Template Name	Eu-Regional-2.0

Below this, there are dropdown menus for "Country" (Austria), "Regional Version" (2.0), "Agency Name" (AT-AGES), and "Tracking Number" (AT-H-1432-001-DC).

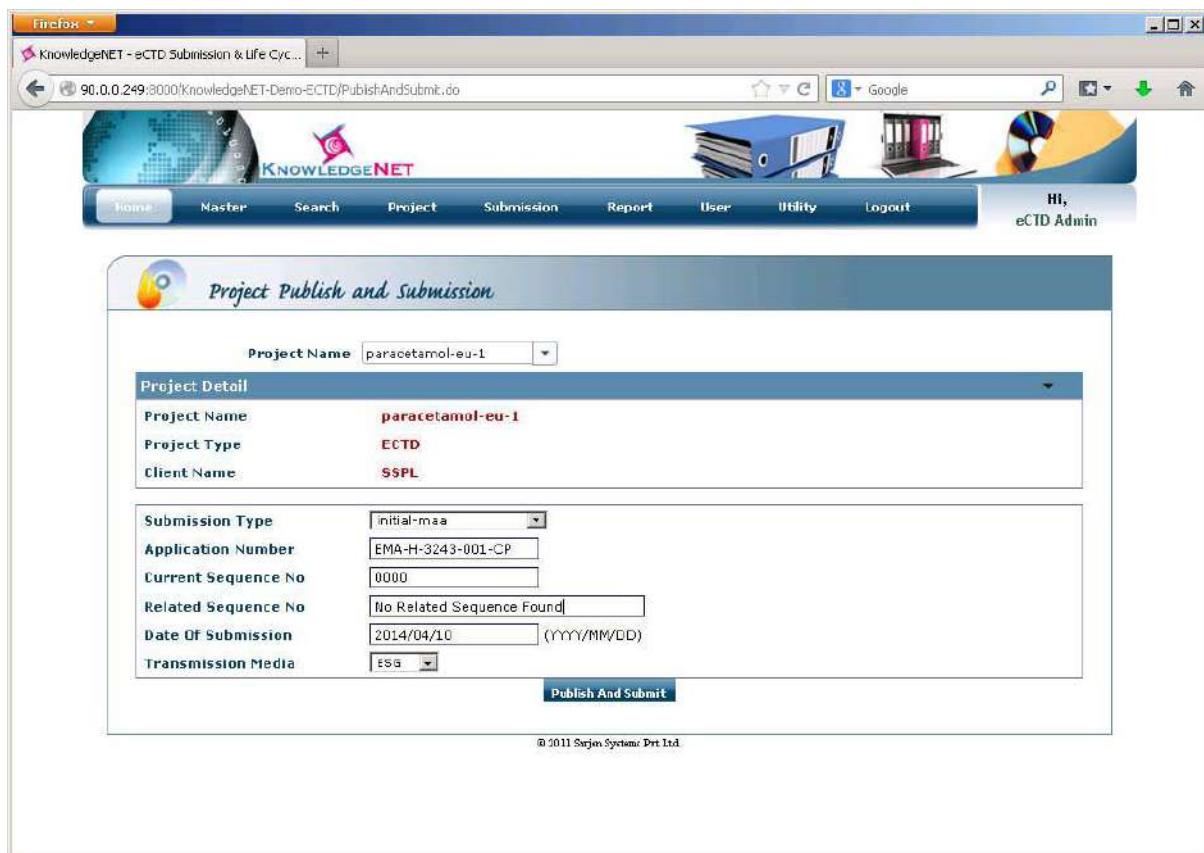
A section titled "Specify following details for EU-Regional" contains the following fields:

High Level Number	<input type="text"/>
Applicant	sarjen systems pvt.ltd.
Procedure Type	Decentralised
Invented Name	paracetamol 500mg
INN	pem
Submission Description	<input type="text"/>

At the bottom right of the form is a "Save Submission Details" button.

Submission >eCTD >Publish And Submit

- Admin above fill all Submission Details then go to **Publish And Submit**
- Below screen will get displayed.

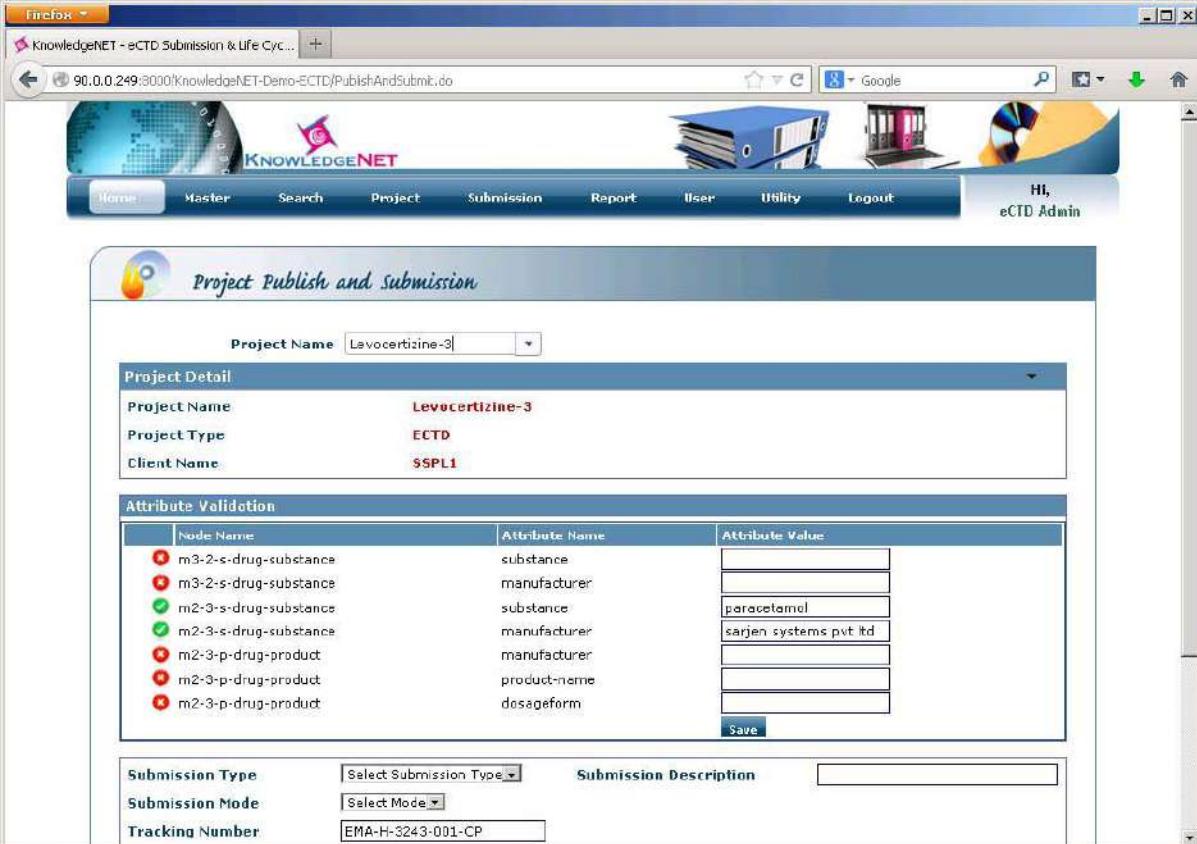


The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The page title is "Project Publish and Submission". The top navigation menu includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile "Hi, eCTD Admin". The main form is titled "Project Detail" and contains the following data:

Project Name	paracetamol-eu-1
Project Detail	
Project Name	paracetamol-eu-1
Project Type	ECTD
Client Name	SSPL
Submission Type	initial-maa
Application Number	EMA-H-3243-001-CP
Current Sequence No	0000
Related Sequence No	No Related Sequence Found
Date Of Submission	2014/04/10 (YYYY/MM/DD)
Transmission Media	ESB

At the bottom of the form is a "Publish And Submit" button. A small note at the bottom center of the page says "© 2011 Sorjon Systems Pvt Ltd."

- On filling the attribute values, the Red Cross image will be changed to green checked image indicating that the missing attribute values have been updated.

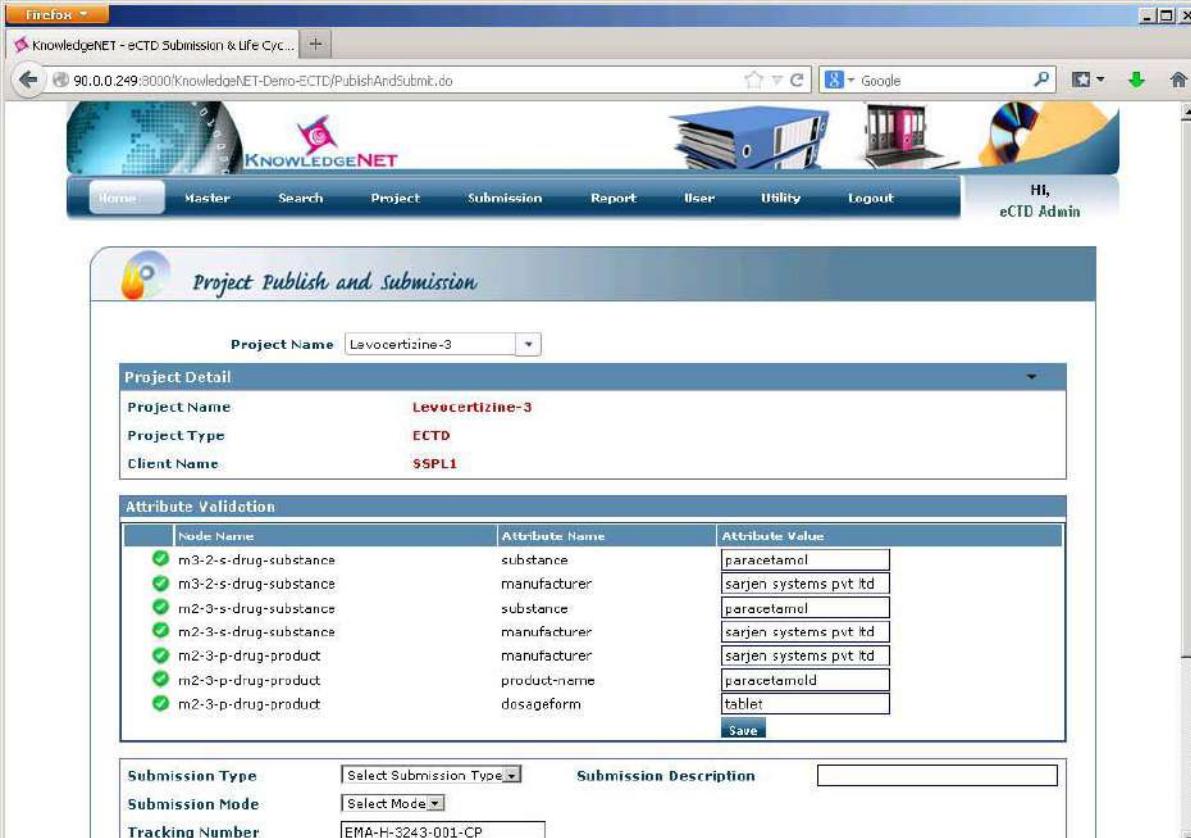


The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The page title is "Project Publish and submission". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile for "eCTD Admin". The main content area has a header "Project Detail" with fields for Project Name (Levocetizine-3), Project Type (ECTD), and Client Name (SSPL1). Below this is a "Attribute Validation" table:

Node Name	Attribute Name	Attribute Value
m3-2-s-drug-substance	substance	<input type="text"/>
m3-2-s-drug-substance	manufacturer	<input type="text"/>
m2-3-s-drug-substance	substance	paracetamol
m2-3-s-drug-substance	manufacturer	sarjen systems pvt ltd
m2-3-p-drug-product	manufacturer	<input type="text"/>
m2-3-p-drug-product	product-name	<input type="text"/>
m2-3-p-drug-product	dosageform	<input type="text"/>

At the bottom of the validation table is a "Save" button. Below the table are fields for Submission Type (Select Submission Type), Submission Mode (Select Mode), and Tracking Number (EMA-H-3243-001-CP).

- On filling the attribute values, the Red Cross image will be changed to green.
- Below screen will get displayed.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The page title is "Project Publish and submission". The top navigation menu includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile section for "eCTD Admin". The main content area contains a "Project Detail" section with fields for Project Name (Levocetizine-3), Project Type (eCTD), and Client Name (SSPL1). Below this is an "Attribute Validation" table:

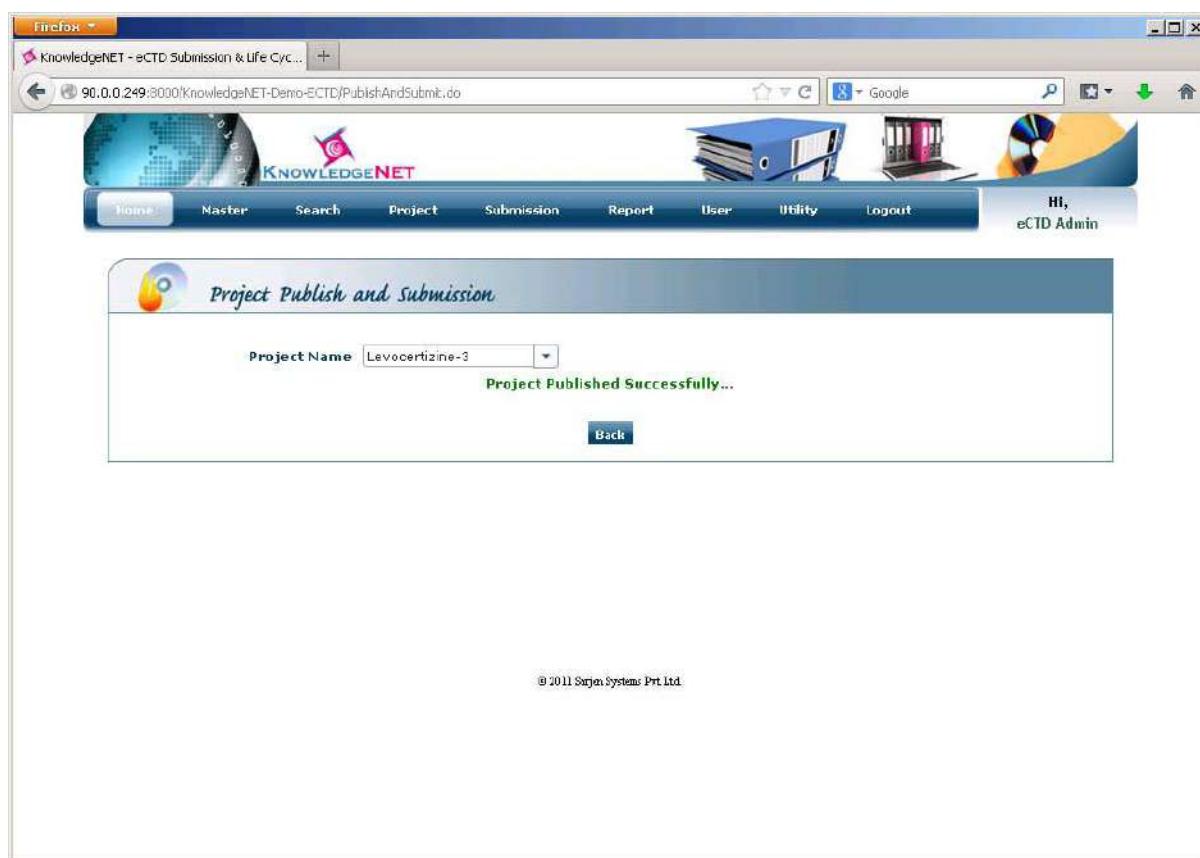
Node Name	Attribute Name	Attribute Value
m3-2-s-drug-substance	substance	paracetamol
m3-2-s-drug-substance	manufacturer	sarjen systems pvt ltd
m2-3-s-drug-substance	substance	paracetamol
m2-3-s-drug-substance	manufacturer	sarjen systems pvt ltd
m2-3-p-drug-product	manufacturer	sarjen systems pvt ltd
m2-3-p-drug-product	product-name	paracetamol
m2-3-p-drug-product	dosageform	tablet

At the bottom of the validation table is a "Save" button. Below the table are fields for Submission Type (Select Submission Type dropdown), Submission Mode (Select Mode dropdown), and Tracking Number (EMA-H-3243-001-CP).

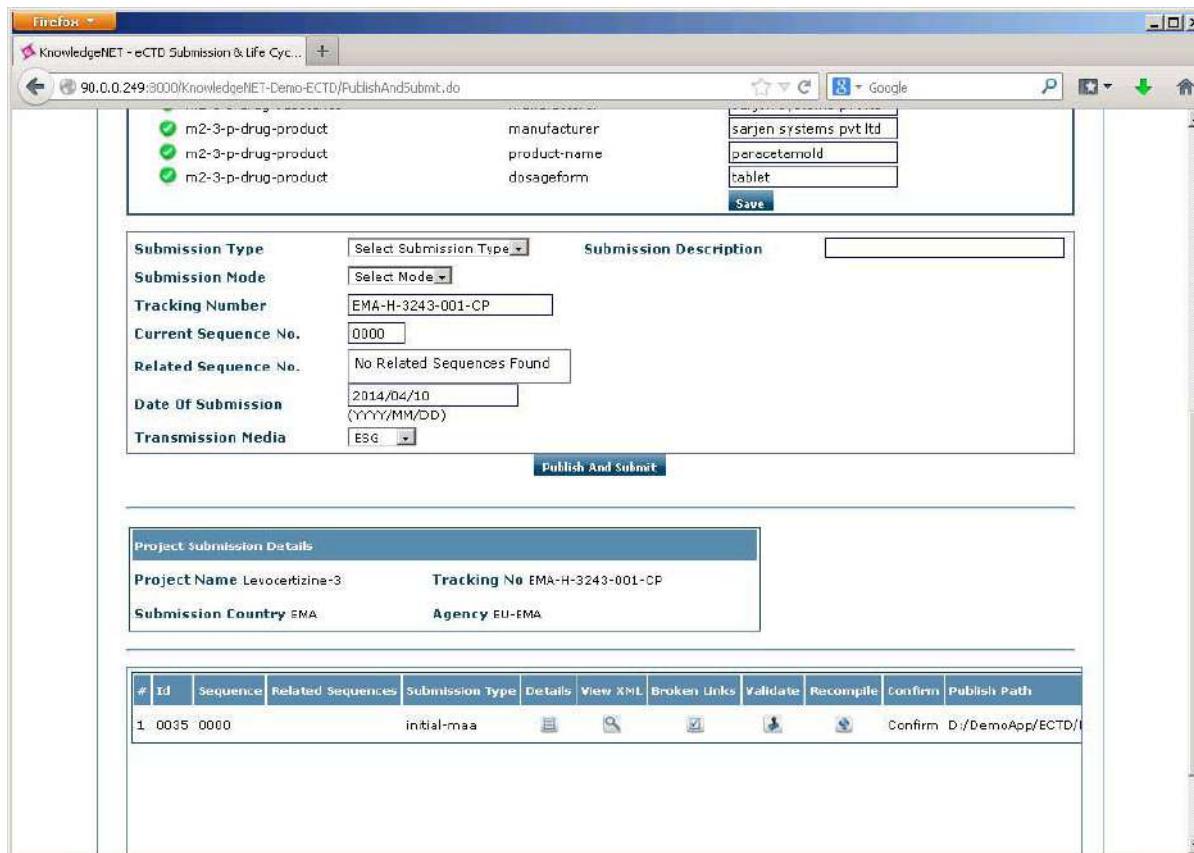
- Admin fill Attributes values than fill up other details such as “Submission type”, “Submission Mode”, “Submission Description” “Date of Submission” and Transmission Media. Some detail System Generate Automatically such as “Tracking No.”, “Current Sequence No.”, and “Related Sequence No.”.

Note: Above all details Mentioned in **Centralised** and **National submission procedure**.

- The below screen shows the details of the project that has been submitted and published successfully.



- Click on “Back” button and below screen will get displayed.

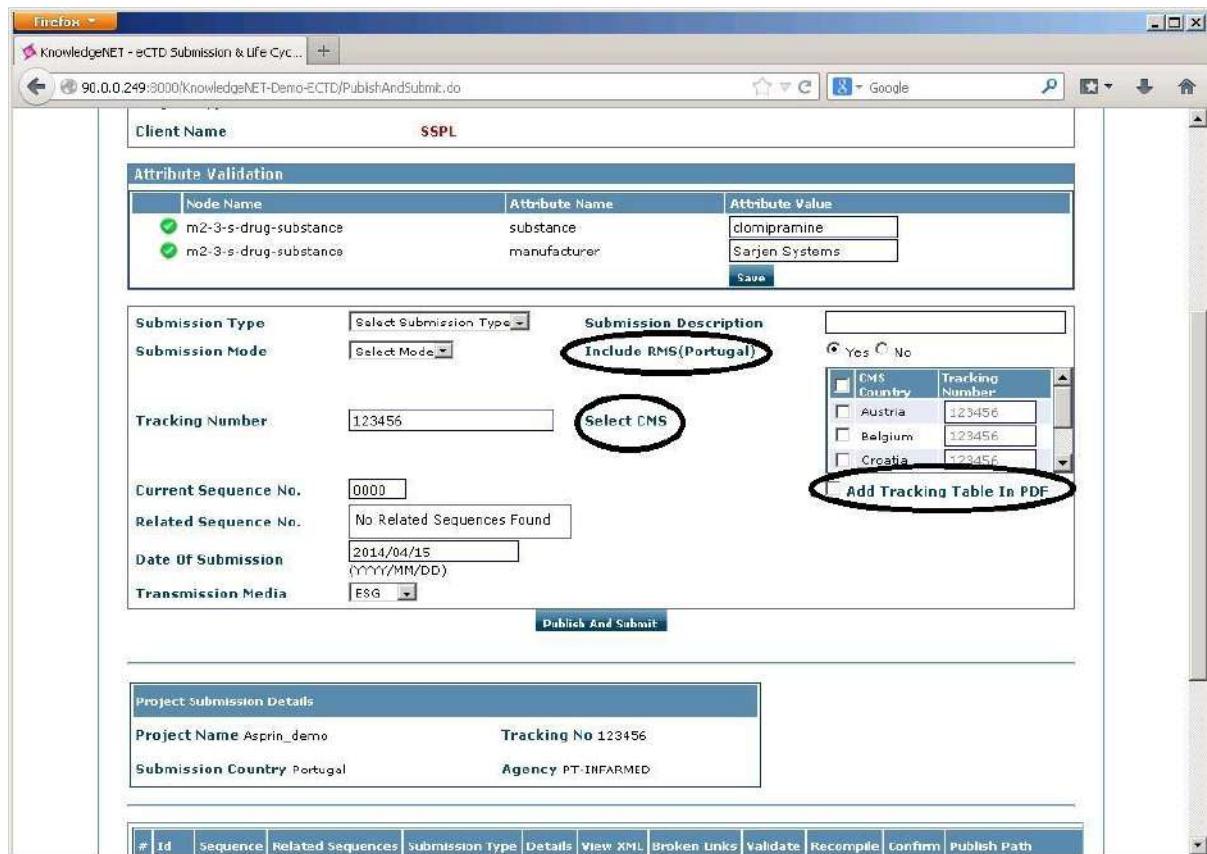


The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The page contains several sections:

- Product Information:** A table with columns for product ID (m2-3-p-drug-product), manufacturer (sarjen systems pvt ltd), product name (peracetemol), and dosage form (tablet). A "Save" button is at the bottom right.
- Submission Details:** Fields include Submission Type (Select Submission Type), Submission Mode (Select Mode), Tracking Number (EMA-H-3243-001-CP), Current Sequence No. (0000), Related Sequence No. (No Related Sequences Found), Date Of Submission (2014/04/10), and Transmission Media (ESG). A "Publish And Submit" button is at the bottom.
- Project Submission Details:** A summary box showing Project Name (Levoceftizine-3), Tracking No (EMA-H-3243-001-CP), Submission Country (EMA), and Agency (EU-EMA).
- Submission Log:** A table with columns for #, Id, Sequence, Related Sequences, Submission Type, Details, View XML, Broken Links, Validate, Recompile, Confirm, and Publish Path. One row is shown: # 1, Id 0035, Sequence 0000, Submission Type initial-maa, and a list of icons for the other columns.

- The above screen shows the details of the project that has been submitted and published successfully.

- **Note:** In **MRP** and **Decentralised** Submission procedure.
- The below screen shows the details of the project that has been **Publish and Submit**.
- **Note:** In **MRP** and **Decentralised** Submission procedure. Admin fill up details other than in Centralised & National submission Procedures as Follows: -
 - Select CMS** Tick mark the **CMS Country** and also **Tick mark the "Add Tracking Table In PDF"**.



The screenshot shows the KnowledgeNET eCTD Submission & Life Cycle Management Module interface. The main window title is "KnowledgeNET - eCTD Submission & Life Cyc...". The URL in the address bar is "90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do".

Client Name: SSPL

Attribute Validation:

Node Name	Attribute Name	Attribute Value
m2-3-s-drug-substance	substance	clomipramine
m2-3-s-drug-substance	manufacturer	Sarjen Systems

Submission Type: Select Submission Type

Submission Mode: Select Mode

Tracking Number: 123456

Current Sequence No.: 0000

Related Sequence No.: No Related Sequences Found

Date Of Submission: 2014/04/15 (YYYY/MM/DD)

Transmission Media: ESG

Submission Description: Include RMS(Portugal) (circled)

Select CMS: (circled)

CMS Country:

CMS Country	Tracking Number
Austria	123456
Belgium	123456
Croatia	123456

Add Tracking Table In PDF: (circled)

Buttons: Publish And Submit

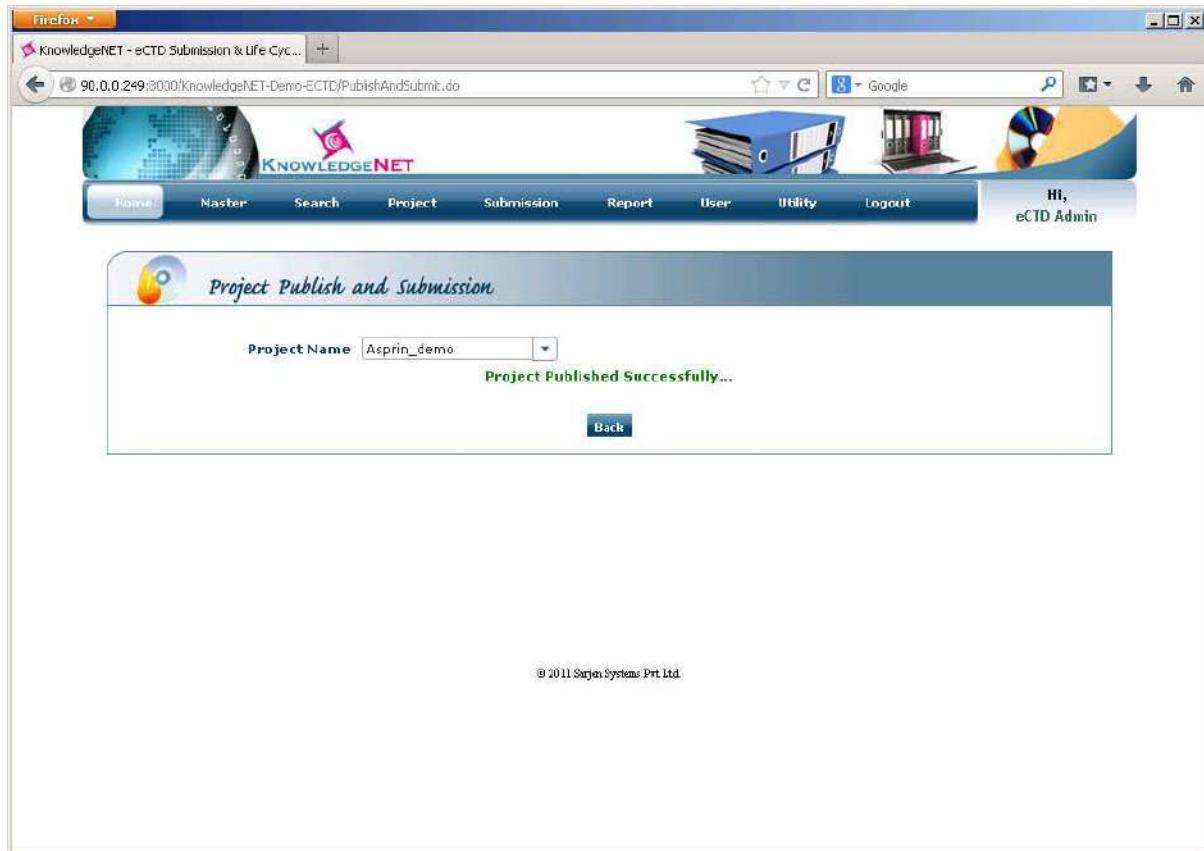
Project Submission Details:

Project Name Asprin_demo	Tracking No 123456
Submission Country Portugal	Agency PT-INFORMED

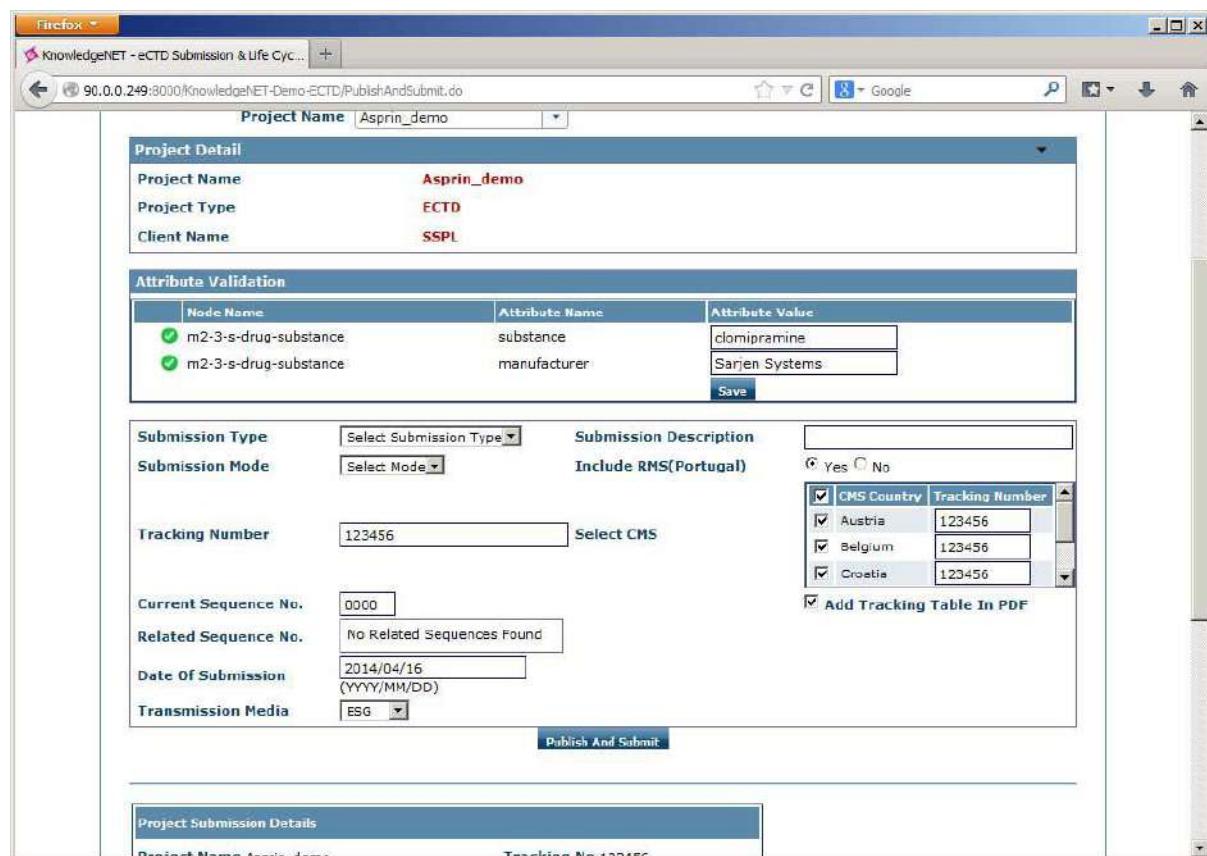
Toolbar: # Id Sequence Related Sequences Submission Type Details View XML Broken Links Validate Recompile Confirm Publish Path

- In above screen shows RMS Country is Portugal.

- The below screen shows the details of the project that has been submitted and published successfully.

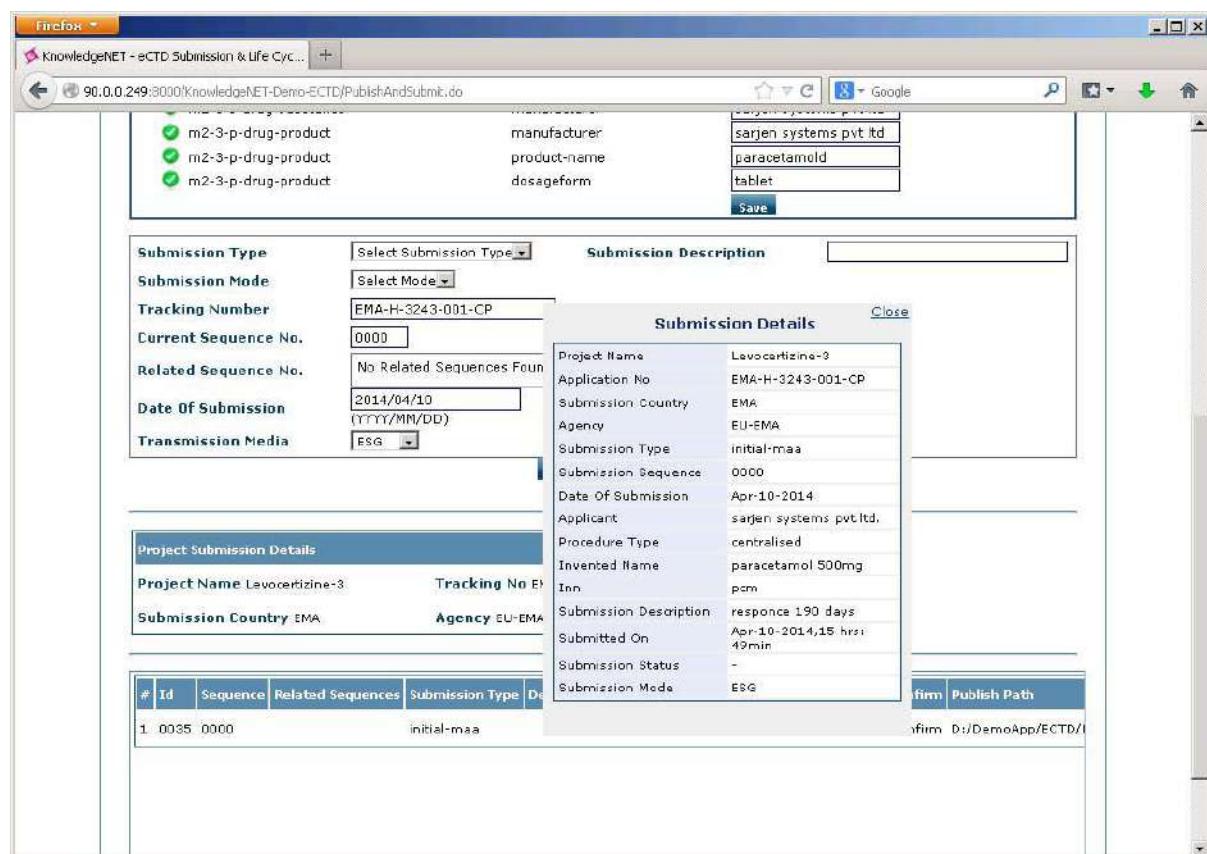


- Click on "Back" button and below screen will get displayed.
- The below screen shows the details of the project that has been submitted and published successfully.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL is 90.0.0.249:8000/KnowledgeNET-Demo-eCTD/PublishAndSubmit.do. The page is titled 'Project Detail' for 'Asprin_demo'. It includes sections for 'Attribute Validation' (with two entries: m2-3-s-drug-substance for substance with value 'clomipramine' and manufacturer with value 'Sarjen Systems'), 'Submission Type' (dropdown), 'Submission Mode' (dropdown), 'Submission Description' (checkboxes for 'Yes' or 'No'), 'Include RMS(Portugal)' (checkbox), 'Tracking Number' (input field with value '123456'), 'Select CMS' (button), 'Current Sequence No.' (input field with value '0000'), 'Related Sequence No.' (input field with value 'No Related Sequences Found'), 'Date Of Submission' (input field with value '2014/04/16 (YYYY/MM/DD)'), 'Transmission Media' (dropdown with value 'ESG'), and a 'Publish And Submit' button. To the right, there is a 'CMS Country' dropdown menu with three entries: Austria (123456), Belgium (123456), and Croatia (123456). A checkbox 'Add Tracking Table In PDF' is also present. At the bottom, there is a 'Project Submission Details' section with 'Project Name Asprin_demo' and 'Tracking No. 123456'.

- **Details:** On clicking "Details" icon in the grid, the below screen will get displayed which shows the submission details of the project.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management Module. The URL is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The main interface includes a grid of items, a top navigation bar with tabs like 'Project Details', 'Submission Details', 'Sequence Details', etc., and a right-hand sidebar with a tree view. A modal dialog box titled 'Submission Details' is open, containing detailed submission information. The 'Submission Details' dialog includes fields such as Project Name (Levocetizine-3), Application No (EMA-H-3243-001-CP), Submission Country (EMA), Agency (EU-EMA), Submission Type (initial-maa), Submission Sequence (0000), Date Of Submission (Apr-10-2014), Applicant (sarjen systems pvt ltd.), Procedure Type (centralised), Invented Name (paracetamol 500mg), Inn (pcm), Submission Description (response 190 days), Submitted On (Apr-10-2014, 15 hrs 49min), Submission Status (-), and Submission Mode (ESG). At the bottom of the dialog, there are 'Print' and 'Publish Path' buttons. The overall interface is clean and professional, designed for pharmaceutical submission management.

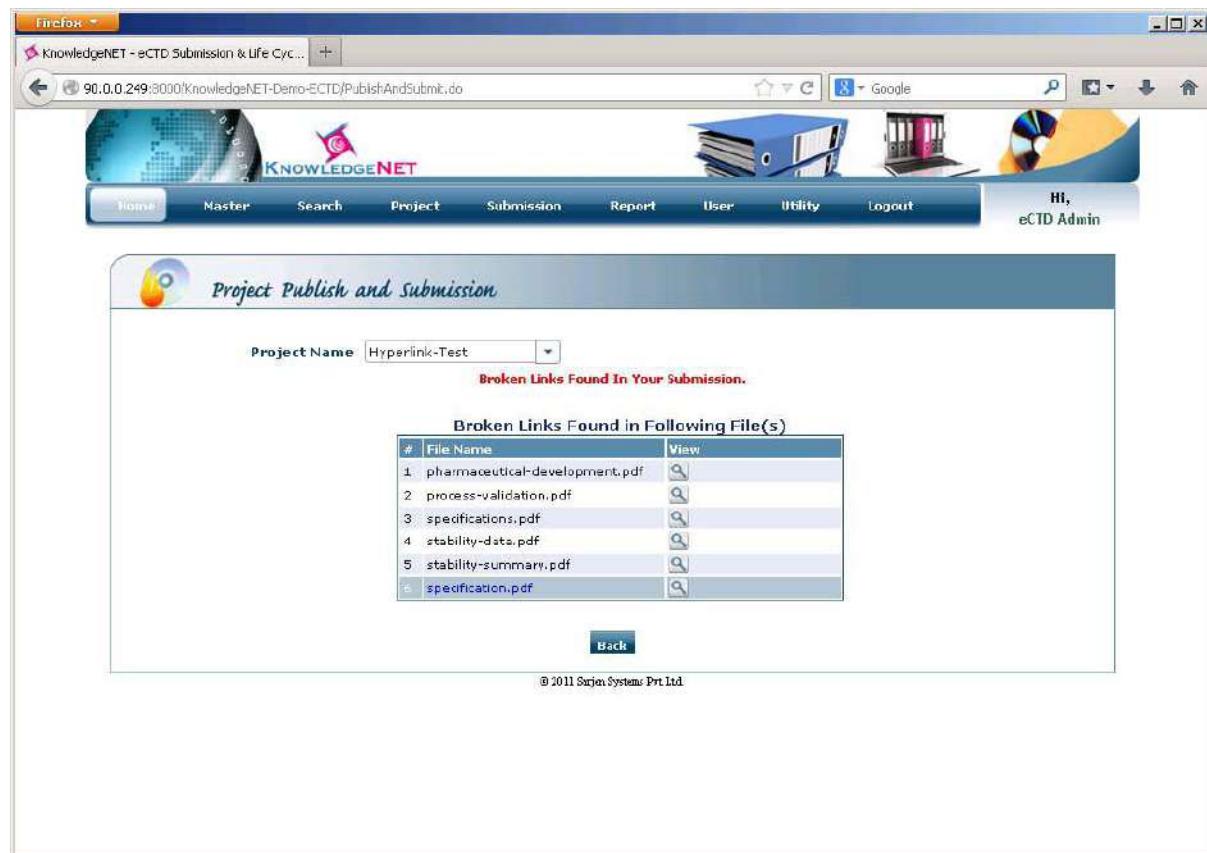
- **XML View:** On clicking the “View XML” icon, it will display the below screen in a new tab.



The screenshot shows a Firefox browser window displaying the eCTD DTD version 3.2 structure. The URL in the address bar is <http://90.0.0.249:8000/docmgmtandpub/ECTD/PublishDestinationFolder/0156/0035/Levocetirizine-3/0000/index.xml>. The page content is a hierarchical tree of XML elements, likely representing the structure of an eCTD submission. Some links are highlighted in blue, and some attribute values are shown in green. The tree includes nodes like m1-administrative-information-and-prescribing-information, EU Module 1 [new], m2-common-technical-document-summaries, m2-2-introduction, m2-3-quality-overall-summary, m2-3-s-drug-substance, m2-3-p-drug-product, m2-3-a-appendices, m3-quality, m3-2-body-of-data, m3-2-s-drug-substance, m3-2-s-1-general-information, m3-2-s-1-1-nomenclature, m3-2-s-1-2-structure, m3-2-s-1-3-general-properties, m3-2-s-2-manufacturer, and m3-2-s-2-1-manufacturer.

- The above screen, the blue color link shows the file uploaded on that node. The operation value is shows next to the file link in red color whether it is new, replace, append or delete.
- The attribute value is shows in green color.
- EU module 1 details will be displayed on clicking ‘[m1-administrative-information-and-prescribing-information](#)’ link.

- **Broken Links:** On clicking ‘Broken Links’ icon in the grid, below screen will get displayed.
- It shows that there are broken links found in the attached PDF files in the project.

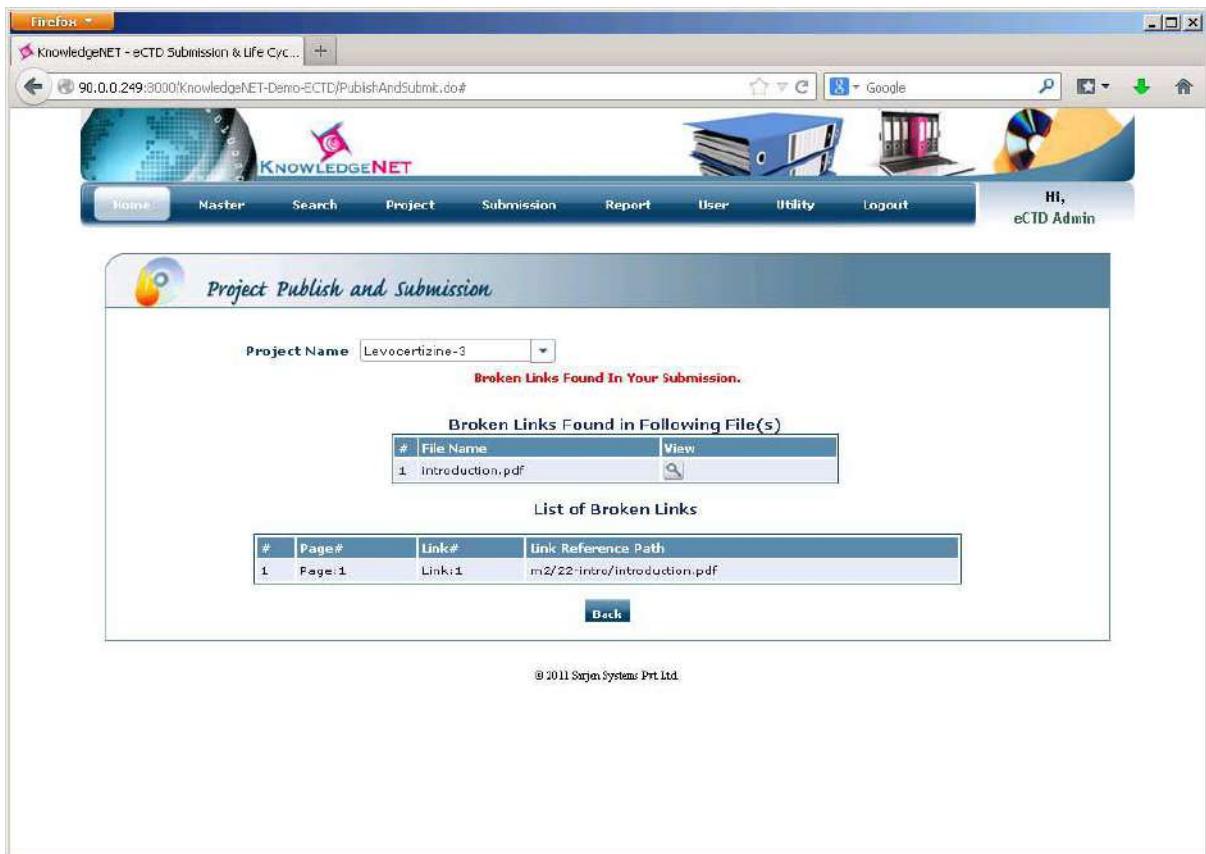


The screenshot shows a Firefox browser window displaying the KnowledgeNET platform. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do. The page title is "Project Publish and Submission". A dropdown menu shows "Project Name: Hyperlink-Test". Below it, a red message says "Broken Links Found In Your Submission.". A table titled "Broken Links Found in Following File(s)" lists six files with their names and a "View" link:

#	File Name	View
1	pharmaceutical-development.pdf	[View]
2	process-validation.pdf	[View]
3	specifications.pdf	[View]
4	stability-data.pdf	[View]
5	stability-summary.pdf	[View]
6	specification.pdf	[View]

A "Back" button is at the bottom left, and a copyright notice "© 2011 Sarjeet Systems Pvt Ltd." is at the bottom center.

- By clicking on View icon in the grid, Admin will get the link details below in the grid as shows in the below screen.
- On clicking ‘Back’ button, user will be redirected to the main page showing the grid containing the details of submission.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cyc... website. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-eCTD/PublishAndSubmit.do#.

The page title is "Project Publish and Submission". The top navigation menu includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting "Hi, eCTD Admin" is visible on the right.

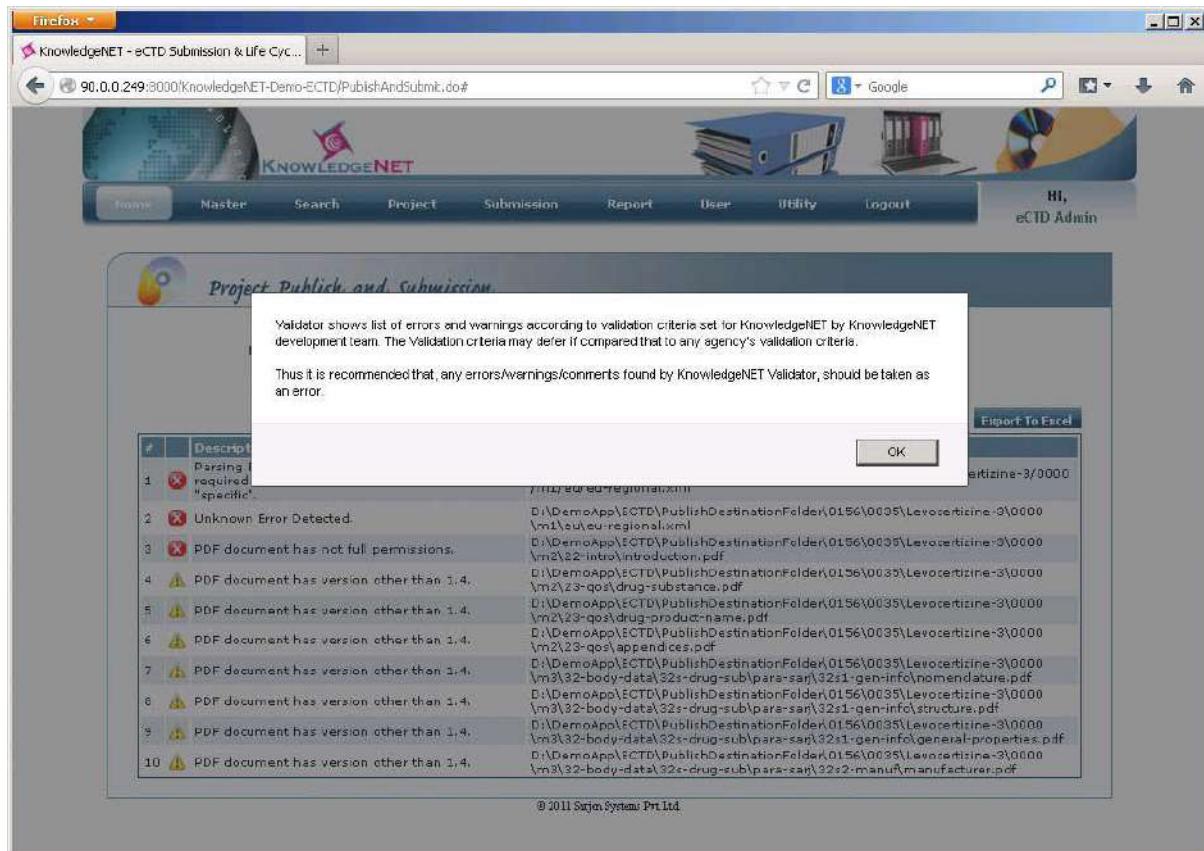
The main content area displays a message: "Broken Links Found In Your Submission." Below this, a table titled "Broken Links Found in Following File(s)" lists one file: "introduction.pdf".

Below the table, another section titled "List of Broken Links" shows a single entry:

#	Page#	Link#	Link Reference Path
1	Page:1	Link:1	m2/22/intro/introduction.pdf

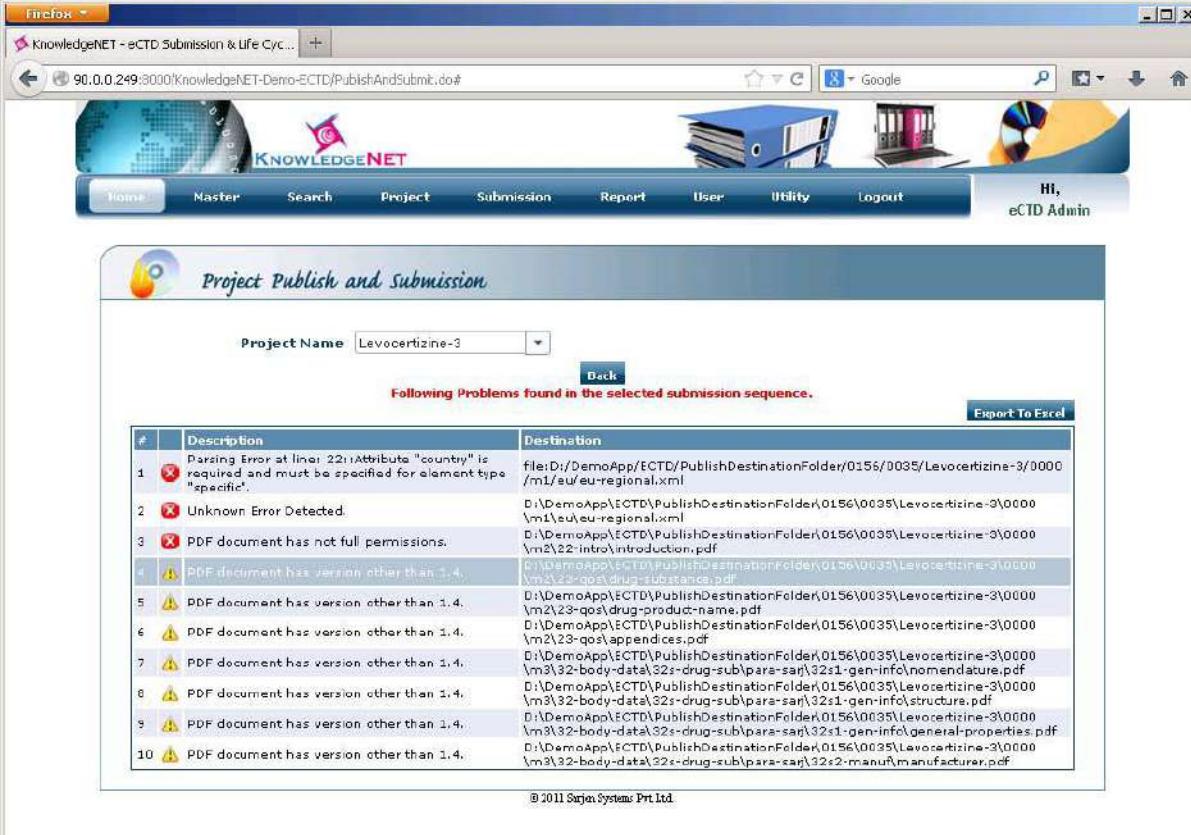
A "Back" button is located at the bottom of this section.

- **Validate:** On clicking Validate icon in the grid, it will show an alert displaying the validation message.



- On clicking 'Ok' button, it will display errors or warnings in the grid as shows in the below screen.

- User can export the validation report to excel by clicking on 'Export To Excel' button.



Project Publish and Submission

Project Name: Levocetizine-3

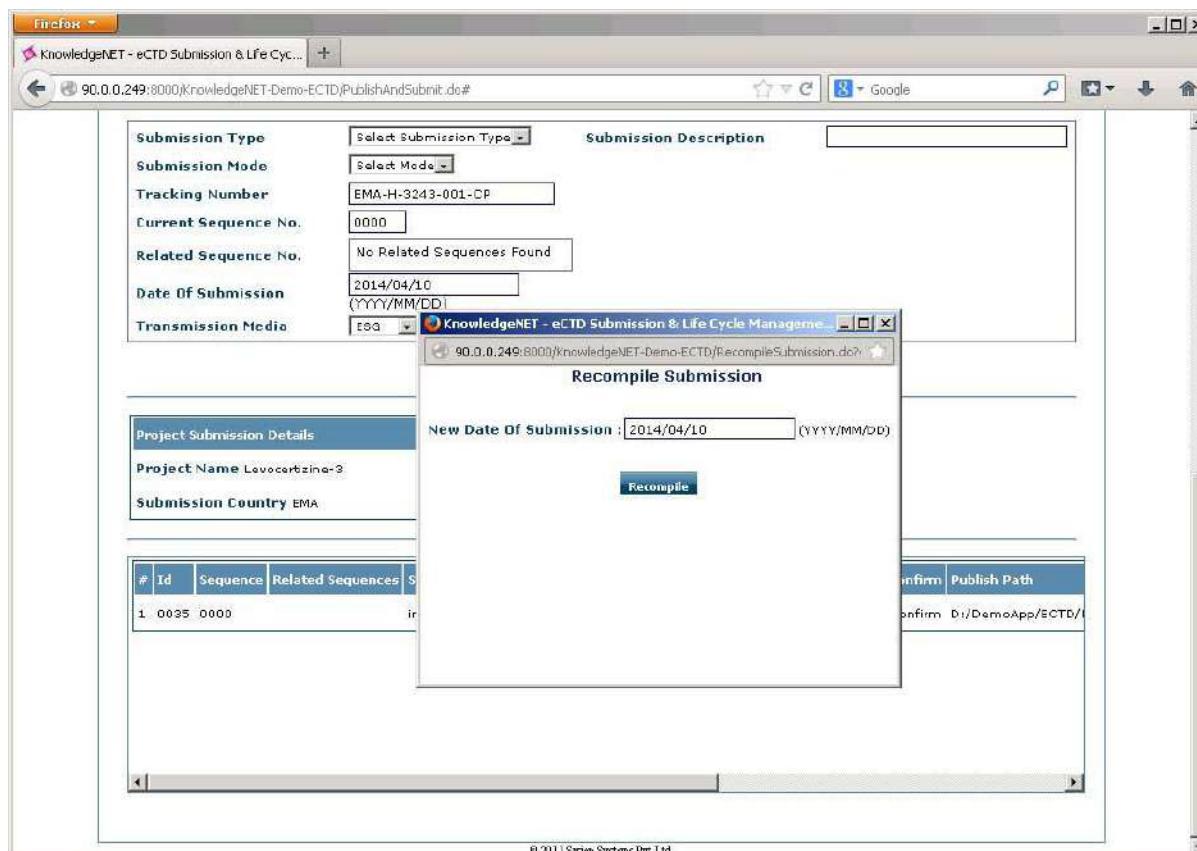
Following Problems found in the selected submission sequence.

#	Description	Destination
1	Parsing Error at line: 22: Attribute "country" is required and must be specified for element type "specific".	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m1\eu\eu-regional.xml
2	Unknown Error Detected.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m1\22-intro\introduction.pdf
3	PDF document has not full permissions.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m1\22-qos\drug-substance.pdf
4	PDF document has version other than 1.4.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m1\23-qos\drug-product-name.pdf
5	PDF document has version other than 1.4.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m1\23-qos\appendices.pdf
6	PDF document has version other than 1.4.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m3\32-body-data\32s-drug-sub\para-sar\32s1-gen-info\nomenclature.pdf
7	PDF document has version other than 1.4.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m3\32-body-data\32s-drug-sub\para-sar\32s1-gen-info\structure.pdf
8	PDF document has version other than 1.4.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m3\32-body-data\32s-drug-sub\para-sar\32s1-gen-info\general-properties.pdf
9	PDF document has version other than 1.4.	D:\DemoApp\ECTD\PublishDestinationFolder\0156\0035\Levocetizine-3\0000\m3\32-body-data\32s-drug-sub\para-sar\32s2-manual\manufacturer.pdf
10	PDF document has version other than 1.4.	

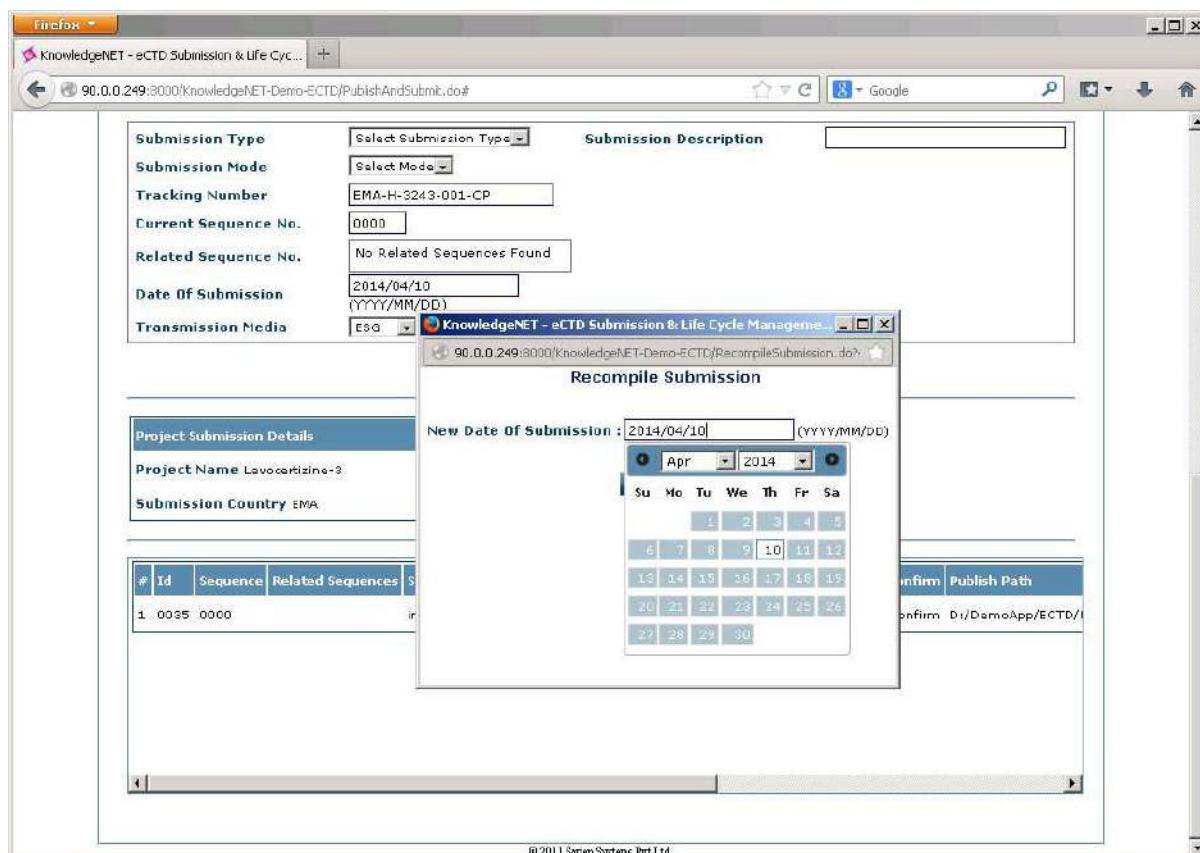
Export To Excel

© 2011 Surjeet Systems Pvt Ltd.

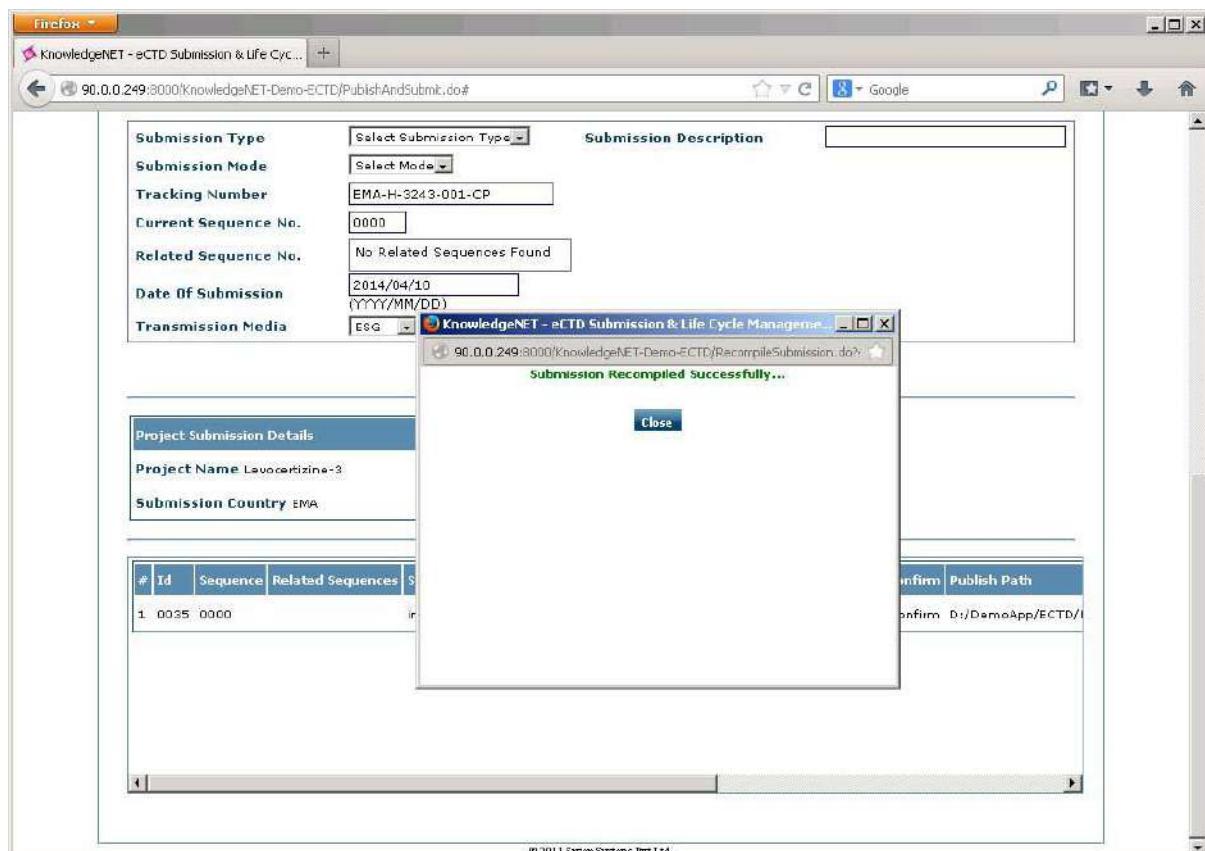
- **Recompile:** On clicking Recompile icon in the grid, a pop up window will open up as shows in below screen.
- On recompiling a project, a whole sequence will be re-published and any changes done in the file(s) will be reflected in the project.



- Select the date on which Admin want to recompile the project and click on 'Recompile' button. A message will get displayed as shows in below screen.



- Click on 'Close' button to close the pop up window.



- **Confirm:** On clicking ‘Confirm’ icon in the grid, a particular sequence will get confirmed.
- If there are any broken links found in a sequence, then a message will get displayed as shows in below screen.

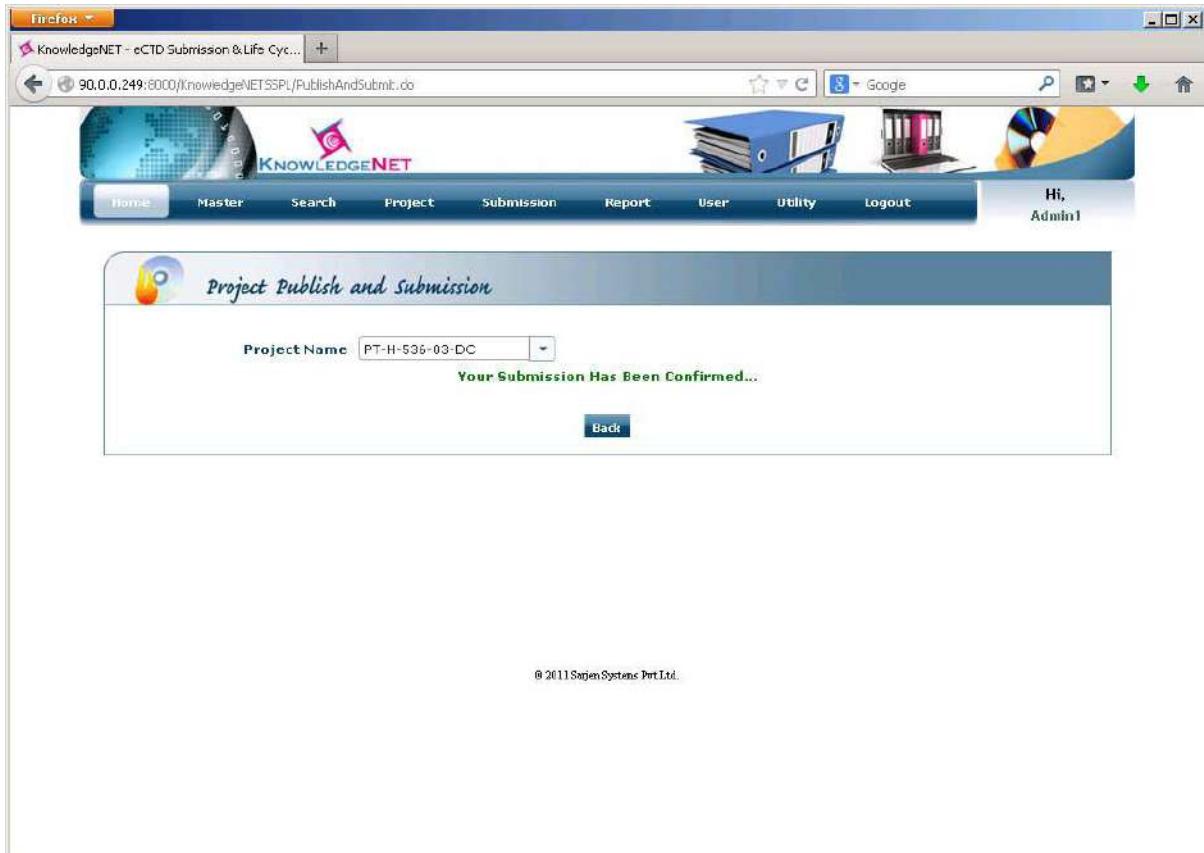


The screenshot shows a web browser window with the URL <http://localhost:8000/KnowledgeNET-Test/PublishAndSubmit.do>. The page title is "Project Publish and Submission". The main content area displays a table titled "Broken Links Found in Following File(s)". The table has two columns: "# File Name" and "View". The table lists 10 files, with the 5th file, "drug-product-name.pdf", highlighted in blue. Below the table are two buttons: "Ignore And Confirm" and "Back". At the bottom of the page, it says "© 2014 Sajin Systems Pvt Ltd". The status bar at the bottom right shows "This PC" and the date/time "3/5/2014 3:35 AM".

#	File Name	View
1	fda-form-356h.pdf	
2	cover-letters.pdf	
3	appendices.pdf	
4	drug-product-name.pdf	
5	drug-product-name.pdf	
6	drug-substance.pdf	
7	drug-substance.pdf	
8	introduction.pdf	
9	regional-information.pdf	
10	summary-clin-efficacy-[indication].pdf	

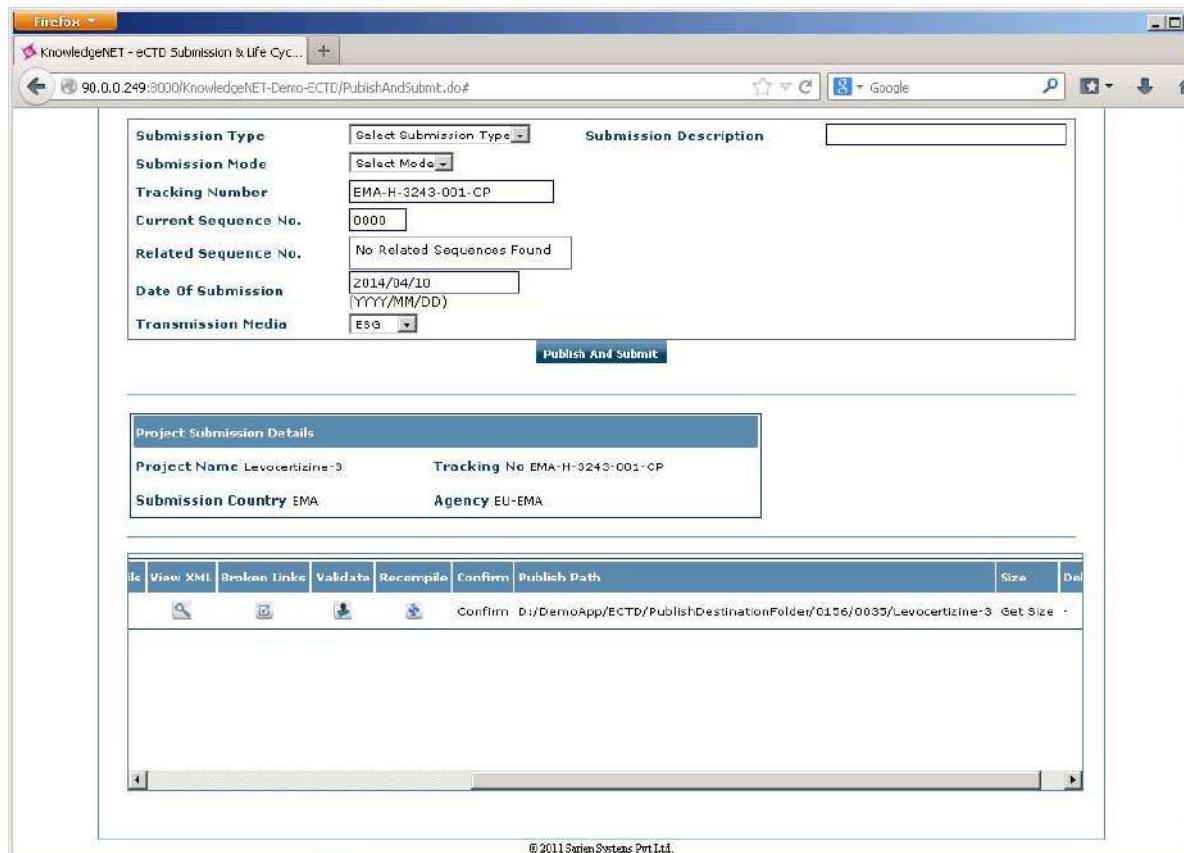
- All the broken links will get displayed in a grid.
- Admin can ignore the links and confirm the sequence by clicking on ‘Ignore And Confirm’ button.
- Click on ‘Back’ button to go back to the main page.

Sequence Confirmed show in grid



The screenshot shows a Firefox browser window displaying the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/PublishAndSubmit.do. The page title is "Project Publish and Submission". The main content area displays a message: "Your Submission Has Been Confirmed..." above a "Back" button. The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, Admin1" is visible on the right. The header features the KnowledgeNET logo and various icons related to document management and technology.

- **Publish Path:** The final folder will be found on clicking ‘Publish Path’ icon in the grid as shows in below screen.
- User shall get a folder structure as shows in below screen and should save that folder structure and use the same for submission purpose.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/PublishAndSubmit.do#.

The main form contains the following fields:

Submission Type	Select Submission Type	Submission Description
Submission Mode	Select Mode	
Tracking Number	EMA-H-3243-001-CP	
Current Sequence No.	0000	
Related Sequence No.	No Related Sequences Found	
Date Of Submission	2014/04/10 (YYYY/MM/DD)	
Transmission Media	E5G	

Below the form is a 'Publish And Submit' button.

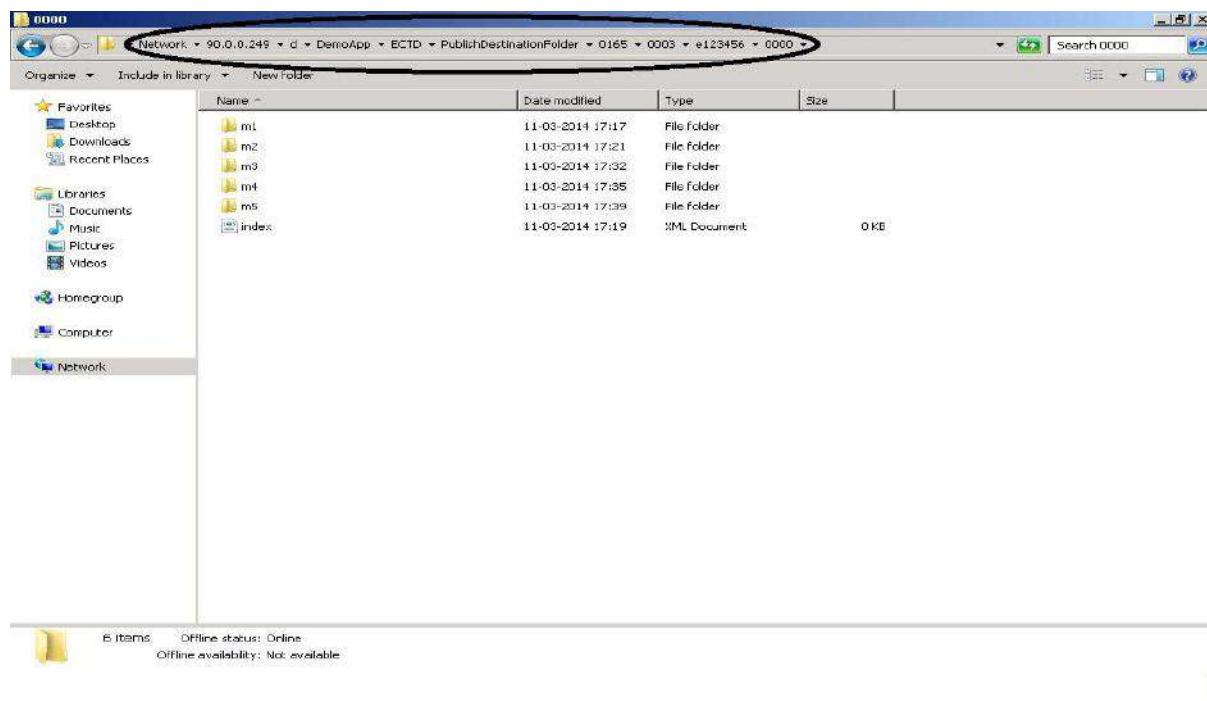
A 'Project Submission Details' section displays:

Project Name Levocetizine-3	Tracking No EMA-H-3243-001-CP
Submission Country EMA	Agency EU-EMA

At the bottom, a toolbar includes: File, View XML, Broken Links, Validate, Recompile, Confirm, Publish Path, Size, Del, and a 'Confirm' button with the path D:/DemoApp/ECTD/PublishDestinationFolder/0156/0035/Levocetizine-3 Get Size.

The status bar at the bottom left indicates: © 2011 Sanjen Systems Pvt Ltd.

- Folder structure and use the same for submission purpose.

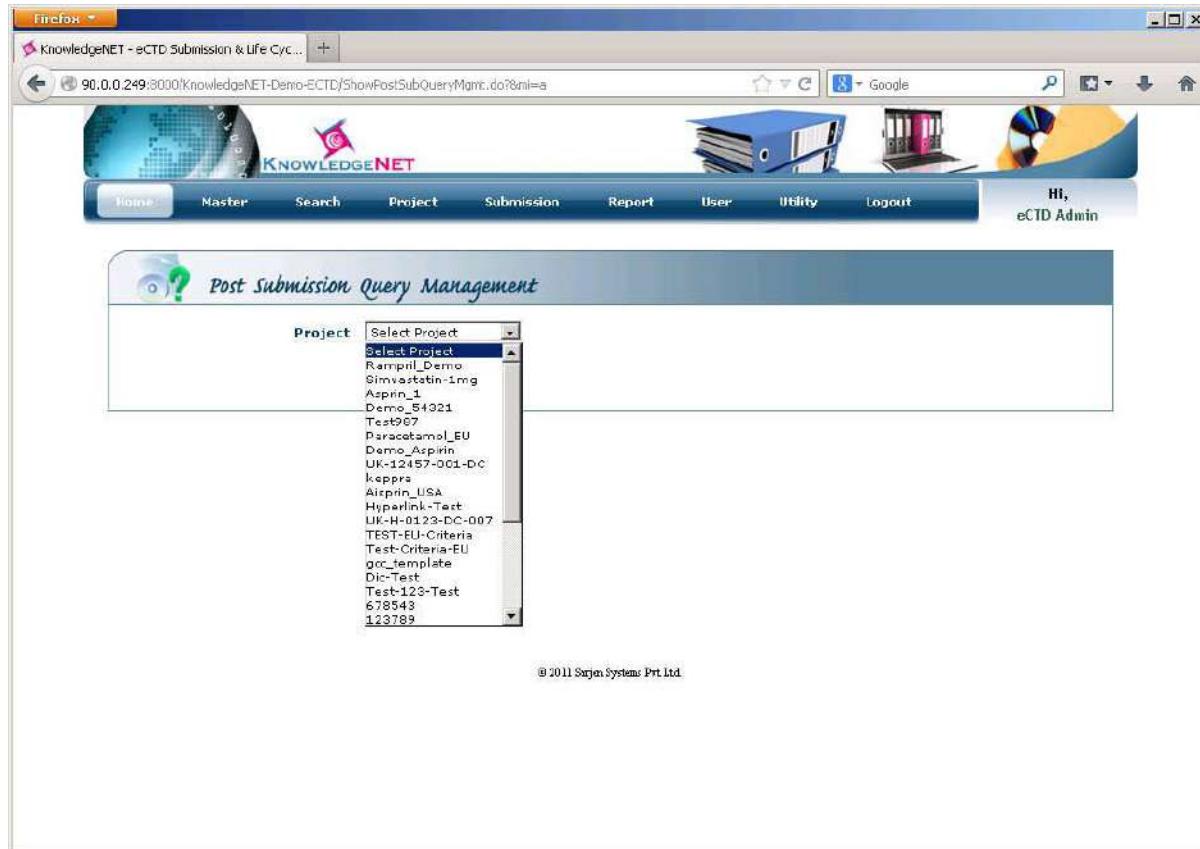


Post Submission Query Management

Note: After the submission (0000 Sequence) if any query arise from **EMA** than add the query at specific affected or required node. Its call Post Submission Query Management

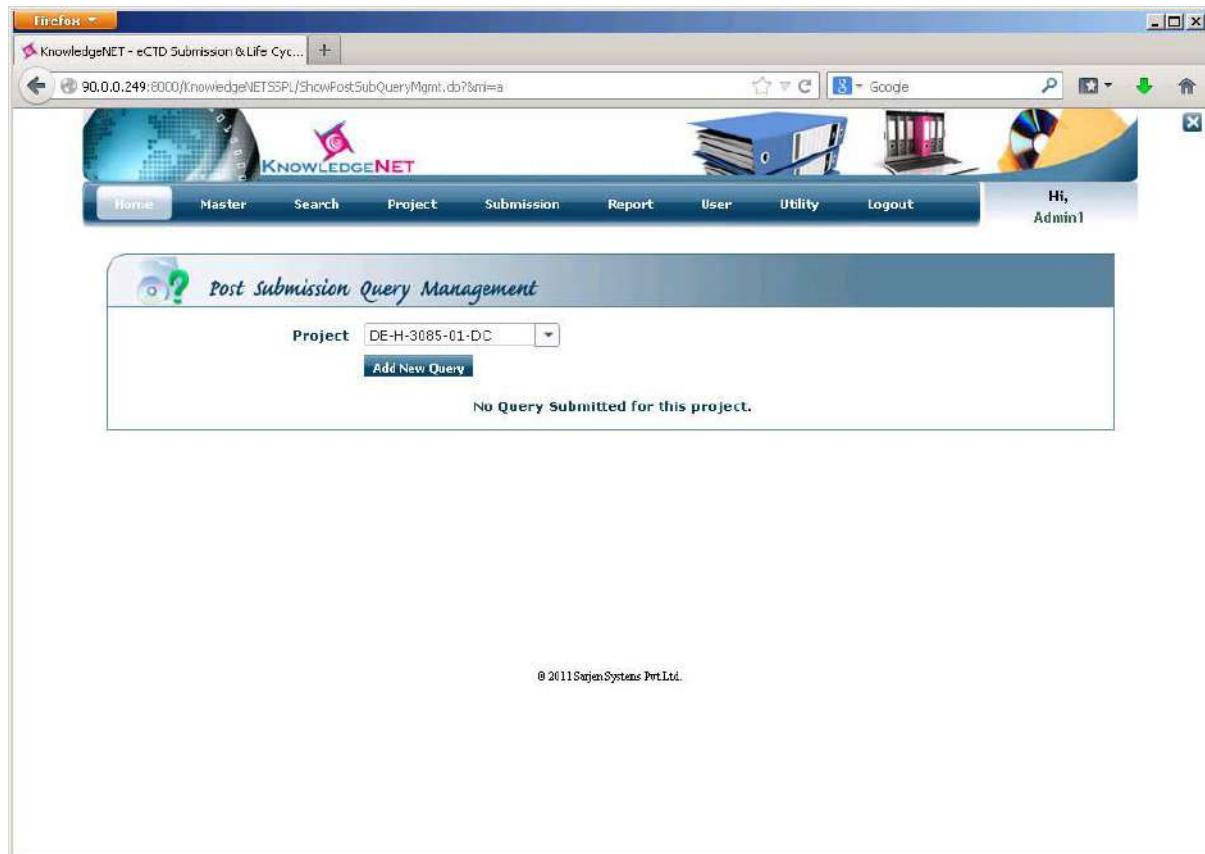
Submission>Query Mgmt.> Add/Edit Query

- Under Query Mgmt. have a subsection Add/Edit Query.
- Click on Add/Edit Query, below screen get display.



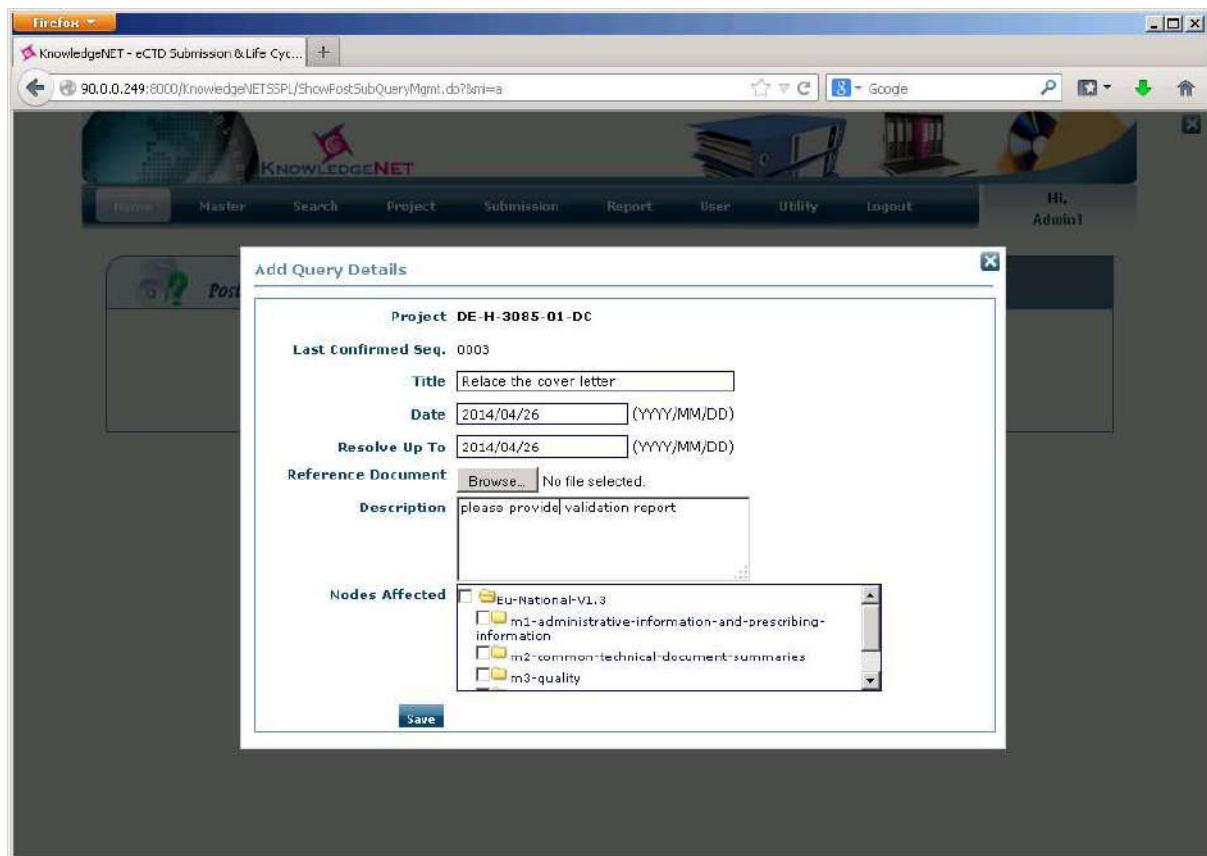
- Select the project from list, for which Admin want to add the query.
- **Note:** Only “confirmed” project show in project list.

- If there was no previous query for the project than below screen get display.



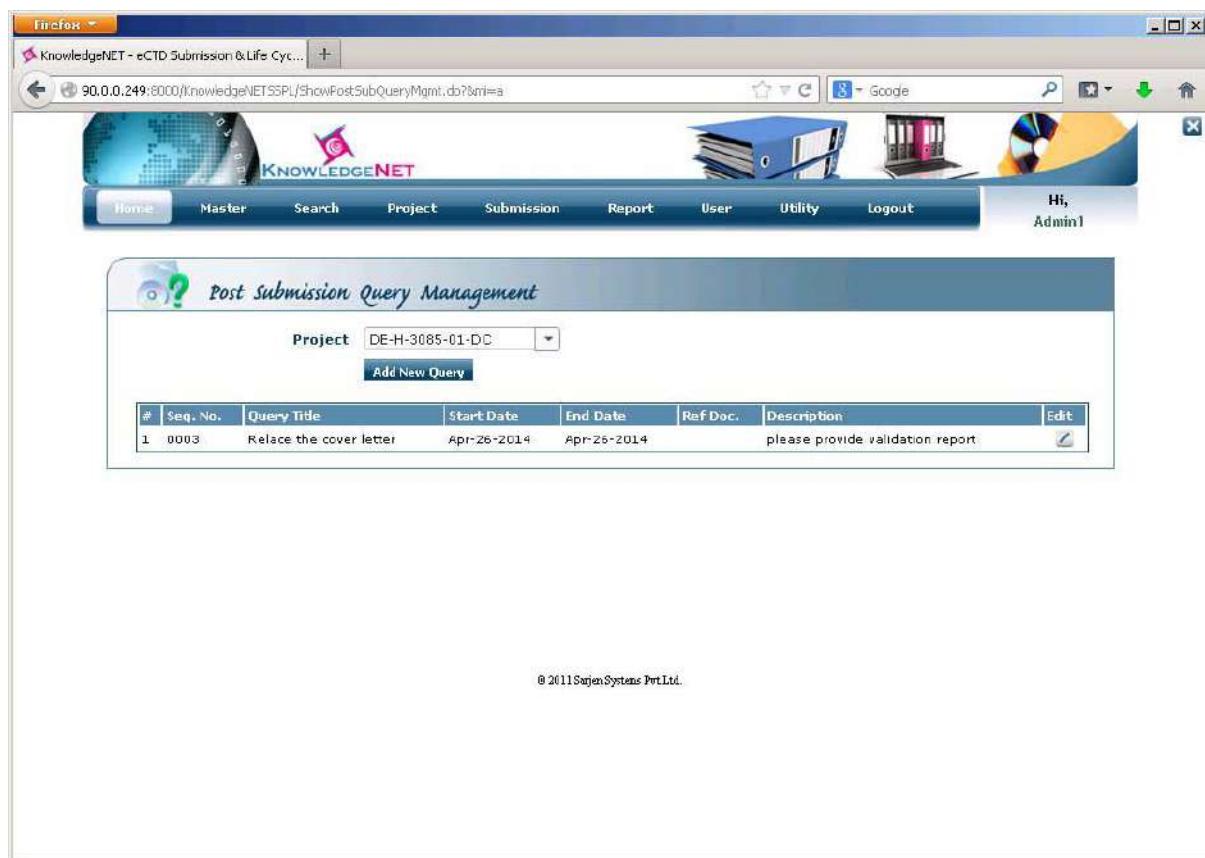
The screenshot shows a Firefox browser window displaying the 'Post Submission Query Management' page. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/ShdwPostSubQueryMgmt.do?smi=a. The page has a blue header with the KnowledgeNET logo. Below the header is a navigation menu with links: Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. On the right side of the header, it says 'Hi, Admin1'. The main content area has a title 'Post Submission Query Management' with a question mark icon. It features a dropdown menu labeled 'Project' with the value 'DE-HI-3085-01-DC'. Below the dropdown is a button labeled 'Add New Query'. A message at the bottom states 'No Query Submitted for this project.' At the very bottom of the page, there is a small copyright notice: '© 2011 Sojen Systems Pvt Ltd.'

- To add a new query, click on “Add New Query”
- A pop-up window get displayed, show in below screen



- Fill query title, date to date, description and node affected than click on Save.
- After the click on save the pop-up disappear automatically and the added query show in grid.

- If user wants to edit the query, in grid click on “Edit”

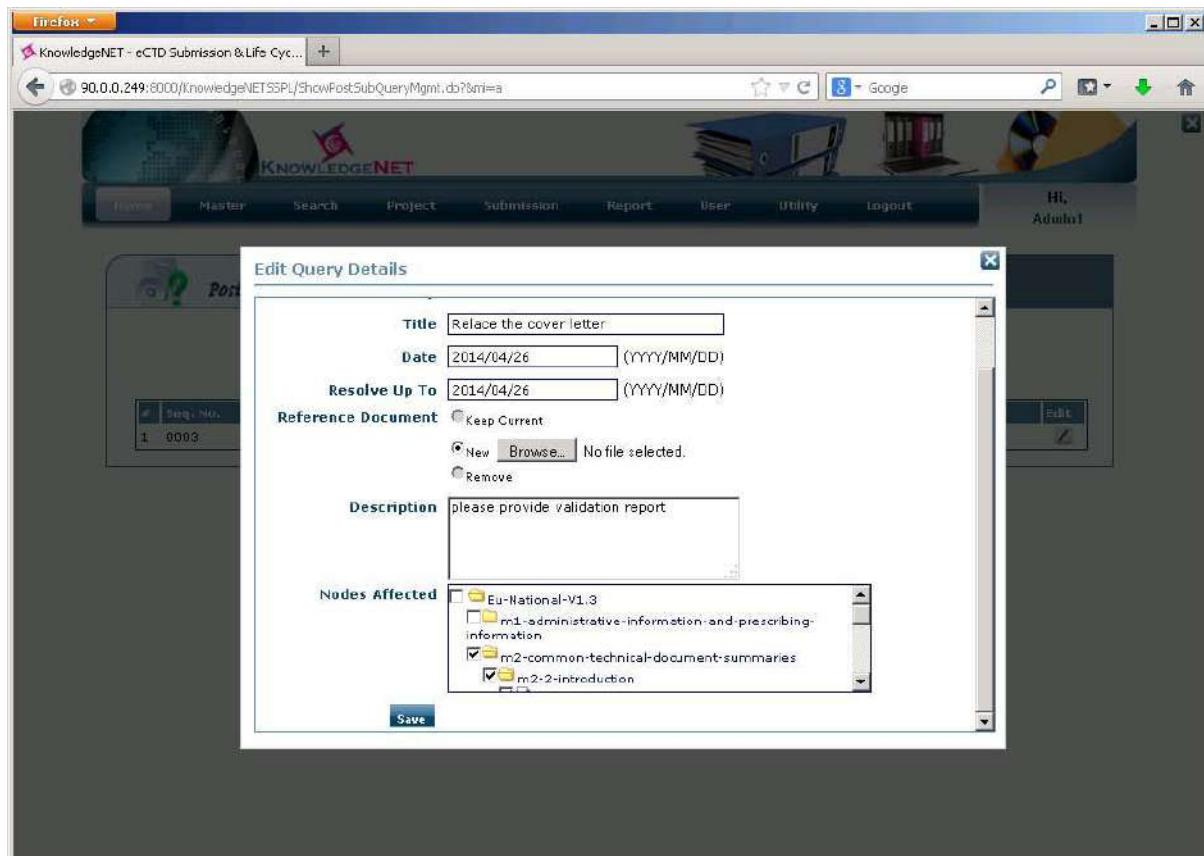


The screenshot shows a Firefox browser window displaying the 'Post Submission Query Management' page. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/ShdwPostSubQueryMgmt.d?smi=a. The page has a blue header with the KnowledgeNET logo and navigation links: Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a 'Hi, Admin1' greeting. Below the header is a sub-header with a question mark icon and the text 'Post Submission Query Management'. A dropdown menu labeled 'Project' shows 'DE-HI-3085-01-DC'. A 'Add New Query' button is visible. The main content area is a table with the following data:

#	Seq. No.	Query Title	Start Date	End Date	Ref Doc.	Description	Edit
1	0003	Relace the cover letter	Apr-26-2014	Apr-26-2014		please provide validation report	

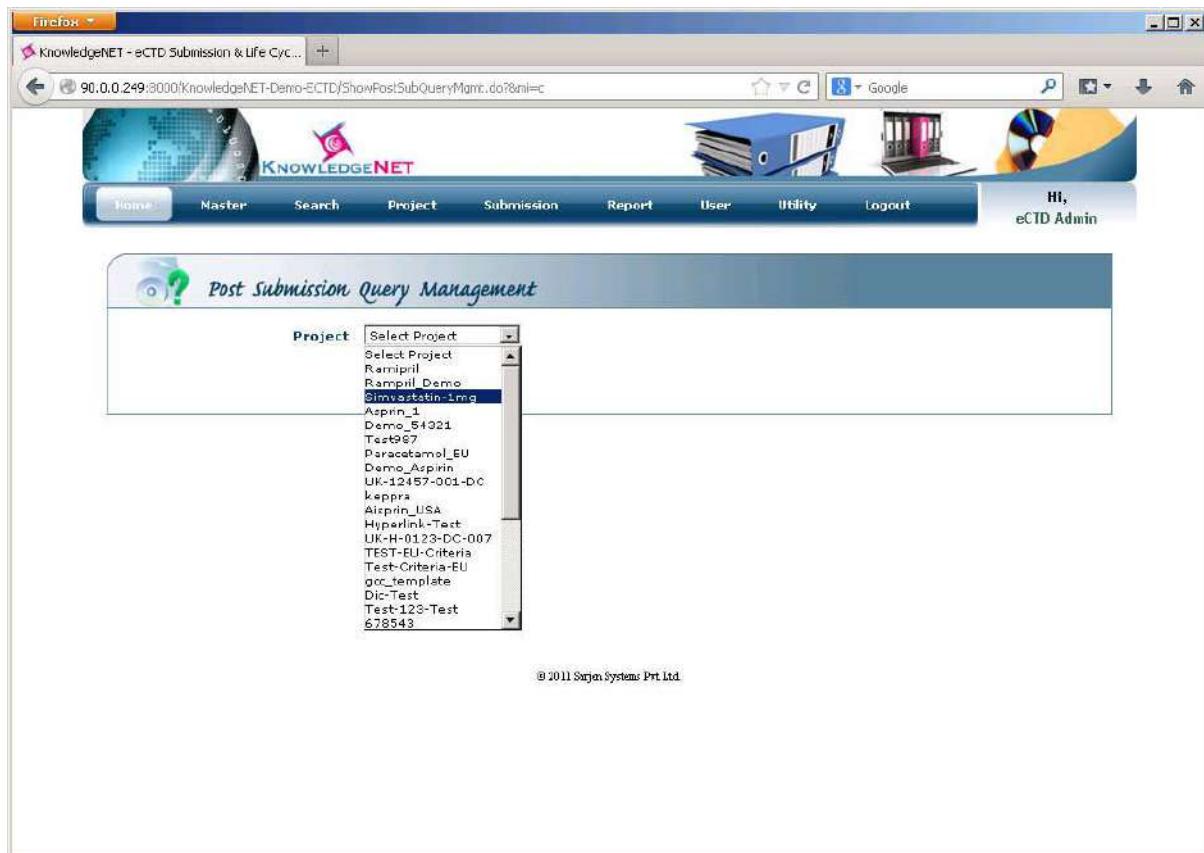
At the bottom left of the page, there is a small copyright notice: © 2011 Sojen Systems Pvt Ltd.

- A pop-up window gets displayed and then edit the query and click on save.



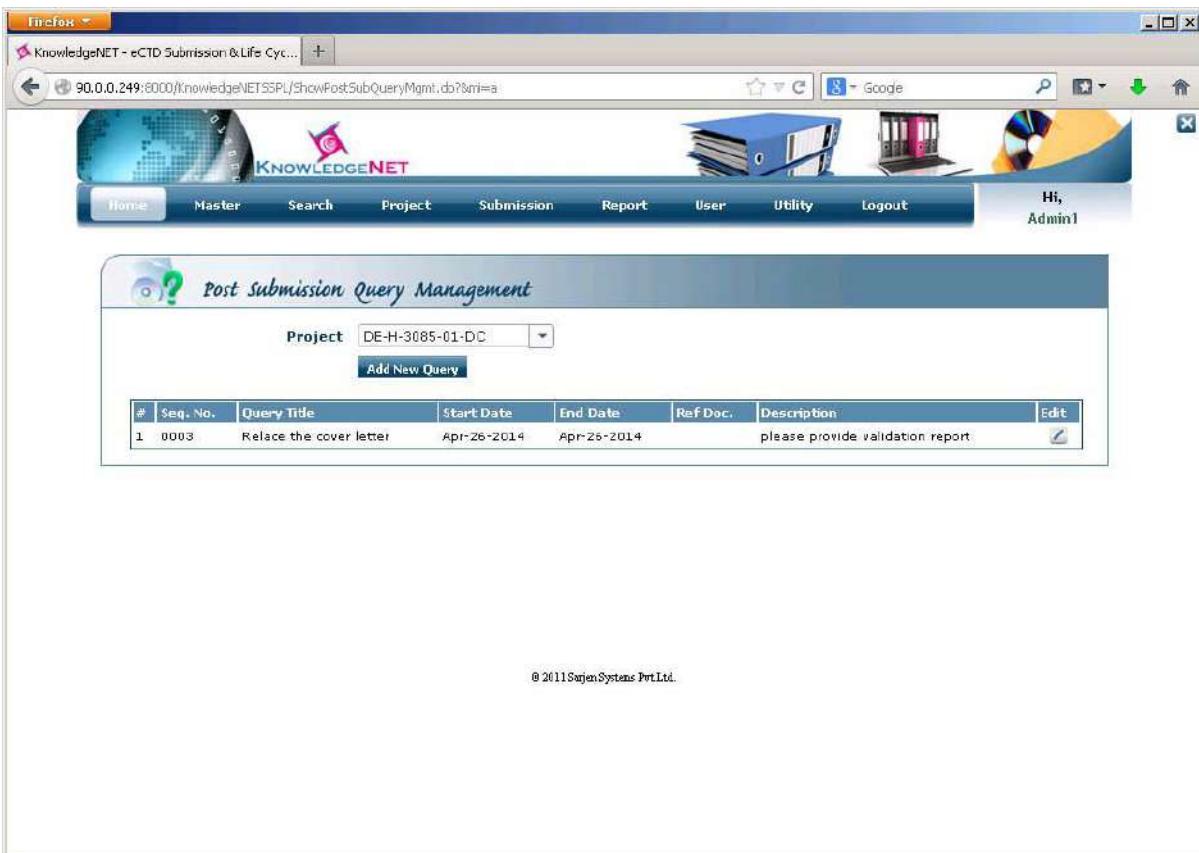
Submission>Query Mgmt.> Change Status

- Changes the status of query, in Query Mgmt. section, a sub-section change status present.
- Click on change status and then select the project from list for which user wants to changes the status.



The screenshot displays a web browser window for the KnowledgeNET eCTD Submission & Life Cycle Management Module. The address bar shows the URL 90.0.0.249:8000/KnowledgeNET-Demo-ECTD>ShowPostSubQueryMgmt.do?&ml=c. The page title is "Post Submission Query Management". A navigation menu at the top includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. On the right, a greeting says "Hi, eCTD Admin". Below the menu, a "Project" dropdown is open, showing a list of projects: Select Project, Simvastatin_Img (highlighted), Ramlipril, Ramlipril_Demo, Aspirin_1, Demo_54321, Test987, Paracetamol_EU, Demo_Aspirin, UK-12457-001-DC, keppra, Aspirin_USA, Hyperlink-Test, UK-H-0123-DC-007, TEST-EU-Criteria, Test-Criteria-EU, occ_template, Dic-Test, Test-123-Test, and 678543. At the bottom left, a copyright notice reads "© 2011 Serjen Systems Pvt Ltd."

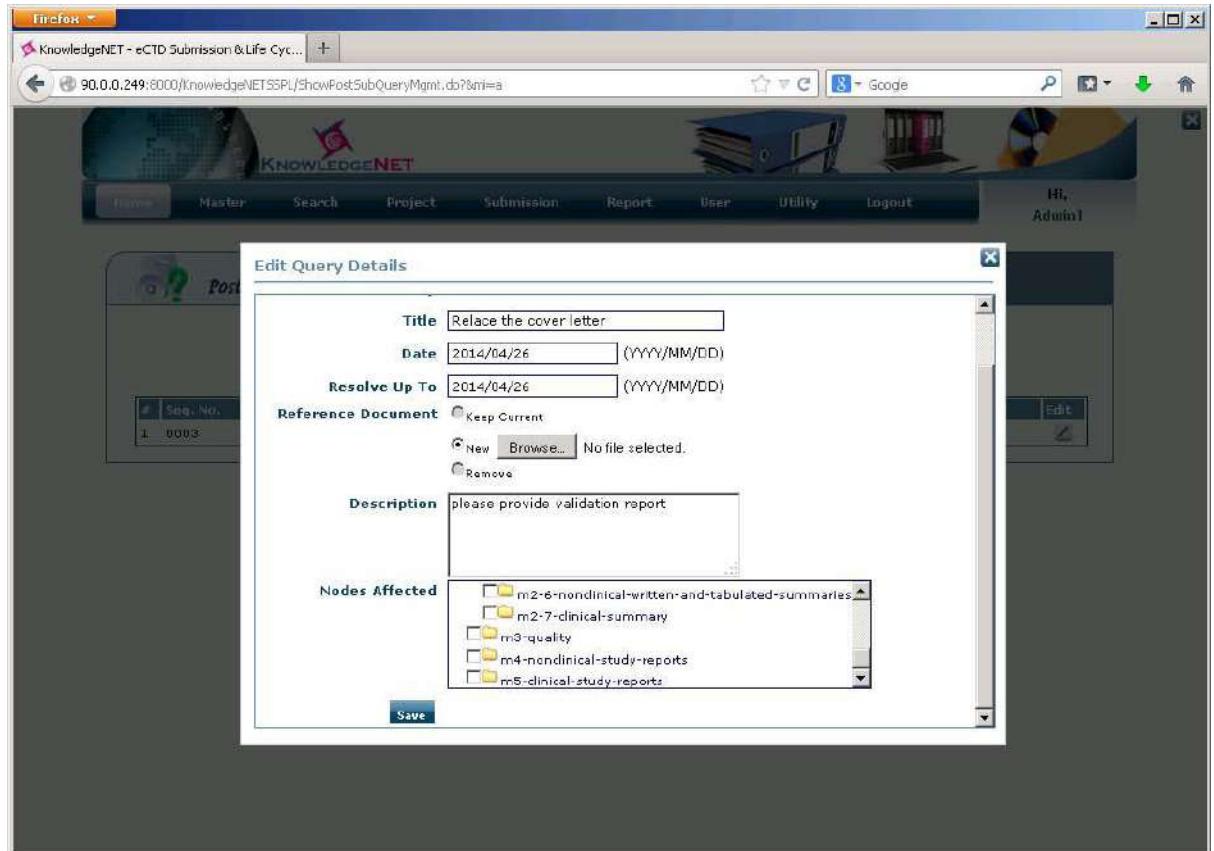
- After Selecting the specific project the below screen get display.
- The below screen show the all query added for a specific project with Reference Document and Query Title and other information.



The screenshot shows a Firefox browser window displaying the 'Post submission Query Management' page of the KNOWLEDGENET system. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/ShdwPostSubQueryMgmt.db?smi=a. The page header includes the KNOWLEDGENET logo and a navigation menu with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'Post submission Query Management' and features a table with one row of data. The table columns are: #, Seq. No., Query Title, Start Date, End Date, Ref Doc., and Description. The data row is: 1, 0003, Relace the cover letter, Apr-26-2014, Apr-26-2014, please provide validation report, and an edit icon. At the bottom of the page, there is a copyright notice: © 2011 Safran Systems Pvt Ltd.

#	Seq. No.	Query Title	Start Date	End Date	Ref Doc.	Description	Edit
1	0003	Relace the cover letter	Apr-26-2014	Apr-26-2014		please provide validation report	

- To change the status of Query, in grid click on the change status icon.
- A pop-up window gets displayed and it shows only the affected node.

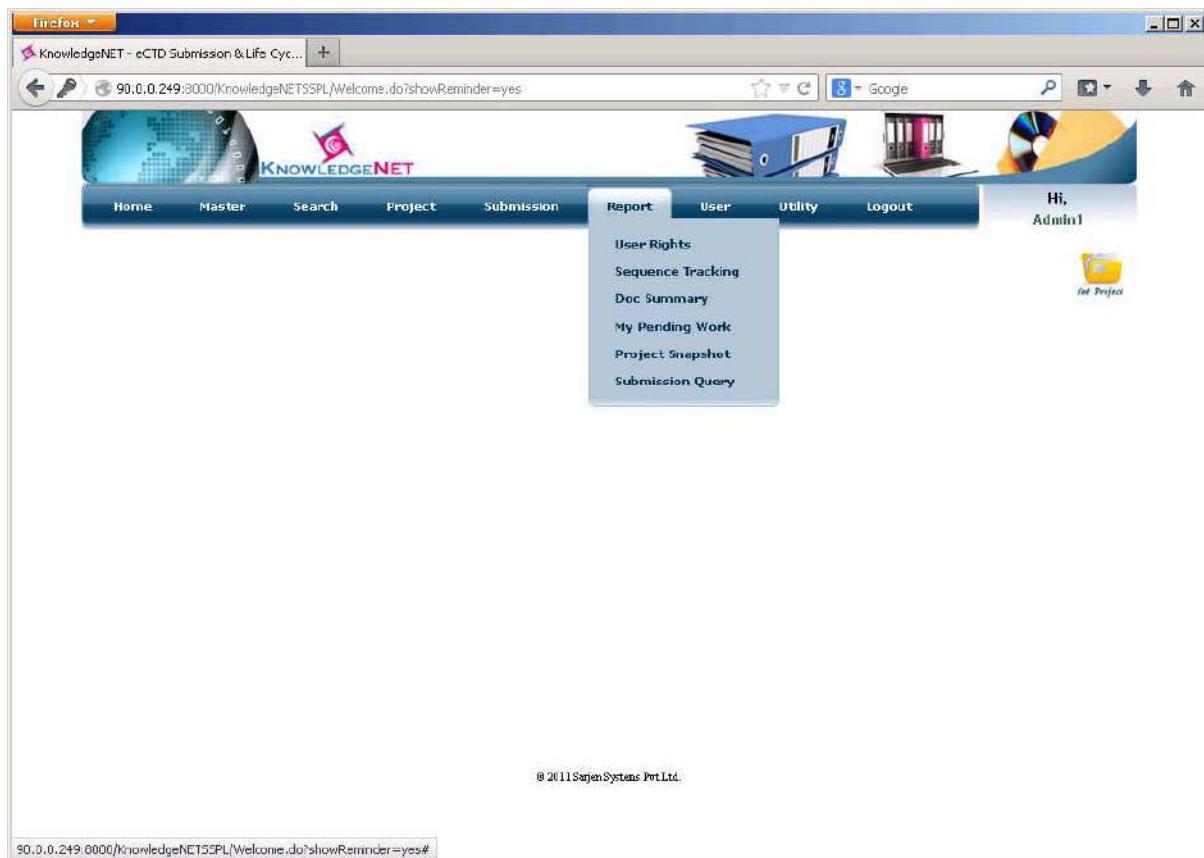


- Select the status of query (New, In-process, Pending and Resolved) and then click on Save.
- The Status of Query changed and it show on query tab present on dashboard.

Report Menu

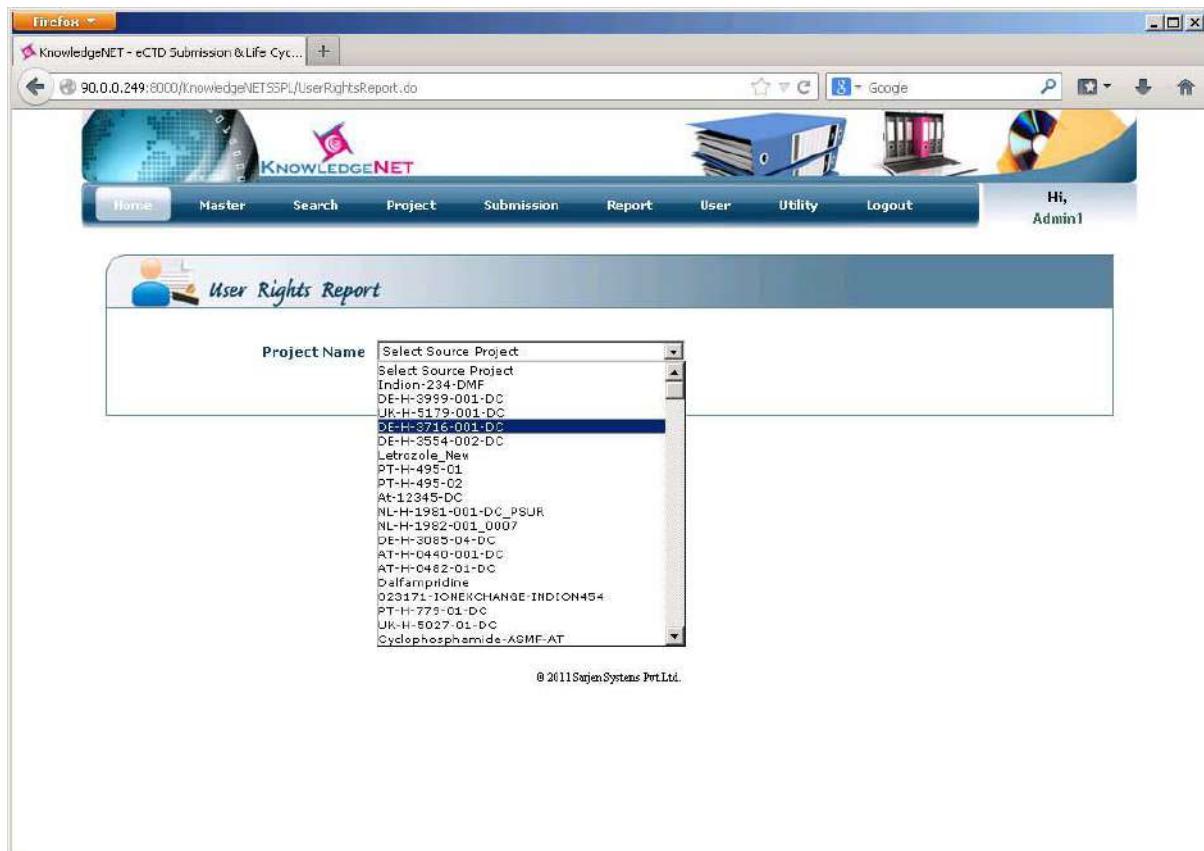
- “Report” Menu will display the submenu items as shows: -

- User Rights
- Sequence Tracking
- Doc Summary
- My Pending Work
- Project Snapshot
- Submission Query



Report >User Rights

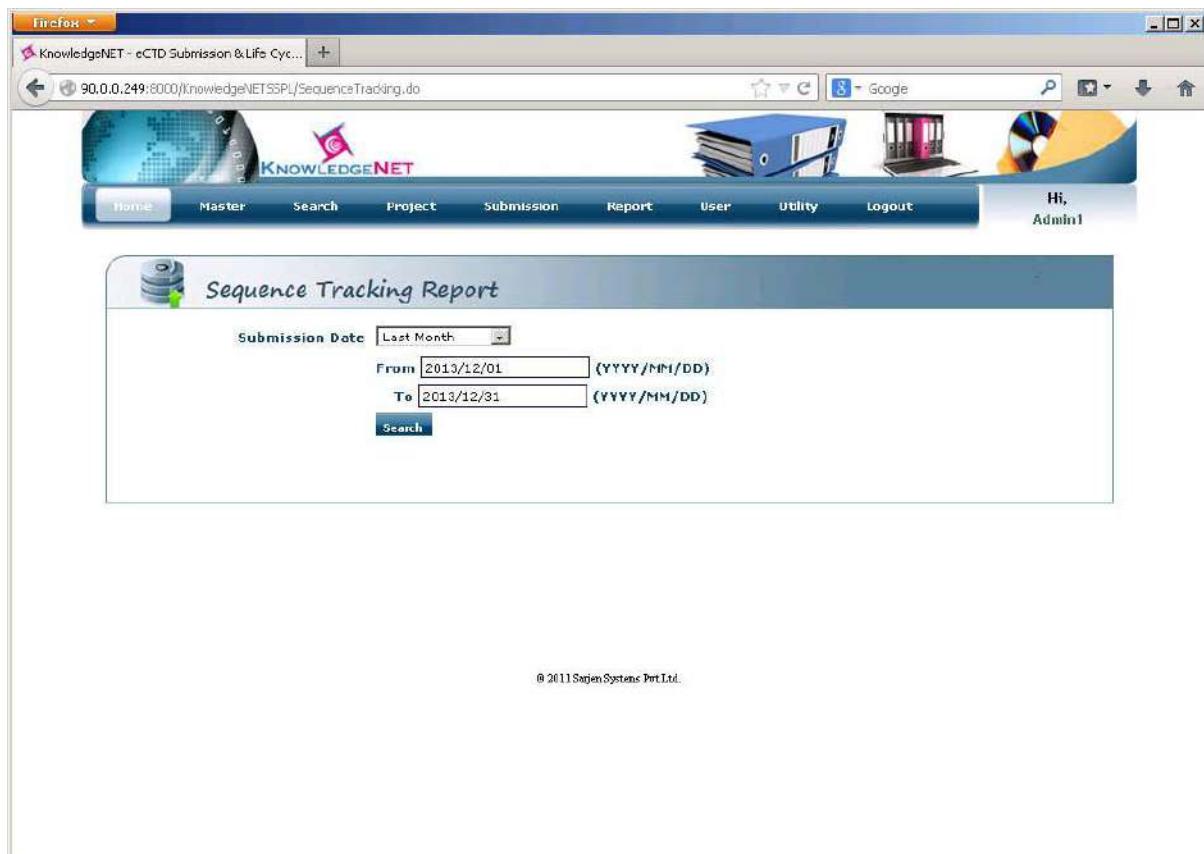
- After select the project name, activity name, user name, sort on and sort by then click the “show Report” below screen shows **User Rights Report** such as User can Read, can Edit and Advanced Rights.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/UserRightsReport.do. The page has a blue header bar with various navigation links: Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a welcome message 'Hi, Admin1'. Below the header is a banner featuring a globe, books, and a CD. The main content area has a title 'User Rights Report' with a small icon. A dropdown menu labeled 'Project Name' is open, showing a list of projects. The project 'DE-H-3716-001-DC' is highlighted. Other projects listed include 'Select Source Project', 'Indion-234-DMF', 'JK-H-5179-001-DC', 'DE-H-3716-001-DC', 'DE-H-3554-002-DC', 'Letrozole_New', 'PT-H-495-01', 'PT-H-495-02', 'At-12345-DC', 'NL-H-1981-001-DC_PSUR', 'NL-H-1982-001_0007', 'DE-H-3085-04-DC', 'AT-H-0440-001-DC', 'AT-H-0482-01-DC', 'Dalfampridine', '023171-JONEKCHANGE-INDION454', 'PT-H-773-01-DC', 'JK-H-5027-01-DC', and 'Cyclophosphamide-AGMF-AT'. At the bottom of the page, there is a copyright notice: '© 2011 Sarjen Systems Pvt Ltd.'

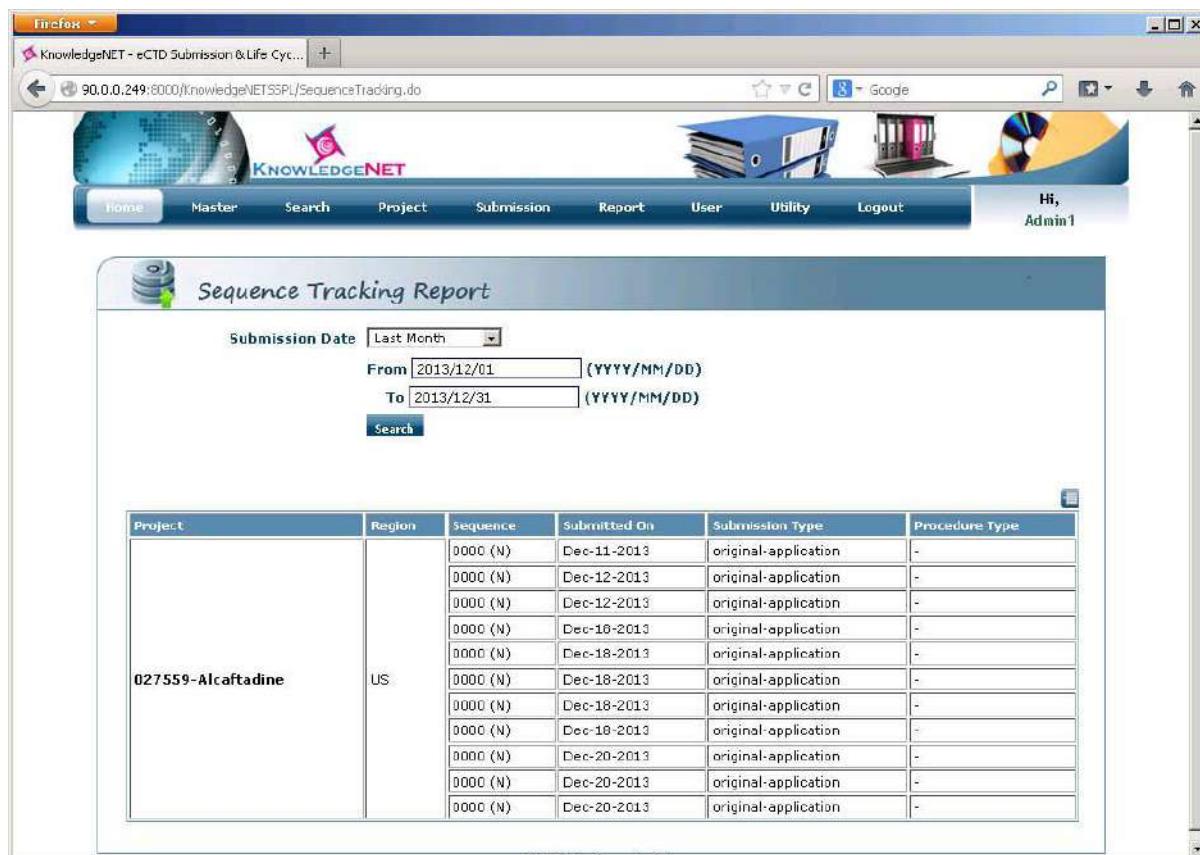
Report >Sequence Tracking Report

- If user want the project tracking report such as monthly, quarterly, half yearly and Yearly.



The screenshot shows a Firefox browser window displaying the 'Sequence Tracking Report' page from the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/SequenceTracking.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'Sequence Tracking Report' and features a 'Submission Date' dropdown set to 'Last Month'. It also has two text input fields for 'From' (2013/12/01) and 'To' (2013/12/31), both labeled '(YYYY/MM/DD)'. A 'Search' button is located below these fields. At the bottom of the page, there is a copyright notice: '© 2011 Sarjen Systems Pvt Ltd.'

- If user fill the Submission Date then click on “Search” the below screen shows
- Below screen shows Sequence Tracking Report such as Project, Region, Sequence, Submitted on, Submission Type, and Procedure type.

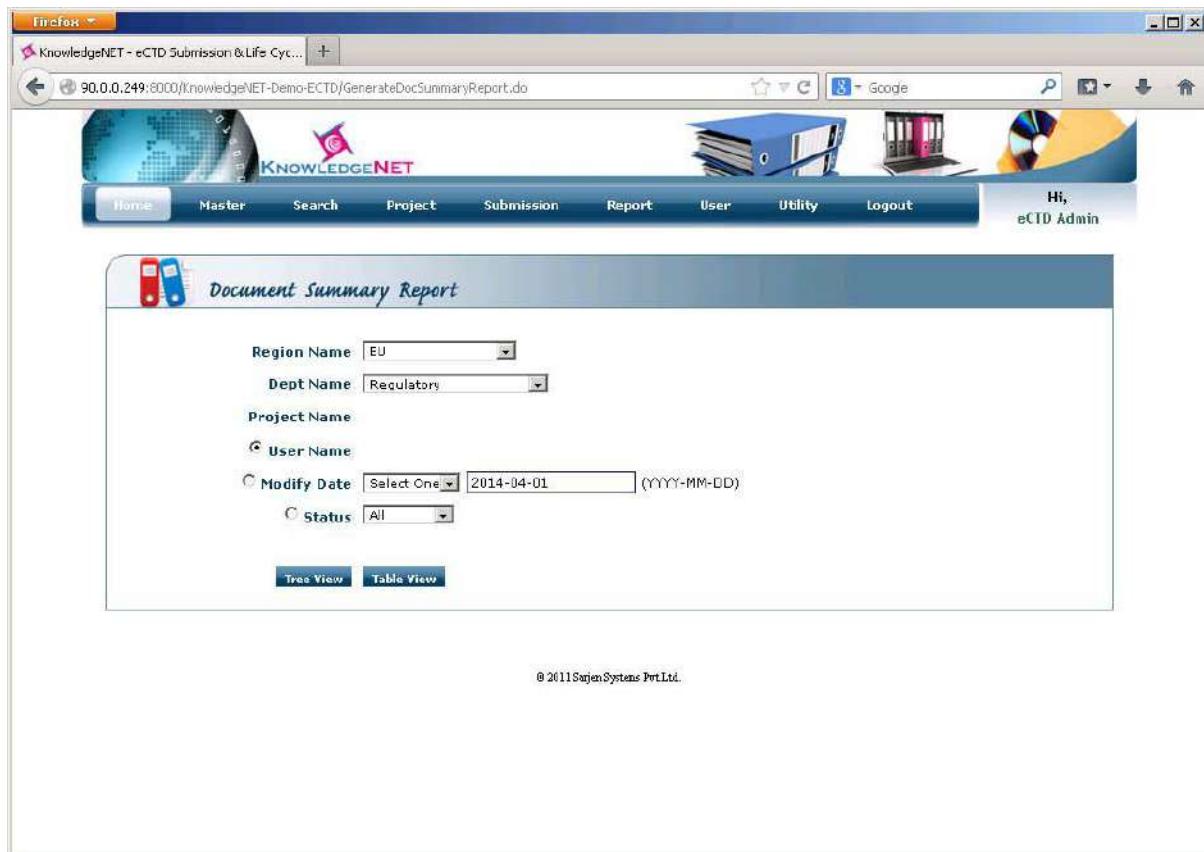


The screenshot shows a Firefox browser window displaying the "Sequence Tracking Report" page from the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/SequenceTracking.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, Admin1" is displayed on the right. The main content area is titled "Sequence Tracking Report" and features a search form with "Submission Date" set to "Last Month". The "From" field contains "2013/12/01 (YYYY/MM/DD)" and the "To" field contains "2013/12/31 (YYYY/MM/DD)". A "Search" button is present. Below the search form is a table with the following data:

Project	Region	Sequence	Submitted On	Submission Type	Procedure Type
027559-Alcaftadine	US	0000 (N)	Dec-11-2013	original-application	-
		0000 (N)	Dec-12-2013	original-application	-
		0000 (N)	Dec-12-2013	original-application	-
		0000 (N)	Dec-16-2013	original-application	-
		0000 (N)	Dec-18-2013	original-application	-
		0000 (N)	Dec-18-2013	original-application	-
		0000 (N)	Dec-18-2013	original-application	-
		0000 (N)	Dec-18-2013	original-application	-
		0000 (N)	Dec-20-2013	original-application	-
		0000 (N)	Dec-20-2013	original-application	-

Report > Doc Summary

- The below screen shows the doc summary report main page. User can view the summary of the document(s) uploaded in a project.



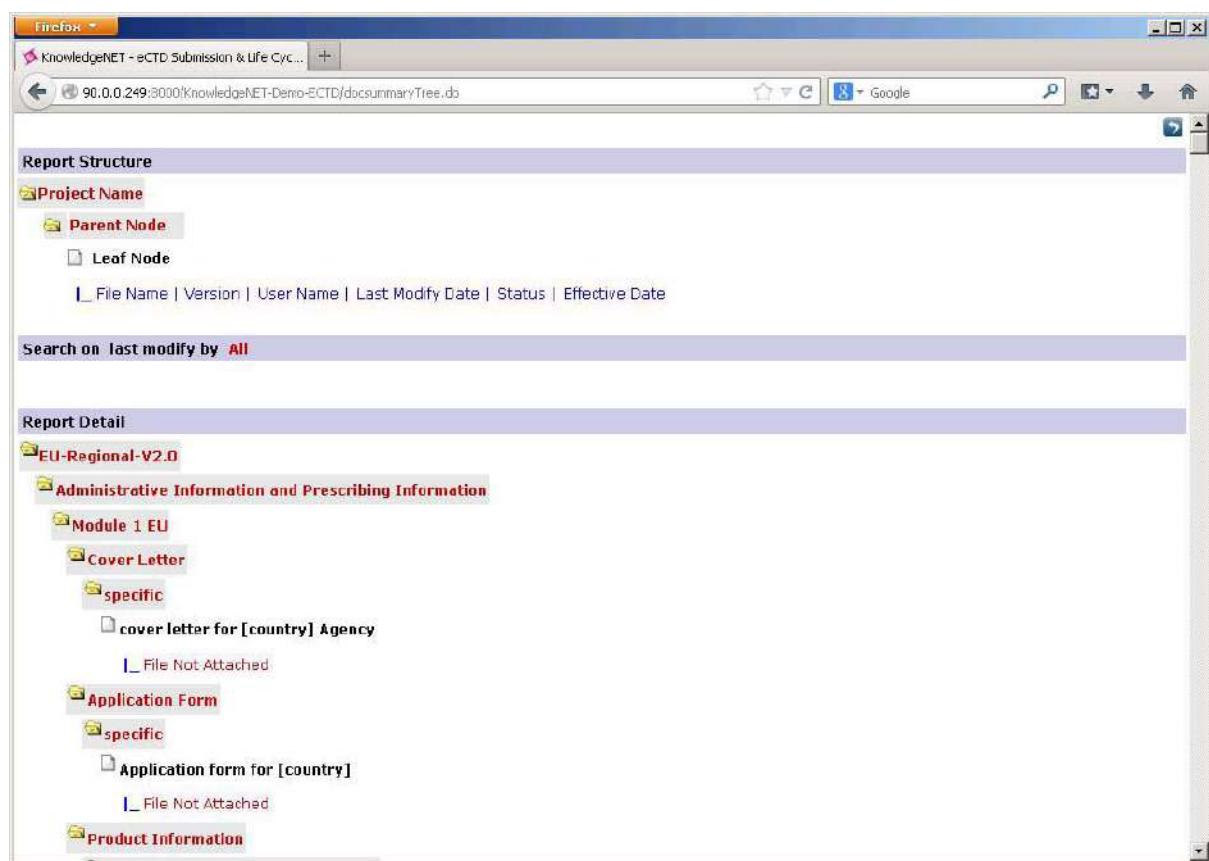
The screenshot shows a web application window titled "Document Summary Report". The URL in the address bar is "90.0.0.249:8000/knowledgeNET-Demo-ECTD/GenerateDocSummaryReport.do". The page header includes the "KNOWLEDGENET" logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting "Hi, eCID Admin" is displayed on the right. The main content area has a blue header "Document Summary Report" with a document icon. Below it are several search filters:

- Region Name: EU (dropdown menu)
- Dept Name: Regulatory (dropdown menu)
- Project Name: (text input field)
- User Name: (radio button)
- Modify Date: Select One (dropdown menu) showing "2014-04-01 (YYYY-MM-DD)"
- Status: All (dropdown menu)

At the bottom of the form are two buttons: "Tree View" and "Table View". The footer of the page contains the copyright notice "© 2011 Sarjen Systems Pvt Ltd."

Tree View:

- To view the document summary report, user has to select the information such as "Region Name", "Department Name", "Project Name" and "User Name" or the "Modify Date" (that is user wants to view the report Before or After the date) or "Status" (report of status "Created", "Reviewed", "Authorized" or "Approved" can be seen).
- On clicking "Tree View", it will display the document summary report in tree view as shows in below screen.

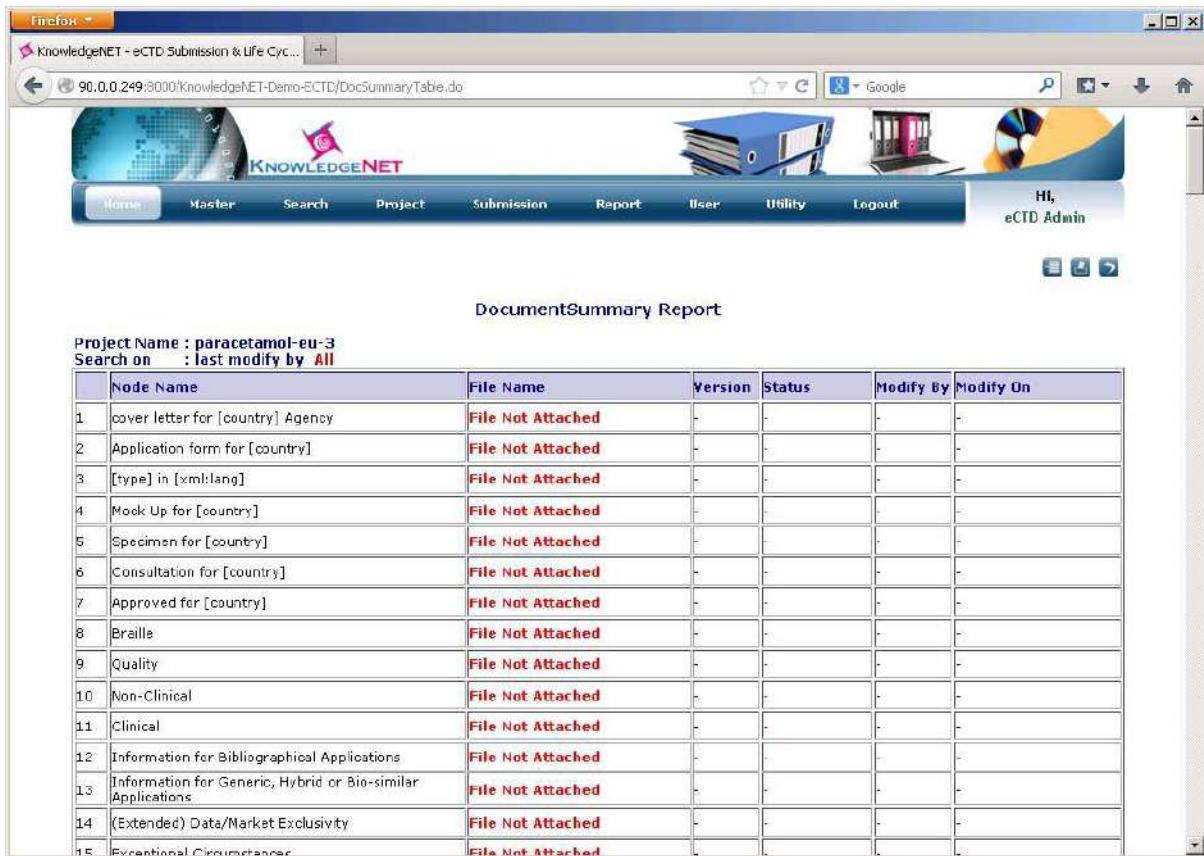


- Above screen displays the document summary report in "Tree view". It will display the "Node Name" (parent Node, leaf node), "File name" (attached file name), "Version" (version of the node), "User Name" (by whom files are uploaded), "Last Modify Date" (date and time of modification), "Status" (status of the project) and "Effective Date" if present.

Note: Click on back icon  (present at above right hand side)

Table View:

- On clicking “Table View”, it will display the document summary report in Table view as shows in below screen.

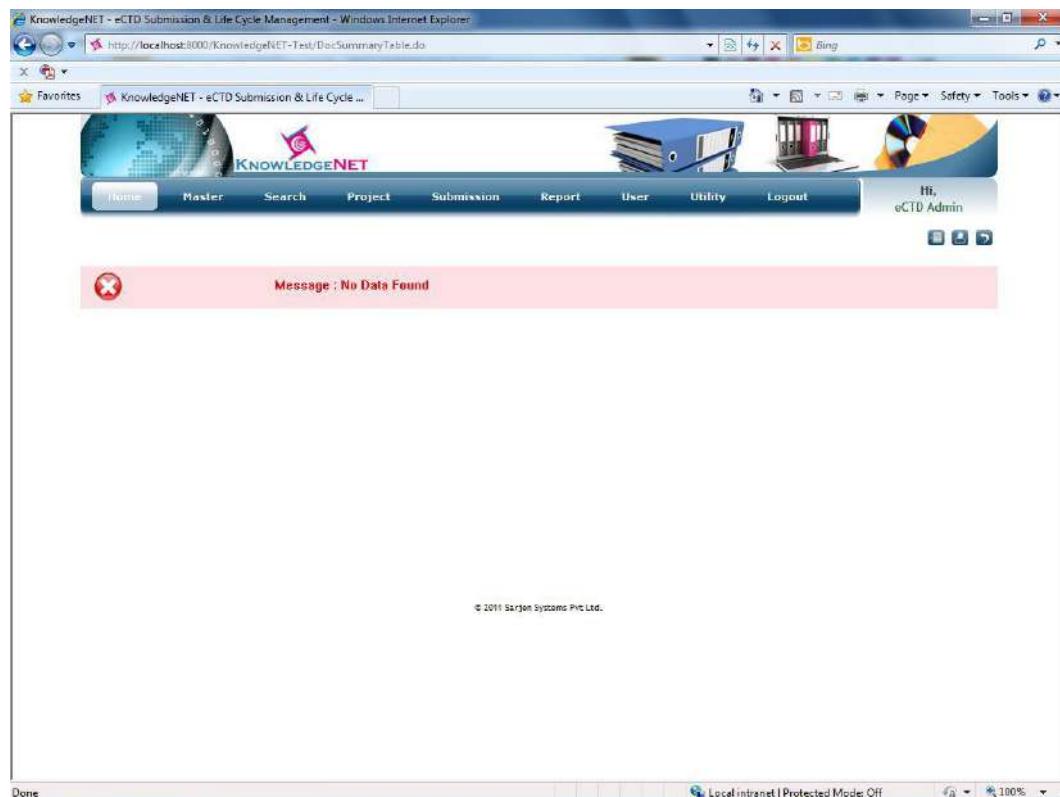


Project Name : paracetamol-eu-3
Search on : last modify by **All**

	Node Name	File Name	Version	Status	Modify By	Modify On
1	cover letter for [country] Agency	File Not Attached	-	-	-	-
2	Application form for [country]	File Not Attached	-	-	-	-
3	[type] in [xml:lang]	File Not Attached	-	-	-	-
4	Mock Up for [country]	File Not Attached	-	-	-	-
5	Specimen for [country]	File Not Attached	-	-	-	-
6	Consultation for [country]	File Not Attached	-	-	-	-
7	Approved for [country]	File Not Attached	-	-	-	-
8	Braille	File Not Attached	-	-	-	-
9	Quality	File Not Attached	-	-	-	-
10	Non-Clinical	File Not Attached	-	-	-	-
11	Clinical	File Not Attached	-	-	-	-
12	Information for Bibliographical Applications	File Not Attached	-	-	-	-
13	Information for Generic, Hybrid or Bio-similar Applications	File Not Attached	-	-	-	-
14	(Extended) Data/Market Exclusivity	File Not Attached	-	-	-	-
15	Exceptional Circumstances	File Not Attached	-	-	-	-

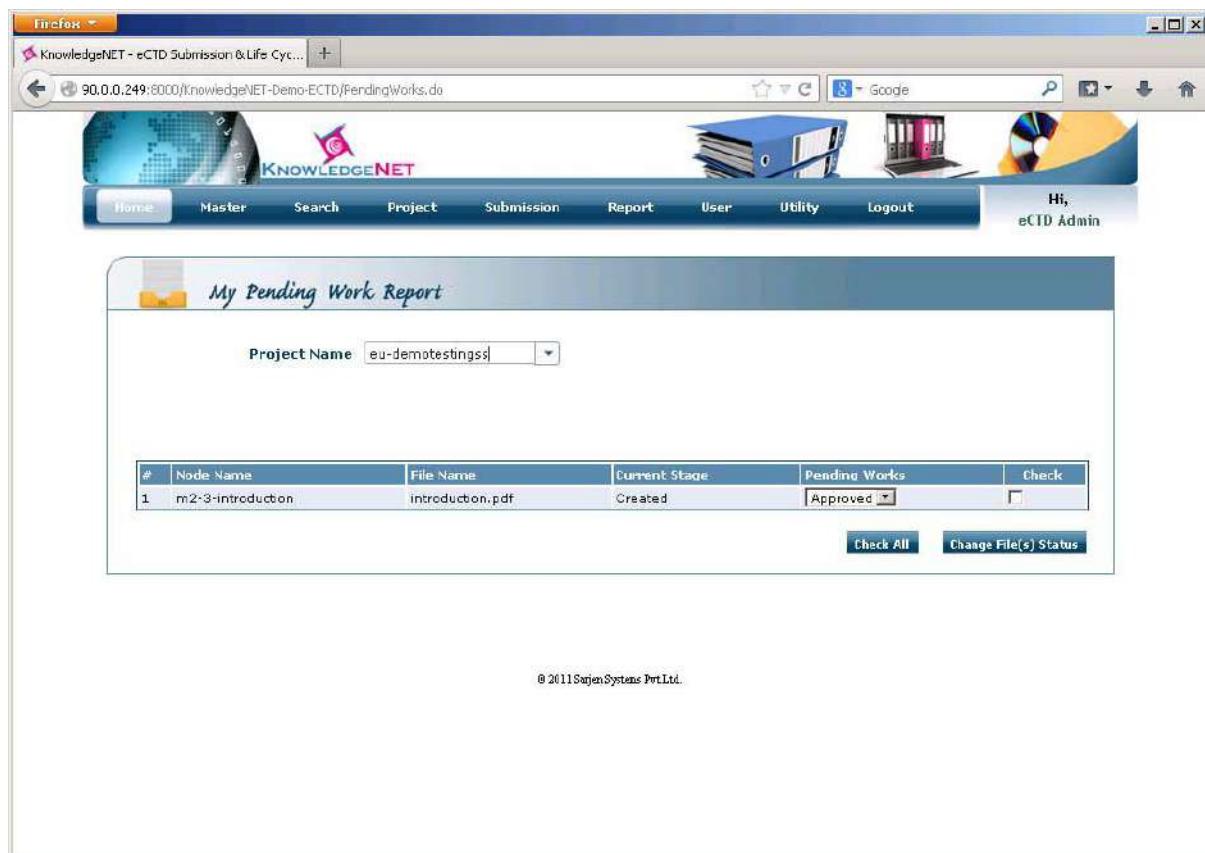
- Above screen displays the document summary report in the “Table View”.
- It will display the “Node Name”, “File name” (name of the attached file on the node), “Version” (version of the node), “Status” (status of the project), “Modify By” (by whom files are uploaded), “Modify On” (date and time of modification).
- On clicking “Print” icon  , it will print the report.
- On clicking “Export” icon  , it will generate the Excel sheet and ask the location for saving the report.
- Note:** Click on back icon  (present at above right hand side)

- If no record found from the selected entry then appropriate message will be display as shows in the below screen shot.



Report >My Pending Work

- Select the Project from list.
- It shows the list of files which is not in “Approved” stage.
- Approve the Files which user are going to submit for eCTD.
- Select Document Stage under “Pending Works” column from the drop down list and click on the check box and finally click on the “Change File(s) Status” to change the status of the documents.

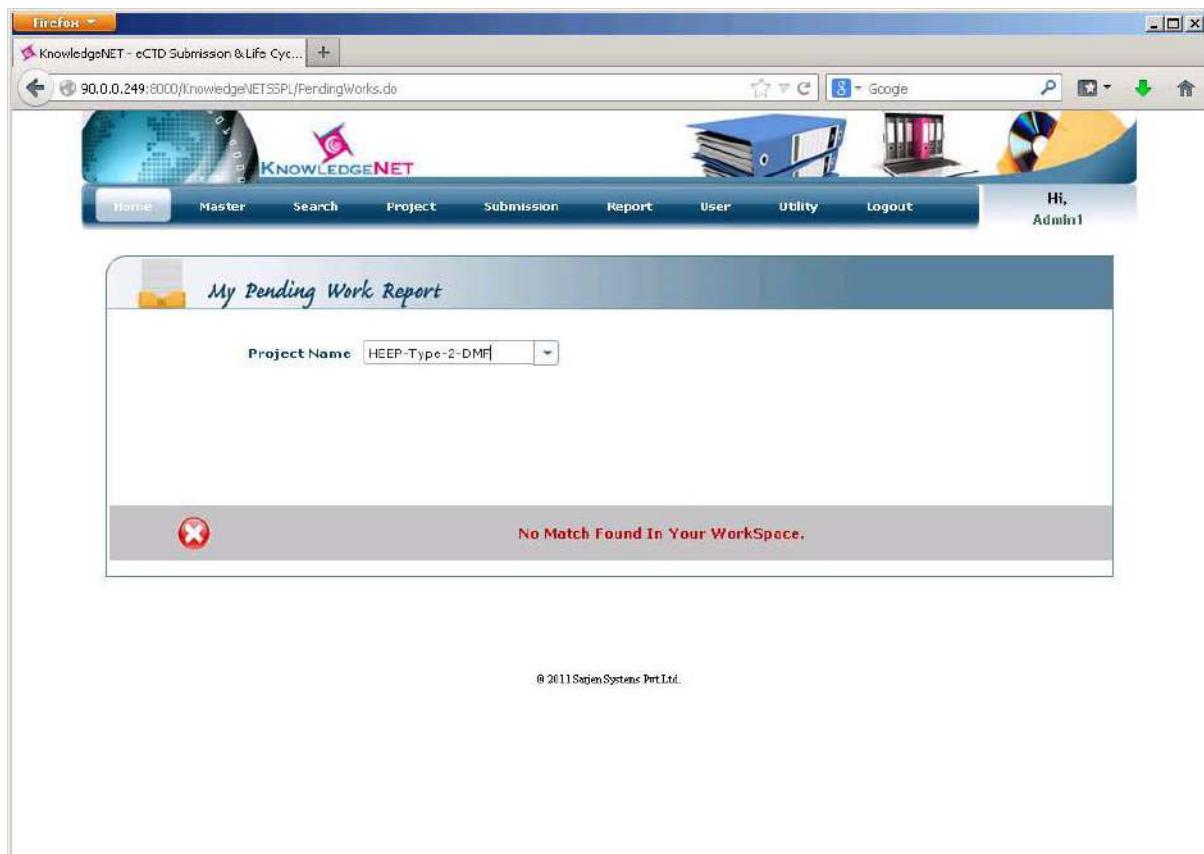


The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/FendingWorks.do. The page title is "My Pending Work Report". The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message "Hi, eCTD Admin" is displayed on the right. The main content area shows a table titled "My Pending Work Report" with one row of data:

#	Node Name	File Name	Current Stage	Pending Works	Check
1	m2-3-introduction	introduction.pdf	Created	Approved	<input type="checkbox"/>

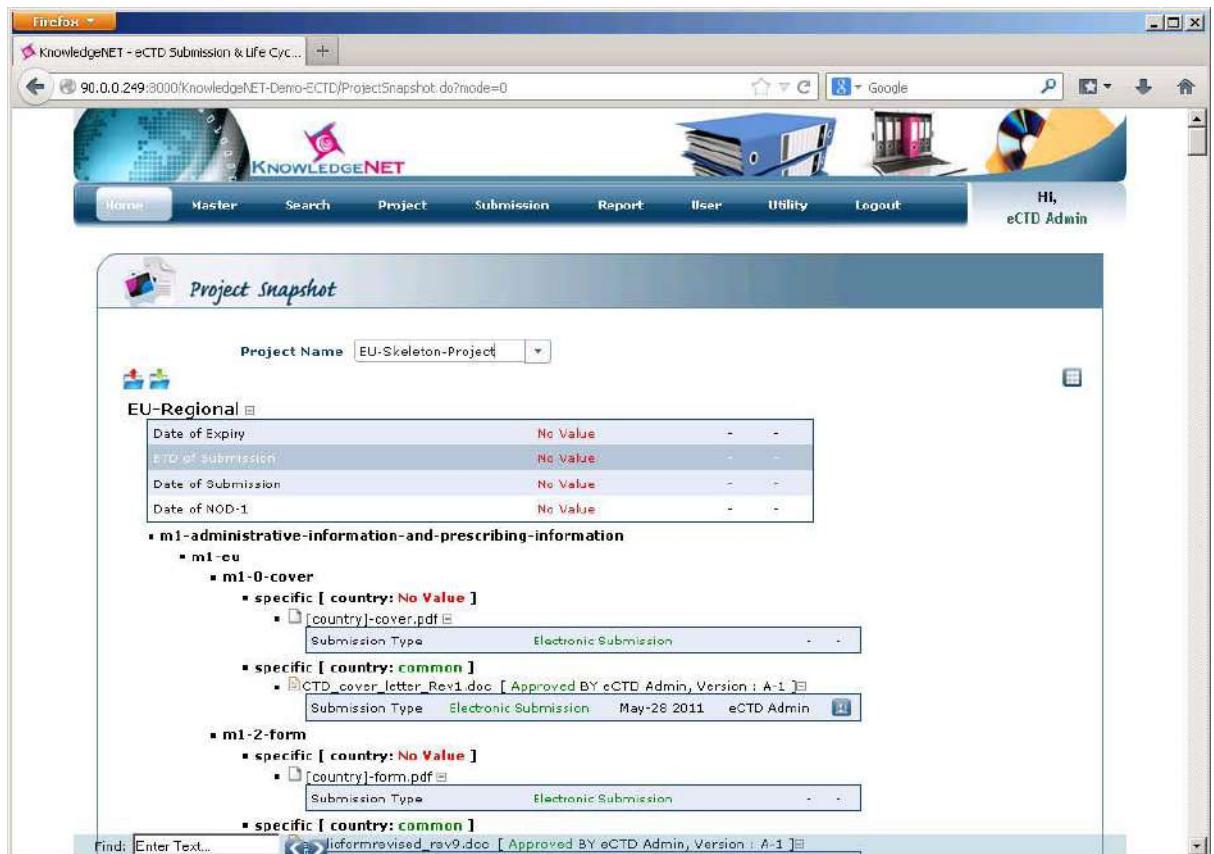
Below the table are two buttons: "Check All" and "Change File(s) Status". At the bottom of the page, a copyright notice reads "© 2011 Safran Systems Pvt Ltd."

- If no data found then appropriate message will be displayed.



Report> Project Snapshot

- Select project 'EU-Skeleton-Project' then below screen get displayed.



The screenshot displays the 'Project Snapshot' page for the 'EU-Skeleton-Project'. The top navigation bar includes links for Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and Hi, eCTD Admin. The main content area shows the following details:

Project Name: EU-Skeleton-Project

EU-Regional:

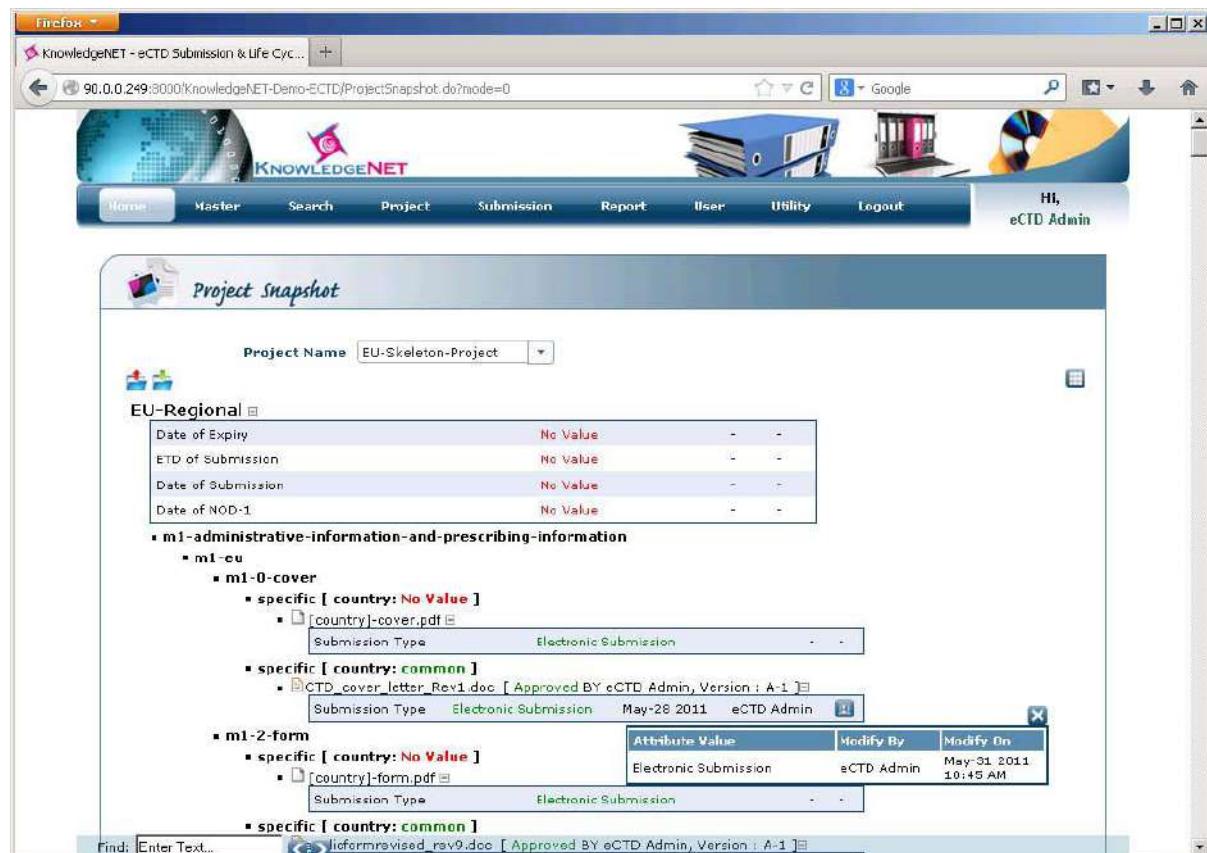
Date of Expiry	No Value	-	-
eCTD of Submission	No Value	-	-
Date of Submission	No Value	-	-
Date of NOD-1	No Value	-	-

m1-administrative-information-and-prescribing-information

- m1-eu**
- m1-0-cover**
- specific [country: No Value]**
 - [country]-cover.pdf [Approved BY eCTD Admin, Version : A-1]
 - Submission Type: Electronic Submission
- specific [country: common]**
 - CTD_cover_letter_Rev1.doc [Approved BY eCTD Admin, Version : A-1]
 - Submission Type: Electronic Submission
 - May-28 2011
 - eCTD Admin

- m1-2-form**
- specific [country: No Value]**
- [country]-form.pdf [Approved BY eCTD Admin, Version : A-1]
 - Submission Type: Electronic Submission
- specific [country: common]**
- Information_revised_rev9.doc [Approved BY eCTD Admin, Version : A-1]
 - Submission Type: Electronic Submission

- User can expand the every particular node to see the complete details, display below.
- User can also find the particular node and have option icon ↑ from where user can directly go to last node to first node.



Project Name: EU-Skeleton-Project

EU-Regional

Date of Expiry	No Value	-	-
ETD of Submission	No Value	-	-
Date of Submission	No Value	-	-
Date of NOD-1	No Value	-	-

m1-administrative-information-and-prescribing-information

- m1-eu
 - m1-0-cover
 - specific [country: No Value]
 - [country]-cover.pdf
 - specific [country: common]
 - [country]-cover_letter_Rev1.doc [Approved BY eCTD Admin, Version : A-1]

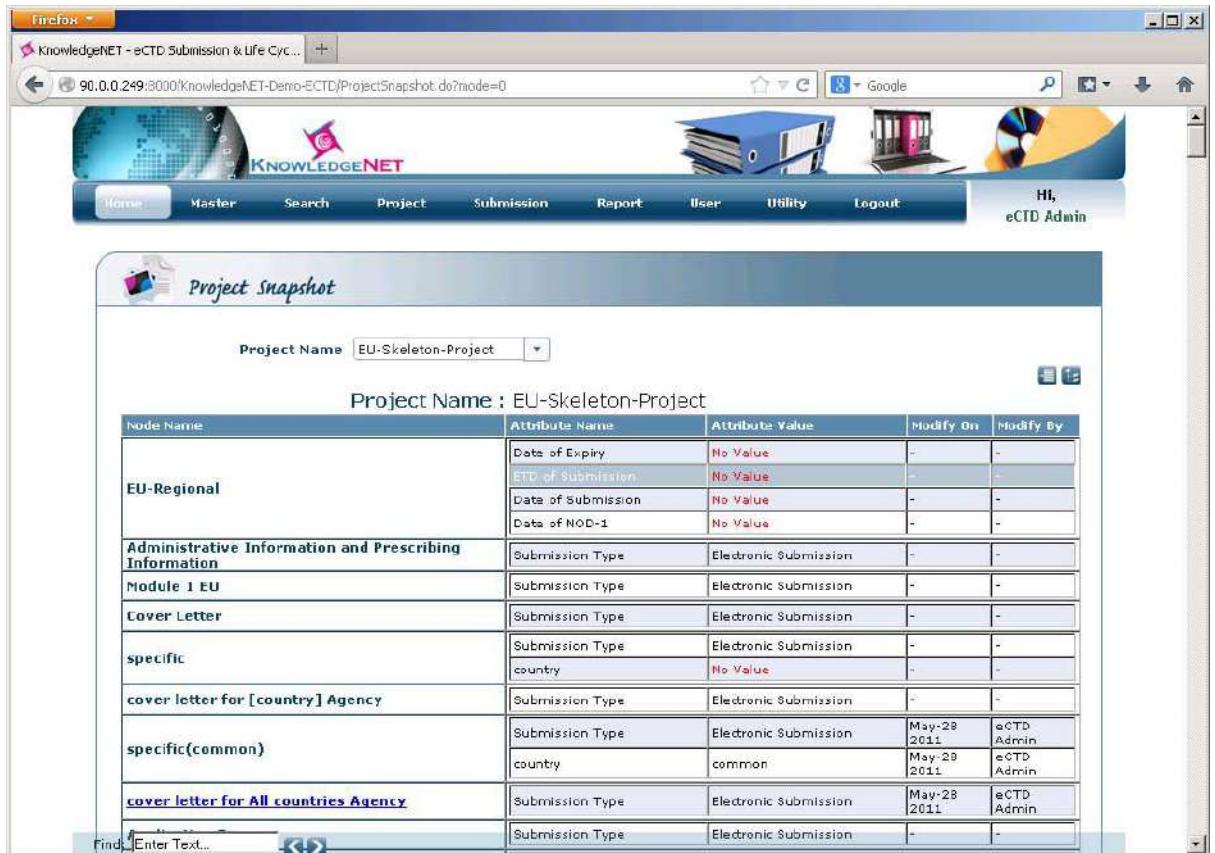
m1-2-form

- specific [country: No Value]
 - [country]-form.pdf

Attribute Value	Modify By	Modify On
Electronic Submission	eCTD Admin	May-31 2011 10:45 AM

Find: Enter Text... Informationrevised_rev9.doc [Approved BY eCTD Admin, Version : A-1]

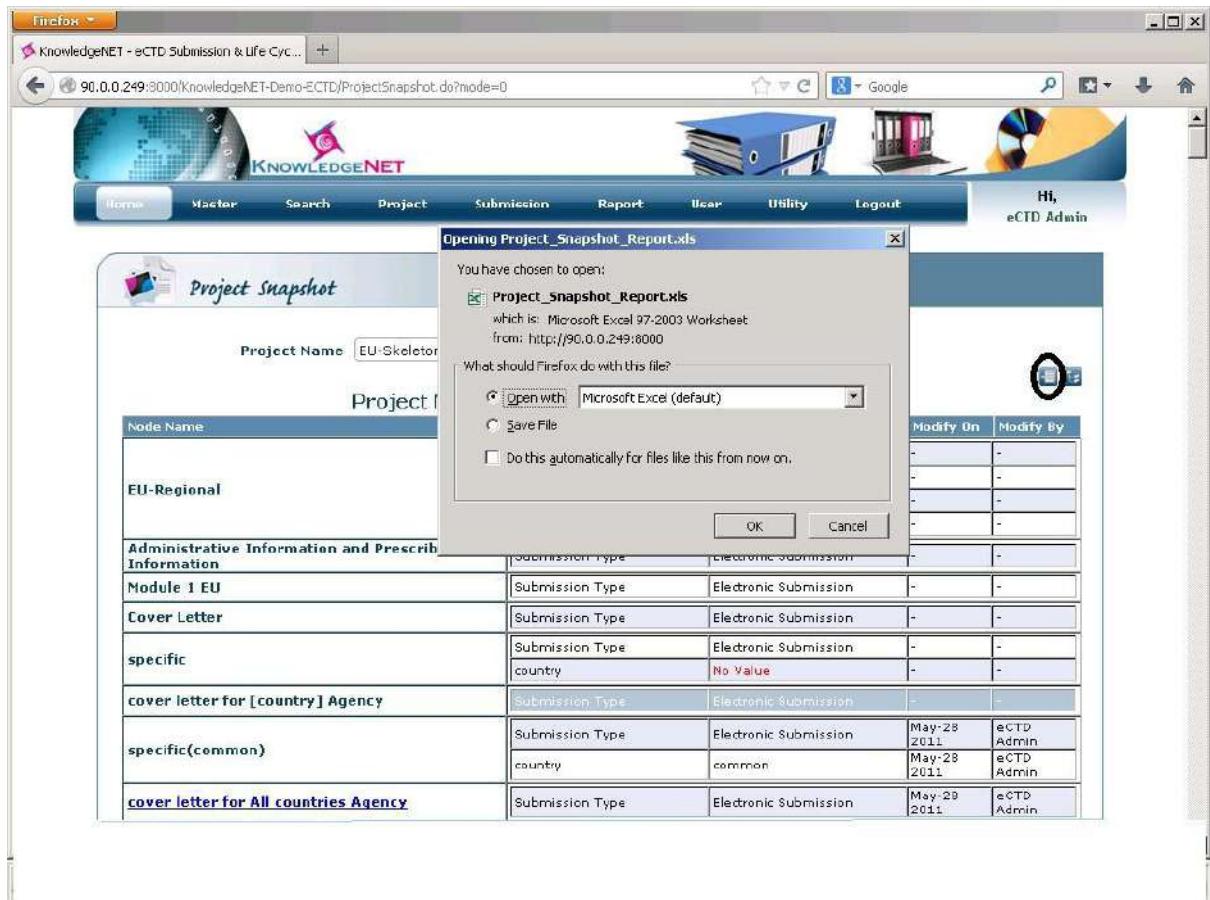
- User can also view in Table format by click on right hand side Icon 



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/ProjectSnapshot.do?node=0. The page title is "Project Snapshot". The top menu bar includes Home, Master, Search, Project, Submission, Report, User, Utility, Logout, and a user profile for "Hi, eCTD Admin". The main content area displays a table titled "Project Name : EU-Skeleton-Project". The table has columns for Node Name, Attribute Name, Attribute Value, Modify On, and Modify By. The table rows show various project details, such as "EU-Regional", "Administrative Information and Prescribing Information", "Module 1 EU", "Cover Letter", "specific", "cover letter for [country] Agency", "specific(common)", and "cover letter for All countries Agency". The "Modify By" column for the "EU-Regional" row shows "eCTD Admin". The "Modify By" column for the "specific(common)" row shows "eCTD Admin". The "Modify By" column for the "cover letter for All countries Agency" row shows "eCTD Admin".

Node Name	Attribute Name	Attribute Value	Modify On	Modify By
EU-Regional	Date of Expiry	No Value	-	-
	ETD of Submission	No Value	-	-
	Date of Submission	No Value	-	-
	Date of NOD-1	No Value	-	-
Administrative Information and Prescribing Information	Submission Type	Electronic Submission	-	-
Module 1 EU	Submission Type	Electronic Submission	-	-
Cover Letter	Submission Type	Electronic Submission	-	-
specific	Submission Type	Electronic Submission	-	-
	country	No Value	-	-
cover letter for [country] Agency	Submission Type	Electronic Submission	-	-
specific(common)	Submission Type	Electronic Submission	May-28 2011	eCTD Admin
	country	common	May-28 2011	eCTD Admin
cover letter for All countries Agency	Submission Type	Electronic submission	May-28 2011	eCTD Admin
	Submission Type	Electronic Submission	-	-

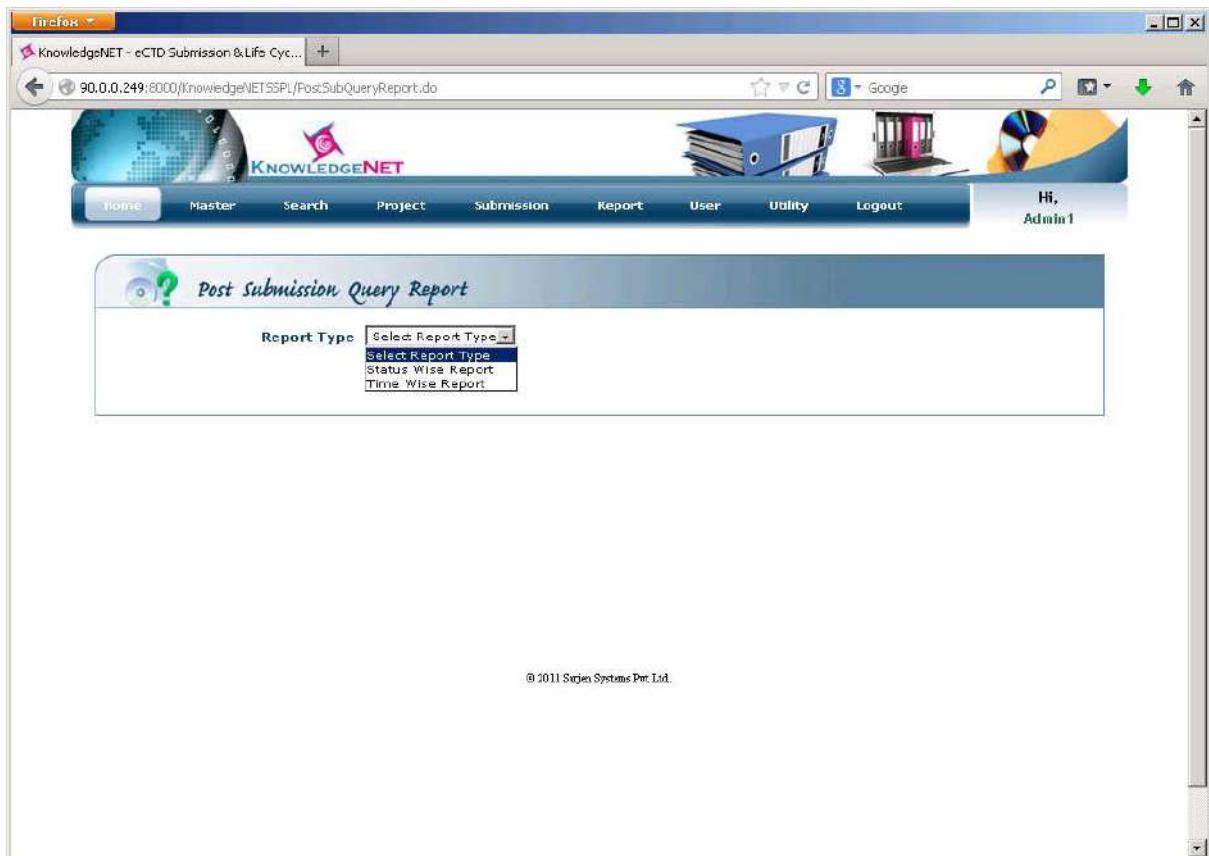
- On clicking “Export” icon  , it will generate the Excel sheet and ask the location for saving the report.



Report > Submission Query

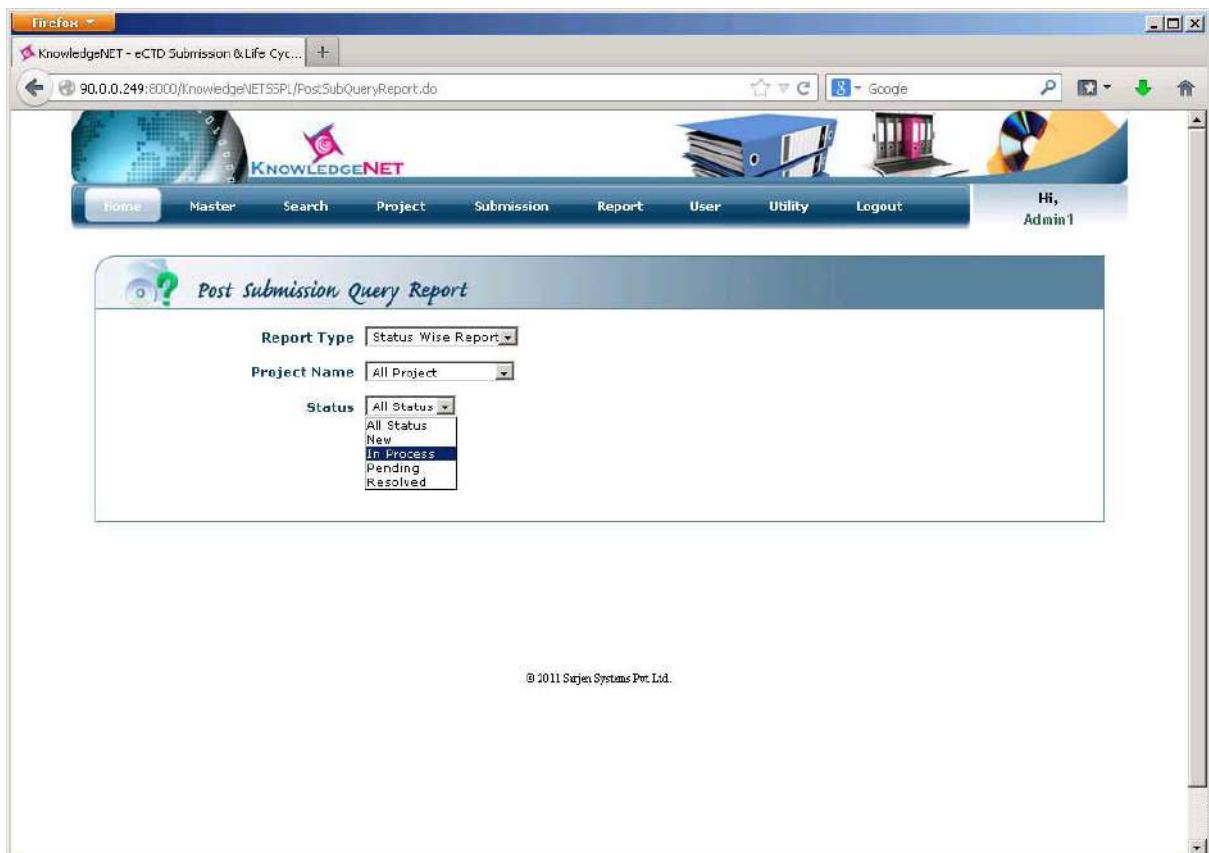
Report > Submission Query > Post Submission Query Report

- If Admin wants to status wise and Time wise Query report shows below screen.



The screenshot shows a Firefox browser window displaying the 'Post Submission Query Report' page. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/PostSubQueryReport.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'Post Submission Query Report' and contains a 'Report Type' dropdown menu with three options: 'Select Report Type', 'Status Wise Report', and 'Time Wise Report'. At the bottom of the page, there is a copyright notice: '© 2011 Surjeet Systems Pvt. Ltd.'

- If Admin wants to status wise report below screen shows select all such as Report Type, Project Name, Status and click on " Search"



Firefox - KnowledgeNET - eCTD Submission & Life Cyc... +

90.0.0.249:8000/knowledgeNETSSPL/PostSubQueryReport.do

Home Master Search Project Submission Report User Utility Logout Hi, Admin1

Post Submission Query Report

Report Type: Status Wise Report

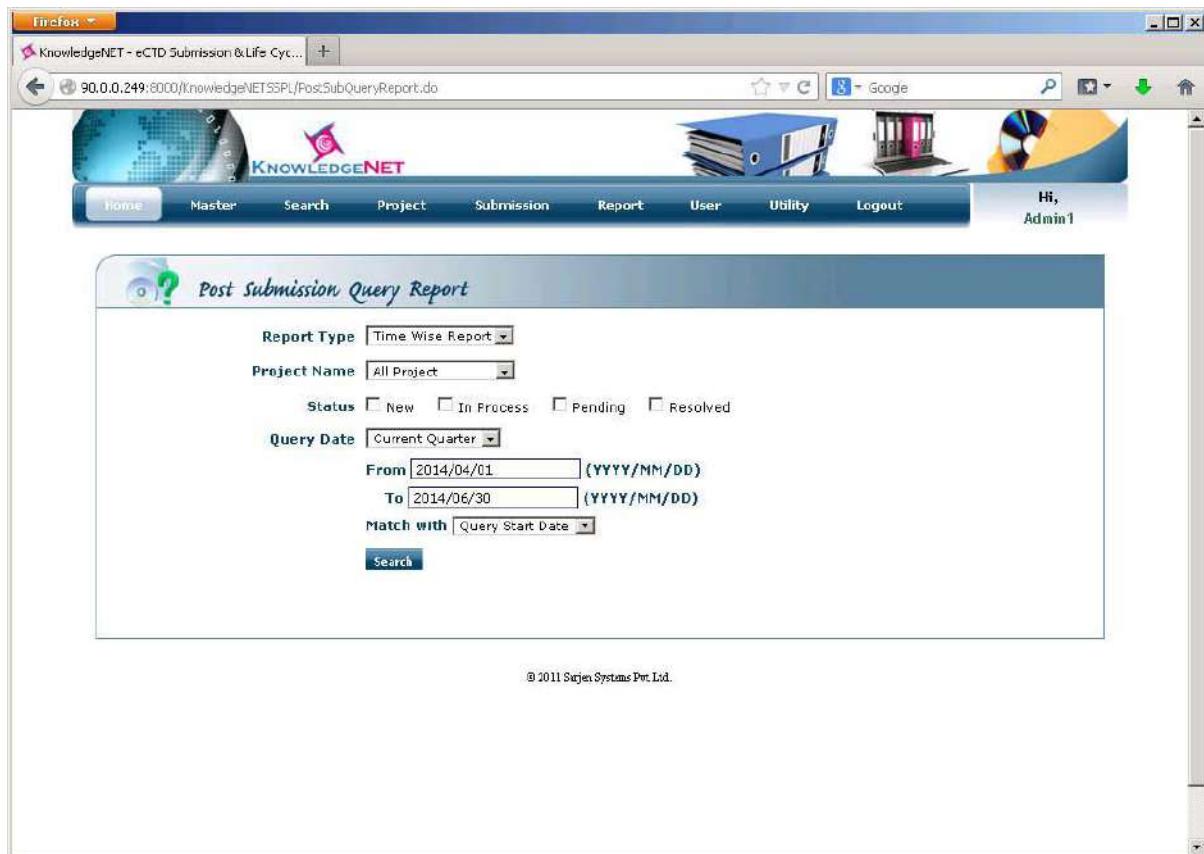
Project Name: All Project

Status: All Status

- All Status
- New
- In Process
- Pending
- Resolved

© 2011 Surjeet Systems Pvt. Ltd.

- If Admin wants to Time wise report below screen shows select all such as Report Type, Project Name, Status, Query Date and match with then click on "Search" below screen shows.



The screenshot shows a Firefox browser window displaying the 'Post Submission Query Report' page. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/PostSubQueryReport.do. The page has a header with the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'Post Submission Query Report' and contains the following form fields:

- Report Type: Time Wise Report (dropdown menu)
- Project Name: All Project (dropdown menu)
- Status: New, In Process, Pending, Resolved (checkboxes)
- Query Date: Current Quarter (dropdown menu)
 - From: 2014/04/01 (YYYY/MM/DD)
 - To: 2014/06/30 (YYYY/MM/DD)
- Match with: Query Start Date (dropdown menu)
- Search button

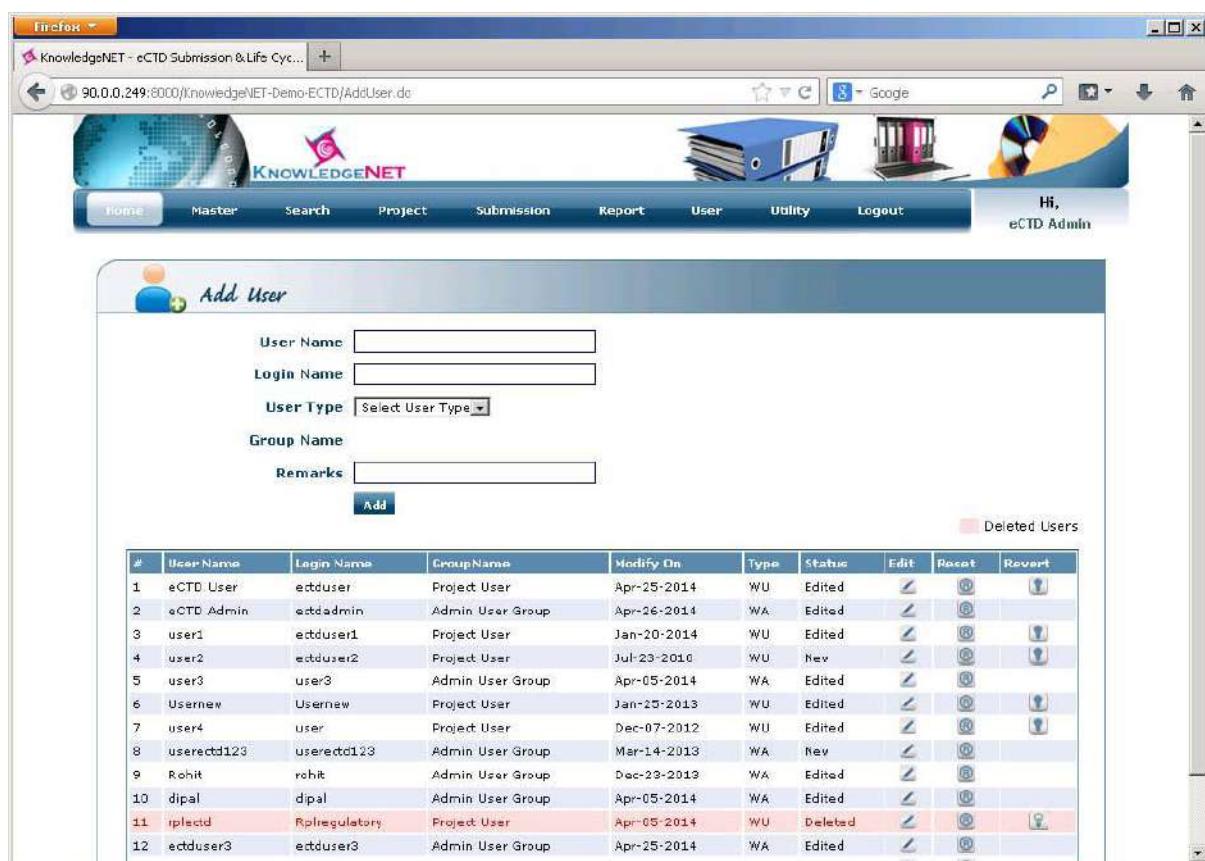
At the bottom of the page, there is a copyright notice: © 2011 Sujen Systems Pvt. Ltd.

User Menu

- ❖ Admin will be able to add a new user through User Menu.

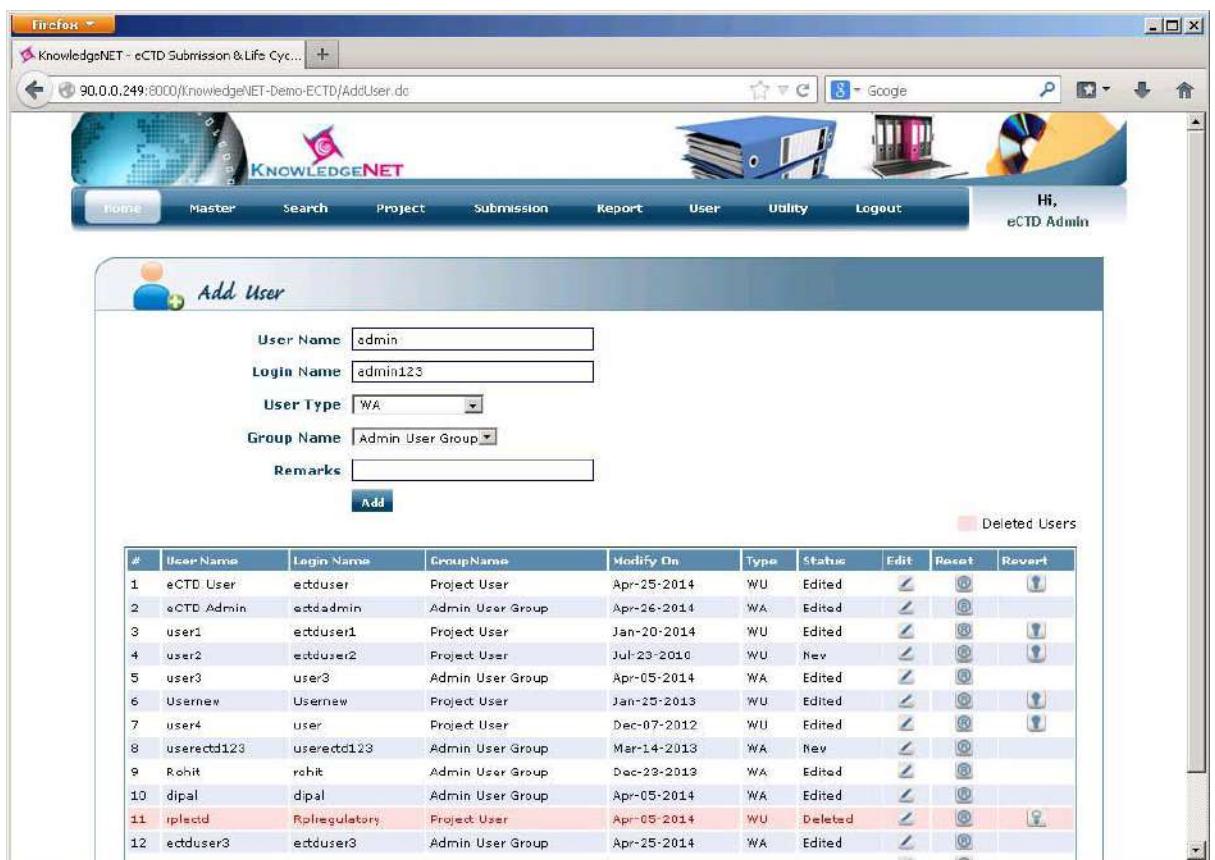
User >Add User

- The below screen shows the sub-menu of User menu.
- Through “Add User”, Admin will be able to view/add/edit/inactivate the user.



#	User Name	Login Name	Group Name	Modify On	Type	Status	Edit	Reset	Revert
1	eCTD User	ectduser	Project User	Apr-25-2014	WU	Edited			
2	eCTD Admin	ectdadmin	Admin User Group	Apr-26-2014	WA	Edited			
3	user1	ectduser1	Project User	Jan-20-2014	WU	Edited			
4	user2	ectduser2	Project User	Jul-23-2010	WU	New			
5	user3	user3	Admin User Group	Apr-05-2014	WA	Edited			
6	Usernew	Usernew	Project User	Jan-25-2013	WU	Edited			
7	user4	user	Project User	Dec-07-2012	WU	Edited			
8	userectd123	userectd123	Admin User Group	Mar-14-2013	WA	New			
9	Rohit	rshit	Admin User Group	Dec-23-2013	WA	Edited			
10	dipal	dipal	Admin User Group	Apr-05-2014	WA	Edited			
11	rplectd	Rperegulatory	Project User	Apr-05-2014	WU	Deleted			
12	ectduser3	ectduser3	Admin User Group	Apr-25-2014	WA	Edited			

- The below screen shows the Add User main page. To add the new user, fill the details as "User Name", "Login Name", select "User Type", "Group Name" and "Remarks".
- After providing all the mentioned information, click on "Add User".
- Record list will display all the mentioned information along with date and time of modification and the "Status" of the record.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cyc... website at 90.0.0.249:8000/knowledgeNET-Demo-eCTD/AddUser.do. The page title is "Add User". The user is logged in as "eCTD Admin".

Add User Form:

User Name	<input type="text" value="admin"/>
Login Name	<input type="text" value="admin123"/>
User Type	<input type="text" value="WA"/>
Group Name	<input type="text" value="Admin User Group"/>
Remarks	<input type="text"/>
<input type="button" value="Add"/>	

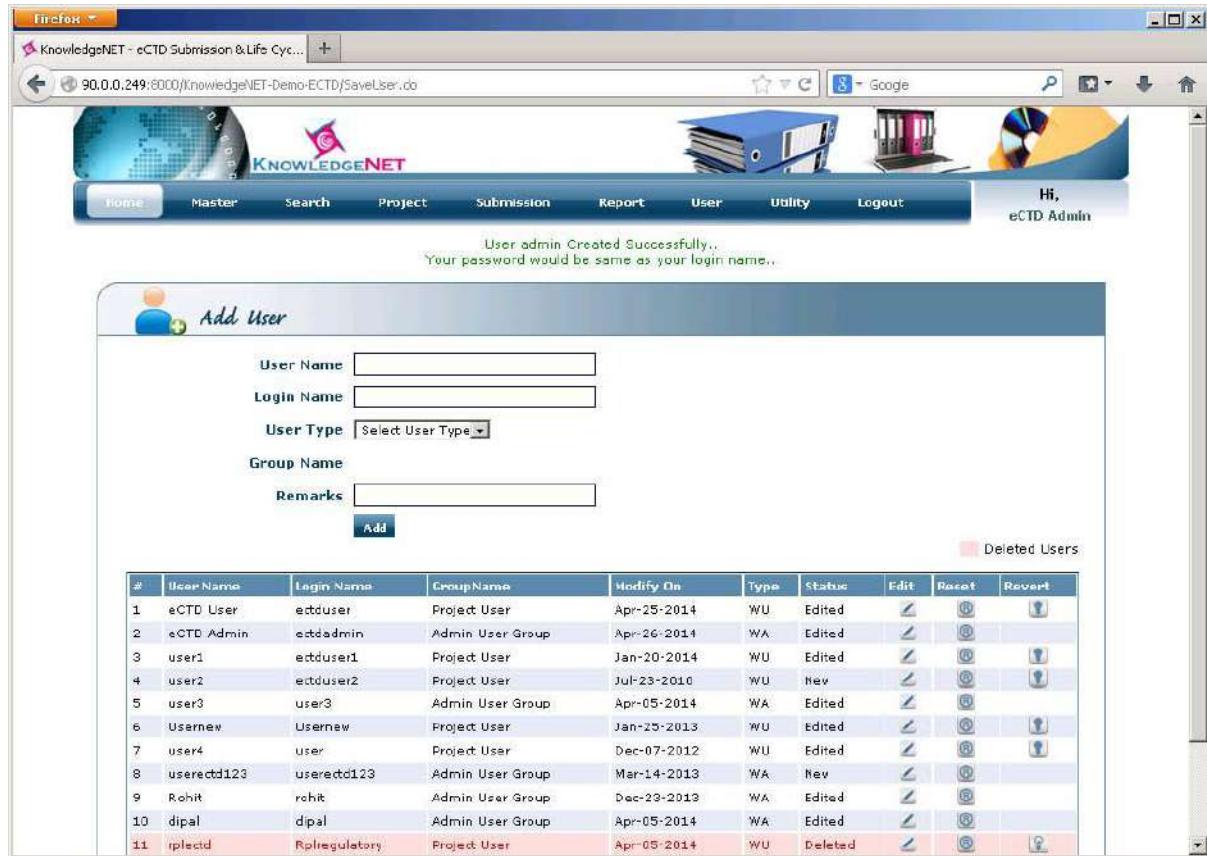
User Record List:

#	User Name	Login Name	Group Name	Modify On	Type	Status	Edit	Reset	Revert
1	eCTD User	ectduser	Project User	Apr-25-2014	WU	Edited			
2	eCTD Admin	ectdadmin	Admin User Group	Apr-26-2014	WA	Edited			
3	user1	ectduser1	Project User	Jan-20-2014	WU	Edited			
4	user2	ectduser2	Project User	Jul-23-2014	WU	New			
5	user3	user3	Admin User Group	Apr-05-2014	WA	Edited			
6	Usernew	Usernew	Project User	Jan-25-2013	WU	Edited			
7	user4	user	Project User	Dec-07-2012	WU	Edited			
8	userectd123	userectd123	Admin User Group	Mar-14-2013	WA	New			
9	Rohit	rohit	Admin User Group	Dec-23-2013	WA	Edited			
10	dipal	dipal	Admin User Group	Apr-05-2014	WA	Edited			
11	iplectd	Rplregulatory	Project User	Apr-05-2014	WU	Deleted			
12	ectduser3	ectduser3	Admin User Group	Apr-25-2014	WA	Edited			

Deleted Users:

Deleted User Record (Row 11)

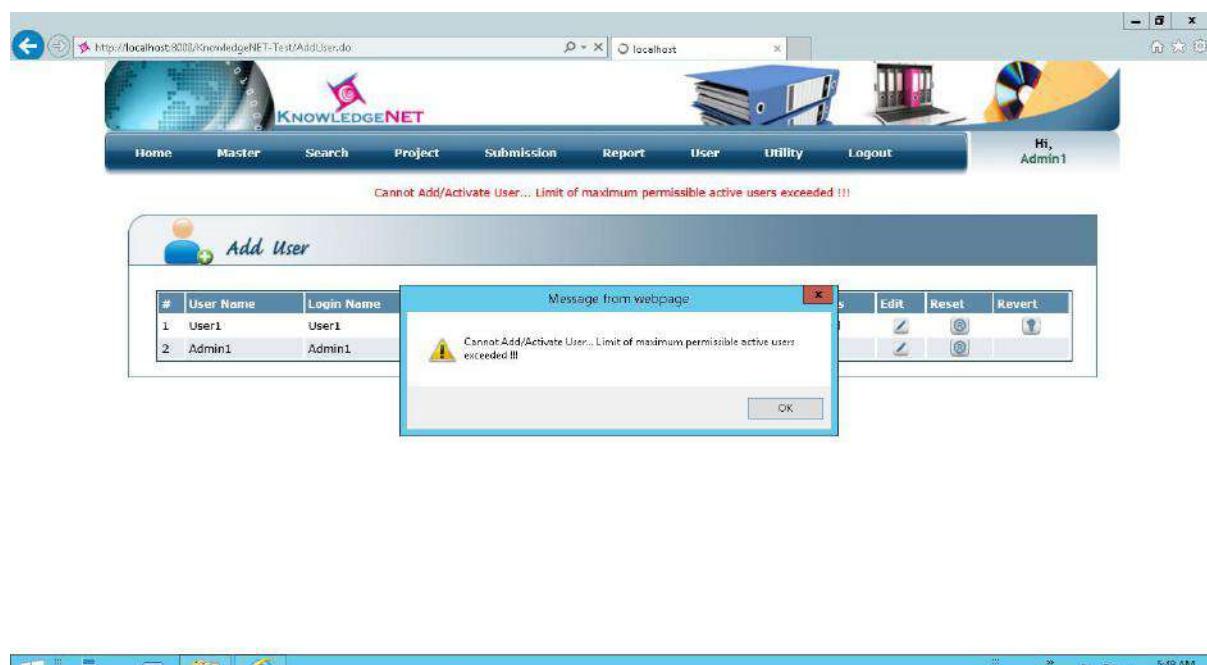
- After clicking on “Add” button, it will display a message as User is created successfully. And that password would be same as login name.



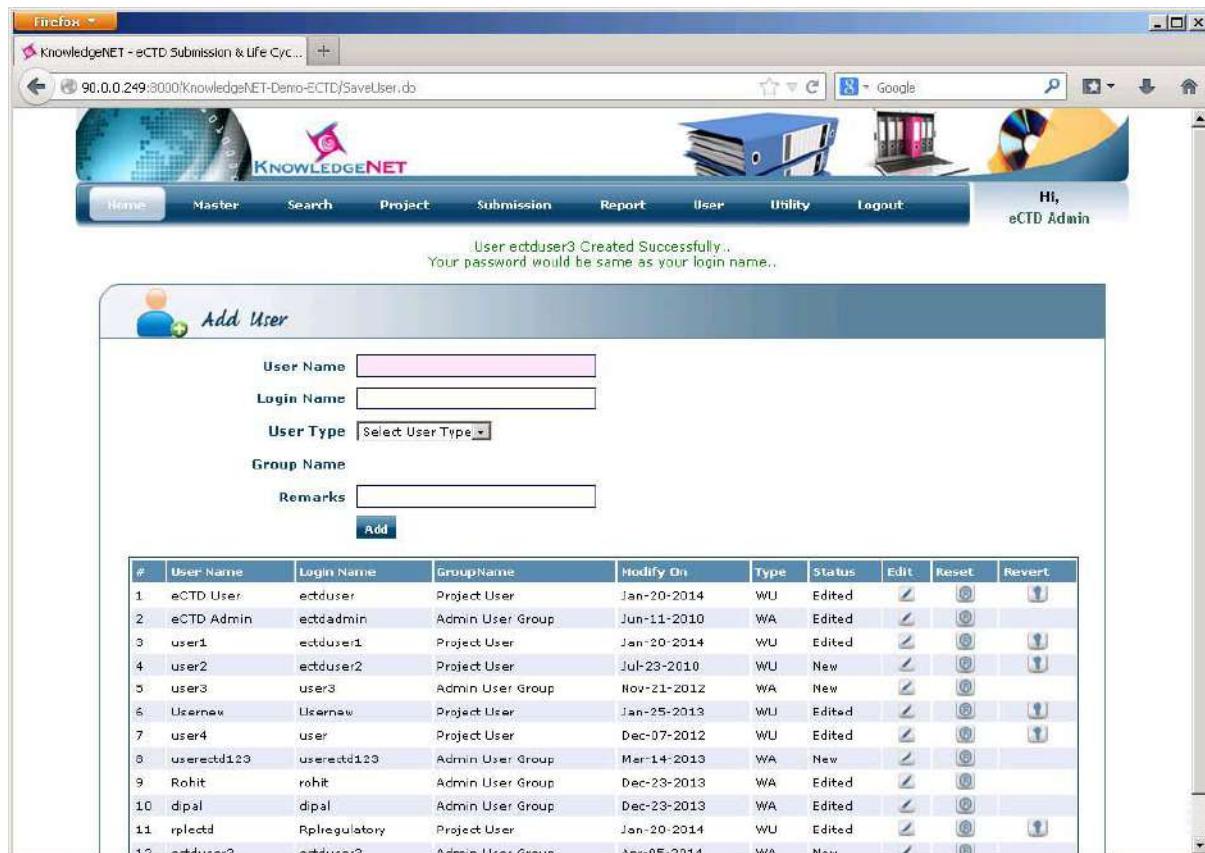
The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/knowledgeNET-Demo-ECTD/SaveUser.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The main content area shows a success message: "User admin Created Successfully.. Your password would be same as your login name..". Below this, there is an "Add User" form with fields for User Name, Login Name, User Type (dropdown), Group Name, and Remarks. An "Add" button is visible. To the right of the form is a table titled "Deleted Users" with 11 rows of data. The table columns are: #, User Name, Login Name, Group Name, Modify On, Type, Status, Edit, Recat, and Revert. The data in the table is as follows:

#	User Name	Login Name	Group Name	Modify On	Type	Status	Edit	Recat	Revert
1	eCTD User	ectduser	Project User	Apr-25-2014	WU	Edited			
2	eCTD Admin	ectdadmin	Admin User Group	Apr-26-2014	WA	Edited			
3	user1	ectduser1	Project User	Jan-20-2014	WU	Edited			
4	user2	ectduser2	Project User	Jul-23-2010	WU	New			
5	user3	user3	Admin User Group	Apr-05-2014	WA	Edited			
6	Usernew	Usernew	Project User	Jan-25-2013	WU	Edited			
7	user4	User	Project User	Dec-07-2012	WU	Edited			
8	userectdd123	userectdd123	Admin User Group	Mar-14-2013	WA	New			
9	Rohit	rhit	Admin User Group	Dec-23-2013	WA	Edited			
10	dipal	dipal	Admin User Group	Apr-05-2014	WA	Edited			
11	rplicid	Rplicid	Project User	Apr-05-2014	WU	Deleted			

- The user created will be added to grid. But as the limit of creating user has exceeded to its maximum limit, it will display a dialog box showing a warning that "Cannot Add/Activate User.... Limit of maximum permissible active users exceeded!!!"
- Click on "Ok" button to exit from the dialog box. Below screen will then get displayed.



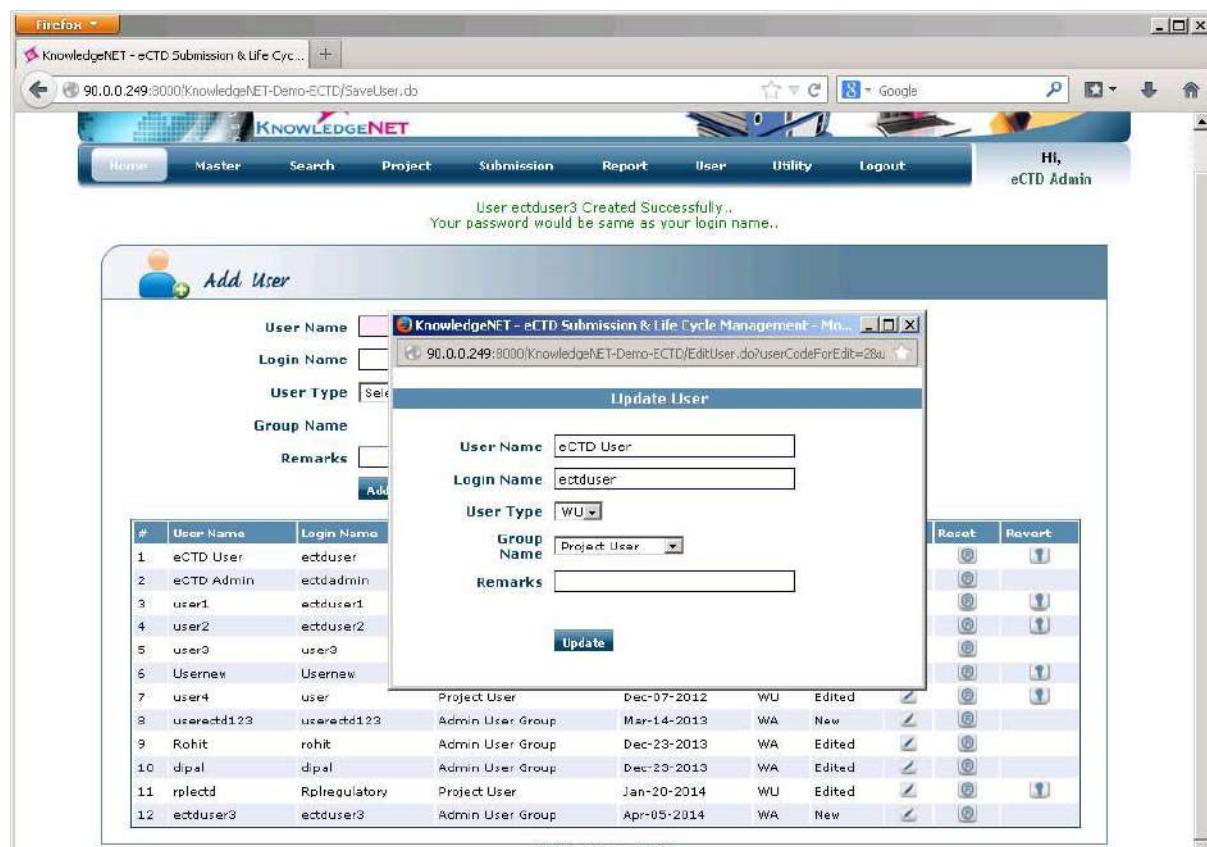
- For each record its “status” will be displayed as below
 - For newly added record the status will be “New”.
 - For edited/reactivated record status will be “Edited”.
 - For inactivated record, the status will be “Deleted”.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/SaveUser.do. The page title is "KnowledgeNET - eCTD Submission & Life Cyc...". The header includes links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, along with a greeting "Hi, eCTD Admin". A success message at the top states "User ectduser3 Created Successfully.. Your password would be same as your login name..". Below this is the "Add User" form with fields for User Name, Login Name, User Type (dropdown), Group Name, and Remarks. An "Add" button is present. At the bottom is a table listing user records:

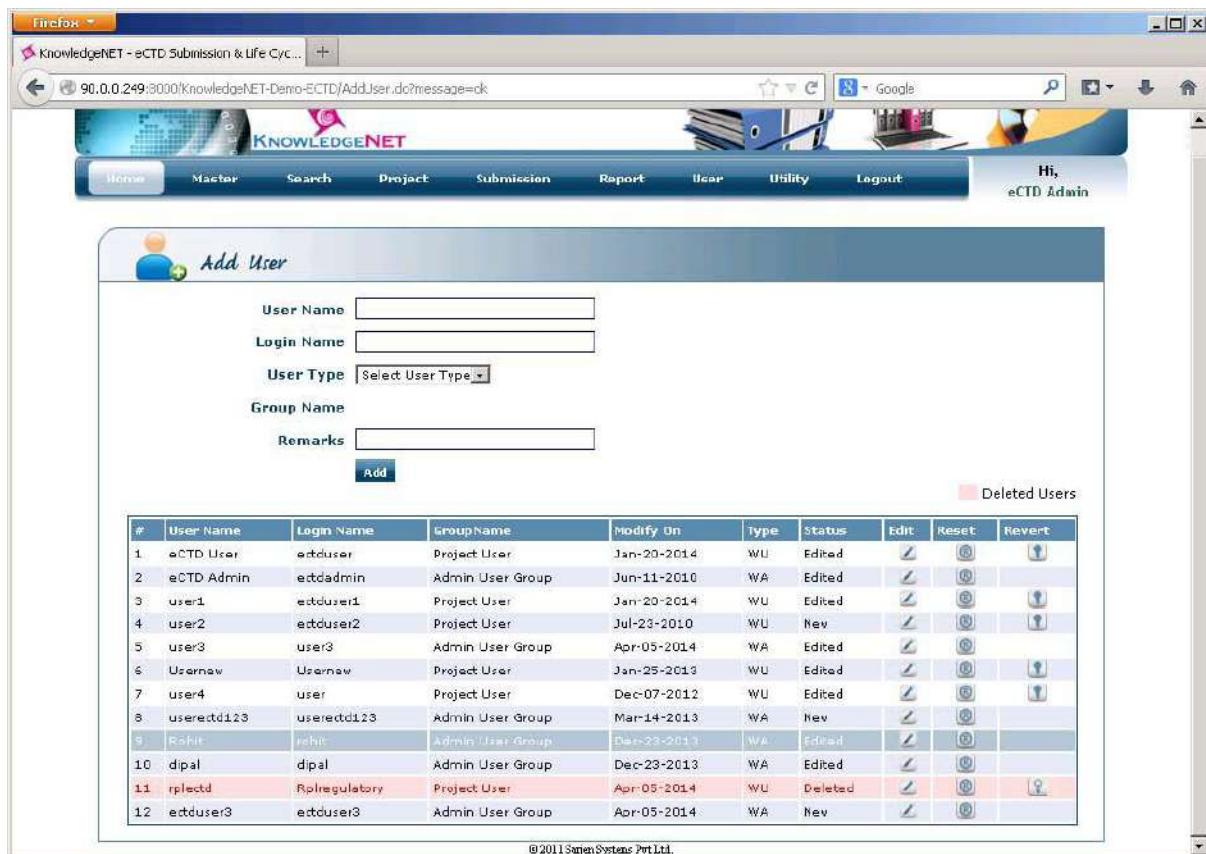
#	User Name	Login Name	Group Name	Modify On	Type	Status	Edit	Reset	Revert
1	eCTD User	ectduser	Project User	Jan-20-2014	WU	Edited			
2	eCTD Admin	ectdadmin	Admin User Group	Jun-11-2010	WA	Edited			
3	user1	ectduser1	Project User	Jan-20-2014	WU	Edited			
4	user2	ectduser2	Project User	Jul-23-2010	WU	New			
5	user3	user3	Admin User Group	Nov-21-2012	WA	New			
6	usernew	Usernew	Project User	Jan-25-2013	WU	Edited			
7	user4	user	Project User	Dec-07-2012	WU	Edited			
8	userectd123	userectd123	Admin User Group	Mar-14-2013	WA	New			
9	Rohit	rohit	Admin User Group	Dec-23-2013	WA	Edited			
10	dipal	dipal	Admin User Group	Dec-23-2013	WA	Edited			
11	rplectd	Rpliegtulatory	Project User	Jan-20-2014	WU	Edited			
12	ectduser3	ectduser3	Admin User Group	Apr-05-2014	WA	New			

- On clicking “Edit”, user information can be edited and below screen will get displayed.
- User information as “User Name”, “Login Name”, “User Type”, “Group Name” and “Remarks” can be edited.
- Click on “Update” button to update the changes done.
- On clicking “Revert” button from the “Add User” page, it will deactivate the user.
- A popup screen will get displayed and on clicking “Ok”, the selected user will get deactivated and the below screen will get displayed.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management application. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/SaveUser.do. The main menu bar includes Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A message at the top right says "Hi, eCTD Admin". Below the menu, a success message states "User ectduser3 Created Successfully... Your password would be same as your login name..". The main content area has two overlapping windows: an "Add User" form and an "Update User" dialog. The "Add User" form contains fields for User Name, Login Name, User Type (selected), Group Name, and Remarks. The "Update User" dialog is overlaid on the add form, showing the same fields with values: User Name (eCTD User), Login Name (ectduser), User Type (WU), Group Name (Project User), and Remarks (empty). There is an "Update" button at the bottom of the dialog. To the left of the dialogs is a table listing users with columns: #, User Name, and Login Name. The table lists 12 users, including rows for "ectd User", "ectd Admin", "user1", "user2", "user3", "Usernew", "user4", "userectd123", "Rohit", "dipal", "rplectd", and "ectduser3". The "ectduser3" row is highlighted. The "ectduser3" row in the table also has an edit icon (pencil) and a delete icon (trash bin). The bottom of the application window has a footer with the text "©2011 Varian Systems Dev Team".

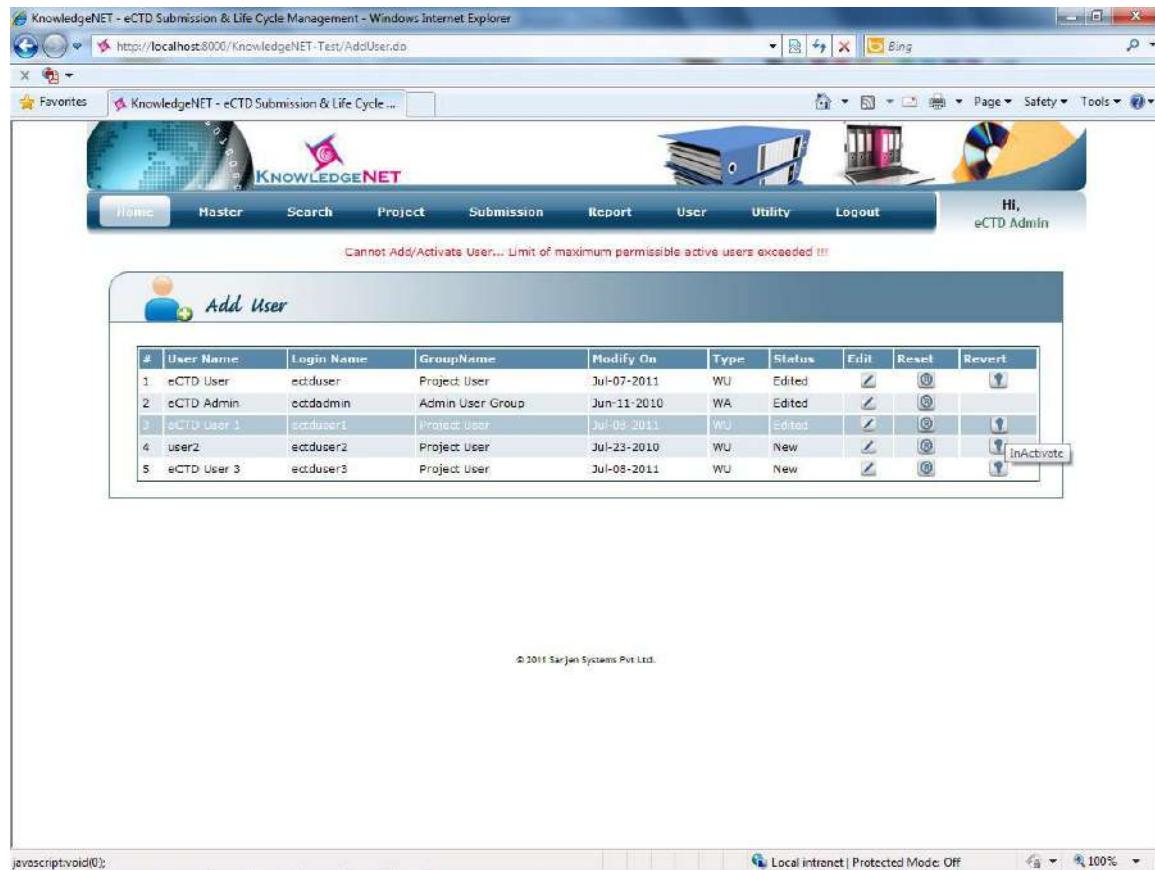
- The below screen shows the inactivated user. Status will get change to “Deleted”. And to indicate the deleted/inactivated users, a message will get displayed below the grid as “Deleted Users” with its respective color.
- On clicking “Revert” icon again, it will change the status of the user to “Edited” and the user will get activated as shows in below screen.



The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cyc... page at 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/AddUser.do?message=ok. The page title is "Add User". The main content area contains fields for User Name, Login Name, User Type (with a dropdown menu), Group Name, and Remarks, along with an "Add" button. Below this is a table grid with columns: #, User Name, Login Name, GroupName, Modify On, type, Status, Edit, Reset, and Revert. The grid lists 12 users, with the 11th user (rplectd) highlighted in red and labeled "Deleted Users" in pink. The "Revert" column for this user is also pink. The footer of the page includes the copyright notice "© 2011 Sarjen Systems Pvt Ltd."

#	User Name	Login Name	GroupName	Modify On	Type	Status	Edit	Reset	Revert
1	eCTD User	ectduser	Project User	Jan-20-2014	WU	Edited			
2	eCTD Admin	ectdadmin	Admin User Group	Jun-11-2010	WA	Edited			
3	user1	ectduser1	Project User	Jan-20-2014	WU	Edited			
4	user2	ectduser2	Project User	Jul-23-2010	WU	New			
5	user3	user3	Admin User Group	Apr-05-2014	WA	Edited			
6	Usernew	Usernew	Project User	Jan-25-2013	WU	Edited			
7	user4	user	Project User	Dec-07-2012	WU	Edited			
8	userectd123	userectd123	Admin User Group	Mar-14-2013	WA	New			
9	Rohit	rohit	Admin User Group	Dec-23-2013	WA	Edited			
10	dipal	dipal	Admin User Group	Dec-23-2013	WA	Edited			
11	rplectd	Rplectd	Project User	Apr-05-2014	WU	Deleted			
12	ectduser3	ectduser3	Admin User Group	Apr-05-2014	WA	New			

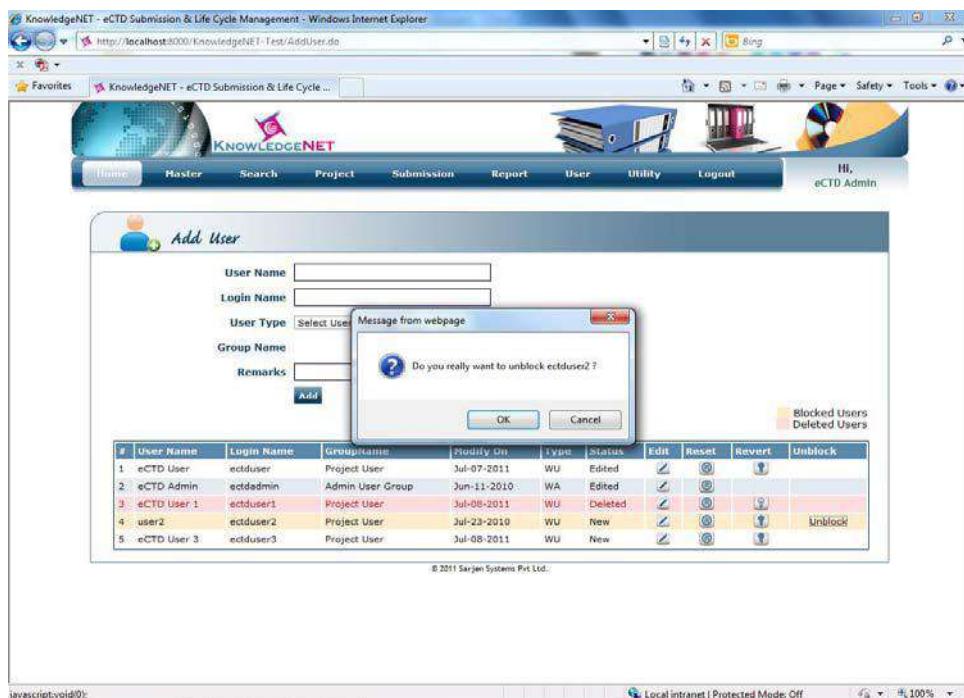
- Now on clicking “Reset” icon, it will ask for confirmation. On clicking ‘Ok’, it will reset the password of the selected user and a message will get displayed as the password will be same as that of login name.



#	User Name	Login Name	GroupName	Modify On	Type	Status	Edit	Reset	Revert
1	eCTD User	ecctduser	Project: User	Jul-07-2011	WU	Edited			
2	eCTD Admin	ecctdadmin	Admin User Group	Jun-11-2010	WA	Edited			
3	eCTD User 1	ecctduser1	Project: User	Jul-05-2011	WU	Edited			
4	user2	ecctduser2	Project: User	Jul-23-2010	WU	New			
5	eCTD User 3	ecctduser3	Project: User	Jul-08-2011	WU	New			

- If user was blocked, it will display in different color. And color code will get displayed at top of the grid.

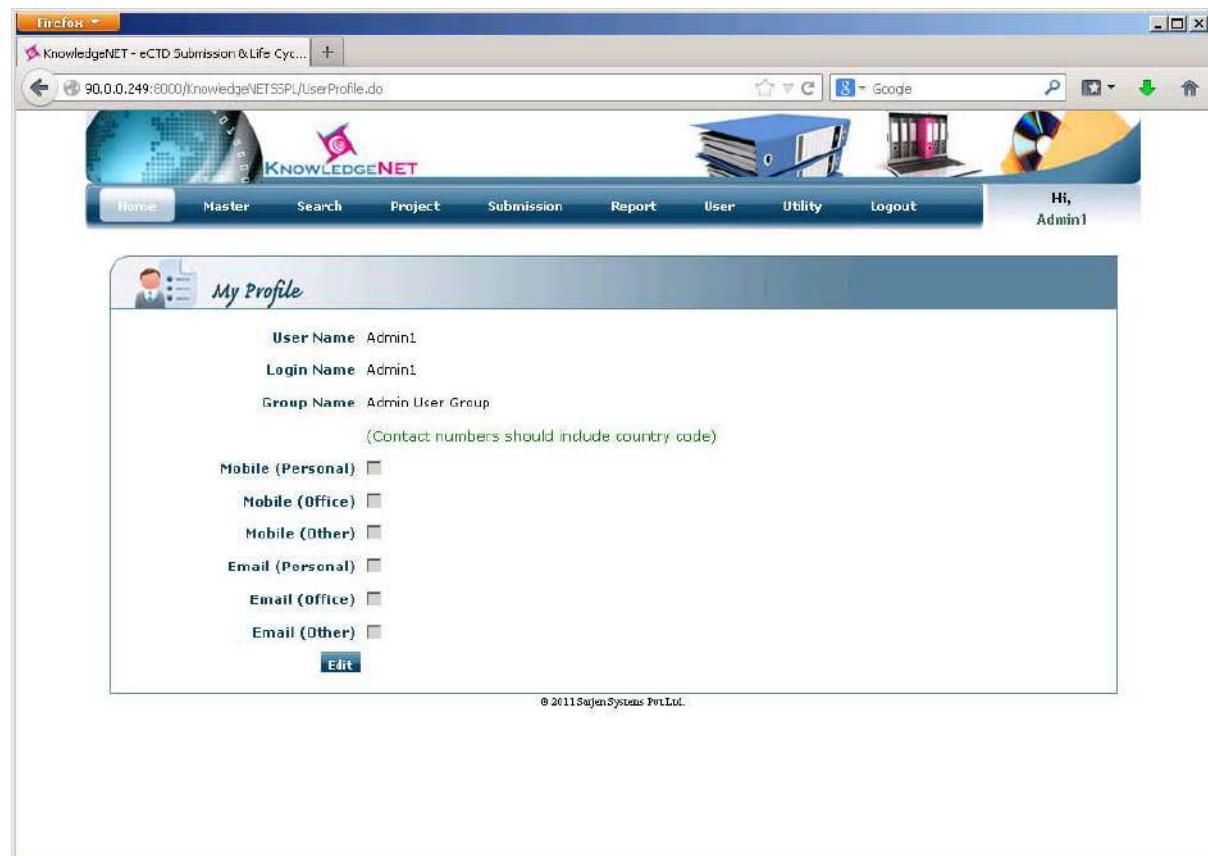
- User can be unblocked by Admin user.
- To unlock the user, click on "Unblock" link.



Admin will be able to add Personal Information (Profile).

User >My Profile

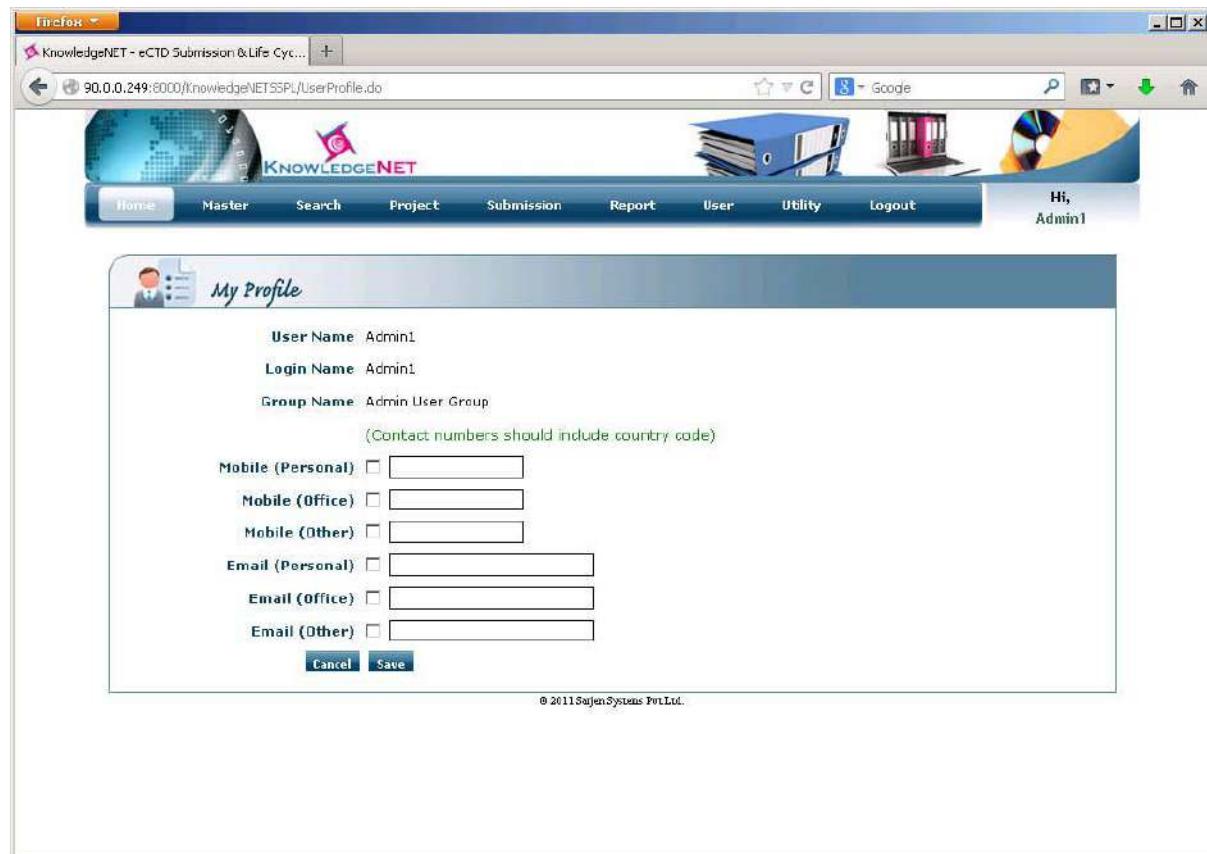
- The below screen shows the main page of My Profile.



The screenshot shows a Firefox browser window displaying the 'My Profile' page of the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/UserProfile.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'My Profile' and displays user information: User Name (Admin1), Login Name (Admin1), and Group Name (Admin User Group). It also includes a note: '(Contact numbers should include country code)'. Below this, there are fields for mobile and email contact information, each with three options: Personal, Office, or Other. At the bottom of the form is a blue 'Edit' button. The footer of the page contains the copyright notice: © 2011 Saizen Systems Pvt Ltd.

- On clicking "Edit" icon,

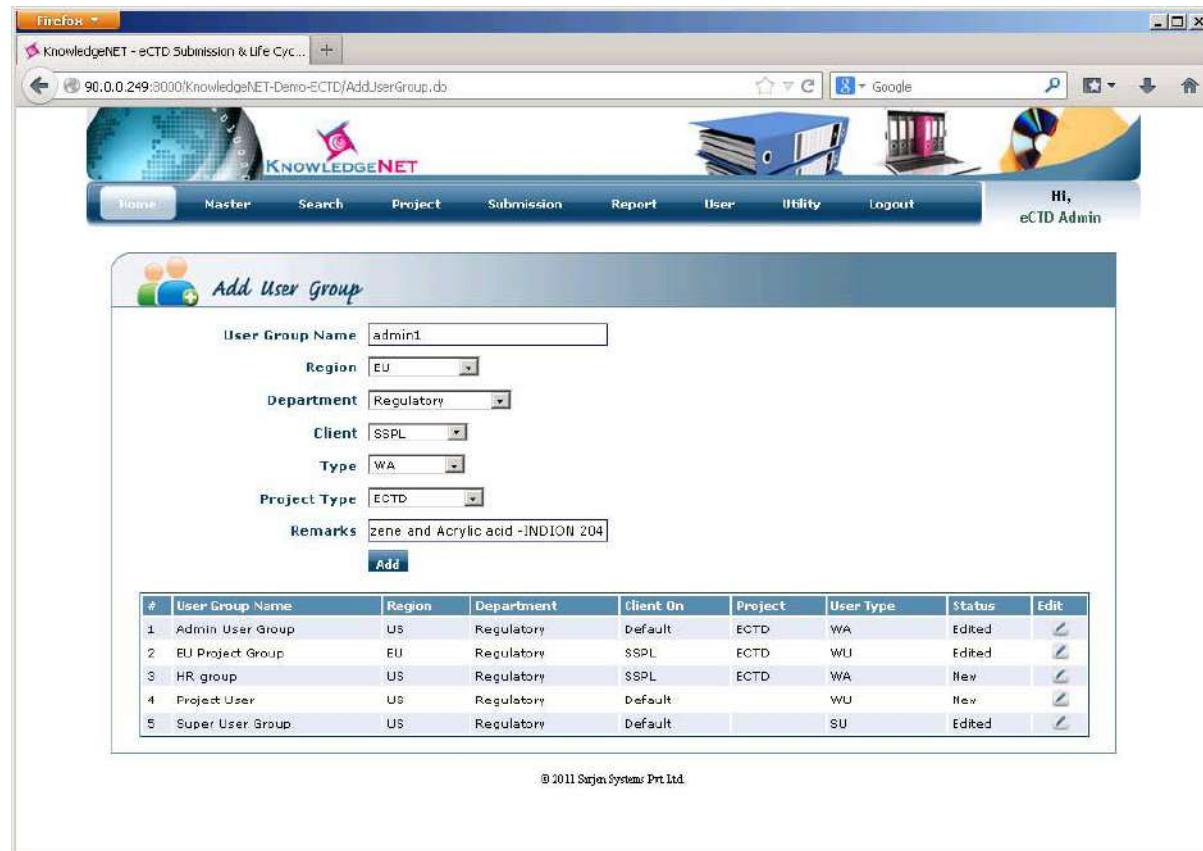
- On clicking “Edit” icon, below screen gets displayed through which Admin can fill and edit the Profile.
- User fill all information then click on “save” button shown in below screen.



The screenshot shows a Firefox browser window displaying the 'My Profile' page of the KnowledgeNET application. The URL in the address bar is 90.0.0.249:8000/knowledgeNETSSPL/UserProfile.do. The page header includes the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A greeting 'Hi, Admin1' is visible on the right. The main content area is titled 'My Profile' and contains fields for User Name (Admin1), Login Name (Admin1), and Group Name (Admin User Group). It also includes contact information fields: Mobile (Personal), Mobile (Office), Mobile (Other), Email (Personal), Email (Office), and Email (Other), each with an associated input field. A note at the top of these fields says '(Contact numbers should include country code)'. At the bottom of the form are 'Cancel' and 'Save' buttons. A copyright notice at the bottom of the page reads '© 2011 Sejen Systems Pvt Ltd.'

Admin will be able to add a new group through User Menu.**User >Add Group**

- The below screen shows the main page of Add Group.
- Admin can fill in the respective details and click on “Add” button to add that particular user group which will get displayed in the grid as shows in below screen.

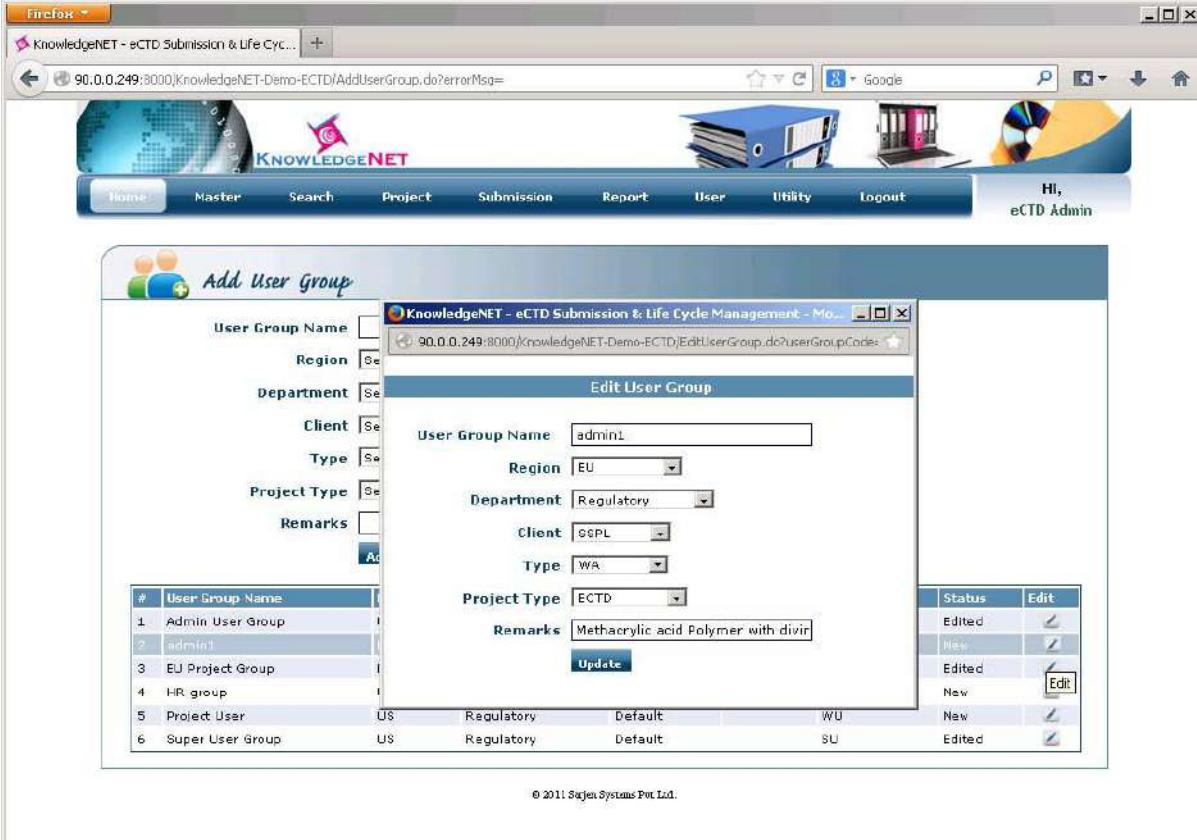


The screenshot shows the 'Add User Group' page of the KnowledgeNET application. The URL in the browser is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/AddUserGroup.do. The page has a header with the KnowledgeNET logo and navigation links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A welcome message 'Hi, eCTD Admin' is displayed on the right. The main content area has a title 'Add User Group' with a plus icon. It contains several input fields: 'User Group Name' (admin1), 'Region' (EU), 'Department' (Regulatory), 'Client' (SSPL), 'Type' (WA), 'Project Type' (ECTD), and 'Remarks' (zene and Acrylic acid -INDION 204). Below these fields is an 'Add' button. At the bottom of the page is a table showing a list of user groups:

#	User Group Name	Region	Department	Client On	Project	User Type	Status	Edit
1.	Admin User Group	US	Regulatory	Default	ECTD	WA	Edited	
2.	EU Project Group	EU	Regulatory	SSPL	ECTD	WU	Edited	
3.	HR group	US	Regulatory	SSPL	ECTD	WA	New	
4.	Project User	US	Regulatory	Default		WU	New	
5.	Super User Group	US	Regulatory	Default		SU	Edited	

At the bottom center of the page, there is a copyright notice: © 2011 Safran Systems Pvt Ltd.

- On clicking “Edit” icon, below screen gets displayed through which Admin can edit the group details.



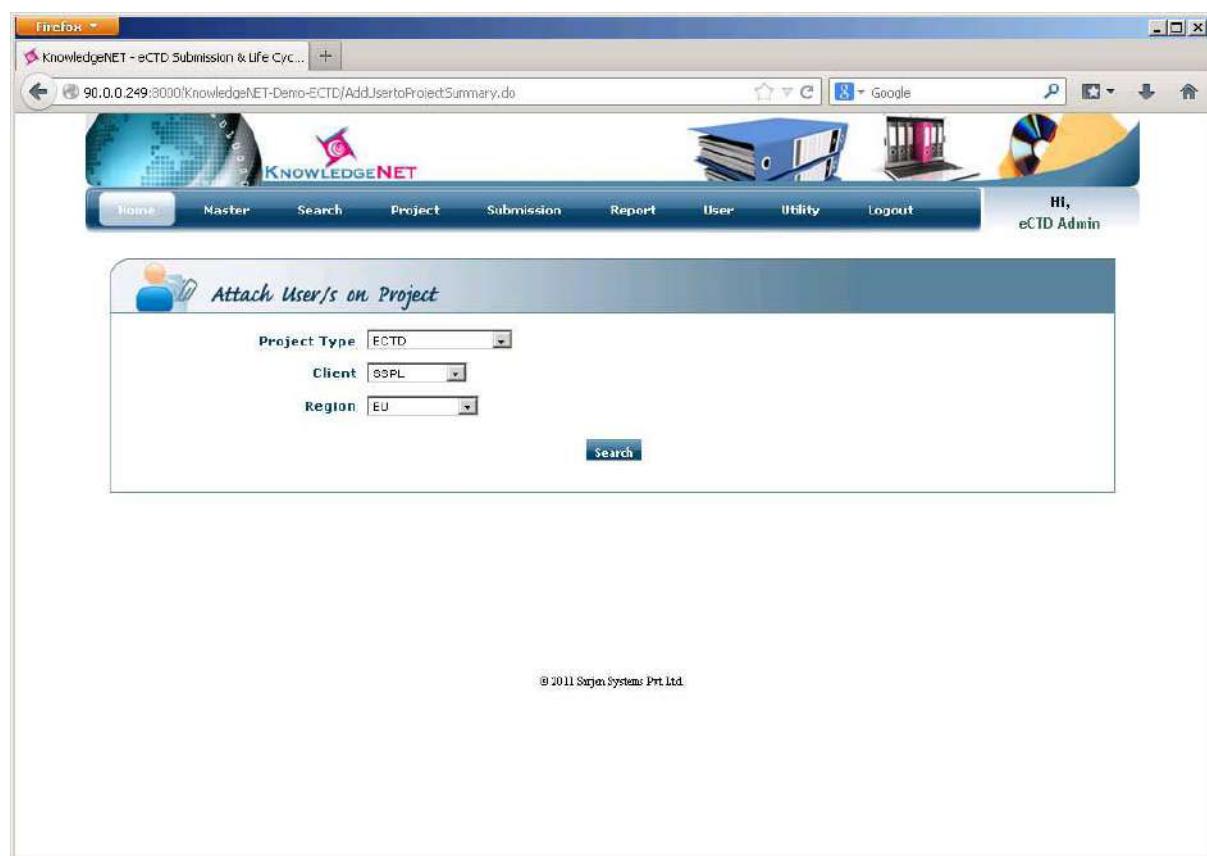
The screenshot shows a Firefox browser window displaying the KnowledgeNET - eCTD Submission & Life Cycle Management module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/EditUserGroup.do?userGroupCode=1. The page title is "Edit User Group". The main content area contains fields for "User Group Name" (admin1), "Region" (EU), "Department" (Regulatory), "Client" (CCPL), "Type" (WA), "Project Type" (ECTD), and "Remarks" (Methacrylic acid Polymer with divir). Below these fields is a "Update" button. To the left of the form is a sidebar with a table titled "User Group Name" showing six entries. To the right is a table titled "Status" with four rows: Edited, New, Edited, and New. At the bottom of the page is a copyright notice: © 2011 Sajen Systems Pvt Ltd.

#	User Group Name	Region	Department	Client	Type	Project Type	Remarks	Status	Edit
1	Admin User Group	US	Regulatory	Default	WU	Edited			
2	admin1	US	Regulatory	Default	WU	New			
3	EU Project Group	EU	Regulatory	Default	EU	Edited			
4	HR group	EU	Regulatory	Default	EU	New			
5	Project User	US	Regulatory	Default	EU	Edited			
6	Super User Group	US	Regulatory	Default	EU	Edited			

- ❖ **Admin will be able to attach user/s, on the project through Users on Project menu.**
- ❖ **To attach user/s on project means Admin will assign rights (read/edit) to the user (on that project).**

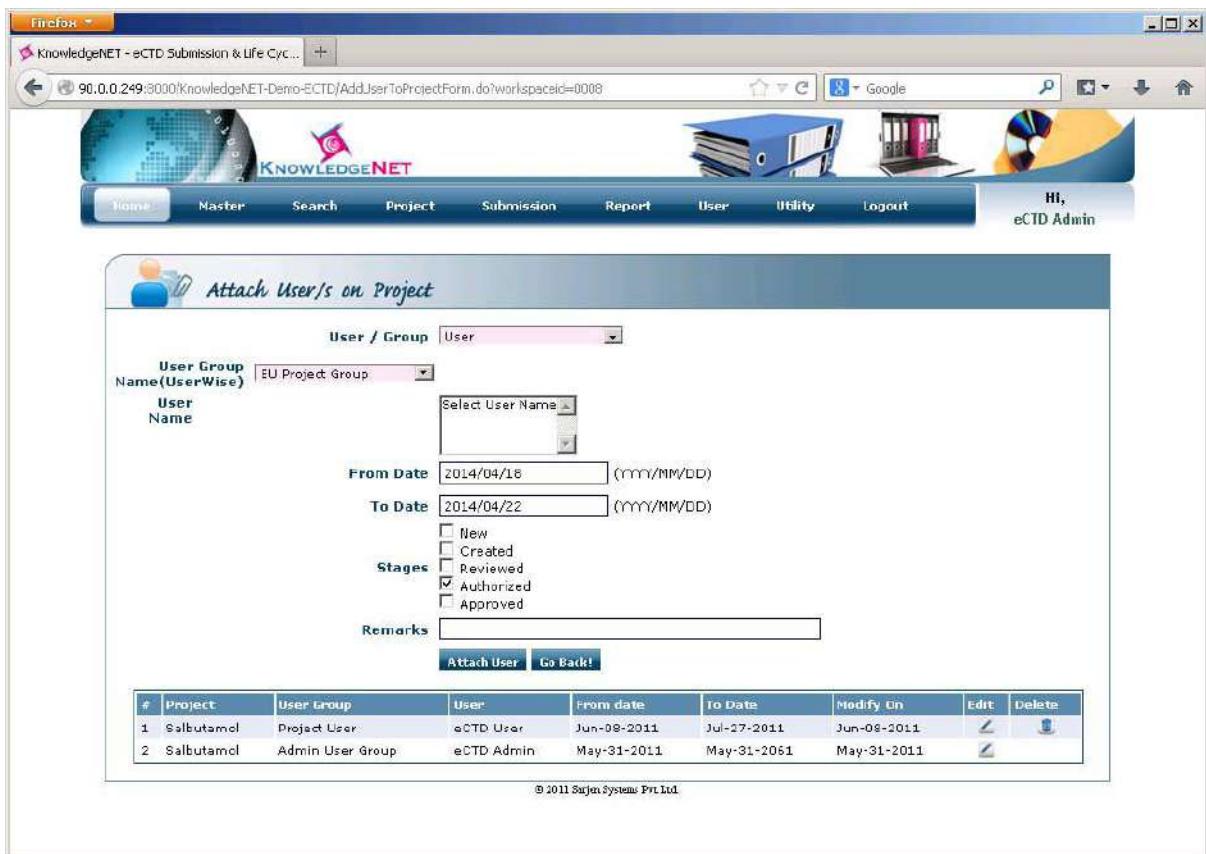
User >Users on Project

- Admin can attach, view and edit the user on the project. And also can attach multiple users on multiple projects.



The screenshot shows a Firefox browser window displaying the KnowledgeNET web application. The URL in the address bar is 90.0.0.249:3000/KnowledgeNET-Demo-ECTD/AddUserstoProjectSummary.do. The page title is "Attach User/s on Project". The header includes the KnowledgeNET logo, a navigation menu with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout, and a welcome message "Hi, eCTD Admin". Below the header is a search form with dropdown menus for "Project Type" (set to ECTD), "Client" (set to GPL), and "Region" (set to EU), followed by a "Search" button. At the bottom of the page, there is a small copyright notice: "© 2011 Suryan Systems Pvt Ltd."

- After filling up the details, click on “Attach User”. The new record will be added and displayed in the grid below.



The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/AddUserToProjectForm.do?workspaceid=0008. The page title is "Attach User/s on Project".

The form fields include:

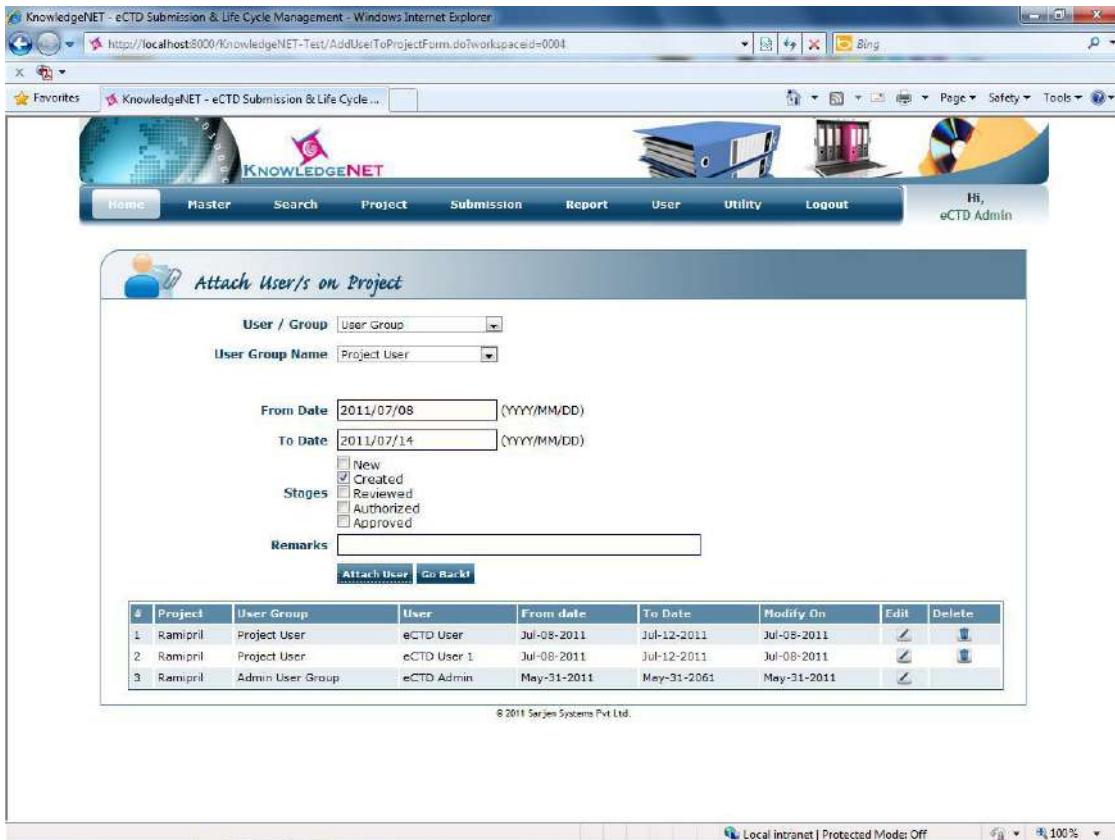
- User / Group: User (dropdown menu)
- User Group Name (UserWise): EU Project Group (dropdown menu)
- User Name: Select User Name (dropdown menu)
- From Date: 2014/04/18 (MM/DD/YYYY)
- To Date: 2014/04/22 (MM/DD/YYYY)
- Stages (checkboxes):
 - New
 - Created
 - Reviewed
 - Authorized
 - Approved
- Remarks: (text input field)

At the bottom of the form are two buttons: "Attach User" and "Go Back!". Below the form is a table showing the results of the search:

#	Project	User Group	User	From date	To Date	Modify On	Edit	Delete
1	Salbutamol	Project User	eCTD User	Jun-08-2011	Jul-27-2011	Jun-08-2011		
2	Salbutamol	Admin User Group	eCTD Admin	May-31-2011	May-31-2011	May-31-2011		

At the very bottom of the page is a copyright notice: © 2011 Surjen Systems Pvt Ltd.

- The below screen shows the users attached on a project.

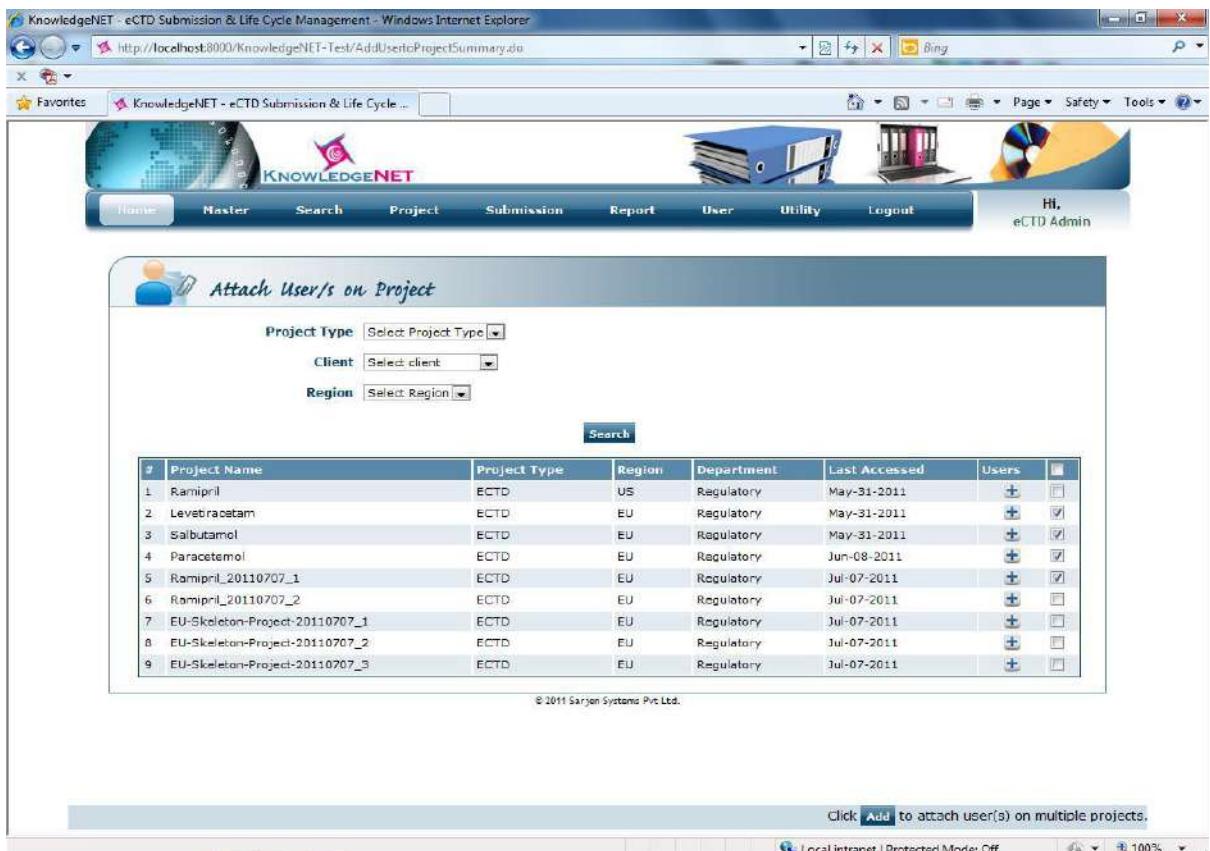


The screenshot displays a web-based application interface for managing users on a project. At the top, there's a navigation bar with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user greeting 'Hi, eCTD Admin' is visible on the right. The main content area has a title 'Attach User/s on Project'. It includes fields for 'User / Group' (set to 'User Group') and 'User Group Name' (set to 'Project User'). There are date selection fields for 'From Date' (2011/07/08) and 'To Date' (2011/07/14), and a checkbox group for 'Stages' with 'Created' checked. Below these are 'Remarks' and 'Attach User' and 'Go Back' buttons. A table lists three users attached to the project:

#	Project	User Group	User	From date	To Date	Modify On	Edit	Delete
1	Ramipril	Project User	eCTD User	Jul-08-2011	Jul-12-2011	Jul-08-2011		
2	Ramipril	Project User	eCTD User 1	Jul-08-2011	Jul-12-2011	Jul-08-2011		
3	Ramipril	Admin User Group	eCTD Admin	May-31-2011	May-31-2061	May-31-2011		

At the bottom of the page, it says '© 2011 Serjent Systems Pvt Ltd.' and shows browser status information like 'Local intranet | Protected Mode: Off' and '100% zoom'.

- To Attach multiple users on multiple project, click on 'Go Back' button and check the check box shows in the last column and then click on "Add button"(last row of the screen which has transparent background) as shows in below screen.

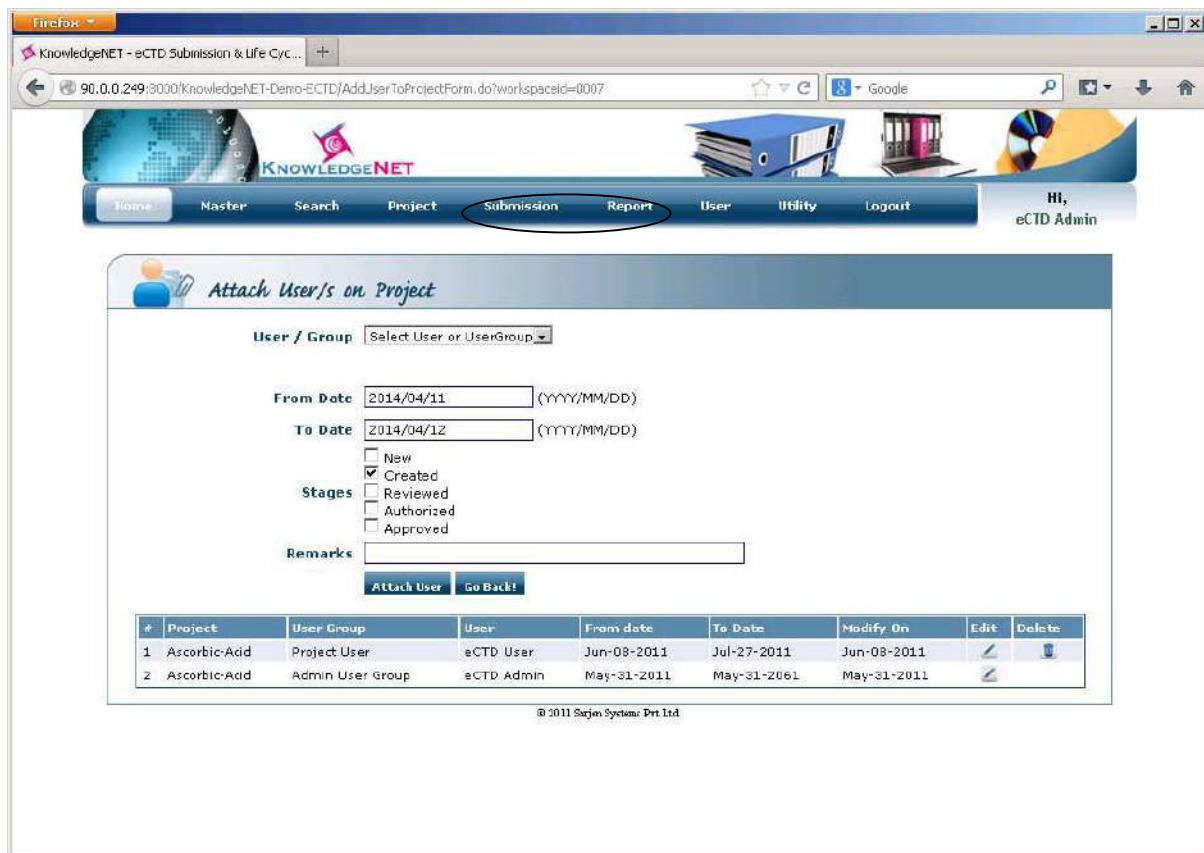


The screenshot shows a web-based application interface for managing eCTD submissions and life cycle management. At the top, there's a navigation menu with links for Home, Master, Search, Project, Submission, Report, User, Utility, and Logout. A user 'eCTD Admin' is logged in. The main content area is titled 'Attach User/s on Project'. It features a search bar and three dropdown menus: 'Project Type' (Select Project Type), 'Client' (Selected client), and 'Region' (Selected Region). Below these are buttons for 'Search' and 'Add'. A table lists nine projects with the following details:

#	Project Name	Project Type	Region	Department	Last Accessed	Users
1	Ramipril	ECTD	US	Regulatory	May-31-2011	<input type="button" value="+"/> <input type="checkbox"/>
2	Levetracetam	ECTD	EU	Regulatory	May-31-2011	<input type="button" value="+"/> <input checked="" type="checkbox"/>
3	Salbutamol	ECTD	EU	Regulatory	May-31-2011	<input type="button" value="+"/> <input checked="" type="checkbox"/>
4	Paracetamol	ECTD	EU	Regulatory	Jun-08-2011	<input type="button" value="+"/> <input checked="" type="checkbox"/>
5	Ramipril_20110707_1	ECTD	EU	Regulatory	Jul-07-2011	<input type="button" value="+"/> <input checked="" type="checkbox"/>
6	Ramipril_20110707_2	ECTD	EU	Regulatory	Jul-07-2011	<input type="button" value="+"/> <input type="checkbox"/>
7	EU-Skeleton-Project-20110707_1	ECTD	EU	Regulatory	Jul-07-2011	<input type="button" value="+"/> <input type="checkbox"/>
8	EU-Skeleton-Project-20110707_2	ECTD	EU	Regulatory	Jul-07-2011	<input type="button" value="+"/> <input type="checkbox"/>
9	EU-Skeleton-Project-20110707_3	ECTD	EU	Regulatory	Jul-07-2011	<input type="button" value="+"/> <input type="checkbox"/>

At the bottom of the page, a note says 'Click Add to attach user(s) on multiple projects.' The status bar at the bottom right indicates 'Local intranet | Protected Mode: Off' and '100%'. The browser title bar shows 'KnowledgeNET - eCTD Submission & Life Cycle Management - Windows Internet Explorer' and the URL 'http://localhost:8000/KnowledgeNET-Test/AddUserstoProjectSummary.aspx'.

- Then select “User Type” and on the basis of user type, below screen will get displayed.

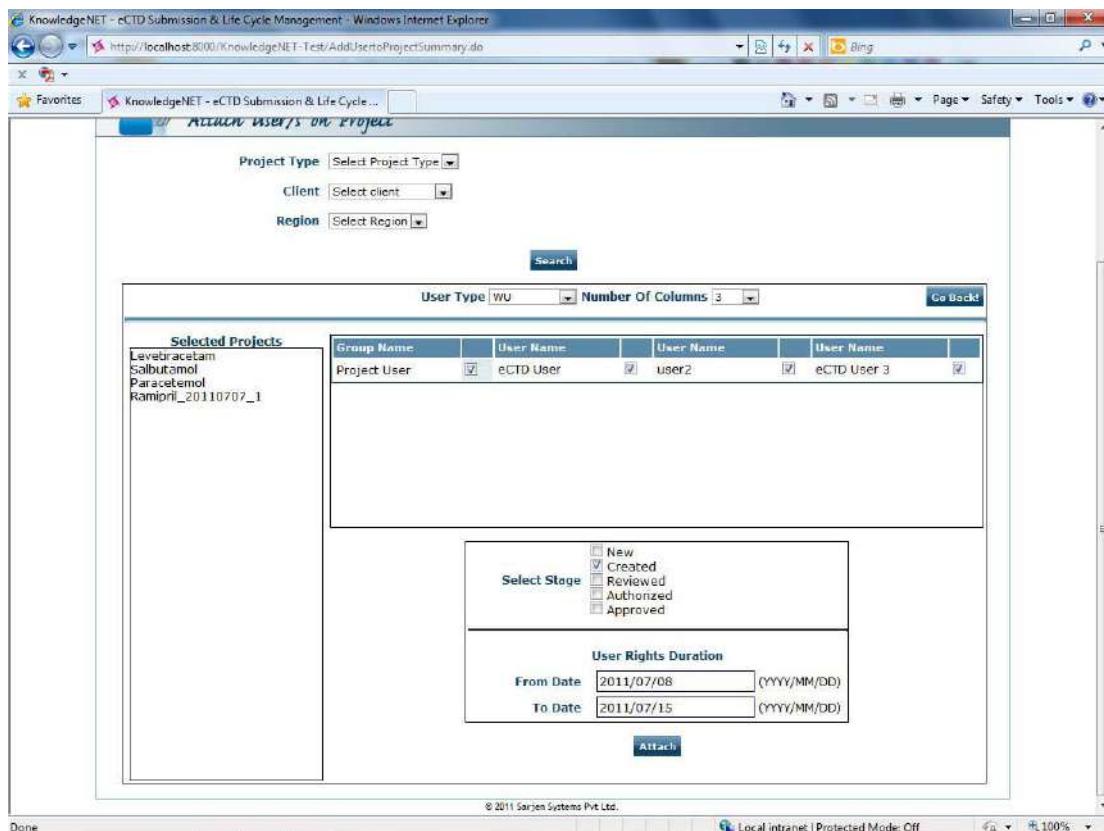


The screenshot shows a Firefox browser window displaying the KnowledgeNET eCTD Submission & Life Cycle Management Module. The URL in the address bar is 90.0.0.249:8000/KnowledgeNET-Demo-ECTD/AddUserToProjectForm.do?workspaceid=0007. The page title is "Attach User/s on Project". The top navigation bar includes links for Home, Master, Search, Project, Submission (which is highlighted with a red oval), Report, User, Utility, Logout, and a welcome message for "Hi, eCTD Admin". Below the navigation bar is a search bar labeled "User / Group" with a dropdown menu set to "Select User or UserGroup". There are date range fields for "From Date" (2014/04/11) and "To Date" (2014/04/12), and a checkbox group for "Stages" with "Created" checked and other options like "Reviewed", "Authorized", and "Approved" available. A "Remarks" text input field is present. At the bottom of the form area are "Attach User" and "Go Back!" buttons. Below the form is a table showing user attachments:

#	Project	User Group	User	From date	To Date	Modify On	Edit	Delete
1	Ascorbic-Acid	Project User	eCTD User	Jun-08-2011	Jul-27-2011	Jun-08-2011		
2	Ascorbic-Acid	Admin User group	eCTD Admin	May-31-2011	May-31-2061	May-31-2011		

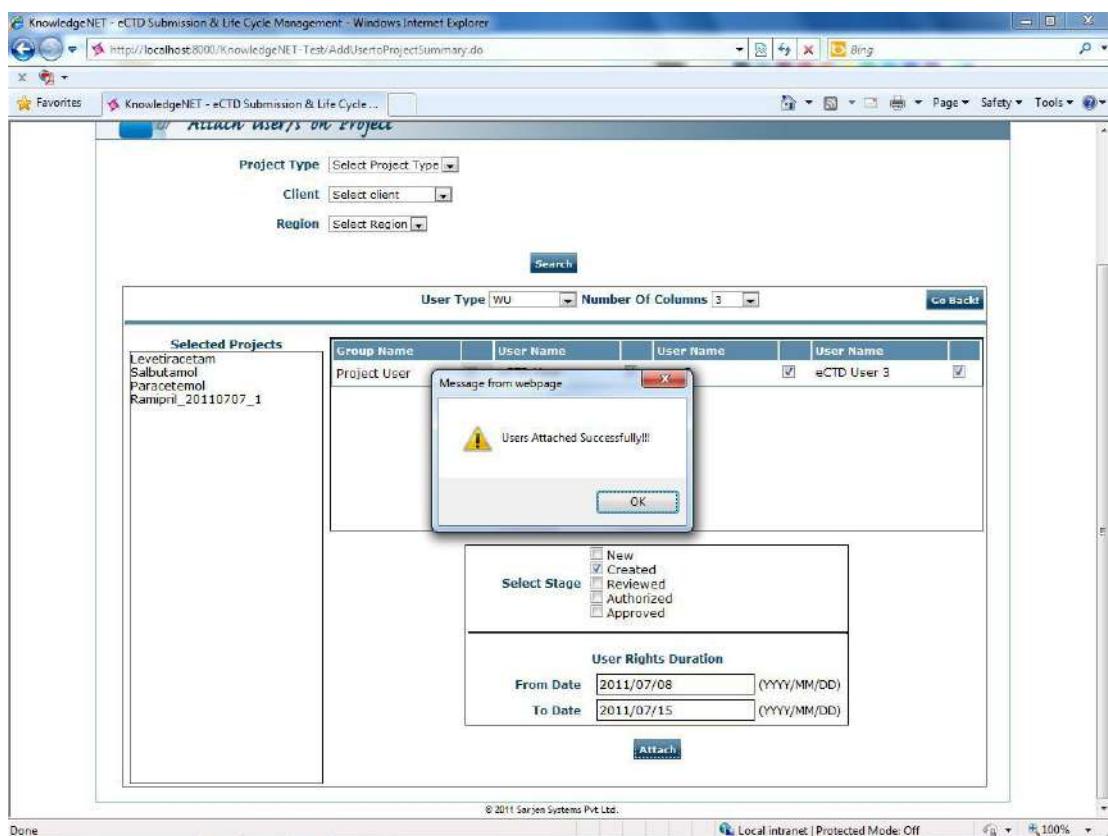
At the very bottom of the page, a small copyright notice reads "© 2011 Sejjen Systems Pvt Ltd."

- Select the “User Name”. Then select the stage and user rights duration and click on “Attach” button. The users will get attached on that project.

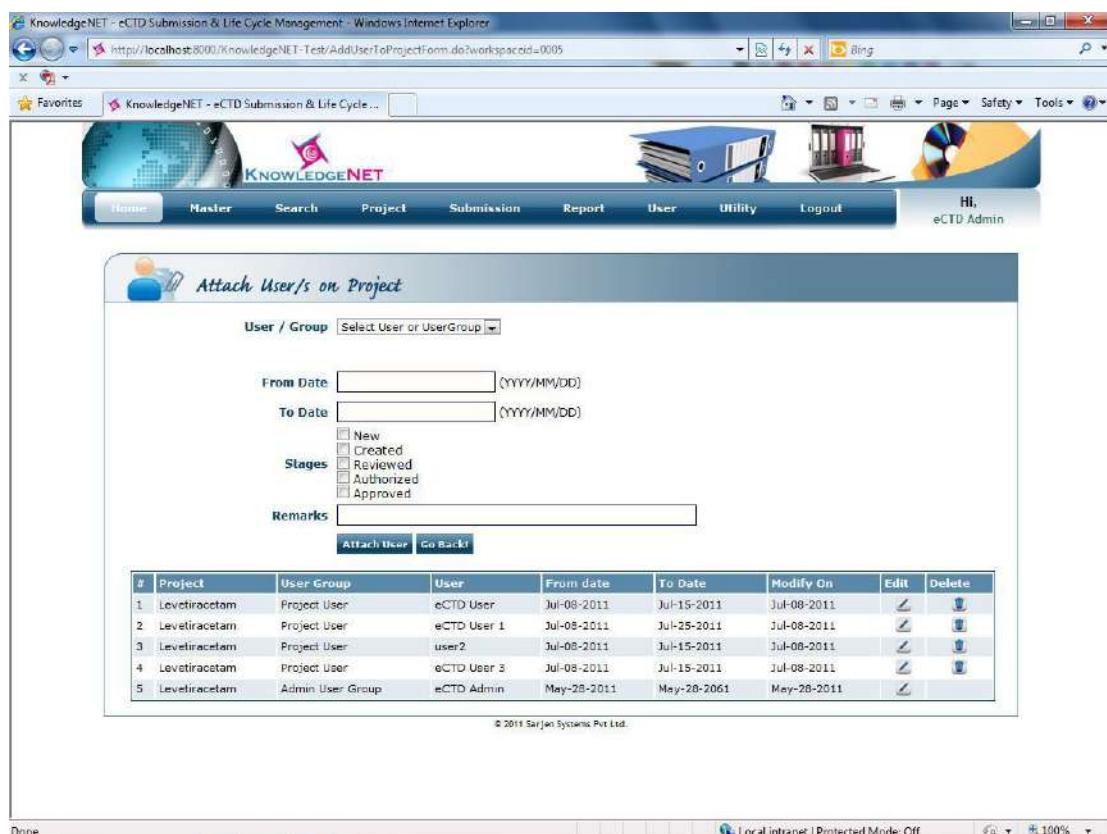


The screenshot shows a web-based application interface for managing users across projects. At the top, there are dropdown menus for 'Project Type', 'Client', and 'Region'. Below these are search and filter buttons ('Search', 'User Type: WU', 'Number Of Columns: 3'). A table titled 'Selected Projects' lists three entries: Levetiracetam, Salbutamol, and Paracetamol, each associated with a 'Project User' group. To the right of the table, a 'Select Stage' section includes checkboxes for 'New', 'Created' (which is checked), 'Reviewed', 'Authorized', and 'Approved'. Below this is a 'User Rights Duration' section with 'From Date' (2011/07/08) and 'To Date' (2011/07/15) fields. At the bottom right is a large blue 'Attach' button.

- A message will get displayed as shows in below screen.



- After attachment of multiple users in the project, grid will shows below.



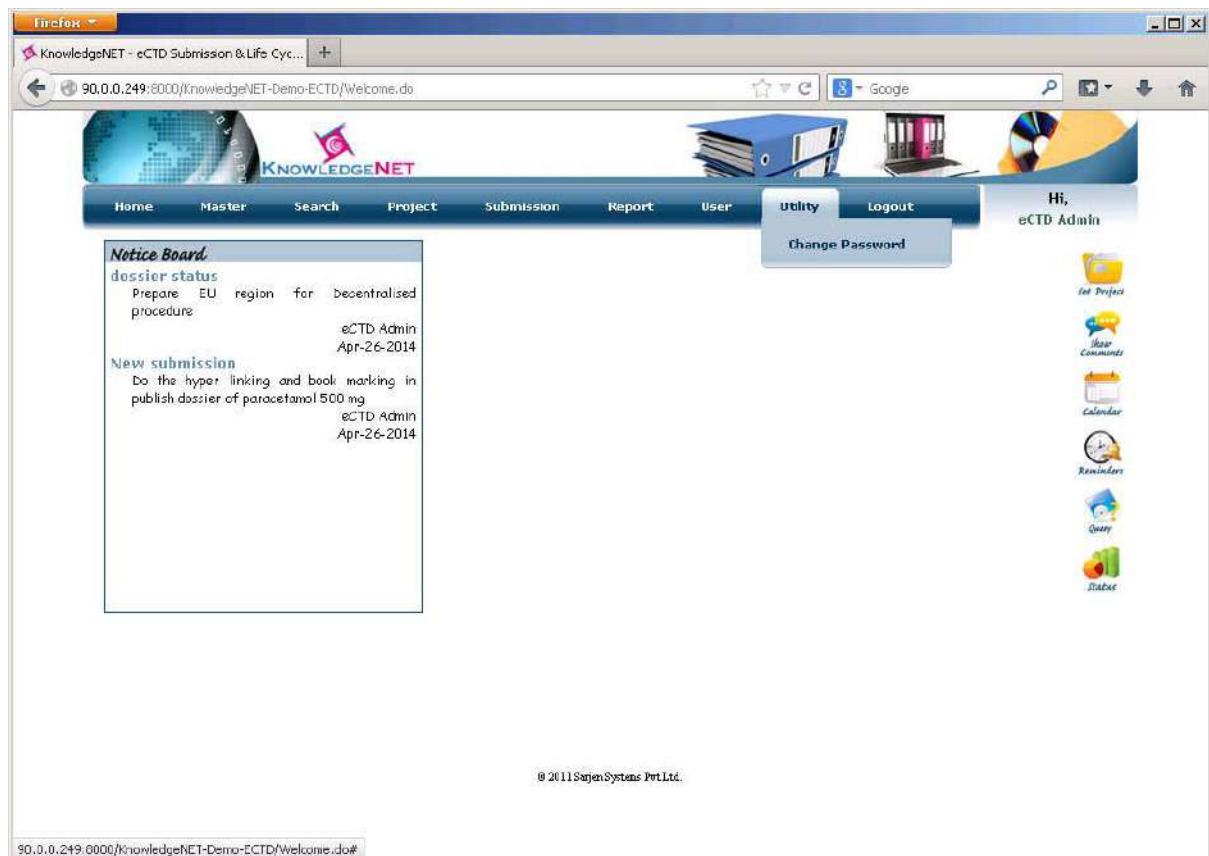
#	Project	User Group	User	From date	To Date	Modify On	Edit	Delete
1	Levetiracetam	Project User	eCTD User	Jul-08-2011	Jul-15-2011	Jul-08-2011		
2	Levetiracetam	Project User	eCTD User 1	Jul-08-2011	Jul-25-2011	Jul-08-2011		
3	Levetiracetam	Project User	user2	Jul-08-2011	Jul-15-2011	Jul-08-2011		
4	Levetiracetam	Project User	eCTD User 3	Jul-08-2011	Jul-15-2011	Jul-08-2011		
5	Levetiracetam	Admin User Group	eCTD Admin	May-28-2011	May-28-2061	May-28-2011		

Utility Menu

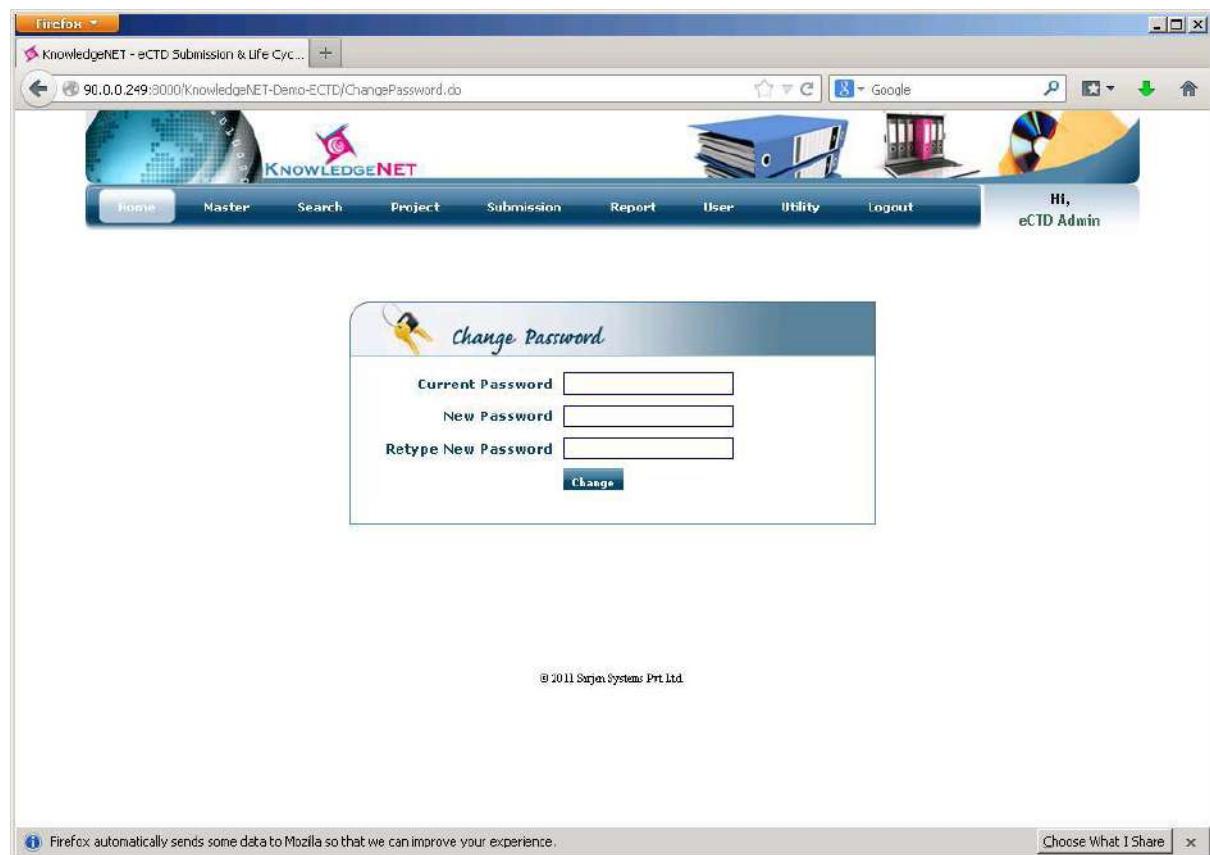
❖ User will be able to change his/her password through:

Utility >Change Password

- The below screen shows the Utility menu which has the submenu “Change Password” through which password can be changed.



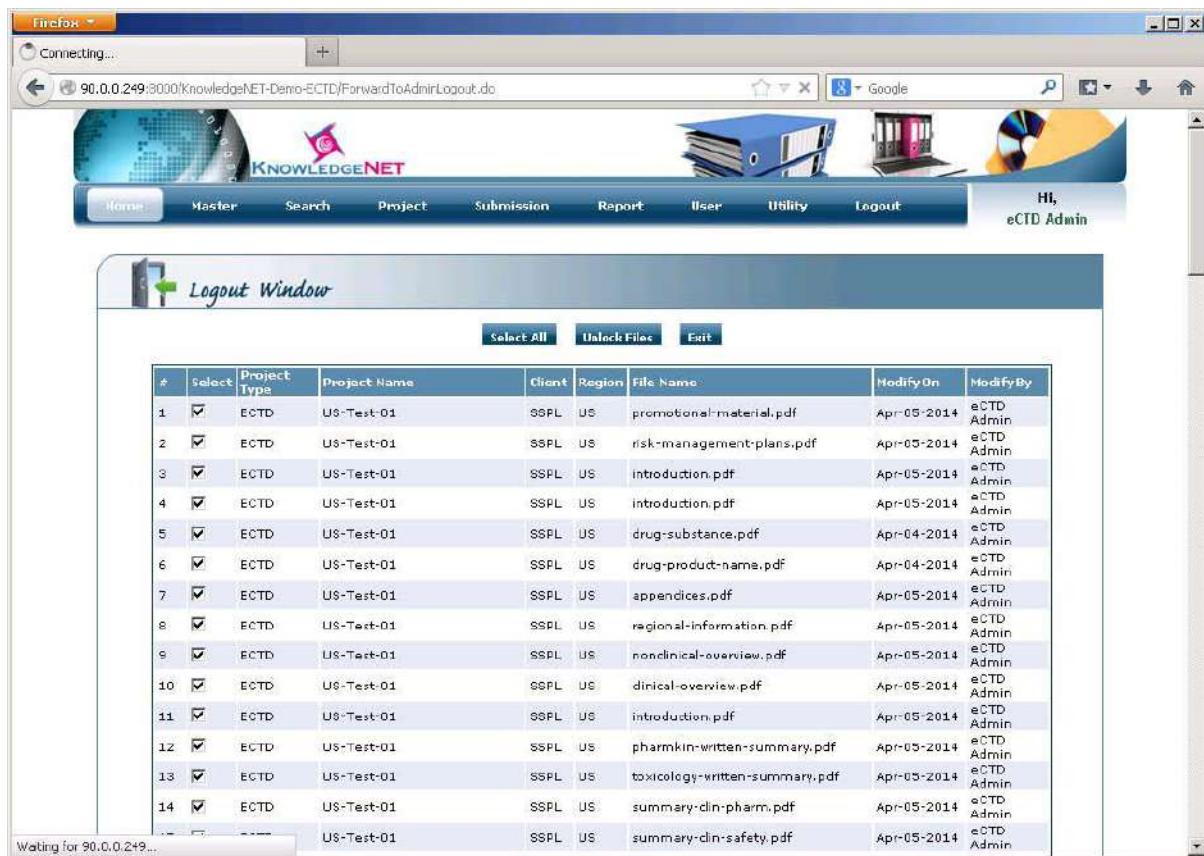
- On clicking "Change Password", it will display the below screen.
 - It will display user's current password.
 - To change current password, user have to enter new password in "New Password" and "Retype New Password" fields.
- On clicking "Change" button, password will be changed.



Logout Menu

User will be able to leave the application through Logout menu.

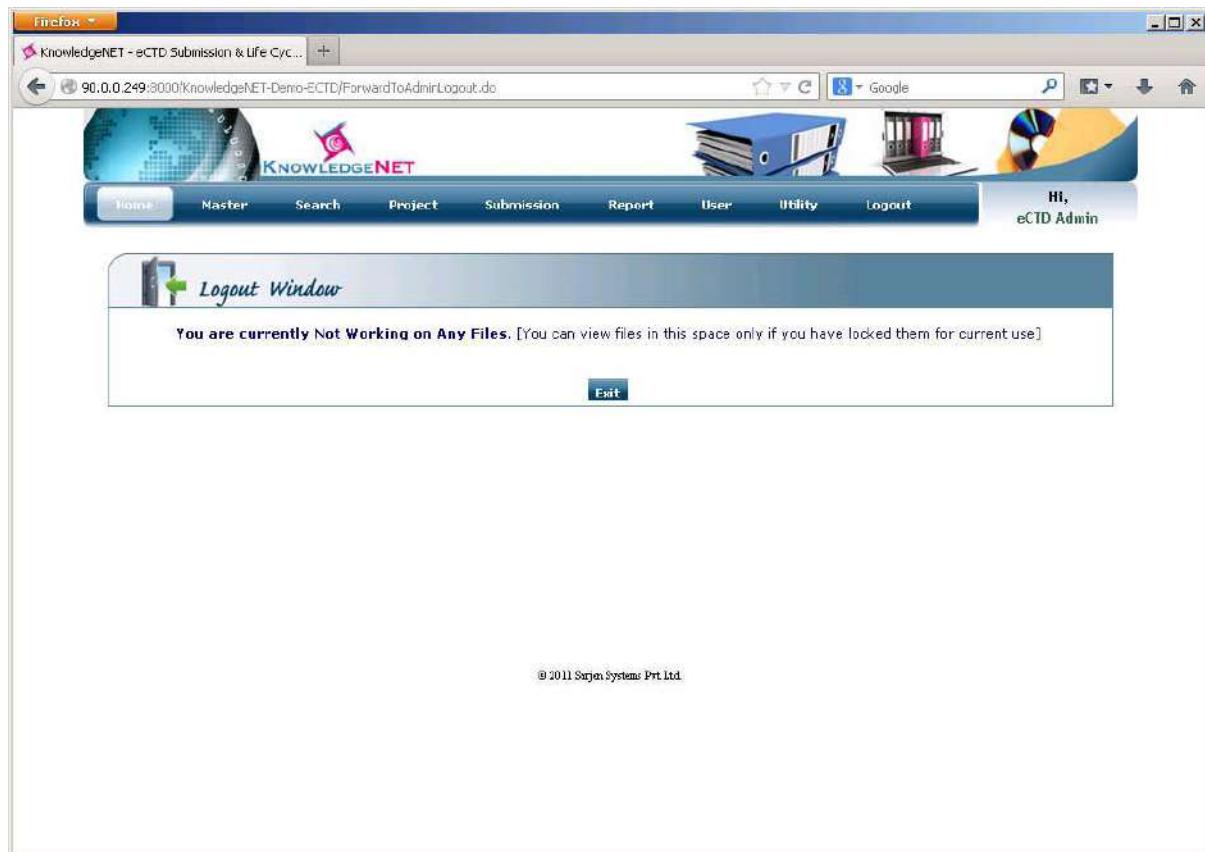
- On clicking “Logout”, it will display the logout window.
- If all files are unlocked, then the below screen will get displayed



#	Select	Project Type	Project Name	Client	Region	File Name	Modify On	Modify By
1	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	promotional-material.pdf	Apr-05-2014	eCTD Admin
2	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	risk-management-plans.pdf	Apr-05-2014	eCTD Admin
3	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	introduction.pdf	Apr-05-2014	eCTD Admin
4	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	introduction.pdf	Apr-05-2014	eCTD Admin
5	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	drug-substance.pdf	Apr-04-2014	eCTD Admin
6	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	drug-product-name.pdf	Apr-04-2014	eCTD Admin
7	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	appendices.pdf	Apr-05-2014	eCTD Admin
8	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	regional-information.pdf	Apr-05-2014	eCTD Admin
9	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	nonclinical-overview.pdf	Apr-05-2014	eCTD Admin
10	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	clinical-overview.pdf	Apr-05-2014	eCTD Admin
11	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	introduction.pdf	Apr-05-2014	eCTD Admin
12	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	pharmacokinetic-summary.pdf	Apr-05-2014	eCTD Admin
13	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	toxicology-written-summary.pdf	Apr-05-2014	eCTD Admin
14	<input checked="" type="checkbox"/>	ECTD	US-Test-01	SSPL	US	summary-clin-pharm.pdf	Apr-05-2014	eCTD Admin
						summary-clin-safety.pdf	Apr-05-2014	eCTD Admin

Waiting for 90.0.0.2+9...

- If all files are not unlocked below screen will get displayed. A message will appear as "if Admin is currently Not Working on Any Files".
- Click on "Exit" to exit from the application.
- **Note:** User will be able to unlock the locked files from the clicking "Select All" and then click on "Unlock Files" button.



On Clicking “Exit”:

- On clicking “Exit”, below screen will be displayed.

