RELOPO – RDC Links as Low Cost Portal

Problem

RDC 4.5.3 as a zero footprint application has made deployment in the field much easier. Besides the electronic data capture users have reporting needs, e.g. data managers want to see the overall study metrics, investigators want to see the status of their study site. In addition evaluation of medical images might require the plug-in of image loading and viewing applications. RDC links offer a convenient, however, immature mean to achieve this. Links cannot be made accessible depending on a user's role. By simply exchanging parameters in the URL users can access information they are not entitled to access. RELOPO refines RDC links to address these concerns and to facilitate deployment in real life. Finally RELOPO allows delivery of HTML reports based on the users' access rights maintained in RDC administration.

Solution

Users' links are modified to make them role specific (see below): data managers are entitled to see links with study and site scope, CRAs can see links with site scope, only. By default links can be used for studies and sites for which access has been granted in RDC admin, only.

Data Manager's links

Links
Patient Status/Summary Report for Study
Missing Pages Report for Study
Query/DCF Status Report for Study
Open Queries Report for Study
Annotated CRF
Patient Status/Summary Report for Site
Missing Pages Report for Site
Query/DCF Status Report for Site
Open Queries Report for Site

CRA's link

Links
Patient Status/Summary Report for Site
Missing Pages Report for Site
Query/DCF Status Report for Site
Open Queries Report for Site

By default an RDC link looks like https://www.relico-trials.net/links/link1?study=demo01&site=001. Everybody who knows the link could access the information. Adding a session_id like https://www.relico-trials.net/links/link1?study=demo01&site=001&session_id=123423 might prevent re-usage of the link. However, an investigator might guess that her/his peers' sites are named 002, 003, or 004 and

could by simply exchanging the site parameter in the URL gain access to data he is not entitled to access. Encryption of links plus adding an expiry period prevents fraud.

See below a Patient Status/Summary Report for Study.

Patient Status/Summary Report in study RELADI - Microsoft Internet Explorer

Patient Status/Summary Report in study RELADI at 18-SEP-2009 15:54

Site: BALTIMORE

PATIENT	VISIT 1	VISIT 2	VISIT 3
2001	PASS 1 COMPLETE		
2002			
2003			
2004			
Sum	1	0	0

Site: OFFENBACH

PATIENT	VISIT 1	VISIT 2	VISIT 3
1001	PASS 1 COMPLETE	BLANK	
1002	APPROVED	PASS 1 COMPLETE	
1003	VERIFIED		PASS 1 COMPLETE
1004	PASS 1 COMPLETE	LOCKED	
Sum	4	3	1

PATIENT	VISIT 1	VISIT 2	VISIT 3
Totals	5	3	1

Refreshing the link after one minute does not work any more. Due to the encryption of the URL (see ?p=CB0035… in the page header) modification of a parameter is almost impossible.

http://dkindler-de:7780/pls/relico02/reladi.d0001?p=CB00355AAAB610EAAF...

The display session has timed out, please requery in RDC, in RDC classic and PDF toggle between Summary and Links tabs

Integration with Excel

The report results can be easily copied from Internet Explorer to Excel for further processing, see below:

Mappe1

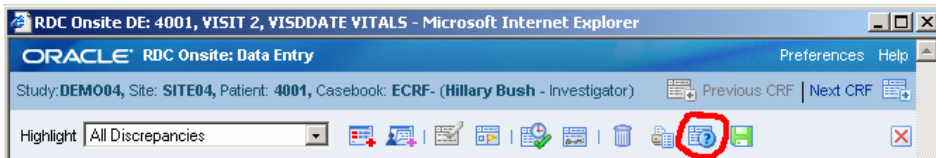|	A	B	C	D
1	PATIENT	VISIT 1	VISIT 2	VISIT 3
2	1001	PASS 1 COMPLETE	BLANK	
3	1002	APPROVED	PASS 1 COMPLETE	
4	1003	VERIFIED		PASS 1 COMPLETE
5	1004	PASS 1 COMPLETE	LOCKED	
6	Sum	4	3	1

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Distribution of Results

For documentation purposes the results can be saved as HTML files. The HTML files can be published through a web server or attached to e-mails.
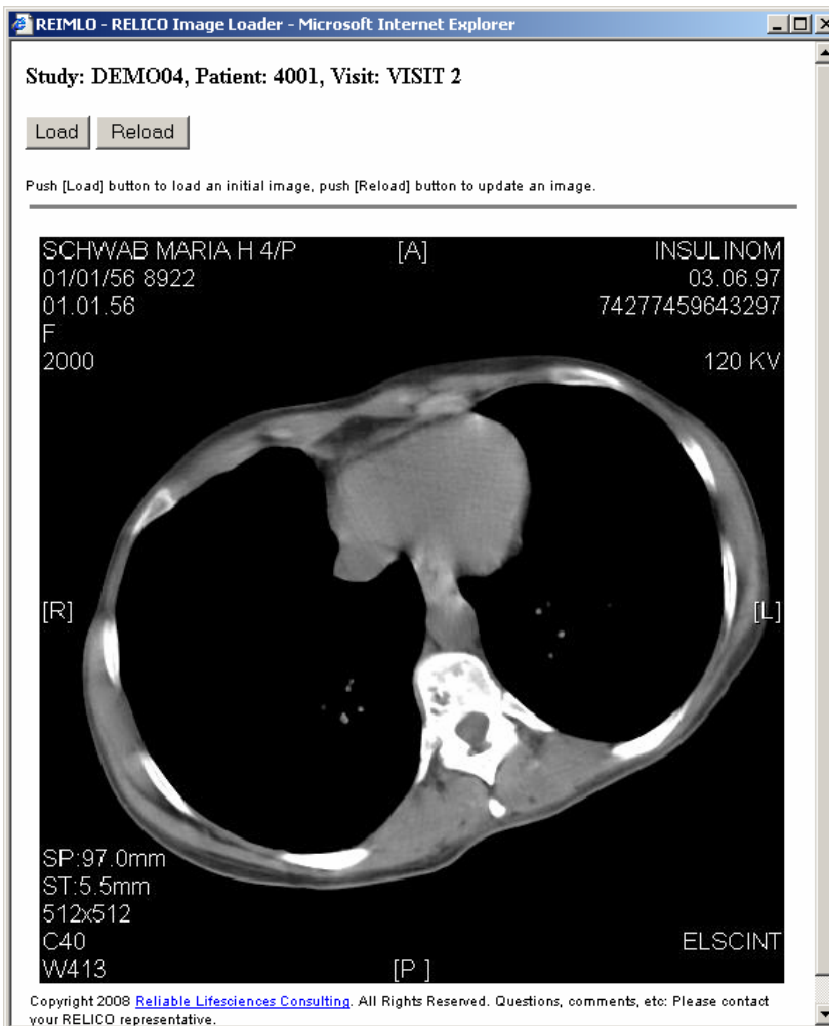

study_status.htm

Imaging

When clicking on the CRF link in RDC Onsite page specific information can be pulled up, e.g. an application to load and present images.

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Building of Reports

RELOPO includes reports and report templates that allow to build HTML reports using PL/SQL. Building a report encompasses two steps. The first step is provisioning a view on the data. The second step is the formatting in HTML. Provisioning of the data is accelerated by RELA(DI). RELA(DI) offers a stable layer of views on top of the stable Oracle Clinical table model to easily create ad-hoc queries against the clinical data. In addition RELA(DI) offers views against the trial plan and design and the trial conduct tables that already derive additional information for ad-hoc reports. RELA(DI) comes as set of views to be deployed with any ad-hoc reporting tool like RELOPO.

Offer

RELOPO is offered as a database schema for RDC 4.5.1, 4.5.3, and 4.6. RELOPO includes RELA(DI) as a set of pre-fabricated views against Oracle Clinical. RELOPA includes example reports. The offer includes documentation and manuals.

Current Customer Basis

- 1 mid-size CRO
- 1 large pharma

Pricing for RELOPO (including RELA(DI))

- €250 per OC user (includes base views and packages and sample reports)
- €50 per OC user annual maintenance and support fee
- customisation and implementation on a time and material basis

For more information please contact:

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