

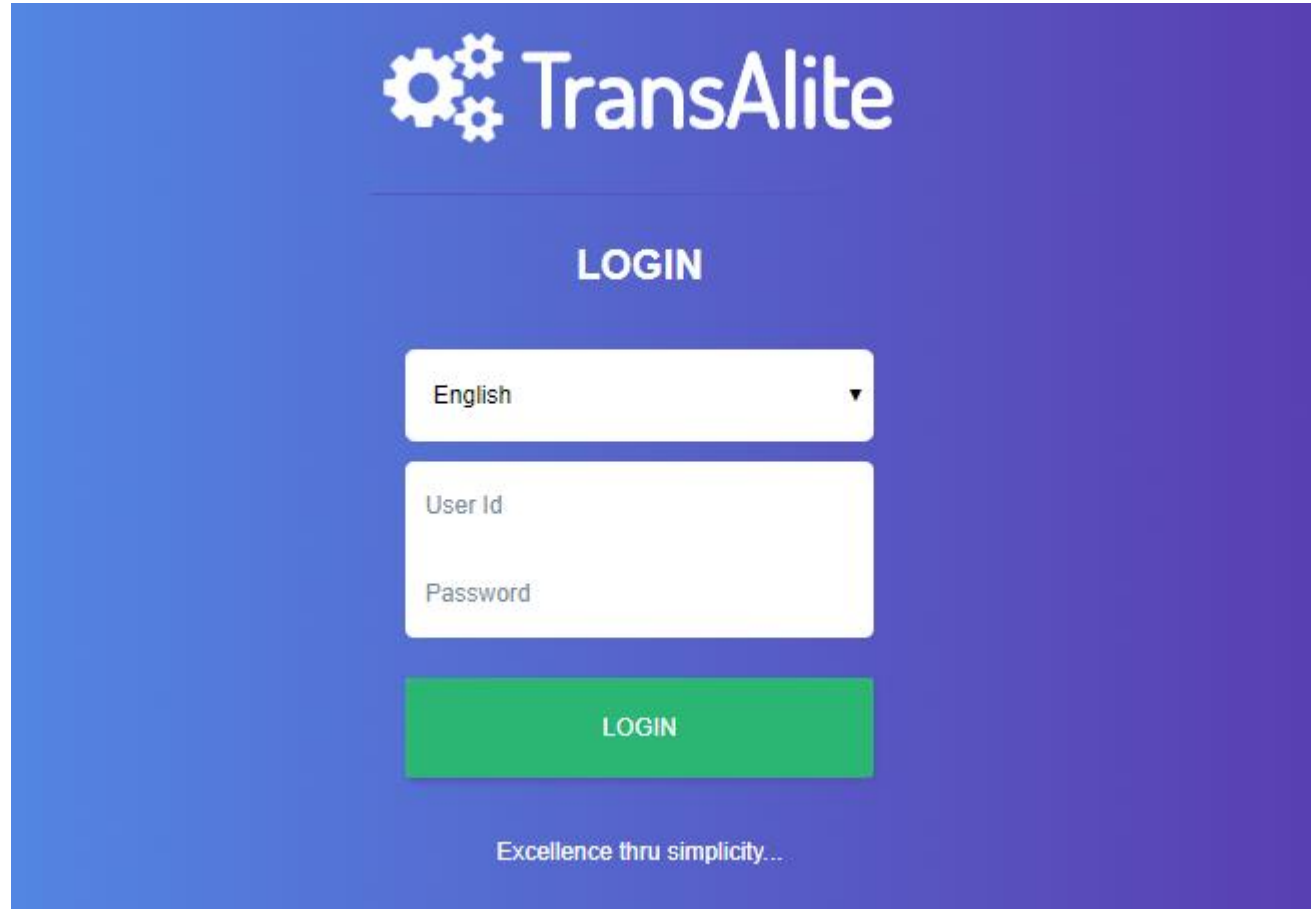


In collaboration with



# TransAlite Cloud

01-October-2017

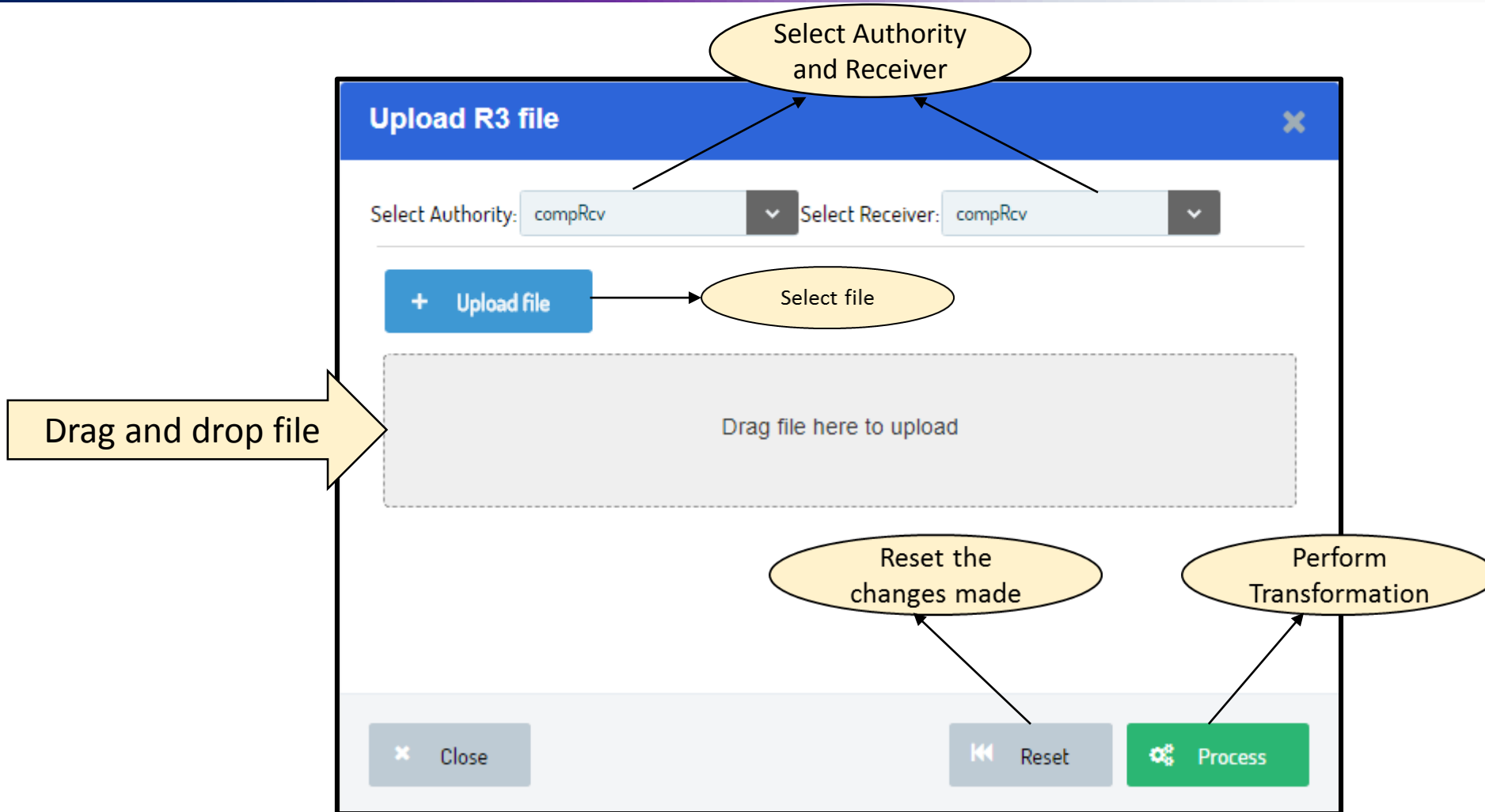


The image shows a login interface for TransAlite. At the top, there is a logo consisting of three interlocking gears followed by the text "TransAlite". Below the logo, the word "LOGIN" is centered. The interface contains a language selection dropdown menu currently set to "English". Below this are two stacked input fields for "User Id" and "Password". A green "LOGIN" button is positioned below the input fields. At the bottom of the interface, the slogan "Excellence thru simplicity..." is displayed.



The screenshot shows the TransAlite web application interface. The top navigation bar is blue and purple, containing the following elements from left to right: a gear icon labeled 'TransAlite', a cloud icon labeled 'Cloud Transformation', a book icon labeled 'Library', a user profile icon labeled 'user123', and a 'Log Out' button. Below the navigation bar, three yellow ovals with black outlines are positioned: 'Link to Quick Transformation' (with an arrow pointing to the 'Cloud Transformation' menu item), 'Link to Library' (with an arrow pointing to the 'Library' menu item), and 'Exit Application' (with an arrow pointing to the 'Log Out' button). In the center of the page, there is a cloud icon with an upward arrow, followed by the text 'Quick R3 Transformation !' and 'Simple,fast and seamless'. Below this text is a green button labeled 'Upload R3'. An arrow points from the 'Upload R3' button to a yellow oval labeled 'Initiate R3 Transformation'. At the bottom left of the page, there is a copyright notice: '© Copyright 2016 AliteWARE Solutions. All rights reserved.'

# Upload



# Analyze (1)..



File, Cases, Summary and downloads

Exit from Cloud

Summary

Log Details

View all Attachments and Downloads

Download individual R2(Case)

Download all in zip package

Summary

General Comparison reports

Logs Finish

Summary

File Name: 1a. EEA SUSAR-patient-death.xml Authority: compRcv  
Case#: 1 Receiver unit: compRcv

Files

Case Level Batch Files

1a. EEA SUSAR-patient-death.xml R2 1a. EEA SUSAR-patient-death.xml

Case Files			Safety Report Id (Ver)	Receiver	Drugs	Events
R2	Attach.	Zip	Report type	Authority		
			SE-EMA-R3-TESTCASE01 Report from Study	compRcv compRcv	Calpol. Spare drug	Massive coronary

Note: Red color indicates serious case



General Comparison reports

**Summary**

File Name: .xml Authority: Receiver unit:

Case# :

**Files**

[Complete Batch File](#) [Case Level Batch Files](#)

[la\\_EEA SUSAR-patient-death.xml](#) [R2\\_la\\_EEA SUSAR-patient-death.xml](#)

**Case(s) :**

**Download Batch;**

- R2 (Batch – Single)
- Consolidated Report
- All attachment separated in folders by Safety report Id

**Download Individuals;**

- Contains folder for each Case
- Every Folder contains;
  - R2 file for case
  - Respective attachments
  - Comparison reports

**Original(uploaded) R3 File**

**Transformed(complete) R2 File**

Case files			Safety Report Id (Ver)	Receiver	Drugs	Events
R2	Attach.	Zip	Report type	Authority		
			SE-EMA-R3-TESTCASE01 Report from Study	compRcv compRcv	Calpol, Spare drug	Massive coronary

5 << < (1 of 1) > >>

# Complete Batch file



General
Comparison reports
Logs
Finish

**Summary**

File Name:	1a. EEA SUSAR-patient-death.xml	Authority:	compRcv
Case# :	1	Receiver unit:	compRcv

**Files**

[Complete Batch File](#)

[Case Level Batch Files](#)

[1a. EEA SUSAR-patient-death.xml](#)

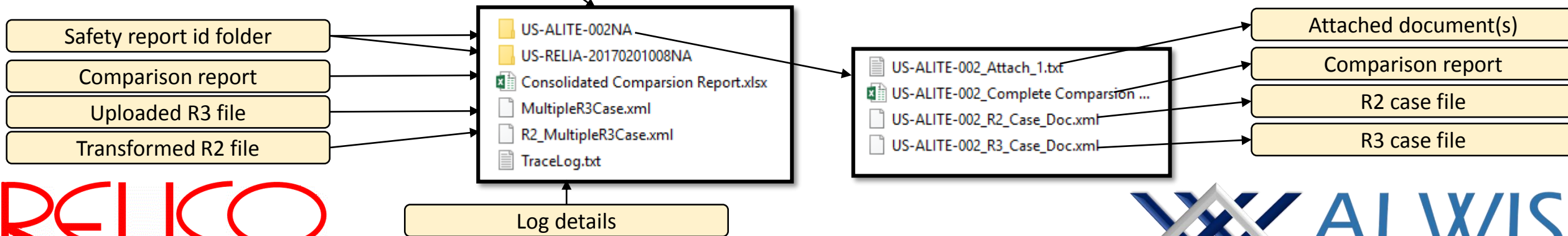
[R2\\_1a. EEA SUSAR-patient-death.xml](#)

**Case(s) :**

5 << < (1 of 1) > >>

Case files			Safety Report Id (Ver)	Receiver	Drugs	Events
R2	Attach.	Zip	Report type	Authority		
			SE-EMA-R3-TESTCASE01 Report from Study	compRcv compRcv	Calpol. Spare drug	Massive coronary

5 << < (1 of 1) > >>





# Case Level Batch file



General Comparison reports Logs Finish

**Summary**

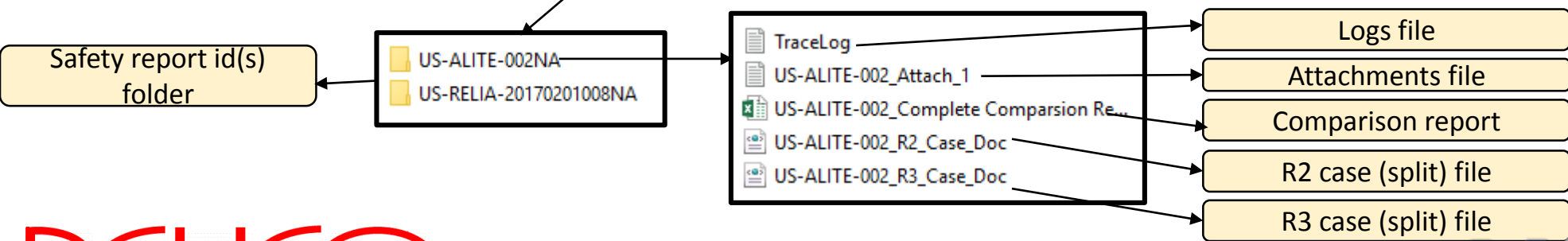
File Name: 1a. EEA SUSAR-patient-death.xml Authority: compRcv  
 Case#: 1 Receiver unit: compRcv

**Files**

[Complete Batch File](#) [Case Level Batch Files](#)  
[1a. EEA SUSAR-patient-death.xml](#) [R2. 1a. EEA SUSAR-patient-death.xml](#)

**Case(s) :**

Case files			Safety Report Id (Ver)	Receiver	Drugs	Events
R2	Attach.	Zip	Report type	Authority		
			SE-EMA-R3-TESTCASE01 Report from Study	compRcv compRcv	Calpol. Spare drug	Massive coronary





# Comparison Reports



Labels from  
for easy  
identification

General Comparison reports

View Download Case

R2 Block Data R3 Block

Missing Tags Appended to Narrative Truncation Occurred

Label	R2 Block Tag	Value	R3 Tag	Truncated Data
▼ ICHICSR Message Header	M.1:<ichicsrmessageheader>		N.1:<MCCI_IN200100UV01>	
Message Type	M.1.1:<messagetype>	ichicsr	N.1.1:<MCCI_IN200100UV01>	
Message Format Version	M.1.2:<messageformatversion>	2.1	N.1.1:<messageformatversion>	
Message Format Release	M.1.3:<messageformatrelease>	2.0	N.1.1:<messageformatrelease>	
Message Number	M.1.4:<messagenumb>		N.1.2:<id>	
Message Sender Identifier	M.1.5:<messagesenderidentifier>	MAHAUDIT1	N.1.3:<sender><device><id>	
Message Receiver Identifier	M.1.6:<messagereceiveridentifier>	EVTEST	N.1.4:<receiver><device><id><exten>	
Message Date Format	M.1.7a:<messagedateformat>	204 - (CCYYMMDDHHMMSS)	NA	
Message Date	M.1.7b:<messagedate>	20170524134234	N.1.5:<creationTime>	

S A T

Truncated Data

# Comparison Reports... (Linking)



Drug	B.4.<drug>	
Drug Characterization	B.4.k.1:<drugcharacterization>	
Substance / Specified Subst	NA	---
Medicinal Product	B.4.k.2.1:<medicinalproduct>	218901001 (1.01): CALPOL ... <a href="#">more</a>

Parent Drug

Provides reference of parent record

Active Substance (within Drug)

Active Substance	B.4.k.2.2:<activesubstance>		G.k.2.3.r.1
Active Substance Name	B.4.k.2.2:<activesubstancename>	TERMID: 568874 (1.52): AD... <a href="#">more</a>	G.k.2.3.r.1
Drug Reaction Relatedness	B.4.k.18:<drugreactionrelatedness>		G.k.9.i
Drug Reaction Asses MedC	B.4.k.18.1a:<drugreactionassesmeddravers>	18.0	NA
Drug Reaction Asses	B.4.k.18.1b:<drugreactionasses>	10037844	G.k.9.i.1
Drug Assessment Source	B.4.k.18.2:<drugassessmentsource>	Renorder	G.k.9.i.2.r.1

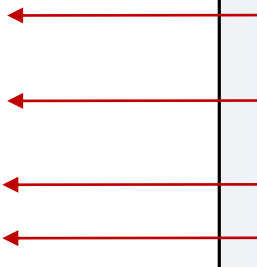
[Medicinal Product - 218901001 (1.01): CALPOL CIPLA NICIP PLUS ESOPHAGEAL ASPIRIN COLD ...] TERMID: 568874 (1.52): ADALIMUMAB KRORIANO INFANCAOCHIANO GOTAKOM OGTAKO MOBALICANO HODOLIVOCO KARINO FASINO MARICANIIIIIO..... HOCIKANO HHHHOEAWFD,

# Comparison Reports...



Line Breaks  
between fields  
appended in  
Narratives for  
better reading

Summary	B.5:<summary>		H
Narrative Include Clinical	B.5.1:<narrativeincludeclinical>	This is a Narrative :If y... <a href="#">more</a>	H.1
		This is a Narrative :If you are allergic to any ingredient in rivastigmine or to carbamate derivatives (eg, meprobamate), you have had a skin reaction to the patch form of rivastigmine in the past and you have not had a negative allergy test you are taking another form of rivastigmine (eg, patch, solution) or another cholinesterase inhibitor (eg, donepezil)	H.1
		ADDITIONAL DOCUMENTS: Source of this Case Safety Report in E2B(R3) Format: Additional documents: ; Sample Autopsy Report; document #1 held by sender; document #2 held by sender	H.3.r
		STUDY NAME: 2010-018231-18#SE-SE-28234345: Pippi's interventional study of Mr Nilsson intervention all over USA studied by The authority of the FDA and EMA authority partners	H.2
		SPONSOR STUDY NUMBER: PMN1 POPAPOTASONA MINICA3 NOTACHA3453256776	H.3.r.1a
		DRUG: 218901001 (1 01): CAI POL CIPI A NICIP PLUS ESOPHAGEAL ASPIRIN COLD ACT DOI POR	

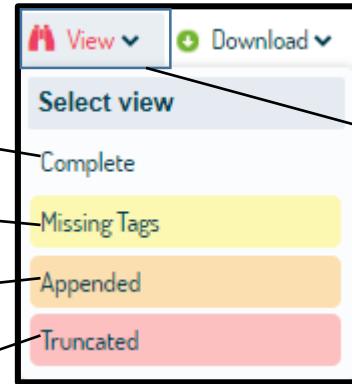


# Analyze (Views)...



## Filter based on Selection

- All tags
- Tags which are available in R3 but no in R2
- Tags where data appends to Narrative
- Data is truncated but not appended in Narrative



Views panel

Label	R2 Block Tag	Value
ICHCSR Message Header	M.1:<ichicsrmessageheader>	
Message Type	M.1.1:<messagetype>	ichicsr
Message Format Version	M.1.2:<messageformatversion>	2.1
Message Format Release	M.1.3:<messageformatrelease>	2.0
Message Number	M.1.4:<messagenumb>	
Message Sender Identifier	M.1.5:<messagesenderidentifier>	MAHAUDIT1

# Analyze (Downloads)...



Label	R2 Block Tag	Value
ICHICSR Message Header	M.1:<ichicsrmessageheader>	
Message Type	M.1.1:<messagetype>	ichicsr
Message Format Version	M.1.2:<messageformatversion>	2.1
Message Format Release	M.1.3:<messageformatrelease>	2.0
Message Number	M.1.4:<messagenumb>	
Message Sender Identifier	M.1.5:<messagesenderidentifier>	MAHAUDIT1

## Download Comparison reports on selection

- All tags
- Tags available in R3 but not in R2
- Tags where data appends to Narrative
- Data is truncated but not appended in Narrative

Download Case

Select download

- Complete
- Missing Tags
- Appended
- Truncated

# Analyze (Case wise)..



View Download Case

Label	R2 Block Tag	Value
ICHICSR Message Header	M.1:<ichicsrmessageheader>	
Message Type	M.1.1:<messagetype>	ichicsr
Message Format Version	M.1.2:<messageformatversion>	2.1
Message Format Release	M.1.3:<messageformatrelease>	2.0
Message Number	M.1.4:<messagenumb>	
Message Sender Identifier	M.1.5:<messagesenderidentifier>	MAHAUDIT1

Select Different cases to view and analyze individually

Case

Select Case

- US-ALITE-002
- US-RELIA-20170201008



# Logs



Logs Finish

S A T

Operation summary

### Log Details

File name: **MultipleR3Case.xml** Message #: **100005**  
Additional Info: **2 Case(s).** Status: **Successfull!**  
Start time: **2017-07-25 17:52:33.603** End time: **2017-07-25 17:52:38.49**

#### Remarks

Successfull!

Status	Step Name	Start Time	End Time	Remarks
👍	Verification of path of tool:	2017-07-25 17:52:33.606	2017-07-25 17:52:33.606	BFCTool.bat found!
👍	Verification of path of XSL files:	2017-07-25 17:52:33.606	2017-07-25 17:52:33.606	XSL files found!
👍	Execute Command	2017-07-25 17:52:33.607	2017-07-25 17:52:33.609	Successfully executed
👍	R2 File created	2017-07-25 17:52:34.347	2017-07-25 17:52:34.347	C:\Users\admin\Desktop\Alite\A folders\CONVERSION_FILES_FOLDER\1233315866.xml
👍	Conversion execution	2017-07-25 17:52:34.347	2017-07-25 17:52:34.347	Conversion completed
👍	Parsing file	2017-07-25 17:52:34.393	2017-07-25 17:52:36.066	Parsing & normalizing completed

Status

Step by step details



# Library/ Company Unit



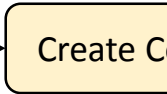
COMPANY UNIT							+ Create
<input type="checkbox"/>	Company Unit Id	Company Interchange Id	Company Name	Department	Email Id	Company Type	
<input type="checkbox"/>	<a href="#">343434343</a>	3232366	FDA	PHARMA	info@gmail.com	Authority	
<input type="checkbox"/>	<a href="#">756565464</a>	8787655554	EMA	PHARMA	info@gmail.com	Partner	



Company Unit Id:	<input type="text" value="Company Unit Id"/>	Interchange Id:	<input type="text" value="Interchange Id"/>
Company Name:	<input type="text" value="Company Name"/>	Company Type:	<input type="text" value="Authority"/>
Unit Type:	<input type="text" value="Receiver"/>	Encoding Type:	<input type="text" value="UTF-8"/>
Department:	<input type="text" value="Department"/>	Email Id:	<input type="text" value="Email Id"/>
Fax:	<input type="text" value="Fax"/>	Address:	<input type="text" value="Address"/>
Export To Outbound:	<input type="text" value="Only XML Files"/>		

Specify Folder

Default Outbound  Specify Outbound



Create C

# Security/ Users



APPLICATION USERS								
		Lock	Unlock	Clear	Advance filter	Create		
5 (1 of 1)								
<input type="checkbox"/>	Id	AppUser Id	First Name	Last Name	Email Id	Company Unit	Created By	Lock Status
<input type="checkbox"/>	101088	Rock22	Rock	Mno	rock@gmail.com	compRcv	Admin	Active
<input type="checkbox"/>	101070	Adam11	Adam	Abc	adam@gmail.com	compRcv	Admin	Active

L

### CREATE USER

App User Id*	<input type="text" value="App User Id"/>	User First Name*	<input type="text" value="First Name"/>
User Last Name	<input type="text" value="Last Name"/>	App Email Id*	<input type="text" value="App Email Id"/>
Password*	<input type="text" value="App Password"/>	Company Unit	<input type="text" value="compRcv"/>
TelePhone	<input type="text" value="Phone"/>	Address	<input type="text" value="Address"/>

<input type="text" value="Search"/>	<input type="text" value="Search"/>
<b>Yet To Assign</b>	<b>Assigned</b>
<input type="checkbox"/> Admin <input type="checkbox"/> Role123	

Create

# Library/ Transform Node



TRANSFORMATION LIBRARY								Clear	Advance filter				
								15	<<	<	(1 of 23)	>	>>
<input type="checkbox"/>	Label	R2 Tag	R2 Length	R3 Length	R2 XPath	R3 XPath	Code List Id						
<input type="checkbox"/>	<a href="#">ICHCSR Message Header</a>	ichicsrmessageheader	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Ichicsr</a>	ichicsr	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Type</a>	messagetype	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Format Version</a>	messageformatversion	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Format Release</a>	messageformatrelease	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Number</a>	messagenumb	100	100	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Sender Identifier</a>	messagesenderidentifier	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Receiver Identifier</a>	messagereceiveridentifier	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Message Date Format</a>	messagedateformat	0	0	r2XPath	r3XPath	7013						
<input type="checkbox"/>	<a href="#">Message Date</a>	messagedate	0	0	r2XPath	r3XPath							
<input type="checkbox"/>	<a href="#">Identification of the Case Safety Report</a>	safetyreport	0	0	r2XPath	r3XPath							

**Thank you!**