

Project N°115632 – WEB-RADR

**WEB-RADR Portal
Configuration**

**WP3A – Mobile Reporting
Platform**

**D3A.8: Instruction manual and online portal for adoption by
additional Member States**

Portal Configuration Documentation

Lead contributor	Manpreet Hare – AMGEN Mhare01@amgen.com
Other contributors	

Due date	29/09/2017
Delivery date	01/09/2017
Deliverable type	Documentation
Dissemination level	Public

Description of Work	Version	Date
	V1.0	01/09/2017

Document History

Version	Date	Description
V1.0	01/09/2017	New document



CONFIGURATION DOCUMENT

ABOUT THIS DOCUMENT	3
Target audience	3
Definitions and abbreviations	3
References	4
Related Documents	4
BACKGROUND	4
Purpose and Scope	4
WEB-RADR CONFIGURATION PORTAL	5
Login / Security	5
Pre-requisite	5
Logging into the Portal	5
Security	6
App Selection	6
Settings	6
RSS	7
Professions	7
Translations	8
Reports	8

ABOUT THIS DOCUMENT

TARGET AUDIENCE

This document, “WEB-RADR Configuration Document,” is intended to serve as a guide for the National Competent Authorities who wish to customize the global settings to their WEB-RADR app.

DEFINITIONS AND ABBREVIATIONS

Terminology	Description
API	Application Programming Interface
EHR	Electronic Health Record
GUID	Globally Unique Identifier
HTTP	Hyper Text Transfer Protocol
ICSR	Individual Case Safety Report
IMI	Innovative Medicines Initiative
JSON	JavaScript Object Notation - Data transfer format
OTS	Off-the-shelf
REST	Representational state transfer
URL	Uniform Resource Locator
XML	eXtensible Markup Language – Data transfer format
NCA	National Competent Authority
Halmed	Croatia NCA; name of Croatian mobile app
Lareb	Netherlands Pharmacovigilance Centre Lareb working for the MEB (Dutch Medicines Evaluation Board)
Bijwerking	Name of the Dutch version of the WEB RADR app
Yellow Card	Name of the UK version of the Web RADR app
MHRA	Medicines & Healthcare Products Regulatory Agency, UK NCA
VigiFlow	An ICSR management system maintained by WHO designed for use by participating member states enrolled under WHO’s international drug monitoring program.
VigiAccess	A WHO database that enables users to browse and view data on suspected adverse drug reactions from various medicinal products
WHO	World Health Organization
ADR	Adverse Drug Reaction
Database Management	The process of acquiring, sorting, cataloging, retrieving, deleting and securing data
HCP	Healthcare Professional
AWS	Amazon Web Services
HTTPS	Hypertext Transfer Protocol (Secure) – a protocol for secure communication over a computer network which is widely used on the Internet. HTTPS consists of communication over Hypertext Transfer Protocol (HTTP) within a connection encrypted by Transport Layer Security or its predecessor, Secure Sockets Layer
XML	Extensible Markup Language – a markup language that defines a set of rules for encoding documents in a format which is both human-readable and machine-readable
SOAP	Simple Object Access Protocol – a protocol specification for exchanging structured information in the implementation of web services in computer networks

REFERENCES

Ref No	Name	URL/Document Id
1.	API URL	<i>Provided by the authority</i>
2.	WEB-RADR project homepage	http://web-radr.eu/
3.	WEB-RADR mobile reporting API authority configurations	01-15-001

RELATED DOCUMENTS

Document Type	Document Title
App Overview	WEB-RADR App Overview Document
App Design	WEB-RADR App Design Document
App Testing	WEB-RADR App Test Scenario
Appendix Document	WEB-RADR App Appendix Document

BACKGROUND

WEB-RADR is a three-year, EU-based project (funded through IMI) dedicated to developing and evaluating digital tools to support pharmacovigilance activities. It arose in response to the ninth call for IMI projects “WEBAE – Leveraging Emerging Technology for Pharmacovigilance”, and is based on the belief that modern pharmacovigilance practices should adapt to these new ways of communicating.

For an in-depth description of the WEB-RADR project and details of all the work-packages, see the WEB-RADR web site (ref **Error! Reference source not found.**).

One of the tools being developed within WEB-RADR is a mobile app designed for patients and healthcare professionals to learn about drug safety news from their local national competent authorities (NCAs) and to report suspected adverse drug reactions (ADRs). The mobile app has been piloted in the United Kingdom, Netherlands, and Croatia, and a generic version of the app has been developed for use by additional NCAs who are interested in facilitating communication of medical product safety information to and from the public (healthcare providers [HCPs] or consumers).

PURPOSE AND SCOPE

This document is intended to support and instruct NCAs on how to configure the WEB-RADR app settings at the local country level within the WEB-RADR portal.

The scope of this document will discuss the features and functionalities available for the WEB-RADR portal configuration. The following areas in the portal login will be discussed:

1. Login / Security
2. App selection
3. Settings
4. RSS
5. Professions
6. Translations

WEB-RADR CONFIGURATION PORTAL**LOGIN / SECURITY****PRE-REQUISITE**

A pre-requisite to get access to the WEB-RADR portal is to contact the site administrator. Only NCA's should be granted access who have the privileges to make customization to their app at a global level. The consequence of making a change in the portal will mean all the apps downloaded by the users will have the latest update. The changes work in real-time.

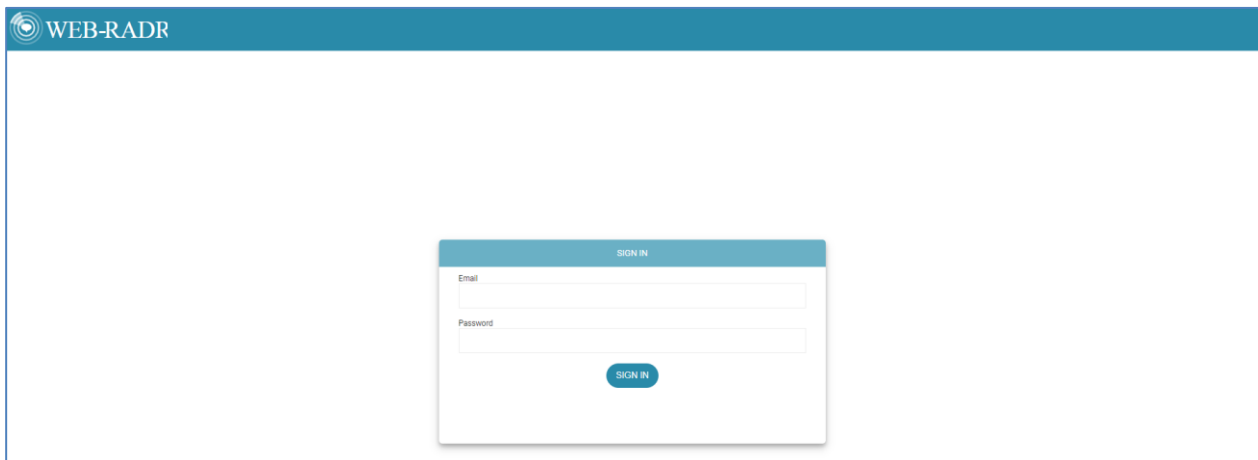
Once the site administrator has provided the user access, they will receive an email from 'Meteor Accounts – noreply@apidemico.com' asking them to click on a link where they will need to enter a new password. Once they have done this, the user is automatically logged into the portal for the first time. At the browser level, they will be prompted to save password or not.

The supported browsers to be used to access WEB-RADR portal in Production as of August 2017 will be: Google Chrome, Internet Explorer and Mozilla Firefox.

LOGGING INTO THE PORTAL

The link provided in the email is the WEB-RADR portal page. This sites URL is <https://dev-imi.epidemi.co/#>

The user will be required to enter their email and password if the password has not been saved locally on the browser settings. Should any instance the user forget there password or have an access request for another login, they will need to contact the WEB-RADR site administrator.



SECURITY

If the user has 3 number of unsuccessful attempts, the user will be locked out of there account. They would need to contact the site admin to get there account enabled.

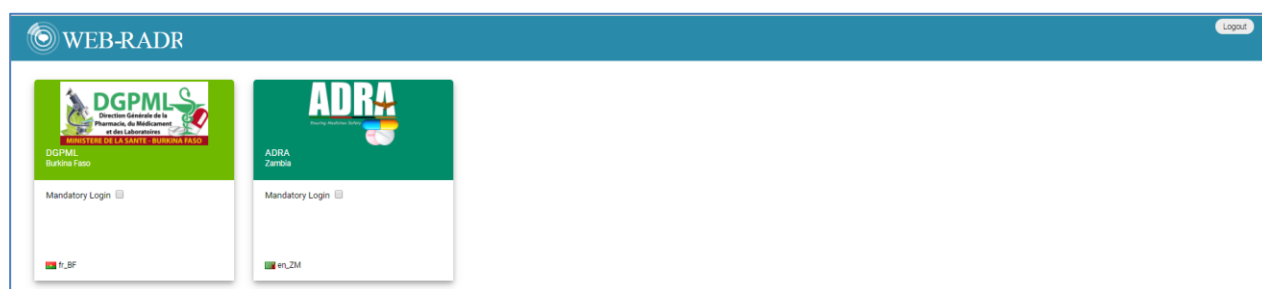
APP SELECTION

Once the user has successfully logged in, they will enter the 'main' portal screen. In this screen, they can select the country based on their privileges. Based on their privileges, only the relevant countries using the WEB-RADR app can be viewed.

The user will need to select one of the WEB-RADR apps based on the country in order to view tabs relevant to it. The tabs are Settings, RSS, Professions, Translations and Reports.

Once the WEB-RADR app has been selected, they would be presented the following tabs below. They are able to move between each tab at any time.

- Settings
- RSS
- Professions
- Translations
- Reports

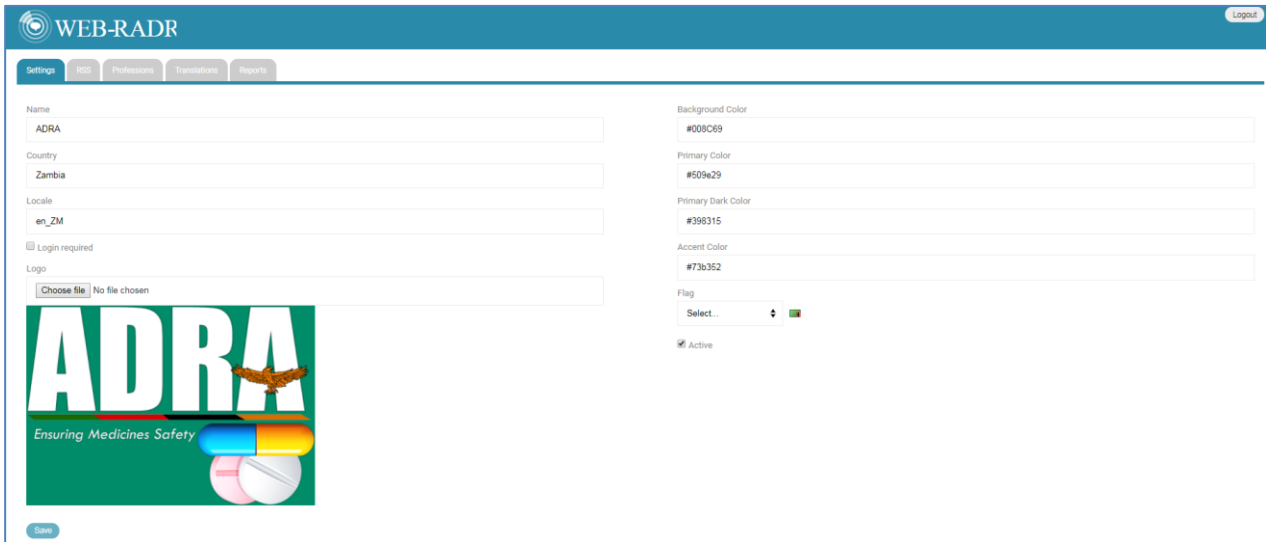


SETTINGS

The purpose of the Settings tab allows the site admin to change the name, country, locale and logo image for the country.

There is checkbox called Login required which enables the authentication process when the admin opens the app.

Most important button is to ensure the Active checkbox is selected to ensure the app is enabled.

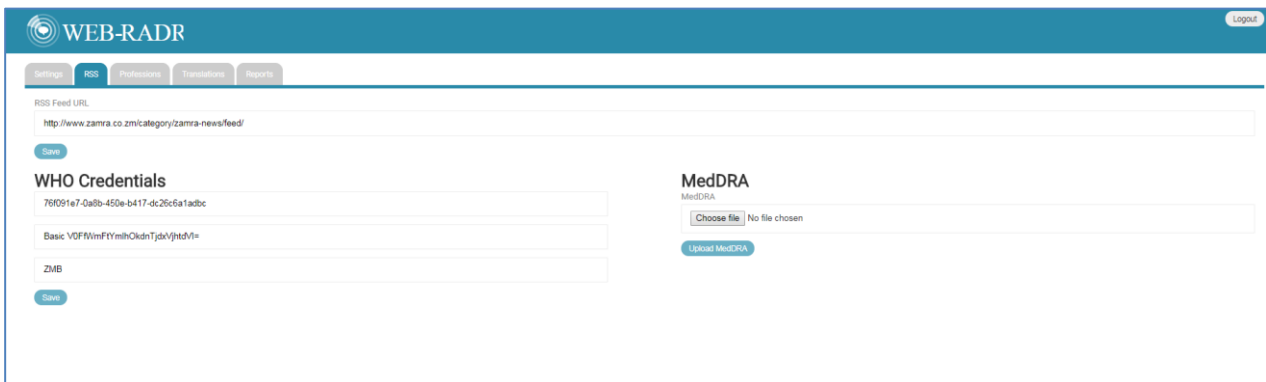


The screenshot shows the 'Settings' page in the WEB-RADR application. The page has a blue header with the 'WEB-RADR' logo and a 'Logout' button. Below the header, there are tabs for 'Settings', 'RSS', 'Professions', 'Translations', and 'Reports'. The 'Settings' tab is active. The form contains several input fields and a logo upload section. On the left, there are fields for 'Name' (ADRA), 'Country' (Zambia), and 'Locale' (en_ZM). There is a checkbox for 'Login required' and a 'Logo' field with a 'Choose file' button. Below the logo field is a preview of the ADRA logo with the text 'Ensuring Medicines Safety'. On the right, there are color selection fields for 'Background Color' (#008C69), 'Primary Color' (#509e29), 'Primary Dark Color' (#398315), and 'Accent Color' (#73b352). There is also a 'Flag' dropdown menu set to 'Select...' and a checked 'Active' checkbox. A 'Save' button is located at the bottom left of the form.

RSS

The purpose of the RSS tab allows the site admin enter the RSS Feed URL, the WHO credentials and any MedDRA file can be uploaded here.

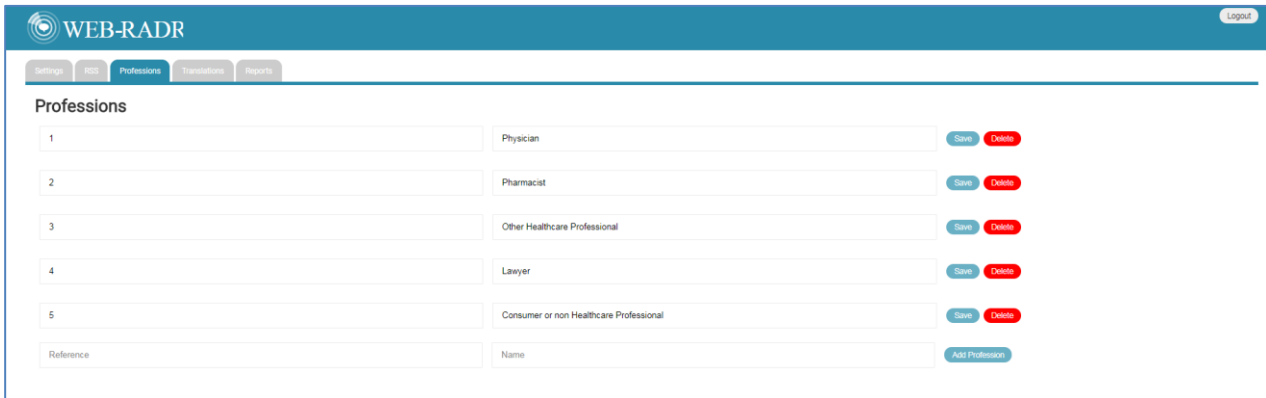
Note: **The size capacity and format type are TBC**



The screenshot shows the 'RSS' and 'MedDRA' settings page in the WEB-RADR application. The page has a blue header with the 'WEB-RADR' logo and a 'Logout' button. Below the header, there are tabs for 'Settings', 'RSS', 'Professions', 'Translations', and 'Reports'. The 'RSS' tab is active. The form contains several input fields and a logo upload section. On the left, there is a 'RSS Feed URL' field with the value 'http://www.zamra.co.zm/category/zamra-news/feed/'. Below it is a 'Save' button. On the right, there is a 'MedDRA' section with a 'Choose file' button and an 'Upload MedDRA' button. Below the 'MedDRA' section is a 'WHO Credentials' section with three input fields: the first contains '76f091e7-7a8b-450e-b417-dc26c5a1adbc', the second contains 'Basic_VDFWmFFYmthOkdnTjdVjhdVt+', and the third contains 'ZMB'. There is a 'Save' button at the bottom left of the WHO Credentials section.

PROFESSIONS

The purpose of the Professions tab allows the site admin modify any profession that should be reflected in the app. This option will be presented in the app when the users selects a new report and it will ask which profession are they a member of.

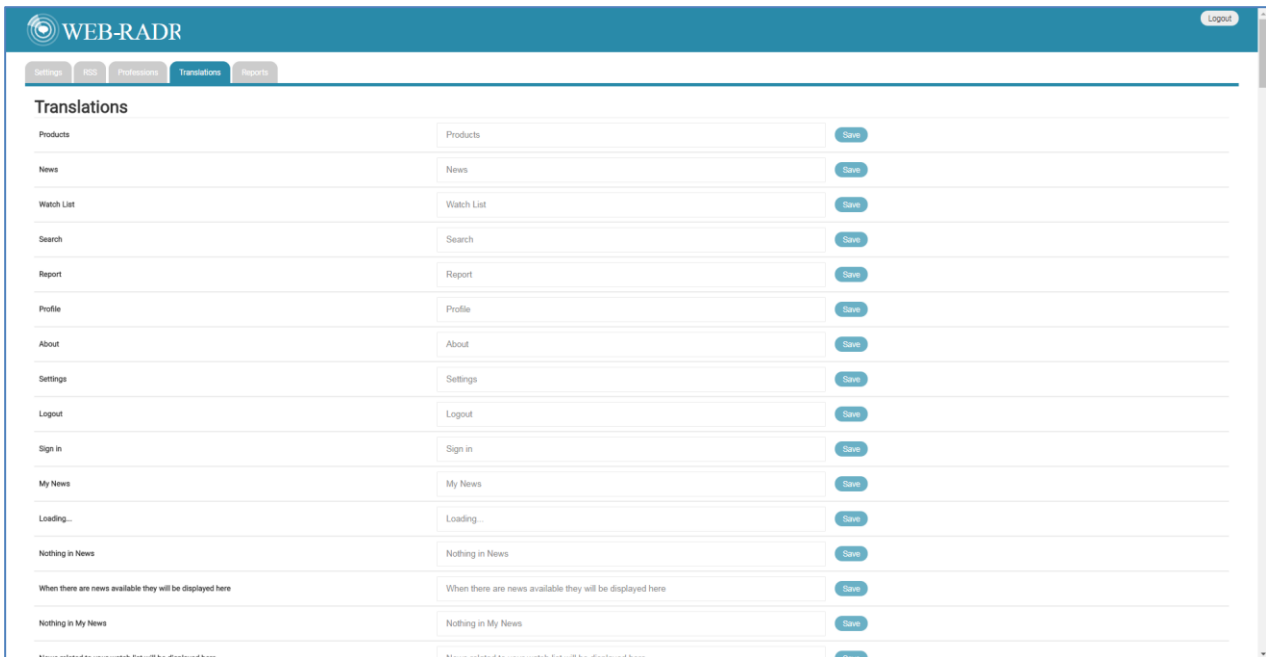


The screenshot shows the 'Professions' management page in the WEB-RADR application. It features a navigation bar with 'Settings', 'RSS', 'Professions', 'Translations', and 'Reports'. The main content area is titled 'Professions' and contains a table with five rows of profession entries. Each row has a 'Reference' field, a 'Name' field, and 'Save' and 'Delete' buttons. At the bottom, there is an 'Add Profession' button.

Reference	Name	Save	Delete
1	Physician	Save	Delete
2	Pharmacist	Save	Delete
3	Other Healthcare Professional	Save	Delete
4	Lawyer	Save	Delete
5	Consumer or non Healthcare Professional	Save	Delete
		Add Profession	

TRANSLATIONS

The purpose of the Translation tab allows the site admin to translate any English term mentioned in the WEB-RADR app into the local country language. The right column contains edit fields where they are able to provide this customization.



The screenshot shows the 'Translations' management page in the WEB-RADR application. It features a navigation bar with 'Settings', 'RSS', 'Professions', 'Translations', and 'Reports'. The main content area is titled 'Translations' and contains a table with multiple rows of translation entries. Each row has a 'Reference' field, a 'Name' field, and a 'Save' button. The entries include terms like 'Products', 'News', 'Watch List', 'Search', 'Report', 'Profile', 'About', 'Settings', 'Logout', 'Sign in', 'My News', 'Loading...', 'Nothing in News', and 'When there are news available they will be displayed here'.

Reference	Name	Save
Products	Products	Save
News	News	Save
Watch List	Watch List	Save
Search	Search	Save
Report	Report	Save
Profile	Profile	Save
About	About	Save
Settings	Settings	Save
Logout	Logout	Save
Sign in	Sign in	Save
My News	My News	Save
Loading...	Loading...	Save
Nothing in News	Nothing in News	Save
When there are news available they will be displayed here	When there are news available they will be displayed here	Save
Nothing in My News	Nothing in My News	Save
News related to your watch list will be displayed here	News related to your watch list will be displayed here	Save

REPORTS

The purpose of the Reports tab allows the site admin to see the reference number for every adverse event created via the WEB-RADR app. This tab provides a high level overview for the app reference, VigiBase Reference and the user's email who submitted the adverse event.

WEB-RADR Logout		
Settings RSS Professions Translations Reports		
Reference	VigiBase Reference	User
ZM-ADRA-20170822175521	4546f03-64d3-4269-0112-101056d37963	phimathew@gmail.com (Anonymous)
ZM-ADRA-20170822174223	88734b48-174f-42e9-072b-0d5f87c1588	stef.bodin@gmail.com (Anonymous)
ZM-ADRA-20170821121317	ee35910f-8947-48a3-bef3-454d11404322	phil.tregunno@gmail.com (Anonymous)
ZM-ADRA-20170818135419	e6708fae-513d-45d0-bc68-4c19a0f61514	stephanie_bodin@yahoo.fr (Anonymous)
ZM-ADRA-20170818134727	9ac7a7fa-e212-405c-884b-c7f6c02254	stephanie_bodin@yahoo.fr (Anonymous)
ZM-ADRA-20170818133901	74e6689e-0209-4a4e-8d7f-e995e7c0b1f	stephanie_bodin@yahoo.fr (Anonymous)
ZM-ADRA-20170818133259	42507287-a43c-4c1e-adc3-855d0956643	gregre@gmail.com (Anonymous)
ZM-ADRA-20170817183139	11d5924b-8bb0-448f-01c1-310e69135b88	zmunkombwe@zamra.co.zm (Anonymous)
ZM-ADRA-20170817183135	608081e0-528c-4e38-9036-445ea3c5800b	zmunkombwe@zamra.co.zm (Anonymous)
ZM-ADRA-20170815094858	70c9173-669e-460e-8b0e-13274639e050	l.sichone@yahoo.com (Anonymous)
ZM-ADRA-20170815023727	ab1390c3-1061-4056-bc7f-990a4386494c	dmwargana2010@gmail.com
ZM-ADRA-20170811144114	f5004c71-c5c8-4844-908b-420920954ea	helticasey.m@gmail.com
ZM-ADRA-20170811142542	d930f9ff-c37e-466d-88e1-aeef93a402756	hsa81313@gmail.com
ZM-ADRA-20170811140034	cd33f849-8c8a-4327-a7ca-0d56f9e8ef86	hsa81313@gmail.com (Anonymous)
ZM-ADRA-20170810174601	8650388-7611-4e4b-8802-0179caa28784	samaleswedgar@gmail.com (Anonymous)
ZM-ADRA-20170721103928	7985968-11ee-4943-904a-1c318e87748c	lucag@poptista.com
ZM-ADRA-20170721101127	00043689-18b9-4d8b-aa6a-7a0c0c22362	lucag@poptista.com
ZM-ADRA-20170703095210	794603c5-085a-4750-b341-4f70becc02a3	lucag@epidemico.com (Anonymous)
ZM-ADRA-20170703095129	f3ba0b6f-3d39-485b-aad9-b8b60244c49	lucag@epidemico.com (Anonymous)
ZM-ADRA-20170703095126	9e430f0f-3ac5-4c63-80ab-e92c0ffca66c	lucag@epidemico.com (Anonymous)
ZM-ADRA-20170702195319	82a468d1-33a4-4753-813e-3af96c25f9b	ronarjov@yahoo.com
ZM-ADRA-20170702195303	9e849c21-c46d-4017-bd3d-0b0c886b3f78	ronarjov@yahoo.com
ZM-ADRA-20170702195258	db3c13d1-60ef-451e-90c3-530c0060c72	ronarjov@yahoo.com
ZM-ADRA-20170702094213	8d106d4-2a70-48eb-act6-8e9e92653805	muma3m@yahoo.com (Anonymous)
ZM-ADRA-20170702094210	00a677ca-e4c5-4101-944d-23a70315e008	muma3m@yahoo.com (Anonymous)
ZM-ADRA-20170701104400	ba397139-df0c-4a20-81c2-840b655ae88c	ronarjov@yahoo.com (Anonymous)
ZM-ADRA-20170701104344	2e9f5568-882d-44ce-a652-7057412b871d	ronarjov@yahoo.com (Anonymous)