Project N°115632 – WEB-RADR

WEB-RADR App Design

WP3A – Mobile Reporting Platform

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

App Design Documentation

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WEB-RADR APP DESIGN DOCUMENT

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ABOUT THIS DOCUMENT

TARGET AUDIENCE

This document, "WEB-RADR App Design Document," is intended to serve as a technical guide to the WEB-RADR app for National Competent Authorities who wish to implement their own 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
REST	Representational State Transfer web service
Drecno	Drug Record Number

REFERENCES

Ref No	Name	URL/Document Id
1.	API URL	*Provided by the authority*
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 Testing	***WEB-RADR App Test Scenario***
Portal Configuration	***WEB-RADR Portal Configuration Document***
Appendix Document	***WEB-RADR App Appendix Document***

BACKGROUND

WEB-Recognising Adverse Drug Reactions (WEB-RADR) is a three-year, EU-based project (funded through the Innovative Medicines Initiative (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 (HCPs) to report suspected Adverse Drug Reactions (ADRs) to medicines and to learn about drug safety news from their local National Competent Authority (NCA). 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 and publish a local country mobile app for pharmacovigilance, based on the WEB-RADR generic app. The WEB-RADR app is intended for use by the public -- HCPs or consumers – and has two main functions:

1. Enabling the reporting of ADRs from the public to their NCA
2. Enabling the communication of safety information regarding approved medicinal products for that country from the NCA to the public

This document contains the following information:

- A high level description of the WEB-RADR app provided in the system overview
- Design constraints and strategies
- Process flows with security measures for Data Control
- Server Management aspects including security, access, database backups and data recovery
- Instructions for the App functionality configuration
- Instruction for setting the App using AWS Servers and NCA database connectivity
- Instructions for publishing the mobile app in Google Play and the App Store
- Admin Portal Overview
- Mapping of the fields on each screen within the app

SYSTEM OVERVIEW

FUNCTIONAL OVERVIEW

The generic WEB-RADR app is an off-the-shelf template for a localized national app that serves two purposes:

1. Providing the following safety information from NCAs (or other health authorities such as WHO, EMA) to the public (both patients and HCPs):
    a. ADR volume statistics regarding selected medicinal products
    b. Safety issues and warnings
2. Facilitate reporting of ADRs by the public and healthcare practitioners to their local NCAs

The WEB-RADR app will have two versions:

- iOS
- Android

The two versions need to be maintained concurrently, and it is intended that the functionality is identical in each, although look and feel may differ to align with standard operating system approaches. Both versions will require localization individually and will also require testing separately.

The template is intended to provide guidelines for what minimum information is required to submit a report and receive news and updates.

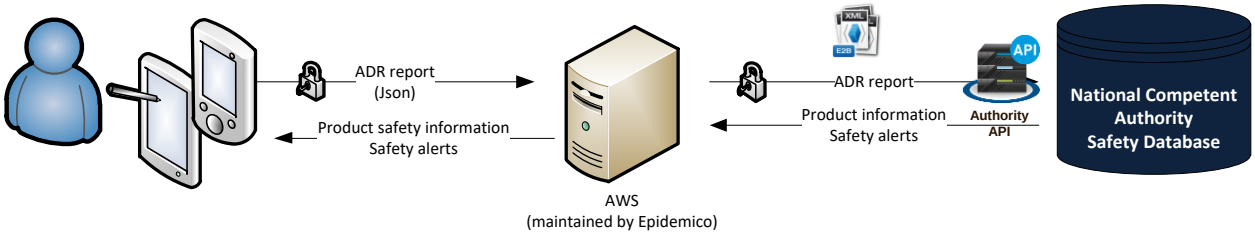
These functions are achieved via the following components:

- Native mobile apps running on both iOS and Android
- An AWS server stores product lists and ADR statistics and is received from VigiAccess
- An API for submitting E2B XML files to the NCA

The generic app is intended to be configured and localized for a select number of national requirements. Configuration of the generic app involves the following steps:

- Providing translations for text within the app
- Adapting the user interface to reflect the NCA's logo, colour scheme, or other marketing materials
- Ensuring the WHODrug which contains a complete list of medical products is always being up to date per country. If there is missing information in WHODrug, the NCA can send the missing information to UMC to be uploaded.
- With the use of the VigiAccess API, it can display ADR statistics based on the VigiBase dataset
- Providing a complete list of medicinal products approved in the country; providing aggregate statistics on ADRs reported for products; providing RSS links or static data to populate safety news alerts
- Establishing the necessary attendant connections between the Epidemico server and the NCA database
- Testing the app to ensure proper configuration and connectivity
- Publishing the mobile app in Google Play

Functional Scope



WEB-RADR APP MEMORY SIZE

The memory sizes for the three developed apps, as of 2 February 2017, are listed below. The YellowCard app is twice the size of the other two apps due to the size of its logo files.

App Name	Size (MB)
Lareb	8.3
Halmed	8.1
YellowCard	17.3

DESIGN CONSTRAINTS AND STRATEGIES

SYSTEM DESIGN CONSTRAINTS AND REQUIREMENTS

The WEB-RADR apps have been built for Android and iPhone users, and are compatible with the most current versions of each respective operating system.

In order to adopt the WEB-RADR app for national use, an NCA must be able to provide the following details:

- Country for publishing the app
- Language(s) required
- NCA logos
- NCA title and color schemes
- Translation into the local languages of all the fields listed (see Portal Configuration document)
- Text for a data privacy notification in local language
- Require user registration with option to save login details
- List of Medicinal Products
- Connectivity details for receiving the XML file of reported Adverse Events
- Connectivity details for sending news alerts and linking the news to the product list

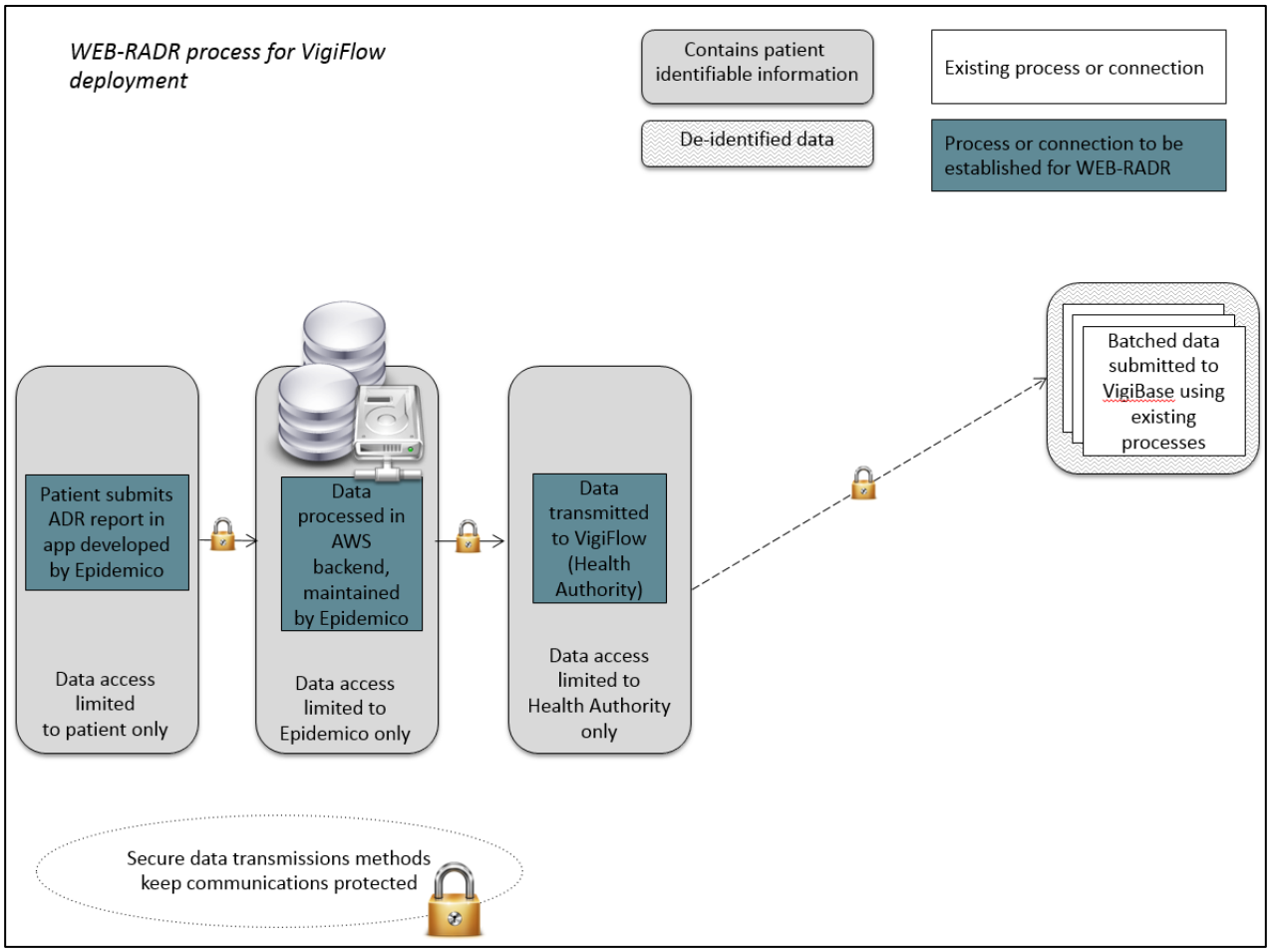
All additional localization requests will be considered customizations and are out of scope of this document.

All these information should be provided from the administration portal to directly configure the local instance of the mobile app.

PROCESS FLOWS

SECURITY MEASURE - DATA CONTROL

The information flow for ADR reports submitted via the app follows existing data flows for reports received from other drug safety data source (e.g. spontaneous, observational). Each NCA is considered the data controller for the reports they receive, while Epidemico serves as the data controller of the raw text fields that are used to create the ADR reports. An AWS server will be used to backup and maintain the data prior to submission to the NCA. This will be managed by Epidemico.



App data flow: Patients and physicians download and use the app to submit an ADR report to their NCA. Data for the reports are processed into standard E2B report format by Epidemico and submitted securely to the NCA's ADR submission portal.

SERVER MANAGEMENT

SECURITY

Epidemico utilized Amazon Web Services (AWS) to store app data via cloud hosting. AWS is compliant with Industry Standards ISO/IEC 27001 and ISO/IEC 27002. The server supports Forward Secrecy and the latest version of the Transport Layer Security (TLS) protocol. In addition, the server is secured with several HTTP security headers, including Strict-Transport-Security, Content-Security-Policy, Public-Key-Pins, X-Frame-Options, X-Content-Type-Options, and X-XSS-Protection.

App data are encrypted in transit during submission to the NCA or to Vigibase. The XML files containing ADR reports are submitted to the NCA using REST over HTTPS. After submission, data are safeguarded according to the NCA's security measures.

ACCESS

The security groups that Epidemico has established on the server ensure that no one outside the Epidemico VPN can connect to the server that is used for the WEB-RADR app, and even within Epidemico, only members of the DevOps

team have login access to the server. In addition, Epidemico has implemented network monitoring and logging procedures to oversee database activity and access.

DATABASE BACKUPS

Database backups are scheduled for five nightly backups, three biweekly backups, and three monthly backups. Backups are run nightly and kept for five days; additionally, backups on the 1st and 15th day of the month will be duplicated to biweekly backups, and backups on the 1st of the month will also be duplicated to monthly backups.

All backups are stored in the same region in which they're made; for the WEB-RADR app, the server is in Ireland, therefore the data will all be stored in Ireland. Backups of encrypted volumes are automatically stored encrypted as well.

DATA RECOVERY

Data recovery consists of simply restoring a volume snapshot as described above to the appropriate volume attached to each instance. The system instance will also have its primary volume backed up in a similar manner, so if the server itself fails it should be a minimal effort to restore a snapshot of the primary volume and reboot the instance.

INSTRUCTIONS

FOR THE APP FUNCTIONALITY CONFIGURATION

Login – account specifications

Use of Event list / MedDRA for suggestions

Specific report validation rules

FOR SETTING UP THE APP – AWS SERVER – NCA DATABASE CONNECTIVITY

The areas are broken down on how the WEB-RADR app and AWS Server would be interacting with one another.

- Reporting of ADR
- Transmission of product list
- Product statistics
- News

REPORTING OF ADR FOR THE APP

The app builds a JSON object based on a pre-established structure between the server and the app. All the information provided that is retrieved from the form is presented on the app. However, the information is not limited by that since the server can retrieve more information if the user that submitted the report was logged when submitted the report.

See Appendix 3 for a JSON file format.

REPORTING OF ADR FOR THE SERVER

The server registers an endpoint that can receive a JSON object that will be validated by pre-established rules. These rules are also applied on the client side. After validating the JSON object, the server checks if there is a user attached to the request and stores that information for later use. The JSON object received from the app is then converted to XML using the E2B protocol rule.

The XML is later sent to the WEB-RADR API and once it has been validated by the API, the report is stored on Epidemico's database and success response is transmitted to the app.

See Appendix 4 for an XML file format

TRANSMISSION OF PRODUCT LIST

Epidemico's AWS server will synchronize their data with the WHODrug Lookup API on a weekly basis using an authentication method. The app will then synchronize the product database with Epidemico's server every time, as necessary. To ensure consistency, the app will check if there is new product data availability on a daily basis.

PRODUCT STATISTICS

The Product Statistics are provided by the VigiAccess API using the already provided authentication model for each partner.

The app will make request to Epidemico's servers by sending the internal references for the Product. Subsequently, having this information, the AWS server retrieves the Vigibase API reference code for the provided Product to then request the statistics data from the VigiBase API. For the countries using the drug list provided by WHODrug, the statistics can be directly provided using the Drecno of the product. This is delivered as part of the product list. For background purposes, Drecno is the identifier of the combination of base substances (or substance for single ingredient products) for the medicinal product. The primary use for the Drecno is to lookup adverse event information for that combination in VigiAccess.

The data provided by Vigibase is then translated to fit the data model that has been structured for the app. If the product does not have any information provided from the Vigibase API, this will be indicated to the user on the app UI. If there is enough information, a BarChart will be generated on the app.

NEWS

All news items are provided directly by each partner and are dependent on the publicly available data source.

On the Server side, the AWS Server checks for the feed on a daily basis and stores any new items or updates any changed based on a unique field provided. The RSS Feed is based on a standard model defined by Joomla. Joomla is an open source CMS service used by most websites to deliver dynamic content. Also, the RSS feed is translated from an XML Object to fit the JSON structure required by the app and is stored on Epidemico's server database. For background purposes,

On the App side, the app will check AWS server daily for any change on the RSS Feed. If any change is flagged, the app will download all new or updated items and store these locally on the apps internal database.

FOR PUBLISHING THE APP IN GOOGLE PLAY STORE AND APPLE STORE

Android/Google Play
Instructions for publishing the app to Google Play can be found at
https://developer.android.com/distribute/googleplay/start.html

Apple/App Store
Instructions for publishing the app to the App Store can be found at
https://developer.apple.com/library/content/documentation/LanguagesUtilities/Conceptual/iTunesConnect_Guide/Chapters/SubmittingTheApp.html

ADMIN PORTAL OVERVIEW

Web RADR Management Board is responsible for the release management of the WEB-RADR app.

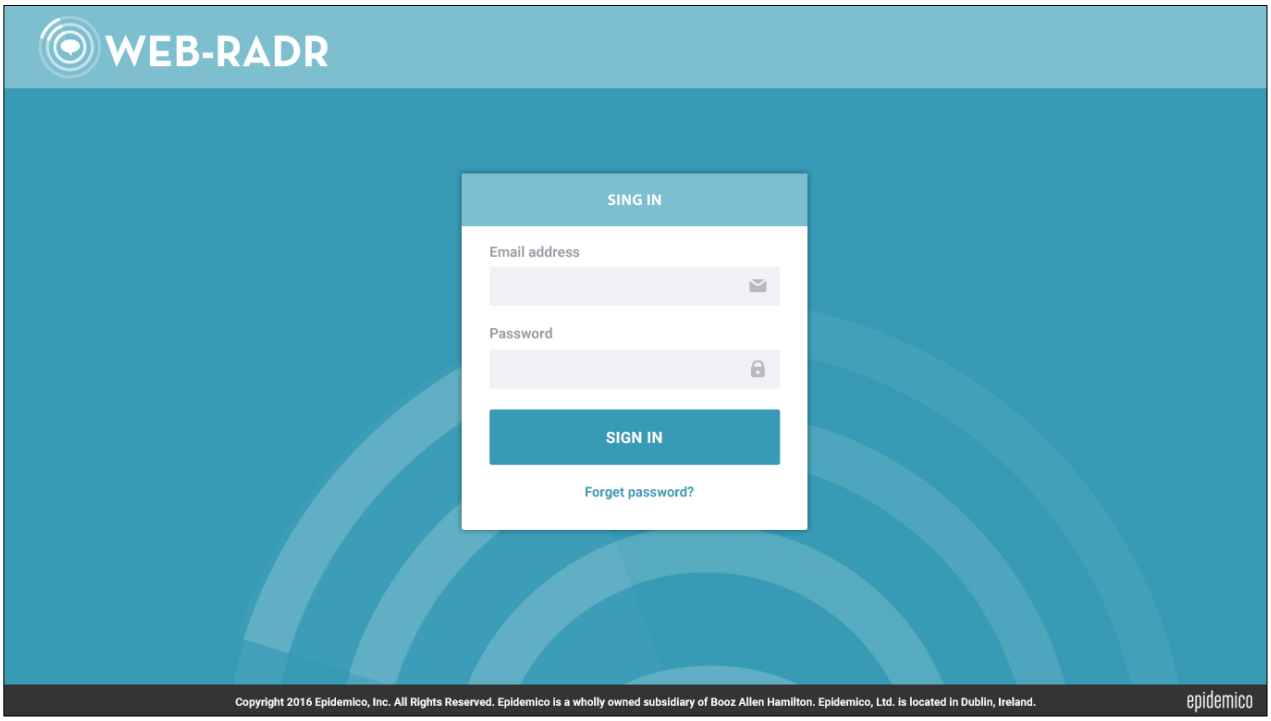
NCAs are responsible for configuring their local instance of the mobile application and maintaining it. The changes made through the administration portal are automatically reflected on both iOS/Android apps without requiring a new version release. Changes are tracked through the audit trail functionality enabled on the admin portal.

Based on the login details provided, the NCA will only able to manage their WEB-RADR app.

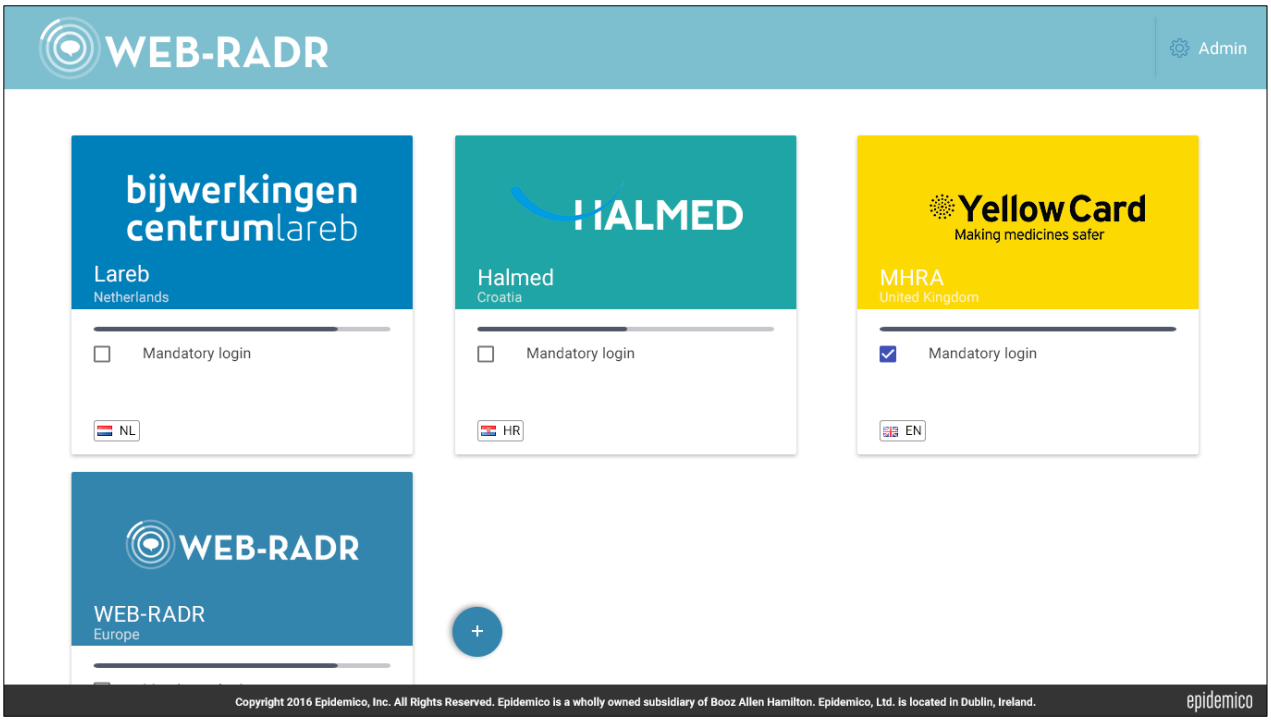
The User Interface (UI) screens for Admin Portal are shown below.

ADMIN PORTAL – USER INTERFACE

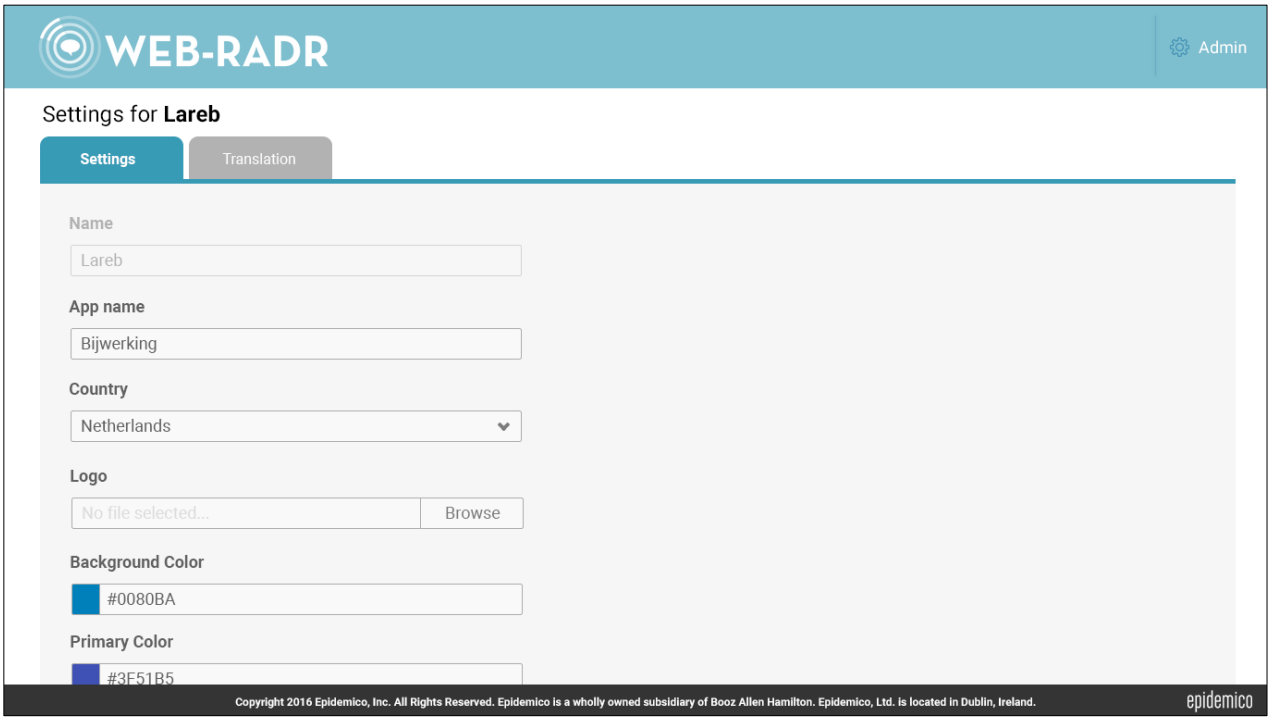
LOGIN DETAILS SCREEN



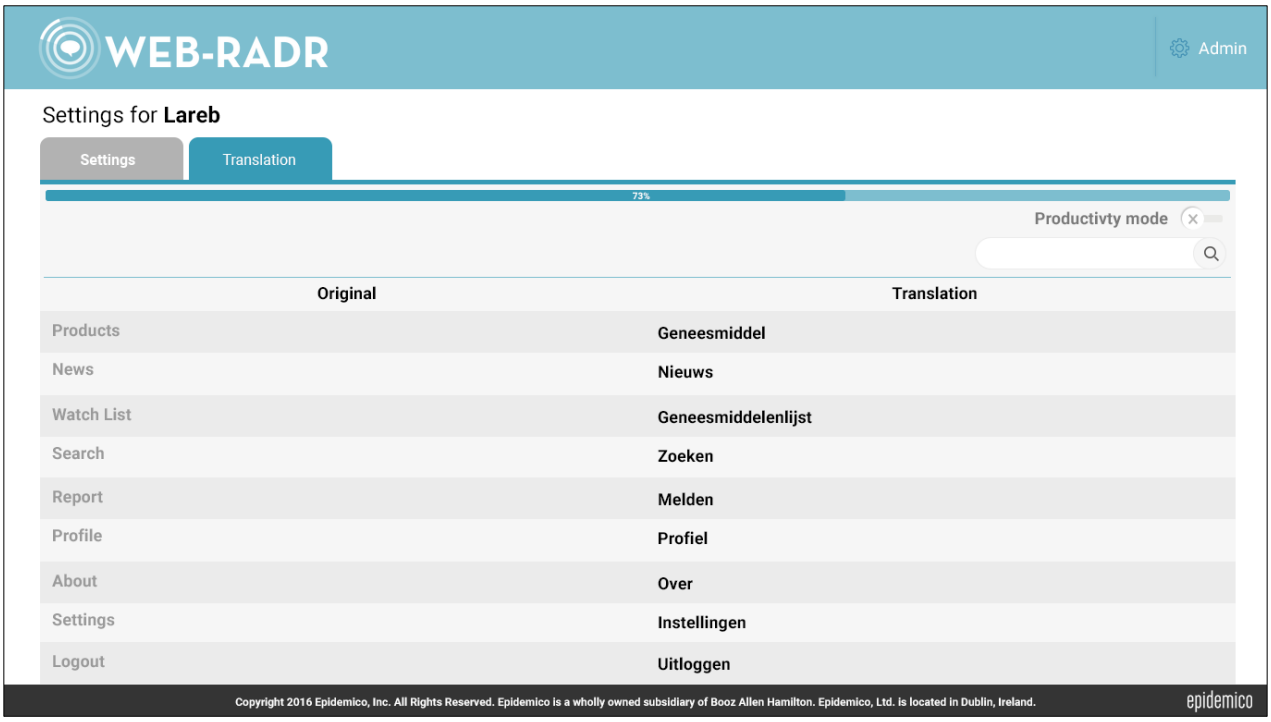
DASHBOARD SCREEN – GENERIC APP SELECTION



SETTINGS SCREEN TAB FOR WEB-RADR APP



TRANSLATION SCREEN FOR WEB-RADR APP



ADMIN PORTAL CONFIGURATION

Instructions for using the Admin Portal to configure the generic app for a new NCA are provided in the Portal Configuration document.

MAPPING

This section describes the elements contained on each screen within the app. Every individual field within each section of the app is broken down in the Mapping section. Please refer to Appendix 1 in the Appendix document for further information.

EXAMPLE OF E2B SUBMISSION

This section shows an example of how the format for an E2B submission as a XML format. Please refer to Appendix 2 in the Appendix document for further information.