



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

IMI WEB-RADR project

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting
17-18 April 2018



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IMI WEBRADR

- Response to IMI call in 2013
- Project Sep 2014- December 2017



Innovative Medicines Initiative

IMI-GB-DEC-2013-13
Annex 1

9th Call for Proposals 2013

Innovative Medicines Initiative

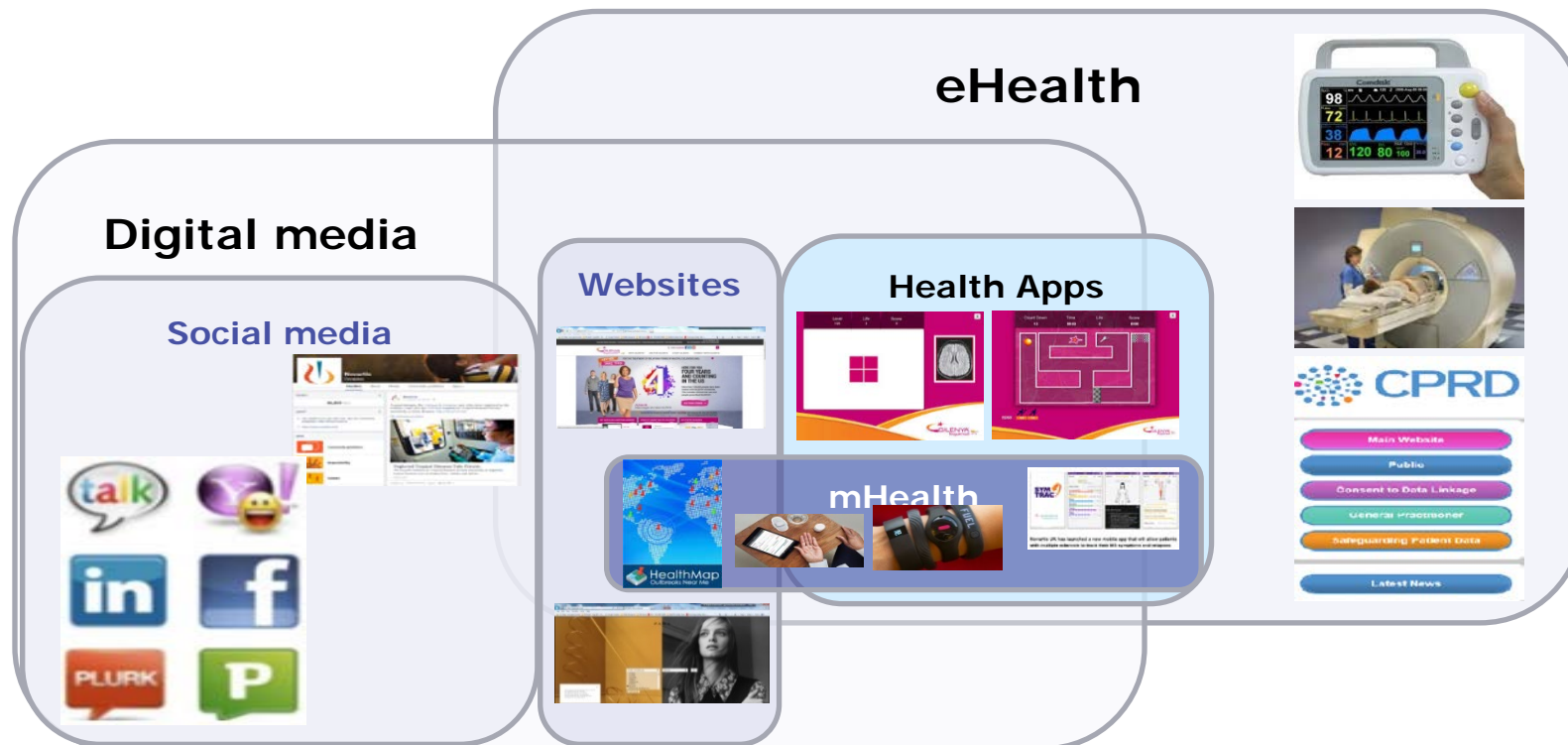
Version 2

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Technology landscape

WEBRADR focus on social media and health apps



Outputs of WEB-RADR

Tasks divided across individual working groups





App for ADR reporting

Promoting 2-way communication between Patients, HCPs and Regulators

Public (Patients, carers
& HCPs)

UK 4000+ users

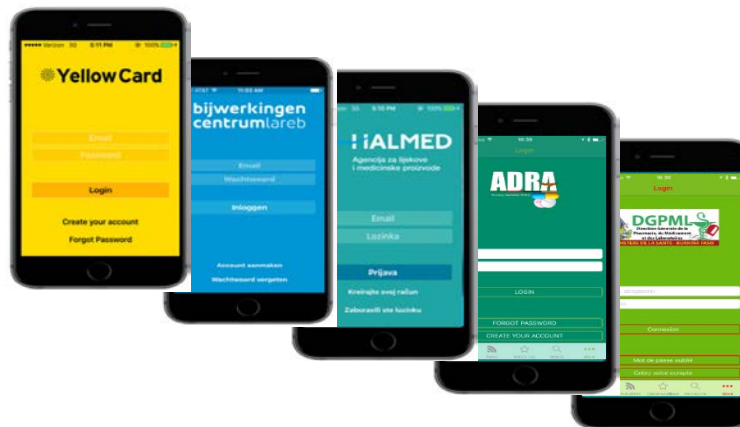
Netherlands 3400+ users

Croatia 695 users

Burkina Faso & Zambia

Adverse reaction reports

ADR report statistics & Safety alerts



iOS / Android mobile devices

**National Competent
Authorities**

MHRA >400 reports

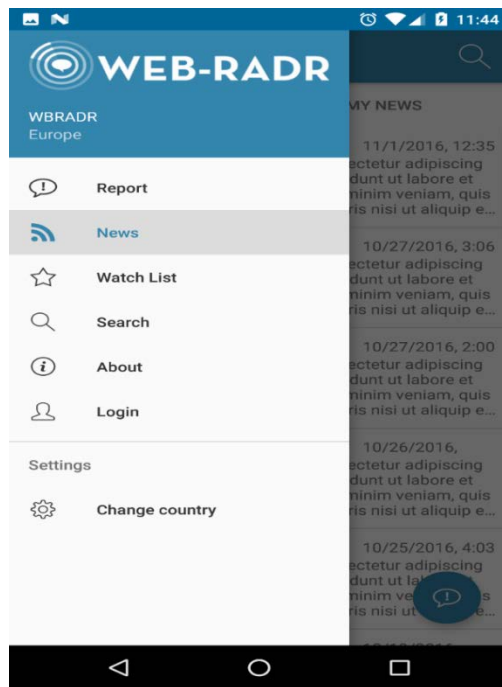
LAREB >150 reports

HALMED >130 reports

DGPML/ZAMRA [Recent launch]

What does the App do?

Country specific branding



- ▶ **Login:** Ensure consent, data privacy and security
 - Mandatory login can be enabled/disabled
 - Country-specific configuration & colours
- ▶ **Product Search:** Search supported by suggestions
 - ⇒ Add product to personalised watchlist
 - ⇒ Deliver & display product specific news ('watch-list')
- ▶ **News feed:** reliable data provided by trusted source
 - Easily retrievable news of safety and risks
- ▶ **Report** side effects to the regulatory authority
 - Retrieve saved/previous submitted report

Social media

- Pharmaceutical industry primarily use social media for commercial reasons
- Some use for 'Patient engagement' and recruitment into clinical trials
 - Many examples of you tube videos from patients and HCP themselves and also from MAHs as part of educational aspects of Risk Minimisation Measures



What is the best way to use my auto-injector?



WEB-RADR has looked at social media for Pharmacovigilance

RPA and machine learning

Terminology overload! Robotic Process Automation, machine learning, natural language processing, Big data analytics

Acquire → Process → Export

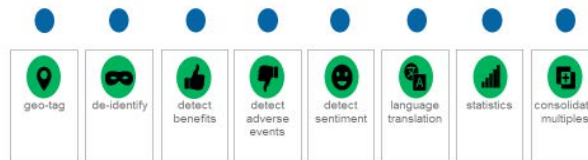
Acquire

Collect unstructured data from social media APIs, third-party authorized resellers, and automated scraping.



Process

Data are passed through a series of apps, emerging as meaningful bits of information.

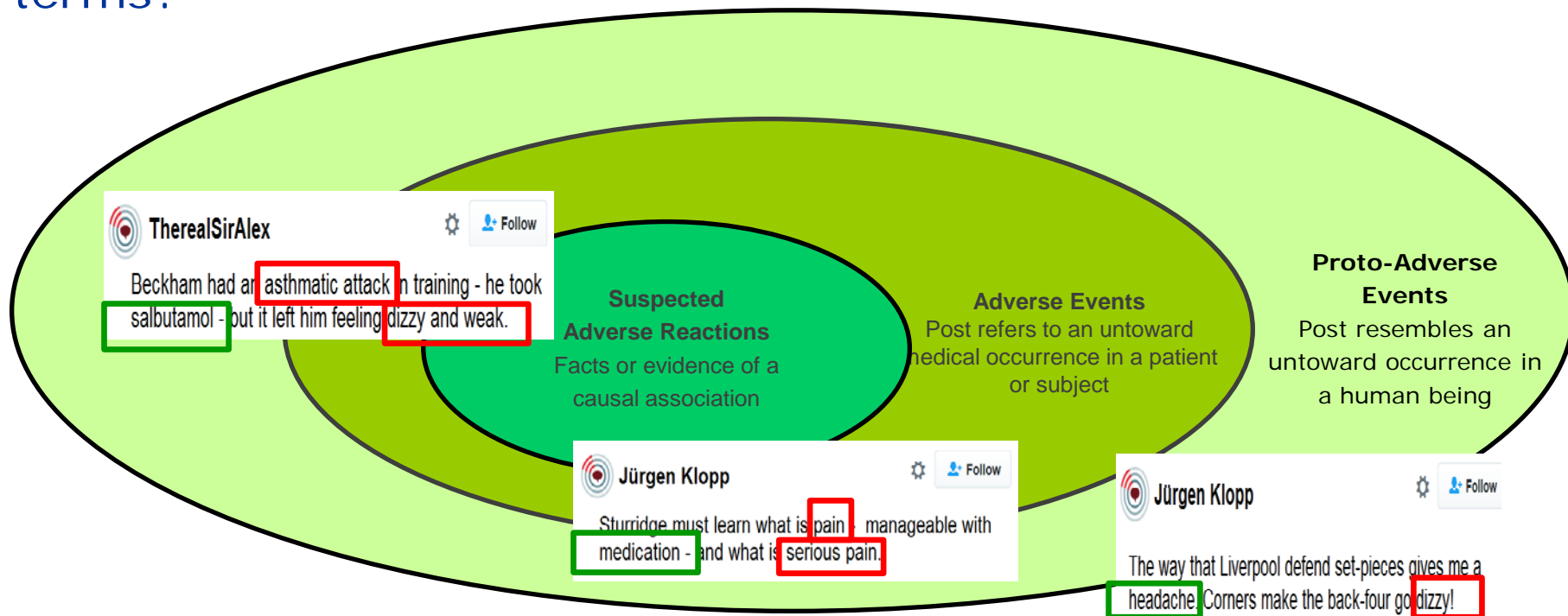


Export

Relevant data are passed to another series of apps in preparation for human interpretation and analysis.



How to classify posts from social media in traditional PHV terms?





apetite surpressed

googley eyed

no appetitey

blind appetite is nonexistent blurry vision 🙄 miss feeling hungry

anorexic

visión
doble

Spelling

Typos

cant eat

blurry

couldn't see

lost appet killed my apetiti

Emoticons

lost teh appetite

can't eat

killed my appetite

googly eyed

Implied

sin hambre

Invented words and hashtags

couldnt see

cross eyec

seeing weird colour

Other Languages

lack of apetite

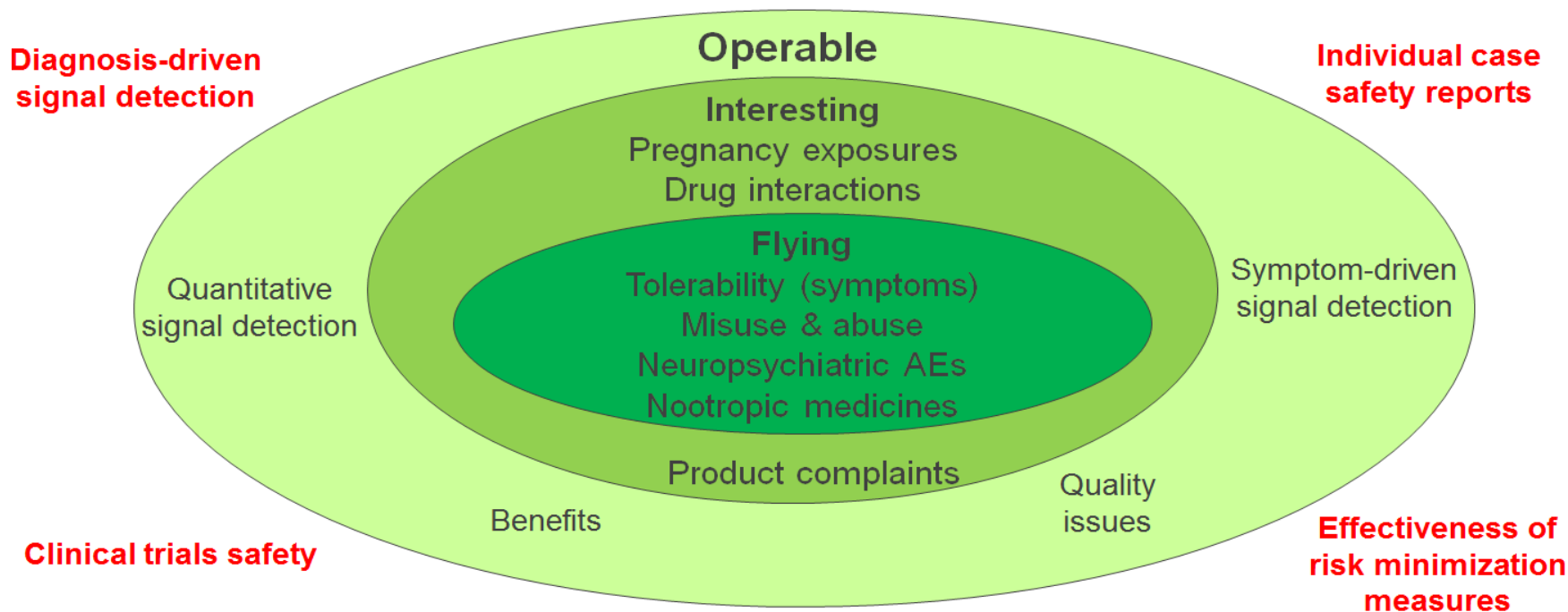
never want to eat

seeing weird

never hungry

blind	doublevision	anorexic	lost appetite
blindness	googley eyed	apetite surpressed	lost my appetite
blurry	googly eyed🙄	appetite is nonexistent	lost teh appetite
blurry vision🙄	lost their eyesight	cant eat	making me eat like a mouse
changes in vision	seeing double	can't eat🤢	miss feeling hungry
couldnt see	seeing weird	didn't get hungry	never hungry
couldn't see	seeing weird color	dont want to eat	never want to eat
cross vision	seeing weird colour	killed my apetite	#notevenhungry
crosseyed	visión doble	killed my appetite	no appetitey
cross eyed	visual snow	lack of appetite	sin hambre
Visual impairment MedDRA 10047571		Decreased appetite MedDRA 10061428	
Visual impairment SNOMED 397540003		Loss of appetite SNOMED 79890006	

Conclusions



IMI-WEB RADR project – regulatory recommendations



- Objectives of IMI WEB-RADR work package 1 :
 - Assess the current regulatory framework
 - Prepare recommendations for consideration as part of future updates of GVP modules on the use of social media in support of pharmacovigilance taking into account results from the WEB-RADR social media analytics and evaluation work packages
 - Recommendations are to inform the EU Network's pharmacovigilance governance and future updates of Good Pharmacovigilance Practice (GVP) modules



High level recommendations for policy

- Current guidance from GVP applies. In addition:
- No requirement to screen social media or follow up with users
- No requirement to create ICSRS from social media
- Social media can be used for signal detection as optional, any insights gained should be fed into the normal regulatory process (PSUR, RMP, Emerging safety Issue)
- Aspects should be defined and documented (such as purpose, choice of social media)
- Can also be used for non interventional studies, GVP applies and protocol required



Project extension

Further development of the App:

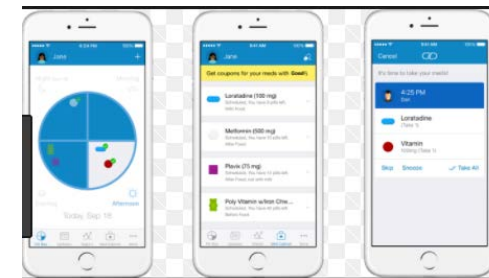
Non interventional studies, Post Authorisation studies, Named Patient use

- Automated recognition of medicinal products for ADR reporting
 - Barcoding of packs
 - Include configurable batch # for biologicals/vaccines
 - Detection of fake, fraudulent, counterfeit medicines
 - Photographic identification based on images
 - Size, colour, shape and pattern recognition

Project extension

- Communication
 - PIL, pack inserts, SmPC
 - aRMM (Education material, dosing cards)
- Establish links to other healthcare apps
 - Adherence to prescribed therapy
 - Diagnostic tests – e.g. visual field test
 - Prognostic calculators,
 - Games - to aid disease therapy and support
 - Patient Support Groups – fora and information

Injected Mealtime Insulin Dose	AFREZZA Dose	# of cartridges needed		
		4 unit (blue)	8 unit (green)	12 unit (orange)
up to 4 units	4 units			
5-8 units	8 units			
9-12 units	12 units		+	
13-16 units	16 units			or/
17-20 units	20 units			+
21-24 units	24 units			





Thank you for your attention

Further information

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