

Recent learnings from the IMI WEB-RADR project

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WEB-RADR aims

Web-Recognising Adverse Drug Reactions

Embacing new technologies

Both public and private partners involved

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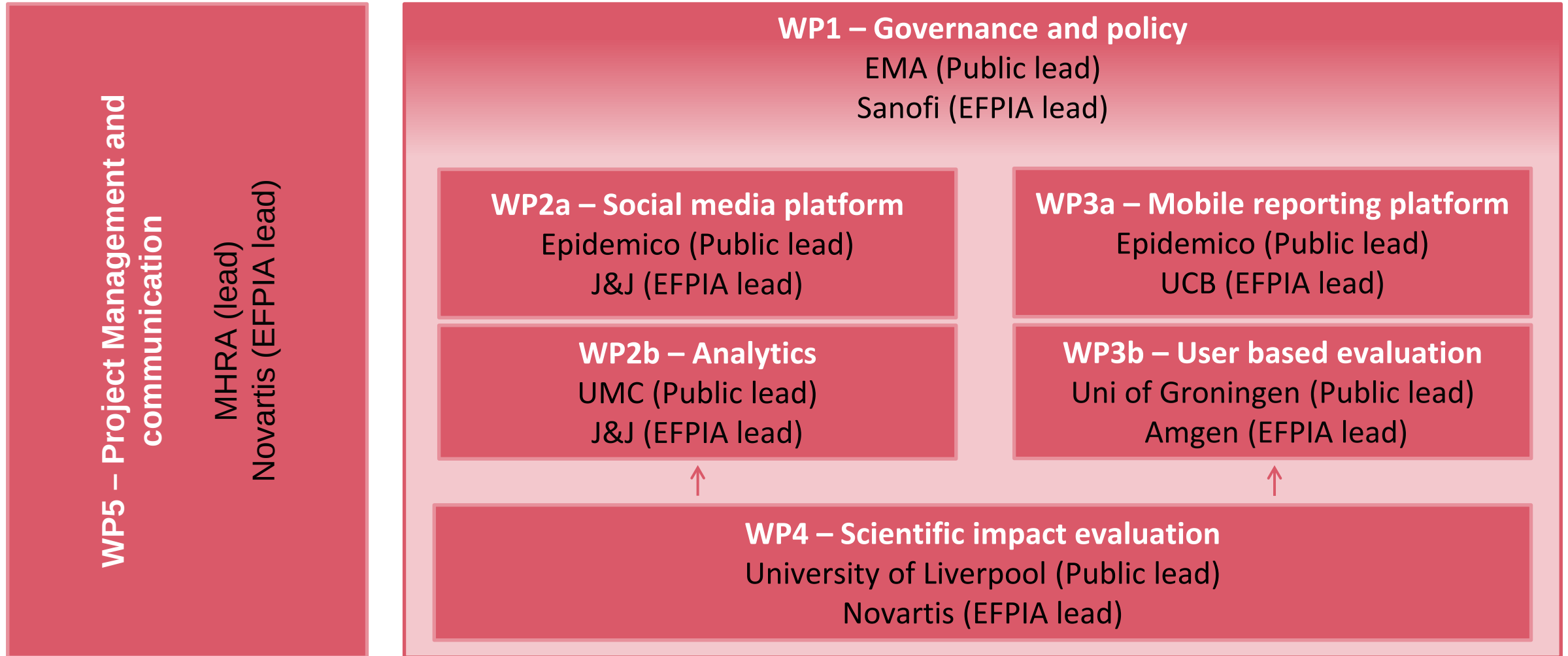
Reports via mobile app vs established reporting schemes

Algorithms and analytics

Develop a policy framework

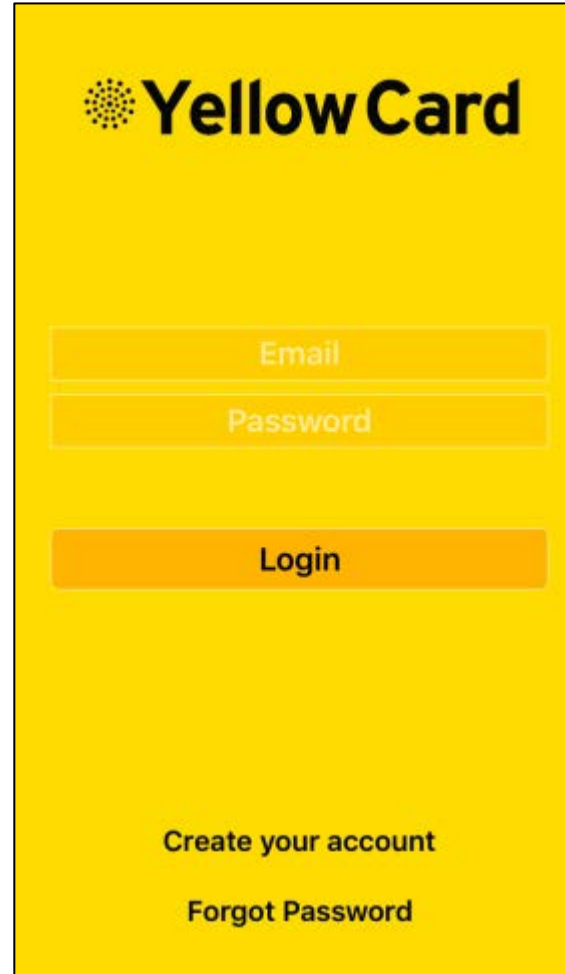
Reshape the pharmacovigilance world

Project design

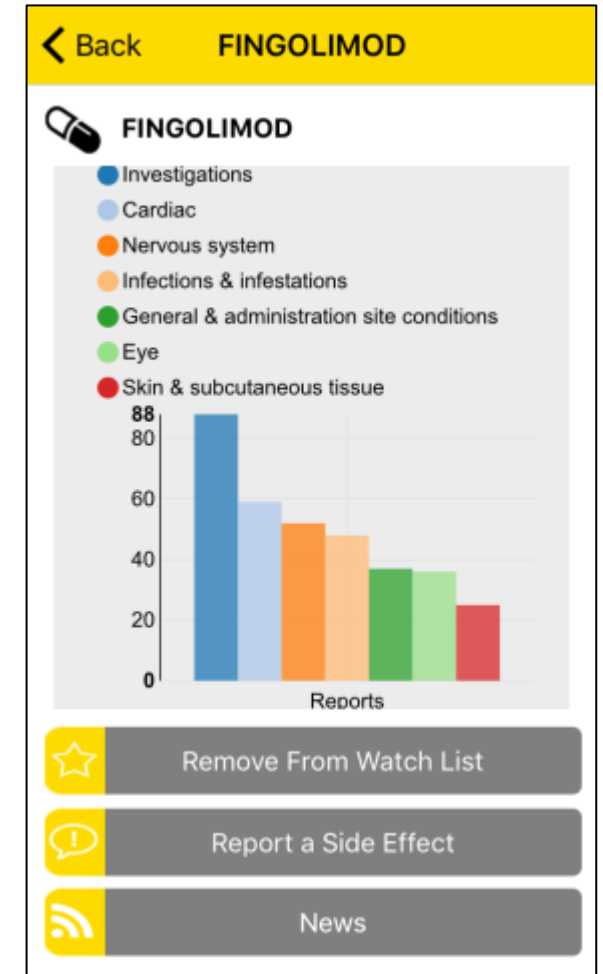


Mobile Apps

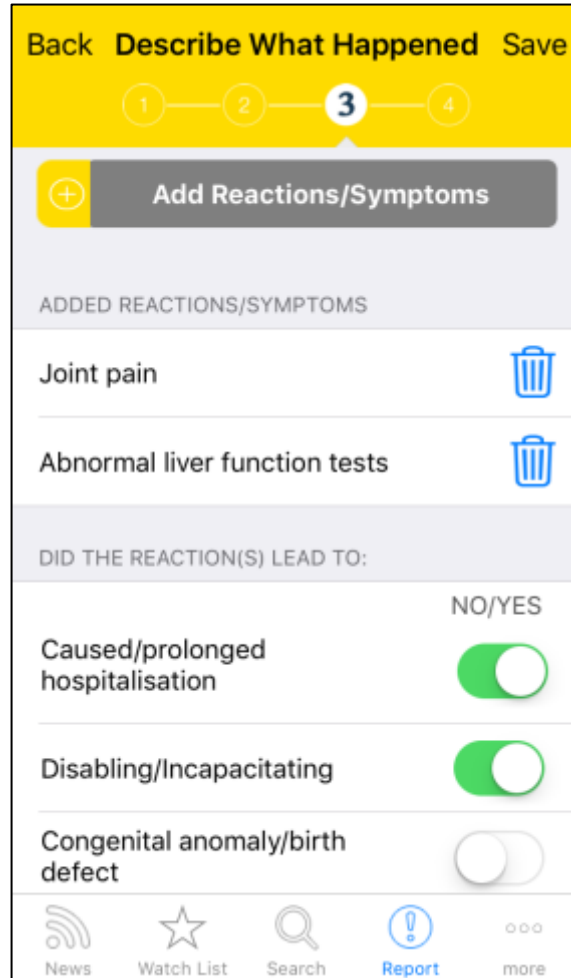
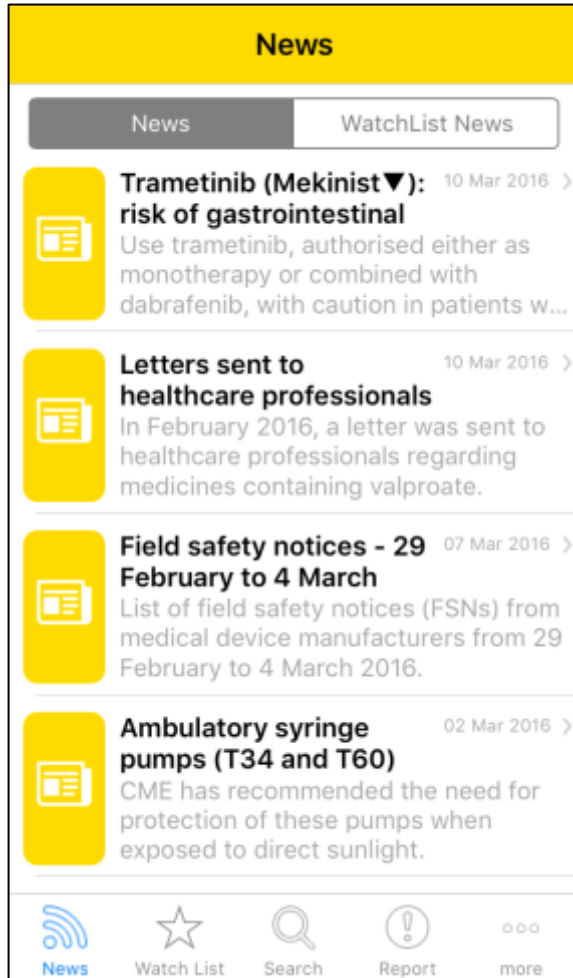
- UK App Launched in July 2015 by the Minister for Life Sciences
- Uptake is free to users
- Dutch and Croatian apps also launched
- Downloads (UK):
 - iOS: 2592
 - Android: 703 (as of 11th September 2016)
- Reports (UK):
 - 181 Received (as of 11th September 2016)



The image shows the login screen of the Yellow Card app. It has a bright yellow background. At the top, there is a logo consisting of a cluster of dots followed by the text "Yellow Card". Below the logo, there are three input fields: "Email", "Password", and a "Login" button. At the bottom, there are two links: "Create your account" and "Forgot Password".



User evaluation



- Identifying barriers and facilitators for using mobile app
 - To report ADRs
 - For accessing drug (safety) information
- Segmenting target groups
 - Patients: adolescents, orphan disease populations, elderly
 - Healthcare professionals
- Targeted & differential app development
- Validate in a range of settings
 - Lab based
 - Clinical settings
 - Surveys
- Comparison to patient notes

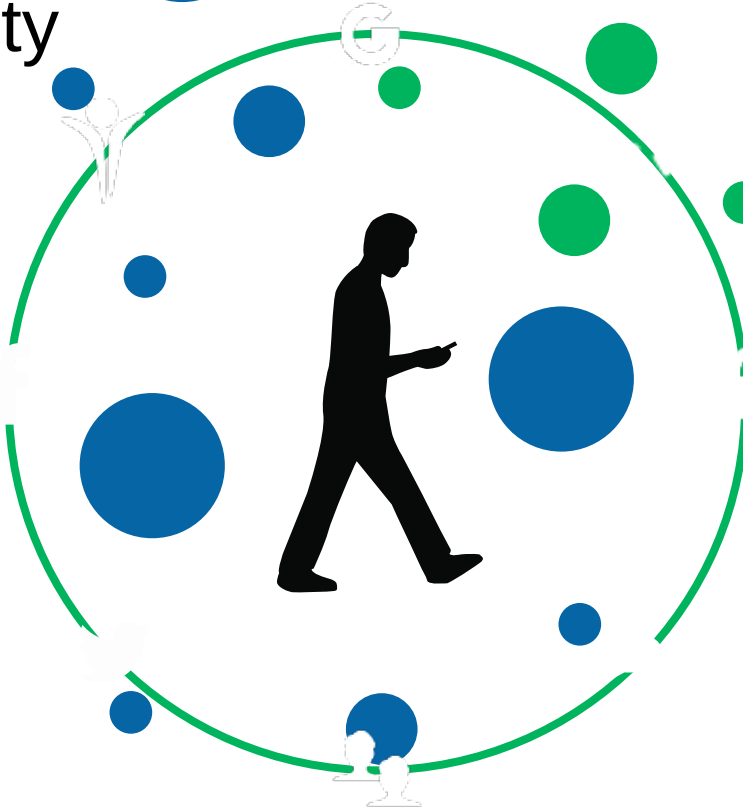
Social Media

Acquire



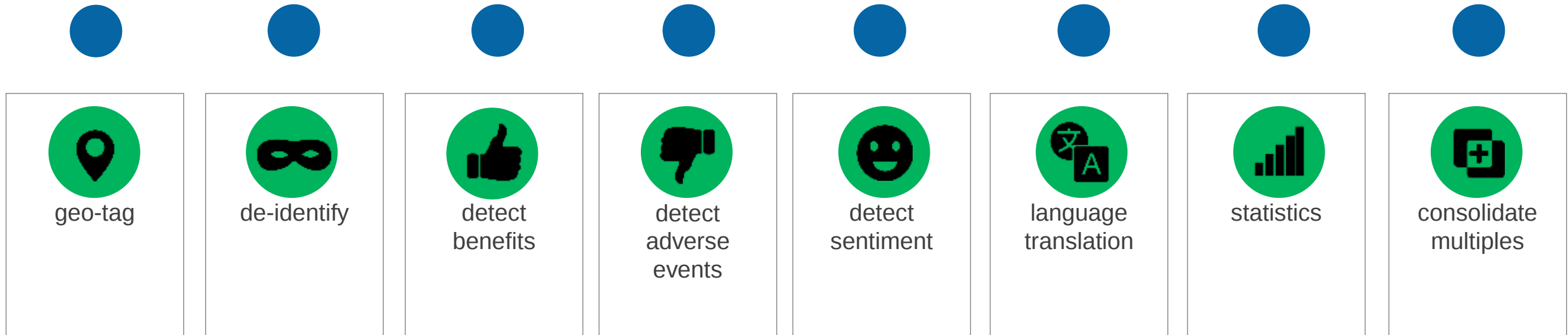
Acquire

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



Process

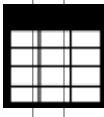
Data are passed through a series of apps, emerging as meaningful bits of information.



Export

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

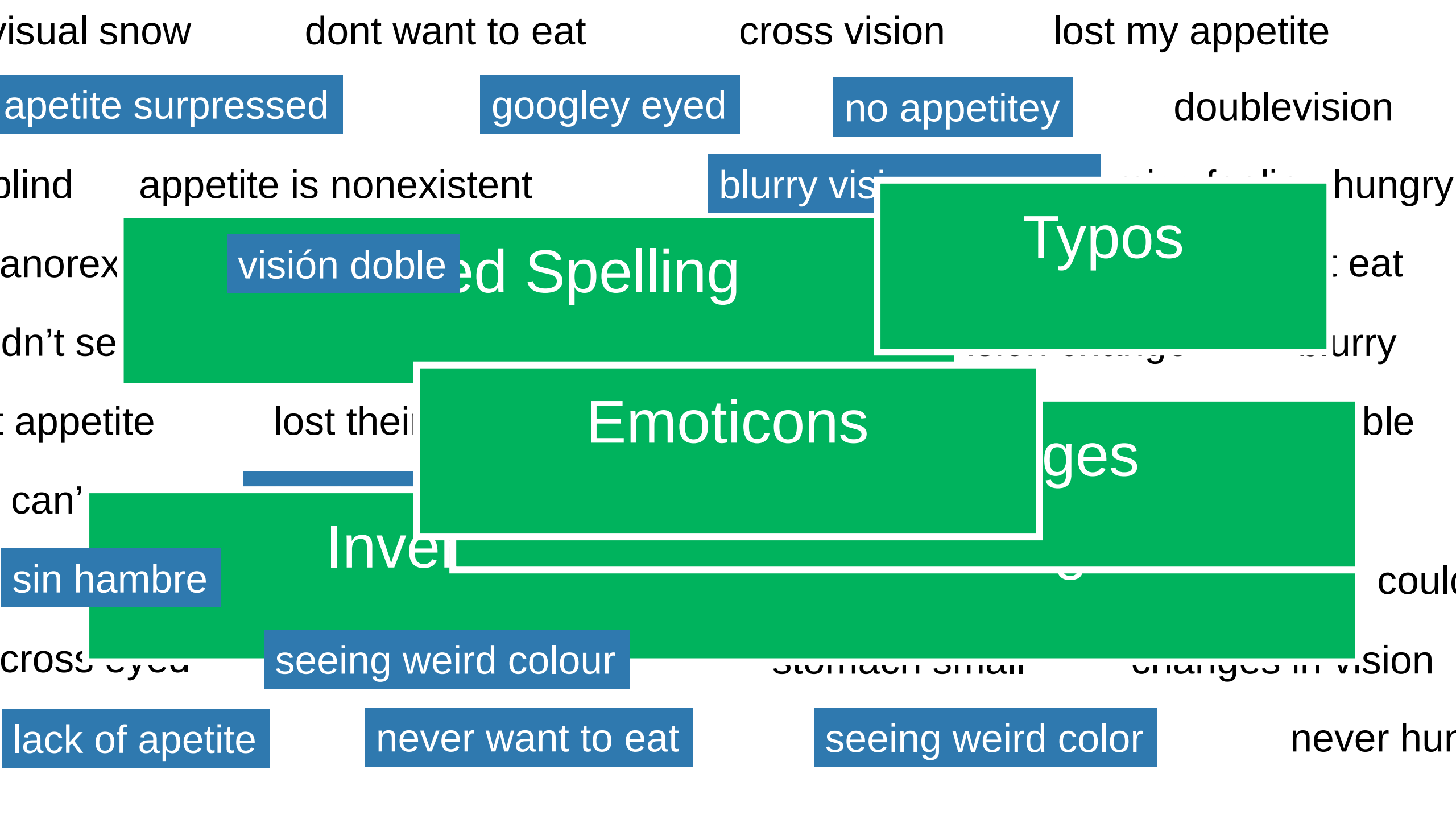


														
geo-tag	API	de-identify	visuals	detect benefits	mobile	detect adverse events	RSS	detect sentiment	CSV	language translation	tables	statistics	reports	consolidate multiples

Export

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





visual snow

dont want to eat

cross vision

lost my appetite

apetite surpressed

googley eyed

no appetitey

doublevision

blind

appetite is nonexistent

blurry visi

hungry

anorex

vision doble

ed Spelling

Typos

: eat

dn't se

urly

t appetite

lost thei

Emoticons

ges

ble

can'

sin hambre

Inver

could

cross eyea

seeing weird colour

stomach small

changes in vision

lack of apetite

never want to eat

seeing weird color

never hun

visual snow	dont want to eat	cross vision	lost my appetite	
apetite surpressed	googley eyed	no appetitey	doublevision	
blind	appetite is nonexistent	blurry vision	 miss feeling hungry	
anorexic	visión doble	#notevenhungry	blindness	cant eat
dn't see	making me eat like a mouse	vision change	blurry	
t appetite	lost their eyesight	didn't get hungry	seeing double	
can't eat	killed my apetite	googly eyed	lost teh appetite	

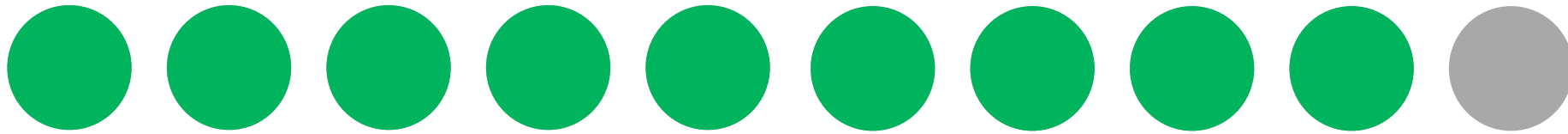
Visual impairment
MedDRA 10047571

Visual impairment
SNOMED 397540003

Decreased appetite
MedDRA 10061428

Loss of appetite
SNOMED 79890006

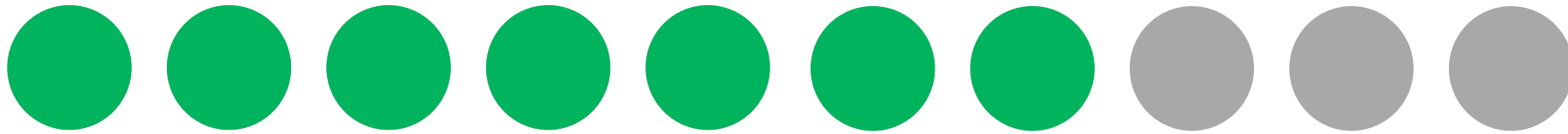
Sensitivity or Recall



Automated tools identify **9** of **10** adverse events
across all products, all time, all data sources (0.88).

The algorithm correctly identifies 9 out of 10 Proto-AEs from the pool of everything.

Positive Predictive Value or Precision



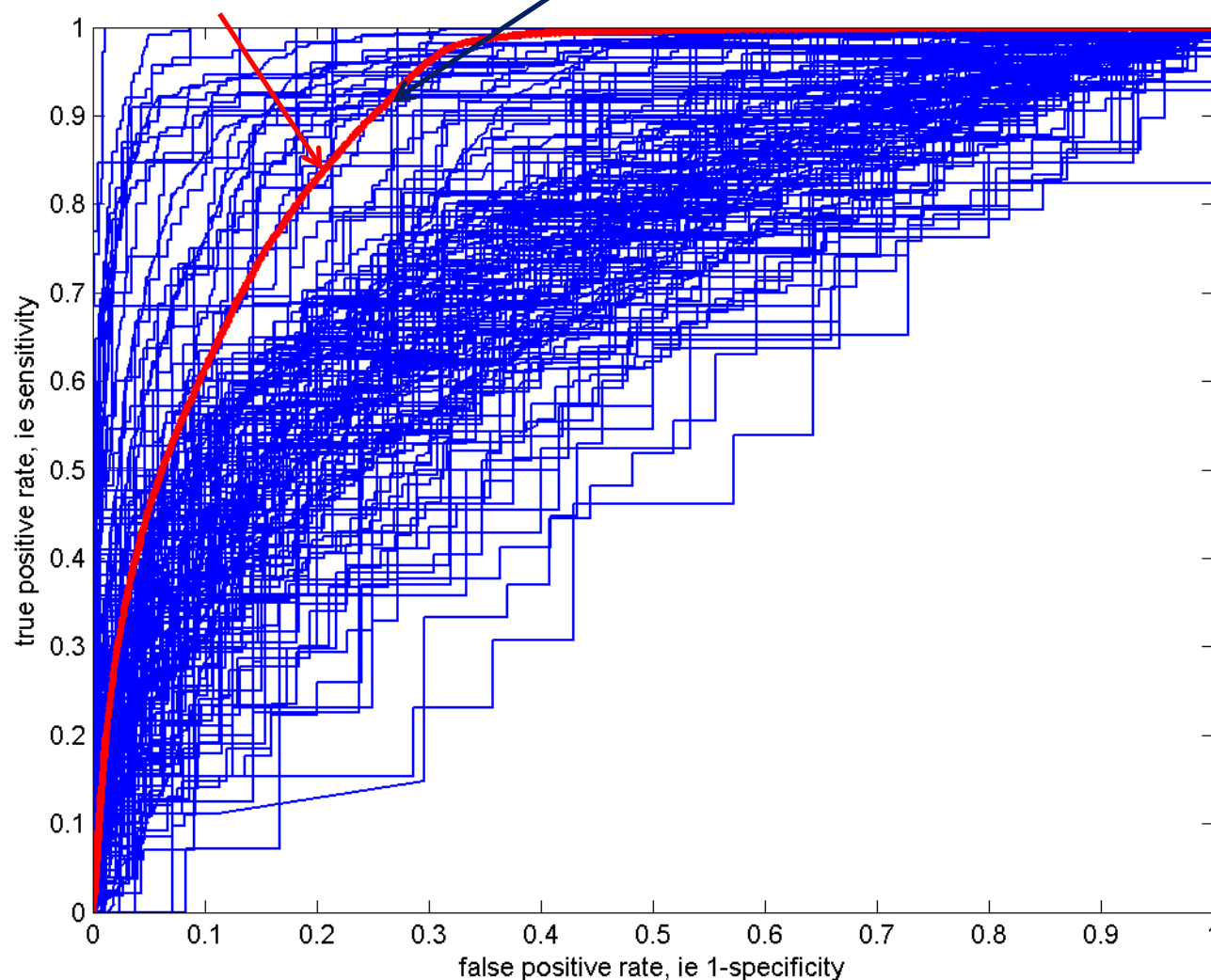
7 OF 10 posts contain adverse event information (0.68).

Can increase to 100% with manual curation (may vary by product).

If the algorithm says it is a Proto-AE, then 7 out of 10 times is actually is.

Performance Varies Across Drugs

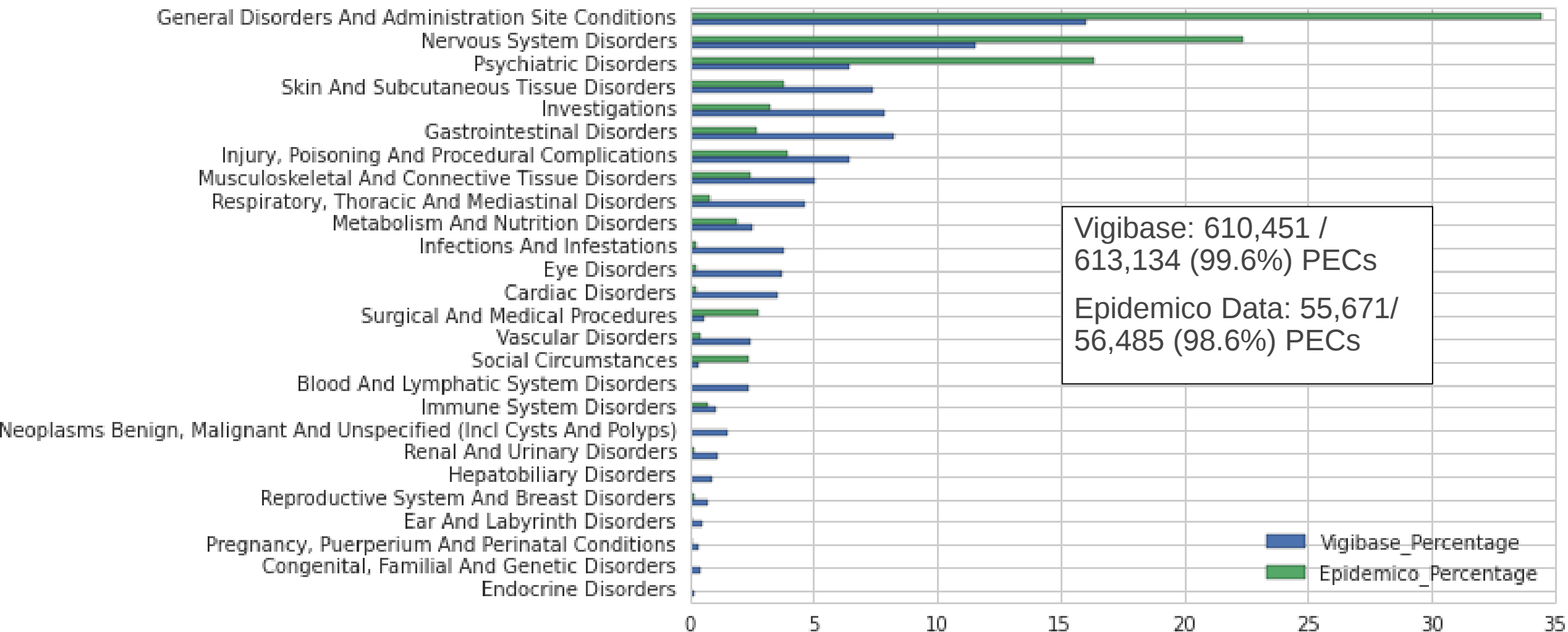
Average Performance Performance in context of specific Drug



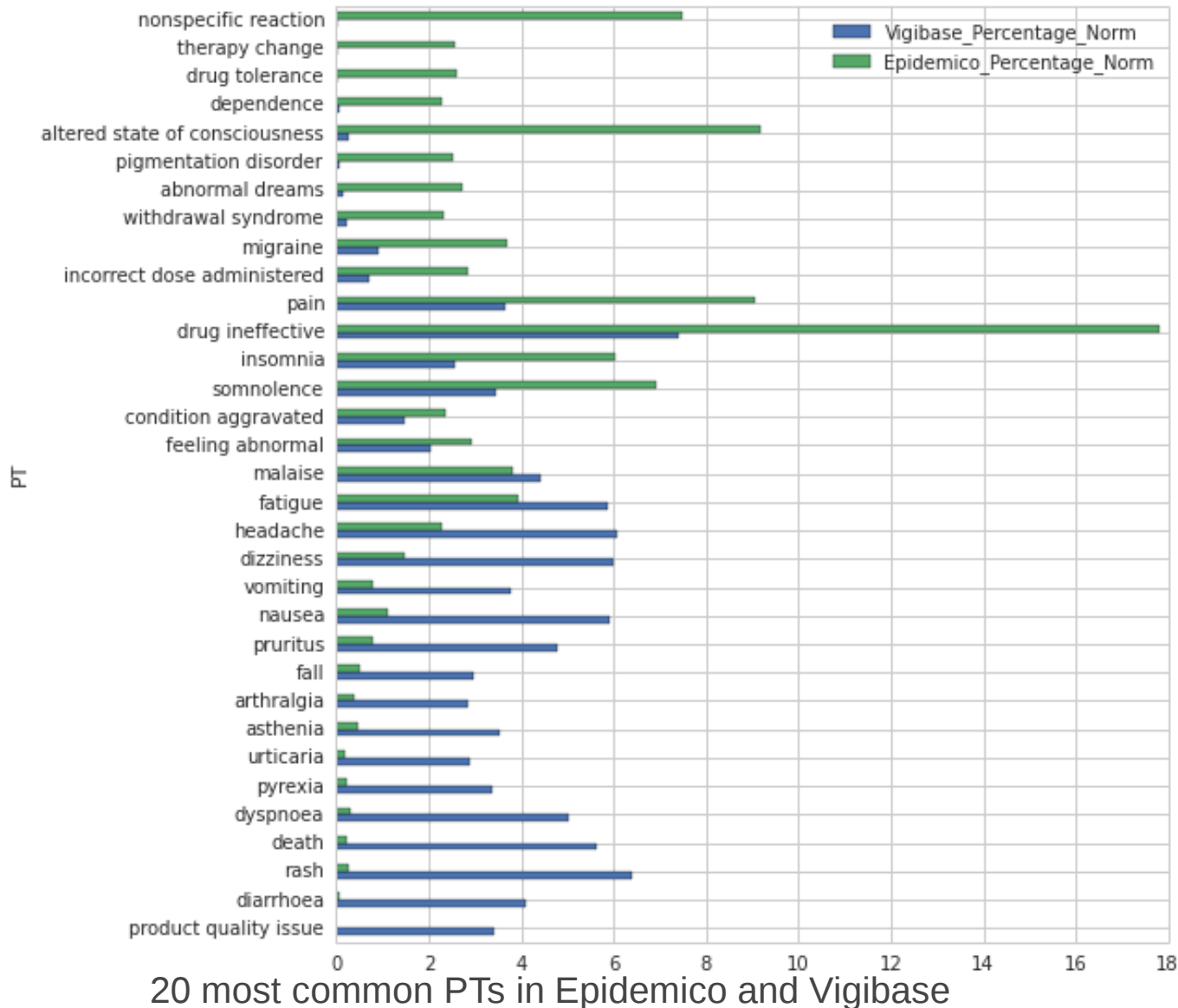
Drug	#Training Data	AUC
humira	1481	0.689893
prednisone	1700	0.740568
co-codamol	2294	0.770509
oxycodone	1767	0.770942
meningococcal vaccine	1866	0.811062
essure	2877	0.931683
flu shot	4569	0.943119
hpv vaccine	1668	0.956768
gardasil	2140	0.970276
vaccine	5959	0.973777
tetanus vaccine	3069	0.975138

Epidemico / Vigibase Comparisons

SOC Comparison



Epidemico / Vigibase Comparisons



	PT	Ratio
239	Injection	270.000000
307	Nonspecific Reaction	231.545455
336	Prescription Form Tampering	149.333333
3	Abdominal Symptom	48.857143
400	Therapy Change	23.432432
129	Drug Tolerance	21.439024
149	Elevated Mood	20.250000
370	Skin Discomfort	15.840000
102	Dependence	13.362069
15	Alcohol Use	13.096774
19	Altered State Of Consciousness	10.393333
331	Pigmentation Disorder	9.906977
124	Drug Diversion	7.687500
5	Abnormal Dreams	5.638037
40	Attention Deficit/Hyperactivity Disorder	4.509434
270	Medical Device Removal	4.000000
171	Feeling Of Relaxation	3.888889
10	Affect Lability	3.681481
433	Withdrawal Syndrome	2.821429
414	Trigeminal Neuralgia	2.477778

Ratio of Epidemico:Vigibase

Where is it useful?

Added value in analysis of:

- Abuse & misuse
- Real world use of medicines



(drugfree.org)

- 'Unexpected benefits'
- Evidence of 'clinical trials' being conducted by users to attain different 'benefits'
- Patterns of abuse both geographically and seasonally
- Patient tolerance and reasons for stopping medication

Where is it useful?

Added value in analysis of:

- Neurological & psychiatric effects
- Pregnancy
- Lifestyle treatments or events



- Large volume of data related to both medicines and events with neuro-psychiatric effects
- Potential for longitudinal analysis of a record; elimination of recall bias over pregnancy?
- Medically less serious events which have a serious impact on the patient and affect compliance

Legal & Ethical considerations

Ethics can only be considered when the legal position is clear



- Public data only?
 - Aggregated private data available as well
- Do people understand how their data can be used?
 - Consent vs responsibility
- When to engage?
 - Responsibility as an HCP vs lack of knowledge about the individuals circumstances

Next Steps

- Complete WEB-RADR research
- Develop policy recommendations
- Ensure sustainability of the project outputs and tools
- Continue research and impact of evolving platforms and technologies
- Embed into regular use where recommended



Thank you. Questions?

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