Social networks, e-health, patients' communication and medicines:

small talks, big data, information?

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EURORDIS

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All Brand Mentions
257,177 posts, 224 pharma brands
100%

Filtered for Relevance
24%

With AE Terms
5%

Contain Side Effect Keywords
(AE Term)
12,530 posts

OTC Rx   OTC Rx   OTC Rx   OTC Rx   OTC
Medicine   Medicine   Medicine   Medicine

3.3% of Side Effect mentions are AERs

1 in 7 have identifiable Name and Contact Info

Adverse Event Reports
0.3% of all Brand Mentions
3.3% of Brand Mentions containing side effect keywords

Source: White paper on Adverse Event Reporting by Visible[R], Oct. 2011,
http://www.visibletechnologies.com/resources/white-papers/adverse-events/

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Signal d...

- AIDS Treatment...
- "Crix Belly"
- ATN: The Crix L... Internet, has dis... ...eople gaining 40 poun...
- ("Crix" for Crixiva... ...: HIV)

AIDS Treatment News
August 15th, 1997

From AIDS Treatment News

Contents:

- Protease Inhibitors' Metabolic Side Effects
- Taxol Approved for Kaposi's Sarcoma
- San Francisco: Changes at Conant Medical Group
- IDSA Annual Meeting, September 12-16, San Francisco
- 1998 Retroviruses Conference: Deadlines Available Soon
- *AIDS Treatment News* Must Increase Prices
- Consensus Letter: Peter Duesberg

For subscription, donation and editorial information and to read our Statement of Purpose, visit AIDS Treatment News' page here at The Body.

Protease Inhibitors' Metabolic Side Effects

Cholesterol, Triglycerides, Blood Sugar, and "Crix Belly."
Interview with Lisa Capaldini, M.D.

by John S. James

[In the last few months we have heard increasing anecdotal reports of a condition which has been named "Crix belly." People may gain 40 pounds or more of fat remarkably quickly in the lower abdomen, and there may also be some muscle wasting in the arms and legs. The cause is unknown. This problem was not seen before the use of protease inhibitors; it is not known if it is associated primarily with indinavir (Crixivan(R)), for which it was named, or if it may be caused by other protease inhibitors as well. Nothing has been published so far.

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Anecdotal posts? Small talks? 20-40% of patients were experiencing this (late onset reaction after several years on treatment):

Fat loss

"Buffalo neck"

Figure 1) Left and right A 52-year-old human immunodeficiency virus (HIV)-1-infected man presented with a football-sized mass in the dorsal cervical area ('buffalo hump'). It had existed as a minor area of fullness for several years, but had dramatically increased in size over the preceding year, after the protease inhibitor indinavir was added to his antiviral regimen

Fat loss, prominent veins

Not seen in clinical trials, but during treatment with authorised combination therapies (post-authorisation)

Belly

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Patients' posts used by regulators: whistle-blowers

- Patients' groups questioned regulators (FDA, EMA) and MAH
- 2/03/1999: "Oversight Committee for Metabolic Disorders of HAART" created by CHMP
  - 5 post-authorisation safety studies, conducted on a voluntary basis by industry
- CHMP 2005: benefit/risk of HAART unchanged despite increased cardio-vascular risk
- PRAC update 2015: Updated advice on body fat changes and lactic acidosis with HIV medicines (http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2015/10/WC500195982.pdf)

- **But: it took months, maybe 1 year, from first patients' discussions on social networks to patients' representatives alerting regulators and then action**
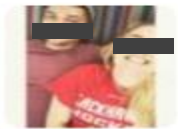
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Analysing social networks

Social media analysis: Proto-SEs

Posts that could be about side-effects
1,5 millions proto-ES for 118 products monitored
(acquisition, filtering interesting posts, duplicate suppression, analysis, imputation)

Albuterol has me feeling all sorts of dizzy and weak this morning

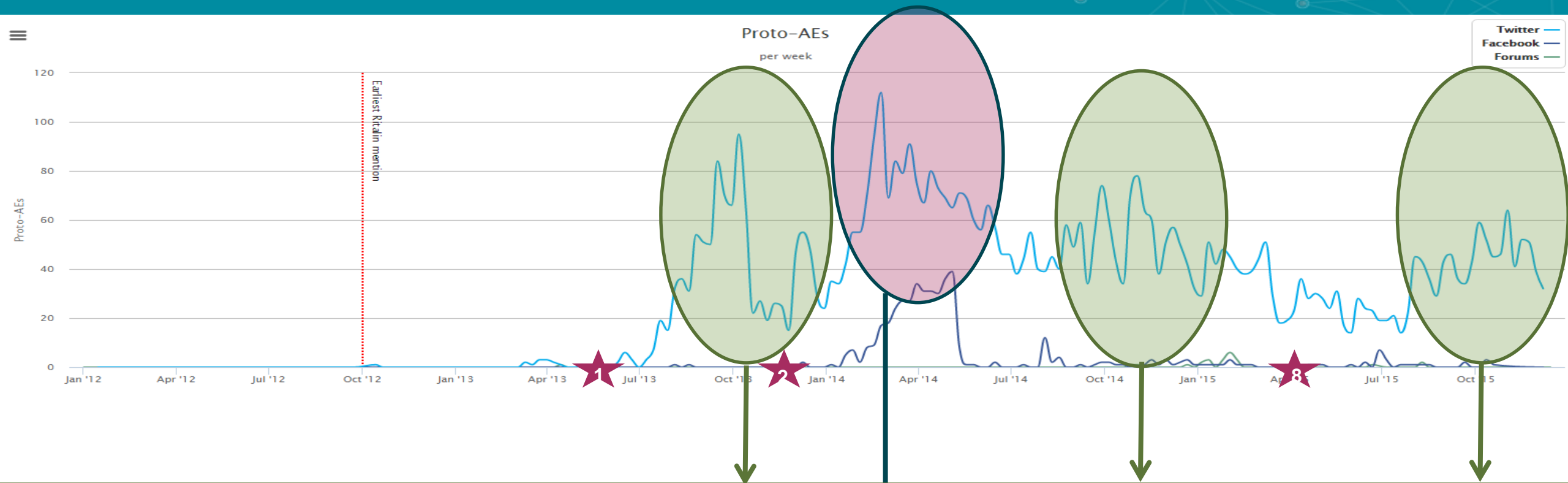6:21 AM - 17 Sep 2015

Asthenia
MedDRA: 10003549
ICD-10: R42

Dizziness
MedDRA: 10013573
ICD-10: R53

Social media conversations on Ritalin over time

October → November – academic work, cold season, contributing to increase mentions

March → April– academic work contributing to increase

Other projects in the field (1)

Vigi4Med

To evaluate the utility of social media as a source of complementary information for pharmacovigilance

- Retrospectively for withdrawn medicines: did patients discuss safety issues before the regulatory decision?
- Prospectively: can unexpected serious ADRs be detected?

- Lardon J, Abdellaoui R, Bellet F, Asfari H, Souvignet J, Texier N, Jaulent MC, Beyens MN, Burgun A, Bousquet C. Adverse Drug Reaction Identification and Extraction in Social Media: A Scoping Review. J Med Internet Res. 2015 Jul 10;17(7):e171. doi: 10.2196/jmir.4304

WEB-RADR

Other projects in the field (2)

ADR-Prism

Can artificial intelligence help understanding what patients say when they discuss ADRs in social media?

- 3 years
- Posts in French "only" (284 Mio people 2015)

Evaluation of the time difference in detecting events in social media versus other sources (vigilance database)

30% of side effects can be detected earlier in social media (up to 38 months earlier)

- Sandrine Katsahian et al. Evaluation of Internet Social Networks using Net scoring Tool: A Case Study in Adverse Drug Reaction Mining http://person.hst.aau.dk/ska/MIE2015/Papers/SHTI210-0526.pdf
- doi:10.3233/978-1-61499-512-8-526

WEB-RADR

And these
are not
health related
information

Figure 2:
Snapshot
disclosure
coded at

Data from a panel of 5,076 Facebo   n 2005.
Silent Listeners: The Evolution of F
Fred Stutzman. Journal of Privacy

WEB-RADR

Innovative Medicines Initiative WEB-RADR project:
mobile technologies and social media as new tools in
pharmacovigilance

Report on the assessment of the relevant
EU data protection legislation and
regulatory guidance

WEB-RADR: Recognising Adverse Drug Reactions

Working together to improve pharmacovigilance through new technology

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age, approximate date and location of hospitalization[2], a match can be found in the health record dataset purchased from the state.

4 Within the electronic record is private patient information including: physician diagnoses, procedures and payment information.

pages™

| Raymond | Boylston | washington | 🔍 |

2

1 Result for Raymond Boylston in WA

Raymond E Boylston

Soap Lake, WA 98851-1435

Age: 60-64

5

Raymond E. Boylston, the man identified in the news article, is linked to "anonymous record" #502855338.

MEDICAL RECORD

RECORD: 502855338
admitend: 10/25/11
STAYTYPE: 1
HOSPITAL: 162
COUNTYRES: 13
AGE_MONTH: 725
ZIPCODE   98851

RACE_WHT Y

ECodeA1   E816

ECodeA3

ECodeA5

3

4 Charges: $71708.47

DescDIAG1

80843: closed fracture of other

specified part of pelvis; pelv

fx-clos/pelv disrup

DescDIAG2

5185: pulmonary insufficiency

following trauma & surgery; post

traum pulm insuffic

DescDIAG3

86500: injury to spleen without

1 – Boylston was 60 years old at the time of hospitalization (which the discharge record shows accurately– 725 months). Boylston's age was inaccurately reported in the news article.

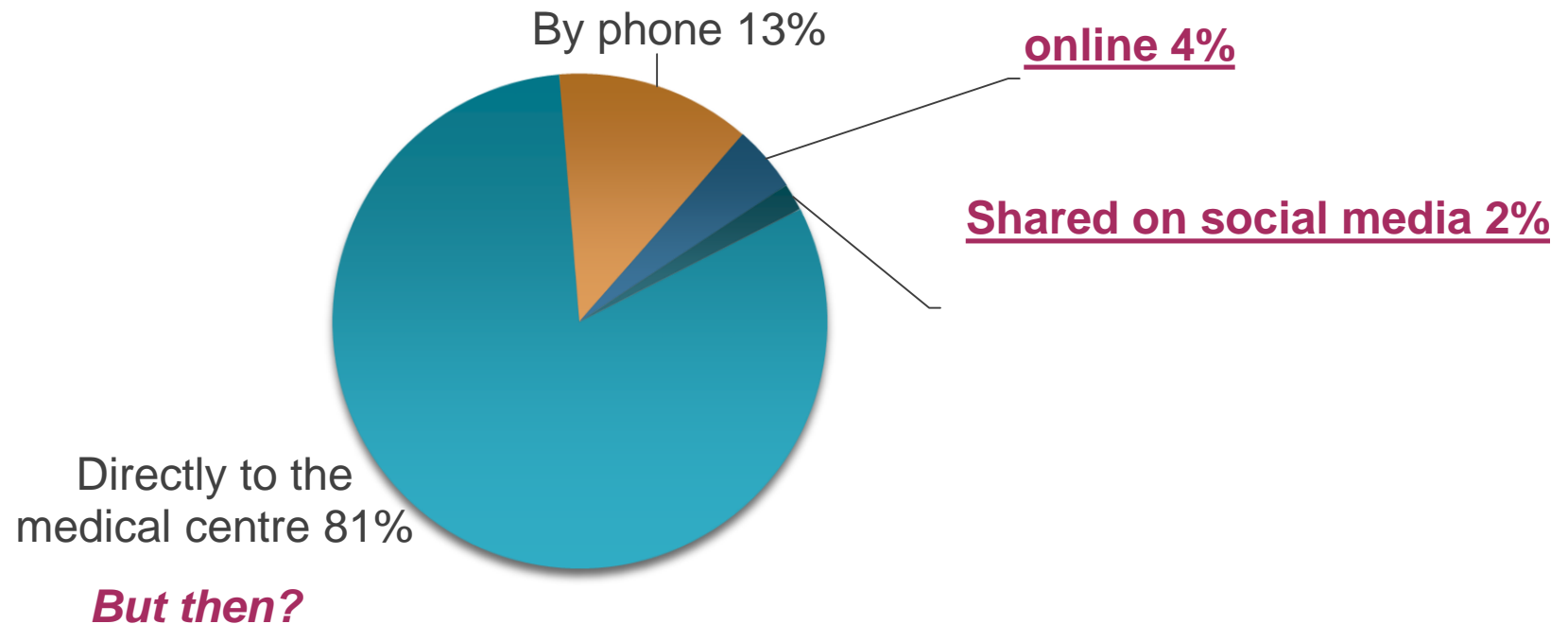2 – Boylston was transported to Lincoln Hospital. He was treated at Providence Sacred Heart in Spokane.

Sources: theDataMap.org, Bloomberg research Graphic by Dave Merrill / Bloomberg Visual Data

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Sharing info on side effects on social media: still an exception / a huge potential

Eurordis **survey on Treatment Information in Rare Diseases 2016.**

1,350 respondents on the use of medicines.

587 said they had a side effect, and 493 reported it.

How did they report?

By phone 13%

online 4%

Shared on social media 2%

Directly to the medical centre 81%

But then?

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Web-RADR: a mobile app to report ADRs Apple App Store and Google Play

▸ **Yellow Card 14/07/2015**
  – Great Britain 90 reports received (59 from professionals, 31 from patients)

▸ **Lareb 29/01/2016**
  – Netherlands, 2 500 uploads
  – 52 reports received, (19 from professionals, 33 from patien
    • Of which 1 signal

▸ **Halmed April 2016**
  – Croatia
  – With OMS Vigiflow

▸ **Zambia, Burkina Faso 2017**

Current functions of the Web-RADR app
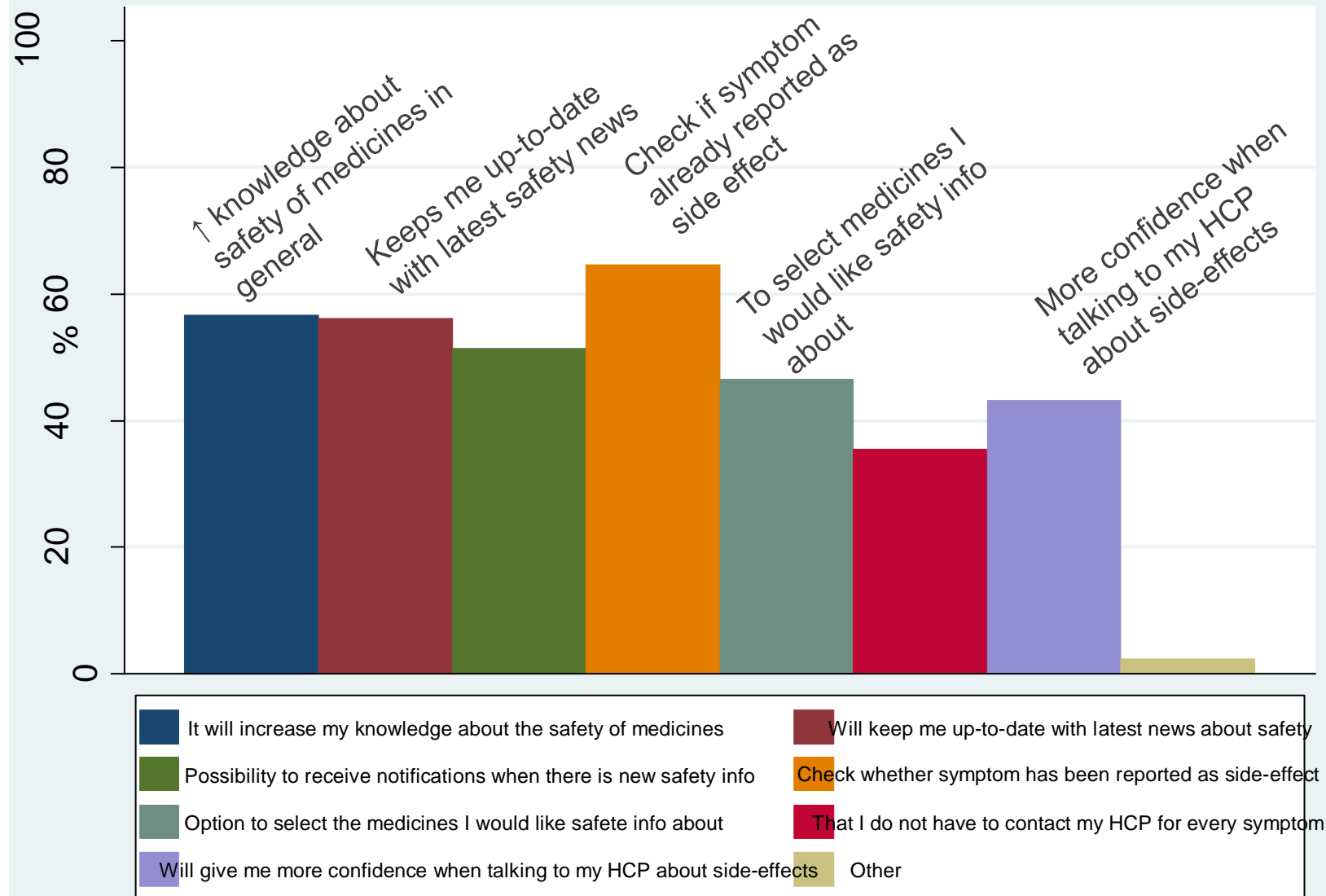
Key features of the mobile app

- Report a suspected ADR to an NCA

And:

- Read generic safety news directly from NCA
- Read news tailored to Watch List
- View graphs of ADRs submitted to the NCA for any product
- View a summary of submitted reports
- Save an ADR report to submit later
- Save a product to Watch List
- In-app notifications

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Information-related benefits: Patients

What are the likely benefits for you in using an app to receive safety information?

Web-RADR user-based evaluation amongst 636 patients, May-September 2016

Peter Mol and WP3B team

Legend:
- It will increase my knowledge about the safety of medicines
- Will keep me up-to-date with latest news about safety
- Possibility to receive notifications when there is new safety info
- Check whether symptom has been reported as side-effect
- Option to select the medicines I would like safete info about
- That I do not have to contact my HCP for every symptom
- Will give me more confidence when talking to my HCP about side-effects
- Other

Web-RADR: establishing a two-may communication between patients and regulators

Research on the utility of social media analysis is only starting (there is more than we think)

Web-RADR can test how the info from social media can be used by regulators

Governance and access to more confidential data will determine ultimate success

Ask

Need for a
choose
preferred

(logy)

- Batch numb

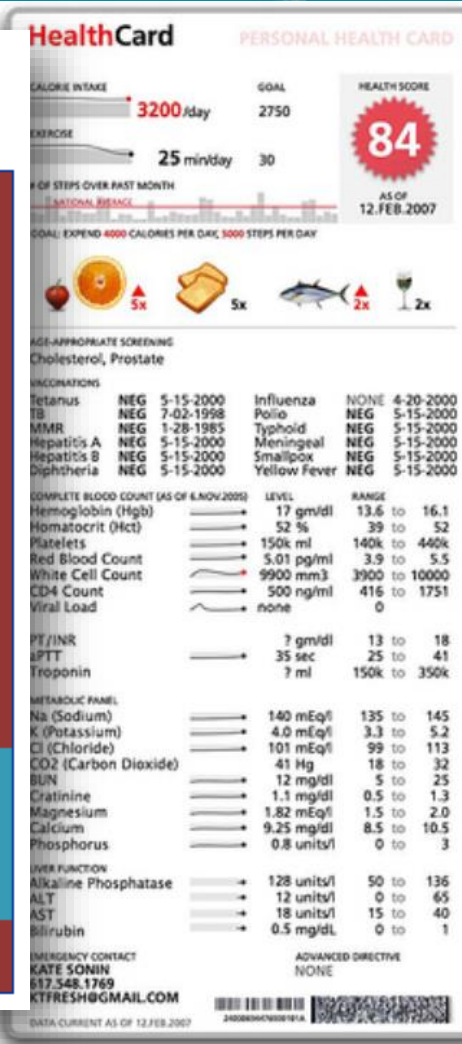## Innovative Medicines Initiative WEB-RADR project: mobile technologies and social media as new tools in pharmacovigilance

Report on the assessment of the relevant EU data protection legislation and regulatory guidance

WEB-RADR: Recognising Adverse Drug Reactions

Working together to improve pharmacovigilance through new technology

Do you want the Web-RADR mobile app in your country?

Aside changing language, colors, and UI…

- Specific fields from NCA's database that may not be standard E2B fields
- Specific E2B codes for reporter qualification
- Choice to activate MedDRA coding functionality for ADRs and indication
- Country-specific product list
- Method for updating News Feed (e.g., RSS)
- Method for updating product information graphs (flat file or API)
- Connectivity with competent authority
- Specific format (JSON, XML) and validation rules for submitting the report to NCA (Json, xml)
- **How much does it cost?**
- **Who will fund these developments when Web-RADR is over?**

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