Real World Data – Biometrics and Beyond

PhUSE SDE, Frankfurt - 06th of May 2014

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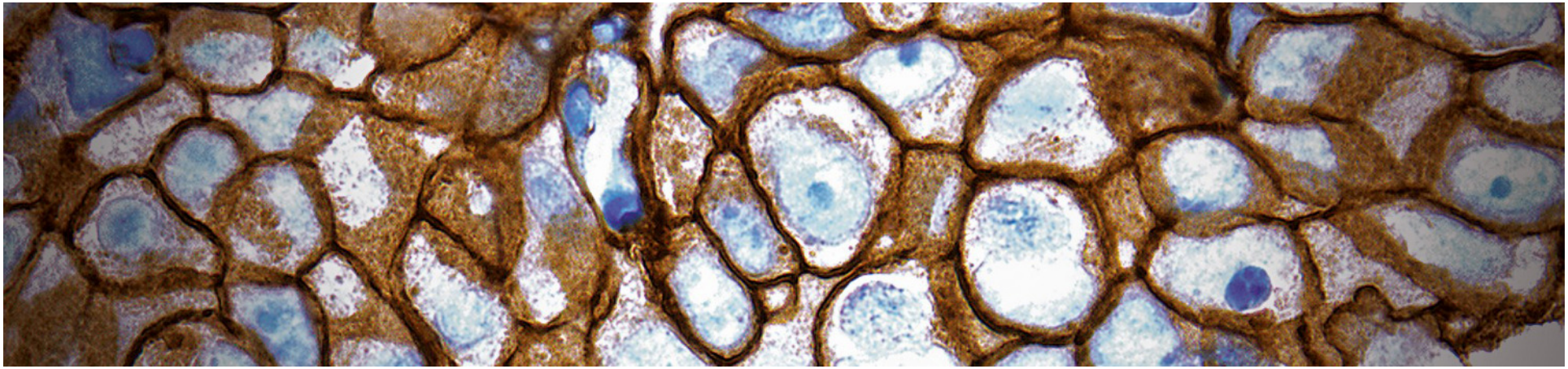
Healthcare Data Analytics



Real World Data
Biometrics and Beyond

- What is Real World Data?
- Current uses within Biometrics
  - Clinical Trial Patient Recruitment
  - Safety Input
  - Molecule Development
  - Risk Estimation
- Current uses outside of Biometrics
  - Comparative Effectiveness
  - Health Economics
- The Future….and beyond

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What is Real World Data?

- Real World Data is any data from external “Real World” sources
  - Insurance claims databases
  - Electronic medical/health records
  - Social media feeds
  - Web trawling of online documentation
  - Biosensor device data
  - Mobile App data
  - Genomic/Proteomic/Xxxxxx-omic data
  - Publicly available environmental data
  - Marketing survey data
- Generally very large, unwieldy, secondary purpose data

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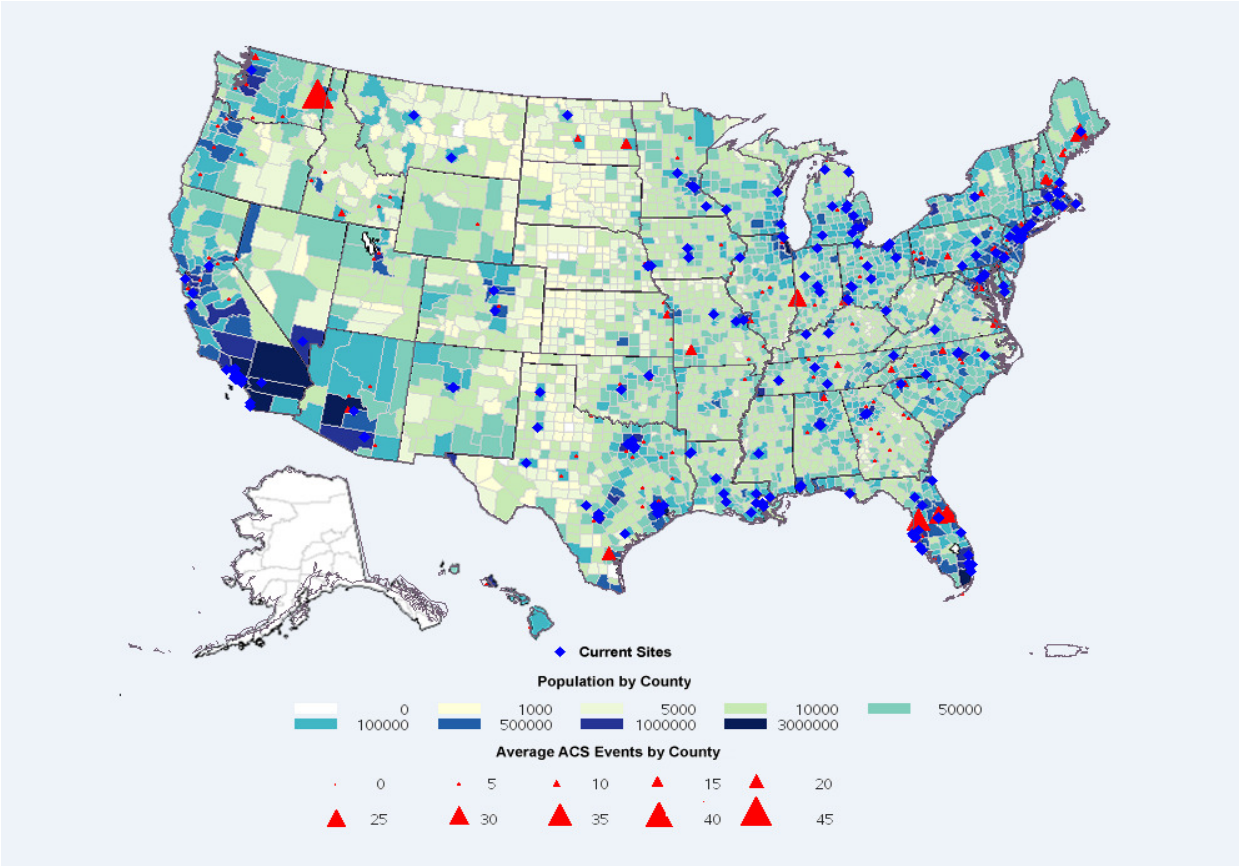
Current uses within Biometrics

Clinical Trial Patient Recruitment

- Data can be used to input into patient recruitment strategies



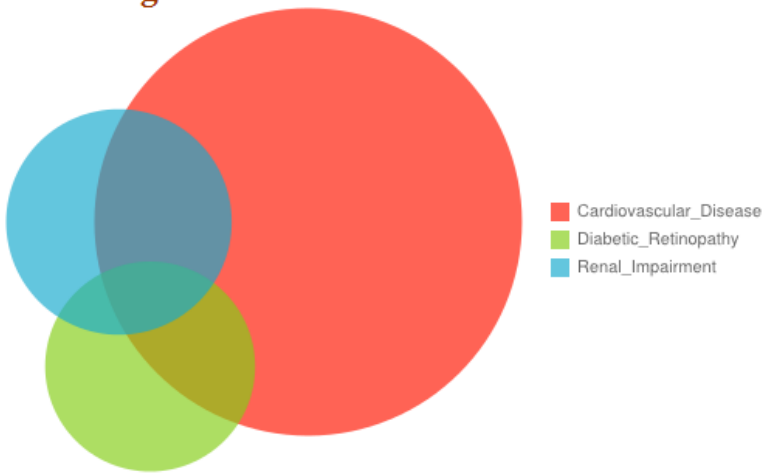
Current uses within Biometrics

Clinical Trial Patient Rec

- Quantification of potential patient recruitment overlaps
  - Two trials for the same indication but slightly different subpopulations
  - Data can provide an overview of the scale of the overlap
  - Allows insights into whether studies will be in direct competition with one another
  - Can influence site selection for both studies

Diabetic Patients With...	Count	Percent (N=2,069,067)
No Conditions Of Interest	1,165,959	(56.4%)
Cardiovascular Disease Only	557,520	(26.9%)
Diabetic Retinopathy Only	83,859	(4.1%)
Renal Impairment Only	70,530	(3.4%)
Cardiovascular Disease and Diabetic Retinopathy Only	61,290	(3.0%)
Cardiovascular Disease and Renal Impairment Only	94,560	(4.6%)
Diabetic Retinopathy and Renal Impairment Only	12,702	(0.6%)
Cardiovascular Disease and Diabetic Retinopathy and Renal Impairment	22,647	(1.1%)
Any Diabetic Retinopathy	180,498	(8.7%)

Venn Diagram



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Current uses within Biometrics
Safety Input

- Safety Surveillance
  - Clinical duty to proactively monitor marketed compounds
- Clinical trial submissions
  - Provide context into clinical trial data being supplied to regulators
  - Investigations can be carried out to provide context into potentially concerning safety aspects of clinical trials
- Investigations of off-label treatment patterns
  - New requirement from the EMA which will feed into the Periodic Benefit Risk Estimation Report (PBRER)

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Current uses within Biometrics Molecule Development

- Pre-defining the disease area under investigation.
- Inform on decisions to end a molecules development early thereby saving money
- Enable the continuance of development perhaps where a unique patient value is seen

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Current uses within Biometrics
Risk Estimation

- Risk plays a major part in all safety analyses
- Creation of Benefit/Risk profiles which feed into Risk Management Plans (RMPs)
- Monitoring of risks associated within populations taking certain compounds or with certain diseases in order to gauge potential impact.
- Given what is known about our molecule, is it ethical to treat patients with a certain history profile?

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Current uses outside of Biometrics
Comparative Effectiveness

- On the market research comparing competing drugs for
  - Efficacy
  - Costs
  - Risk/benefit ratios
  - Regional variations in usage
- Allows companies to better target and place their drugs on the market to better benefit patients
- Can provide evidence to payers in order to back up arguments for inclusion of a drug into the approved usage lists (formularies).

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Current uses outside of Biometrics
Health Economics

- Analyses can be done (mainly using the insurance claims data sources) into the charges and expenditures relating to certain treatments
- Funding bodies (NICE, etc.) may not be willing to pay for your drug
  - Cost/benefit ratios can be analyzed and provided
  - Comparative studies can be performed into competitor compounds
  - Evidence can be gathered to help build an argument

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The Future….and beyond
Genomic Analysis

- Increasing volumes of genomic data becoming available.
- More opportunities to link this data to patients in the real world.
- Allows for more intelligence around real world genotypes.
  - Ancestry
  - Health condition risks
  - Predictive profiling around ageing and diseases

The Future….and beyond
Publication Trawling

- Using text analytics to “mine” for intelligence from online publication sites (PubMed, Clintrials.gov, etc.)
  - Disease profiling
    - Co-medications
    - Co-morbidities
    - Standard of care
    - Disease burden
  - Risk identification
    - Patient
      - potential risks to patients to be avoided
    - Business
      - purchasing of new compounds, can identify how viable automatically based on CT successes or by looking into documentation around the drug family
      - Can measure the REAL success of clinical trials, not just the apparent success and meeting of goals

The Future….and beyond
Environmental factors

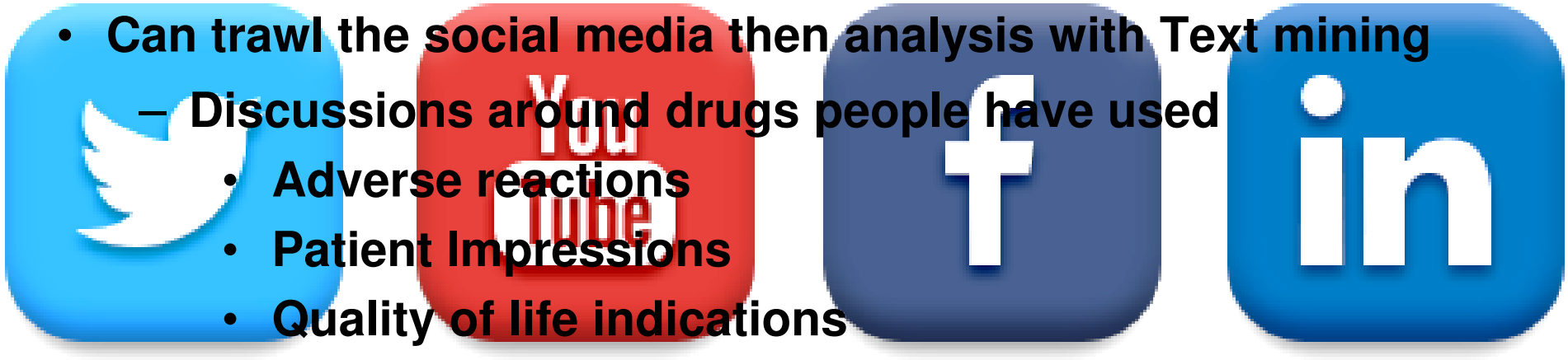
- Combining health data with publicly available data sources around environment
  - High voltage lines
  - Traffic
  - Pollution
  - Climate change
  - Pollen counts
  - Temperature data
  - Pesticide use

The Future….and beyond
Feedback forums

- Feedback forums for patients
  - Text mining can be used to extrapolate patient experience/adverse reactions
  - Demographics available
  - Potential for medical history linkages
  - Location obtained

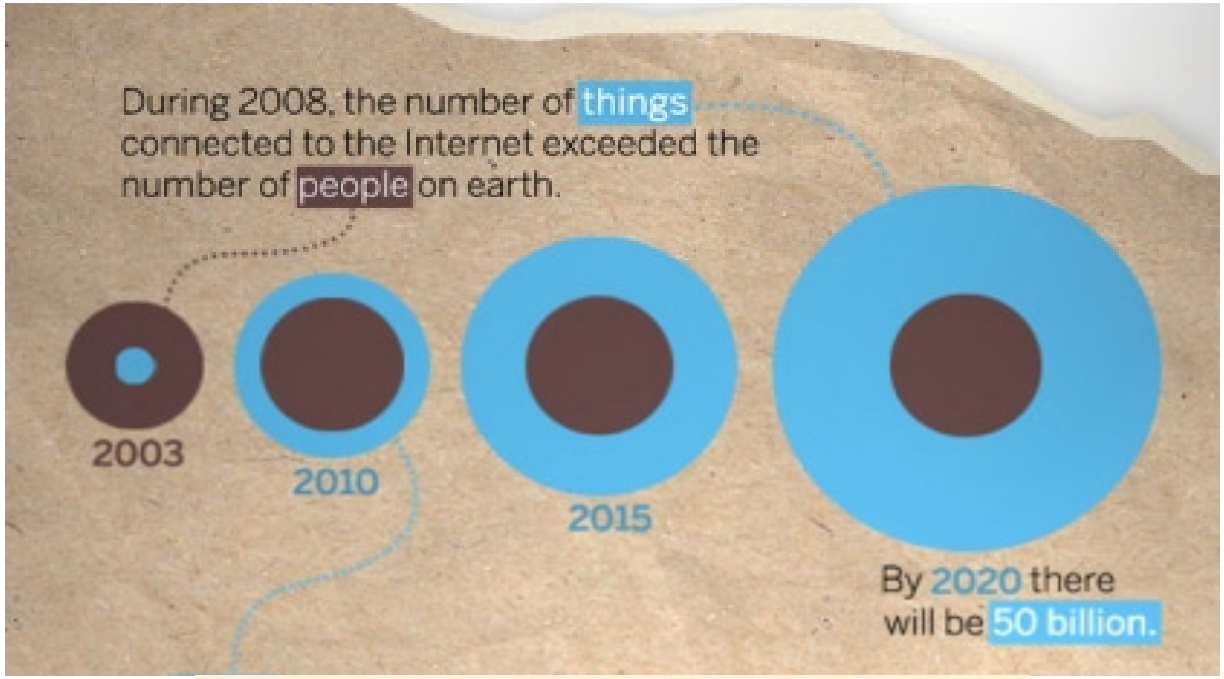
The Future….and beyond
Social Media

- Can trawl the social media then analysis with Text mining
  - Discussions around drugs people have used
    - Adverse reactions
    - Patient Impressions
    - Quality of life indications
    - Company perceptions
  - Discussions around disease areas
  - Safety patterns
    - Could help identify bad batches of medications or even help identify when and where “fake” drugs are being sold




The Future….and beyond
The Internet Of Things

- What is the internet of things?



Fridges that talk, watches that listen and thermostats that learn your secret domestic habits: these are some of the most visible examples of the so-called "internet of things"

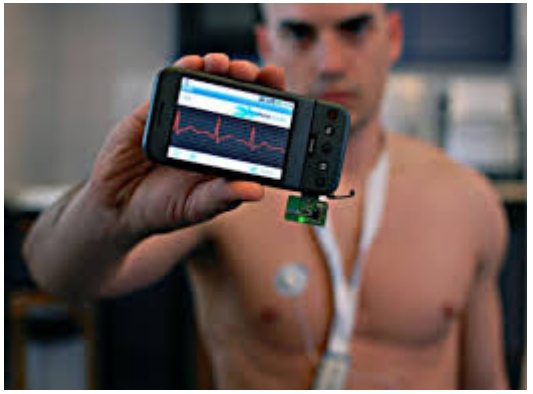
1 - http://www.bsr.org/en/our-insights/bsr-insight-article/the-opportunities-and-challenges-of-things-connected-to-the-internet
2 - http://blogs.ft.com/tech-blog/2014/05/who-will-be-the-google-of-the-internet-of-things/

The Future….and beyond
Biosensor data

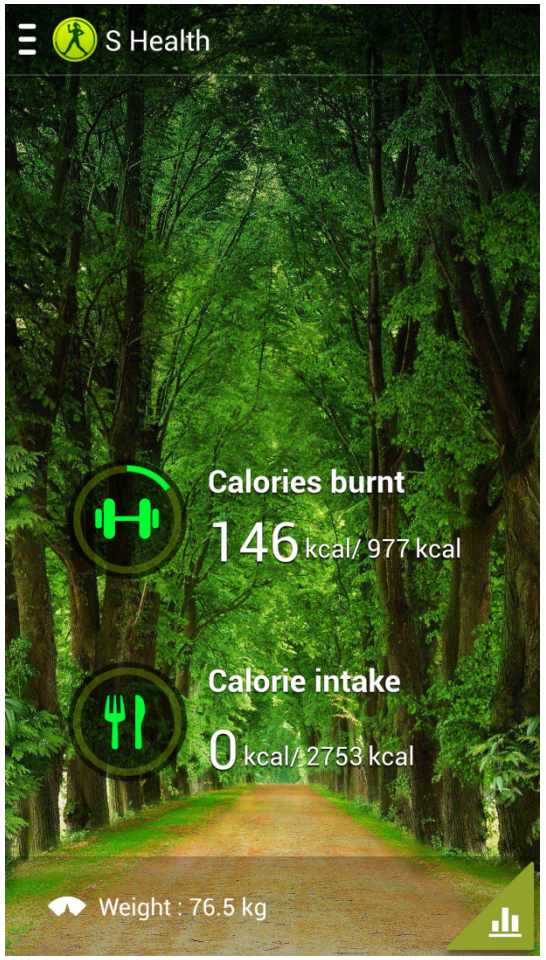
Lactate threshold monitor pairs with Garmin computers and watches

The Future….and beyond
Mobile Apps

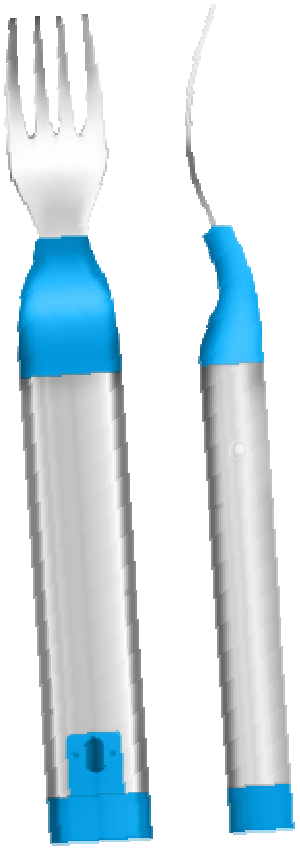
Fig. 1. iPhone wireless accelerometer application for characterizing Parkinson's disease tremor.



The Future….and beyond
Self reporting



The Future….and beyond
Device data



Conclusion

- RWD is already making a huge impact in the clinical trials area, helping to reduce the cost of development, increasing the chances of technical success, increasing patient safety and reducing the time to market
- However, this is just the beginning. As more and more “things” become connected to the internet, more and more data is becoming available with ever increasing complexity and data linkages
- Companies need to start thinking about their strategies for how to invest in these areas. Developing mobile apps or self reporting devices and ensuring that the data is properly utilised
- With so much going on and so many possibilities the key is going to be targeting the right data for answering the right questions

Any Questions?

Doing now what patients need next