

Datos de Vida Real e Investigación Clínica

Dr. Ramon Colomer

Hospital Universitario La Princesa, Madrid

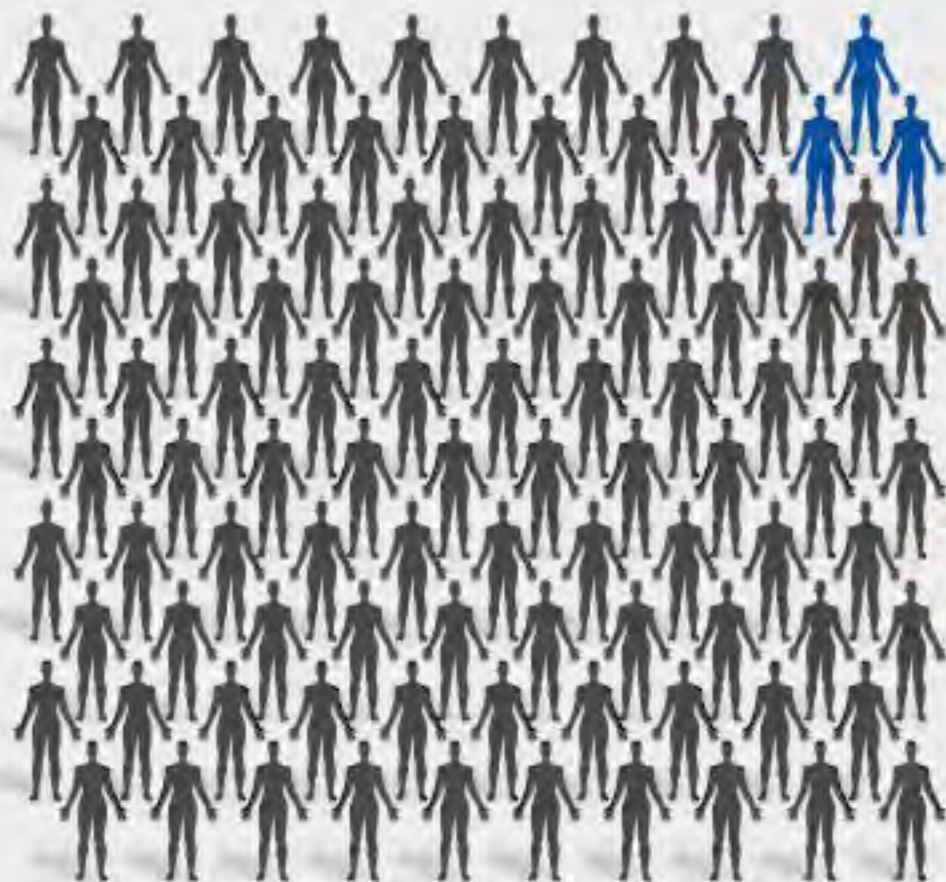
Universidad Autónoma de Madrid



225.000 personas se
diagnostican cada
año de cáncer en
España

A donut chart with a thick grey border. The center is white and contains text. A small orange segment is highlighted on the right side of the donut. An orange line extends from this segment, turning 90 degrees downwards to point at a second text block.

Solo el **3%** participan
en ensayos clínicos

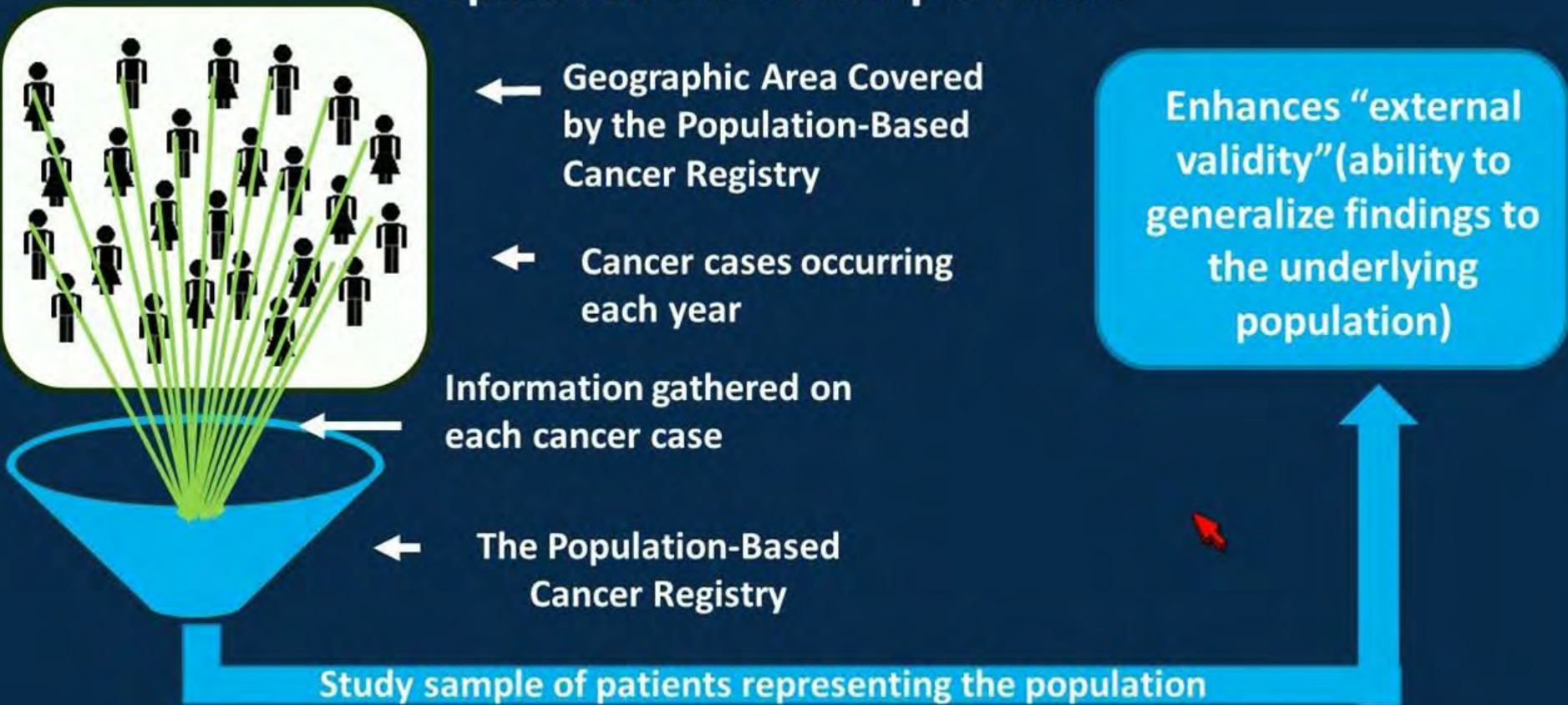


3% of
cancer
patients
enrolled in
clinical trials

97%

are not
represented

Population-Based Sample Frame





Google Flights

Un algoritmo
ayuda a comprar
el billete más
barato

Vuelos

Ida y vuelta

Solo ida

Varias ciudades

Turista

1 adulto

Madrid (todos los aeropuertos)

Estados Unidos

mié., 30 de noviembre

dom., 4 de diciembre

Escalas

Compañía aérea

Horarios

Más

Descubre destinos

FECHAS

PLACES

INTERESES

30 nov. – 4 dic.

Estados Unidos

Cualquier destino

Noviembre

Diciembre

enero de 2017

Febrero

Marzo

Abril

Fin de semana

1 semana

2 semanas

Seleccionar fechas específicas

Seattle

832 €

Boise

1.094 €

Reno

1.089 €

Los Ángeles

639 €

Houston

768 €

Winnipeg

592 €

Minneapolis

897 €

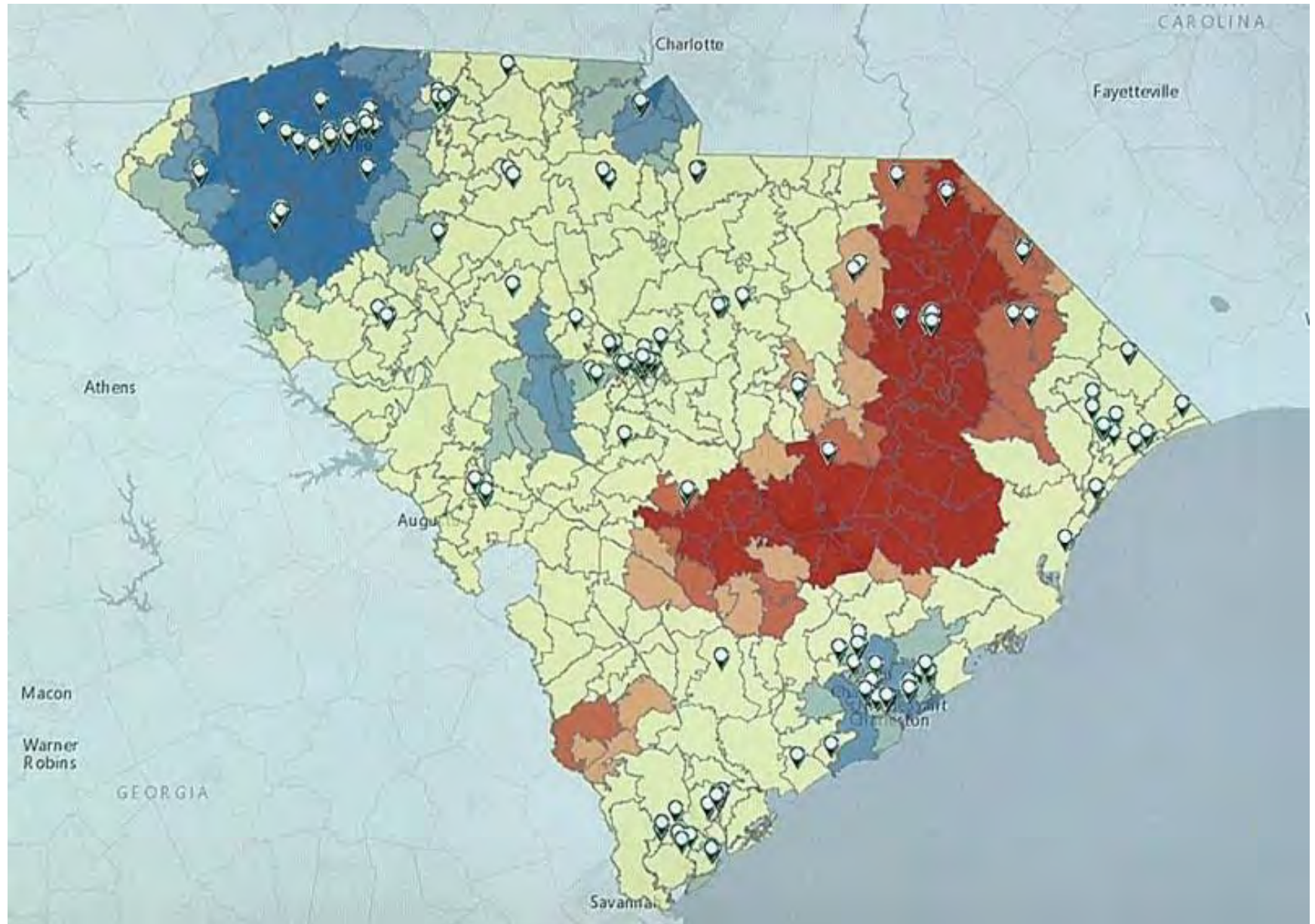
Chica

748 €

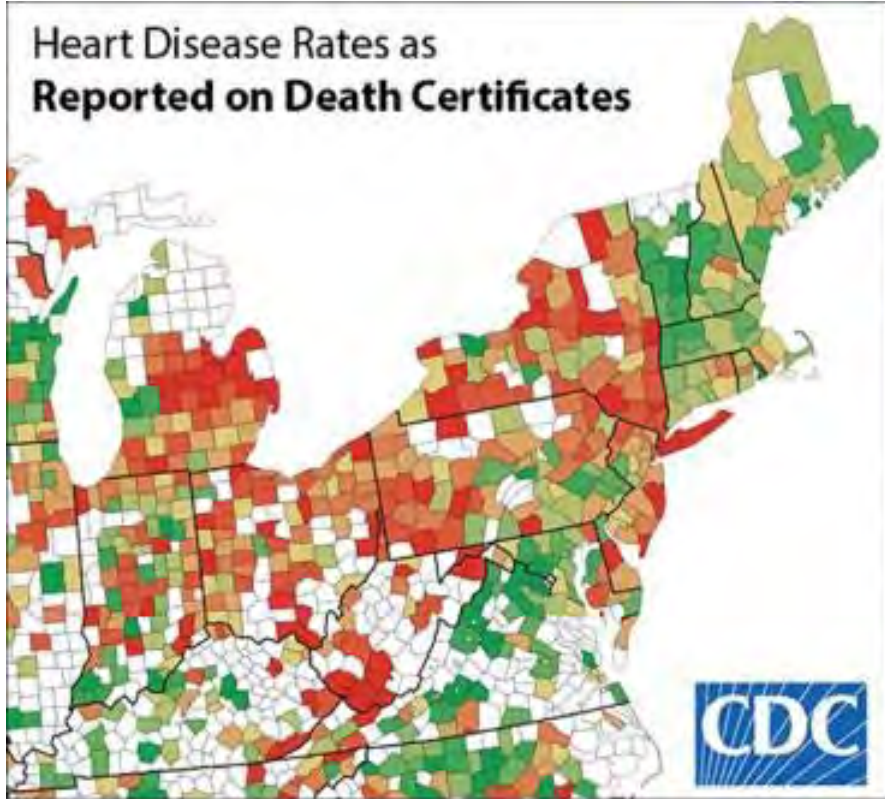
Los Ángeles

Museo · Shopping · Concierto · Estudio cinematográfico · Arte

Incidence of low birth weight babies based on zip codes in South Carolina

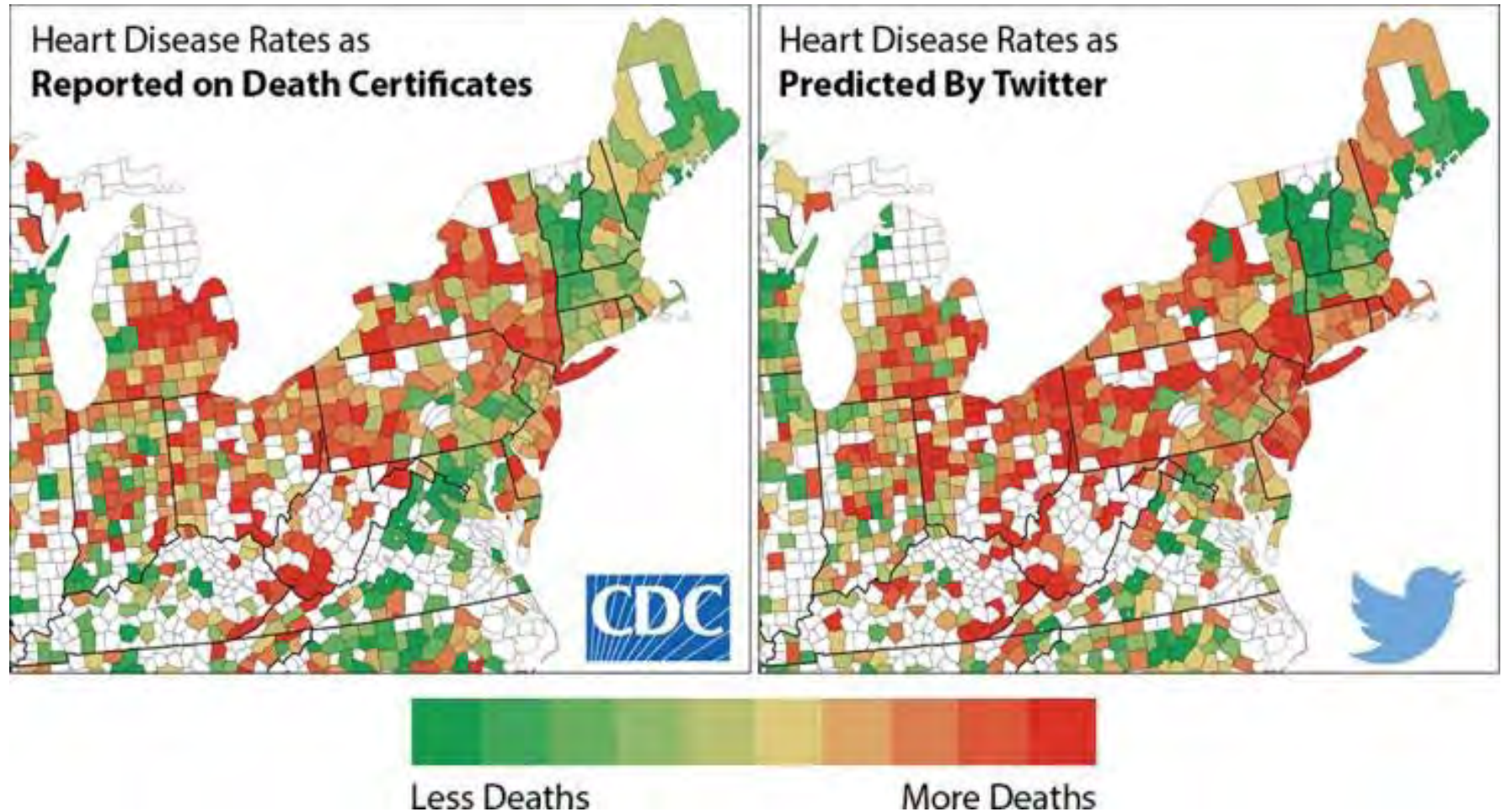


Heart Disease Rates as
Reported on Death Certificates



Less Deaths

Twitter Can Predict Rates of Coronary Heart Disease, According to Penn Research



journal [Psychological Science](#)

Correlation between a CDC study on cardiovascular disease and a study conducted based on hostility in Twitter tweets





87% of Oncologists Consider 'Real World' Evidence when Recommending Treatment

How often do you consider the 'real world' evidence on product effectiveness and safety, when you prescribe oncology medications?

	All	
All the time	95	37%
Most of the time	129	50%
Sometimes	27	11%
Rarely	3	1%
Never	2	1%
DK/NA	1	0%
	257	1



Too Much Information: The Doctor's Data Dilemma



By 2020, doctors will face

200x

the amount of medical data
and facts that a human could
possibly process.¹



And it will get worse...
The volume of medical data
doubles
every five years.²



81% of physicians
can't even spare
5 hours
per month
to keep up.²



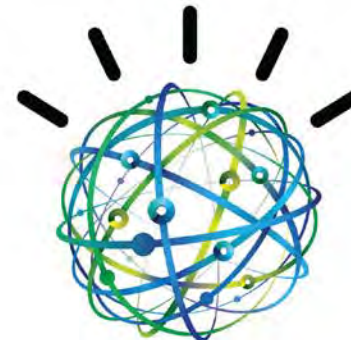
The answer? IBM® Research and Cleveland Clinic are bringing Watson™ to medical school to create a learning application for students.



Watson will help students
navigate medical
information and make the
best decisions for
improving patient care.



Students will also be able
to **teach and train**
Watson to advance its
knowledge.



WATSON™

¹ William Stead, IOM Meeting, October 8, 2007. Growth in facts affecting provider decisions versus human cognitive capacity
² University of Oulu, Finland January 15, 2009

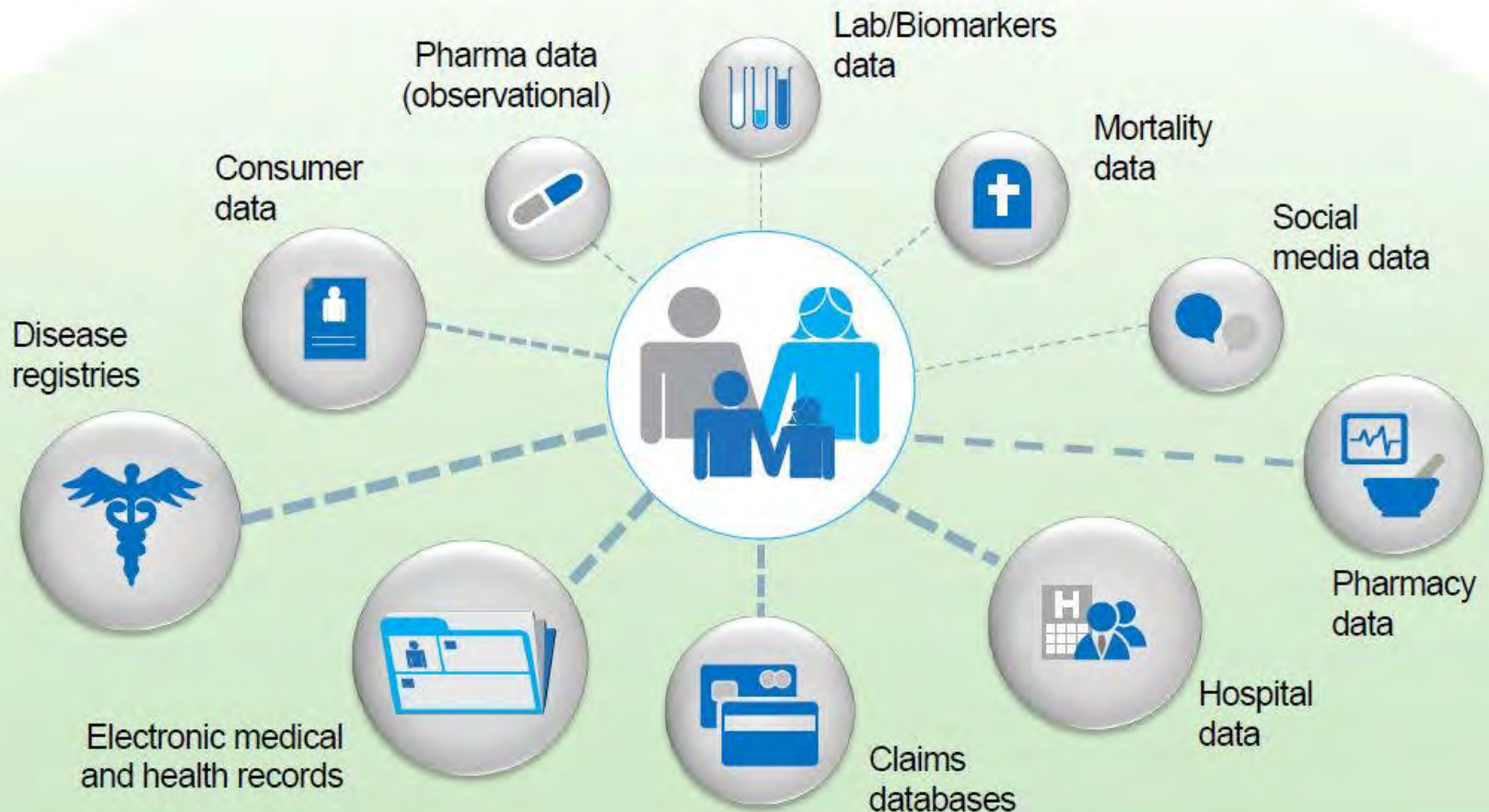
Too much information?



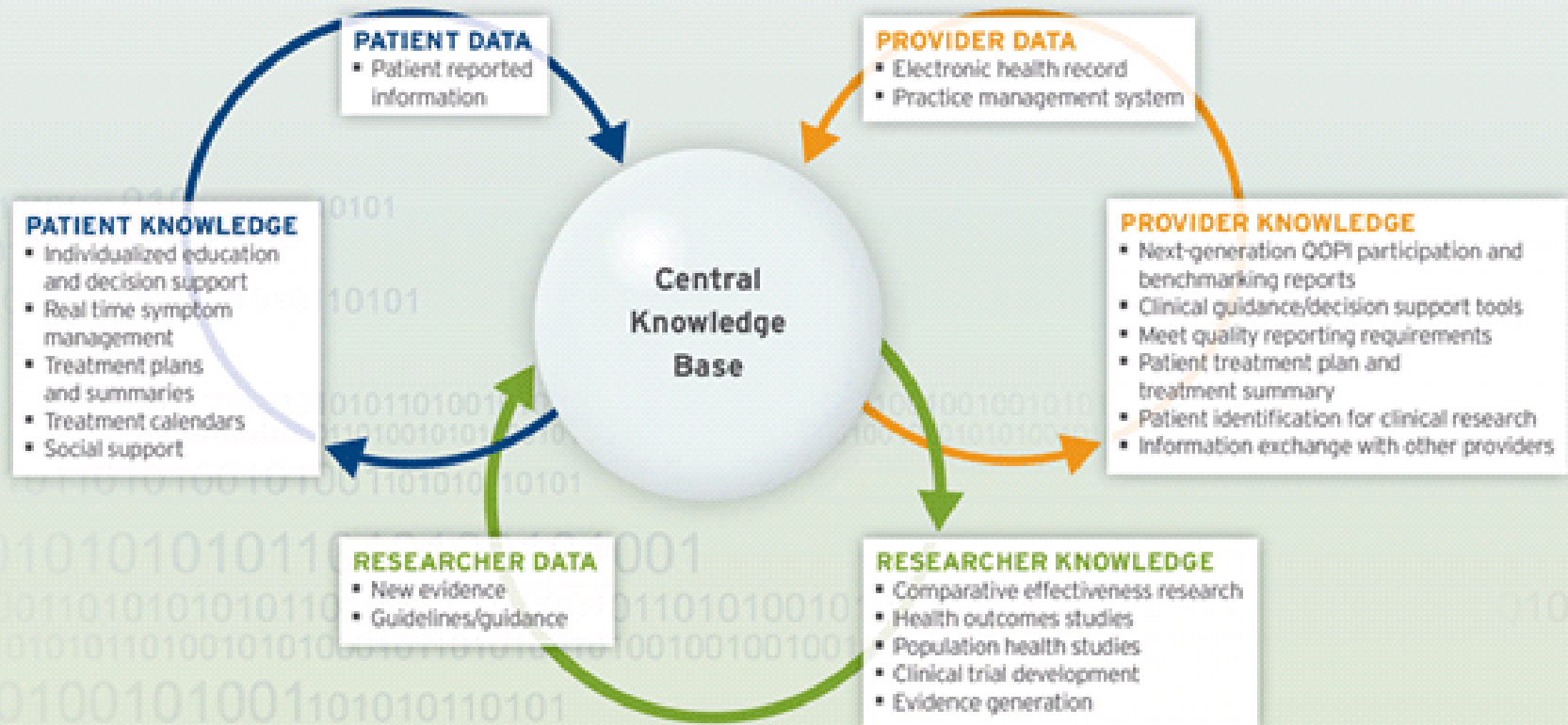
Too much information?

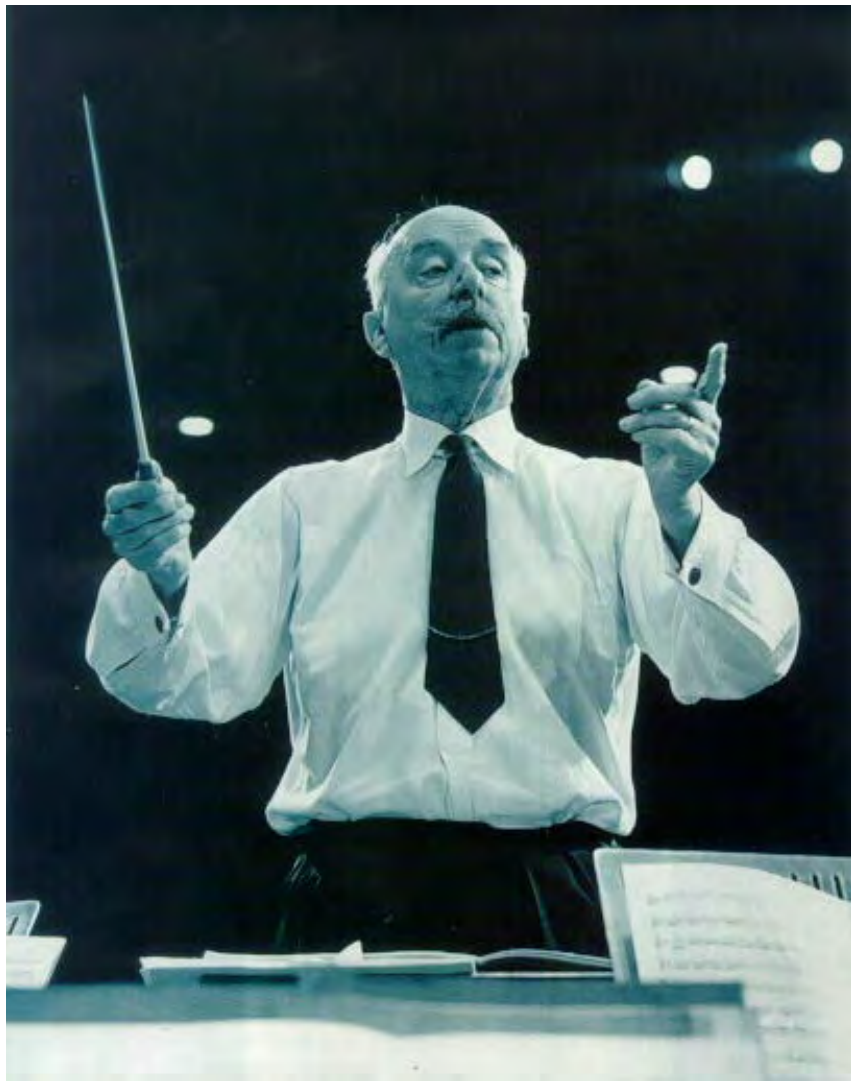
Sources of Real-World Data (RWD)

RWD is PATIENT data



Too much information?





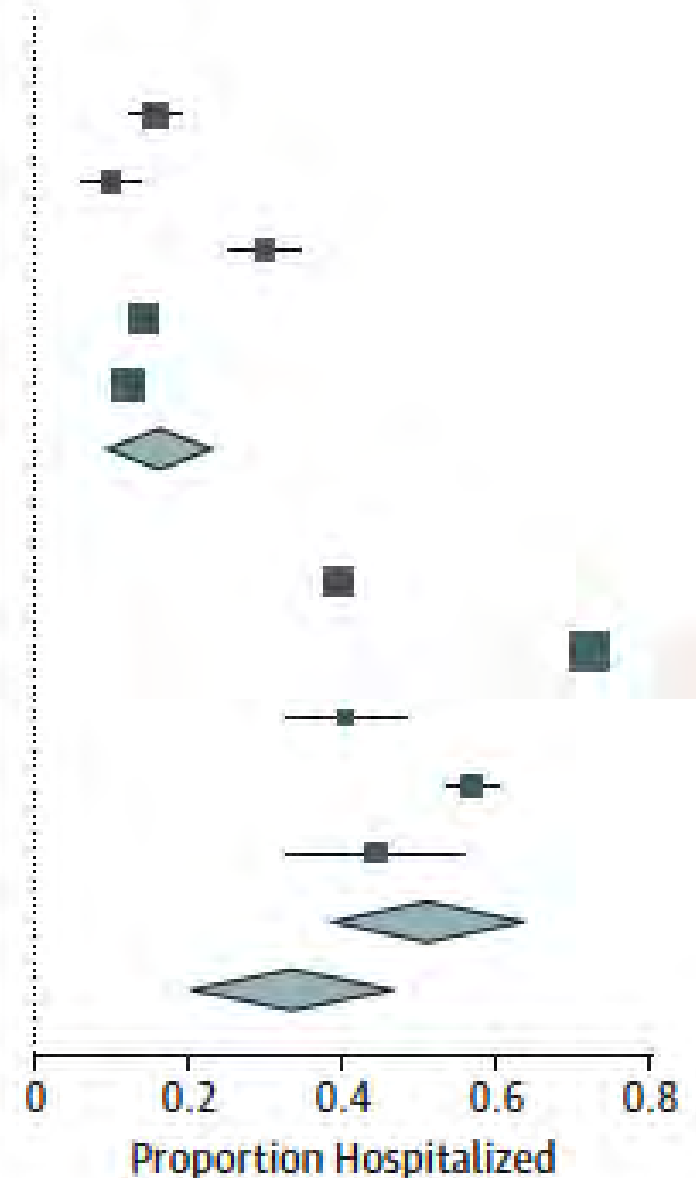
Aplicaciones de la RWE en Investigación

- Responder preguntas que no pueden contestarse en EECC
- Congresos específicos: ISPOR 2016
- Algunas experiencias en España
- Workshops agencias reguladoras

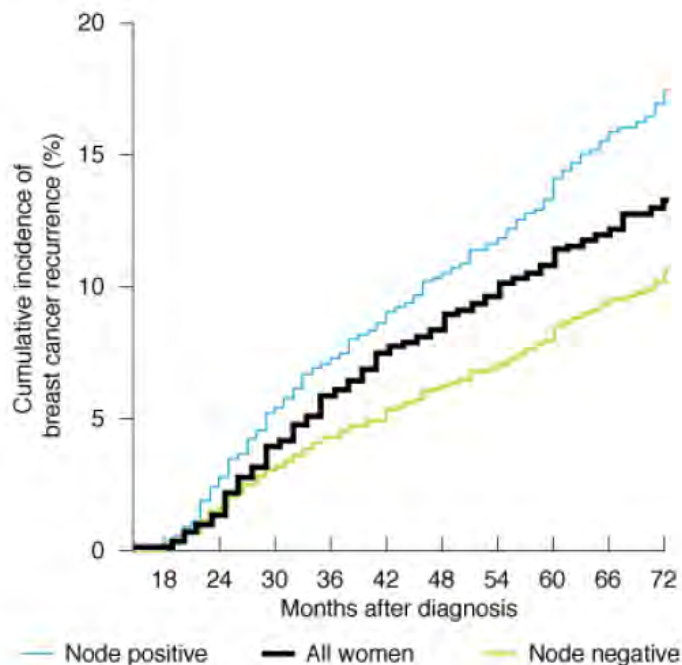
Aplicaciones de la RWE en Investigación

- **Responder preguntas que no pueden contestarse en EECC**
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Source	Proportion Hospitalized (95% CI)
RCT patients	
Hanna et al, ¹¹ 2004	0.16 (0.12-0.19)
Sederholm et al, ¹² 2005	0.10 (0.07-0.13)
Helbekkmo et al, ¹³ 2008	0.30 (0.25-0.34)
Novello et al, ¹⁴ 2010	0.14 (0.12-0.16)
Gridelli et al, ¹⁵ 2012	0.12 (0.10-0.14)
Summary	0.16 (0.09-0.23)
Real life patients	
Lang et al, ¹⁶ 2009	0.40 (0.38-0.41)
Vera-Llonch et al, ¹⁷ 2011	0.72 (0.71-0.73)
Früh et al, ¹⁸ 2013	0.41 (0.33-0.48)
Pan et al, ²⁰ 2013	0.57 (0.54-0.59)
Zauderer et al, ¹⁹ 2013	0.44 (0.33-0.56)
Summary	0.51 (0.38-0.63)
RE model	0.33 (0.20-0.46)



Breast cancer recurrence following active treatment: determining its incidence in the NSW population



Conclusion

Our results indicate that women with primary breast cancer in NSW practice develop recurrent breast cancer at the rate of 3.3% annually in the period 18 months to 6 years after diagnosis – substantially higher than the 2.0% annually reported previously.⁹ In a 2007 Australian survey, consumers reported ‘up-to-date information’ and ‘managing concerns about cancer coming back’ as among their greatest unmet needs⁸, highlighting the need for timely and accurate recurrence data from Australian practice. The method we report for ascertaining breast cancer recurrence can be used to assess population-level changes over time and to investigate the real-world impact of specific treatments on outcomes in the absence of available Cancer Registry data on recurrence.

RWE en Investigación

- Publicaciones sobre preguntas que no pueden contestarse en EECC
- **Congresos específicos: ISPOR 2016**
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ISPOR 19th Annual European Congress

29 October-2 November 2016
Austria Center Vienna
Vienna, Austria



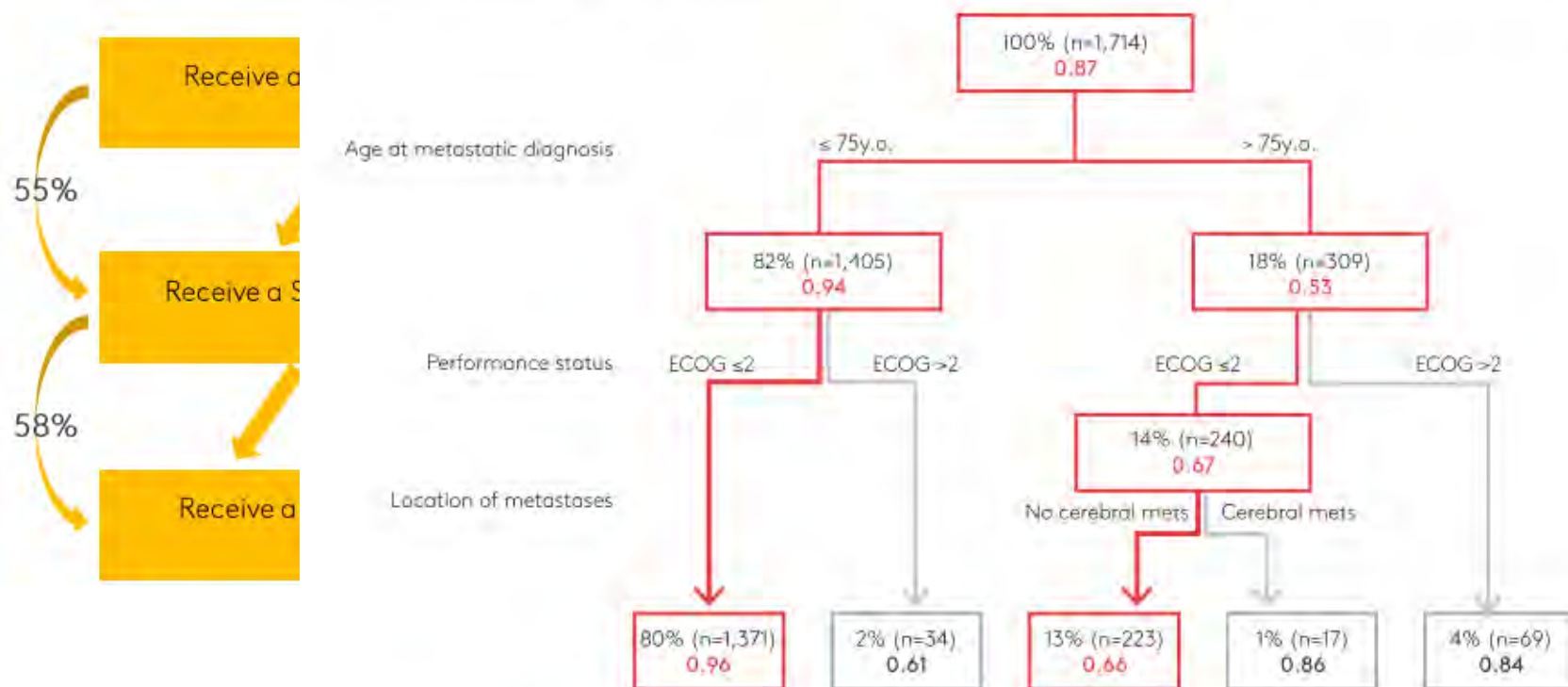
Managing Access to Medical Innovation: Strengthening the Methodology-Policy Nexus

International Society for Pharmacoeconomics and Outcomes Research

TREATMENT RATES IN PATIENTS WITH HER2+ METASTATIC BREAST CANCER AND THE FACTORS INFLUENCING TREATMENT DECISIONS

R. Colomer¹, P. Hall², M. Szkulciecka-Debek³, R.C. Bondi⁴, A. Flinois⁵, S. Auziere⁶, J-Y. Le Cléac'h⁵
¹Hospital Universitaria La Princesa, Madrid, Spain; ²Edinburgh Cancer Centre, Edinburgh, UK; ³Roche Polska, Warsaw, Poland; ⁴Roche SAS, Basel, Switzerland; ⁵Kantar Health, Paris, France

Factors Determining Physicians' Decisions to Administer a First Antitumor Treatment or SCO



Figures in red: likelihood to receive a first treatment for that group of patients

Figures in black: likelihood to receive SCO for that group of patients

Real-World Treatment Patterns in High-Risk and Metastatic Melanoma: Evidence From the SEER-Medicare Linked Database

Debanjali Mitra,¹ Keith L. Davis,¹
Srividya Kotapati,² Uchenna Iloeje²

¹RTI Health Solutions, 200 Park Offices Drive, Research Triangle Park, NC 27709. ²Bristol-Myers Squibb, 5 Research Parkway, Wallingford, CT 06492, US

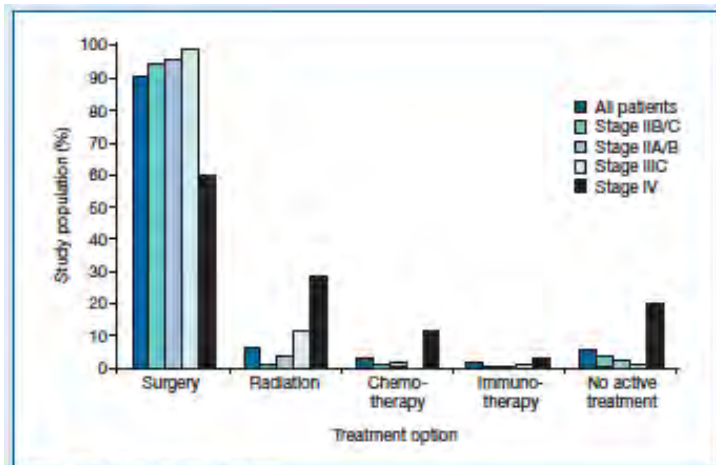


Figure 2. First-line treatment options.

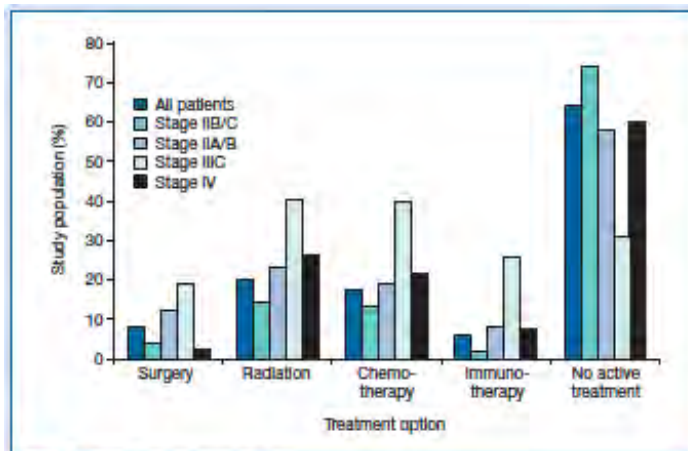


Figure 3. Second-line treatment options.

Conclusions

- Results suggest that beyond surgery as a first-line approach, relatively few patients received other types of treatment as either first- or second-line therapy.
- Findings demonstrate the need for more efficacious treatment alternatives for high-risk and metastatic melanoma.
- Additional analyses of administrative data characterizing real-world treatment patterns in melanoma are needed to help inform the direction of future clinical trials.

RWE en Investigación

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Spanish RWE plan: retrospective and prospective studies



Outcomes of the Spanish cohort of early access to pertuzumab and trastuzumab emtansine.



A prospective registry study in patients with unresectable locally advanced or metastatic breast cancer patients (MBC)



RegistEM Study



KnowHER

Outcomes of the Spanish cohort of early access to pertuzumab and trastuzumab emtansine.



RegistEM

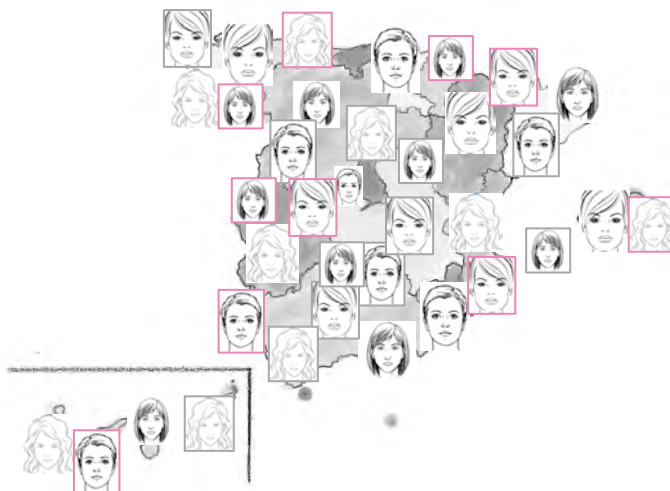
A prospective registry study in patients with unresectable locally advanced or metastatic breast cancer patients (MBC)



RegistEM

A prospective registry study in patients with unresectable locally advanced or metastatic breast cancer patients (MBC)

- N=1400
- **252 HER2 positive patients**
- 978 Luminal patients
- 170 Triple Negative patients



Global Umbrella study
UMBTDM1



RegistEM Study



RegistEM study will analyze:



The patient and tumor characteristics.



The treatment patterns along the course of the advanced or MBC disease.



Efficacy data (PFS, OS, RR) for each breast cancer subtype as well as by line and class of anticancer therapy in routine clinical practice.

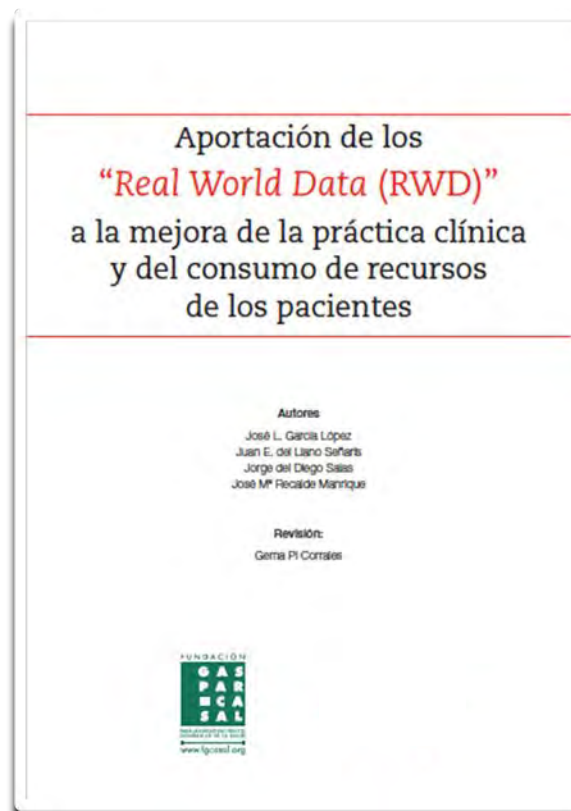
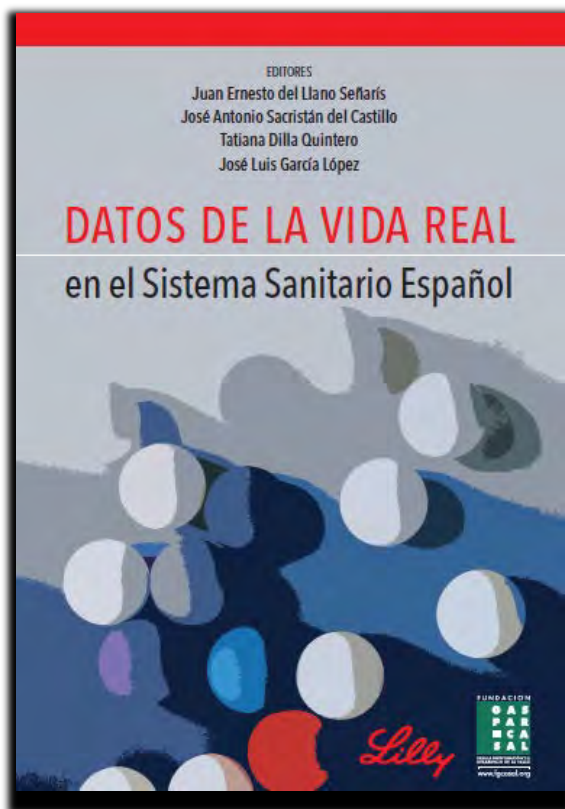


The adherence to pre-defined clinical guidelines regarding treatment regimen decisions.



Biomarker analysis.





RWE en Investigación

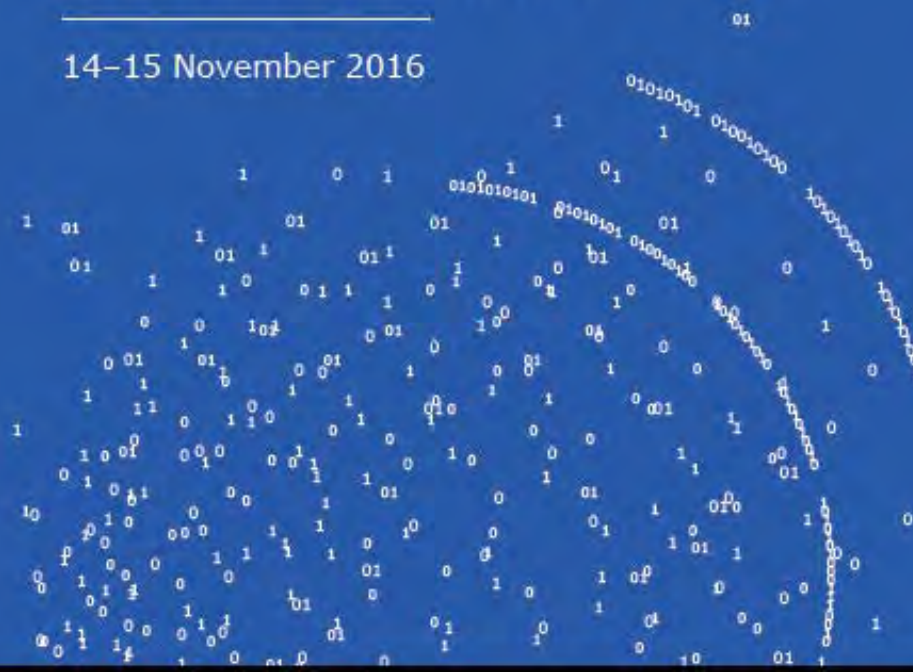
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Identifying opportunities for 'Big Data' in medicines development and regulatory science

14-15 November 2016



Datos de la Vida Real e Investigación Clínica



Building Cancer Registries to Fight Disease in Developing Nations

Cancer registries improve disease detection and treatment because they...



Identity cancer trends and high-risk groups

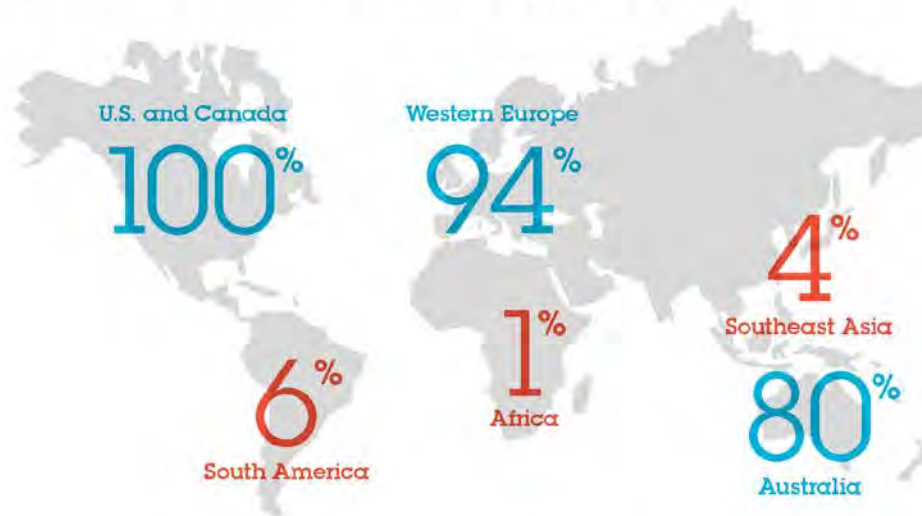


Help set priorities for health resources and programs



Advance clinical and health research

Cancer registries cover the majority of populations in developed regions—but almost none in emerging economies.



IBM and the Union for International Cancer Control are **building cancer registries in developing nations**, creating the world's largest clinical dataset on cancer patients.

Comparison of Survival Outcomes Among Cancer Patients Treated In and Out of Clinical Trials

Joseph M. Unger, William E. Barlow, Diane P. Martin, Scott D. Ramsey, Michael LeBlanc, Ruth Etzioni, Dawn L. Hershman

JNCI J Natl Cancer Inst (2014) 106(3): dju002 doi:10.1093/jnci/dju002

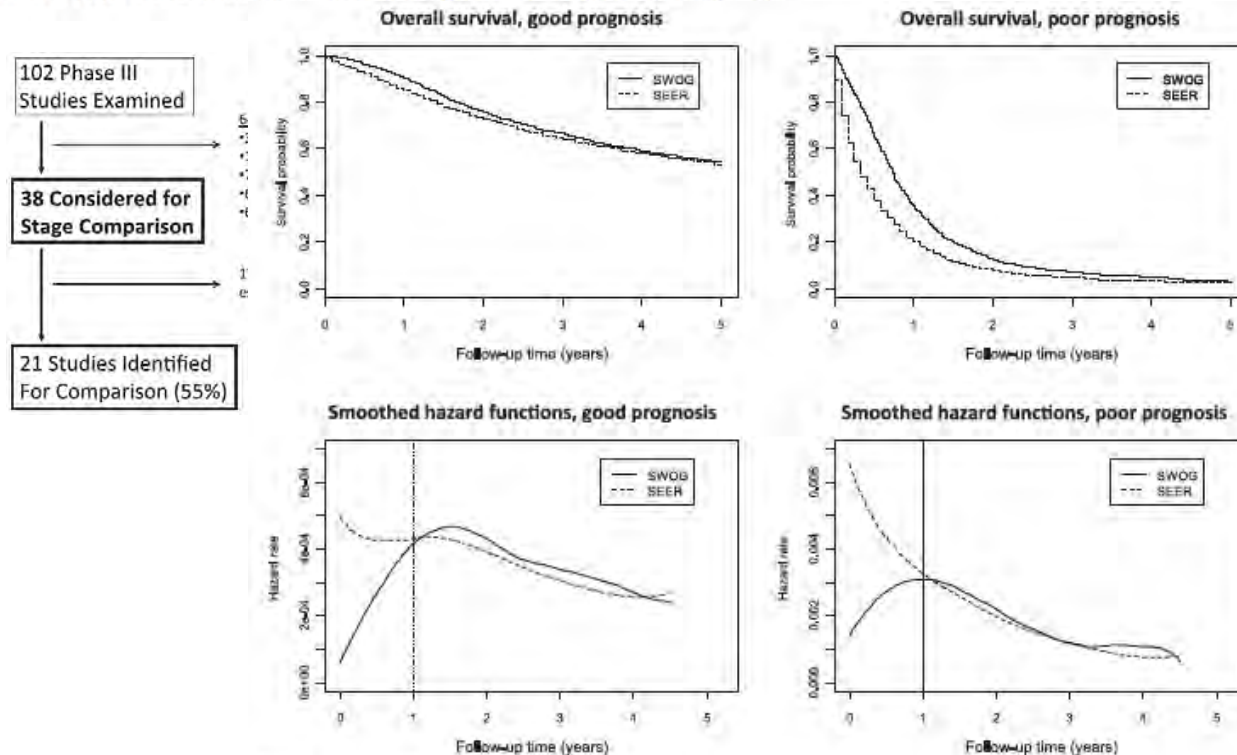


Figure 4. Overall survival and corresponding hazard functions for aggregate (equally weighted) study data by prognosis.

Clinical Characteristics, Treatment Patterns, and Outcomes for Patients with HER2-Positive Metastatic Breast Cancer Treated with Pertuzumab in the First-Line in a Real-World Setting



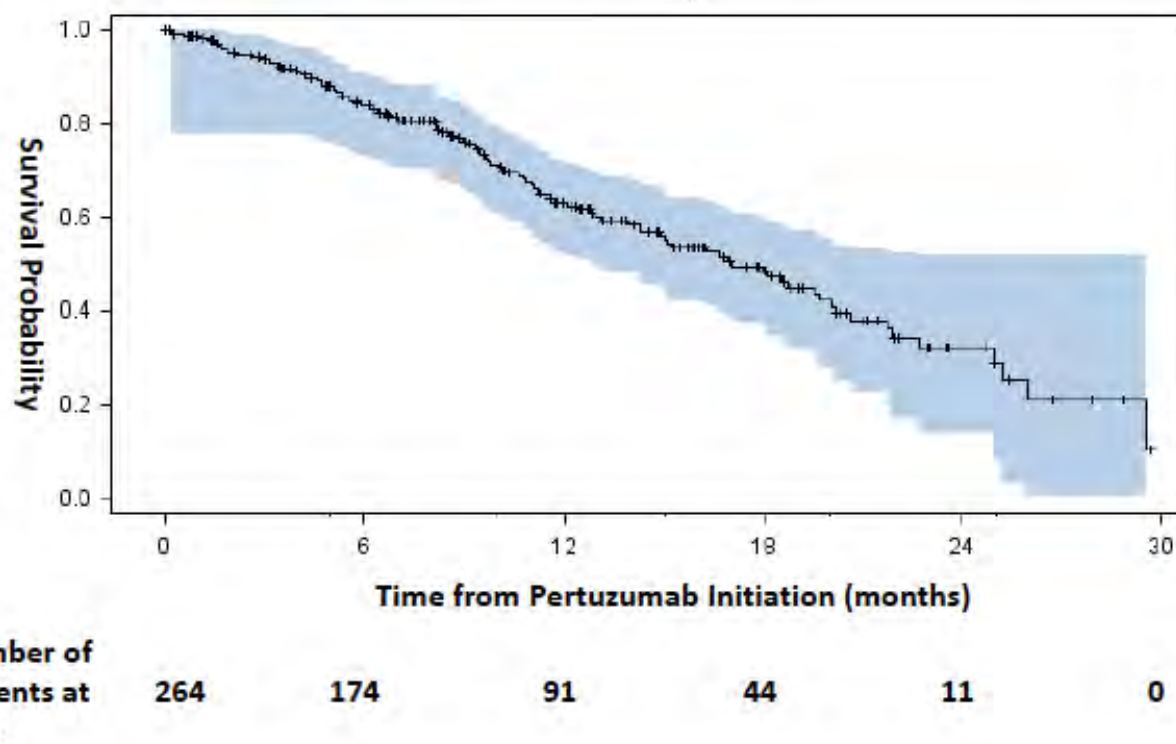
Cancer Treated with Pertuzumab in the First-Line in a Real-World Setting

Nicholas Robert¹, Hans-Peter Goertz², Pooja Chopra¹, Xiaolong Jiao¹, Bongin Yoo², Debra Patt¹, Vincent Antao²

¹The US Oncology Network, McKesson Specialty Health, Houston, TX, USA; ²Genentech, Inc., South San Francisco, CA, USA



Figure 1: Progression-free Survival from Initiation of Pertuzumab (Kaplan Meier analysis)



- The PFS and toxicities were similar to those observed in the CLEOPATRA trial

Real world anaplastic lymphoma kinase (ALK) rearrangement testing patterns, treatment sequences and survival of ALK-inhibitor treated patients

Jessica Davies,¹ Michael Martinec,² Mathieu Coudert,³ Paul Delmar,³ Ursula Becker,³ Gracy Crane¹

¹Roche Products Ltd, Welwyn, UK; ²F. Hoffmann-La Roche, Boulogne-Billancourt Cedex, France; ³F. Hoffmann-La Roche AG, Basel, Switzerland

Figure 1. Patient flow

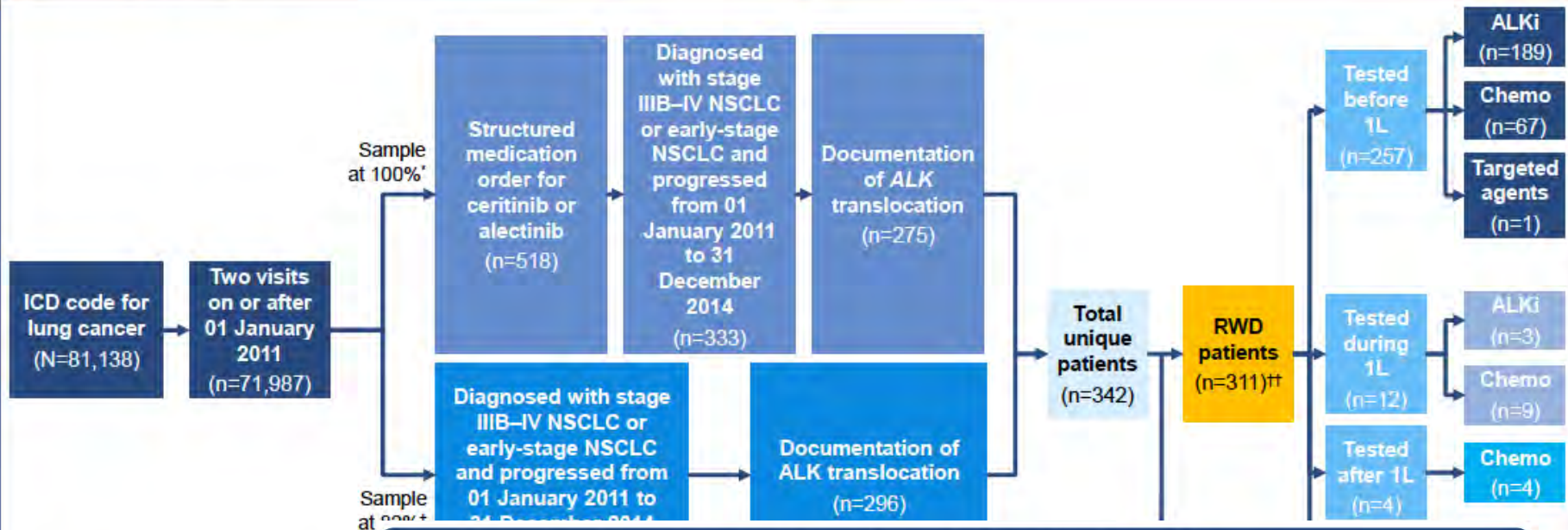
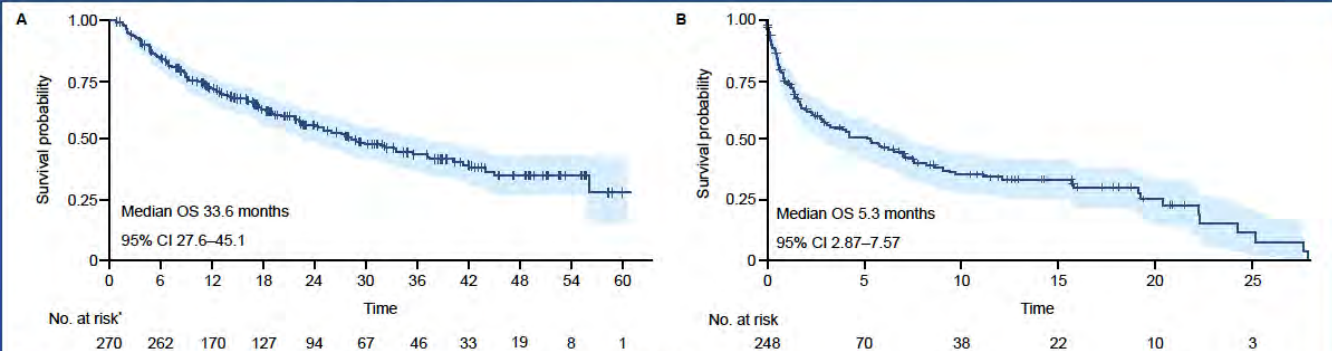


Figure 3. Kaplan Meier curve of (A) OS from advanced diagnosis and (B) OS post-crizotinib treatment



*The 30 patients who did not receive treatment according to the Flatiron database were excluded from this analysis.
†The 30 patients who did not receive treatment according to the Flatiron database were excluded from this analysis.
††Thirteen patients did not have ALK test data and are not included in the analysis.

1L = first-line; ALKi = ALK inhibitor; RWD = real-world
*All patients (100%) in the Flatiron database with a structured medication order for crizotinib, ceritinib or alectinib. These patients were used for the analysis of treatment sequences.
†A sample (82%) of all patients with an ICD code for lung cancer was used for the analysis of diagnosis and progression.
††Thirteen patients did not have ALK test data and are not included in the analysis.