What can journals do to promote clinical trials ?

Dr. Wim Weber
European research editor, BMJ

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What is the problem ?

1. Not enough trials

2. Trials do not address patients' needs

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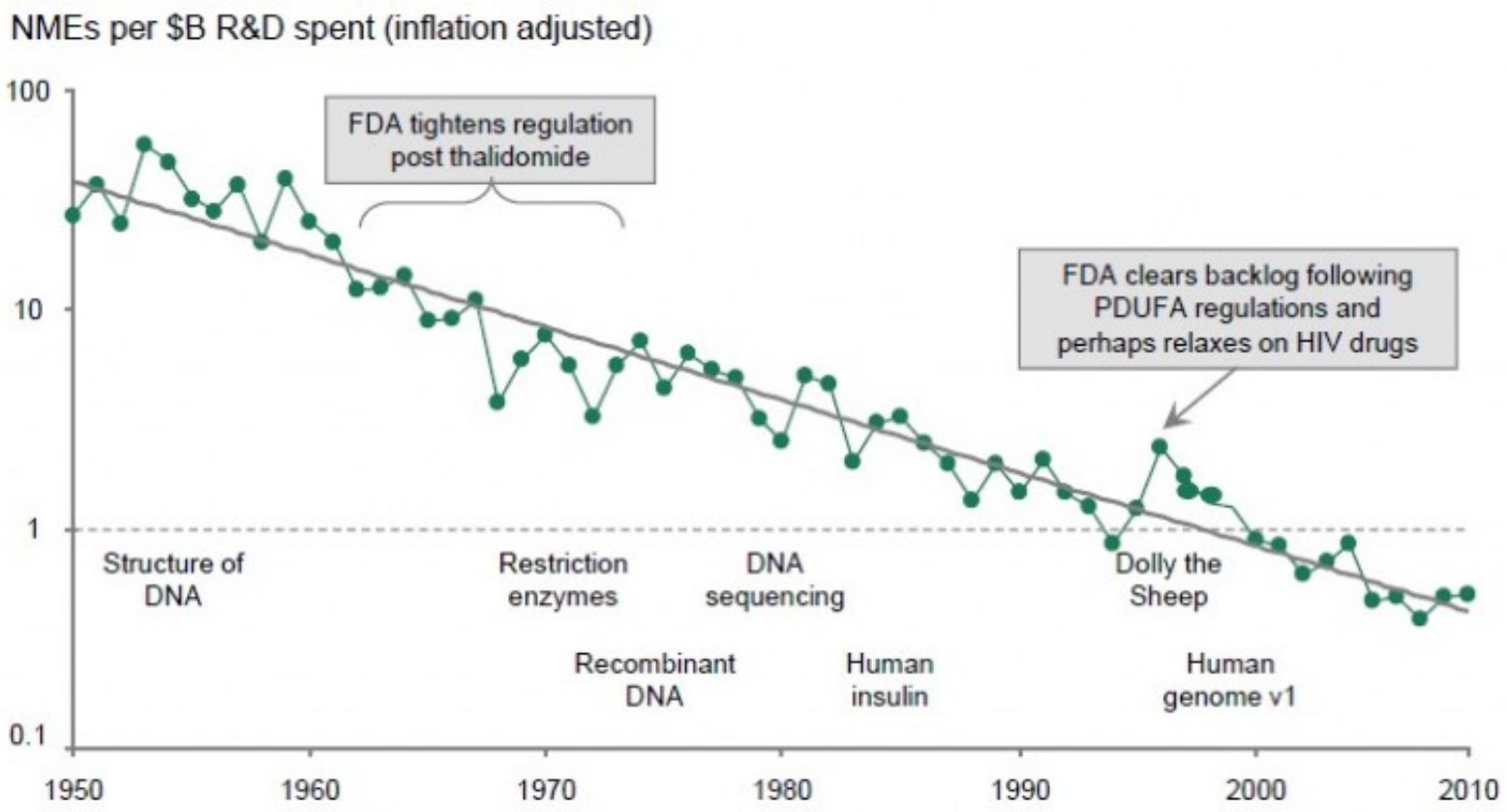
New medicines cost more



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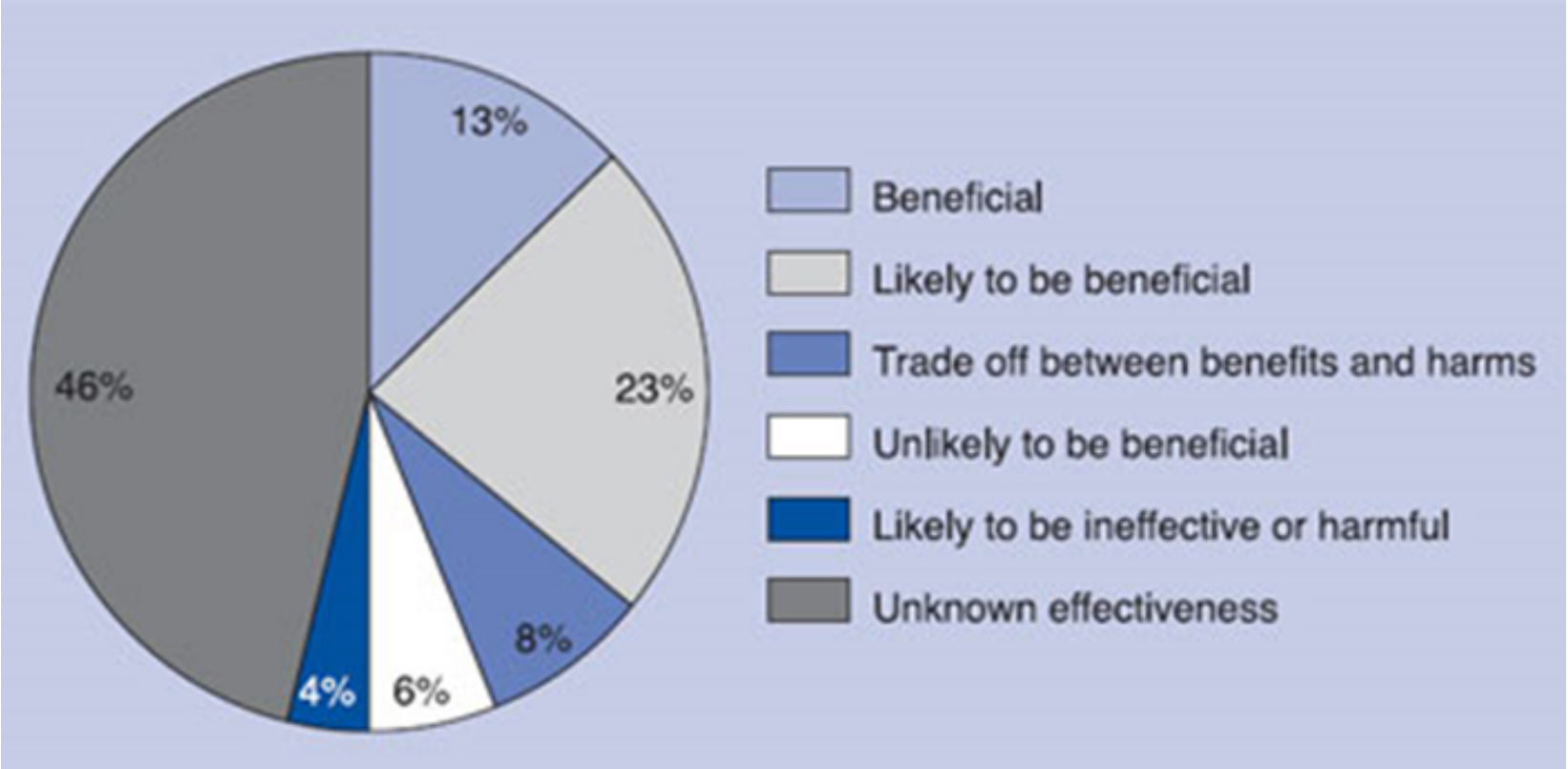

BMJ Clinical Evidence 2007

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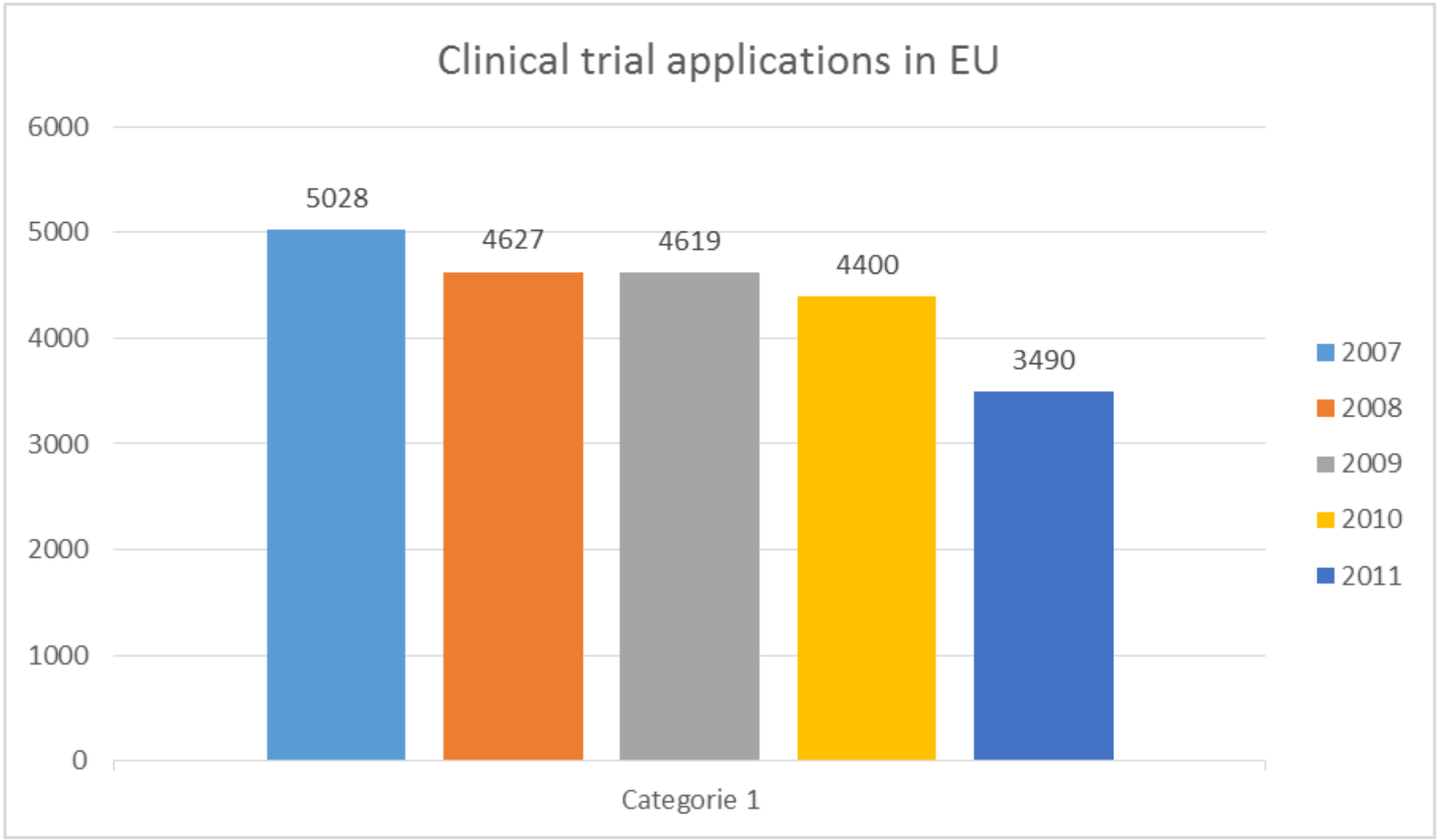
Clinical trial applications EU



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Not enough trials

- Not enough negative trials

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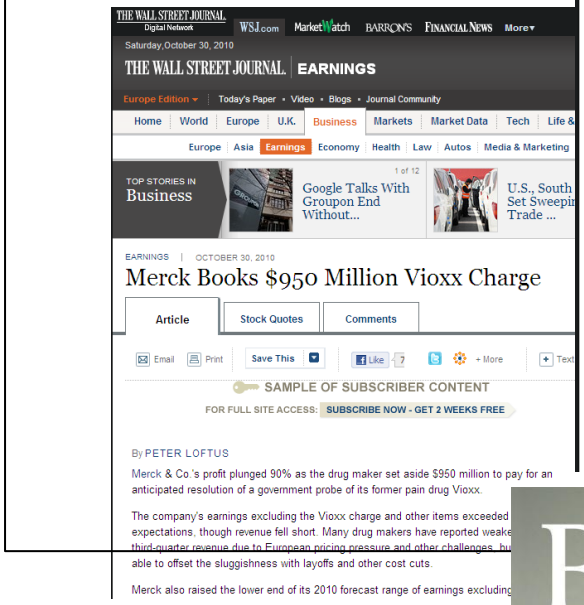
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By PETER LOFTUS
Merck & Co.'s profit plunged 90% as the drug maker set aside $950 million to pay for an anticipated resolution of a government probe of its former pain drug Vioxx.
The company's earnings excluding the Vioxx charge and other items exceeded
expectations, though revenue fell short. Many drug makers have reported weake
third-quarter revenue due to European pricing pressure and other challenges, bu
able to offset the sluggishness with layoffs and other cost cuts.
Merck also raised the lower end of its 2010 forecast range of earnings excludin


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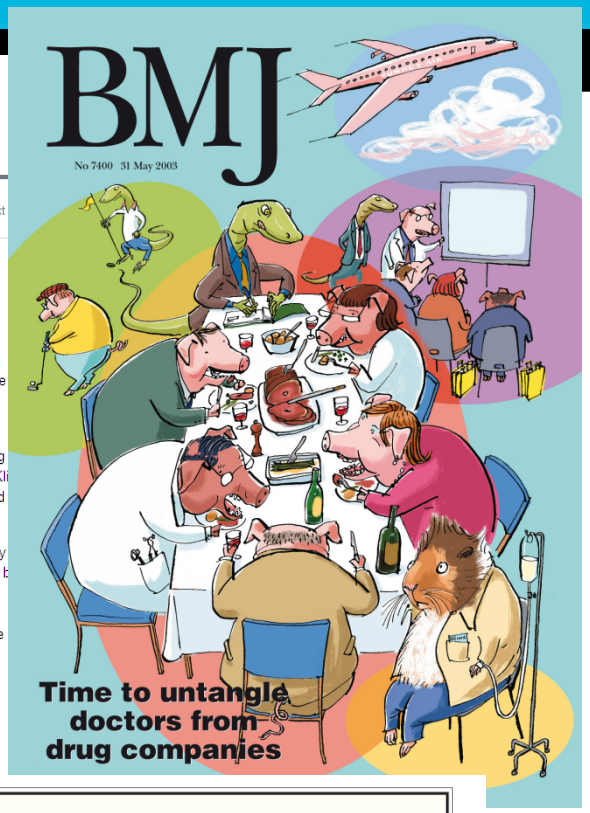
FOR FULL SITE ACCESS: SUBSCRIBE NOW - GET 2 WEEKS FREE
By ALICIA MUNDY, JENNIFER CORBETT DOOREN And JEANNE WHALEN
WASHINGTON—U.S. regulators put tight curbs on the diabetes drug Avandia and European authorities said they were stopping its sales, effectively ending widespread use of a medicine that was once a multibillion-dollar-a-year seller.
View Full Image
Bloomberg News
Avandia
The Food and Drug Administration and European regulators said they were taking action on Avandia, made by GlaxoSmithKli PLC, because of data tying it to increased risk of heart attacks.
The FDA move marks a tougher stance by the agency's leadership, named last year b President Barack Obama, and signals to pharmaceutical makers and patients that mass-market drugs with troublesome side effects are getting closer scrutiny.
for real business.


BMJ
No 7400 31 May 2003
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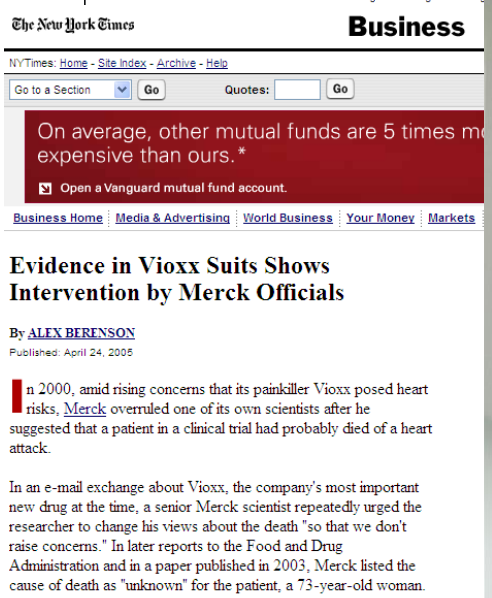
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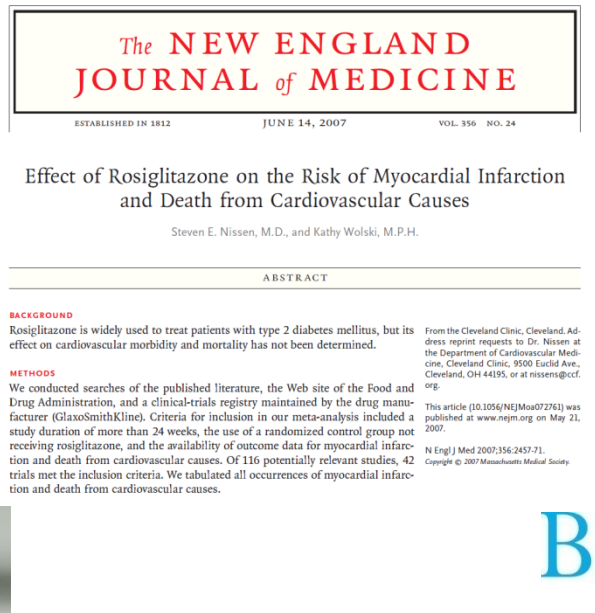
Evidence in Vioxx Suits Shows Intervention by Merck Officials
By ALEX BERENSON
Published: April 24, 2005
In 2000, amid rising concerns that its painkiller Vioxx posed heart risks, Merck overruled one of its own scientists after he suggested that a patient in a clinical trial had probably died of a heart attack.
In an e-mail exchange about Vioxx, the company's most important new drug at the time, a senior Merck scientist repeatedly urged the researcher to change his views about the death "so that we don't raise concerns." In later reports to the Food and Drug Administration and in a paper published in 2003, Merck listed the cause of death as "unknown" for the patient, a 73-year-old woman.


The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 JUNE 14, 2007 VOL. 356 NO. 24
Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes
Steven E. Nissen, M.D., and Kathy Wolski, M.P.H.
ABSTRACT
BACKGROUND
Rosiglitazone is widely used to treat patients with type 2 diabetes mellitus, but its effect on cardiovascular morbidity and mortality has not been determined.
METHODS
We conducted searches of the published literature, the Web site of the Food and Drug Administration, and a clinical-trials registry maintained by the drug manufacturer (GlaxoSmithKline). Criteria for inclusion in our meta-analysis included a study duration of more than 24 weeks, the use of a randomized control group not receiving rosiglitazone, and the availability of outcome data for myocardial infarction and death from cardiovascular causes. Of 116 potentially relevant studies, 42 trials met the inclusion criteria. We tabulated all occurrences of myocardial infarction and death from cardiovascular causes.
From the Cleveland Clinic, Cleveland. Address reprint requests to Dr. Nissen at the Department of Cardiovascular Medicine, Cleveland Clinic, 9500 Euclid Ave., Cleveland, OH 44195, or at nissens@ccf.org.
This article (10.1056/NEJMoa072761) was published at www.nejm.org on May 21, 2007.
N Engl J Med 2007;356:2457-71.
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Cochrane review 2006:

Oseltamivir 150 mg daily prevented lower respiratory tract complications

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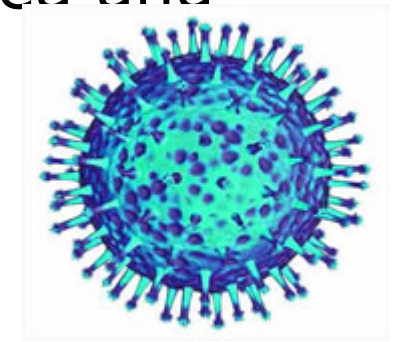
2009: Cochrane review updated, but:

- Only 2 / 10 RCTs published
- The pooled analysis was done by Roche
- Obtaining the original data has been very difficult

After 5 years Roche made all data available: and the new meta-analysis was published :

- There were **83** RCTs
- There is no evidence for effect on complications
- There are substantial side effects: nausea and psychiatric symptoms



BMJ 2014;348:g2545

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The situation has improved

- Trial registration is mandatory since 2005
- Publication is mandatory in EU since 2014

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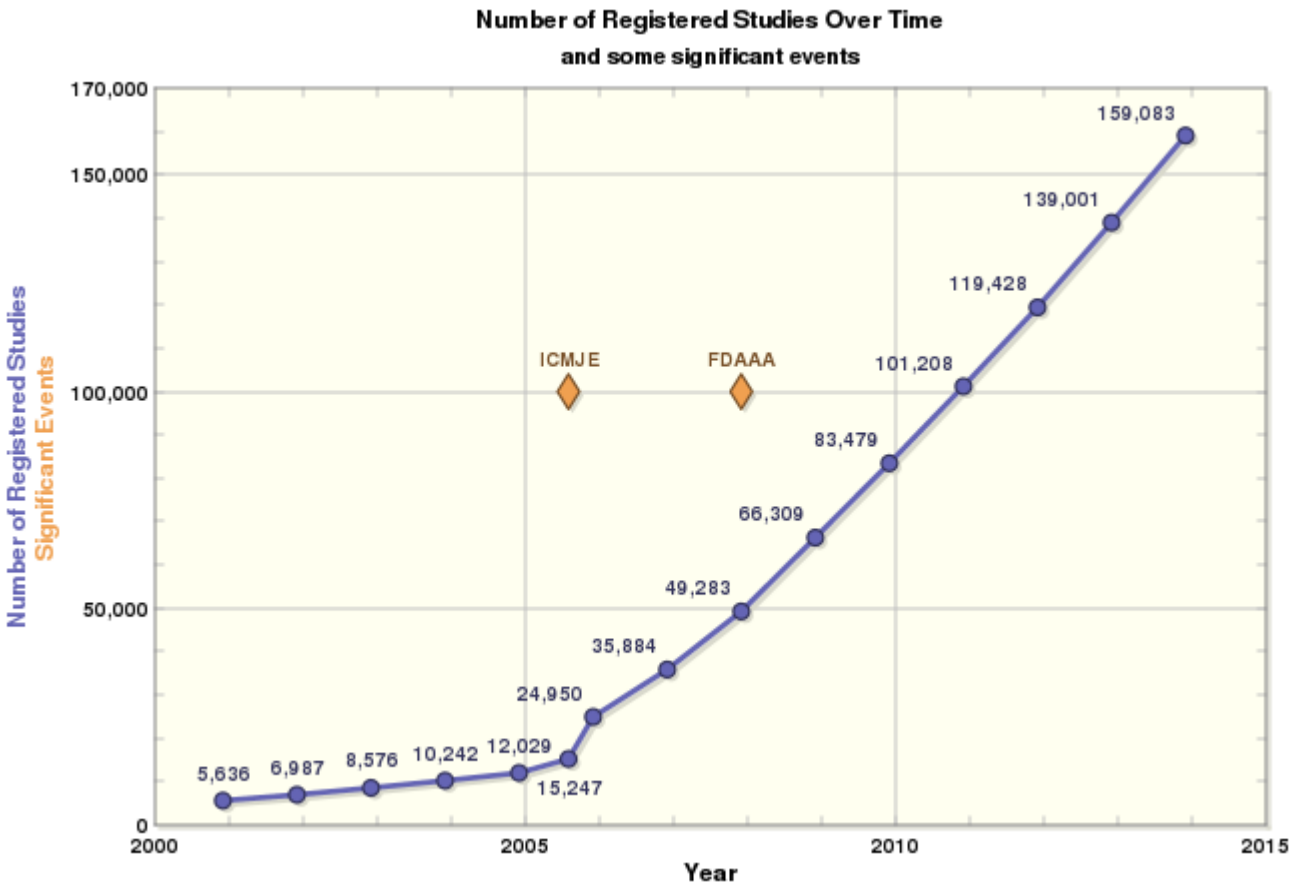
New EU legislation

Trials must be registered

Results must be published



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OPEN Project

- Less than half of medical research is published
- Less than half of surveyed European ethical committees ask for trial registration or check that approved studies are published.

- More than two thirds of surveyed medical journals does not require trial registration, as they see it as a “competitive disadvantage.”

http://www.open-project.eu/publications

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What can journals do?

- Simply enforce the existing rules

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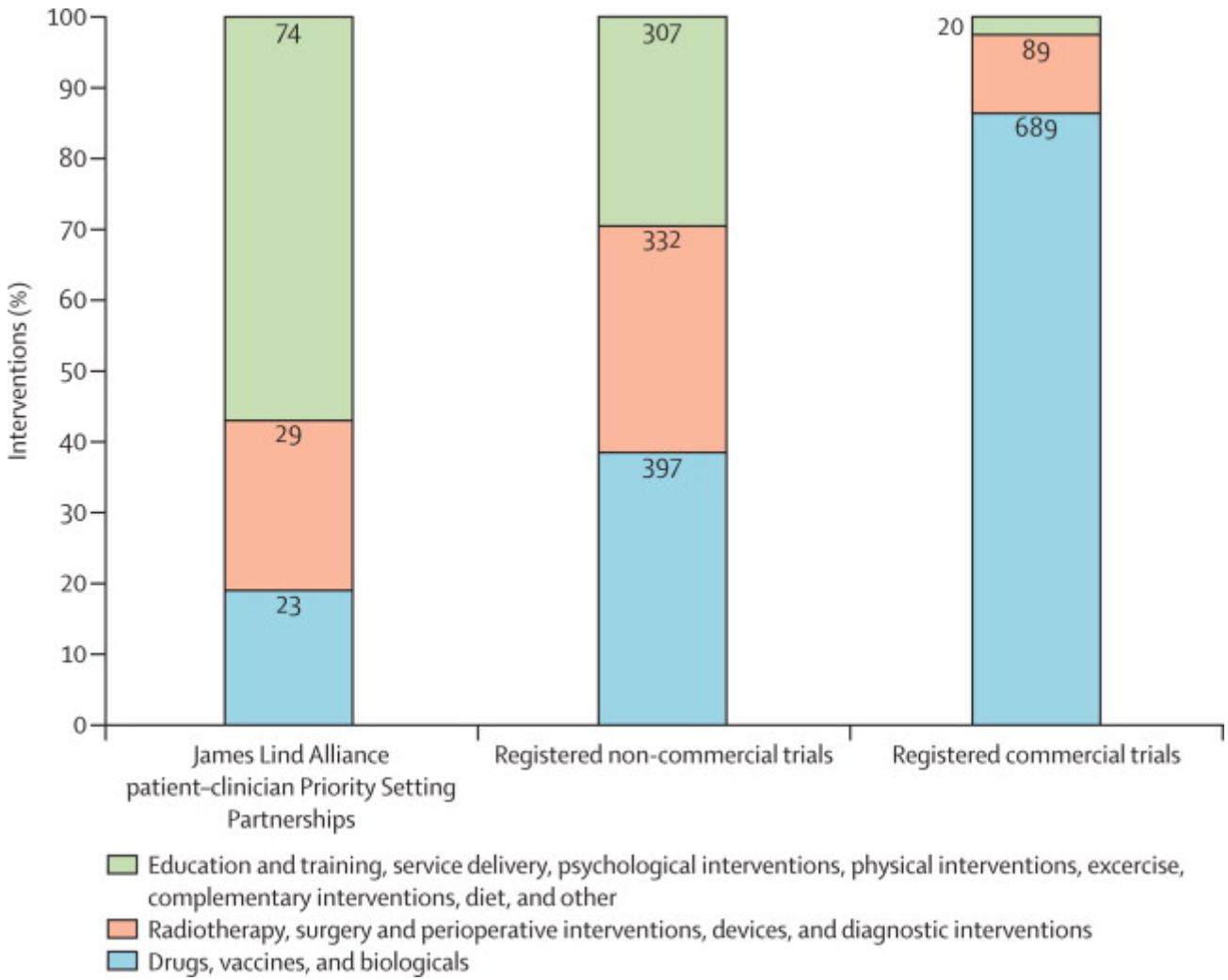
Do trials study what patients want ?



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Experiment with patient reviews

- 2013: Patient partnership editor
- Dr. Tessa Richards has set up a patient panel

- All papers describing a RCT will also be reviewed by a patient

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Thanks

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