



Roma, 9-12 novembre 2017

INFORMED CONSENT

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ITALIAN CHAPTER





INFORMED CONSENT

& PROCEDURES



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INFORMED CONSENT & IMMEDIATE BENEFITS



INFORMED CONSENT

& BENEFITS TO COME



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**Out of many people receiving intervention,
a few will benefit (= high NNT).**



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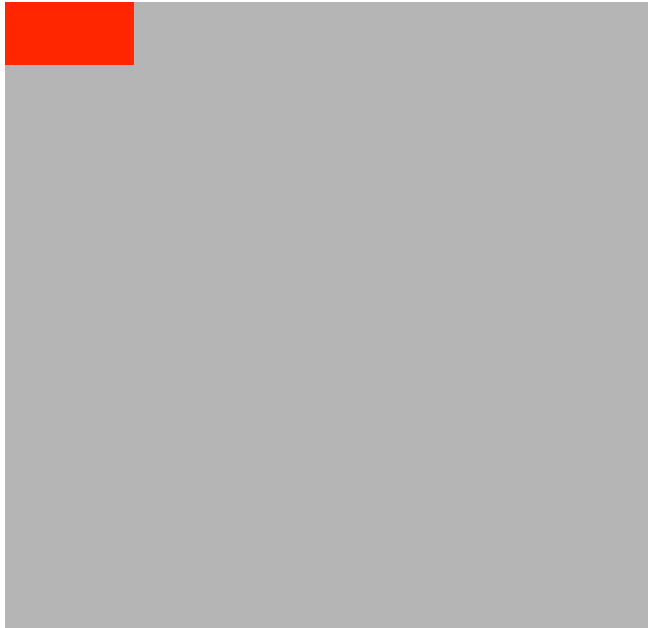
INFORMED CONSENT

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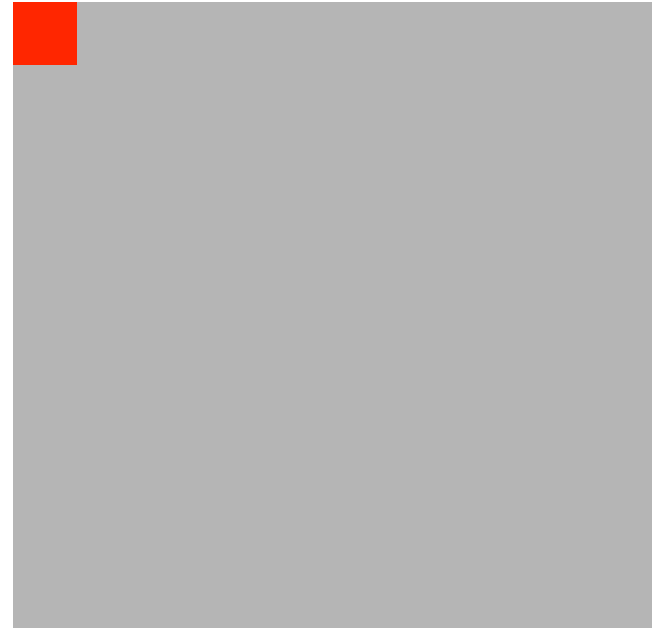
INTERVENTION: NO

△ after X time



INTERVENTION: YES

△ after X time



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& BENEFITS TO COME



Out of many people receiving intervention, a few will benefit (= high NNT).

Individual benefit difficult to verify (non event) & often confused with detection.



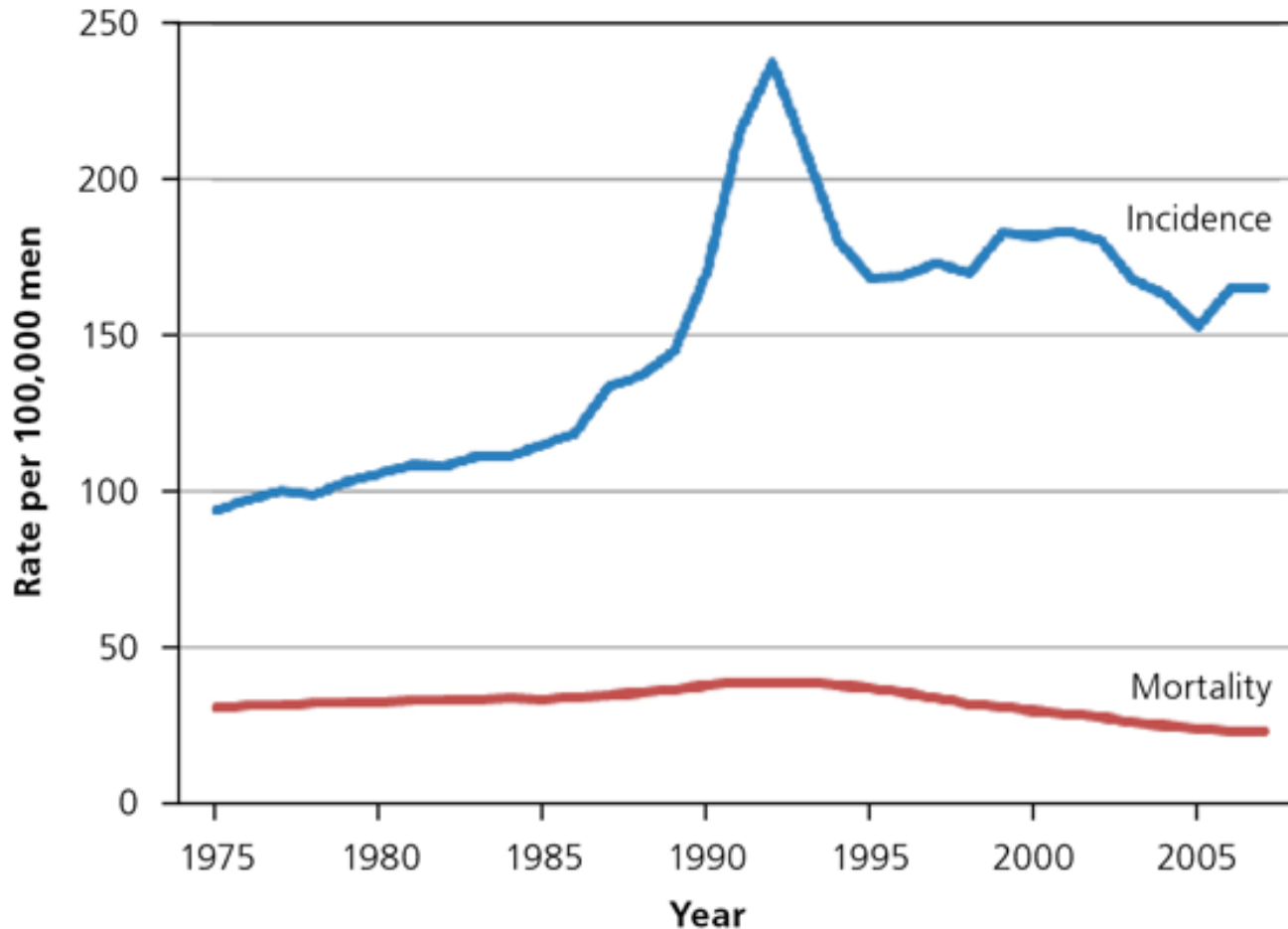
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NEJM 2011; 365 : 2013

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Out of many people receiving intervention, a few will benefit (= high NNT).

Individual benefit difficult to verify (non event) & often confused with detection.

Out of many people receiving intervention, a few will be harmed (= high NNH).



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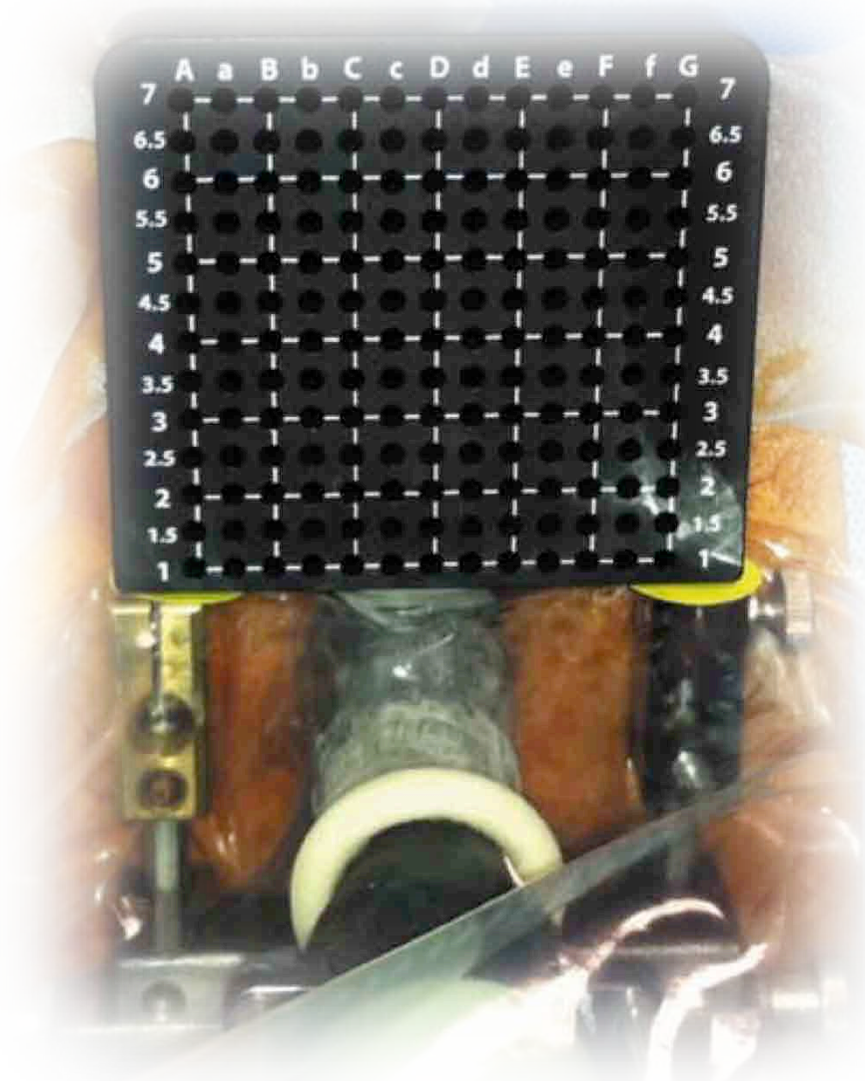
& BENEFITS TO COME

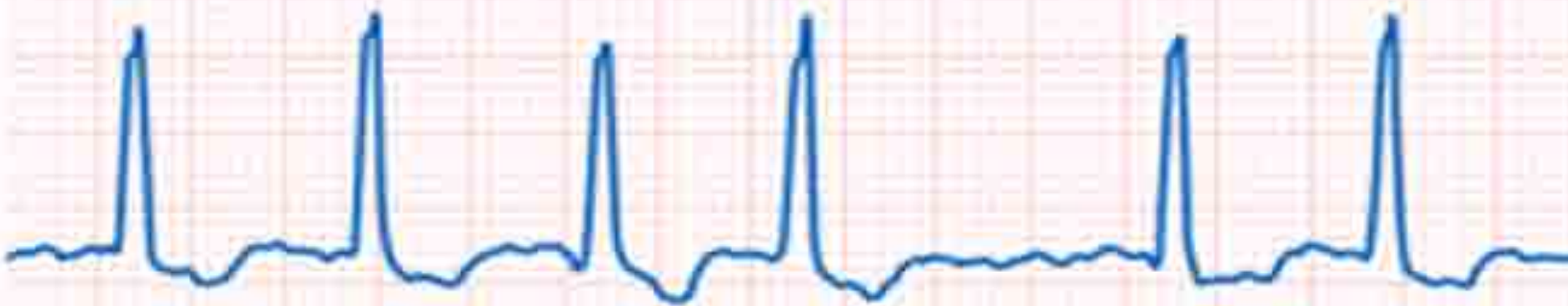




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**Pradaxa® 75 mg
hard capsules**

Dabigatran etexilate



Xarelto® 10 mg

film-coated tablets
Rivaroxaban

For oral use:



hard tablets







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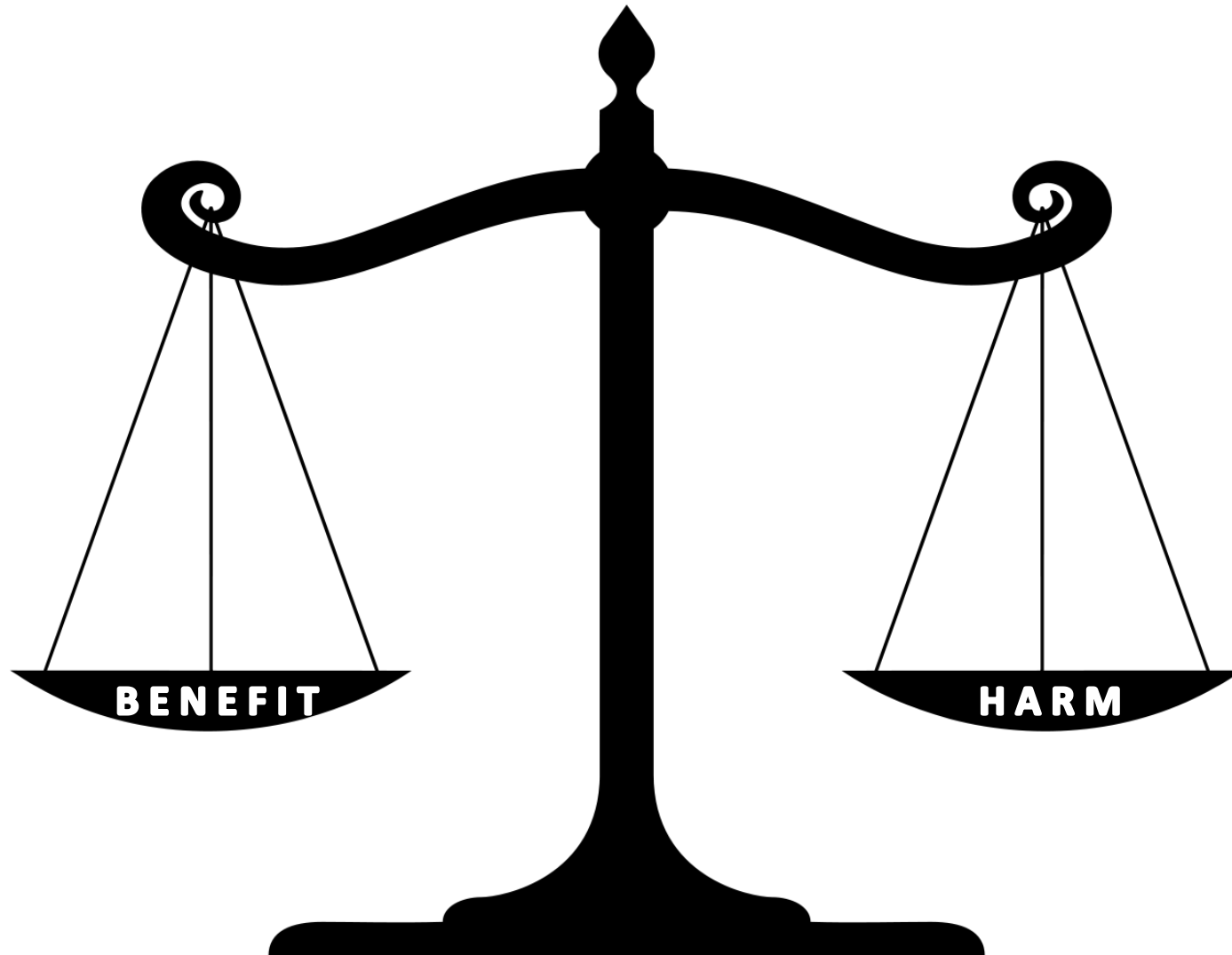




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Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests

JAMA Int Med 2015 vol. 175 : 274 - 286

Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests

JAMA Int Med 2015 vol. 175 : 274 - 286

Benefit

Real

Harm

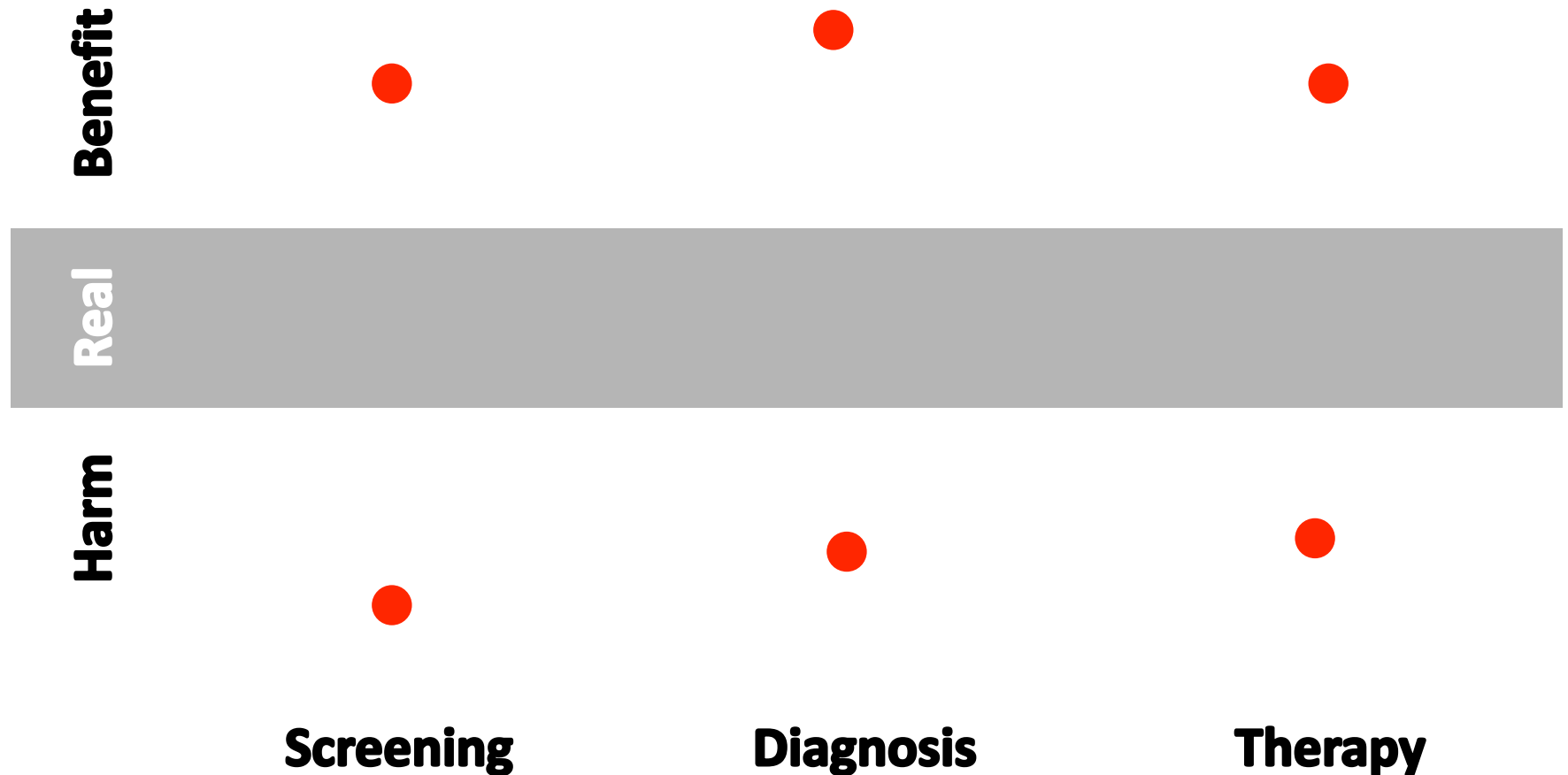
Screening

Diagnosis

Therapy

Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests

JAMA Int Med 2015 vol. 175 : 274 - 286

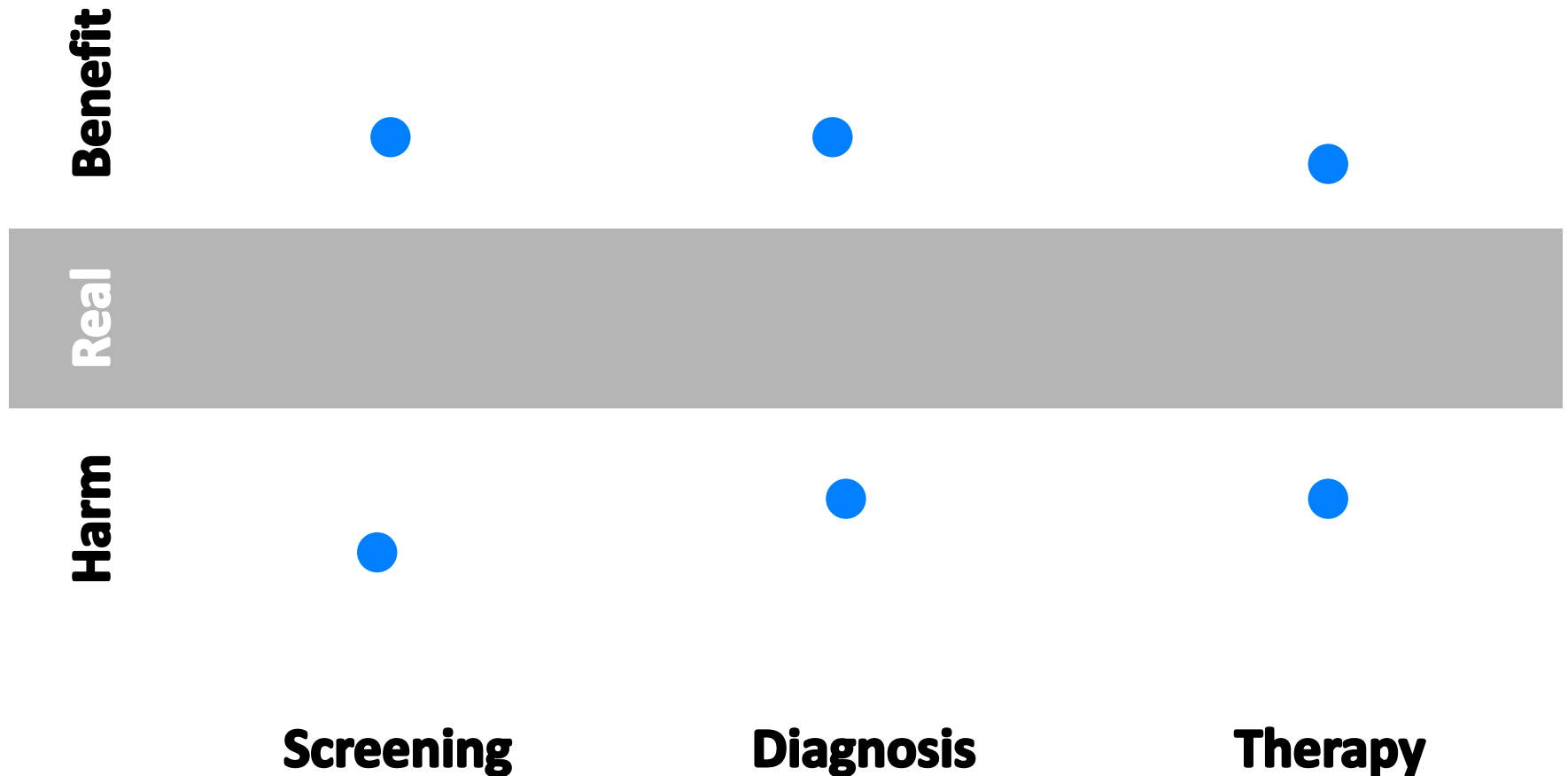


Clinicians' Expectations of the Benefits and Harms of Treatments, Screening, and Tests

JAMA Int Med 2017 vol. 177 : 407-419

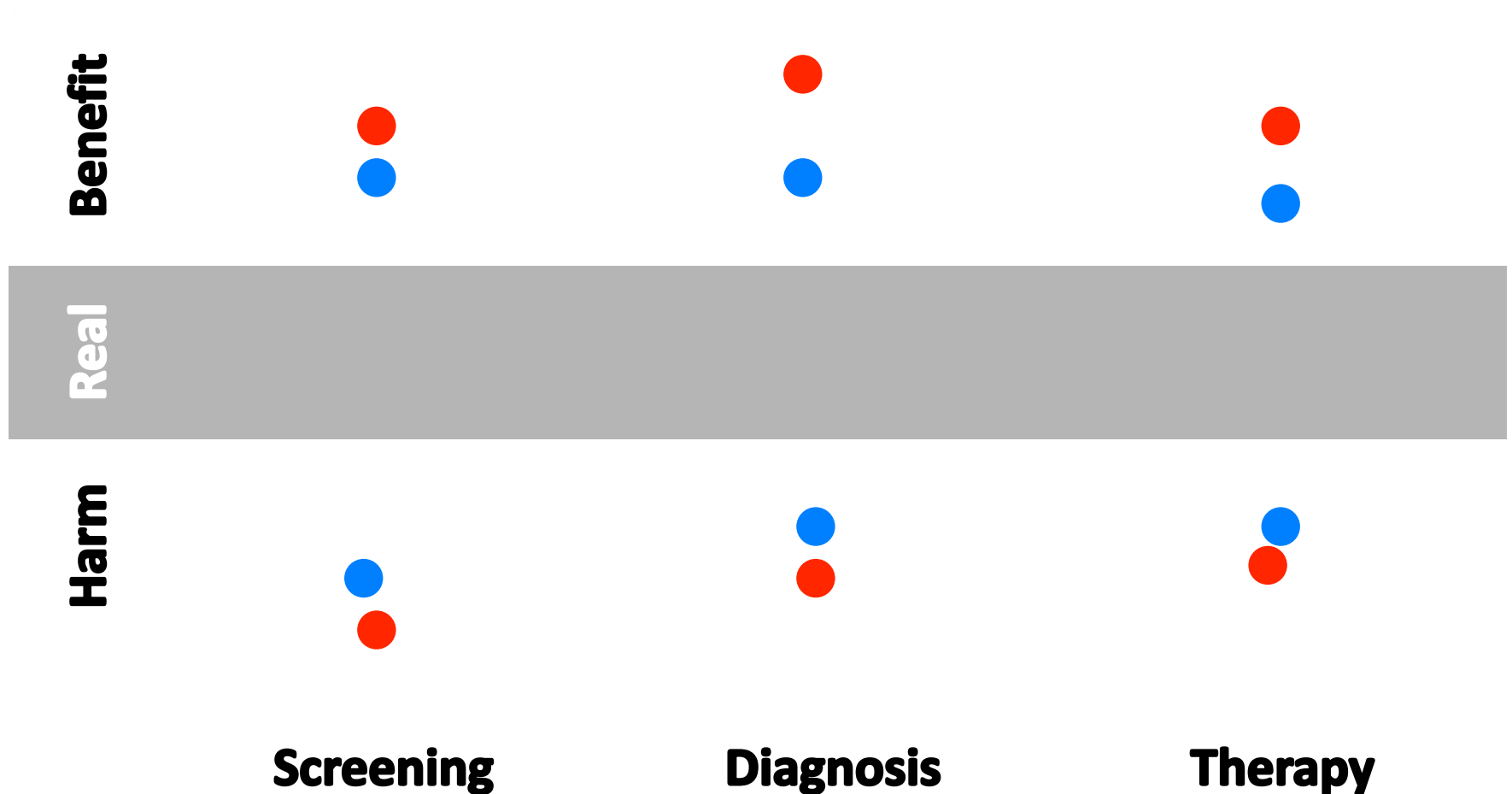
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Optimism Bias



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**Communication
Benefit & Harm**

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Relative benefit should not be used to make clinical decisions.



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**"IT'S GREAT TO
BE A STATISTIC!"**

20% relative risk reduction

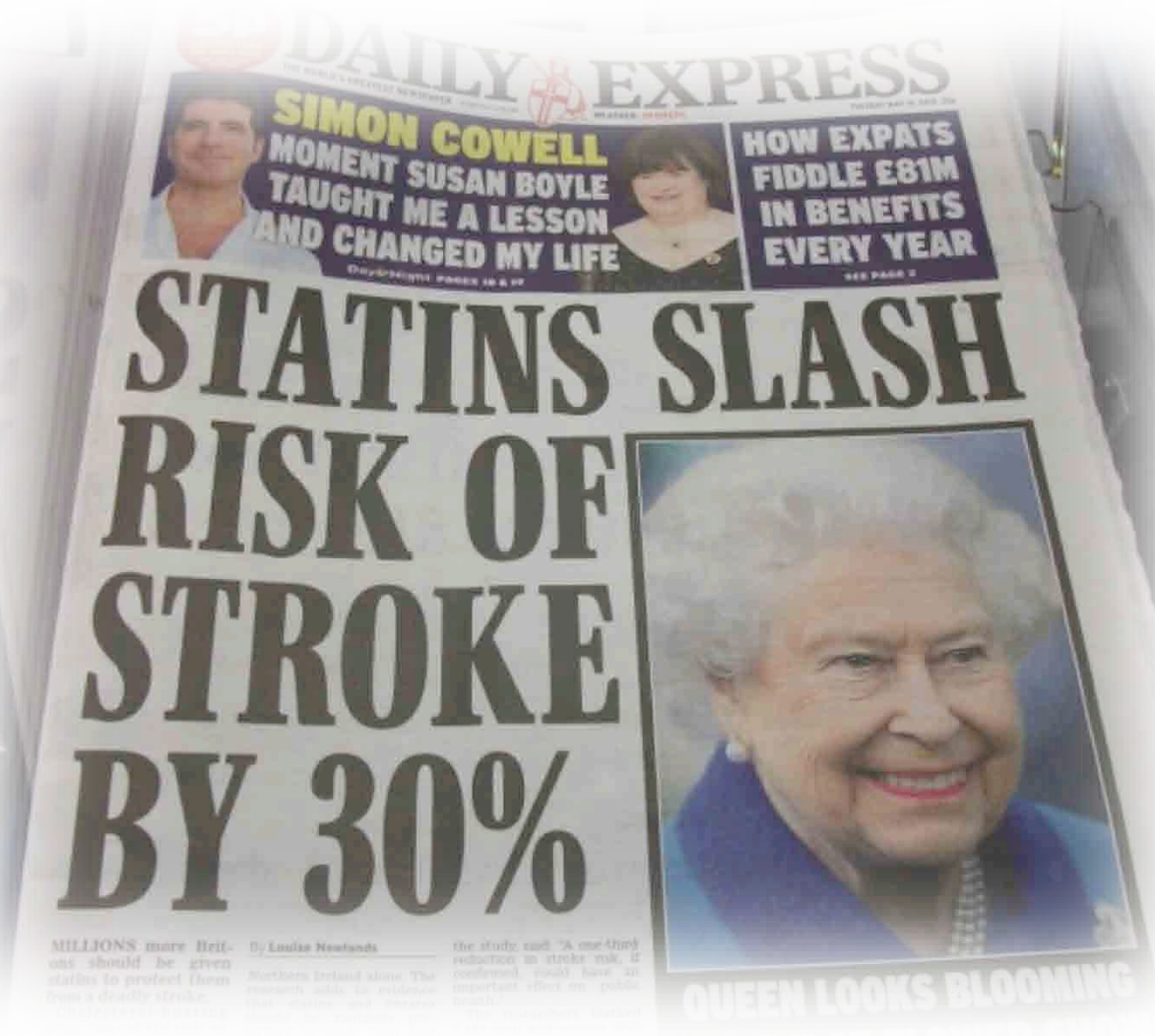
The landmark study, **CURE**,¹ shows that PLAVIX, when added to standard therapy (including aspirin), provides an additional 20% relative risk reduction in CV death/stroke/MI for patients with unstable angina/non-ST-elevation MI



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They slow tumours, reveal major studies

Tragic Kenne

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Relative benefit should not be used to make clinical decisions.



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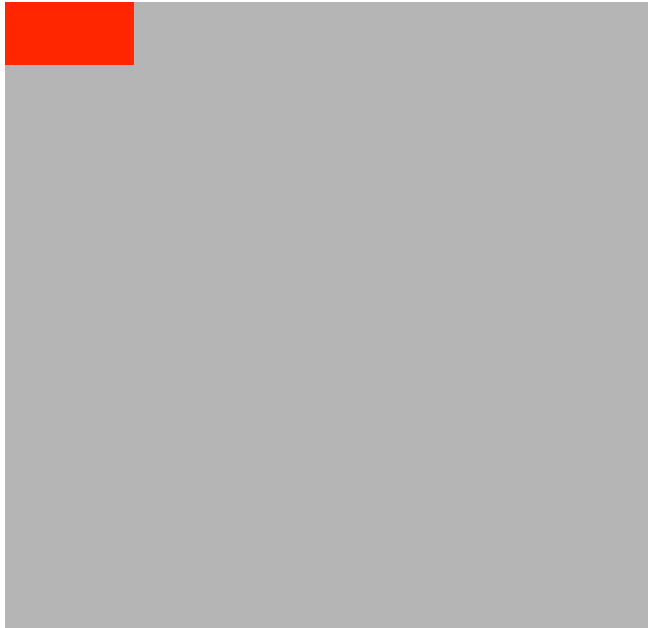
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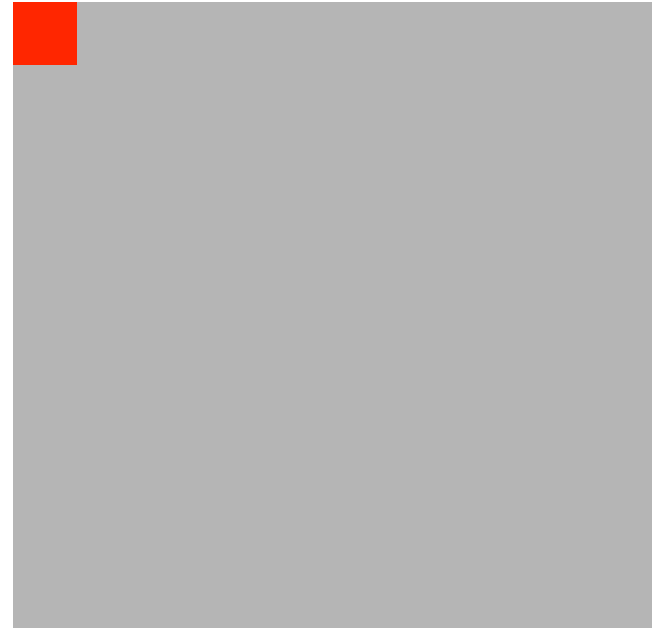
STATIN: NO

† after 5 years



STATIN: YES

† after 5 years



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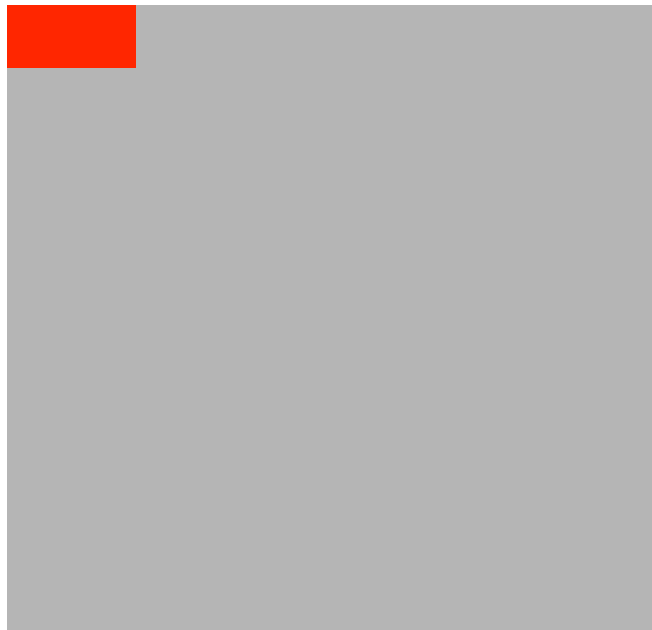


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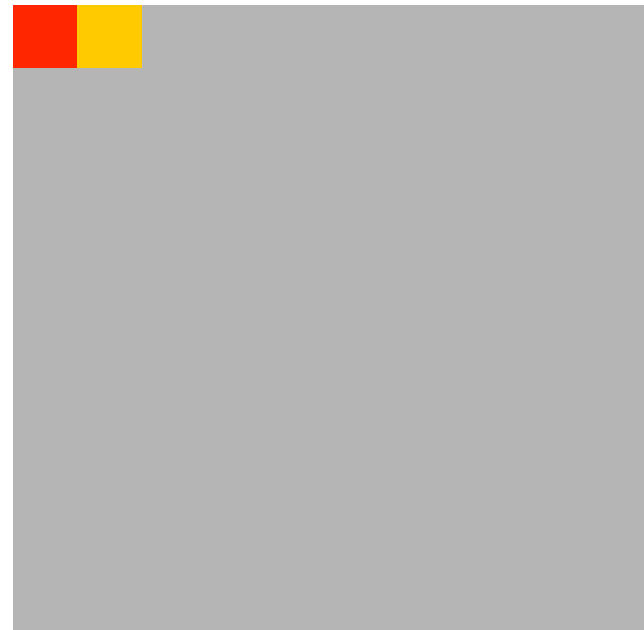
STATIN: NO

† after 5 years



STATIN: YES

† after 5 years





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Absolute benefit should be used to make clinical decisions.

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Out of 100 people who take a statin every day for 5 years, 1 will be spared death by cancer.

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Out of 100 people who take a statin every day for 5 years, 1 will be spared death by cancer.

Out of 100 people who take a statin every day for 5 years, 99 will not experience any benefit.

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1 out of 100 people who take a statin every day for 5 years will be spared death by cancer.

Out of 100 people who take a statin every day for 5 years, 99 will not experience any benefit.

Out of 100 people who take a statin every day for 5 years, some will experience side effects of statins.



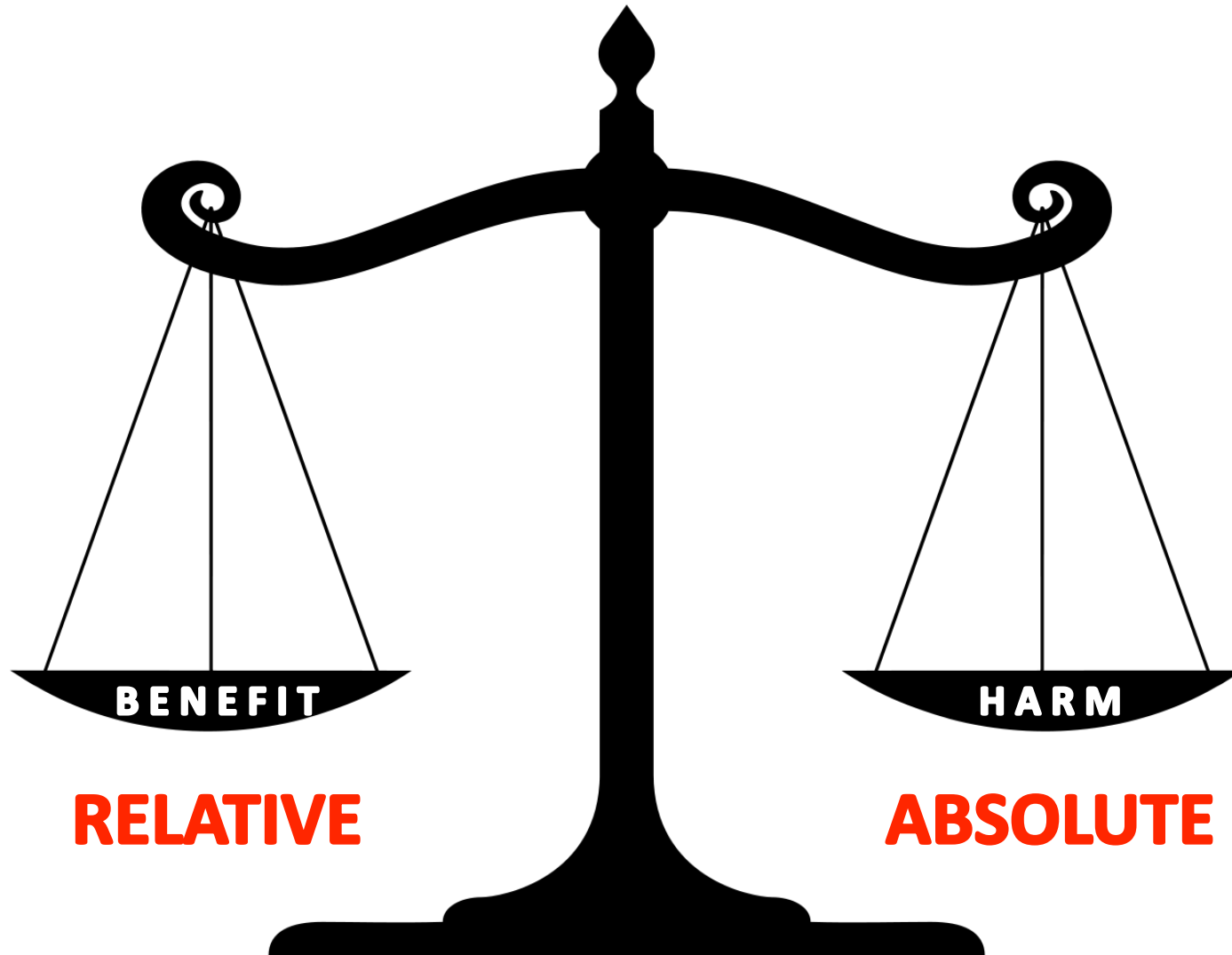
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To Sum It Up :

- 1. NNT & NNH**
- 2. Optimism Bias**
- 3. Relative vs Absolute Risk Reduction**
- 4. Positive & Negative Framing**
- 5. Mismatched Framing**



Thank You