The contribution of physicians to patients globally

How doctors fail to advocate for Cancer patients?

How should doctors advocate for cancer patients?

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The Nicholas Gonzalez Foundation- Chair, Scientific Advisory Board, USA
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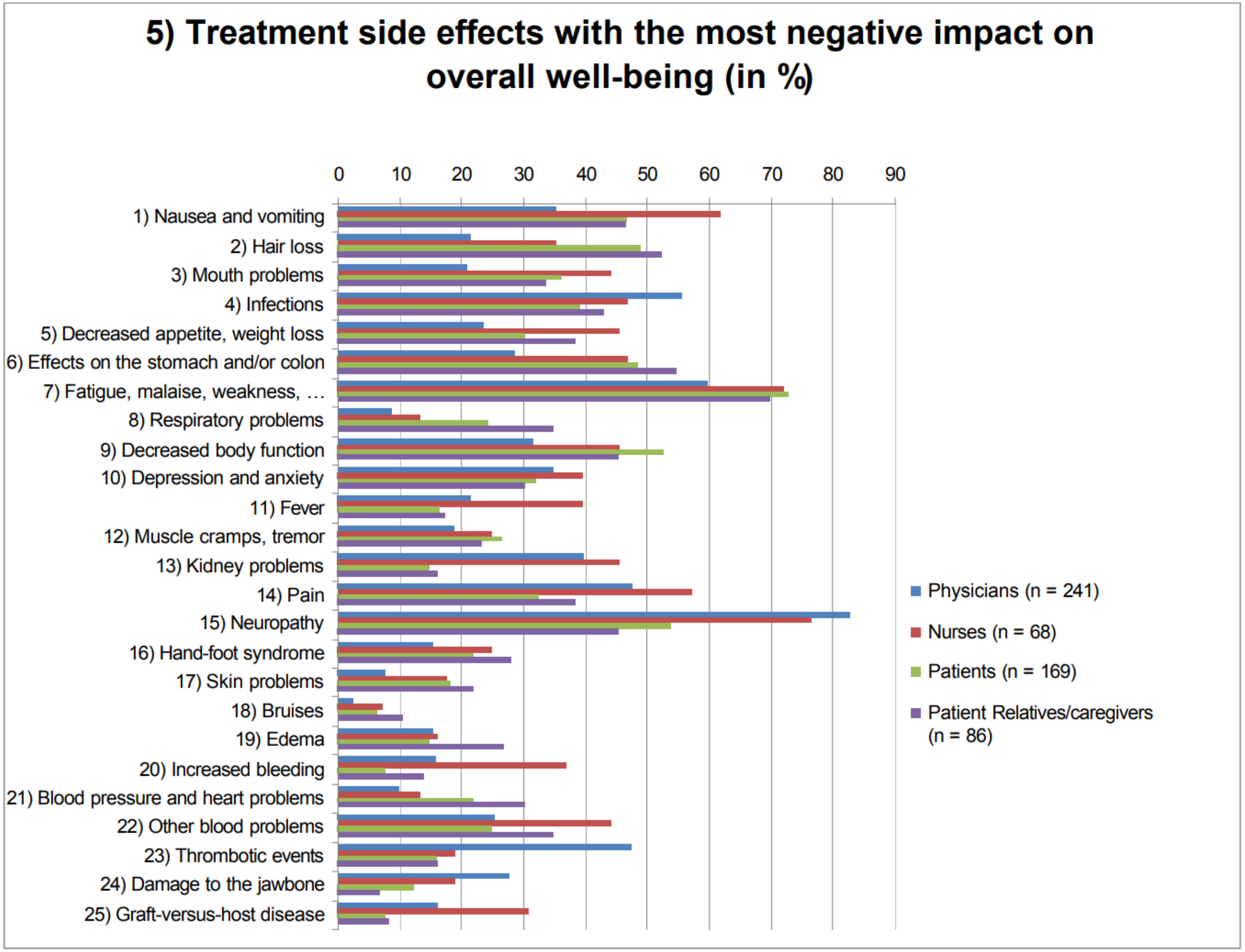
INSPIRE2LIVE COVID-19 Cancer Working Group Co-chair ,The NETHERLANDS

Inspire2Live Annual Congress 2022, September 14

- **According to the patients who answered this question, the myeloma treatment side effect with the most negative impact on a myeloma patient's overall well-being is fatigue/malaise/weakness/dizziness/somnolence/sedation/insomnia (72.8%)**
- **Physicians 60%**

Myeloma patients responded that the second-most negative myeloma treatment side effect concerning a patient's overall well-being was neuropathy (53.9%), followed by decreased body function (52.7%), hair loss (49.1%), and effects on the stomach and/or colon (48.5%),

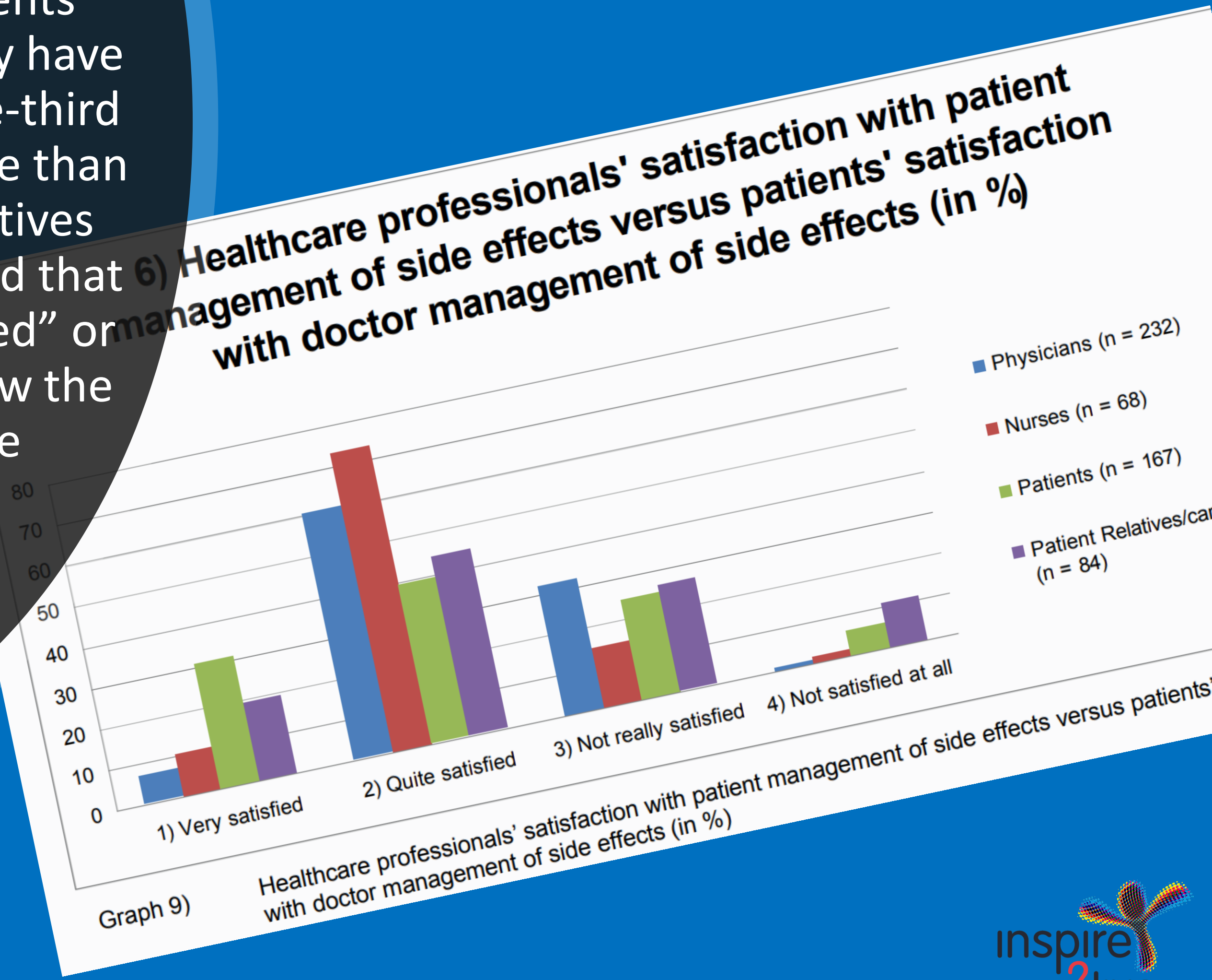

5) Treatment side effects with the most negative impact on overall well-being (in %)

Graph 7) Myeloma treatment side effects with the most negative impact on overall well-being (in %)

Overall 39.6% change btw patient and doctor

- About one-third of the physicians (32.8%) and about one in six nurses (16.2%) were “not really satisfied” or “not satisfied at all” with how myeloma patients manage the side effects they have experienced. And about one-third of patients (30.5%) and more than one-third of the patient relatives and caregivers (36.9%) stated that they were “not really satisfied” or “not satisfied at all” with how the doctor has managed any side effects experienced during myeloma treatment.

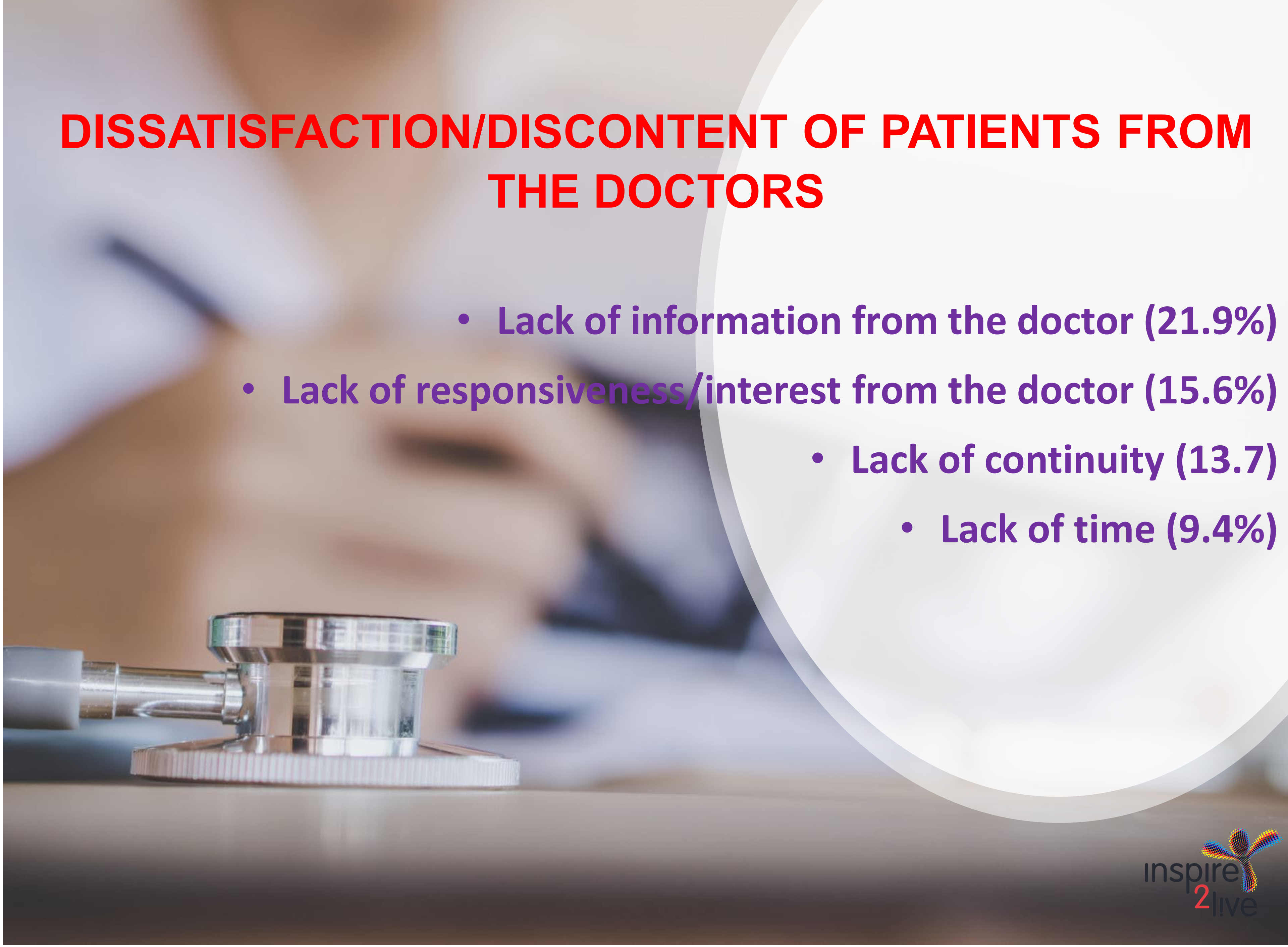
Not documented..



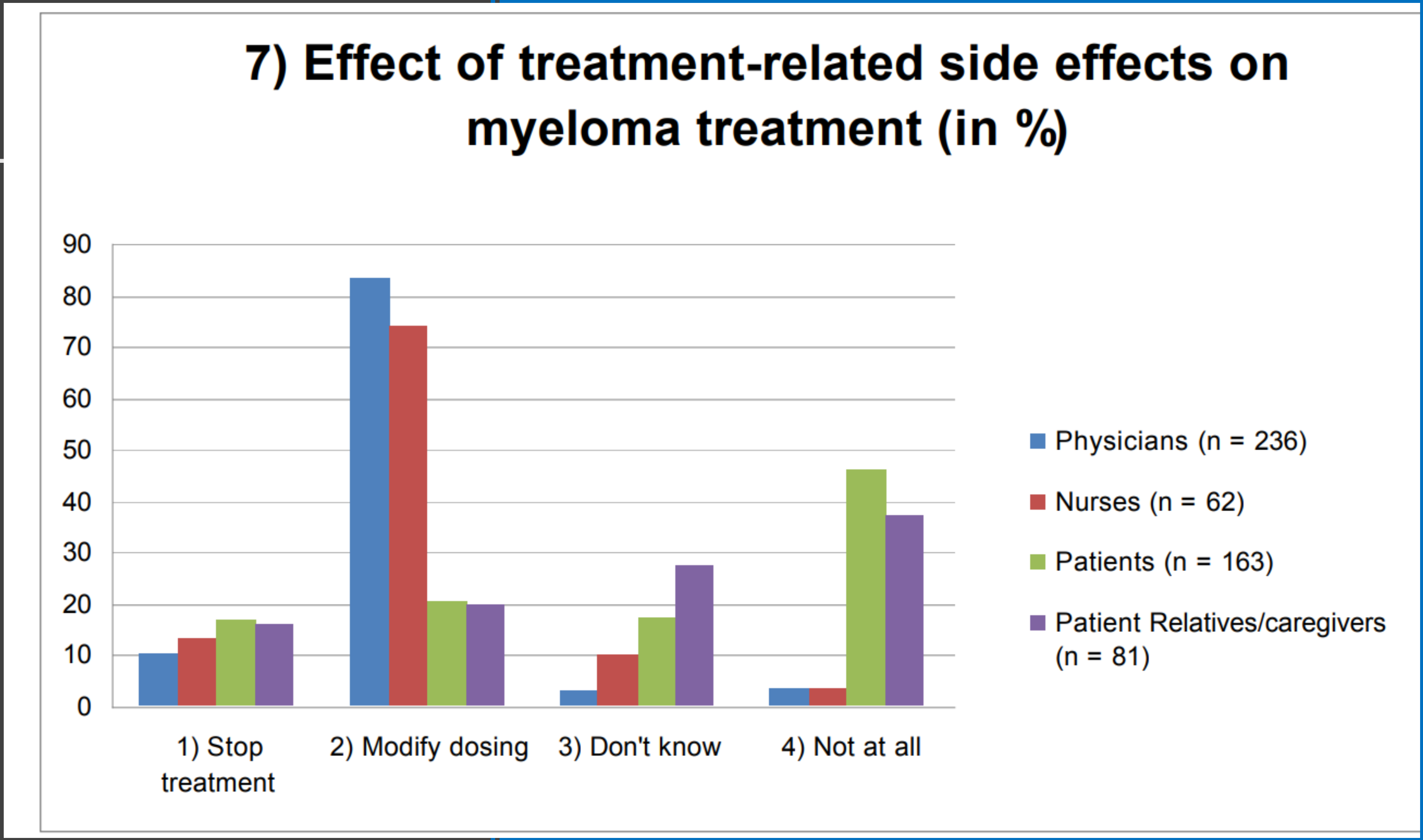
6) Healthcare professionals' satisfaction with patient management of side effects versus patients' satisfaction with doctor management of side effects (in %)

Graph 9) Healthcare professionals’ satisfaction with patient management of side effects versus patients’
with doctor management of side effects (in %)

DISSATISFACTION/DISCONTENT OF PATIENTS FROM THE DOCTORS



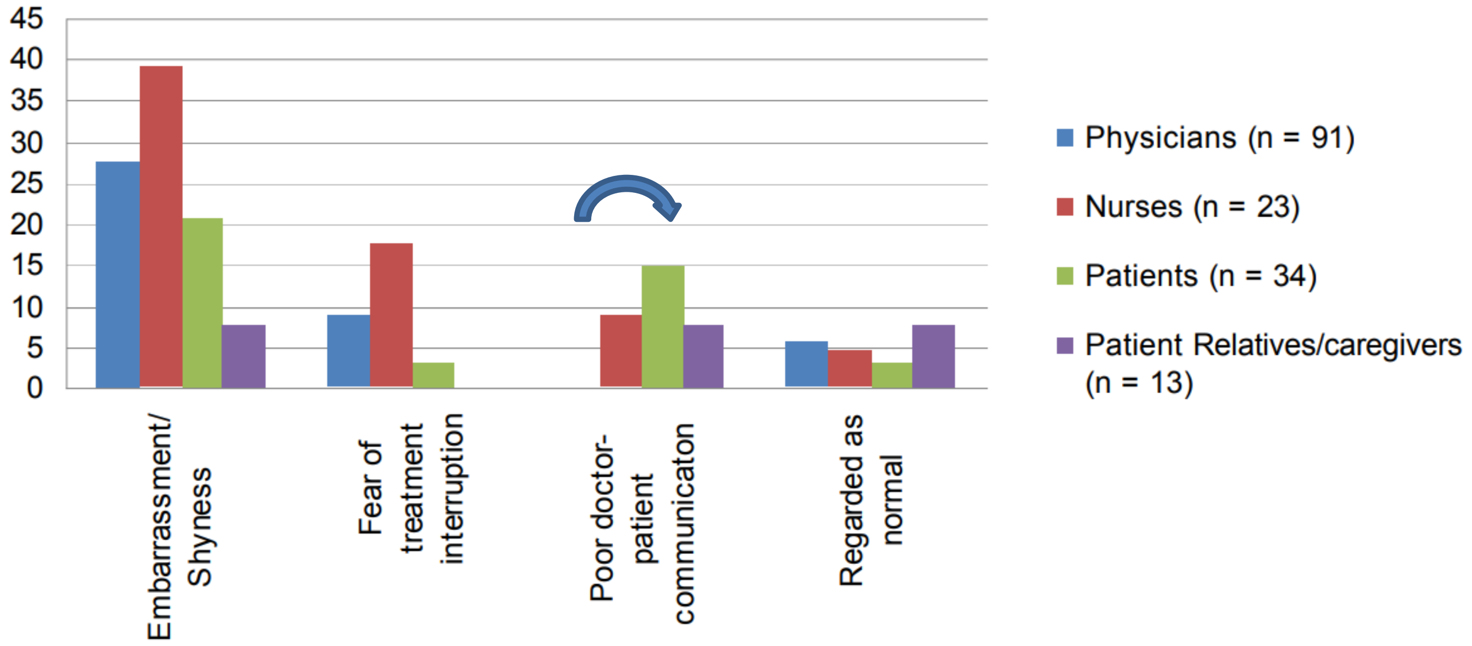
- Lack of information from the doctor (21.9%)
- Lack of responsiveness/interest from the doctor (15.6%)
- Lack of continuity (13.7)
- Lack of time (9.4%)

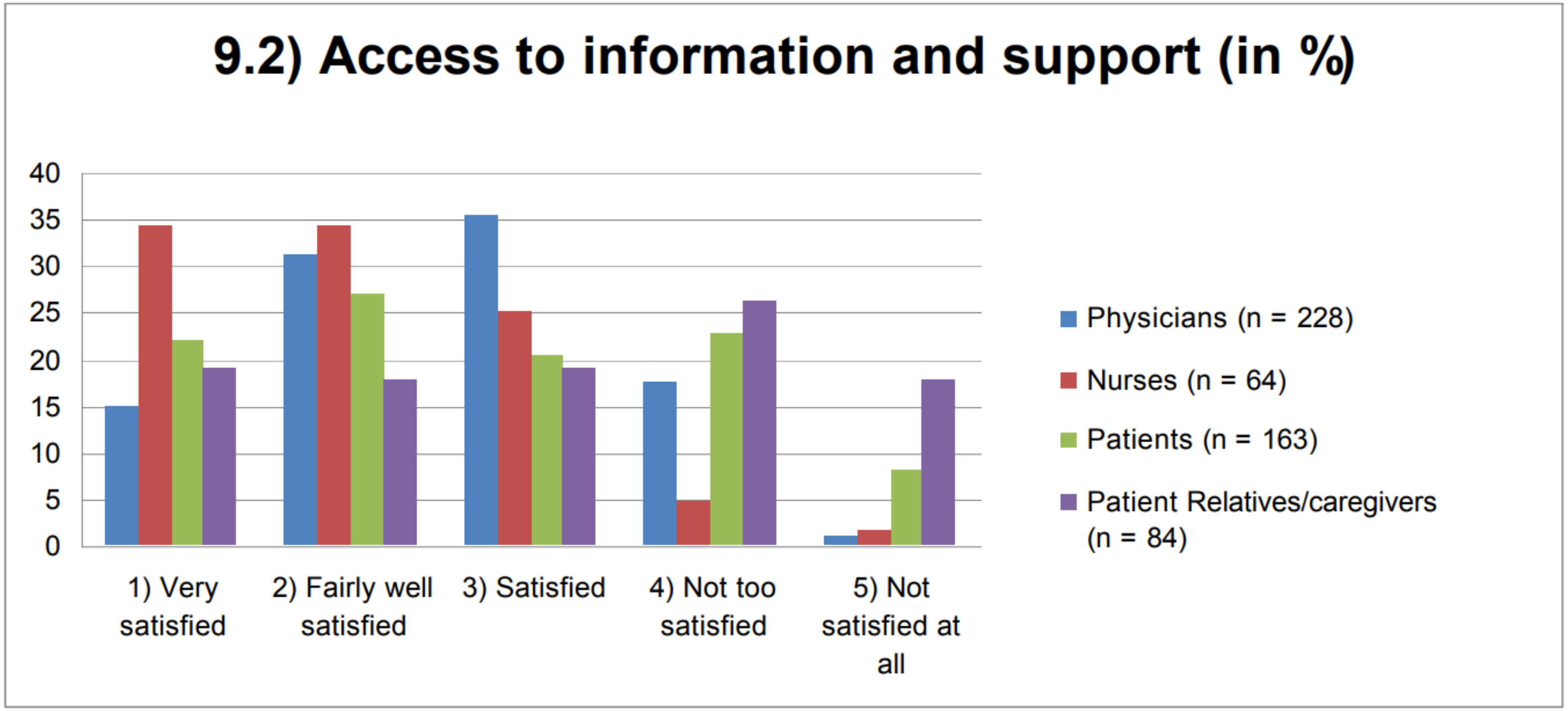


7) Effect of treatment-related side effects on myeloma treatment (in %)

90% Drs 35% patients

8.2) Potential reasons for not reporting treatment side effects (in %)





9.2) Access to information and support (in %)

1/5 drs, 2/5 patients not satisfied

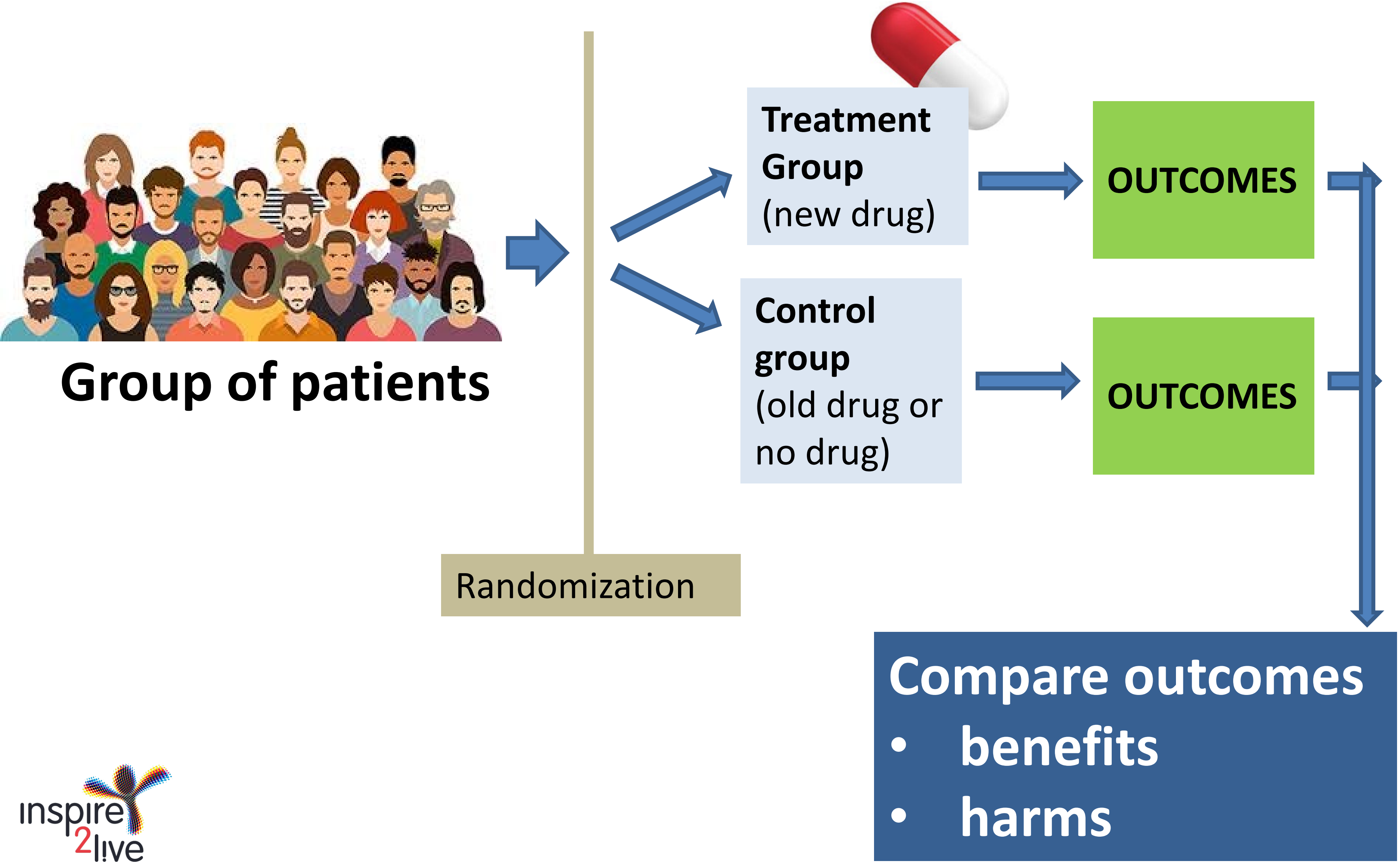
Clinical Trial Transparency

Why should Doctors care

Working

- **Honestly,**
- **Objectively,**
- **Properly**
- **Morally**
- **Bravely**

What are clinical trials?



Group of patients

Randomization

Treatment Group
(new drug)

Control group
(old drug or no drug)

OUTCOMES

OUTCOMES

Compare outcomes
- **benefits**
- **harms**

Without active unbiased doctors There is no trial transparency…

…the seller controls product information.

Would you take these pills?

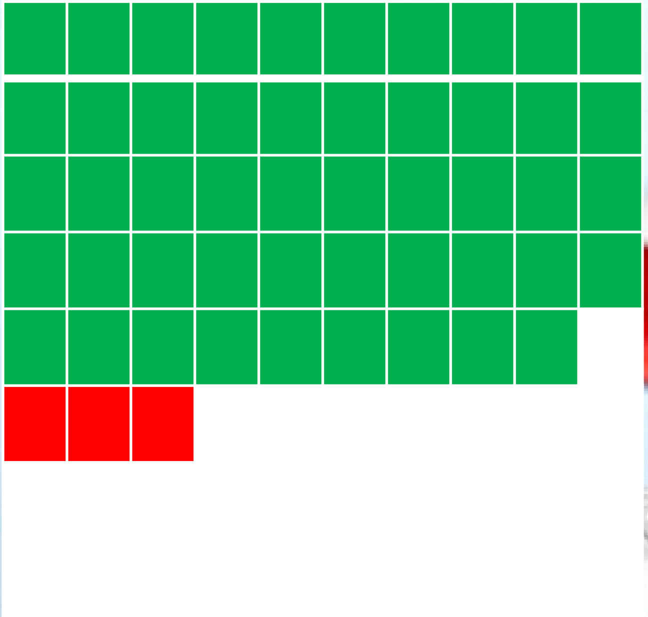
What the FDA saw:

- **74 trials total**
- 38 trials had positive results
- 36 trials had negative results

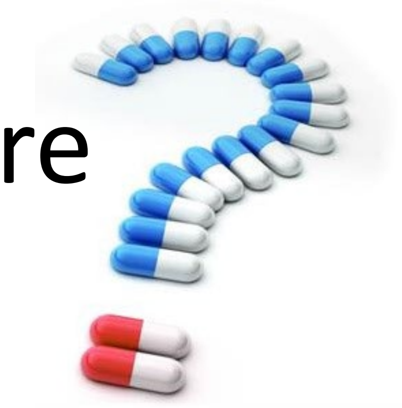
Would you take these pills?

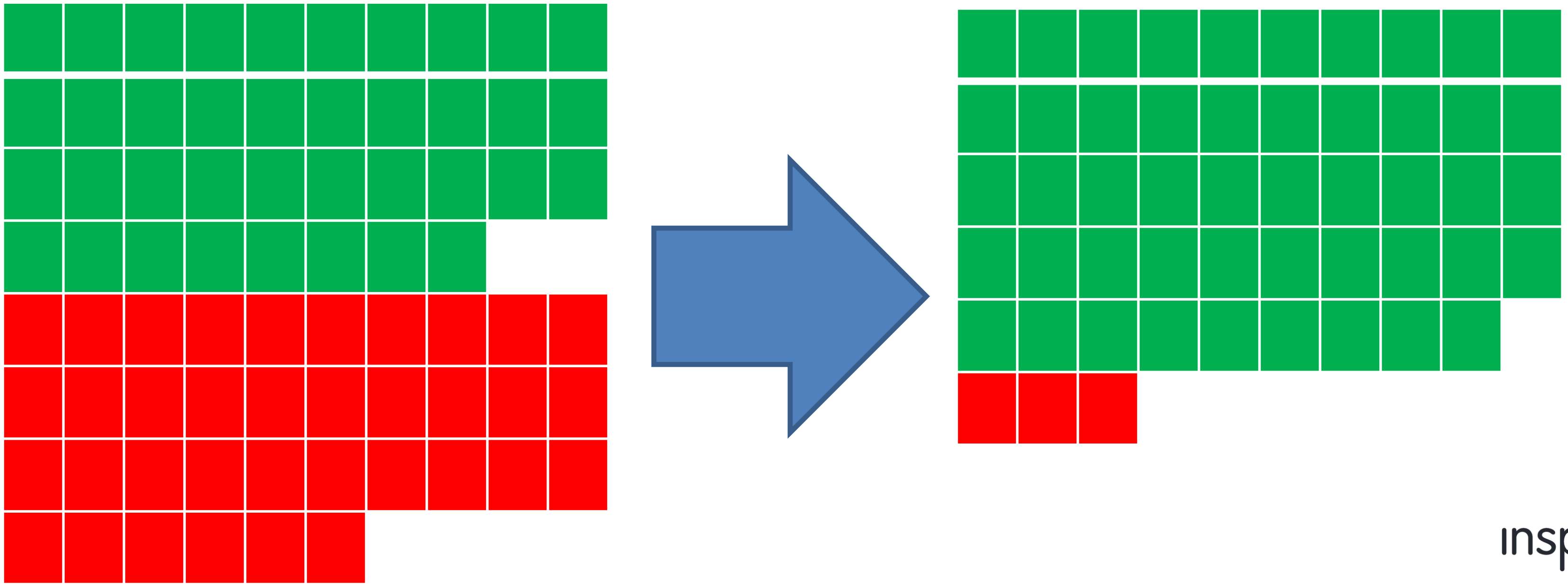
What independent scientists and doctors saw:

- **52 trials total**
- 49 trials had positive results
- only 3 trials had negative results



What happened here



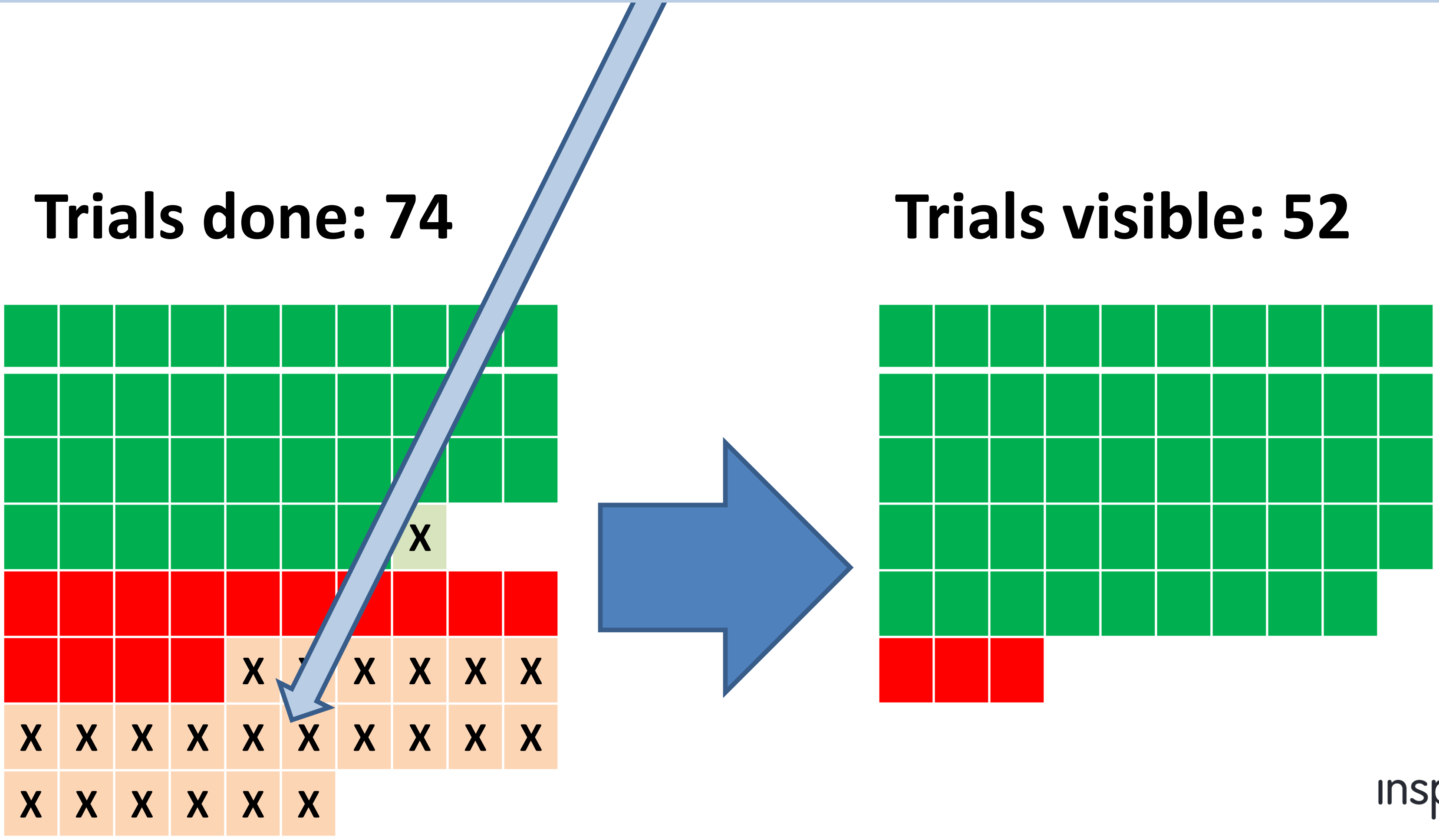


Trials done: 74

Trials visible: 52

1. Publication bias

- **The results of around half of trials never get published**



Trials done: 74

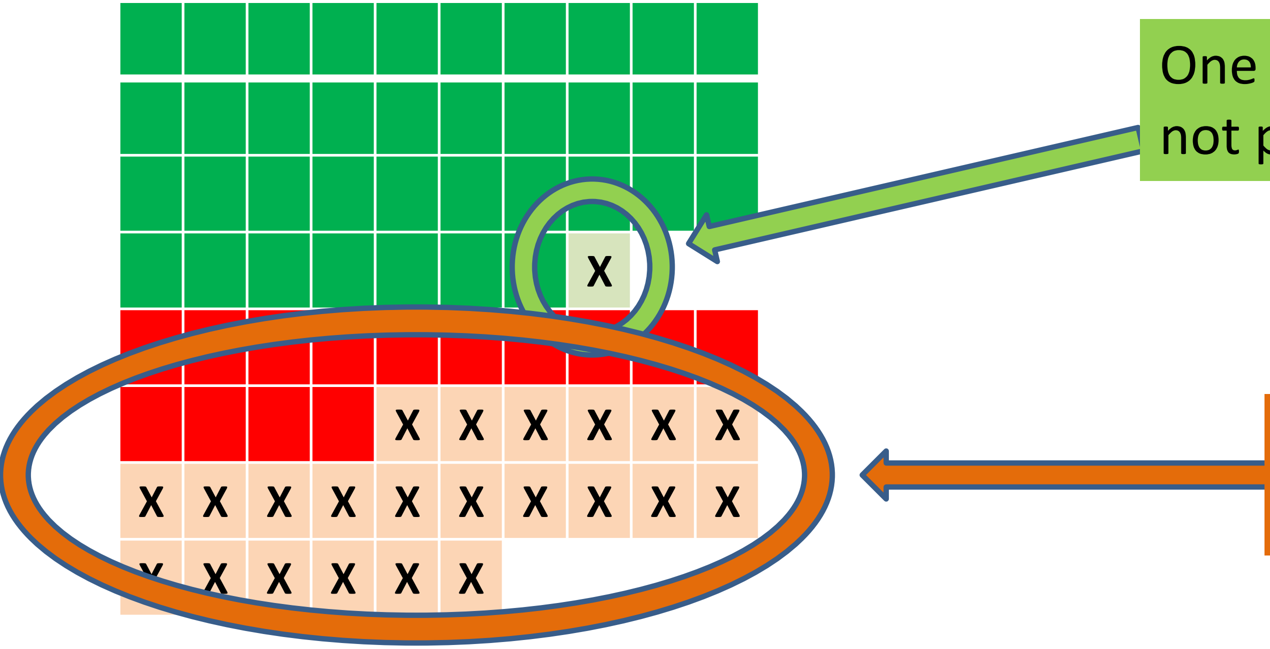
Trials visible: 52

1. Publication bias

- **The results of around half of all trials never get published**

- **Trials with negative results are far less likely to get published**

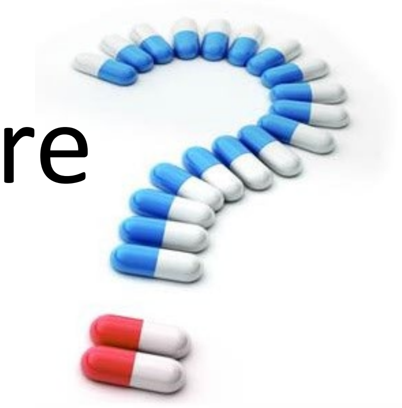
Trials done: 74

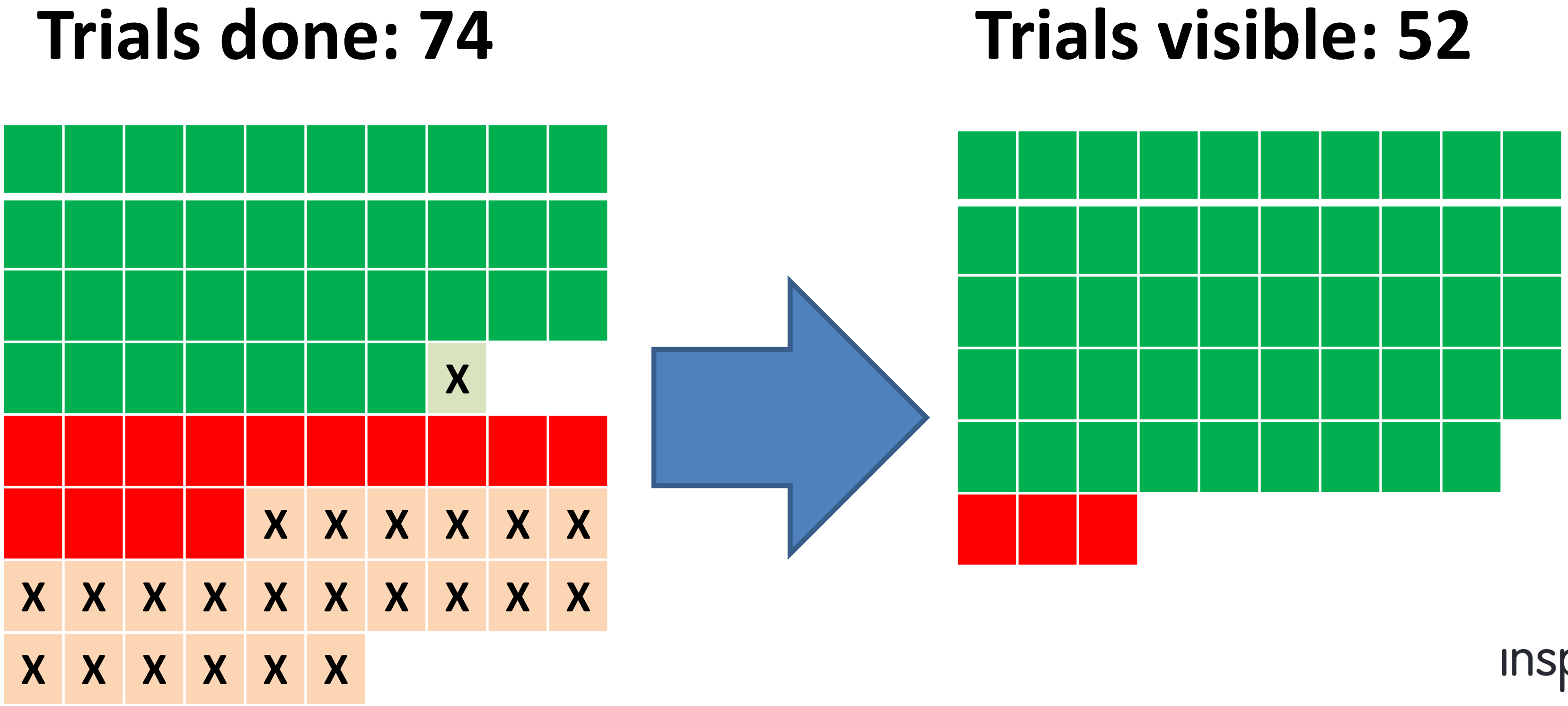


One positive trial
not published

22 negative trials
not published

What happened here





Trials done: 74

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Trials visible: 52

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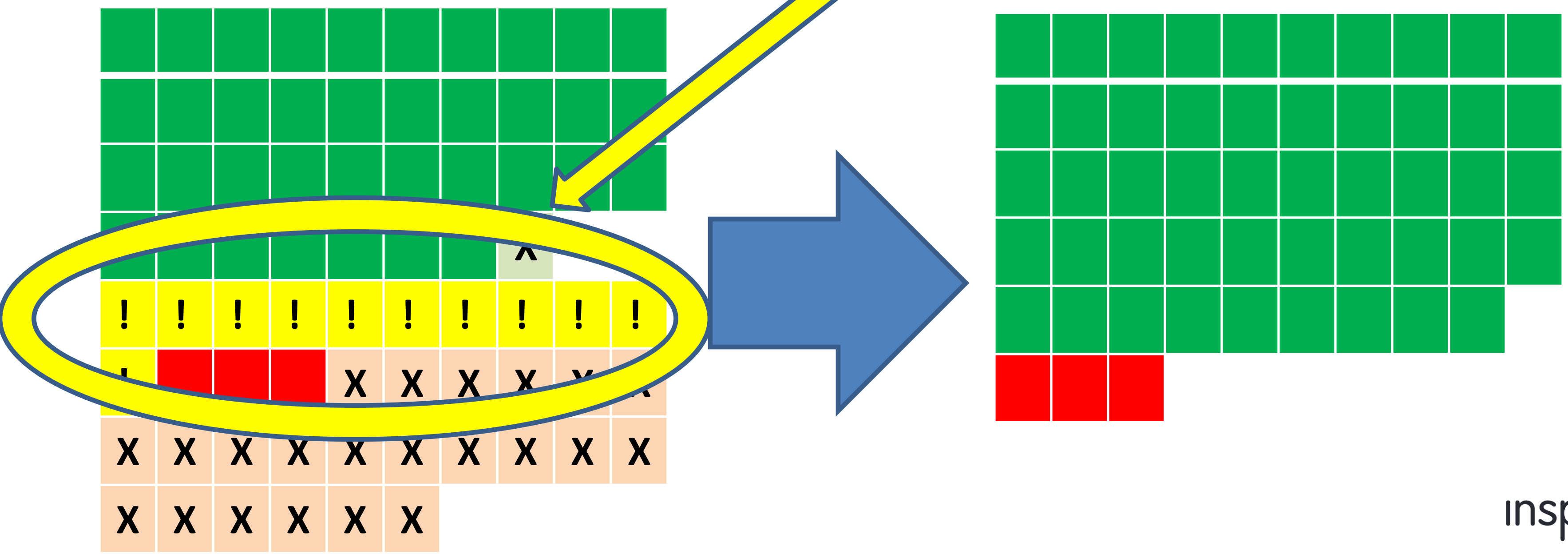
2. Evidence distortion

- **Negative trials misreport outcomes as positive**

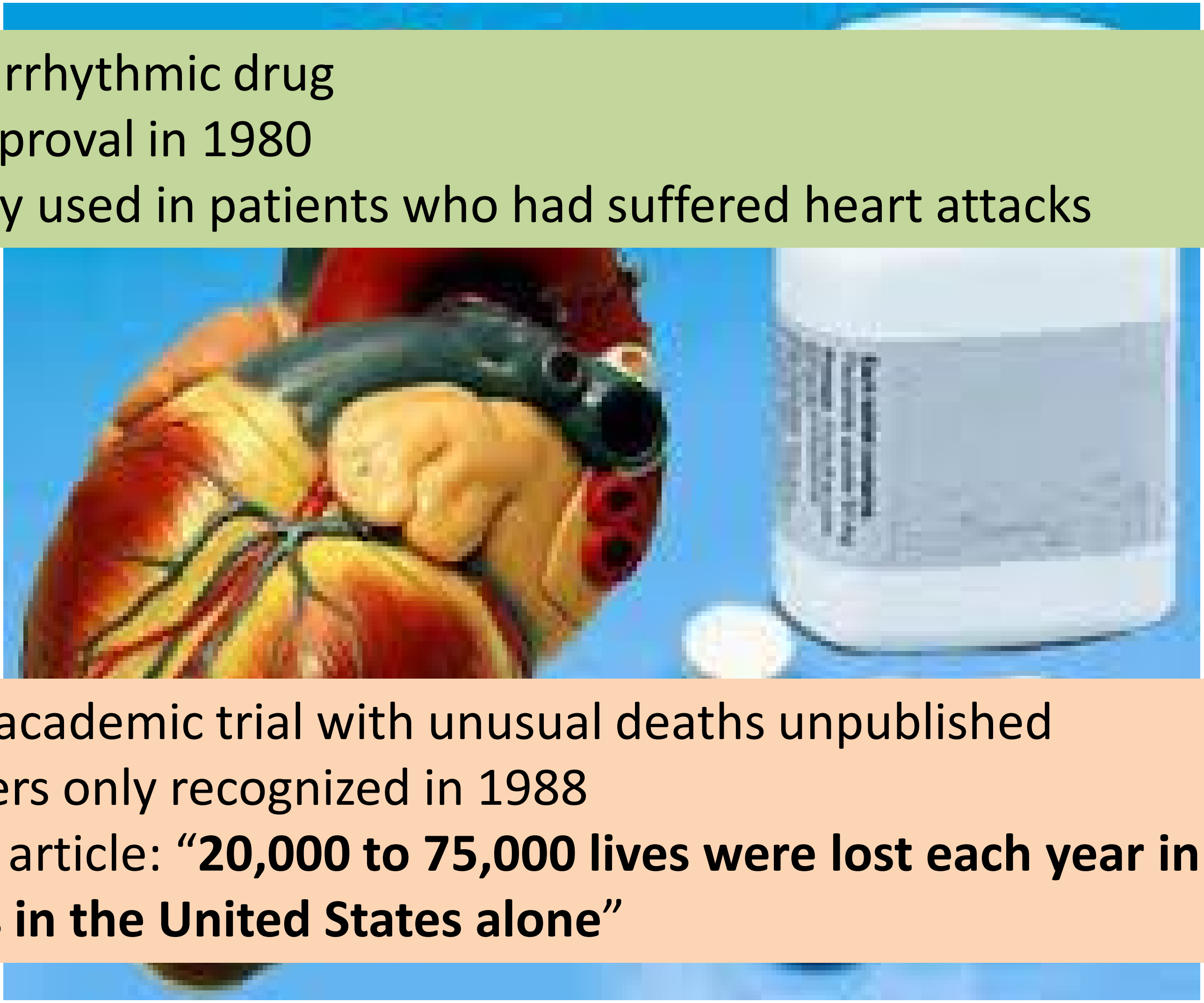
11 negative trials reported as positive

Trials done: 74

Trials visible: 52



Case study 1: Lorcainide



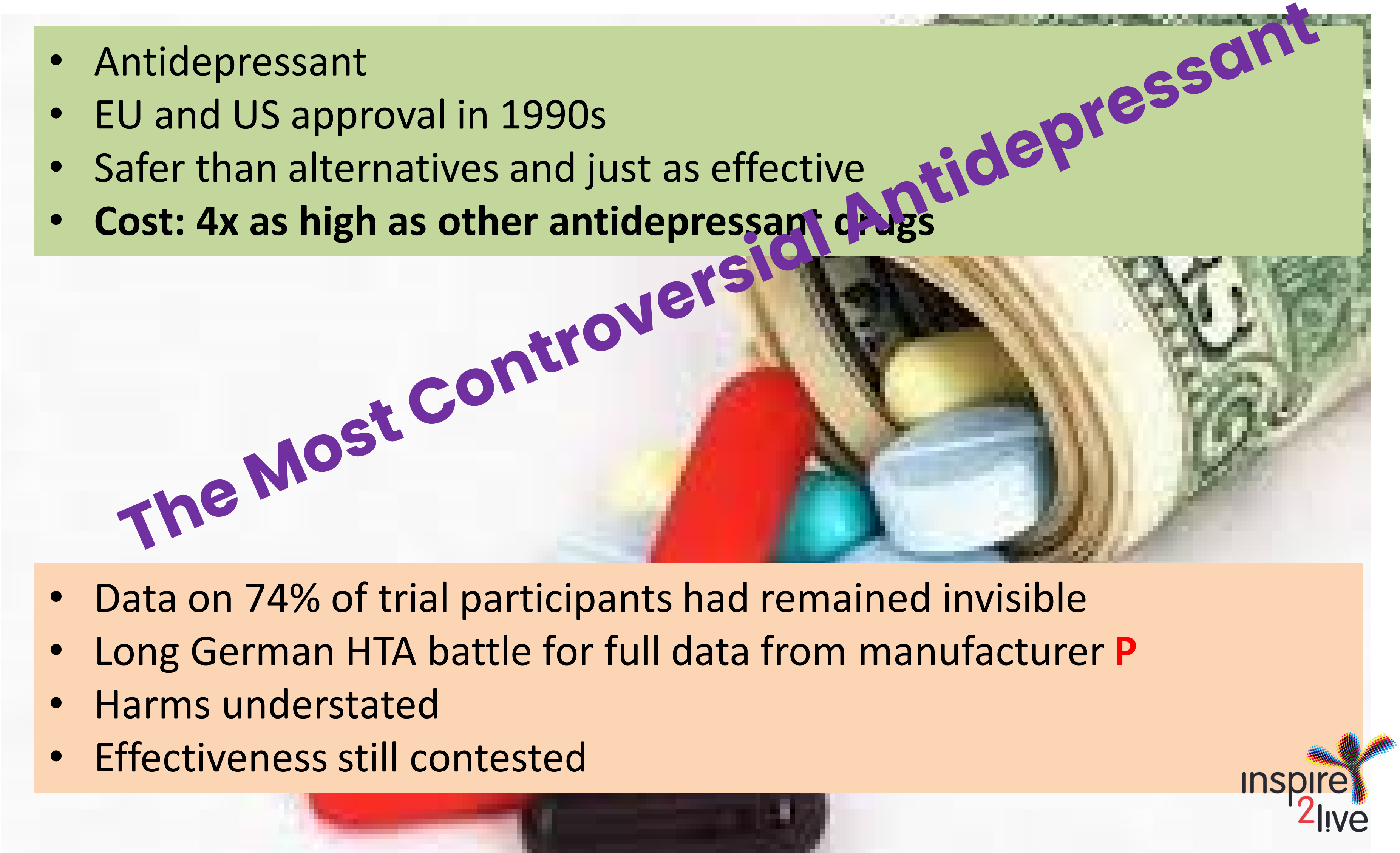
- Anti-arrhythmic drug
- US approval in 1980
- Widely used in patients who had suffered heart attacks

- 1980 academic trial with unusual deaths unpublished
- Dangers only recognized in 1988
- JAMA article: “**20,000 to 75,000 lives were lost each year in the 1980s in the United States alone**”

Case study 2: Reboxetine

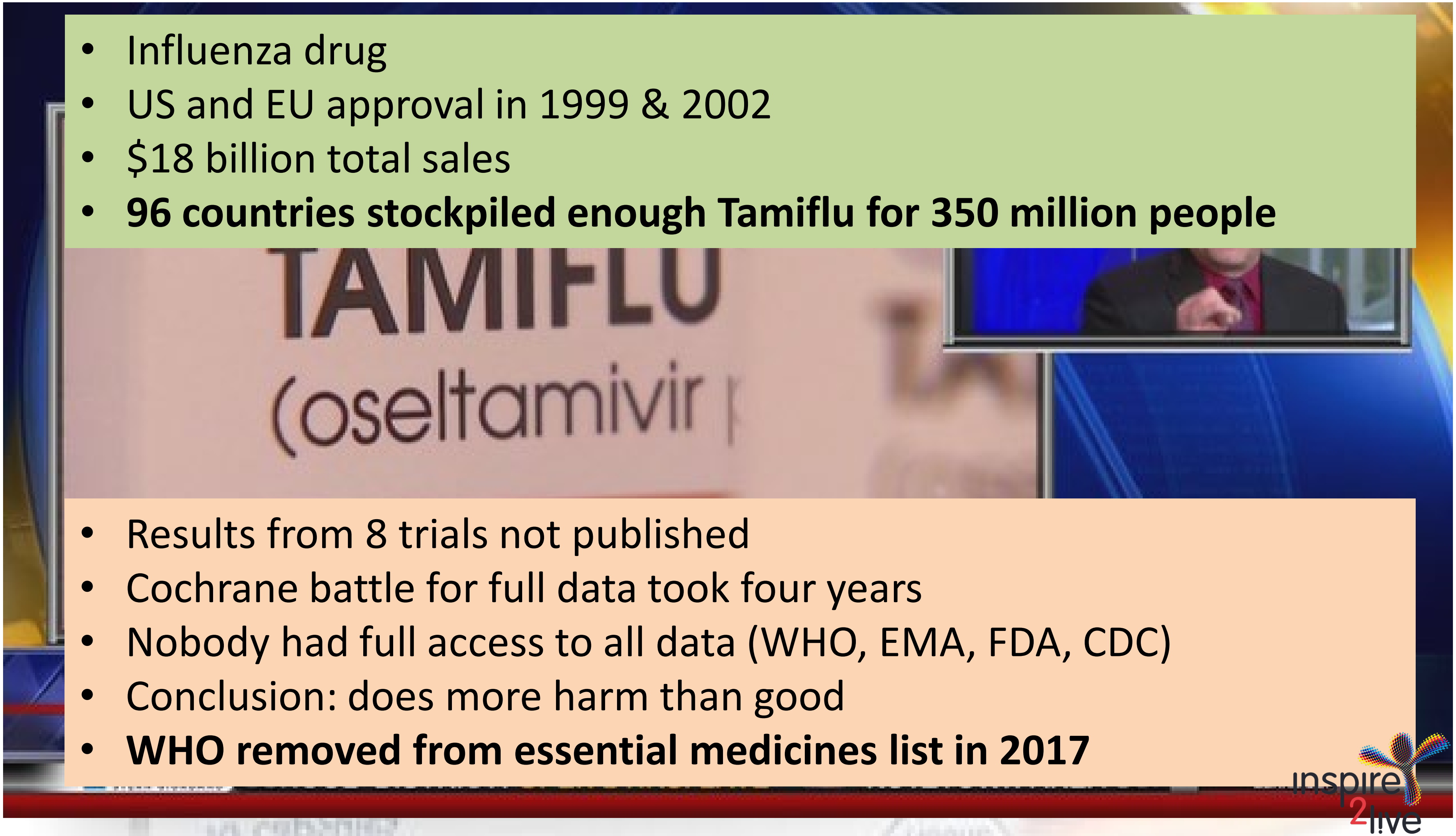
- Antidepressant
- EU and US approval in 1990s
- Safer than alternatives and just as effective
- **Cost: 4x as high as other antidepressant drugs**

The Most Controversial Antidepressant



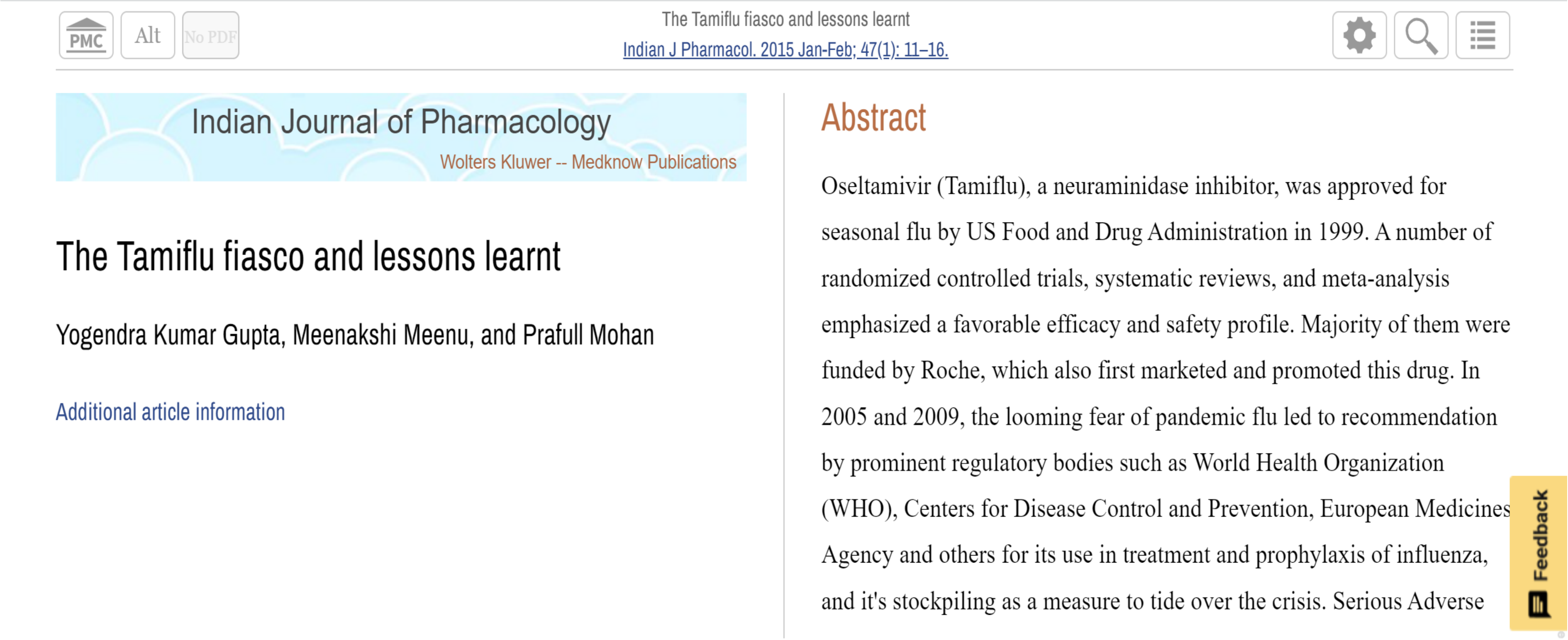
- Data on 74% of trial participants had remained invisible
- Long German HTA battle for full data from manufacturer **P**
- Harms understated
- Effectiveness still contested

Case study 3: Tamiflu



- Influenza drug
- US and EU approval in 1999 & 2002
- $18 billion total sales
- **96 countries stockpiled enough Tamiflu for 350 million people**

- Results from 8 trials not published
- Cochrane battle for full data took four years
- Nobody had full access to all data (WHO, EMA, FDA, CDC)
- Conclusion: does more harm than good
- **WHO removed from essential medicines list in 2017**



The Tamiflu fiasco and lessons learnt

Indian J Pharmacol. 2015 Jan-Feb; 47(1): 11–16.

Indian Journal of Pharmacology
Wolters Kluwer -- Medknow Publications

The Tamiflu fiasco and lessons learnt

Yogendra Kumar Gupta, Meenakshi Meenu, and Prafull Mohan

Additional article information

Abstract

Oseltamivir (Tamiflu), a neuraminidase inhibitor, was approved for seasonal flu by US Food and Drug Administration in 1999. A number of randomized controlled trials, systematic reviews, and meta-analysis emphasized a favorable efficacy and safety profile. Majority of them were funded by Roche, which also first marketed and promoted this drug. In 2005 and 2009, the looming fear of pandemic flu led to recommendation by prominent regulatory bodies such as World Health Organization (WHO), Centers for Disease Control and Prevention, European Medicines Agency and others for its use in treatment and prophylaxis of influenza, and it's stockpiling as a measure to tide over the crisis. Serious Adverse

These problems are systemic

Only 9 trials out of 67 published in top medical journals were accurately reported

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Only 11% of publications in journals provided a complete and consistent account of all serious

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Out of 455 completed trials involving children, 96 had never published results anywhere. Tens of

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35% of results from all clinical trials of 15 drugs allowed onto the market remained unpublished

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198 deaths were recorded in clinical trials of four new drugs, but only 29 deaths were fully reported in journals…

(2016 study)

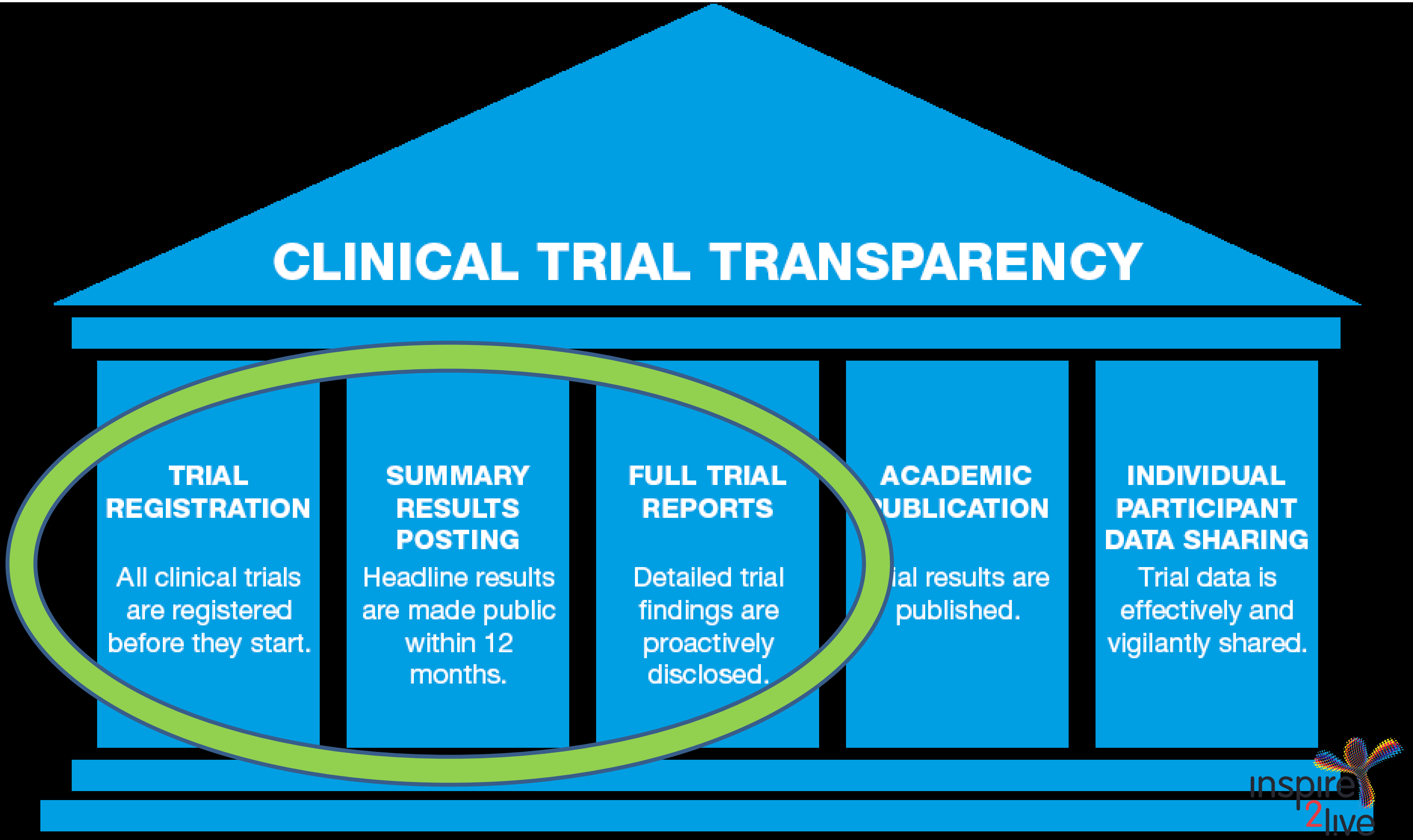
No transparency means…

- **Positive effects hyped**
- **Public health funds misspent**
- **Research funding wasted ($85 billion p.a.)**
- **Scientific progress slowed down**

Important: It’s not just Big Bad Pharma who paralyzes Doctors

- Government research funders and agencies
- Foundations and charities
- Universities

Clinical trial transparency



CLINICAL TRIAL TRANSPARENCY

TRIAL REGISTRATION
All clinical trials are registered before they start.

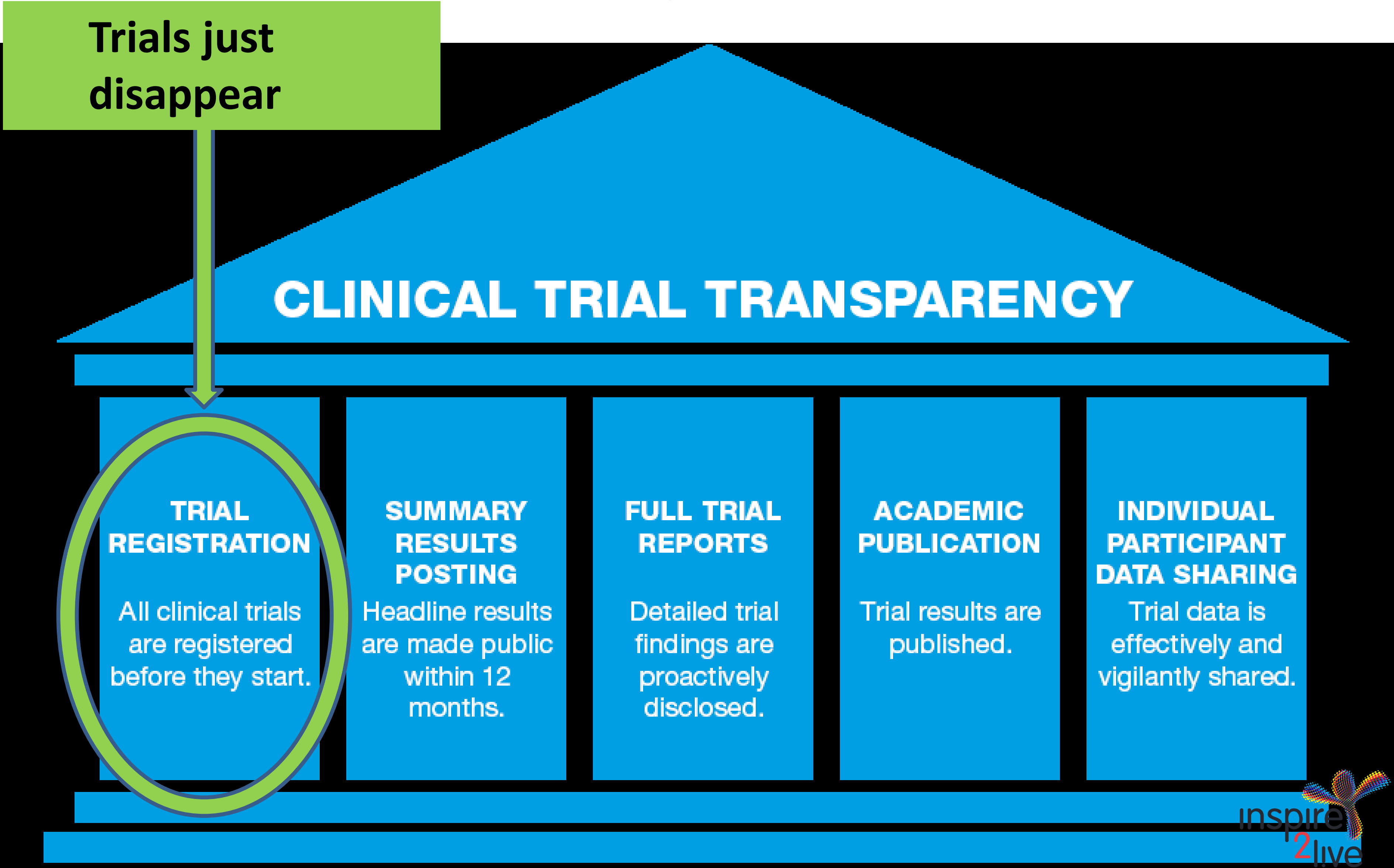
SUMMARY RESULTS POSTING
Headline results are made public within 12 months.

FULL TRIAL REPORTS
Detailed trial findings are proactively disclosed.

ACADEMIC UBLICATION
ial results are published.

INDIVIDUAL PARTICIPANT DATA SHARING
Trial data is effectively and vigilantly shared.

Trial registration



Trials just disappear

CLINICAL TRIAL TRANSPARENCY

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Solution: Trial registration

Advantages:

- Stops trials from "disappearing"
- No moving of goalposts
- All key information in one place

NIH U.S. National Library of Medicine

ClinicalTrials.gov

265,000 studies

EU Clinical Trials Register

56,000 trials

Progress: Trial registration

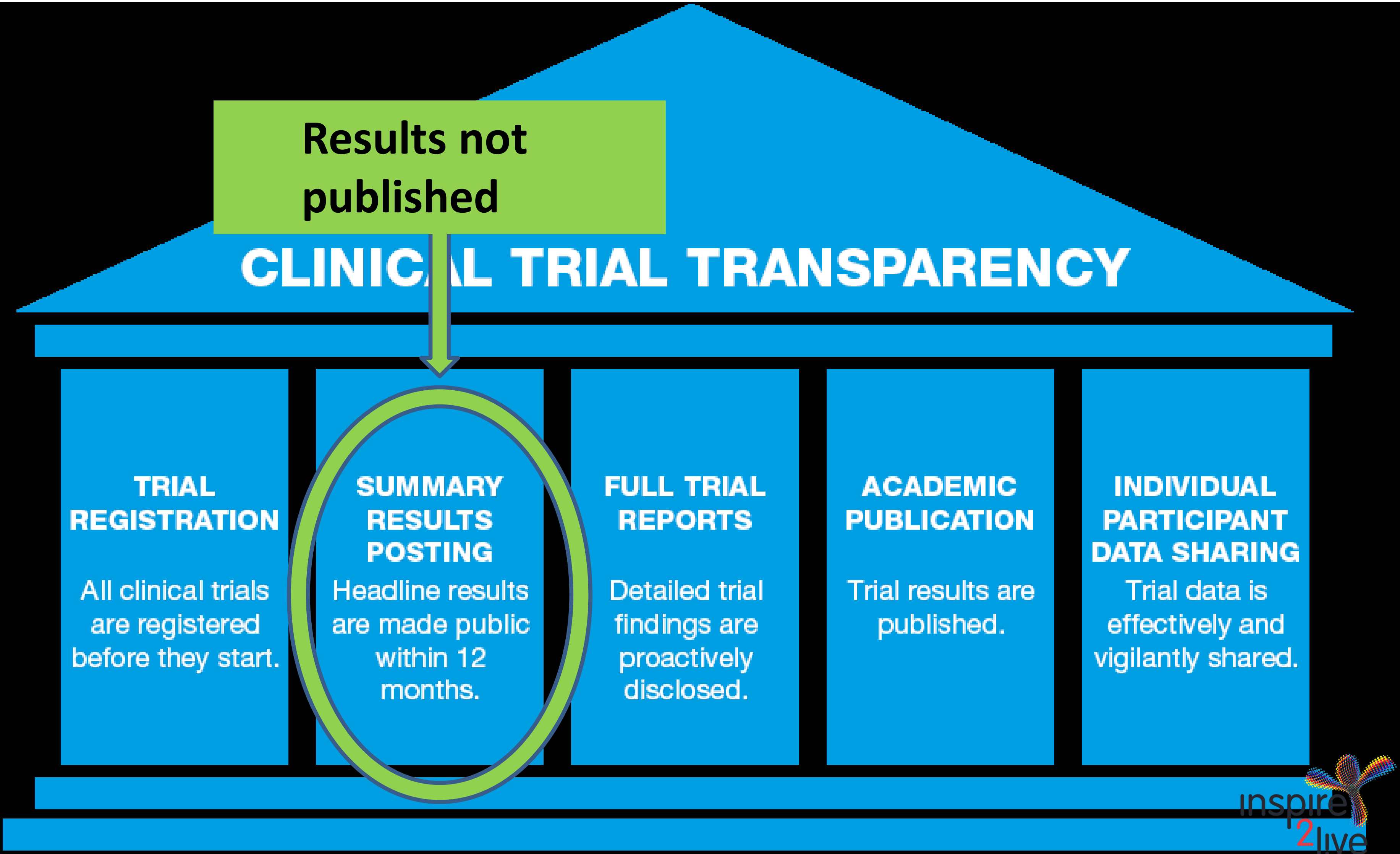
Promise:

- Clear WHO standards (all trials)
- EMA requires it for some trials
- National rules in many countries…
  … set by various bodies

Reality:

- Compliance not monitored
- No sanctions imposed
- Many trials still unregistered, or badly registered

Clinical trial transparency



Results not published

CLINICAL TRIAL TRANSPARENCY

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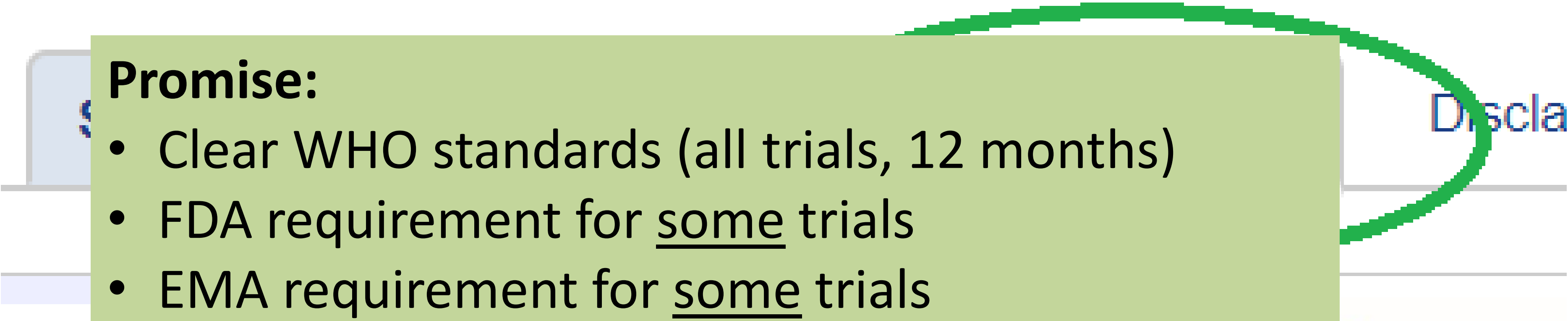
Solution: Summary results

Advantages:
- Fast results sharing
- More accurate data
- Permanent record
- Public access – no paywall

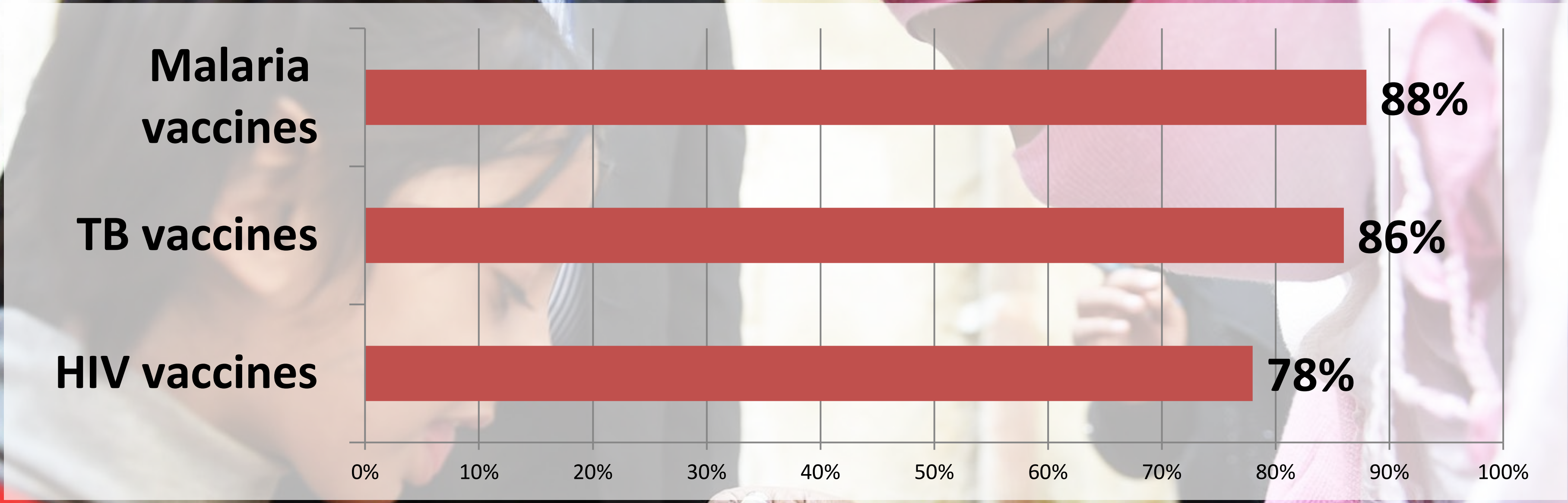
Progress: Summary results



Promise:
- Clear WHO standards (all trials, 12 months)
- FDA requirement for <u>some</u> trials
- EMA requirement for <u>some</u> trials

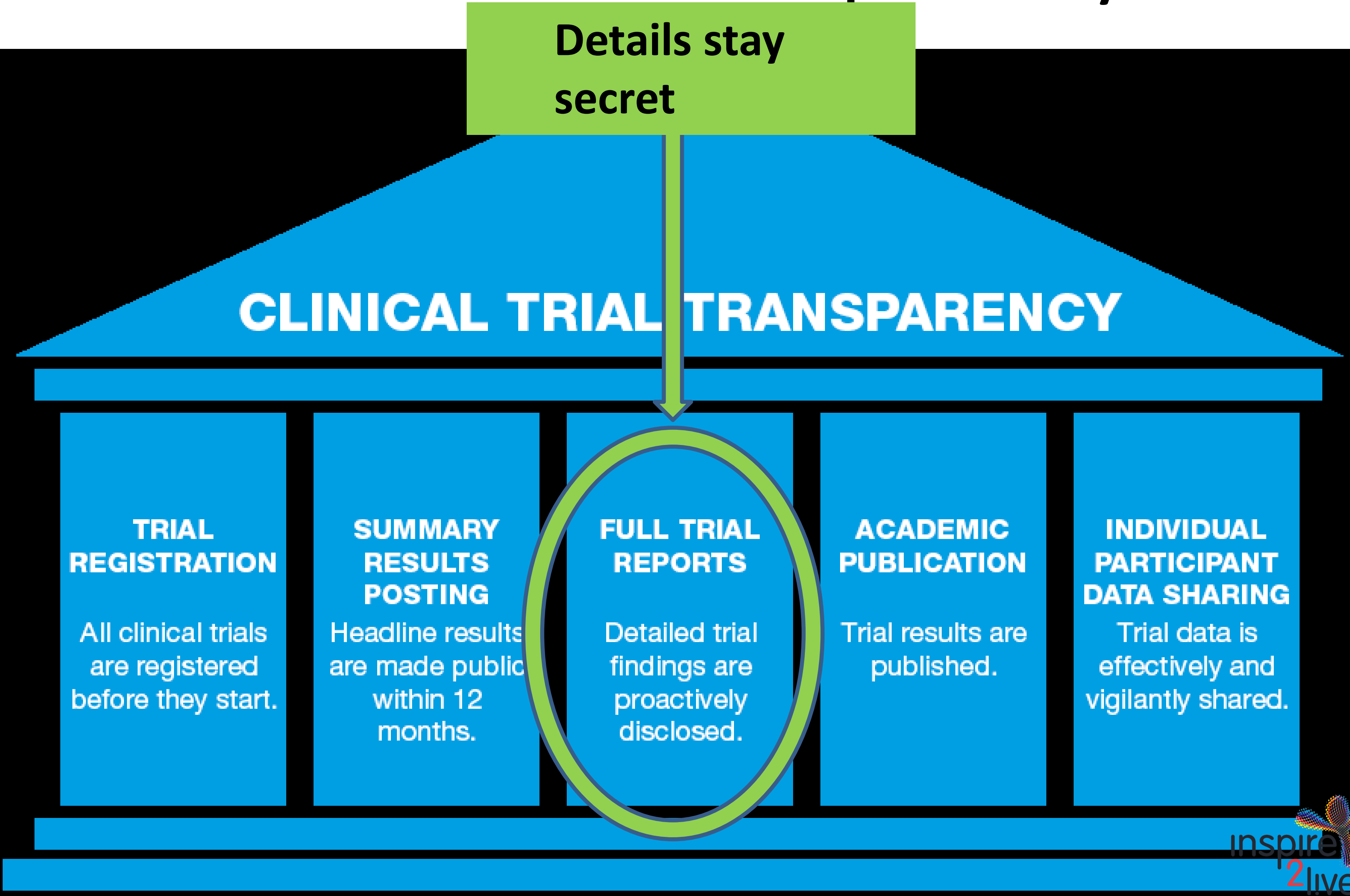
Reality:
- No monitoring, no sanctions
- US: $200 million in fines uncollected this year(2020/21)
- EU: member states fail to enforce regulation
- Routinely violated in US & EU

Snapshot: Missing summary results



494 completed clinical trials of vaccines against malaria / TB / HIV

Clinical trial transparency



Details stay secret

CLINICAL TRIAL TRANSPARENCY

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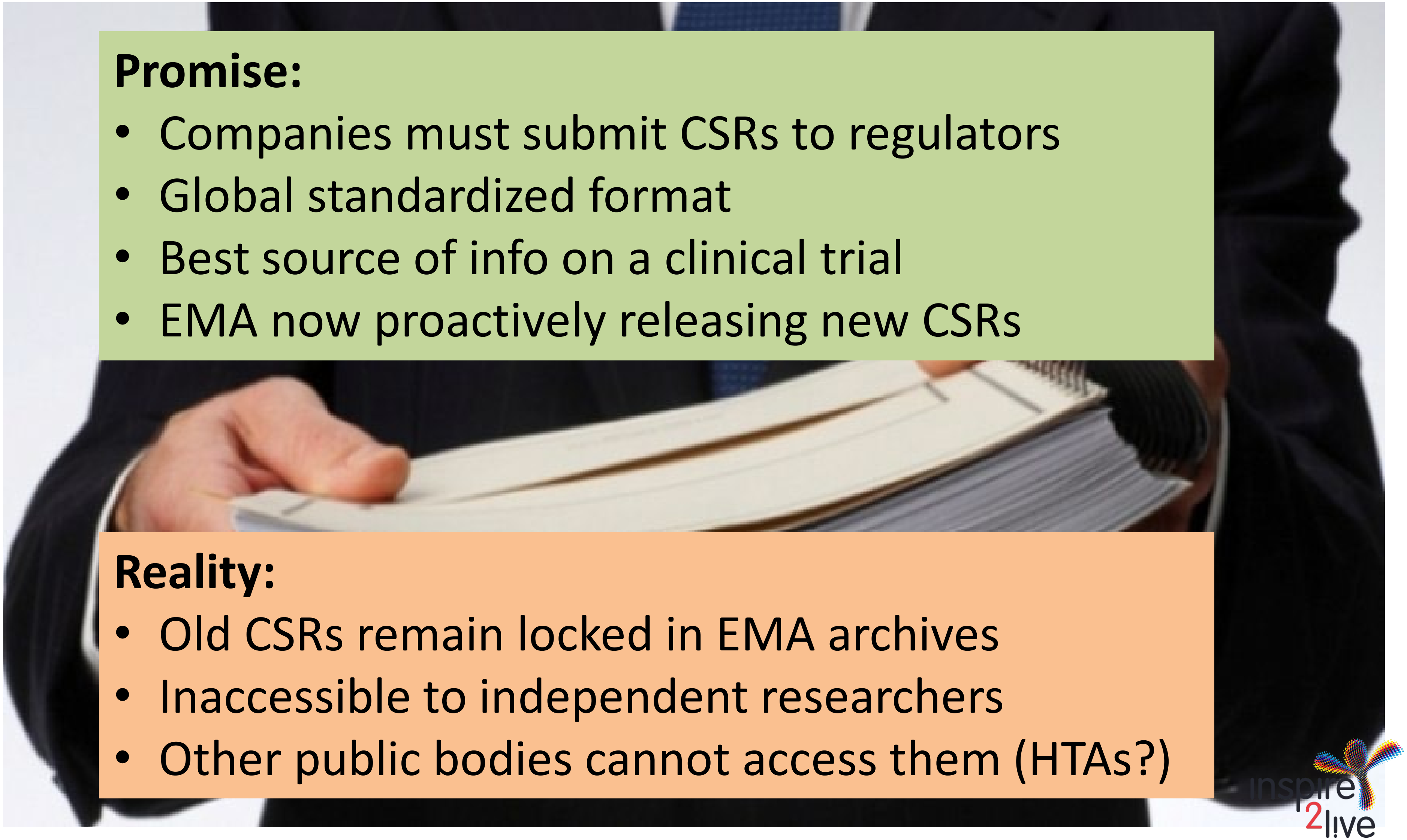
Progress: Clinical Study Reports



Promise:

- Companies must submit CSRs to regulators
- Global standardized format
- Best source of info on a clinical trial
- EMA now proactively releasing new CSRs

Reality:

- Old CSRs remain locked in EMA archives
- Inaccessible to independent researchers
- Other public bodies cannot access them (HTAs?)

Policy asks

- **Campaign founded in 2013**
- “All trials registered and fully reported”
- More than 700 supporter groups

- **WHO Joint Statement 2017**
- Detailed time-bound commitments
- 21 signatories to date

- **Transparency International et al 2017**

- Step 1: Public funders sign WHO Statement
- Step 2: Enforce existing rules
- Step 3: Strengthen legal and regulatory frameworks

Policy asks

EU national governments

- Public funders sign up to WHO Joint Statement
- Monitor & enforce EU summary results rules
- Ensure all trials in the country are transparent

Trial funders and sponsors

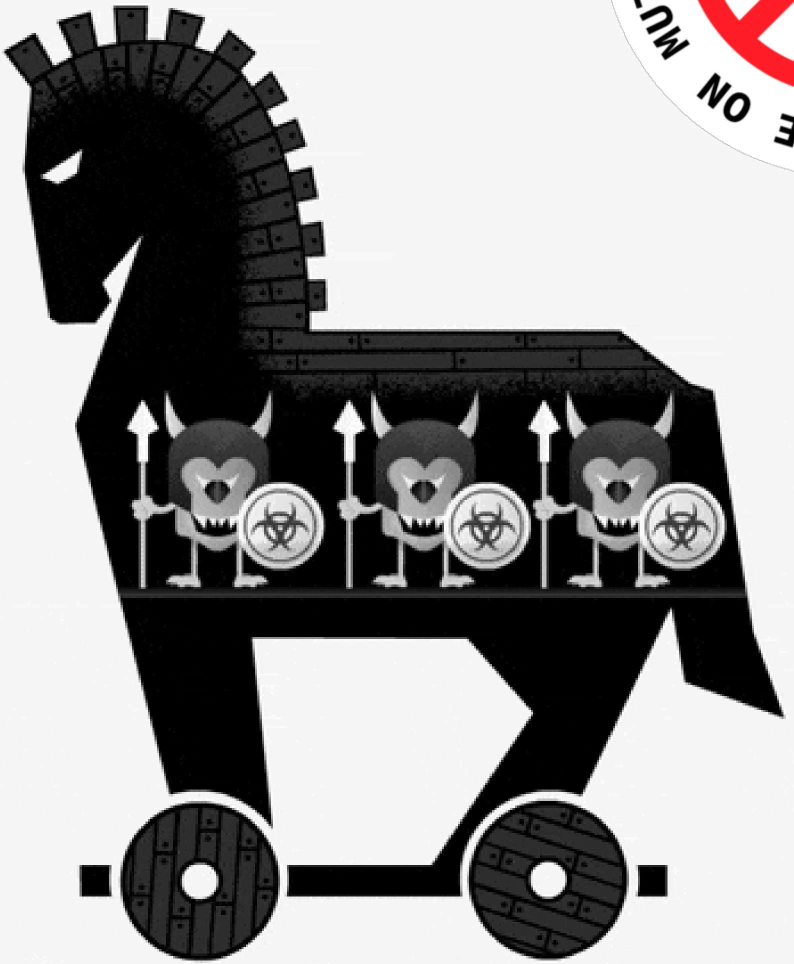
- Sign up to WHO Joint Statement
- Post missing results for all past trials

European Medicines Agency

- Release all old Clinical Study Reports

Some of the stakeholders including doctors and eve

patient advocates.. Unfortunately muted & became biased and..



Strategy

Who could do that

Political framing + policy solutions

Build a broad coalition for change

Share analysis, templates and tools

Direct involvement/pressure for change

Proposition

The primary care physicians can act

***as* professional cancer patient advocate**

Working as a member of a certified cancer patient organization ? TBD

- Once a diagnosis of cancer is made, patients are often inundated with an avalanche of information and options. The professional cancer patient advocate can play the role of an informed partner and compassionate coach, helping patients to become active participants in their treatment and to recover a life that they may feel is out of control.

- Primary care physicians, who often are more removed from cancer care institutions or health systems than are specialists, are freely able to help patients and caregivers navigate the treatment process and challenge the system when necessary.

- In the role of the **professional cancer patient advocate**, the primary care practitioner can provide invaluable support in numerous ways.

Bernay T. Becoming a professional cancer patient advocate: a new niche market practice for primary care physicians. West J Med. 2001 Nov;175(5):342-3. doi: 10.1136/ewjm.175.5.342. PMID: 11694488; PMCID: PMC1071617.

- The customary role of the primary care physician is to refer a patient with a diagnosis of cancer to an oncologist. Frequently, once the oncologist moves into place and starts the process of working up and staging the disease, the primary care physician steps back.

- Communication between the oncologists and primary care practitioner often becomes distant and infrequent; sometimes, it breaks down entirely. Some patients, depending on the course of their disease, do not return to the primary care provider but receive their care from the oncologists or their surgeon.

- If patients do return to see their primary care physician, it is only for routine health care because the oncologists direct their cancer care. **In either case, the primary care physician is no longer the primary coordinator of care.**

- **Cancer patients are often confused by this change and wonder why their own “regular doctor” is not more active in their treatment and disease management.**

- The primary care physician is well suited to step beyond the usual role as a referring physician to become **a professional cancer patient advocate** to stay involved in the care of their patient.

- The advocate can also be a resource for the many lifestyle, family, and quality-of-life decisions that must be made. Physicians can acquire additional continuing education training in the skills necessary to step into the process as mediator, true advocate, negotiator, coach, counselor, and triage agent

Proposition

Ways in which the primary care physician can act as professional cancer patient advocate

- Understanding the diagnosis
- Informing family and friends
- Noting how illness might affect family, lifestyle, and work decisions
- Researching and choosing a medical team
- Arranging or attending meetings with cancer specialists
- Helping to determine treatment
- Understanding and managing treatment options
- Gathering a complementary medicine team to provide mind/body support while undergoing traditional treatment
- During remission, determining and monitoring ongoing maintenance treatment and necessary checkups
- Helping with rehabilitation
- Being alert to recurrence
- Providing palliative care (referral to hospice and end of life care)
- Referring patients to resources that can help with insurance
- Referring patients to resources that can help with finances
- Cutting through hospital red tape
- Referrals for legal advice
- Offering support or referral to psychological services
- Helping patients to negotiate work and business affairs
- Helping patients arrange daily household maintenance and transportation regimen
- Getting strategically prepared for new treatments on the horizon

A CATALYST FOR CHANGE:
THE EUROPEAN CANCER PATIENT'S
BILL OF RIGHTS

- **The award-winning project, entitled 'The European Cancer Patient's Bill of Rights:**

A Catalyst for Change and an empowerment tool for cancer patients across Europe' involves an equal partnership between cancer patients, healthcare professionals and cancer researchers.

SUGGESTION

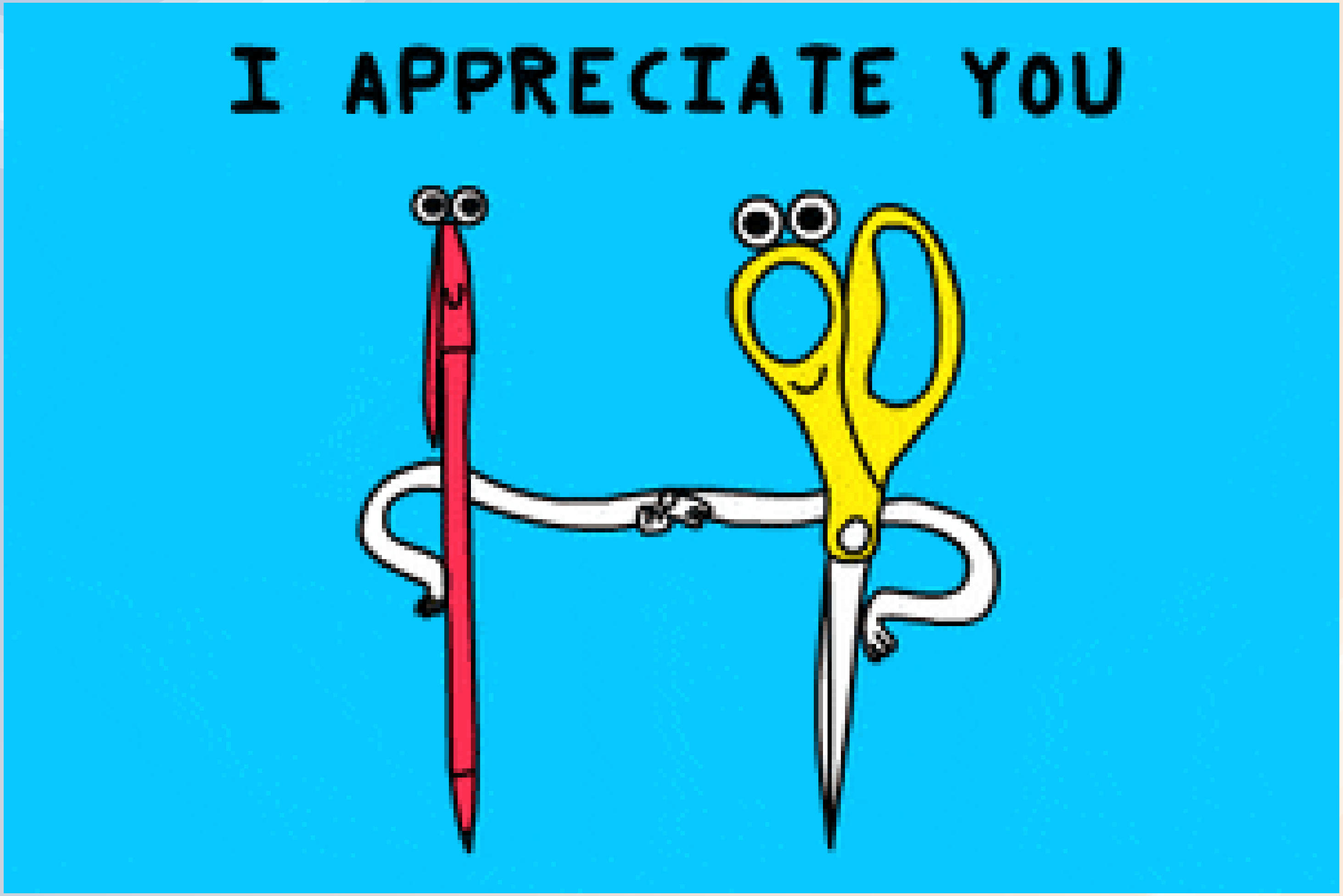
FOR THE NEXT UPDATE ON

‘The European Cancer Patient’s Bill of Rights:

- The right of every European citizen to receive cancer advocacy from a professional cancer patient advocacy group and /or be part of it.

- And that each professional cancer patient advocacy group should have a professional cancer patient advocate

(ie.The primary care physician)


I APPRECIATE YOU